

# Pricing and Reimbursement Questions



European Lawyers' Conference on Pharmaceutical  
and Health Care Affairs



## INTRODUCTION

This work endeavors to provide a concise and practical comparative guide on the current status of pricing and reimbursement of medicinal products for human use in the main EU jurisdictions and some other jurisdictions close to the EU that are commonly of interest to companies.

Conférence Bleue is a network of highly renowned lawyers specialized in pharmaceutical and health care law that meet regularly to exchange information. One of the topics regularly discussed at these meetings has been pricing and reimbursement. Conférence Bleue decided to compile and publish this information, and share it with our guests, clients and friends.

The document reflects the status quo as of March 2015. Pricing and reimbursement laws and policies are in permanent review in most jurisdictions, and this is one of the reasons why it was decided to edit and distribute the document in CD format. Conférence Bleue intends to provide regular updates to the work, which aims to become one of the reference guides on the subject.

Conférence Bleue was founded in 1997 and it has become the most prestigious European network of independent firms specialized in pharmaceutical and health law thanks to its 25 members, that are reference legal advisors in their respective countries. All of them have a broad history and experience that enables them to anticipate the trends on pharmaceutical, healthcare and medical law. For more information, please visit <http://www.conference-bleue.com/>



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# Belgium

## 1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied

Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?

No pharmaceutical product can be marketed in Belgium without obtaining a price granted by the competent Minister. However, there is no requirement that the company obtains a reimbursement authorisation, although this is the usual case for prescription and innovative drugs.

**1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."**

N/A

**1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).**

N/A

**1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.**

N/A

**1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

N/A

**1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

N/A

**1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

N/A

**1.7 Orphan Medicinal Products.**

N/A

**1.8 Parallel imports from another Member State.**

N/A

**1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

N/A

**2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

Applications for obtaining pricing and reimbursement are submitted to different governmental agencies. However, these are usually processed in parallel to avoid unnecessary waste of time and to ensure that the agencies results are co-ordinated.

The relevant body for the approval of prices and price increases in medicinal products is the "Federal Public Service Economy, SMEs, Self-Employed and Energy; Directorate General Regulation and Organisation of Markets; Section Prices" is the relevant body for the approval of prices and price increases of medicinal products.<sup>1</sup> The final decision on pricing is adopted by the National Minister of Economics. Opinions on the reimbursement of medicine are issued by the "Commission for Reimbursement of Medicines" (Commissie Tegemoetkoming Geneesmiddelen - Commission de Remboursement des Médicaments). The Commission forms part of the National Institute of Health and Disability Insurance (RIZIV - INAMI). The overall responsibility falls with the National Ministry of Social Affairs.<sup>2</sup>

The major pieces of relevant legislation have as follows:

**General legislation**

- Law on measures adopted in the area of healthcare of 10 August 2001;
- Law on measures adopted in various areas, including healthcare insurance of 27 December 2005; and
- Royal Decree of 8 June 1994 on medical prescription.

**Pricing legislation**

- Ministerial Decree of 29 December 1989 on reimbursed pharmaceutical products
- Ministerial Decree of 29 December 1989 on non-reimbursed pharmaceutical products;
- Ministerial Decree of 20 April 1993, which contains a general price control mechanism not limited to medicinal products;

- Ministerial Decree of 2 April 1996, concerning the maximum sales price and the maximum margins for wholesale and dispensing; and
- Ministerial Decree, 5 May 2006 on generics.

**Reimbursement legislation**

- Law on the Mandatory Health Insurance of 14 July 1994;
- Royal Decree of 21 December 2001 Concerning the Procedures, Terms and Conditions for Contribution by Mandatory Insurance for Health Care and Benefits towards Costs of Pharmaceutical Specialties; and
- Royal Decrees of 16 May 2006 on the procedures, timelines and conditions in relation to the reimbursement of medicinal products.

**3 Other Financial controls relating to supply**

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

N/A

**4 Pricing Criteria**

**For those products identified in the answer to Q1 for which a price must be agreed:**

**4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?**

In Belgium, External/International Reference Pricing is used as supportive criterion, however, pharmaceutical price cuts were introduced in 2013 based on international prices (Austria, Finland, France, Germany, Ireland and the Netherlands) for reimbursed patented medicines, which had been on the market at least five years. For the 2013 exercise, the pharma companies could either accept this price cut or propose another price cut, having the same budget impact.<sup>3</sup> The IRP in Belgium is calculated on the basis of the *average price* of the reference countries or alternatively the price in the country of the medicine's origin.

**4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?**

Therapeutic value is the primary focus of the assessment, with pharmaco-economics for some products. In first in-

1. Official webpage accessible at: [www.mineco.fgov.be](http://www.mineco.fgov.be).

2. Official webpage accessible at: [www.mineco.fgov.be](http://www.mineco.fgov.be).

3. Final Report of the European Commission on External reference pricing of medicinal products: simulation-based considerations for cross-country coordination, 2014, available at: [http://ec.europa.eu/health/healthcare/docs/erp\\_reimbursement\\_medicinal\\_products\\_en.pdf](http://ec.europa.eu/health/healthcare/docs/erp_reimbursement_medicinal_products_en.pdf).



stance the competent agency assesses therapeutic value at hand of efficacy, safety, comfort/convenience of use, applicability and where possible effectiveness in practice. Where significant added therapeutic value is identified, the product is classified as class 1, other products are classified as class 2. Maximum prices for class 2 products are set in function of prices abroad and prices of comparator products. Class 1 products can get a price-premium above comparator products. Additional pharmaco-economic studies may be required to justify the size of this premium.

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

Price setting and price increases require the prior approval of the Minister of Economic Affairs to whom an application must be sent containing information as to the applicant, including its financial situation, the relevant product and the elements which may justify the proposed price or price increase, including the manufacturing cost and a comparison with the prices applicable in other EU countries. Prior to any decision, the Minister must consult one of the following Committees: the Pricing Committee for Pharmaceutical Products (in case of reimbursed pharmaceutical products) or the Price Regulation Commission (in case of non-reimbursed products).

The decision of the Minister must be sent to the applicant within: 90 days (which may be extended to sixty days in very exceptional cases) for prescription only pharmaceutical products.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

Price determinations may be reviewed at any time following request of i) the company; ii) the Ministry of Economics, or iii) the competent Committee. For a description of the respective procedure under the reimbursement regime, please see answer to Question 11.1., below.

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 adobe?**
- **Reduce the price generally or for a period?**

We have not identified any relevant provisions

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

Price freezes were enforced from 1995 to 2005 and again in 2009 and 2010; and price cuts are frequently applied on the so-called 'old' drugs (reimbursed for more than 12, 15, and/or 17 years). In 2001, a reference reimbursement scheme (système de remboursement de référence -referentietrugbetalingssysteem) was introduced in Belgium.

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

We have not identified any relevant provisions.

## 7 Other Types of price control

**Does your jurisdiction control any of the following prices:**

### 7.1 Full line or other wholesaler selling price

### 7.2 Pharmacy selling price

Wholesalers and pharmacist margins are pre-defined and vary according to the status of reimbursed, non-reimbursed or generic medicine (see, Ministerial Decrees of 29 December 1989 and Ministerial Decree of 5 May 2006).

Moreover, since 1999 the Social Security authorities have organized a data collection system called "Pharmanet" to obtain better insight into the consumption trends of pharmaceuticals and their impact on the country's overall drug expenditures, including spending across various therapeutic categories. Pharmanet is permanently used to monitor the system (Social Security expenditure and patient spending) <sup>4</sup>

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

In Belgium public health and social affairs issues, including the reimbursement of medicine, are federal matters decided on a national level and as such may not be altered by local administration. According to the existing reimbursement framework, patients often have to make a co-payment, which, at least in part, is intended to help prevent over-consumption. For reimbursed medicines, payment by the patient can be limited to the non-reimbursed part

4. For more information on "Pharmanet" please see [http://www.inami.fgov.be/fr/statistiques/medicament/Pages/statistiques-medicaments-pharmacies-pharmanet.aspx#Qu'est-ce\\_que\\_Pharmanet\\_?](http://www.inami.fgov.be/fr/statistiques/medicament/Pages/statistiques-medicaments-pharmacies-pharmanet.aspx#Qu'est-ce_que_Pharmanet_?)

of the price, provided the pharmacy is a member of the “third payer” system. Under this system, the pharmacist collects co-payment and is reimbursed for the remainder by the social security system. In particular, Belgium applies two different systems of co-payments. The first is a reimbursement system that applies for ambulatory care in which the patient pays first the full cost of services and then obtains a refund for part of the expense from the sickness fund. The second is a third-party payer scheme, applying to inpatient care and pharmaceuticals, for which the sickness fund directly pays the provider while the patient only pays co-payment, supplement and non-reimbursed service.

**8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

Belgium follows a “positive list” of drugs whose reimbursement is covered by the compulsory health insurance (see, appendix to Royal Decree of 21 December 2001).

**8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

A formal federal approval is required that is not subject to any local or regional reassessment

**8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

The reimbursement proposals are as a general rule based on the following criteria: the therapeutic value of the product expressed in three classes (see above); the price and reimbursement basis proposed by the applicant; the value of the product in the medical practice in relation to the therapeutic and social needs; the budgetary impact on health care expenditures; and the relation between the health care cost and the therapeutic value of the product.

There is no hierarchy in these criteria although some key informants recognised therapeutic value weighing relatively more followed by budget impact and cost-effectiveness. Health technology assessment (HTA) reports conducted by the Belgian Health Care Knowledge Centre (KCE) can also be used to inform experts.

**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

Please see answers to Question 12 below on the reimbursement of unlicensed, off-label and orphan drugs.

## 9 Reimbursement – Administrative Arrangements

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

Following the relevant legislation (see answer to Question 2, above), the marketing authorisation holder that wishes to obtain a reimbursement status for her medicinal product is required to submit an application for the inclusion of this medicinal product in the list of reimbursed medicinal products (“positive list”). The application should be submitted to the Commission for Reimbursement of Medicinal Products (“CRM”).

Table 15: reimbursement criteria according to the Class claim

Therapeutic value	Class 1	Class 2	
Drug price and equivalent reimbursement basis proposed by the applicant	Class 1	Class 2	Class 3
Clinical effectiveness and likely impact of the product, taking into account therapeutic and social needs	Class 1	Class 2	Class 3
Budget impact for INAMI/RIZIV	Class 1	Class 2	Class 3
Cost-effectiveness of the product from the perspective of the INAMI/RIZIV	Class 1		

Criteria are mentioned in the Law of 14 July 1994, art.35bis,§2 and in the Royal Decree of 21 December 2001, art 4.

As a general rule, following the submission of the application the experts of RIZID- INAMI prepare an assessment report within 60 days of the filing of the request, describing and critically assessing the evidences presented in the drug reimbursement request file ("day 60"-report). The assessment report is then presented at a CRM/CTG meeting. Based on the assessment report and the discussions during the meeting, the CRM/CTG prepares a preliminary reimbursement proposal ("day 120"-proposal). The drug reimbursement proposals are appraised by NIHDI experts and the CRM/CTG members and subsequently voted during CRM/CTG meeting.

The motivated positive or negative reimbursement proposal is then transferred to the Minister of Social Affairs and Public Health within 150 days of the filing of the drug reimbursement request file. The Minister of Social Affairs and Public Health, who is allowed to deviate from the reimbursement proposal, must take a final decision within 30 days. The procedure must take no more than 180 days, which could be suspended in certain circumstances.

Note that in 2007, a simplified administrative reimbursement procedure was introduced for certain generic medicines, medicines registered on the basis of a bibliographic application, and parallel imported medicines (Royal Decree of 15 February 2007 amending the Royal Decree of 21 December 2001). Under this procedure, a decision must be taken within 60 days (subject to suspension) and without the involvement of the Commission for Reimbursement of Medicines.

Following the aforementioned procedures, the reimbursement decision comes into force the first day of the month that follows a ten-day period after its publication in the Belgian Official Journal (Moniteur belge-Belgische Staatsblad).

## 10 Reasons for decisions on Pricing and Reimbursement

**The Transparency Directive 89/105/EEC requires Member State authorities to provide a "statement of reasons based on objective and verifiable criteria" in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it from reimbursement (negative lists).**

### 10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?

The appraisal process has been gaining in transparency since 2007. In particular, for positive reimbursement decisions, the following documents are available on the INAMI/RIZIV website:

- the evaluation report of the reimbursement request file, as approved by the CRM/CTG expert members;
- the written remarks and/or objections of the applicant; and
- the CRM/CTG reply to the applicant's remarks and/or objections.

Positive reimbursement decisions are published by means of ministerial decrees, although the decision process and rationale is not documented. Negative decisions are currently not publicly available.

### 10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?

In its report on the drug reimbursement system, the Belgian Health Care Knowledge Center reported as noteworthy that neither the key issues discussed in the plenary sessions, nor the result of the voting, nor the final drug reimbursement proposal sent to the minister are currently publicly available.

Moreover, key informants to the aforementioned study acknowledged that "the decision process at the ministerial level is far from transparent". For example, it is often the case that the rationale justifying why the final decision deviates from the CRM/CTG reimbursement advice, is not clearly communicated or clearly understood by the CRM/CTG members.<sup>5</sup>

## 11 Reconsiderations / Appeals

### 11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?

Following the provisions of the Royal Decree of 21.12.2001, the reimbursement decision can be subject to a reappraisal procedure at the request of: i) the company; ii) the Ministry of Social Affairs, or iii) the Reimbursement Committee. In particular, there are two types of review procedures:

The Secretary of State's enforcement decisions under the statutory pricing scheme are subject to appeal to the NHS Medicines (Control of Prices and Profits) Appeal Tribunal (The Health Service Medicines (Price Control Appeals) Regulations 2000/124).

- **Individual reappraisal** is primarily conducted for reasons of uncertainty with the aim to reassess the decisional criteria with new available evidence. It affects (1) all drugs from Class 1; (2) drugs from Class 2 or 3 for which an individual revision was specifically requested by the Minister; (3) drugs whose reimbursement modalities have been modified

5. "Drug reimbursement systems: international comparison and policy recommendations", KCE reports 147C, Belgian Health Care Knowledge Centre Federaal Kenniscentrum voor de Gezondheidszorg Centre fédéral d'expertise des soins de santé 2010, available at: [https://kce.fgov.be/sites/default/files/page\\_documents/KCE\\_147C\\_Drug\\_reimbursement\\_systems\\_4.pdf](https://kce.fgov.be/sites/default/files/page_documents/KCE_147C_Drug_reimbursement_systems_4.pdf).

and for which an individual revision was specifically requested. The applicant must submit a reassessment report with up-to-date evidence regarding e.g. clinical efficacy and effectiveness; real-life cost-effectiveness; size of the target group; turnover and sales volume; reimbursement modalities in other EU member states any other elements requested.

- On the CRM/CTG's or the Minister's initiative, the CRM/CTG can also conduct a **group reappraisal**, i.e. pharmaceuticals with identical or analogous indications. A group reappraisal may either relate to general group reasons or specific budgetary concerns.

### **11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

The applicant is entitled to appeal the minister's decision to the Administrative Court (Conseil d'Etat – Raad van State) but only on procedural grounds. Other stakeholders are, in principle, entitled to appeal the decision although in practice, this rarely occurs. The standard time-limits foreseen under the Belgian Code for Administrative procedure apply.<sup>6</sup>

### **11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

Compliance of the Belgian authorities with the respective EU Directives has been challenged before the National Administrative Court and has been referred to the Court of Justice.<sup>7</sup> In response thereto, national legislation has been amended and now explicitly specifies that in the absence of an administrative decision within the therein stipulated time-frame, the company's application is considered as accepted.

## **12 Unlicensed products and off-label use**

### **12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?**

If a medicinal product is not yet on the Belgian reimbursable pharmaceutical products lists, the patient can apply

for compassionate use or for reimbursement through the Special Solidarity Fund, the objective of which is the reimbursement of medical expenses for rare diseases, rare indications and innovative techniques which are not (yet) refunded by the compulsory health insurance. In particular:

- **Programmes of compassionate use:** making available, for compassionate reasons, of a medicinal product that can qualify for the centralised procedure to a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who cannot be treated satisfactorily by an authorised medicinal product. The medicinal product concerned must either be the subject of an application for a Marketing Authorisation in accordance with Article 6 of the European Regulation or must be undergoing clinical trials (Law of 01.05.2006).
- **The Medical Need Programmes:** making available a medicinal product to a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who cannot be treated satisfactorily by an authorised medicinal product. The medicinal product concerned must have a Marketing Authorisation but
  - o either the given indication has not been authorised yet, or
  - o although authorised, the medicinal product is not yet available on the market in this indication.
- A patient may also request the reimbursement of an **orphan drug** or treatment unavailable in Belgium. However, reimbursement will only be granted if the patient has been through all other reimbursement options, including all applicable legislation at national, European or international level. This means that reimbursement through the SSF cannot be obtained if the reimbursement of the orphan drug has been refused by the CMDOD. (Law of 27.04.2005).

### **12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?**

Yes, pharmaceutical products used for an indication other than the one they have been approved for (i.e., off-label use) may not be reimbursed, unless exceptionally covered by the "Special Solidarity Fund" procedure described above.

## **13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go**

6. The period during which an annulment action is admissible before the Council of State is in principle 60 days, as of the publication, notification or cognisance of the contested act, depending on the case. Applications for judicial review before the Council of State must be filed at the latest on the 30th day after the contested decision was notified.

7. Case C-245/03 Merck, Sharp & Dohme BV v. État belge, ECLI:EU:C:2005:41, Case C-296/03 GlaxoSmithKline, ECLI:EU:C:2005:42.

## **beyond the controls identified in the answer to question 1.**

The maximum prices for orphan drugs are fixed by the Federal Public Service Economy as is the case for all drugs. Turning to the procedure for reimbursement, this considers budget impact, but not cost-effectiveness. Therefore, unlike the procedure foreseen for standard drugs, pharmaceutical companies do not have to submit a formal cost-effectiveness analysis as part of a drug reimbursement request file for an orphan drug.

### **14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

The payback system has been used in Belgium since 2002. The amounts to be returned are calculated on the basis of: a) turnover of all reimbursed medicines, without exception, and b) on the entire pharmaceutical budget. However, the government can decide to subdivide the payback per group of products (example: statins). In 2006, a special provision fund was created, funded by the pharmaceutical industry, to pay back 100% in case of overspending but limited to a maximum of €100 million. Since 2008, this special fund has been replaced by a new system in which the companies' contributions are based on the reimbursed pharmaceuticals turnover for the year of budget overruns. the companies' contributions are based on the reimbursed pharmaceuticals turnover for the year of budget overruns <sup>8</sup>

8. European Observatory on Health Systems and Policies, Health System Profiler for Belgium, available at: <http://hspm.org/countries/belgium25062012/livinghit.aspx?Section=5.6%20Pharmaceutical%20care&Type=Section>.

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He advised Almirall in their patent dispute with Boehringer Ingelheim, in which Boehringer agreed to remove its blocking positions and the European Commission investigation was closed. He also represented Nycomed in the recent investigation by the Commission, which was closed without making any finding that the company violated the law and without imposing any fine. In addition, Mr. Schulz secured favorable judgments for Abbott in two Greek court cases initiated by Greek pharmaceutical wholesalers requesting large quantities of prescription medicines in order to export them. He has also represented GlaxoSmithKline in a number of cases before the European Courts in Luxembourg.

He also has significant experience in ensuring that clients' business practices respect the EU competition rules and has assisted a number of leading multinational companies to develop customised compliance programmes.

# Czech Republic

## 1 **Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied**

**Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?**

As a general rule, all products which are covered by general health insurance (irrespective of whether – in the individual case – the price was actually reimbursed from public health insurance funds or was paid by the patient) are subject to pricing controls. Products which are not covered by public health insurance (i.e., which are not incorporated – “listed” – in the general health insurance system) are not subject to regulated prices.

The regulatory powers with respect to the pricing of products lies with the State Institute for Drug Control (SÚKL), and manifest themselves in three different forms of regulation: (i) stipulating a maximum price on the level of the manufacturer/importer, (ii) regulating the margin, and/or (iii) imposing a binding method or formula for calculation of the price.

SÚKL hands down its regulatory decision to stipulate maximum prices (usually coupled with a decision on the amount of reimbursement within the public health insurance system) within individual procedures triggered by an application by the manufacturer/importer. Regulated prices of products are also subject to reviews at regular intervals (upon request by the manufacturer/importer or as a matter of official duty).

The product categories described in the items below are not specially regulated, so that we may generally say that they (being reimbursed products) are regulated in the form of maximum prices (with the exception of products listed in a price decision by the health ministry – these are subject to binding methods for calculation of the price).

### 1.1 **Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met.”**

N/A

### 1.2 **Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other “lifestyle” medicines).**

Products that are not covered by general health insurance are not subject to pricing controls.

**1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.**

N/A

**1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

N/A

**1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

N/A

**1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

N/A

**1.7 Orphan Medicinal Products.**

N/A

**1.8 Parallel imports from another Member State.**

N/A

**1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

Dietary foods for special medical purposes are also subject to price controls, as are medical devices. Again, the primary criterion is whether or not they are included in the public health insurance system. On a side note, we should mention that the laws governing medical devices will in the near future be revised as a part of a far-reaching amendment effort that will also have consequences for the way in which their prices are regulated.

## **2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

The setting of maximum prices and of the amount of reimbursement from public health insurance falls within the competence of the State Institute for Drug Control (SÚKL), based on Act No. 526/1990 Coll. on Prices, Act No. 48/1997 Coll., on Public Health Insurance, and Pricing

Decree 1/2013/FAR of the health ministry. Separate forms (to be submitted to SÚKL) are available to apply for the stipulation of the maximum price and for the stipulation of the reimbursement element, but one may also file a joint application for both, so as to achieve a decision within the course of a single procedure.

## **3 Other Financial controls relating to supply**

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

The Czech authorities engage in no additional financial control (aside from monitoring adherence to the above-mentioned price regulation). Controls are being conducted at healthcare providers and providers of pharmacy services in connection with their compliance with spending and reimbursement rules.

## **4 Pricing Criteria**

**For those products identified in the answer to Q1 for which a price must be agreed:**

**4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?**

Reference baskets are used to determine the maximum price of a product.

As a general rule, the maximum price for the manufacturer of a given pharmaceutical is derived from that pharmaceutical's three lowest prices in countries belonging to the reference basket. The reference basket represents the overwhelming majority of EU member states. Not included in the reference basket are the following EU member states: Bulgaria, Estonia, Cyprus, Luxembourg, Malta, Germany, Austria, and Romania. The procedure thus works as follows: if we wish to stipulate the maximum price for which the manufacturer may sell the given product, we identify the prices at which the manufacturer launched the product in the markets of those countries within the reference basket. We then pick the three countries in which the price was the lowest and take the average, which becomes the maximum price at which the manufacturer may bring the product to market in the Czech Republic.

If the product has not been brought to market in at least three countries of the reference basket, then the above procedure cannot be used and rule No. 2 comes into play instead: the maximum price is then being determined as the average of the lowest three prices among all EU



countries - i.e., in determining the maximum price of the to-be-assessed medicinal product, all EU countries are being taken into account in which the given product was brought to market by the given manufacturer. From among all those, we chose the three countries with the lowest price. The Czech maximum price is then the average of the manufacturer's price in these three countries.

Obviously, the second rule can only be applied if the medicinal product was introduced to the market of at least three EU countries. If this is not the case, then rule No. 3 takes over, under which we first seek to identify that alternative medicinal product which, in therapeutic terms, comes closest to the product at hand (irrespective of whether in the Czech Republic or in the EU); the cheapest price for this therapeutically comparable product is then used as the maximum price for our product.

#### **4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?**

In determining the maximum price, all that matters are the prices of products in the countries that belong to the reference basket; clinical or cost-effectiveness are being disregarded. Effectiveness is only taken into account when determining the conditions and the amount of reimbursement within the public health insurance system (see sub-section 8.4 further below)

## **5 Pricing control timelines**

### **5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?**

Pricing control takes place before the State Institute for Drug Control, based on individual applications (requests) for setting the maximum price. These and related issues are handled by a separate department of SÚKL: Prices and Reimbursements.

Under the Public Health Insurance Act, the State Institute must hand down a decision on the maximum price and on the amount or conditions of reimbursement within 75 days from the day of commencement of proceedings. In the case of joint proceedings (for setting a maximum price and for setting the amount and conditions of reimbursements), the time period within which a decision must be handed down is 165 days.

## **6 Prices increases and reductions**

### **6.1 How often are price determinations ordinarily reviewed?**

N/A

### **6.2 What controls apply to the right of company to:**

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 above?**

N/A

- **Reduce the price generally or for a period?**

To answer both questions asked in sub-section 6.2 in one statement: The market authorization holder may freely move the price of product (both upwards and downwards), always on the assumption, of course, that the maximum price (or, as the case may be, the profit margin) stipulated by SÚKL is not exceeded.

### **6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?**

Currently, no price freezes are in place for any medicinal products whatsoever.

### **6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?**

Upon the market entry of the first generic product, the maximum price of the original non-generic product (the "branded product") remains the same; however, the amount of remuneration for all products (i.e., the original branded product as well as the first generic product) within the given reference group drops by 32 %.

## **7 Other Types of price control**

**Does your jurisdiction control any of the following prices:**

### **7.1 Full line or other wholesaler selling price**

The wholesaler selling price is regulated by setting a maximum price for the product (see sub-section 1 et seq. above).

### **7.2 Pharmacy selling price**

The benefits for the provision of pharmacy services are regulated by way of setting a maximum margin - i.e., a restriction of the markup charged as "price for the transactional service of the person engaged in the distribution (other than as manufacturer or importer) and the filling of prescriptions (i.e., the dispensation) of medicinal products and of dietary foods for special medical purposes".

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

The reimbursement framework in the Czech Republic functions on a national scale. All duties and tasks related to drug reimbursements are managed and overseen by SÚKL. This includes setting the conditions under which medicinal products are reimbursed from public health insurance funds and at what amount, reviews, and subsequent controlling (monitoring) activities. The reimbursement system as such is being financed by the various public health insurance companies that collect contributions from insured individuals enrolled in the public health insurance system. The price of those products which are only partially reimbursed by insurers is co-paid by the patient. The conditions and amount of reimbursement are stipulated by SÚKL in individual procedures triggered by an application for registration, and are subject to regular reviews.

### 8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?

In accordance with the law, the State Institute for Drug Control publishes a list of medicinal products and of dietary foods for special medical purposes that are reimbursed from public health insurance funds (the “List”). The List is re-published regularly as at the 1st day of each calendar month, and contains the complete set of medicinal products covered by public health insurance (under the abbreviation LP - léčivé přípravky) and of dietary foods for special medical purposes (PZLÚ - potraviny pro zvláštní lékařské účely) on whose reimbursement the State Institute decides, including the maximum prices or reported manufacturer’s prices, the amount and conditions of reimbursement, and the maximum allowable co-payment by final consumers.

Aside from the List, SÚKL also keeps a “negative list” of those products which are not reimbursed.

### 8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?

The procedure in which SÚKL issues its decision on the amount and conditions of reimbursement for specific products is a formal procedure, and SÚKL decisions are therefore principally open for a review within the context of an appeal to the health ministry. The said decisions are never reassessed on the local or regional level.

### 8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?

The reimbursement decision is issued by SÚKL following a review of the criteria set out in Section 39b of the Czech Public Health Insurance Act. These criteria are:

- therapeutic efficacy and safety;
- seriousness of the illness for which the drug is indicated;
- to be submitted by the participant in proceedings (i.e., the applicant): an assessment of the cost-effectiveness and of the impact of using the medicinal product (or the dietary food for special medical purposes) on the public health insurance funds, expressed as costs per patient and estimated number of patients treated per year, in those cases in which the amount and conditions of reimbursement are being set (or changed), and in those cases of an (in-depth or summary) review of medicinal products or dietary foods for special medical purposes in which the applicant asks for a broadening of the terms under which reimbursement is granted, leading to an increase in the number of treated patients, an increase of the reimbursement compared to the basic rate, or in one additional increased reimbursement compared to the current state (or compared to other medicinal products or other dietary foods for special medical purposes within the given reference group);
- public interest (Sec. 17 (2));
- suitability of the route of administration, dosage form, strength, and package size;
- standard dosage;
- required minimum duration of medication;
- required degree of collaboration of the individual to whom the drug is administered;
- substitutability by another medicinal product or dietary food for special medical purposes reimbursed by public health insurance, and a comparison of the prices and set reimbursement rates for such substitutes with the to-be-assessed medicinal product or dietary food for special medical purposes;
- anticipated impact of the reimbursement on health insurance funds;

- procedure recommended by expert institutions and experts, always under the aspect of cost efficiency and with a view to the impact on health insurance funds.

**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

Doctors must not deviate from the decision on reimbursements (as no such option or exception is enshrined in the law), and they must therefore fully submit to the decision of SÚKL. The hypothetical decision on a full reimbursement in exceptional cases would have to be made by the specific health insurance company with which the patient is registered.

## **9 Reimbursement – Administrative Arrangements**

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

The tasks and duties in connection with the reimbursement of products also fall to SÚKL, which based upon Sec. 39b of Act No. 48/1997 Coll., on public health insurance, has the power to decide on the amounts and conditions of reimbursement. The cited provision states, among other things, the factors which SÚKL is to take into account in its decision-making process (such as efficacy and safety, the seriousness of the illness being treated, etc.)

SÚKL decides on the amount and conditions of reimbursement for specific products based upon an application (though it may also do so in the absence of an application, subject to the conditions set out in Sec. 39b (10) of the Public Health Insurance Act).

SÚKL must decide on the amount and conditions of reimbursement within 75 days from the commencement of proceedings; in the case of joint proceedings on the stipulation of the maximum price and on the amount and conditions of reimbursement, this time period is 165 days (Sec. 39g (2) of the Public Health Insurance Act).

## **10 Reasons for decisions on Pricing and Reimbursement**

The Transparency Directive 89/105/EEC requires Member State authorities to provide a “statement of reasons based on objective and verifiable criteria” in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it from reimbursement (negative lists).

**10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

Each SÚKL decision must be furnished with a proper statement of reasons, and is usually accompanied with expert opinions on which SÚKL based its conclusions. All decisions must always be open to scrutiny (i.e., reviewable), and thus come with proper reasoning.

**10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

Decisions on the review of prices and conditions, in particular, leave some room for filing appeals on grounds of procedural mistakes made by the State Institute, given that these decisions are often made under time pressure and that the State Institute simply lacks the capacity to provide a proper level of reasoning. Especially in these cases, there are opportunities to ask for a review of the relevant decisions by exercising legal remedies.

## **11 Reconsiderations / Appeals**

**11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

In such a case, the applicant may file an appeal against the relevant SÚKL decision within 15 days from the day on which the decision was announced. The higher instance - i.e., the appellate authority, or body of appeals - in these standard appellate proceedings (which are conducted pursuant to the Code of Administrative Procedure - Act No. 500/2004 Coll.) is the Czech health ministry.

**11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

Dissatisfied applicants only have recourse to the courts if they first explored the avenue of appealing to the health ministry but their appeal was not accommodated. Only in such a case may the applicant bring a lawsuit against the decision of the administrative authority before the regional court of venue; it must do so within two months from the date of service of the decision in which the health ministry (in its capacity as the body of appeals) dismissed the appeal.

**11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

The general courts have jurisdiction to resolve disputes arising from decisions on the stipulation of prices and conditions of reimbursement taken by SÚKL and the health ministry. However, actual practice clearly teaches us that in such cases, the party initiating the judicial dispute needs to put a great amount of additional effort into putting together its case and preparing for the proceedings, in that there exists as of yet no solidified case law with respect to these highly specialized issues. Also, the courts do not avail of panels of judges with the requisite expert / specialized background for these matters.

## **12 Unlicensed products and off-label use**

### **12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?**

In this respect, a rule applies according to which “the State Institute may stipulate reimbursement for an unlicensed medicinal product if current scientific understanding provides a sufficient basis for its application and using the said product is the only available treatment option, or if using the said product is cost-efficient compared to accessible treatment, whereas the State Institute will do so for the duration of a specific, approved therapy schedule. The State Institute may stipulate reimbursement for a licensed medicinal product also for an indication that is not listed in the summary of product’s characteristics, if current scientific understanding provides a sufficient basis for its application and using the said product is the only available treatment option, or if using the said product is cost-efficient compared to accessible treatment.”

### **12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?**

The restriction is implied by the amount of reimbursement awarded to the relevant unlicensed product itself, on which the State Institute decided as described above.

## **13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.**

Patient access schemes or other special schemes are generally not used. In exceptional cases, a health insurer may decide to procure and reimburse treatment at the facilities of a foreign healthcare provider (which would then include also the concomitant medication). However, this concerns absolutely exceptional cases, and will only occur if considerable pressure is exercised on the health insurer.

## **14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

Pharmacies do not pay any additional margin or other charges on their turnover achieved on reimbursed product. The pharmacies do not have pay-back or claw-back obligations.

3

# Denmark

## 1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied

Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?

N/A

### 1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."

**Pricing:** Medicinal products are subject to free pricing in Denmark, i.e. the MA holder decides the price of its products.

The MA holder sets the price and reports it to the Danish Health and Medicines Authority ("DHMA"). The price is reported in a fortnightly publication, the Medicines Tariff (see [www.medicinpriser.dk](http://www.medicinpriser.dk)), which sets out the price of all registered and marketed medicines. The reported price applies throughout the country.

Please note that the price level may affect the DHMA's decisions regarding reimbursement. In recent years, there have been several cases where the marketing authorisation holder has had to lower the price in order to keep general reimbursement status for a product.

**Reimbursement:** Prescription-only products are only (partly) reimbursed if granted general (automatic) or conditional reimbursement status upon an application from the MA holder. The MA holder cannot formally apply for conditional reimbursement for a prescription-only product. If the prescription-only product does not meet the criteria for general reimbursement, the DHMA determines on a case by case basis whether the product meets the criteria related to treatment of specific diseases or patient groups (conditional reimbursement).

There is no time limit within which an application must be submitted. In practice the MA holder wants to send an application in due time. It is possible to apply for general reimbursement for a prescription-only product before the marketing authorisation is available (special rules apply).

### 1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).

**Pricing:** See Q 1.1.

**Reimbursement:** N/A.

### 1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.

Pricing: N/A.

**Reimbursement:** Medicinal products used in (public) hospitals or clinics are fully paid by public funds and are thus free of charge for the patients.

### 1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).

Pricing: See Q 1.1.

**Reimbursement:** OTC medicines are only (partly) reimbursed if prescribed by a doctor to pensioners or patients with a chronic disease who require treatment with that medicine.

### 1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.

Pricing: See Q 1.1.

**Reimbursement:** Generic versions of products that have already been granted general reimbursement or general conditional reimbursement will automatically be granted the same reimbursement status, provided that the price of the generic product is the same or lower than the existing product.

### 1.6 Biosimilar medicinal products (whether the first or subsequent available product)

Pricing: See Q 1.1.

**Reimbursement:** No special rules apply.

### 1.7 Orphan Medicinal Products.

Pricing: See Q 1.1.

**Reimbursement:** No special rules apply.

### 1.8 Parallel imports from another Member State.

Pricing: See Q 1.1.

**Reimbursement:** Parallel imported products are covered by the reimbursement status of the original and directly distributed product.

### 1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.

Pricing: See Q 1.1.

**Reimbursement:** Vaccines are only (partly) reimbursed if granted conditional reimbursement status upon an application from the MA holder to the DHMA.

## 2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

Medicinal products are subject to free pricing in Denmark, cf. Q 1.1 above.

The DHMA decides on medicinal product's reimbursement status, cf. section 144(1)-(3), section 152(2) and (4) and section 158A(1) and (4) of the Danish Health Act.

## 3 Other Financial controls relating to supply

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?

No.

## 4 Pricing Criteria

**For those products identified in the answer to Q1 for which a price must be agreed:**

### 4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?

N/A

### 4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?

N/A

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

N/A

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

N/A

### 6.2 What controls apply to the right of company to:

- Increase its price and are the criteria applied for approval different from these given in the answer to 4 above?

N/A

- Reduce the price generally or for a period?

N/A

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

The Danish authorities have not introduced any legislative measures to freeze prices on medicinal products.

However, the Danish Association of the Pharmaceutical Industry (Lif), the Ministry of Health and the Danish Regions have entered into an agreement of price reductions and a cap on the prices of hospital-only medicinal products for the period 1 January 2013 – 31 December 2015. According to the agreement, prices of hospital medicines may not exceed the price applicable to individual packs on 18 May 2009 as subsequently adjusted under the parties' price-cap agreement of 4 June 2009. This price-cap was further lowered by 2.5 percent on 1 April 2013 and by 2.5 percent on 1 April 2014.

In addition, the Danish Association of the Pharmaceutical Industry (Lif) and the Danish Ministry of Health have entered into an agreement on a cap on medicine prices in the period 2012 – 2014. The agreement only relates to prescription-only medicinal products with general reimbursement and conditional reimbursement. According to the agreement, the prices shall be the prices as of 30 August 2006, as subsequently adjusted under the parties' price-cap agreement of 19 December 2008. This price-cap was raised by 1.5 percent on 1 April 2013 and 1.5 percent on 1 April 2014.

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

No

## 7 Other Types of price control

Does your jurisdiction control any of the following prices:

### 7.1 Full line or other wholesaler selling price

No

### 7.2 Pharmacy selling price

Yes. As a general rule the pharmacy selling price is calculated by adding a fixed percentage, a fixed amount and a fixed prescription charge (currently 9.3 percent, DKK 10.96 and DKK 8.00) to the price notified by the MA holder. Detailed rules are set out in the Danish Executive Order on Calculation of Consumer Prices etc. on Medicinal Products.

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

The Danish healthcare reimbursement system is national and financed by the state.

Medicinal products used in the (public) in-patient sector are fully paid by public funds and are thus free of charge for the patients.

In the outpatient sector the public health service reimburses part of a patient's expenditure on prescription-only medicines which has been granted a positive reimbursement status (general reimbursement or conditional reimbursement) by the DHMA. The general rule is that persons over the age of 18 have their annual expenditure exceeding DKK 915 reimbursed as follows (2014):

- Expenditure between DKK 915 and DKK 1,495: 50 percent is reimbursed.
- Expenditure between DKK 1,495 and DKK 3,235: 75 percent is reimbursed.
- Expenditure exceeding DKK 3,235: 85 percent is reimbursed

There are special rules on increased reimbursement for persons under the age of 18 and on reimbursement for the chronically and terminally ill.

Pharmacy charges apply, see Q 7.2.

**8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

Denmark operates the following positive lists:

- Prescription-only medicines with general reimbursement status
- Prescription-only medicines with conditional reimbursement status
- OTC-medicines with conditional reimbursement status.

The lists can be found here (updated every fortnight): <http://sundhedsstyrelsen.dk/en/medicines/reimbursement/general-reimbursement/medicines-eligible-for-reimbursement>

**8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

Medicinal products' reimbursement status must be approved formally.

Both medicinal products granted reimbursement and products not granted reimbursement are subject to ongoing reassessment over a five-year period.

Ad hoc reassessments outside the five-year assessment schedule may be carried out in special circumstances where new information appears about effect, adverse reactions, inappropriate consumption, new treatment recommendations, expansion of indications, significant price changes etc.

**8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

The DHMA makes the formal decision on a medicinal products reimbursement status. In most cases the DHMA has requested a recommendation from the Reimbursement Committee before the decision is made.

When assessing whether general reimbursement shall be granted for a medicinal product, the DHMA applies the following criteria, cf. Section 1(2) of the Danish Executive Order on Reimbursement of Medicinal Products:

- The medicinal product has a safe and valuable therapeutic effect on a well-defined indication, and

- the relationship between the price of the medicinal product and its treatment value is fair.

To document the cost-effectiveness of a medicinal product, a health economic analysis (based on the DHMA's standardised reporting structure for health economic analyses) may be enclosed in the MA holder's application for general reimbursement. A health economic analysis could be used in situations where a new treatment principle is to be valued against existing treatment or against non-treatment, or if the price of a medicinal product is higher than the treatment price of other reimbursable medicinal products treating the same condition without it actually constituting a new treatment principle.

The MA Holder is free to choose whether or not to enclose a health economic analysis in the application.

**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

Doctors can apply the DHMA for individual reimbursement for a medicinal product to a certain patient (single reimbursement) based on the patient's needs and medical history. The DHMA grants single reimbursement if the medicinal product has an important effect of treatment upon the patient and other relevant treatment methods have been considered to be inadequate or inappropriate.

## **9 Reimbursement – Administrative Arrangements**

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

The MA holder sends an application to the DHMA by using a standard form available from the DHMA's website. The application may be filed electronically or in hard copy.

The DHMA decides on the application, but is most often advised by a Reimbursement Committee that evaluates the application.

The DHMA must deliver its decision no later than 90 days after receipt of an adequate application for an authorised product. If the application material is inadequate, the time limit is suspended, and the DHMA must inform the applicant immediately of any further information needed.

The processing time for medicinal products with a new active substance or a new route of administration is usually 2-3 months.

For applications for products with the same active substance, same route of administration and indications as an already reimbursable product, but with a new pharmaceutical form, the processing time is usually 2 weeks.



## 10 Reasons for decisions on Pricing and Reimbursement

The Transparency Directive 89/105/EEC requires Member State authorities to provide a “statement of reasons based on objective and verifiable criteria” in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it from reimbursement (negative lists).

**10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

In general, yes.

As mentioned above the DHMA normally presents an application for general reimbursement to the Reimbursement Committee. The members of the Committee are appointed based on their medical skills and relevant experience in order to ensure a wide-ranging expertise.

If the Reimbursement Committee recommends that the medicinal product neither be granted general reimbursement nor general conditional reimbursement or if the Reimbursement Committee recommends that the medicinal product be granted conditional reimbursement, the DHMA will present the Committee's recommendation to the applicant for consultation. The recommendation is enclosed a copy of the DHMA's medical presentation, price survey and a possible evaluation of a health economic analysis.

The DHMA's decision on reimbursement includes a statement of reasons based on the criteria mentioned in the Danish Executive Order on Reimbursement of Medicinal Products. See Q 8.4 above.

**10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

Yes. If not, a company may in its appeal take the position that the DHMA has not provided a sufficient reasoning. In such cases, the DHMA will elaborate its reasoning if necessary.

## 11 Reconsiderations / Appeals

**11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

A decision made by the DHMA may be appealed to the Danish Ministry of Health, Holbergsgade 6, 1057 Copenhagen K, Denmark. However, the Ministry cannot reassess the DHMA's scientific estimate.

**11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

Decisions made by the DHMA and the Danish Ministry of Health can be brought before the Danish courts. There are no fixed time limit within which a case must be brought before the courts, but it must be within a reasonable time.

**11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

To our knowledge, legal proceedings have only been initiated in one case on the basis of a rejection of reimbursement for a certain medicinal product, but the judgment was not in favour of the company. In general, Danish courts are reluctant to examine the discretion exercised by the administration.

## 12 Unlicensed products and off-label use

**12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?**

The patient's expenditure on unlicensed products prescribed on a compassionate use basis is reimbursed if the patient is granted single reimbursement from the DHMA. There is no control of the price level, however the price may influence on the reimbursement decision.

**12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?**

There are no restrictions on reimbursement for off-label use, if the medicinal product in question has been granted a general reimbursement status. Conditional reimbursement or single reimbursement may also be granted for off-label use.

**13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.**

No

- 14** Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).

No.

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# Estonia

## 1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied

Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?

There is no requirement to get an approval of the price and/or reimbursement status of products before they are placed on the market. If a manufacturer wishes to get to his product a reimbursement status he can apply for it at any time (usually the product has been already in the market for some time).

### 1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."

No.

### 1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).

No.

### 1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.

No. If there is a pricing tender process, then the general tender process (public procurement) requirements and conditions apply (lowest price or agreed price, effectiveness, etc).

### 1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).

No.

### 1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.

No.

### 1.6 Biosimilar medicinal products (whether the first or subsequent available product)

No.

**1.7 Orphan Medicinal Products.**

No.

**1.8 Parallel imports from another Member State.**

No.

**1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

As said above, there is no requirement to get an approval of the price and/or reimbursement status of products before they are placed on the market.

**2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

As mentioned above in Q.1, there is no requirement to get an approval of the price before they are placed on the market. The reimbursement system is a separate proceeding. If a manufacturer wishes to get a reimbursement status for his product he shall submit an application with required additional documents to the Minister of Social Affairs. The medicines under the reimbursement system are subject to reimbursed price determination process (see below answers to Q.8).

**3 Other Financial controls relating to supply**

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

The Government of the Republic of Estonia has established by regulation threshold values for mark-ups in wholesale and retail trade of medicinal products. However, the threshold value of mark-up per one proprietary medicinal product must not exceed 6.40 euros.

**Current threshold values for mark-ups in wholesale:**

The purchase price of one original (€)	Threshold value (%)
Up to 1,60	20
1,61-2,88	15
2,89-6,39	10
6,40-12,78	5
over 12,78	3

**Current threshold values for mark-ups in retail:**

The purchase price of one original (€)	Threshold value	
	Proportional mark-up (%)	Fixed mark-up (€)
Up to 0,64	0	0,38
0,65-1,28	40	0,38
1,29-1,92	35	0
1,93-2,56	30	0
2,57-3,20	25	0
3,21-6,39	20	0
6,40-44,74	25	0
over 44,74	0	5,11

**4 Pricing Criteria**

**For those products identified in the answer to Q1 for which a price must be agreed:**

**4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?**

N/A.

**4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?**

As said above in Q.1, there is no requirement to agree on a price before they are placed on the market. Such information - clinical and cost-effectiveness - is required only in reimbursed price determination process (see below answers to Q.8).

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

As said above in Q.1, there is no requirement to agree on a price.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

As said above in Q.1, there is no requirement to agree on a price. As there are the Government has established a threshold values for mark-ups in wholesale and retail trade of medicinal products, the holders of an activity licence for wholesale distribution of medicinal products are required to submit by March 1 each year to the Ministry of Social Affairs a consolidated turnover report concerning the medicinal products not subject to medical prescription and medicinal product subject to medical prescription, except veterinary medicinal products, dispensed by all their wholesalers during the preceding year. The turnover report must set out the sales volume of medicinal products expressed in sales in packaging, the turnover expressed in wholesale purchase prices (without value added tax) and the turnover from products sold to retail pharmacies expressed in pharmacy purchase prices (without value added tax). The turnover data expressed in wholesale purchase prices must be grouped into price groups that constitute the basis for wholesale mark-ups, and the turnover data expressed in pharmacy purchase prices must be grouped into price groups that constitute the basis for retail mark-ups.

The same applies to retail pharmacies, which have an obligation to submit annual reports to the State Agency of Medicines with statistical data.

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 adobe?**

As brought out in Q.3, the mark-up of a medicinal product must not exceed the set threshold values for mark-ups (see above Q.3.1 and 3.2) and the threshold value of mark-up per one proprietary medicinal product must not exceed 6.40 euros.

- **Reduce the price generally or for a periodd**

The reduction of price of OTC medicines is not regulated by law. Therefore companies are free to reduce the price (if the contract concluded between the wholesaler and retailer does not stipulate otherwise).

The reduction of price of remunerated prescription medicines is regulated by law. The price cannot be lower than limit price or if there is a price agreement then different than the agreed price. The reduction can be made only at the expense of seller's profit (i.e. between the threshold value for mark-up). However, quite often the sales contracts between the manufacturer/wholesaler and the retailer have a fixed sum under which the product shall be not sold.

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

No. The law does not determine overarching price freeze.

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

No, there is no such obligation. However usually the branded product originator will lower his price.

## 7 Other Types of price control

**Does your jurisdiction control any of the following prices:**

### 7.1 Full line or other wholesaler selling price

As explained above in Q.3 the Government has established a threshold values for mark-ups of medicinal product (see above Q.3.1). Also, the holders of an activity license for wholesale distribution of medicinal products are required to submit by March 1 each year to the Ministry of Social Affairs a consolidated turnover report concerning the medicinal products not subject to medical prescription and medicinal product subject to medical prescription, except veterinary medicinal products, dispensed by all their wholesalers during the preceding year. The turnover report must set out the sales volume of medicinal products expressed in sales in packaging, the turnover expressed in wholesale purchase prices (without value added tax) and the turnover from products sold to retail pharmacies expressed in pharmacy purchase prices (without value added tax). The turnover data expressed in wholesale purchase prices must be grouped into price groups that constitute the basis for wholesale mark-ups, and the turnover data expressed in pharmacy purchase prices must be grouped into price groups that constitute the basis for retail mark-ups.

The prices are also monitored by the State Agency of Medicines.

### 7.2 Pharmacy selling price

The threshold values for mark-ups of retail medicinal product are given above in Q.3.2. The retail pharmacies

have an obligation to submit annual reports with statistical data to the State Agency of Medicines.

In addition, the State Agency of Medicines permanently monitors the selling prices and every now and then visits pharmacies to control the selling prices.

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

The reimbursement framework is a national system, which is based on a remuneration of a retail sale (i.e. for patients). However, in order to get a medicine into the list of reimbursed medicinal products, the application with the relevant documents shall be submitted to the Minister of Social Affairs by a manufacturer.

The reimbursement system also involves a co-payment by the patient.

Medicinal products are compensated for according to the reference prices and price agreements in case they exist; in other cases the refund will be based on the product's retail price. Medicinal products are compensated for on the basis of the diagnosis. Discount rates for medicinal products:

**100% discount** - Patient shall make a contribution of 1.27 euros and in case there is a reference price or a price agreement pay the sum that exceeds that price. Health Insurance Fund will cover 100% of the sum that exceeds 1.27 euros and is below reference price or price agreement.

**90% discount** - Patient makes a contribution of 1.27 euros per prescription, pays 10% of the sum between 1.27 euros and the price agreement/reference price, and everything exceeding the reference price/price agreement. The Health Insurance Fund shall pay 90% of the sum between 1.27 euros and the reference price/price agreement.

**75% discount** - The patient makes a contribution of 1.27 euros per prescription, pays 25% of the sum remaining between 1.27 euros and the reference price/price agreement and everything exceeding the reference price/price agreement. The Health Insurance Fund shall pay 75% of the amount between 1.27 euros and the reference price/price agreement.

**50% discount** - The patient shall make a contribution of 3.19 euros, pay 50% of the sum between 3.19 euros and the reference price/price agreement and everything exceeding the reference price/price agreement. The Health

Insurance Fund shall pay 50% of the amount exceeding 3.19 euros, but not more than 12.79 euros per prescription.

There are exceptions from the above rates to the following patient groups:

- children under 4 years old;
- children aged 4 to 16 years;
- insured persons over 63 years of age, in addition, all persons who have been granted a pension under State Pension Insurance Act.

### 8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?

There is no “positive list” or “negative list”. The medicines that are reimbursed are prescription-only medicines.

### 8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?

As mentioned above in Q. 8.1, adding a medicine to the list of reimbursed medicinal products is a formal process carried out by the Ministry of Social Affairs.

The list of reimbursed medicinal products is reviewed and amended in every 4 times a year - January, 1st, April, 1st, July, 1st and October, 1st.

### 8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?

First, manufacturer shall submit an application with all required documents and information to the Minister of Social Affairs.

The Ministry of Social Affairs will evaluate the compliance of the application and supplementary documentation submitted with the requirements and, if necessary, set the applicant within 15 days a term for elimination of deficiencies (the term shall be 10-60 days).

If there are no deficiencies in the application, the Ministry of Social Affairs shall forward (within 15 days) the application to the State Agency of Medicines and to the Health Insurance Fund for their opinion. Both, the State Agency of Medicines and the Health Insurance Fund give (within 30 days) their written opinions about the application.

The Ministry of Social Affairs forwards both opinions to the Commission of Medicines concluded by the Minister of Social Affairs, to get its opinion.

The Minister of Social Affairs shall make the decision and inform the applicant within 180 days from receiving the application.

The following criteria are taken into account upon establishment of the list of medicinal products:

- (i) The need of an insured person to obtain a medicinal product as a result of the provision of a health service;
- (ii) The proven medical efficacy of a medicinal product and the need of an insured person to obtain other medicinal products in the course of their treatment;
- (iii) The economic justification of the use of a medicinal product;
- (iv) The existence of alternative medicinal products or means of treatment;
- (v) Conformity with the financial resources of health insurance.

**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

No. They can only make a proposal along with the patient to Health Insurance fund to remunerate a certain medicine in one case bases.

## **9 Reimbursement – Administrative Arrangements**

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

See above the answer to Q. 8.4.1.

## **10 Reasons for decisions on Pricing and Reimbursement**

The Transparency Directive 89/105/EEC requires Member State authorities to provide a “statement of reasons based on objective and verifiable criteria” in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it from reimbursement (negative lists).

**10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement deci-**

**sion) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

Yes. The State Agency of Medicines, the Health Insurance Fund and the Commission of Medicines can involve experts to the process by giving their opinions. All opinions and the final decision shall be grounded.

**10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

Yes.

## **11 Reconsiderations / Appeals**

**11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

As the final decision is made by the Minister of Social Affairs, there is no internal administrative appeal mechanism. The applicant can appeal the decision to administrative court.

**11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

Yes, to administrative court, within 30 days.

**11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

There have been only few appeals among which half have been successful.

## **12 Unlicensed products and off-label use**

**12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?**

Such medicine cannot be in the national list of reimbursed medicinal products. Such costs can be reimbursed on a case-by-case basis if the patient has a private agreement with the Health Insurance Fund. However, it is very rare and shall need to have a very good reasoning by the doctors and experts.



**12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?**

There is no clear answer. The medicines that are reimbursed are sold under the prescription only. It is the responsibility of a doctor to ensure the right use of the medicine. However, no one can really control how and for what the medicine is consumed.

**13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.**

There are no special schemes for reimbursement price for particular classes of products, it is rather disease and diagnose specific. By concluding the list of reimbursed medicinal products, the diseases and diagnoses have been taken already into account (i.e. under 100% reimbursement list are medicines for HIV, cancer, diabetes, epilepsy, etc).

For orphan medicines there are usually price agreements between the manufacturer and Health Insurance Fund, but that does not involve the patient and is rather the matter between the state and the manufacturer.

**14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

No. The pharmacists will get the set price that is determined by the list of reimbursed medicinal products or if there is a price agreement, then the agreed price. If pharmacists achieve deep discounting by suppliers, it is their margin, which however must not exceed the threshold value for mark-up.

## CONTRIBUTOR

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### Thomas Hoffmann

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Having obtained his law degrees (2005 1. State exam, 2006 PhD, both at Heidelberg university) and his 2. State exam (2007, Heidelberg), Thomas Hoffmann was admitted to the German bar in 2008 and started his career at the Kiev office of a major international law firm. After obtaining an LL.M. in Polish business law in 2009 (Jagiello-nian University Kraków), he started to write his habilitation on insolvency law at the Institute of East European Law at the University of Kiel - an institution at which he simultaneously wrote legal opinions for German courts on legal disputes on various East European legal systems throughout the next two years. In 2011, he was appointed as "DAAD-Fachlektor" at the university of Tartu, Estonia, representing the German Academic Exchange service (DAAD) in all questions relating to legal academic exchange between the Baltic States and Germany and teaching in this function German law and international business law at the university of Tartu and other universities in the region. From 2011-2014, he was member of the committee drafting the new Estonian intellectual property law codification at the Estonian ministry of Justice.

Since 2013, he contributes his legal experience to bnt attorneys-at-law in Tallinn. The Estonian office of bnt was founded in 2006 and restructured by merger with Estonian law firm Bergmann in 2011. Since then a small but excellent team of lawyers has been led by attorney-at-law Aet Bergmann, who has 17 years of experience as a lawyer and a multicultural background. We offer legal services to foreign and Estonian corporate clients.

# Finland

## 1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied

**Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?**

In general, no such requirements exist, but medicinal product's costs can be reimbursed only when the MA holder has applied for reimbursement and a reasonable wholesale price and the Pharmaceutical Pricing Board ("the Board"), which operates under the Ministry of Social Affairs and Health, has confirmed these. A medicinal product with MA can also be marketed without a confirmed reasonable wholesale price, but in such case the product is not reimbursed according to the Health Insurance Act (1224/2004).

### 1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."

No. Please see above

### 1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).

If the reimbursement is not sought and no reasonable wholesale price has been applied to be confirmed, the pricing may be implemented without restrictions.

### 1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.

Hospital product pricing does not follow the same principles as pharmacy product pricing, as they are not in the reimbursement system. The pricing may be implanted freely and based on competitive bidding.

### 1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).

Non-prescription medicines can also be reimbursed, provided that the doctor has prescribed the medicine to the patient and the Board has confirmed a reasonable wholesale price and the reimbursement for the medicine.

### 1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.

If generic medicinal products are in the reimbursement system, their reference price is stated according to the Reference Price System. Some generic medicinal products may not, however, have their own reference group.

### 1.6 Biosimilar medicinal products (whether the first or subsequent available product)

The pricing and reimbursement process is the same mentioned above in Q1 and general conditions apply.

### 1.7 Orphan Medicinal Products.

Please see above.

### 1.8 Parallel imports from another Member State.

Please see above.

### 1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.

Question is not applicable in Finland.

## 2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

Please see answer to the Q1. Obtaining a reasonable wholesale price and reimbursement for MA products is not obligatory, but they are prerequisites for the reimbursement. The Board makes decisions regarding the price and reimbursements according to the Health Insurance Act (1224/2004) and Medicines Act (395/1987).

## 3 Other Financial controls relating to supply

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

According to the Medicines Act section 37 a, the MA holder is obliged to inform the body maintaining drug price in-

formation, the Board, the wholesale price of the pharmaceutical product (the price notification).

The pharmacist's retail price is defined according to the price list of drugs regulated by a government's decree. This retail price is based on wholesale price reported by the MA holder, gross margin based on wholesale price and VAT. In practice, the wholesaler must also sell the product at a wholesale price reported by the MA holder.:

## 4 Pricing Criteria

**For those products identified in the answer to Q1 for which a price must be agreed:**

### 4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?

One of the criteria for determining the reasonable wholesale price is price of the product in other EEA countries. In practice, the Finnish Pricing Board does not readily accept price suggestions which are in the upper half of the countries where the same product is on the market.

### 4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?

The Reference Price System is applied in Finland, according to which medicinal products are divided in reference groups by substances. Reference prices are determined based on MA holders' price notifications and prices are updated four times a year. This determined reference price is the highest possible price, based on which the reimbursement can be calculated. The price notification is the prerequisite for the reimbursement for the products in this system.

In Finland, reference price groups of the Reference Price System are formed by substance basis. Please see above.

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

The administrative system follows the Health Insurance Act and the Board confirms the reasonable wholesale prices of medicinal products after MA holder has applied this. Due to the nature of the Finnish system, there is no time limit for submitting an application, but there are time limits for handling the application.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

The wholesale price decision is valid (at maximum) from three to five years and during this time MA holder may apply for price increase. If the medicinal product is part of the Reference Price System, the prices are updated quarterly.

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 adobe?**

In principle, MA holder may seek to increase its wholesale price by applying this, but the requirements for the reasonable wholesale price have to be fulfilled. In practice, this is very challenging. Please see above Q 6.1.

- **Reduce the price generally or for a period?**

This is possible, but increasing the price to its previous level would be a risk and will not necessarily succeed without losing the reimbursement status, as the higher price might be considered no longer reasonable.

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

Due to the price competition caused by product exchange and Price Reference System, the wholesale prices of medicinal products have decreased in Finland.

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

The Board has an established practise according to which price reduction is, in practise, obligatory to maintain reimbursement.

## 7 Other Types of price control

Does your jurisdiction control any of the following prices:

### 7.1 Full line or other wholesaler selling price

Question is not applicable in the Finnish system. There is only one type of regulated price, an approved "reasonable wholesale price" in Finland.

### 7.2 Pharmacy selling price

Pharmacy selling prices are determined by the price list for drugs and notified wholesale price. Please see above answer to the Q3.

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

The Finnish reimbursement system is a national system that forms a part of the Finnish National Health Insurance system. This insurance scheme covers all permanent residents of Finland.

### 8.2 Does your jurisdiction purport to operate a "positive list" or "negative list" in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?

In Finland only approved medicinal products may be reimbursed. This requires that MA holder has applied for reimbursement and a reasonable wholesale price.

There are three types of reimbursement (2014): Basic (35% of the price), Lower special reimbursement (65% of the price) and Higher special reimbursement (100% of the price). The special reimbursement categories are set according to the severity of the treated condition and the necessity of the drug treatment and they are specified by a government regulation. Some medicinal products may also have a restricted eligibility for reimbursement.

### 8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?

Reimbursement status is a formal decision.

### 8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?

The Board makes the decision of reimbursement. The medicinal product's therapeutic value is taken into consideration in the decision on basic reimbursement status and the assessment is made by overall consideration.

- 8.5** Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?

The doctor may refuse generic substitution based on medicinal or therapeutic grounds. In such case, the reimbursement is granted from the original medicinal product.

## **9 Reimbursement – Administrative Arrangements**

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

The MA holder has to apply for reimbursement and a reasonable wholesale price from the Board. The decision must be delivered within 180 days of receiving the application.

## **10 Reasons for decisions on Pricing and Reimbursement**

**The Transparency Directive 89/105/EEC requires Member State authorities to provide a “statement of reasons based on objective and verifiable criteria” in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it from reimbursement (negative lists).**

**Criteria for the reasonable wholesale price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.**

- 10.1** In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?

The Social Insurance Institution of Finland (Kela) gives its statement regarding the reasonable wholesale price before the Board's decision. The Board also states its reasoning for its decisions.

- 10.2** In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?

The challenge is not the absence of reasoning but the Board might also refer to its established practices when determining the reasonable wholesale prices that might not be completely uniform with factors referred in law.

## **11 Reconsiderations / Appeals**

- 11.1** What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?

The applicant can reapply.

- 11.2** Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?

An appeal regarding a dissatisfactory decision of the Board can be lodged with the Supreme Administrative Court within 30 days of receiving the decision.

- 11.3** Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?

Courts have ruled their decisions in favour of pharmaceutical companies in many cases, but unfortunately in practise, the way of appeal is too slow to have other significant benefit than value regarding possible similar cases in the future.

## **12 Unlicensed products and off-label use**

- 12.1** Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?

In principle, reimbursement is bound to the indication, but as the tools for identifying off label prescription are not comprehensive, reimbursement may in practice occur.

If the treatment takes place in a hospital, hospital care is paid by municipality or federation of municipalities and the patient is responsible solely for daily hospital charge.

- 12.2** Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?

Please see above.

- 13** Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.

No. In practise cancer treatments take place in hospitals and in such cases no reimbursement is granted. Please see Q 12.2.

- 14** Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).

Question not applicable in the Finnish system.

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6

# France

## **1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied**

**Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?**

There is no requirement imposed on the MA holder or its representative to obtain a price and reimbursement for any kind of category of products in France. A pharmaceutical company is free to decide if it wants that its product is reimbursed or not. If it takes the decision to have a reimbursed product, then it de facto accepts to enter into pricing negotiations. It is not necessary to agree a price for a medicinal product if the cost is not to be funded by the health systems. In practice, pharmaceutical companies always want to have their products reimbursed.

### **1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."**

No requirement.

### **1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).**

No requirement.

### **1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.**

No requirement.

The price of medicinal products only used within public bodies such as hospitals is negotiated by each public body within tenders for public procurement contracts.

### **1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

N/A only reimbursed products undergo pricing procedure. Products have to be prescribed by a physician to be reimbursed. Consequently OTC products are paid for by patients.

### 1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.

No requirement.

### 1.6 Biosimilar medicinal products (whether the first or subsequent available product)

No requirement.

### 1.7 Orphan Medicinal Products.

No requirement.

### 1.8 Parallel imports from another Member State.

No requirement.

### 1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.

N/A

## 2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

The pricing and reimbursement procedures are run by separate procedures but simultaneously.

The **price** of a reimbursed medicinal product sold in pharmacies is set in negotiations between the "Comité économique des Produits de Santé" (Economic Committee of Health Product – CEPS) and the pharmaceutical company. As set out above, the price of medicinal products that are used only in hospitals are negotiated through the tender process, and does not have to be agreed with the CEPS.

The **reimbursement** application has to be sent to the Minister of Health with copy to the Transparency Commission of the Health High Authority ("Haute Autorité de Santé" – HAS). The Transparency Commission gives opinions to the Ministry of Health on the applications on the inclusion on the two lists of reimbursed products (the list of reimbursable medicinal products for the sales to individuals and the list of medicinal products approved for use in public bodies), their renewal and modifications.

The **legal provisions** applying to pricing and reimbursement can be found in:

- French Social Security Code (CSS)
- French Public Health Code (CSP)

- Agreement between the CEPS and the Syndicate of Pharmaceutical Companies (LEEM) dated 5 December 2012.

## 3 Other Financial controls relating to supply

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

The Agreement signed between the LEEM and the CEPS dated 5 December 2012 specifies the taxes called "remises" to be paid by pharmaceutical companies on the basis of the quantity of products sold to pharmacies and hospitals.

Every year, the CEPS splits the market into therapeutic groups of products (which is called "agrégats thérapeutiques") and fixes for each group a level of authorized increase of quantity of products sold.

If the increase of the group of products is above the authorized level, a percentage fixed every year of the income has to be paid back by the company selling products within the said group. This tax is called "remise par agrégats thérapeutiques".

There is also a "remise" on the turn-over of the company if the increase of the yearly turnover is above a fixed percentage (currently 10%).

Within the framework of an individual agreement signed between a company and the CEPS on pricing, innovative product, orphan medicinal products or paediatric medicinal products can be exempted of one tax called "remise par agrégats thérapeutiques". The agreement will specify whether the exemption is partial or total and its length.

## 4 Pricing Criteria

**For those products identified in the answer to Q1 for which a price must be agreed:**

### 4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?

The Agreement between the CEPS and the LEEM dated 5 December 2012 indicates that the price of all products for France should not be less than the lower price of Germany, Spain, Italy or the UK. The company must communicate to the CEPS the expected volume of sales for these countries. Every year, the company must communicate to the CEPS the prices, the volumes of sales and the reimbursement in these countries.

Regarding innovative products, the company must undertake that the price proposed is consistent with the prices accepted in Germany, Spain, Italy and the UK and update the data every year.

**4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?**

Based on the dossier filed by the Company, the price setting by the CEPS takes into account:

- the ASMR (improvement of the medical service provided, “Amélioration du Service Médical Rendu”) level,
- the results of an medico-economic assessment,
- the prices of other medicinal products with the same therapeutic field,
- the expected quantity of sales in France,
- the conditions of use of the product (Art. L.162-16-4 of the CSS).

## 5 Pricing control timelines

**5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?**

The price of reimbursed medicinal product sold in pharmacies is set in negotiations between the CEPS and the pharmaceutical company, and it is formalized in an agreement. Such an agreement on pricing made between CEPS and the companies lasts a maximum of four years (Art. L.162-17-4 of the CSS). As set out above, the price of medicinal products that are used only in hospitals are negotiated through the tender process, and do not have to be agreed with the CEPS.

If there is not such an agreement, the price is fixed by an unilateral decision of CEPS, unless otherwise decided by the Ministers of Health and Social Security within a 15-day period following the CEPS’ decision (Art. L.162-16-4 of the CSS). The Ministers’ decision will prevail. It is also then a unilateral decision which can be challenged by the pharmaceutical company in front of Court.

A decision on the inclusion of the list of reimbursed medicinal products and price must be taken within 180 days from the receipt of the application for reimbursement by the Minister (Art. R.163-9 I of the CSS). This application is transmitted to the CEPS. In practice, this time period is not always complied with.

## 6 Prices increases and reductions

**6.1 How often are price determinations ordinarily reviewed?**

According to the Agreement between the CEPS and the LEEM dated 5 December 2012, the agreement signed between the pharmaceutical company and the CEPS is reviewed once a year during the first semester of the year regarding the list of prices and products.

**6.2 What controls apply to the right of company to:**

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 above?**

This is not possible unless based on new available data (see below).

- **Reduce the price generally or for a period?**

Once the price is fixed with the CEPS, this price is applied as such. The prices can be reviewed at the request of the company or of the CEPS when there are modifications in the elements that justified the price as for example new available data in France and in the EU concerning, in particular, the assessment of the product, the medico-economic analysis, the volume of sales or the prices.

**6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?**

No

**6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?**

The price of a generic product is at least 60% less than the price of the innovator product.

According to the “Letter of Orientation” of the Minister of Health to the CEPS dated 2 April 2013, the price of the innovator product will have to decrease gradually to the price of the 1st generic product within a 5-year period.

The first reduction of price of the innovator product is of 20% at the launching of the 1<sup>st</sup> generic product.

## 7 Other Types of price control

**Does your jurisdiction control any of the following prices:**

**7.1 Full line or other wholesaler selling price**

No

**7.2 Pharmacy selling price**

The price fixed during negotiations with the CEPS for prescription products is the selling price to patients. It includes the fixed margin rate of the pharmacists and the applicable taxes.

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

The reimbursement scheme is national. The mandatory health insurance system ("Assurance Maladie Obligatoire") covers the entire population. The amount of the expenditure target of the Social Security (health insurance) is fixed annually by the parliament which votes the Social Security Funding Law ("Loi de Financement de la Sécurité Sociale"). The health insurance system is funded through contributions from employers and employees and taxes.

**When the medicinal product is supplied in a hospital,** the patient does not contribute specifically. The cost of the medicinal product is included in the price of the hospitalisation or of the act carried out in the hospital, which is paid for by the health insurance.

For innovative products or products for rare diseases, the products can be listed on the list of products reimbursed additionally to the hospitalisation services.

The difference between the price of the product and the reimbursed amount of the hospitalisation made cannot be charged to the patient.

This difference is financially supported for by the hospital.

**When supplied in a pharmacy,** only products prescribed by the physician are reimbursed. A part of the price is charged to the patient. It is called "ticket modérateur". The percentage of the price of this product reimbursed to the patient is based on the improvement of the medical service provided (ASMR): 100%, 65%, 30% and 15% of the price.

### 8.2 Does your jurisdiction purport to operate a "positive list" or "negative list" in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?

France operates two positive lists of reimbursed products: one for products sold in pharmacies and one for products used in hospitals.

### 8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?

There is a formal decision in form of an order of the Ministry of Health which is published in the Official Gazette.

Registration of a product on the lists must be renewed every five years.

### 8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?

The Transparency Commission gives opinions to the Ministry of Health and the Social Security Ministry on the applications on the inclusion on the lists of reimbursed products, their renewal and modifications.

After receiving the application for inclusion, the Transparency Commission evaluates the product on the basis of the Medical Service Provided ("Service Médical Rendu", SMR). The application must show the value of the product in terms of Public Health.

According to Article R. 163-3 of the CSS:

"I. Medicinal products are included on the list mentioned in the first paragraph of Article L. 162-17 in the view of the assessment of the medical service provided by such products indication by indication. This assessment takes into account the efficacy and adverse reactions of the product, its role within the therapeutic strategy, in particular with respect to other available therapies, the seriousness of the affection to which it is destined, the preventive, curative and symptomatic character of the medicated treatment and its interest to Public Health. The medicinal products that do not provide a sufficient medical service in the view of other available medicinal products or therapies shall not be included on the list."

According to new Article R.161-71-1 CSS, a medico-economic assessment is required within the framework of the inclusion or renewal of inclusion on the lists of reimbursed products if two conditions are fulfilled:

- Products having or claiming a high level of ASMR.
- Products which represent a significant expenditure impact for Health Insurance due to its effects on the care system, the professional practices, the conditions of caring of patients and if relevant pricing.

Consequently, pharmaceutical companies must provide to the newly created Commission for Economic Evaluations and Public Health (Commission d'évaluation économique et de santé publique - CEESP) a medico-economic evaluation

study relating to the product concerned and submit the medico-economic models or data necessary to the said assessment as well as the data necessary for the inclusion on the lists of reimbursed products. In a letter dated 24 September 2013, the HAS indicated that for an immediate operability of the new system in place, it decided to add a third condition: only those products generating a turnover of over 20 million Euros in France per year are concerned. The turnover must be understood as a forecast all taxes included for a product and not for an indication.

Two types of products are excluded:

- products for which a decrease of the price is decided by the CEPS,
- products which patent fell in the public domain.

The efficiency opinion is given based on the comparative analysis, between the different pertinent therapeutic alternatives, of the costs / benefit ratio expected or observed for health and quality of life of the patients.

#### **8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

For long-term diseases (such as cancers), the doctor may ask the Social Security to bear 100% of the expenses of the patient. A specific form has to be filled in by the doctor and the patient on the disease and its treatment.

## **9 Reimbursement – Administrative Arrangements**

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

According to Article R.163-8 of the CSS, in order for a medicinal product to be reimbursed by the Illness Insurance Fund, the pharmaceutical company seeking to commercialize a medicinal product must file an application in order to obtain its inscription on the list of reimbursed products and send it to the Social Security Minister (a copy is sent to the Transparency Commission of the HAS) and to the National Union of Illness Insurance Funds ("Union nationale des caisses d'assurance maladie"). (Please note that at the same time, the pharmaceutical company proposes a price for its medicinal product to the CEPS for products that will be sold to patients individually, but not to those available in hospitals. The two procedures are run simultaneously).

After receiving the application for inclusion, the Transparency Commission evaluates the product on the basis of the SMR. The application must show the value of the product in terms of Public Health (see question 8.4).

A decision on the inclusion of the list of reimbursed medicinal products and price must be taken within 180 days from the receipt of the application by the Social Security Minister (Art. R.163-9 I of the CSS).

Please note that for generic product, the decision is usually quicker as the dossier is not examined by the Transparency Commission. Nevertheless, no timeframe is given in the CSS.

## **10 Reasons for decisions on Pricing and Reimbursement**

**The Transparency Directive 89/105/EEC requires Member State authorities to provide a "statement of reasons based on objective and verifiable criteria" in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it from reimbursement (negative lists).**

**Criteria for the reasonable wholesale price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.**

### **10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

Yes. Case law requests that the Transparency Commission opinion is reasoned. The opinion of the Transparency Commission must mention the reasons that conducted the Commission to render its opinion. The Administrative Supreme Court reaffirmed this principle in some decisions. In case of lack of reasons, the order of inscription on the list of reimbursed products is cancelled. The reimbursement procedure must consequently be re-started. Please note that the opinion of the Transparency Commission is not challengeable in front of a Court, it is just an advice to the Ministry of Health and the Social Security Minister.

### **10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

Generally speaking, yes.

## **11 Reconsiderations / Appeals**

### **11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

According to Article R. 421-2 of the French Administrative Justice Code, it is possible to introduce an ex-gratia application. This ex-gratia application must be transmit-

ted to the Minister of Health / Social Security within two months following the date of publication of the order regarding the price and the reimbursement in the French Official Gazette.

If there is no reaction regarding an ex-gratia application within two months, this means the application has been refused. (This is most frequently the case).

At the end of this two-month period or if the Minister gives an explicit negative answer, a new period of two months begins. During this last period, a contentious application can be introduced.

Please note that the introduction of an ex-gratia application is not mandatory. A "recours en excès de pouvoir" (see 11.2) (contentious application) can be introduced directly. None of them are suspensive.

### **11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

A proceeding on the merits ("recours en excès de pouvoir") requesting the cancellation of the price / reimbursement can be introduced. The Administrative Supreme Court ("Conseil d'Etat") is competent "at the first and the last level". No appeal is consequently possible. The procedure is a written procedure. The introduction of the action has no suspensive effect.

#### **Time limit**

- If an ex-gratia application was first filed: within two months after the explicit negative answer to the ex-gratia application or within two months following a two-month period of silence of the Minister.
- Direct action in front of the Court: within two months following the publication of the order in the French Official Gazette.

An interim proceeding aiming at temporally suspending an administrative decision or its effects is also possible. The suspension if obtained will cease effect when the decision on the merits regarding the requested cancellation ("recours pour excès de pouvoir") is taken by the Court. The following conditions must be fulfilled:

- There must be an emergency to suspend the decision.
- There must be serious reasons to think that the decision is illegal
- A "recours en excès de pouvoir" must have been filed in parallel as detailed above.

It is rather difficult to obtain.

### **11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

The companies challenging the reimbursement/pricing decisions are rarely successful.

It appears by reading case-law that to be successful, the best argument for companies is to demonstrate that a member of the Transparency Commission had a conflict of interest. Indeed, the members of the Transparency Commission must be impartial and must have no conflict of interest.

For the first time, the Supreme Administrative Court has in a decision dated 16 May 2013 (Laboratoire Addmedica) suspended in an interim procedure a decision of the CEPS regarding the determination of the price of the medicinal product SIKLOS of Laboratoire Addmedica.

Indeed, the CEPS decided to fix the price of the product SIKLOS in line with the price in the USA (67 EUR and 13, 40 EUR according to the dosage). Laboratoire Addmedica challenged this decision of pricing.

The Supreme Administrative Court decided that the CEPS could not legally fix the price of SIKLOS 1000mg and SIKLOS 100mg by mere reference to the US price of the product DOXIA in the same indication. It must also take into account the price of SIKLOS in other EU Member States, the difference of foreseen volume of sale in the USA and in the EU and for a product for which no therapeutic alternative exists in France, the costs for the company required for the marketing of the product.

The Supreme Administrative Court further decided that a new price has to be fixed within 3 weeks and that the price could not be less than 200 EUR for SIKLOS 1000mg and 40 EUR for SIKLOS 100mg.

## **12 Unlicensed products and off-label use**

### **12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?**

Article L.5121-12 of the CSP sets down the conditions for the grant by the ANSM of a temporary authorisation for use ("autorisation temporaire d'utilisation") the so-called "ATU", which corresponds to a compassionate use or named-patient based prescription. Products under ATU can only be delivered in hospitals.

Article L.162-16-5-1 of the CSS specifies that the "exploitant" of ATU medicinal product must declare to the CEPS the amount of the maximum "indemnity" (price) which it requires for the ATU medicinal product from hospitals. The CEPS makes these declarations public.

The exploitant of the ATU medicinal product informs the CEPS annually of the turnover corresponding to these medicinal products as well as the number of units supplied.

If there is no exploitant in France, the internal pharmacy of the health establishment which wants to buy the product declares to the CEPS the compensation which is requested to it, if such compensation has not already been declared to the CEPS.

If the price fixed during the negotiation with the CEPS for the medicinal product once it has its MA is lower than the price requested for the medicinal product under the ATU, the CEPS can request the company to pay back part or all of the price difference.

According to Article L.5123-2 CSP, the medicinal products covered by a ATU can be brought, supplied, reimbursed and used by public bodies (public hospitals) without having to be listed within the corresponding list of reimbursed products. Medicinal products covered by an ATU are 100% reimbursed to public hospital by the Social Security Scheme.

The product covered by an ATU and then by a MA can be brought, supplied, reimbursed and used by public bodies (public hospitals) until the decision to list the medicinal product having now its MA.

#### **12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?**

The pricing and reimbursement of a product prescribed off-label is only possible if Recommendation for Temporary Use (RTU) for off-label prescription has been granted by the French Agency (Article L.162-17-2-1 of the CSS).

The pricing and reimbursement are decided by order of the Ministry of Health after advice of the National Social Security Fund ("Union Nationale des Caisses d'Assurance Maladie").

If the product is already reimbursed for one indication, the same conditions on reimbursement apply for the off-label use.

If the product has been repackaged or prepared for a retail supply, the price is fixed by decision of the Ministry of Health taking into account the price in force for the reimbursed indication(s), the cost of the preparation and the posology indicated in the RTU.

If the product is not listed in the lists of reimbursed products, it is reimbursed in the limit of the annual fixed rate basis per patient set by decision of the Ministry of Health after advice of the National Social Security Fund.

#### **13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.**

No.

#### **14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

N/A, there is no pay-back/claw-back by authorities in France for pharmacists. The remuneration of the pharmacists is based on margin rates fixed by the Ministers of Economy, Health and Social Security.

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She has 33 years' experience in contentious and non-contentious matters in industrial property, French and European regulatory including pricing and reimbursement, compliance and product liability.

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Juliette Peterka holds a post-graduate degree (DEA) in intellectual property law and an LL.M. in industrial property law from the Ludwig-Maximilian University of Munich. Juliette was admitted to the Paris Bar in 2000. She advises on both contentious and non-contentious matters for companies dealing in Life Sciences. Her practice covers, in particular, IP, regulatory, compliance and commercial work. After having worked with Paule in UK and US law firms, Juliette joined PDG Avocats.



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# Germany

## 1 **Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied**

**Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?**

### 1.1 **Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."**

Generally, there is no formal approval of the manufacturer's selling price and/or reimbursement status of prescription-only branded products on patent or off patent required. Products are therefore subject to free pricing but the reimbursement price will be negotiated.

The reimbursement prices of known active substances are generally determined according to the drug price regulation. According to the latter, the medicinal product's reimbursement price generally equals the manufacturer's selling price minus mandatory rebates. However, the Federal Joint Committee may create reference price groups for medicines with the same active substance, with therapeutically and pharmacologically comparable active substance, or with therapeutically comparable effects that determine reimbursement prices of substance classes, § 35 of the Social Code Book V (SGB V). Usually they are initiated once generics enter the market but it is possible to also create them out of patented pharmaceuticals only, too.

For pharmaceuticals that contain new active substances, the early benefit assessment will be carried out and the reimbursement price will be negotiated afterwards based on the result of the early benefit assessment. According to § 35a SGB V in connection with Capital 5 § 1 sect. 2 of the Code of Procedure of the Federal Joint Committee, medicinal products are considered new if they "contain active agents whose effect at the time of the first admission is not widely known in medical science. A medicinal product with the new active agent for the purpose of this regulation shall be considered as medicinal product with a new active agent, to the extent that, for the first approved medicinal product, data exclusivity exists."

The NAS status will regularly be determined by the authority that grants the marketing authorisation. However, the necessity of the early benefit assessment as consequence of the NAS is determined independently by the Federal Joint Committee as responsible reimbursement authority. It happens therefore that these two committees have

different opinions on whether the product is an NAS, and the Federal Joint Committee finally assesses whether an early benefit assessment will be carried out.

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**1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other “lifestyle” medicines).**

There is no need for price approval for such product group. Generally, lifestyle medicines or other are not reimbursable unless the respective SHI (Statutory Health Insurance Funds) will agree.

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**1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.**

The reimbursement price for medicines in the hospital sector are covered by DRGs (Diagnosis related Groups: Costs according to certain key diagnoses that cover the whole medical treatment). Each DRG is calculated to cover the costs of the hospital, namely the physicians' services, in-patient care and the necessary medicinal products. If the costs for a medicine are not sufficiently covered by the respective DRG, the hospital may agree with the relevant bodies in the SHI on a supplementary benefit, on a national or regional level, to ensure that the actual incurred costs for an in-patient treatment are covered. The responsible body for calculating DRGs in Germany is the Institute for the Hospital Financing System, and the respective DRG catalogue is enacted each year upon the collaboration of the GKV-SV (the National Association of Statutory Health Insurance Funds), the Private Health Insurance Association and the German Hospital Federation.

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**1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

OTC-products are, since 2004, generally not reimbursable (there are exemptions for children and under 18 year old persons), and are paid for by patients directly. Manufacturers of OTC-products are free in pricing; the Drug Price Regulation does not apply, so that there are no legal rebates that are subtracted from the manufacturer's selling price. Also the pharmacist can set prices freely.

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**1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

For generic medicinal products, there does not exist a special pricing scheme that differs from the above mentioned one (Question 1.1). In relation to the reimbursement price, the Drug Price Regulation determines the mandatory rebates from the manufacturer's selling price; the reimbursement price however might often be regulated by reference price groups once generics enter the market.

According to the “economy principle”, set out in §§ 2, 12 SGB V and § 16 of the Drug Price Regulation, the cheapest out of therapeutically equivalent medicinal products has to be prescribed. Otherwise, doctors will have to fear recourses (i.e. pay back the difference between the price level of the cheapest drug and the one prescribed). Therefore, doctors will in the end be required to prescribe generics as their prices will be below the original products' ones.

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**1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

There does not exist any specific regulation in relation to the price or reimbursement for biosimilar medicinal products that differs from the above mentioned one (Question 1.1). However the early benefit assessment in relation to reimbursement price does not need to be carried out, as the Federal Joint Committee currently considers biosimilars as not new active substances. Hence they are free in pricing, but it is also likely that reference price groups according to § 35 SGB V will be built out of different biosimilars which will equalize prices.

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**1.7 Orphan Medicinal Products.**

Provided that orphan drugs pursuant to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products are concerned, the additional benefit of the authorised orphan medicinal product does not have to be proven by the pharmaceutical manufacturer within the early benefit assessment (which has to be carried out anyway). According to section 130b (1) sentence 10 of the SGB V, orphan medicinal products need not prove any medical benefit or any additional medical benefit compared with the suitable comparative therapy, since this is legally acknowledged for orphan medicinal products by the marketing authorisation.

However, this privilege does not apply to orphan medicinal products with a turnover in the statutory health insurance fund above € 50 billion in the last 12 months. The turnover is calculated by considering the sales price including value added tax. In this case, the Federal Joint Committee will request evidence from the pharmaceutical manufacturer within three months with respect to the additional benefit of the orphan medicinal product as under the above-mentioned procedure.

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**1.8 Parallel imports from another Member State.**

Parallel imports from other Member States are allowed if the respective medicinal product is approved in another Member State of the EU (or EEA country). The approval of parallel imported drugs is determined according to a simplified procedure if the preparation is approved by the respective authority of the export Member State, and the preparation is identical with a preparation that is approved in Germany.

However this has no influence on the reimbursement price. The imported pharmaceuticals will always be cheaper and therefore need to be prescribed because of the economy principle. If the German price for the preparation was a negotiated price after the early benefit assessment, the company who carries out the parallel import has to go through price negotiations, too. The basis will be the early benefit assessment of the original preparation.

**1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

N/A

**2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

Pricing and reimbursement authorities differ in Germany. The relevant reimbursement authority is the Federal Joint Committee which has to carry out the Early Benefit Assessment and decide about whether reference price groups will be built, exclusions from prescription are made and so on.

The authority in charge for pricing and mandatory rebates is the National Association of Statutory Health Insurance Funds (Spitzenverband der Gesetzlichen Krankenversicherung). If the manufacturer can set the pharmaceuticals' prices freely, he will only have to display the mandatory rebates but does not have to await any pricing decision.

Pricing and reimbursement decisions are regularly dealt with separately. Relevant laws are the §§ 35 et. seqq. SGB V and 130 et. seqq. SGB V. Also, the German Drug Price Regulation is applied by the National Association of Statutory Health Insurance Funds and concerns the mandatory rebates: The manufacturer decides freely about the manufacturer's selling price. The pharmacy's retail price is calculated by adding the surcharge according to the German Drug Price Regulation. After, again, subtraction of the mandatory rebates and the rebate that has been negotiated with the GKV SV after the early benefit assessment, the reimbursement price is defined.

**3 Other Financial controls relating to supply**

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products**

**within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

In Germany, there are no controls of profit made.

**4 Pricing Criteria**

**For those products identified in the answer to Q1 for which a price must be agreed:**

**4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?**

N/A

**4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?**

Prices for new medicinal products containing new active substances are determined after the Early Benefit Assessment according to the remuneration calculation model. Criteria for the price negotiations are (1) the additional benefit assessed by the Early Benefit Assessment, (2) annual therapy costs of comparable drugs and (3) the EU sales price balanced according to turnover and pharmacy retail price.

Thus the European prices are taken into account but only as one criterion for the negotiations that are, apart from that, conducted openly. The result of these price negotiations is the reimbursement price that is applied from the 12th month on after introducing the medicinal product in Germany (see Question 5).

**5 Pricing control timelines**

**5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?**

With market access in Germany, a drug can be sold to the manufacturer's selling price after application of the German Drug Price Regulation. The date of introduction the medicinal product in Germany is the listing in the large German drugs tariff (Lauer-Taxe). The manufacturer has to apply for its inclusion at the IFA-Institute. If the medicinal product contains new active substances, the Early Benefit Assessment procedure will be carried out in order to determine the reimbursement price. The price for medicinal products with additional benefit may be determined by the pharmaceutical manufacturer for the duration of 12 months, beginning when the medicinal product has been placed on the market. Within this

12-month period, the reimbursement amount is to be negotiated between the pharmaceutical manufacturer and the GKV-SV. The manufacturer then has to submit a benefit dossier in which he proves the additional benefit of its preparation. After the Federal Joint Committee carries out the Early Benefit Assessment together with the German Institute for Quality and efficiency in Health care (IQWiG-Institute), reimbursement price negotiations start and will determine the reimbursement price that is applied from the 12<sup>th</sup> month on after market access.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

There are no price reviews in Germany.

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 adobe?**

The manufacturer's selling price can be increased freely at any time. However, reimbursement prices will not differ accordingly because the mandatory rebates, then, will increase, too: According to § 130a sec. 3a SGB V, the price moratorium has limited the reimbursement prices of all pharmaceuticals to the level of 2009 (Question 6.2).

- **Reduce the price generally or for a period?**

Prices can be reduced freely; there is no respective law that prohibits decreases.

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

Pharmaceutical manufacturers are legally obliged to grant a discount of 16 per cent on their finished medicinal products, based on the manufacturer's selling price listed in the Lauer-Taxe. This discount level has been introduced in 2010 and recently prolonged until the 31 December 2017. Hence the pharmaceutical's prices of 1 August 2009 are applicable until 2017. The reason for that was increasing pharmaceuticals spending by the SHIs and the short terms need to stop this increase.

It applies to medicinal products that are dispensed by community hospitals for the outpatient sector and by community pharmacies for the outpatient care. The increase to the manufacturers' discount has been introduced jointly with a price moratorium, which considers the official price listed in the Lauer-Taxe on 1 August 2009. This was supposed to have the effect that pharmaceutical manufacturers would not compensate for the increase in the manufacturers' discount by increasing the price before the discount applied.

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

There is no obligation to lower the price. However, reference price groups are often created shortly after generic preparations enter the market which will affect the reimbursement price.

Also, the economy rule according to §§ 2, 12 SGB V requires the prescription of generic products if they are more cost-effective. As consequence, branded products will have lower prices in due time.

## 7 Other Types of price control

Does your jurisdiction control any of the following prices:

### 7.1 Full line or other wholesaler selling price

According to the German drug price regulation, the wholesaler selling price is determined according to § 2 sec. 1 of the regulation. It may not increase by more than 3,15 per cent resp. 37,80 Euro, plus a fix surcharge of 70 cent as well as the statutory turnover tax.

### 7.2 Pharmacy selling price

Likewise, the pharmacy selling price may not exceed a fixed surcharge of 3 per cent plus 8,35 Euro plus 16 Cent for the promotion of the emergency service plus the statutory turnover tax.

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

According to § 27(1) SGB V, persons insured within the SHI are entitled to treatment if necessary to diagnose a disease, to heal a disease, to reduce its deterioration or to reduce clinical pain. This includes, pursuant to § 27(1) 2 No. 3 SGB V, the supply of medicines.

However, the reimbursement of medicines in the outpatient sector within the SHI is subject to numerous restrictions:

- the medicine supplied to the insured must be legally placed on the market in Germany;
- the economy principle set out in § 2, 12 SGB V;
- the medicine must be available in pharmacies only (see § 31(1) SGB V);

- the reimbursement by the SHI must not be excluded by § 34 SGB V.

Firstly, according to No. 3 of the Pharmaceutical Guideline issued by the Federal Joint Committee, persons statutorily insured are entitled to the supply of medicines provided that the respective medicines are legally placed on the market in Germany, that is, with a marketing authorisation or another respective authorisation (e.g. a registration), or none is required due to § 21(2) AMG. Secondly, with respect to the economy principle, please note the above. Thirdly, persons statutorily insured are entitled to medicines within the SHI solely if these medicines are classified as 'pharmacy-only medicine'. Fourthly, according to § 34 AMG, the medicine is excluded from the supply within the SHI if the medicine is not available on prescription, if the medicine is intended for the treatment of a minor ailment, or if the medicine can be classified as a 'lifestyle' medicine.

Finally, the medicines must be incorporated in the Lauer-Taxe, regardless of whether the medicines will be reimbursed in the outpatient or the hospital sector. The Lauer-Taxe is an official databank that contains information of authorised finished medicinal products that are reported to the Information Centre for Proprietary Medicinal Products. After the inclusion in the Lauer-Taxe, the medicine receives a central pharmaceutical number (PZN), a nationwide identification key for products distributed by pharmacies. Beside the PZN, the Lauer-Taxe also includes information regarding the respective medicine such as product characteristics, form of administration, package size and package price. It is legally ruled that the PZN serves as an identification key for the reimbursement of medicines within the SHI, (§ 300 SGB V), and the PZN is, for this purpose, also listed on the prescription. After a marketing authorisation has been granted, the Federal Joint Committee reviews, in an 'early benefit assessment procedure', whether a new medicinal product has any additional benefit regarding the existing therapies. The 'early assessment procedure' is carried out by the Federal Joint Committee on the basis of a dossier submitted by the marketing authorisation holder. Provided that no dossier will be submitted by the marketing authorisation holder, the Federal Joint Committee is under no obligation to get active and the additional benefit is deemed to be not proven. However, price negotiations will be carried out anyway and the product will be reimbursed to the negotiated price after 12 months.

- 8.2 Does your jurisdiction purport to operate a "positive list" or "negative list" in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

There is no positive list for reimbursement (only the Lauer-Taxe that lists all preparations available in Germany) but

a negative list - the exclusion of prescription for OTC preparation and preparations that the Federal Joint Committee has defined as excluded from prescription according to the annex III to the Medicinal Products Directive. The substances listed are regularly seen as non beneficial and/or not cost-efficient as for example many combination preparations of generic mono-compounds.

- 8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

The reimbursement status is the subject of a formal approval; every preparation that is not excluded from prescription (as described in Question 8.2) must be reimbursed by the SHI once the doctor has decided for it and once there is no therapeutically equivalent alternative that is more cost-effective.

- 8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

There is no formal decision needed, however, doctors will ask the Medical Service of the Health Funds for a pre-assessment in case of very expensive preparations.

- 8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

Doctors can override a recommendation but they will need to have the reimbursement commitment of the SHI in advance in order to avoid recourses.

## 9 Reimbursement – Administrative Arrangements

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

In Germany, there do exist some legal instruments to regulate the reimbursement price of medicinal products, in particular with regard to the outpatient sector. They have a direct impact on the price setting of medicines within the SHI. These instruments are stipulated in the SGB V, which are as follows:

- the reference price system (§ 35 SGB V)

- economy principle (§ 2, 12 SGB V); and
- the therapy information (§ 92(2) SGB V).

A reference price system can be set by the Federal Joint Committee for medicines with the same active substance, or medicines with therapeutically and pharmacologically comparable active substance, or medicines with therapeutically comparable effects. The reference price is based on the price of all products of the group into which the medicines are categorised and constitutes the maximum amount being reimbursed for the respective medicines by the SHI. If the price has been set at a higher level by the pharmaceutical company, the difference must be paid by the patient receiving the medicine. However, according to the Basis for Decision-making by the Subcommittee-Medicines for Defining Reference Prices dated 19 July 2007, no reference price group should be set for patented medicines based on a new active substance and deemed to represent a significant therapeutic advance – which the early benefit assessment aims for.

The Act for the Restructuring of the Drug Market (AM-NOG) proposes a new form of price setting for innovative medicinal products and sets new conditions for pricing and reimbursement of medicinal products. Since 2011, the reimbursement of a new medicinal product has been aligned regarding its therapeutic value. According to the AMNOG, the value of an innovative medicinal product is determined in comparison with existing therapies. Only if an additional benefit (assessed in the early benefit assessment) can be proven to the Federal Joint Committee with respect to existing therapies, a higher price might be negotiated with the National Association of Statutory Health Insurance Funds (GKV-SV). Medicinal products without any additional benefit are only reimbursed at the level of comparable products or therapies.

The economy principle can be specified or defined by therapy information, such as indication, effect, effectiveness and risks of new pharmaceuticals. In consequence, the medicine for which therapy information exists (issued by the Federal Joint Committee) would only be reimbursed in the case of a certain indication and a specific therapeutic scheme.

To identify additional benefit, medicinal products with new active ingredients or new areas of application are to be assessed by the Joint Federal Committee (Federal Joint Committee) in 'early assessment procedures'. The Federal Joint Committee is authorised to delegate the assessment to the Institute for Quality and Efficiency in Health Care or to another third party. The assessment is based on a dossier that is drafted by the pharmaceutical manufacturer. The dossier must be submitted to the Federal Joint Committee before the medicinal product is placed on the market for the first time. According to § 4(1) of the Ordinance for the Assessment of the Benefit of Drugs with new Active Ingredients (AM-NutzenV), the dossier must contain the following information: Authorised indications (1), medical benefits (2), additional medical

benefit compared with the suitable comparative therapy (3), number of patients and patient groups for which the therapeutically meaningful additional benefit exists (4), the costs for the therapy to the statutory health insurance (5) and an estimation of the requested quality (6).

According to § 2(4) AM-NutzenV, the additional benefit of a medicinal product is defined as any quantitatively or qualitatively improved patient-relevant therapeutic effect, compared with the effect of a suitable comparative therapy (such as improvement of health, reduction of illness duration, extension of survival, reduction of side effects or improvement of the quality of life).

The reimbursement price for medicinal products without additional benefits is limited to the costs of the comparative therapy, either by including the medicinal product in the reference price group or, if the requirements for reference price system are not fulfilled, by negotiating a respective price with the GKV-SV.

According to § 130b of the Social Code Book 5 (SGB V), the GKV-SV and the pharmaceutical manufacturer must conclude a contractual agreement on a reimbursement amount. This contractual agreement applies to all health funds, in other words, to the statutory health insurance funds and to the private insurance funds. If no agreement is reached within six months, an arbitration board becomes involved and decides within three months.

## 10 Reasons for decisions on Pricing and Reimbursement

**The Transparency Directive 89/105/EEC requires Member State authorities to provide a "statement of reasons based on objective and verifiable criteria" in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it from reimbursement (negative lists).**

**Criteria for the reasonable wholesale price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.**

### 10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?

Before applying for the early benefit assessment and other procedures carried out by the Federal Joint Committee, the manufacturer can apply for a scientific advice meeting (Beratungsgespräch) in which the FJC supports and answers questions that concern scientific or procedural aspects of the assessment procedure.

Also, the decision on the early benefit assessment or the pricing decision will have detailed reasoning that enables companies to address negative decisions: The scientific assessments of the IQWiG as well as the Decisions of the

FJC are published on the internet. Especially, the IQWiG-reports normally encompass up to 400 pages. However, there is no possibility to challenge the early benefit assessment decision made by the Federal Joint Committee, only the reimbursement pricing decision can be appealed. However the Courts will examine all procedural steps as a whole.

#### **10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

The Decisions of the Federal Joint Committee and the arbitral award on the price of the GKV-SV will be reasoned in some detail. If a company will file a claim against either of the decisions, the level of reasoning generally is sufficient to file actions against it.

## **11 Reconsiderations / Appeals**

#### **11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

There do not exist special appeal mechanisms if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status. However, the Federal Joint Committee offers scientific advice meetings (Beratungsgespräch) before procedures start, after any authorities' decision, there will be oral hearings. If the reimbursement pricing decision is made, the applicant can file a claim to the courts directly although this is only possible after the pricing decision and not against the early benefit assessment decision that serves as basis for the pricing negotiations.

#### **11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

The applicant needs to file a lawsuit at latest four weeks after the pricing decision of the GKV-SV. For the courts, there is no timeline applicable. Even in cases of interim relief, procedures might take up to two years. Principal proceedings usually take up to 6 years time.

#### **11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

There have been procedures in recent times regarding all pricing and reimbursement issues. Our experience shows that they take too much time and decisions will not be interesting in most of the times anymore. Also, courts tend to accept the price negotiated by the parties and

they see it as a negotiation result – which it only is if the arbitration board has not fixed the price by itself.

Therefore it is beneficial to claim any argument within the price negotiations and to try to find a reimbursement price on a consensual basis rather than filing a lawsuit against the decision.

## **12 Unlicensed products and off-label use**

#### **12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?**

Medicinal products that are made available under conditions for compassionate use (the AMG, section 21(2) No. 6) do not require a marketing authorisation as a prerequisite to be placed on the market. In this respect, the Federal Ministry of Health recently issued the Ordinance for Compassionate Use that stipulates the legal requirements for placing unlicensed medicinal products on the market in Germany before a marketing authorisation has been obtained by the pharmaceutical company. Besides the requirement to notify the compassionate use programme to the higher federal authority (BfArM or PEI), the requirements are, inter alia, as follows:

- the existence of objective evidence that the patients suffer from a life-threatening disease or a disease leading to severe disability;
- the existence of objective evidence that there is no other satisfying treatment option with medicinal products approved in the European Community; and
- the existence of objective evidence that a marketing authorisation application has been submitted for the medicinal product or that clinical trials with this medicinal product are still ongoing.

Costs of unlicensed products and compassionate use or named-patients basis are covered by the SHI in individual cases and prices will be the manufacturers' selling prices.

#### **12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?**

With respect to off-label use (i.e. prescription outside of the approved indication), the administration of a medicine outside its licensed indications can be reimbursed by the SHI, provided that certain conditions are fulfilled. In many rulings, German courts have laid down that if a medicine is administered for the therapy of a chronic and serious disease, a seriously debilitating disease or a disease that is life-threatening, for which no other satisfactorily therapy is available and for which reliable safety data can be obtained, the medicine will be reimbursed within the system of the SHI. With respect to medicines administered

in a compassionate use programme, the reimbursement (within the system of the SHI) has been subject to even stricter requirements than those applying to the reimbursement of medicines for off-label use. However, since the 15th amendment of the AMG was enacted (September 2009), medicines administered in compassionate use programmes are excluded from reimbursement within the system of the SHI.

**13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.**

No, there is no patient access agreements scheme in Germany.

**14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

No, there is no pharmacist pay-back system.



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# Greece

## 1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied

Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?

**1.1** Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."

N/A

**1.2** Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).

N/A

**1.3** Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.

N/A

**1.4** Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).

N/A

**1.5** Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.

N/A

**1.6** Biosimilar medicinal products (whether the first or subsequent available product)

N/A

**1.7** Orphan Medicinal Products.

N/A

**1.8** Parallel imports from another Member State.

N/A.

### 1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.

For all the above categories of products a price approval by the competent authority "Ministry of Health pricing committee" is required. Additionally, with the exception of 1.4, in order for the above products to be included in the positive list, an approval is required by the competent authority "Ministry of Health reimbursement list committee".

## 2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

Pricing approvals are regulated by Ministerial Decision of the Ministry of Health GP oik 61771 of 15 July 2014 (Government Gazette 1907/B/2014). Applications for the price of a medicinal product are examined and elaborated on the basis of the relevant pricing provisions by the National Drug Organisation (EOF) which operates under the supervision of the Ministry of Health. EOF's proposal is introduced to the Ministry of Health pricing committee which approves or rejects EOF's proposal.

Reimbursement approvals are conducted pursuant to Ministerial Decision of the Ministry of Health 82961 of 9 September 2013 (Government Gazette 2219/B/2013). Applications for inclusion of a medicinal product on the positive or negative reimbursement list are examined and approved by the Ministry of Health reimbursement list committee.

More in particular

#### Pricing Issues:

On patent products (the so called reference medicinal products):

The prices of the on patent products are determined according to the above relevant Ministerial Decision 61771 of 15 July 2014 on the basis of the average of the three lowest prices in EU Member States which publish reliable data under the condition that the product is marketed in at least three other EU Member States. The prices of medicinal products, as approved by the competent authority (Ministry of Health), are published in the relevant price bulletin which is uploaded on the Ministry of Health's website.

#### – Off patent products:

Following expiry of the patent of the active substance of a medicinal product, its price is reduced to the lowest of (a) either 50% of the last under protection

price; or (b) the average of the 3 lowest prices in the EU Member States.

#### – Generic products:

The price of a generic product is set at the 65% of the price of the respective on patent product (the so-called reference medicinal product) before losing its patent.

Medicinal Products produced in Greece:

The prices of this category of products are determined on the basis of a cost assessment that includes the cost of production, packaging and the cost of administration – marketing and distribution.

Medicinal products sold to the State (Products sold to State Hospitals)

The maximum hospital price is determined on the basis of the ex-factory price of the product reduced by 8.74%.

#### – Orphan medicinal products

Orphan medicinal products are also priced on the basis of the three lowest prices in EU Member States. However this category of products may be priced even if prices are offered in only two other EU Member States. On the contrary, on patent products, as already mentioned, are priced only if they are marketed in three other EU Member States (see to question 4.1).

### Reimbursement Issues

As already stated above, reimbursement issues are regulated by Ministerial Decision 82961/2013. According to this Ministerial Decision as well as article 21 of Law 4052/2012 (Government Gazette 41/A/2012) the anatomic therapeutic chemical classification (ATC) of the World Health Organisation is applied for the drafting and revision of the positive reimbursement list.

Additionally, a reference price system for each therapeutic category is introduced. The reference price in question is determined by the lowest price of the cost of daily treatment among the products of the same therapeutic category.

The Social Security Funds reimburse the on-patent medicinal products which have been granted marketing authorisation after 1 January 2012 provided that it is established that they are compensated by social security funds in two thirds of EU Member States or in at least at 12 EU Member States.

Moreover according to Ministerial Decision DYG 3a/oik 104744 (Government Gazette 3356/B/2012), new generics are automatically included in the positive list upon approval of their prices. Moreover, new generics whose on patent product (reference product) is included in the negative list are also automatically included in this list upon approval of their price.

### 3 Other Financial controls relating to supply

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

Various rebates are imposed by the authorities to the MA Holder ( MAH) .The rebates in question are the following :

- According to Ministerial Decision No F 42000/8809/1081/2012 (Government Gazette 1504/B/2012) a rebate is imposed on the MAH for its products included in the positive reimbursement list which amount to 9% on the wholesale price.
- Also, according to the same Ministerial Decision, an escalated rebate ranging from 2 to 8% is imposed quarterly on the MAH depending on the volume of sales for each medicinal product. The rebate in question is imposed where sales of a product exceed 400.000 Euros.
- Additionally, a rebate is imposed on pharmaceutical companies by Ministerial Decision G /5/oik 6931 2014 (Government Gazette 3676/B/2014). According to the Ministerial Decision in question from 15.03.2015, for the special cases where a medicinal product with no generic is selected or a therapeutic cluster which in total contains a unique or more active substances without any generics and the price of the product in question is higher than the reimbursement price, then , provided that the difference in price between the reimbursement price and the retail price does not exceed 6 Euros it is paid by the patient. In case the price difference is higher than 6 Euros the amount exceeding 6 Euros is paid as follows: 50% by the patient, 30% by the MAH and 20% by the Social Security Fund
- According to article 13 of Law 3452/2013 (Government Gazette 64/A/2013) an additional 2% is added to the existing 9% rebate for the inclusion in the positive reimbursement list, for medicinal products containing active substances that have been classified high priced for severe diseases ( article 12 par. a of Law 3816/2010).
- Furthermore a 1.5% rebate is added as a discount on the hospital price for all medicinal products of the special list of medicinal products for severe diseases set out in par. b of article 12 of Law 3816/2010, with which Social Security Funds and the hospitals are supplied.
- In the case the medicinal products with new active substances which are priced for the first time, apart from the fixed entrance fee, an additional 5% rebate or a discount is accordingly introduced, as an entrance

fee for the inclusion of all new medicinal products under a reimbursement regime, for a period of one year from their inclusion date. If the MAH does not fully comply, the medicinal product is removed from the positive list.

### 4 Pricing Criteria

**For those products identified in the answer to Q1 for which a price must be agreed:**

#### 4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?

According to article 6 of Ministerial Decision 61771/2014 of 15 July 2014 cited above, (question 1.1) the maximum producer's or importer's price (ex-factory) of an on patent product, so-called reference product, is defined as the average of the three lowest prices in EU Member States which publish reliable data, or other reliable sources , like EUROPID . In order for a medicinal product to be priced for the first time it must have been priced at least in three EU Member States.

#### 4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?

No other criteria are applied.

### 5 Pricing control timelines

#### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

Prices of all medicinal products are revised twice a year and the price bulletins are issued in January and July of each year.

New medicinal products, according to article 5, par. 2 of the above cited Ministerial Decision 61771/15-7-of 15 July 2014 are priced after the marketing authorisation is obtained. The timelines provided are those determined by the EU Transparency Directive 89/105 as this is transposed into Greek national legislation.

However this is not usually the case in practice since the pricing of new medicinal products is frequently considerably delayed. According to the above article 5 par. 2, the prices of generic medicinal products are approved within a shorter time frame from the one provided by

the Transparency Directive (30 days from the date the relevant applications were filed).

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

See to question 5

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 adobe?**

According to article 5 par. 4 of the above cited Ministerial Decision GP/oik 61771 of July 15 2014 no increase is permitted when prices are revised. Nevertheless, increases are accepted in case of corrections or errors made by the competent authority when determining the prices.

In addition to the above, according to the same article 5 par. 7, an increase in the price of an OTC product is prohibited until 1 January 2016. .

- **Reduce the price generally or for a period?**

According to the above-mentioned article 5 of Ministerial Decision 61771 of 15 July 2014 at any time the MAH may file an application to the competent authority requesting a reduction of the price of its product.

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

According to article 13, par. 5 of the above-mentioned Ministerial Decision 61771 of 15 July 2014, a price freeze may be imposed on certain categories of medicinal products. A review shall be carried out at least once a year to ascertain whether the macroeconomic conditions justify that the freeze be continued unchanged.

In exceptional cases the MAH can ask for a deviation from the price freeze if there are special reasons. The relevant decision is fully justified and announced to the applicant within 90 days.

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

Before answering the question one has to take into consideration that in Greece the medicinal products are categorised as branded / on patent (so called reference products), off patent products and generic products .The prices of the branded/on patent products are only lowered when the patent has expired. More in particular:

According to article 7 of the above-mentioned Ministerial Decision 61771/of 15 July 2014, when the branded product

loses its patent its price is set at the 50% of the price it had before losing its patent. When a generic product is entering the market, according to article 8 of the same Ministerial Decision, its price is set at the 65% of the price of the branded product before losing its patent.

Therefore the criteria for reducing the price of a branded on patent product is the expiry of its patent.

## 7 Other Types of price control

**Does your jurisdiction control any of the following prices:**

### 7.1 Full line or other wholesaler selling price

According to article 3 of above Ministerial Decision 61771/ of 15 July 2014 profit margins are set to the wholesalers varying between 1,5% and 7,8 % on the maximum net ex-factory price.

### 7.2 Pharmacy selling price

According to article 3 of above Ministerial Decision 61771/ of 15 July 2014 profit margins are set to pharmacists varying to 35% for OTC products and prescription medicinal products not anymore reimbursed by social security funds following a decision of the competent authority (EOF). For all medicinal products reimbursed by the social security funds the profit margin of the pharmacists varies depending on the price of the product from 30% for products with a price of 0,50 Euros to 2,25% for products with a price of 3000 Euros. Additionally , for products with a price higher than 3.000 Euros the profit margin is fixed at 2%.

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

The total of medicinal products which are reimbursed by the Social Security Funds is categorized to therapeutic categories (ATC class) and are reimbursed according to the reference price of each one of the categories in question (see also to question 2).

According to Ministerial Decision DYG 3a /10447/2012 published within the Government Gazette 2883/B/2012 a co-payment of 10% is provided for certain chronic diseases as well as a co-payment of 0% is provided for serious diseases (HRV / Cancer ). For the rest of the products a co-payment is provided at 25%

**8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

Medicinal products, following an approval of the reimbursement committee of the Ministry of Health, are included either in the positive or to the negative list on the basis of a reference price system (see to question no. 2 / reimbursement issues). In addition to the above, an OTC list exists as well as a so-called list of expensive medicinal products, (products of law 3816/2010).

**8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

The reimbursement status is national and is subject to formal approval of the competent authority (reimbursement Committee of the Ministry of Health). Reassessment is available at the next review of the reimbursement list.

**8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

The Decision is made by the reimbursement committee of the Ministry of health on the basis of ATC criteria (see also to question 2).

**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

According to Ministerial Decision oik 15942/2014 (Government Gazette 1186/ B/2014) INN prescription is mandatory. Doctors are obliged to prescribe the active substance. . They are not allowed to override there decision on the special needs of a particular patient .

## **9 Reimbursement – Administrative Arrangements**

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

Following the approval of the prices of new products the positive list is revised within 60 days from the publication of the relevant price bulletin. The prices of medicinal products already included in the positive reimbursement list, are revised according to Ministerial Decision 82961/2013 published to the Government Gazette 2219/B/2013, within 30 days after the publication of the relevant price bulletin.

## **10 Reasons for decisions on Pricing and Reimbursement**

**The Transparency Directive 89/105/EEC requires Member State authorities to provide a “statement of reasons based on objective and verifiable criteria” in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it fr price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.**

**10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

Such reasoning is notified by the Ministry of Health to the individual companies. This is provided by the relevant legislation transposing into the Greek legal system the provisions of the Transparency Directive 89/105.

**10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

The reasoning the most of the times is monosyllabic ( approved / not approved ) and therefore is not considered by the companies as sufficient.

## **11 Reconsiderations / Appeals**

**11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

With respect to the pricing issue, appeals of the companies must be filed to the pricing committee. Unfortunately no time-line has been set by the legislator. However companies usually file their appeals for pricing as soon as possible. The accepted appeals, according to the above Ministerial Decision GP oik 61771/ of July 15 2014 are published on the corrective price bulletin which is issued within 20 days from the date the initial price bulletin was issued.

In respect to the reimbursement issue according to the above Ministerial Decision DYG3(a) 104744 an appeal should be filed by the MAH within 15 days from the date

of publication of the positive list to the reimbursement Committee of the Ministry of Health

**11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

The applicant can file a petition before the First Instance Administrative Court requesting an indemnity for the financial loss suffered due to a mistaken calculation on the price of his product. The time limit for such petition is 60 days from the day the Ministerial Decision was published to the Government Gazette.

**11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

Companies can file an application to the Council, of State ( High Administrative Court ) for non compliance by the competent authority of the provisions of Ministerial Decisions concerning pricing and reimbursement issues with the Law authorising issue of the relevant Ministerial Decision. The application filed by the companies will refer to not compliance of the ministerial decision with the law which authorises the minister to issue the latter.

However the companies are reluctant in taking such legal actions against the authorities. The Hellenic Association of Pharmaceutical Companies in its capacity to secure the interests of its member companies usually takes such legal actions before the Council of State.

**12 Unlicensed products and off-label use**

**12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?**

Unlicensed products can be imported on a named-patient basis following a relevant application filed to EOF by the attendant doctor. The medicinal product is imported in the country through the Institute of Pharmaceutical Research and Technology, the so-called IFET, which operates under the control of the Ministry of Health. The medicinal product is reimbursed by the Social Security Funds at the price proposed by the manufacturer.

**12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?**

According to article 47 of law 4316 /2014 published in the Government Gazette 270/A/2014, off-label indications of medicinal products can be prescribed and reimbursed

from the Social Security Funds only in special cases and in accordance with the references of international literature and documented on an individual basis.

**13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.**

Patient access agreements are not yet established in Greece.

**14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

Yes, according to article 26 of law 4052/2012 published in the Government Gazette 41/ A/2012 , pharmacists are subject to an escalated claw back based on the turnover of the pharmacy .The claw back in question is imposed as follows: For a turnover up to 3000 Euros no claw back is required For a turnover varying from 3001 to 10.000 Euros a claw back of 2% is imposed , for a turnover from 30.001 to 40.000 Euros a claw back of 5% is imposed and for a turnover exceeding the 40.001 Euros a claw back of 6% is imposed.

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## CONTRIBUTOR

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# Hungary

## 1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied

**Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?**

The prices of non-reimbursed medicinal products, whether OTC or Rx are not subject to any regulatory approval or prior agreement in Hungary, unless a medicinal product is admitted into the social security reimbursement system. The reimbursement status of a medicine is always subject to the approval of the National Health Fund (in Hungarian: "Országos Egészségbiztosítási Pénztár"; a.k.a. "OEP").

### 1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."

There is no requirement to obtain prior regulatory approval for the price of prescription-only branded products; however reimbursement status – if requested by the MA Holder – has to be approved by the National Health Insurance Fund, on the basis of the MA Holder's application. In the course of the proceedings aiming the admission into the social security reimbursement system, the producer price has to be approved by the National Health Insurance Fund and on the basis of the approved producer price, the consumer price will also be determined.

The question of whether the medicinal product contains a NAS may arise in the course of the admission proceedings into the social security reimbursement system. The rate of social security reimbursement for the price of medicinal products not containing NAS may not exceed the rate of reimbursement already granted to the reference medicinal product.

There is no explicit legal definition for NAS under the Hungarian laws and regulations. There is however a definition for the term "active substance." Active substance shall mean any substance or mixture of substances intended to be used in the manufacture of a medicinal product, which – as a result of the manufacture of the product – becomes an active ingredient of the medicinal product that is intended to exert a pharmacological, immunological or metabolic action in order for restoring, correcting or modifying physiological functions or making a medical diagnosis.

### **1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other “lifestyle” medicines).**

There is no requirement to obtain prior regulatory approval for the price of prescription-only products without reimbursement status.

### **1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.**

For the purposes of medicine supply of publicly financed inpatient healthcare institutions, a centralized public procurement system has been effective since May 1, 2012. This centralized public procurement is managed by the National Institute for Quality- and Organizational Development in Healthcare and Medicines (in Hungarian: “Gyógyszerészeti és Egészségügyi Minőség- és Szervezetfejlesztési Intézet”; a.k.a. “GYEMSZI”), and principally includes all hospital medicinal products, except those subject to another, reimbursed-type public procurement. As a result of the public procurement procedure the product prices are included in the respective public procurement contracts, generally combined with product rebate offered by the MA holder and/or wholesaler. In practice, the product price offered in the public procurement tender by the MA Holder and/or wholesaler are made public but the pricing mechanism may be kept confidential as business secret.

The term “hospital medicinal products” does not only mean medicines intended exclusively for hospital use but includes other Rx products. In practice, a list of hospital medicinal products prepared by the National Council for Medicine Therapies (in Hungarian: “Országos Gyógyszerterápiás Tanács”), specifies the scope of medicines that are subject to centralized procurement.

Hospital medicinal products may be subject to three different types of public procurement procedures: (i) national level procurement; (ii) hospital level procurement; and (iii) reimbursed-type public procurement.

Under the reimbursed-type public procurement only products admitted into the social security reimbursement system may be the subject of the tender. The reimbursed-type public procurement includes both medicinal ‘products under separate budget allotment’ (in Hungarian: “különkeretes gyógyszerek”) and ‘active substances in itemized reimbursement’ (in Hungarian: “tételes elszámolás alá eső hatóanyagok”).

The law also provides for certain exceptions to the national level (centralized) public procurement system, specifically with respect to those medicinal products that are not included in the list and for those listed substances for which procurement arrangement has not yet been concluded. Supply of these products remains within the scope of the hospital level procurement i.e., public procurements initiated by the healthcare institutions.

### **1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

There is no requirement to obtain prior regulatory approval for the price of OTC products; however reimbursement status – if requested by the MA Holder – has to be approved by the National Health Insurance Fund on the basis of the MA Holder’s application. In the course of the proceedings seeking admission into the social security reimbursement system, the producer price has to be approved by the National Health Insurance Fund and on the basis of the approved producer price, the consumer price will also be determined.

### **1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

There is no requirement to obtain prior regulatory approval for the price of generic medicinal products irrespective of whether supplied under their common name or as branded generics; however reimbursement status – if requested by the MA Holder – has to be approved by the National Health Insurance Fund, on the basis of the MA Holder’s application. In the course of the proceedings seeking admission into the social security reimbursement system, the producer price has to be approved by the National Health Insurance Fund and on the basis of the approved producer price, the consumer price will also be determined.

### **1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

There is no requirement to obtain prior regulatory approval for the price of biosimilar medicinal products but reimbursement status – if requested by the MA Holder – has to be approved by the National Health Insurance Fund, on the basis of the MA Holder’s application. In the course of the proceedings seeking admission into the social security reimbursement system, the producer price has to be approved by the National Health Insurance Fund and on the basis of the approved producer price, the consumer price will also be determined.

### **1.7 Orphan Medicinal Products.**

There is no requirement to obtain prior regulatory approval for the price of orphan medicinal products; however reimbursement status – if requested by the MA Holder – has to be approved by the National Health Insurance Fund, on the basis of the MA Holder’s application. In the course of the proceedings seeking admission into the social security reimbursement system, the producer price has to be approved by the National Health Insurance Fund and on the basis of the approved producer price, the consumer price will also be determined.

### 1.8 Parallel imports from another Member State.

There is no requirement to obtain prior regulatory approval for the price of medicinal products imported as a result of parallel import from another Member State; however reimbursement status – if requested by the MA Holder – has to be approved by the National Health Insurance Fund, on the basis of the MA Holder's application. In the course of the proceedings seeking admission into the social security reimbursement system, the producer price has to be approved by the National Health Insurance Fund, and on the basis of the approved producer price the consumer price will also be determined.

Parallel import of medicinal products must be first licensed by the National Institute for Quality- and Organizational Development in Healthcare and Medicines (GYEMSZI) and the importer must notify both the MA Holder registered for the Hungarian market and the responsible government agency (GYEMSZI), at least 30 days before the planned start date of the parallel import.

### 1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.

N/A.

## 2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

N/A

### 2.1 Relationship between Pricing and Reimbursement Elements

Regulatory price approval is only required in case of admittance into the social security reimbursement system as part of the reimbursement admission proceedings. In case of admission into the social security reimbursement system the producer price must be first approved by the Health Insurance Fund, based on the application of the pharmaceutical company and following price negotiations with the National Health Insurance Fund.

The producer price as approved by the National Health Insurance Fund will serve as basis for the final retail price, which is determined by the National Health Insurance Fund as a result of the proceedings seeking the medicinal product's admission into the reimbursement system. In case the admission of a medicinal product into the social security system is requested, the pricing and reimburse-

ment elements of the request are dealt with within the same procedure.

The gross consumer price of a reimbursed medicinal product is composed of the producer (ex-factory) or import price plus the maximum wholesale and retail sale margins and the applicable 5% VAT. At the end of the supply chain, the payment of the gross consumer price is shared between the patient and the National Health Insurance Fund, depending on the respective reimbursement decision of the National Health Insurance Fund.

In the reimbursement decision, the National Health Insurance Fund establishes the amount (percentage) of reimbursement and the reimbursed price payable by the patient, both on the basis of the producer or import price as determined by the MA Holder, and accepted by the National Health Insurance Fund.

As an exception from the above general rule in case of hospital medicinal products, the pricing elements are dealt in the course of the respective public procurement procedures separately from the reimbursement elements (if any) which are dealt with by the National Health Insurance Fund. In case of the reimbursed-type public procurement, the prior admission of the drug into the social security reimbursement system is a precondition to the successful procurement.

### 2.2 Government Agencies

The National Health Insurance Fund is responsible for rendering any decision on the reimbursement status of any medicinal product in Hungary. Public procurement proceedings regarding hospital medicinal products and/or certain active substances are performed by both the National Health Insurance Fund and the National Institute for Quality- and Organizational Development in Healthcare and Medicines (GYEMSZI).

### 2.3 Applicable Legislation

The procedure for the admission of medicinal products into the social security reimbursement system, including the regulation on the pricing elements, is mainly governed by the following laws:

- Act XCVIII of 2006 on the General Provisions Relating to the Safe and Efficient Supply of Medicinal Products and Medical Appliances, and on the Distribution of Medicinal Products (the "Drug Economy Law");
- Decree No. 32/2004 (IV. 26.) ESzCsM of the Minister of Health, Social and Family Matters on the Aspects of the Admission of Registered Medicinal Products and Nutriment Satisfying Special Nutrition Needs into the Social Security Reimbursement System and on the Modification of the Admission or the Reimbursement (the "Reimbursement Decree"); and
- Decree No. 5/2007 (I. 24.) of the Minister of Health on the wholesale and retail sale margin of medicinal

products admitted to the social security reimbursement system (the "Price Margin Decree").

### **3 Other Financial controls relating to supply**

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

#### **3.1 Wholesale and Retail Sale Price Margin**

Wholesale and retail price margins of reimbursed medicinal products are set by law. The gross consumer price of a reimbursed medicinal product is composed of the producer (ex-factory) or import price plus the maximum wholesale and retail sales margins and the applicable 5% VAT. Concerning authorized medicinal products, the maximum amount of wholesale margin is between 4.4% and 8% of the producer price, depending on the level of the producer price; whereas the minimum amount of wholesale margin is between HUF 40 and HUF 100 (EUR 0.15 and 0.3). The maximum amount of retail sales margin depends on the amount of the wholesale price but in any event cannot be higher than HUF 990 (EUR 3) per medicinal product. .

#### **3.2 No Inducement Rule**

Pharmacy operators may not enter into any agreement or accept any benefit that prejudices or threatens to prejudice the efficient and safe medicine supply of patients. In pharmacies, the persons engaged in professional activities are not allowed to undertake any contractual commitment or accept any benefit that can restrict or compromise their professional independence, with special regard to their obligation to provide impartial and objective advice to the patient.

#### **3.3 Claw-back Tax**

MA Holders and wholesalers are subject to a statutory claw-back tax based on the monthly sales of their medicinal products within the social security reimbursement system and sold in pharmacies.

For MA holders, the amount of the claw-back tax is 20% of the proportionate amount of the monthly reimbursement amount received compared to the to the producer price (import price). There is an additional 10% payment obligation (calculated in the same way) with respect to the products that have been reimbursed for at least 6 years, provided that the producer price approved by the National Health Insurance Fund as the basis for social security reimbursement exceeds HUF 1,000 (EUR 3) and there is no other reimbursed medicinal product available with the

same active substance and form distributed under a different brand name by a different MA holder.

Wholesalers' payment obligation amounts to 2.5% of the monthly amount of the wholesale price margin realized regarding the reimbursed medicines that were sold to pharmacies.

### **4 Pricing Criteria**

**For those products identified in the answer to Q1 for which a price must be agreed:**

#### **4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?**

International reference pricing model is applied by the National Health Insurance Fund when they approve the producer price of the medicinal product during the proceedings for the admission into the social security reimbursement system. International reference pricing model is applied if the reimbursement application concerns (i) an active substance that has not yet been admitted into the reimbursement system; (ii) a new pharmaceutical form and new method of administration; (iii) a new indication; (iv) a new combination if any of the active substance in the combination is not yet reimbursed; (v) a price increase; (vi) a change in the reimbursement category; or (vii) products with significant therapeutic benefits, admission at a higher price, and granting reimbursement.

Concerning international reference pricing, the "lowest price in Europe rule" is applied in the reimbursement procedure, whereas the MA Holder must propose a producer price – serving as the base rate for the reimbursement and the consumer price – that does not exceed the price of the same product or another product with the same active substance with the lowest price among such products that are currently available on the market in any EU or EEA member state, and the medicinal product concerned must be reimbursed in at least three of these EU and/or EEA member states.

The National Health Insurance Fund annually reviews the approved producer prices of the products that have received the highest total amount of reimbursement by comparing their prices with the prices of other products with the same or similar active substances currently available on the market in any EU and/or EEA member state. In the course of this review the National Health Insurance Fund compares the prices of products marketed in Hungary with the producer prices of those products marketed abroad that are made by the same manufacturer.

Regarding the determination of the price of products in reference countries, the National Health Insurance Fund may research the relevant data available to it, or contact the responsible agency in other EU and/or EEA member states requesting medicine price information.

## 4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?

### (i) Pricing Criteria

In the course of the reimbursement procedure the pricing decision of the National Health Insurance Fund is primarily governed by the available budget of the National Health Fund and lead by principle of cost-efficiency. The budget of the National Health Fund is determined annually in the national budget of Hungary adopted by the Parliament.

Further to the international reference pricing model ("the lowest price in Europe rule") the following (internal reference) pricing criteria are also applied for determining the price that will serve as the basis of the reimbursement.

#### — First Generic Rule

The first generic rule requires that the producer price must be at least 40% (forty percent) lower than the producer price of the other (referenced) product with the same active substance that was first admitted into the reimbursement system. Then the producer price of the second generic product must be at least 20% lower than that of the first one and the third generic product's producer price must be at least 10% lower than that of the second generic product. The next three products are approved if their producer price is at least another 5% lower than the producer price of the product last admitted. Subsequent products are approved only if their producer price is lower than that of the approved product with the lowest producer price.

However, if the first generic product is approved for reimbursement with a producer price that is at least 60% lower than the producer price of the referenced product first admitted into the reimbursement system, then reimbursement approval will be granted for all products subsequently seeking approval if their producer price is lower than that of the first generic product.

#### — First Biosimilar Rule

The first biosimilar rule requires that the first biosimilar product may be approved for reimbursement at a producer price that is at least 30% lower than the producer price of the reference biological product already admitted into the reimbursement system. The producer price of the second biosimilar product must be at least 10% lower than that of the first biosimilar product and the price of the third biosimilar product must be at least 10% lower than that of the second biosimilar product. The producer price of all subsequent biosimilar products must be lower than that of the approved product with the lowest producer price.

#### — Public Procurement (Hospital Medicines)

In centralized and hospital level public procurements, pricing criteria do not include international or internal therapeutic category reference pricing. Instead, tender appraisal may depend either on the lowest price or on the best-value-for-money criteria (as typical in public procurements). The contracting authority may also request product rebates in the tender invitation. Legal remedies are available upon request submitted with the Public Procurement Arbitration Board, with respect to any conduct or omission which is contrary to the laws governing public procurement procedures.

#### — Insignificant Modification to the Product

Additional pricing rules stipulate that the new packaging, the new presentation, the new strength or the new pharmaceutical form of a product may only be approved for reimbursement with the same or lower producer price than that of the already reimbursed medicinal product.

### (ii) Information on Clinical Cost-Effectiveness

Substance or therapeutic reference pricing is applied within the social security reimbursement system by the National Health Insurance Fund.

Under substance or therapeutic reference pricing the National Health Insurance Fund may classify reimbursed medicinal products into the so-called fixed groups based on the active substance (same active substance, method of administration, strength and duration of action) or the therapeutic efficacy (medicinal products suitable for the treatment of the same disease, if in the four-level five-digit ATC group they serve the same therapeutic purpose and have identical indication). Further to the above, the Health Insurance Fund may regularly require the MA Holders to participate in price competitions in order to drive down producer prices.

Within the fixed amount reimbursement groups, the actual amount of reimbursement depends on the medicine's position in the group, which always reflects the outcomes of regular price competitions: (i) medicines with the most favorable daily therapy cost receive the maximum of the percentage based reimbursement applicable to the concerned group; (ii) medicines classified to the so-called preferred reference price range receive the fixed amount reimbursement granted to the price of the reference product or a fixed amount reimbursement calculated according to their daily therapy costs; and (iii) medicines outside the preferred reference price range receive a 15% (fifteen percent) lower amount of reimbursement than the products inside the preferred reference price range.

### (iii) Information on Clinical Cost-Effectiveness

Information on clinical and cost-effectiveness is provided by the MA Holder as an annex to its application for the admission into the social security reimbursement system. The substantiation of the cost effectiveness and therapy effectiveness of the product is the general prerequisite of any approval for the reimbursement system. The National

Health Insurance Fund reviews the data provided by the MA Holder concerning clinical cost-effectiveness and may also conduct related investigations.

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

In addition to the price approval for the admission of a medicinal product into the reimbursement system – in a general administrative procedure – there is no separate administrative system in Hungarian law for the MA Holder (or his authorized representative) to obtain a price. The general deadline available for the National Health Insurance Fund to enter a decision (including the approval of the producer price) on the MA Holder's application is 90 days.

The rules of the administrative procedure for the admission of a medicinal product into the social security reimbursement system are detailed in our answer to Q9.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

According to the applicable legislation, the National Health Insurance Fund must review the price determinations of reimbursed products at least annually.

In practice, the National Health Insurance Fund constantly reviews the producer prices accepted as the basis of reimbursement, and may at any time commence proceedings ex officio for the amendment of such price.

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 adobe?**

The MA Holder is free to determine the price including price increase or price reduction of non-reimbursed (Rx or OTC) products. .

In case of other reimbursed products, the MA Holder has to obtain approval of the National Health Insurance Fund to increase the producer price serving as the basis of reimbursement. The National Health Insurance Fund renders its decision in accordance with the normal administrative framework, which is 90 days from the receipt of the application. In practice, it is uncommon for the National Health Insurance Fund to approve a price increase application.

Procurement contracts concluded within the framework of public procurement procedures (hospital medicinal products) may stipulate the possibility and procedure

of a price increase by the MA Holder; but again, this is uncommon in practice.

- **Reduce the price generally or for a period**

As regards non-reimbursed products – whether Rx or OTC – the MA Holder is free to determine the price including temporary or permanent price reduction.

In case of reimbursed medicinal products, the approval of the National Health Insurance Fund is not required; but the MA Holder must notify the National Health Insurance Fund about the price reduction. The National Health Insurance Fund publishes this notification within one month.

Procurement contracts concluded within the framework of public procurement procedures (hospital medicinal products) may stipulate the possibility and procedure of a price reduction (whether temporary and permanent) by the MA Holder.

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

Currently there is no price freeze action in force in Hungary.

Price freezes can be ordered by the Government (in form of a Government Decree), if necessary to avoid temporary supply shortages or to maintain the balance of the pharmaceutical market.

Prior to the currently effective regulations, the laws generally required a change in the taxation, financial or other regulatory instruments affecting the economy in whole or in a substantial part, in which case the Government could freeze prices for maximum six months. Based on this general provision, the Hungarian Government last froze the producer and wholesale prices of different medicinal products, both reimbursed and non-reimbursed, in 2004. Exception was only made for those products whose manufacturers or distributors had entered into an agreement with the National Health Insurance Fund and agreed to meet certain special payment obligations. This Government Decree was successfully challenged before the Constitutional Court of Hungary as contrary to the provisions of the Constitution. The Constitutional Court found the Government Decree unconstitutional and annulled it on the grounds that (i) there was no underlying change in the regulatory instruments that could justify the price freeze; (ii) the Government differentiated between market actors producing or distributing the same products on the same market; (iii) the Decree provided for unfavorable provisions with retroactive effect for those who had not concluded an agreement with the National Health Insurance Fund; (iv) and the Government failed to set the effective time period of the price freeze.

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

There is no general obligation on the branded product originator to lower its price when the first generic product enters the market.

As far as the procedure for reimbursement is concerned, generic product entry may affect the price of the originator's product if they are rendered into the same active substance based fix group or the same therapeutic efficacy based fix group. The National Health Insurance Fund must exclude a medicinal product from the social security reimbursement system if its daily therapeutic cost is twice or more than

- the daily therapeutic cost of the reference product in the substance based fix group; or
- the mathematical average of the daily therapeutic costs of all products belonging to the therapeutic efficacy based fix group.

## 7 Other Types of price control

**Does your jurisdiction control any of the following prices:**

### 7.1 Full line or other wholesaler selling price

Wholesale and retail price margin of reimbursed medicinal products are determined by law and are set forth in Decree No. 5/2007 (I. 24.) on the Sales Margin of Medicinal Products Prescribed with Social Reimbursement (the "Price Margin Decree").

The gross consumer price of a reimbursed medicinal product is composed of the producer (ex-factory) or import price plus the maximum wholesale and retail sale margins and the applicable 5% VAT. In case of authorized medicinal products, the maximum amount of the wholesale margin may be between 4.4% and 8% of the producer price, depending on the level of the producer price; whereas the minimum amount of the wholesale margin must be between HUF 40 and HUF 100 (EUR 0.15 and 0.3).

The maximum amount of the retail sale margin depends on the amount of the wholesale price but in any event cannot be higher than HUF 990 (EUR 3) per medicinal product. Regarding medicinal products without marketing authorization, the maximum amount of the wholesale margin may rise up to 20% of the producer price and the retail sale margin may be 40% of the wholesale price.

Wholesale and retail sale margins are not regulated in case of non-reimbursed medicinal products.

### 7.2 Pharmacy selling price

The pharmacy selling price of reimbursed medicinal products is determined by the producer price approved by the National health Insurance Fund and the amount of the wholesale and retail sale margins. Apart from this, pharmacy operators may not enter into any agreement or accept any benefit that prejudices or threatens to prejudice the efficient and safe medicine supply towards patients

("no inducement rule"). In pharmacies, the persons engaged in professional activities are not allowed to undertake any contractual commitment or accept any benefit that can restrict or compromise their professional independence, with special regard to their obligation to provide impartial and objective advice to the patient.

## 8 Reimbursement – general principles and Transparency directive compliance

**8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?**

### (a) Scope of the Reimbursement System

The Hungarian reimbursement system is organized on national level. All reimbursement decisions are made by the National Health Insurance Fund having nationwide competence. Medicinal products are reimbursed either on the basis of their specific admission into the social security reimbursement system, or through the so-called named patient basis (individual) reimbursement.

### (b) Funding of the Reimbursement System

The funding of the social security reimbursement system is predominantly based on the national social security insurance system. Social security insurance is a compulsory, national insurance. The revenues of the social security insurance system are composed of the health insurance contributions paid by both employees and employers.

### (c) Co-payment

Insured patients during their hospitalization in publicly financed inpatient healthcare institutions receive the necessary medication free of charge. Otherwise, if purchased from community (public) pharmacies, the patient must pay the reimbursed price if the product is reimbursed and the full price if it is not.

### (d) Prescription/Dispensing Charges

There are no prescription and/or dispensing charges in the Hungarian reimbursement system.

**8.2 Does your jurisdiction purport to operate a "positive list" or "negative list" in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

Hungary applies a "positive list" in accordance with Section 6 of the Transparency Directive. Accordingly, a medicinal product is only covered by health insurance if the National

Health Insurance Fund has admitted the medicinal product into the reimbursement system by a formal decision.

**8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

Medicinal products are admitted into the reimbursement system as a result of a formal approval decision of the National Health Insurance Fund. Since reimbursement is solely based on national laws and regulations, the reimbursement status of a medicinal product may not be reassessed by local or regional authorities. The National Health Insurance Fund regularly reviews the medicinal products admitted into the positive list of reimbursed products, and if any doubt arises, inter alia, concerning the cost-efficiency of the medicinal product, it may exclude the product from the reimbursement system.

**8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

**(a) Competent Authority**

The MA Holder must file an application for reimbursement with the National Health Insurance Fund. The National Health Insurance Fund makes a reimbursement decision on the basis of the application dossier and some other criteria as stipulated below.

**(b) Criteria Applied**

The criteria of the positive decision of the National Health Insurance Fund are as follows:

- (i) the MA Holder must submit a formal application requesting the reimbursement of the medicinal product;
- (ii) the National Institute for Quality- and Organizational Development in Healthcare and Medicines (GYEMSZI) or the EMA has recognized the safety and efficacy of the medicinal product and authorized the marketing of the product;
- (iii) the cost-effectiveness of the medicinal product has been verified;
- (iv) the medicinal product is cost-effectively available for the designated therapeutic use;
- (v) the MA Holder (applicant) must undertake to comply with the regulations pertaining to the costs of the insurer;
- (vi) the necessary social security funding is available or can be made available; and

- (vii) the MA Holder undertakes the distribution and stockpiling of the medicinal product.

**(c) Health Technology Assessment**

The MA Holder must enclose an assessment to its application for reimbursement concerning the medicinal product's therapeutic value compared to an appropriate comparative therapy. This assessment forms an integral part of the application dossier, which is examined and evaluated by the Health Technology Assessment Committee (in Hungarian: "Egészségügyi Technológia-értékelő Bizottság") and the National Institute for Quality- and Organizational Development in Healthcare and Medicines (GYEMSZI) before the National Health Insurance Fund adopts its decision regarding the reimbursement status of the medicinal product. The National Health Insurance Fund must cooperate with these two professional agencies in the course of the proceedings, and must assess their recommendations concerning the health technology assessment of the medicinal product.

**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

**(a) Named Patient Based Reimbursement**

As a general rule, physicians cannot override the decision of the National Health Insurance Fund on the reimbursement status of medicinal products.

Insured patients – or their treating specialist physicians – may initiate proceedings on a named patient base for the individual reimbursement of a medicinal product not yet admitted into the social security reimbursement system if necessitated by a specific treatment. In this case the National Health Insurance Fund must render the decision on a case-by-case basis depending on the circumstances and costs of the individual treatment and within the limits of the budget of the National Health Insurance Fund. In case of a positive decision, the National Health Insurance Fund will provide assistance for the purchase of the allopathic medicinal product ("Named Patient Based Reimbursement").

In order to receive the Named Patient Based Reimbursement, the insured person must submit a request for individual reimbursement with the National Health Insurance Fund. The request must indicate the following:

- (i) the name, address, and social security number of the insured patient;
- (ii) the summary of the case history covering the previous three months, in order to verify that the applicant in fact needs the requested product;
- (iii) the recommendation of the treating physician, indicating the name of the medicinal product; the packaging; the exact dosage; the reason for switch-



ing to another medicinal product – if applicable; the efficacy of previous therapies; the expected efficacy of the new treatments; and the expected duration of the reimbursement; and

(iv) the name of the pharmacy which would serve as the dispensing pharmacy.

The National Health Insurance Fund must render a decision on the application for the individual reimbursement within 12 days following the filing of the application or immediately, in case of an emergency. In the course of its decision-making the National Health Insurance Fund must consider (i) the patient's case history; (ii) the severity of the disease; (iii) justification from a medical standpoint for the use of the medicinal product; (iv) the costs and cost-effectiveness; (v) the health advantage the medicinal product; (vi) the frequency of occurrence of the symptom; and (vii) the assessment of a competent specialist. Furthermore, the National Health Insurance Fund must also consider comparable technologies which are reimbursed, and the reasons why the patient cannot be treated with them. The decision of the National Health Insurance Fund must indicate (i) the data and quantity of the medicinal product; (ii) the price serving as the basis of the reimbursement; and (iii) the amount and duration of the reimbursement. Individual reimbursement can be granted for the maximum period of one year.

Named Patient Based Reimbursement is an exceptional method of medicinal product reimbursement, and its frequency largely depends on the available financial resources of the National Health Insurance Fund.

#### **(b) Control on Prescription Practices**

The physician's therapeutic decisions must be primarily based on the professional rules (professional protocol) and adjusted to the patient's specific condition. Professional rules are set out in professional protocols published from time to time by the minister responsible for healthcare.

In certain cases, for medicinal products belonging to special categories (therapeutic field), the so-called financing protocols govern the applicable medical care and therapy order. These are also determined by the minister responsible for healthcare. Financing protocols include – with respect to cost efficiency – the uniform algorithm of diagnostic and therapeutic steps of medical care for the specified disease or disease group that may be provided with public financing.

Where financing protocols exist, they prevail over professional protocols. Any deviation must be justified by the patient's condition or therapeutic reasons. Otherwise, the healthcare institution or the doctor will be obliged to pay back the financing amount that had been charged to the National Health Insurance Fund, or if especially requested by the patient, the patient must pay for the applied treatment.

## **9 Reimbursement – Administrative Arrangements**

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

### **(a) Procedure**

The reimbursement procedure commences when the MA Holder files an application (with various annexes) for reimbursement with the National Health Insurance Fund. The MA Holder must also pay an administrative service fee of HUF 1,500,000 (cca. EUR 5,000). In certain simplified procedures – where the subject of the application is an already reimbursed active substance – the service fee is HUF 300,000 (cca. EUR 1,000).

In the application, the MA Holder must indicate the requested reimbursement method and category for the medicinal product concerned, which can be either

- (i) 100% reimbursement for medicinal products purchased through public procurement;
- (ii) indication based reimbursement at 100%, 90%, 70% or 50% reimbursement rates; or
- (iii) normative reimbursement at 80%, 55%, 25% or 0% reimbursement rates.

On the basis of the application, the National Health Insurance Fund must render a decision on the admission of the medicinal product into the social security reimbursement system. In case of a negative decision, the National Health Insurance Fund must disclose the reasons for the rejection. If the reason is solely related to the budgetary concerns of the National Health Insurance Fund, the MA Holder may file the same application within two years without paying any additional service fee. In case of a positive decision, the National Health Insurance Fund stipulates the following in its decision:

- i producer price approved serving as the basis of the reimbursement;
- (iv) reimbursement method and category;
- (v) applicable rate or amount of the reimbursement;
- (vi) reimbursed price payable by the patient;
- (vii) commencement date of the reimbursement.

### **b) Timeline**

As a general rule, the National Health Insurance Fund has 90 days from the date of receipt of the complete application dossier to render the reimbursement decision. The administrative deadline is 60 days in case of new generic versions of already reimbursed medicinal products.

If the reimbursement application concerns a new active substance according to which legislative action is needed, the National Health Insurance Fund may suspend the proceedings until the applicable legal regulation is amended for the maximum period of 90 days. In lack of the neces-

sary amendment, the National Health Insurance Fund must render its decision on the basis of the existing and effective legal regulations.

## **10 Reasons for decisions on Pricing and Reimbursement**

The Transparency Directive 89/105/EEC requires Member State authorities to provide a “statement of reasons based on objective and verifiable criteria” in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it if price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.

### **10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

The National Health Insurance Fund must provide its statement of reasons based on objective and verifiable criteria in case of a negative reimbursement decision. The reasons of rejection must directly relate to one or more statutory criteria applied in the course of the proceedings [see, answer to Q 8.4(b)].

If the statement of reasons relate to the cost-effectiveness and/or health technology assessment of the medicinal product, the reasoning of the National Health Insurance Fund must be based on and evidenced by the assessment of the expert opinions of the Health Technology Assessment Committee and the National Institute for Quality- and Organizational Development in Healthcare and Medicines (GYEMSZI).

### **10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

In practice, the formal legal reason most likely used in the negative decision of the National Health Insurance Fund is the lack of appropriate financial resources (budgetary constraints), for the admission of a new product into the social security reimbursement system. Is it hard to successfully challenge a negative decision because the National Health Insurance Fund is almost always under-financed.

Chances for a successful challenge are better if the National Health Insurance Fund has

- (i) violated the applicable procedural rules (e.g. disregarded the expert opinion of the Health Technology Assessment Committee without due reasons for doing so; or failed to provide proper statements of reasoning);

- (ii) unduly exceeded its margin of appreciation (e.g. when assessing the cost-effectiveness data on the basis of the application and the expert opinions);

- (iii) based its decision on internal rules that are non-compliant with the applicable laws and regulations.

## **11 Reconsiderations / Appeals**

### **11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

The reimbursement decision of the National Health Insurance Fund may not be appealed or otherwise challenged within the public administration. It must be noted though that the National Health Insurance Fund may correct or change its reimbursement decision ex officio if it becomes aware of any deficiency of the decision.

Reimbursement decisions may only be challenged before the administrative court of law by way of judicial review. Judicial review may only be initiated if alleging (and evidencing) that the National Health Insurance Fund has violated any laws or regulations in the course of its proceedings, provided that the violation had a (material) effect on the reimbursement decision.

### **11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

The reimbursement decision of the National Health Insurance Fund may only be challenged by judicial review on the basis of any material violation of the applicable laws by the National Health Insurance Fund.

The petition must be addressed to the competent court and filed with the National Health Insurance Fund within 30 days from the date when the reimbursement decision was first delivered to the applicant.

After receiving the petition, the National Health Insurance Fund must forward it to the competent court within 15 calendar days together with the relevant part of the administrative case file.

The court must render its decision within a “reasonable” time, depending on the specifics of the case.

### **11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

According to prevailing court practice, the statements of reasons of the National Health Insurance Fund’s reimbursement decision must properly substantiate the lawfulness of the decision [see, EBH2009. 2018]. Pursuant

to the relevant case law, the principle of financeability, transparency, verifiability, foreseeability, publicity, and cost-effectiveness must apply in the course of the decision-making mechanism of the National Health Insurance Fund.

In case the reimbursement decision complies with the aforementioned minimum standards of reasoning, it is likely that the court will dismiss the statement of claims of the applicant.

## **12 Unlicensed products and off-label use**

### **12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?**

Unlicensed medicinal products may only be reimbursed on a named patient basis, if approved by the National Health Insurance Fund on a case-by-case basis [see, answer to Q8.5].

As regards the control over the price level, the National Health Insurance Fund must, in the course of rendering a decision on the approval of the named patient based reimbursement application, consider – inter alia – pricing issues and budgetary effects, and must also determine the level and/or the amount of the percentage/amount reimbursement granted.

### **12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?**

As a general rule, the reimbursement of a medicinal product is granted on the basis of the contents of the marketing authorization. It follows, that the off-label use of a medicinal product may not be reimbursed even if the product is admitted in the social security reimbursement system, due to the fact that the off-label use is not compliant with the marketing authorization.

The off-label use of any medicinal product is subject to the specific, individual authorization of the Health Technology Assessment Committee and the National Institute for Quality- and Organizational Development in Healthcare and Medicines (GYEMSZI), which is granted upon the request of the patient's treating physician.

Social security reimbursement for the off-label use of a medicinal product may only be granted on an individual basis within the named patient based reimbursement system [see, answer to Q8.5].

## **13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.**

Patient access schemes – in the sense as defined and applied in the UK – are not applied in Hungary.

Public medicine procurements may serve a similar purpose as patient access schemes, where contracted purchase prices do not affect the medicine's original list price, where it would be otherwise applicable. Specifically, the reimbursed-type public procurements aim to purchase medicinal products for particularly expensive therapies (e.g., oncology, hematology, orphan drugs, etc.), according to the actual needs of hospitals. Public procurement contracts must be posted on the contracting authorities' websites, save confidential business information, the disclosure of which would cause disproportionate harm to the successful tenderer's business activities. The National Health Insurance Fund has recently agreed to the confidential treatment of the net and gross medicine unit prices.

## **14 Are pharmacists subject to any annual or other pay-back/claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

Pharmacists and pharmacies, as retailers, are currently not subject to special claw-back tax.

Until December 31, 2012, any pharmacy engaged in the supply of medicinal products to the general public with an aggregated quarterly price margin from the sale of reimbursed medicinal products exceeding the amount of HUF 10,000,000 (cca. EUR 33,000) was subject to a "pharmacy solidarity tax".

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# Ireland

## 1 **Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied**

**Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?**

It is not necessary to agree a price for a medicine before it is placed on the Irish market. A reimbursement price is set by the State before a medicine is reimbursed under the Irish state reimbursement schemes. Medicinal products are funded by the State in Ireland, through reimbursement of the pharmacist.

Under the Health (Pricing and Supply of Medical Goods) Act 2013 (the "2013 Act"), the Health Service Executive ("HSE") must maintain a "Reimbursement List" in respect of drugs, medicines and medical and surgical appliances. If the product is not on the Reimbursement List, the supplier may make an application to have the product added to the list in order to be eligible for reimbursement. In general, non-prescription items are not covered by the state reimbursement schemes, however, certain non-prescription items for pain relief and allergies are reimbursable, where such items have been prescribed by a doctor.

### 1.1 **Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."**

Reimbursement or initial pricing approval for all products is necessary if the product is to be eligible for reimbursement by the State. Under the 2013 Act, HPRA is required to maintain a "List of Interchangeable Medicinal Products", however, a new product may not be added to the List of Interchangeable Medicinal Products unless the Health Products Regulatory Authority ("HPRA") is satisfied that it has the same qualitative and quantitative composition in each of its active substances as each of the active substances of the other medicinal products which fall within the group.

Under the 2013 Act, an active substance in a medicinal product is deemed to be the same as another active substance in another medicinal product notwithstanding that the two medicinal products contain different salts, esters, ethers, isomers or mixtures of isomers, or the two medicinal products contain different complexes or derivatives of the active substance concerned, provided that the two active substances do not significantly differ in relation to safety or efficacy in respect of human use.

### **1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other “lifestyle” medicines).**

It is not necessary to obtain approval of the price or reimbursement status before placing such products on the market where reimbursement will not be sought.

### **1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.**

A tender process is generally not undertaken in Ireland. Products will be subject to reimbursement under the state reimbursement schemes. Typically private clinics would purchase at the re-imbursement price.

### **1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

This will be dependent on whether or not they are eligible for reimbursement under the state reimbursement schemes.

### **1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

There is no difference in the procedure for approving the pricing / reimbursement of generic products. The price that can be charged for the originator product is affected by the entry onto the Irish market of a generic following the expiry of the originator's patent pursuant to the agreement between the HSE, the Department of Health and the Irish Pharmaceutical Healthcare Association (“IPHA”). The 2013 Act introduced a system of generic substitution and reference pricing for authorised medicines.

### **1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

The HPRA is not authorised to add a medicinal product to a group of interchangeable medicinal products if the Board is satisfied that there is a difference in bioavailability between the medicinal product and the interchangeable medicinal products which currently fall within the group of interchangeable medicinal products which may lead to a clinically significant difference in efficacy between them.

### **1.7 Orphan Medicinal Products.**

Not provided for.

### **1.8 Parallel imports from another Member State.**

Parallel imports of medicinal products from other EU member states and EEA countries into Ireland are allowed under two schemes: the dual pack import registration and

parallel product authorisation. Products centrally authorised by the EMA are not covered by these schemes and require separate notification to the EMA before parallel importation.

### **1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

None.

## **2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

The pricing and reimbursement of products are dealt with together under the Irish system. HPRA is the competent authority responsible for regulating medicinal products and medical devices. The Department of Health is responsible for determining the healthcare policy and expenditure which it does through the HSE.

A Framework Agreement between IPHA, an organisation representing the international research-based pharmaceutical industry in Ireland, the Department of Health (the “DoH”) and the HSE (the “IPHA Agreement”), which came into effect on 1 November 2012, contains a mechanism for the pricing of branded medicines that are reimbursed by the State through the reimbursement schemes, or that are supplied to State funded hospitals and agencies. The HSE may negotiate special supply arrangements for medicines supplied to State funded hospitals and agencies. The IPHA Agreement does not apply to the supply of medicines to private hospitals. Private hospitals may therefore negotiate independently of the terms of the IPHA Agreement, although in practice they often pay similar rates to the State. The IPHA Agreement remains in effect until 1 November 2015.

In addition, the 2013 Act came into effect in Ireland as of 24 June 2013. The 2013 Act prescribes additional factors, over and above the IPHA Agreement, that may be taken into account by the HSE when considering the proposed price of an item to be included on the Reimbursement List.

## **3 Other Financial controls relating to supply**

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products**

**within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

Each month the HSE will notify manufacturers and importers of medicinal products of the quantity and value of their medicines that have been dispensed under the Irish state reimbursement schemes. The manufacturer or importer must then rebate to the HSE an amount equal to 4% of the price to wholesaler of those products, although there is an exception for those patent expired products whose prices have been reduced following the entry onto the market of an identical pharmaceutical form.

## 4 Pricing Criteria

**For those products identified in the answer to Q1 for which a price must be agreed:**

### 4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?

Under the 2013 Act, the HSE may, when setting a reference price for, or reviewing a reference price set for, a relevant group of interchangeable medicinal products, take into account the equivalent relevant prices (if practicably available) of the relevant listed items in all other Member States where one or more than one of the relevant listed items is marketed.

### 4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?

The HSE will take the following into account when setting a reference price for, or reviewing a reference price set for, a relevant group of interchangeable medicinal products:

- (a) the ability of suppliers of the relevant listed items to meet patient demand for the relevant listed items,
- (b) the value for money afforded by the relevant listed items,
- (c) the equivalent relevant prices (if practicably available) of the relevant listed items in all other Member States where one or more than one of the relevant listed items is marketed,
- (d) the relevant prices of therapeutically similar listed items,
- (e) the resources available to the HSE, and
- (f) the terms of the IPHA Agreement (or similar).

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

Under the IPHA Agreement, products may be submitted online for pricing and reimbursement approval (manual applications will be accepted until the online facility is available) to the HSE for use and assessment according to their labelled indications as approved in the Summary of Product Characteristics. Consideration of such applications should take no longer than 30 days. Therefore, new medicines should become reimbursable within the State reimbursement schemes within 75 days of the date of the reimbursement application.

In the event that a product requires pharmacoeconomic assessment this should take no longer than 90 days (subject to standard clock stopping rules). Pharmacoeconomic assessments may be conducted on products that may be high cost or have a significant budget impact on the Irish healthcare system, or to determine the cost effectiveness of certain products. The subsequent activities relating to pricing and reimbursement should take no longer than 45 days. The channel of distribution will be agreed with the HSE at the time of submission. The maximum time period for the completion of all steps in the process (excluding clock stoppages) is 180 days.

Under the 2013 Act, the supplier of an item may make an application to the HSE requesting the HSE to add the item to the Reimbursement List. Where the HSE receives an application it must, within 180 days or such longer period as may be necessary, determine the application (after consulting such experts as it thinks fit).

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

The HSE is required, under the 2013 Act, to treat each item on the Reimbursement List as if it were not on the Reimbursement List but subject of an application for such, every three years from the 24 June 2013, or alternatively, five years from that date, where permitted by the Minister at the request of the HSE.

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 above?**

Under the IPHA Agreement there is a price freeze in place whereby the price to wholesaler of each item of medicine covered by the Agreement will not be increased

for the term of the Agreement, except in exceptional circumstances.

— **Reduce the price generally or for a period**

No restriction

**6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?**

Under the IPHA Agreement there is a price freeze in place whereby the price to wholesaler of each item of medicine covered by the Agreement will not be increased, except in exceptional circumstances. The agreement is in place until 1 November 2015.

**6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?**

The price that can be charged for the originator product is affected by the entry onto the Irish market of a generic only following the expiry of the originator's patent. Where an identical pharmaceutical form of a patent expired medicine, approved by HPRA or the European Commission, becomes available for prescription within the reimbursement schemes or is supplied to State funded hospitals and agencies, the price of the originator product is reduced to 70% of the original price with a further reduction to 50% of the original price twelve months following the initial price reduction. The HSE notifies the originator company of the availability of an identical pharmaceutical form of the originator product, and the price reduction takes effect within 60 days of HSE notification.

## **7 Other Types of price control**

**Does your jurisdiction control any of the following prices:**

**7.1 Full line or other wholesaler selling price**

Yes, under the IPHA Agreement the price to wholesaler of each item of medicine covered by the Agreement will not be increased for the term of the Agreement

**7.2 Pharmacy selling price**

Yes, for reimbursed products.

## **8 Reimbursement – general principles and Transparency directive compliance**

**8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in**

**part by prescription / dispensing charges levied on the patient at the time of dispensing?**

In Ireland, the State pays for approx. 80% of all medicines. The ultimate cost to the State of medicines dispensed in the community depends on which community medicine scheme the patient uses to access the medicines.

Medicines supplied by a hospital: Public patients, other than medical card holders under the General Medical Services (GMS) Scheme, pay certain minimum fees for access to healthcare.

Medicines supplied by community pharmacies: The HSE Primary Care Reimbursement Service (PCRS) operates a number of community reimbursement schemes. The contribution required by patients towards the cost of a medicine depends on the scheme for which they are eligible. The scheme in question may depend on the patient's means, illness, or the type of drug being supplied.

(a) Where medicines are supplied, and reimbursed, under the GMS Scheme, patients must pay €1.50 per prescription item, subject to a monthly ceiling of €19.50 per family. The GMS Scheme provides free general medical services, including access to doctors, surgeons, dentists and medicines, to those who cannot afford such services.

(b) Individuals, or families, ordinarily resident in the State and not eligible under the GMS Scheme, pay a maximum of €144 on approved drugs, medicines and appliances per calendar month, irrespective of family, financial circumstances or nationality, and any amount above the current threshold of €144 is funded by the State through reimbursement of the pharmacist under the Drugs Payment (DP) Scheme. Certain non-prescription items are covered by the DP Scheme, although they must have been prescribed by a doctor in order to qualify under the scheme.

(c) Persons suffering from one or more of a number of specified long term illnesses, including diabetes, epilepsy and cystic fibrosis are entitled, under the Long Term Illness (LTI) Scheme, to the necessary drugs, medicines and appliances without charge, irrespective of income.

(d) High technology drugs such as anti-rejection drugs for transplant patients and medicines used in conjunction with chemotherapy are reimbursable under the High Tech Drugs (HTD) Scheme, if the patient is not eligible for these medicines under the GMS or LTI Schemes. Under the HTD Scheme the patient pays the first €144 towards the cost of the drugs per calendar month, in accordance with the DP Scheme, with the remainder funded by the State.

**8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not**



**be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

Ireland operates a positive Reimbursement List.

**8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

The status is a formal approval, and it is subject to review as described in response provided for Question 6.1. Under the 2013 Act, the HSE reserves the right to treat a listed item (including a listed item which was once a deemed listed item) as if it were not on the Reimbursement List but were the subject of an application for inclusion in such. In addition the HSE may also recommend a particular product from the reimbursement list, over and above other products with the same indications for use, generally on pricing criteria.

**8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

Under the terms of the IPHA Agreement, products may be submitted for pricing and reimbursement approval to the HSE for use and assessment according to their labelled indications as approved in the Summary of Product Characteristics. Pharmacoeconomic assessments may be conducted on products that may be high cost or have a significant budget impact on the Irish healthcare system, or to determine the cost effectiveness of certain products. Such pharmacoeconomic assessments for new medicines may be conducted in parallel with the marketing authorisation assessment by the HPRA or European Commission. Following receipt of a positive Health Technology Assessment ("HTA") decision, it should take no longer than 45 days for such products to become reimbursable within the State reimbursement schemes.

The QALY threshold to be used in the HTA process is €45,000, although this may be increased or waived in the case of exceptional products following "meaningful discussions between the HSE, DoH, relevant clinicians and the MAH. In the event of a negative HTA outcome, an appeal may be lodged with an expert committee whose members are chosen by the HSE, the Department of Health and IPHA. The decision of the expert committee is binding and should be received within 60 days. Following receipt of a negative decision, negotiations may commence between the HSE and the manufacturer to agree an acceptable price. In some cases, patient access schemes have been

entered into which take the form of performance-based risk-sharing schemes which link reimbursement of the product to its performance. Pursuant to such schemes, the HSE agrees to fund a medicinal product for a defined period of time, in return for which the manufacturer agrees to refund to the HSE the cost of the drug in those patients who did not meet the targeted clinical outcome within that period of time.

**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

Under the 2013 Act, the HSE may, at its discretion and subject to such conditions as it considers appropriate, make arrangements to supply an item to a patient notwithstanding that the item is not a listed item if the HSE is satisfied that –

- (a) the patient requires that item for clinical reasons, and
- (b) there is no listed item which is a suitable alternative for that item in so far as that patient is concerned.

## **9 Reimbursement – Administrative Arrangements**

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

See response to question 5.

## **10 Reasons for decisions on Pricing and Reimbursement**

**The Transparency Directive 89/105/EEC requires Member State authorities to provide a "statement of reasons based on objective and verifiable criteria" in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it fr price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.**

**10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

Under the 2013 Act, the HSE shall, as soon as is practicable after making a relevant decision (but, in any case, not later than 14 days after making the relevant decision), give notice in writing of the relevant decision, together with

its reasons for the relevant decision, to the supplier of the item or listed item the subject of the relevant decision. In addition, where the HSE has made a relevant decision based on any expert opinions or recommendations, it shall attach copies of all such opinions and recommendations to the notice concerned be given to the supplier of the item or listed item the subject of the relevant decision.

**10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

As far as we are aware the process is transparent and understood by the industry but some recent changes in the criteria applied, on foot of the 2013 Act, have raised concerns.

## **11 Reconsiderations / Appeals**

**11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

Under the IPHA Agreement, where a new medicine is subject to assessment, the HTA decision will be notified within 90 days of the receipt of the HTA application. Should reimbursement be refused appeal may be made to an expert committee, the membership of which will be agreed between the Health Service Executive, the Department of Health and IPHA. In reaching its decision, the expert committee will consider views of relevant stakeholders. The expert committee's decision will be made within a further 60 days and will be accepted as binding.

Under the terms of the IPHA Agreement, where it is proposed to make a relevant decision under section 18 of the 2013 Act, any person required to be notified under the pertinent section may seek a review of the proposal by an expert committee, which review will be carried out within the timeframe set out in Schedule 1 Part 2 of the legislation for making representations to the HSE, with respect to the proposal. Membership of the expert committee will be agreed between the IPHA, the HSE and the DoH.

**11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

Under the 2013 Act, the relevant person aggrieved by a relevant decision may, within 30 days from the date on which the relevant person was given the relevant notification, appeal to the High Court against the decision.

**11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical**

**implications of these judgments for a pharmaceutical company?**

We are not aware of any reported judgments in which the authorities have been successfully challenged in the national courts in relation to reimbursement policies or decisions relating to specific products.

## **12 Unlicensed products and off-label use**

**12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?**

The cost may be reimbursed but it would be on a case by case basis.

**12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?**

Products would not be entitled to be reimbursed for off-label use.

## **13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.**

Patient access schemes in Ireland are used as a mechanism to lower the price paid by the HSE for particular medicinal products. Such schemes are relatively transparent, but are uncommon.

Patient access schemes have been entered into which take the form of performance-based risk-sharing schemes which link reimbursement of the product to its performance. Pursuant to such schemes, the HSE agrees to fund a medicinal product for a defined period of time, in return for which the manufacturer agrees to refund to the HSE the cost of the drug in those patients who did not meet the targeted clinical outcome within that period of time.

## **14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social**

**security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

No

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Colin Kavanagh is Head of the Life Sciences Group at Arthur Cox, one of Ireland's leading law firms. Colin and his team advise Irish and multi-national pharmaceutical, medical device, biotech, cosmetic, food, beverage and agri-business companies in Ireland on a wide range of corporate, transactional, commercial, regulatory, intellectual property and promotional matters. Recent work in the sector includes advising on domestic and cross border mergers and acquisitions, corporate tax and IP based restructurings, post-acquisition integrations, the construction and expansion of manufacturing facilities, the sourcing of related equipment and raw materials, logistics and distribution, clinical trials, licensing, competent authority and notified body audits, regulatory aspects of wholesaling and brokering of products, promotion, pricing and reimbursement.

11

# Italy

## 1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied

Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?

### 1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."

Price negotiation is necessary as well as mandatory for medicinal products intended for treatment of chronic diseases or material to guarantee the Fundamental Level of Health Care (LEA, Livelli Essenziali di Assistenza Sanitaria). Negotiation is carried out with the Italian Medicines Agency (AIFA, Agenzia italiana del farmaco) according to the criteria set forth in the Resolution of the Interministerial Committee for Economic Planning (Comitato Interministeriale per la Programmazione Economia – CIPE), dated February 1, 2001, no. 3 (hereinafter, "Deliberazione CIPE") (see answer to question 4.2 below).

There are two reimbursement classes: "Class A" and "Class H" (hospital only products). "Class C" indicated products not reimbursed by the NHS, whose price is freely set by the manufacturer.

Please consider that prescription is not a necessary condition for reimbursement. There are in fact prescription only-products classified in class C.

### 1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).

The Italian National Healthcare System is the main and almost exclusive payer in Italy, therefore the system is essentially publicly driven. Price and reimbursement negotiation is mandatory only for seeking reimbursement under the NHS.

### 1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.

For both class A and H products the ex-factory price negotiated with AIFA is the maximum sale price to the NHS (i.e. to public hospitals). Then of course, within the public procurement procedure, in order to be competitive, the company may apply commercial discounts (up to its

total discretion). In order to be competitive, offered prices shall take into account the reference average price for the concerned category of good. In fact, pursuant to the recent spending review measures (Law Decree 95/2012), the Authority on Public Procurements has elaborated, for any and all categories of supplies to public hospitals (medicines, medical devices, consumables etc.), the average reference price which shall be considered ideally convenient for the NHS. Significant deviations from the average price are deemed as not economically sustainable for the NHS (i.e. above 20%). For medicinal products, this exercise brought to a reference price for each active substance, which represents an important parameter for the bidders in setting their offer.

Please consider that class C (not reimbursable) products are subject to a statutory 50% price cut off when sold to public hospitals.

#### **1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

OTC products are not reimbursed under Italian National Healthcare System; in fact, such products are at the complete patient's expense. They are included in Class C; their price can be set directly by the pharmaceutical companies, without negotiation with AIFA; it can be increased only in January of odd years, without exceeding the official rate of the inflation.

#### **1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

Pursuant to Article 12, paragraph 6, of the Law Decree September 13, 2012, no. 158, generics and biosimilar are automatically placed within the same reimbursement class as the reference branded product.

When the marketing authorization holder of a generic/biosimilar medicinal product offers a price that is clearly convenient for the National Healthcare System, the approval of both price and reimbursement status is granted without negotiation.

The price is deemed "clearly convenient for the National Healthcare System" when is lower than the price of the reference branded product, according to such reduction percentages (at least 20 % lower) as set forth in a Decree of the Ministry of Health – today, Decree of MoH dated April 4, 2013.

The size of this required minimum rebate depends on two parameters: (i) price of the originator product and (ii) the average NHS expenditure over the last three year period for the originator product. The higher is the expenditure the greater is the minimum rebate (for example, for sales over 180 million Euro, price of the generic shall be at least 75% lower than the price of the reference product if the

latter is in class A or at least 50% if the reference product belongs to class H).

The patent position of the originator affects not the pricing negotiation rather the reimbursement of the generic products: the same Law Decree 158/2012 has in fact stated that generics cannot be admitted to reimbursement by the NHS before the expiry date of the patent of the originator.

#### **1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

Please, see answer to question 1.5.

#### **1.7 Orphan Medicinal Products.**

The general rules on price and reimbursement apply to orphan medicinal products too, although it is evident that they are enforced in the light of the features of such products. In particular, the main difference is about timing: in fact, the price and reimbursement application of orphan drugs may be filed before the marketing authorization is granted, whereas, in general, the pharmaceutical companies has to have been already granted the marketing authorization in order to file a P&R application.

#### **1.8 Parallel imports from another Member State.**

The same principles set out under answer 1.5 above apply also to parallel import.

#### **1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

Also "off-label" medicines are relevant to the purposes of the reimbursement status. In fact, upon the condition of lacking a valid, reimbursed, therapeutic alternative, AIFA may authorize "off label" use of authorized drugs or the use of non-licensed drug in accordance with mandatory therapeutic scheme and strict monitoring conditions as set out in the so called "648list". Inclusion in the list means that the "off label" use is basically "acknowledged" by AIFA, after its technical-scientific assessment, and the prescription is not made under the personal liability of the physician. "Off label" use pursuant to 648 list is reimbursed by the NHS within an expenditure limit of about 15.000.000,00 Euro.

## **2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

In the Italian system, the price and reimbursement elements are dealt with together in the procedure before AIFA, i.e. the Italian Medicines Agency.

The decisions issued by AIFA are made under Law Decree no. 269/2003 (converted in Law no. 236/2003), as well as Law Decree no.158/2012 (converted in Law no.189/2012).

### 3 Other Financial controls relating to supply

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

The Italian law provides for two types of financial restrictions, which represents also containment measure of the pharmaceutical public expenditure: (i) the product ceiling and (ii) the company budget.

The first restriction is referred to each single company product and is provided within the same decision setting out the product's price and reimbursement status. The provision of the ceiling depends on the negotiation between the marketing authorization holder and AIFA, which takes into account the therapeutic efficacy of the product, in the light of the expected future sale volume. When the ceiling is exceeded, the company has to give the surplus back.

The second restriction is represented by the cap of the aggregate sales to the NHS for all the company products, with a distinction between hospital products and the other. This is usually referred to as "company budget" and is assigned on a yearly basis by AIFA to each pharmaceutical company.

When such limits are exceeded, the pharmaceutical companies have to pay the surplus back to the Regions.

### 4 Pricing Criteria

**For those products identified in the answer to Q1 for which a price must be agreed:**

#### 4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?

In Italy, there is not a proper international reference price criteria used in the negotiation. However, AIFA do take into consideration the European average price.

#### 4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is informa-

#### tion on clinical and cost-effectiveness required or normally supplied voluntarily?

As said, price is the outcome of a negotiation between AIFA - through CPR [Price and Reimbursement Committee] and CTS [Technical/Scientific Committee] - and the MA holder. The negotiated price is the "ex-factory" price; price to the public is then obtained adding to the ex-factory price the margins (so called "quote di spettanza") due to wholesalers and pharmacists which are fixed by the law. Should the agreement not be reached, the medicine is placed in Class C. The pricing agreement has a validity of 2 years.

Price is determined on the basis of the following criteria:

A positive cost/effectiveness ratio in one of the following situations:

- the new medicinal product proves useful for the prevention and the treatment of considerable pathologies or symptoms in relation to which no other effective therapy exists;
- the new medicinal product proves useful for the prevention and the treatment of pathologies or symptoms in relation to which the already available medicinal products do not provide a suitable effect;
- the new medicinal product proves to have a more favourable risk/benefit ratio than the already available medicines (included in the "Prontuario") for the same indication;

Other elements relevant for NHS, adequately assessed when:

- Expenditure between DKK 1,495 and DKK 3,235: 75 the new medicinal product does not have a relevant clinical superiority over the already available products;
- the new medicinal product is already as effective and safe as the already available medicinal products;
- the new medicinal product proves to have a more favourable risk/benefit ratio than the already available medicines (included in the "Prontuario") for the same indication;

In any case, other elements shall be supplied, with reference to:

- the medicinal product under negotiation, if already marketed in other countries (prices, consumer data, reimbursement conditions, etc.);
- therapeutic class;
- market share achievable within the following twenty four months, in the specific market;
- predictable variation of the expenditure for NHS, in its different elements;
- any other information useful for the parties of the negotiation.

Moreover, the following elements can be considered:

- sales volumes;

- availability of the medicinal product in question for the NHS;
- discounts for hospitals and healthcare facilities;
- sales volumes and prices of other medicinal products marketed by the same company.

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

In general, the pricing and reimbursement negotiation with AIFA can be initiated (i) after the grant of the MA under the national or mutual recognition procedure; (ii) after the CPMP final opinion, in case of centralised marketing authorisation or (iii) before the grant of the MA for hospital-only drugs, orphan drugs and drugs having an exceptional therapeutic or social relevance in the assessment of the Technical Scientific Committee of AIFA.

The negotiation shall be concluded in 180 days, but the term is not mandatory. Orphan drugs as well as drugs “having an exceptional therapeutic and social relevance” (article 12, par. 3, Law Decree n. 158/2012) are granted a fast-track: the pricing and reimbursement procedure must in fact be carried out in no more of than 100 days. For these products, in case the MA holder does not start voluntarily the pricing/reimbursement procedure within 30 days from the MA decree, AIFA may urge him to start the procedure. Should the MA holder still remain inactive, AIFA will give public notice of that on its website.

Once the AIFA determination has been published on the Official Gazette, the only remedy is to challenge the decision before the Administrative Court of Lazio.

The procedure is the same both for originators and genericists.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

The pricing agreement, related to the reimbursed medicinal products, has a 24 months validity, renewable for a further 24 month period, unless one of the parties request for a renegotiation at least 90 days prior the expiration of the first term.

Renegotiation can be also requested during the 24 months in the case of a modification of the therapeutic indications or dosage potentially leading to an increase in the consumption of the product. In particular, when AIFA expects an increase in the consumption of the product given to the new indications approved, the price is likely

to be reduced in order to maintain the fixed expenditure for the product.

As to the not reimbursed medicinal products, their price can be set directly by the pharmaceutical companies, without a negotiation with AIFA; it can be increased only in January of the odd years, without exceeding the official rate of the inflation.

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 above?**
- **Reduce the price generally or for a period?**

Any variation of the agreed price triggers the re-opening of the pricing negotiation with AIFA. Therefore we refer to answer 6 above.

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

Today, the only restrictions in force are the abovementioned product ceiling and the company budget.

Overarching price freeze for austerity or might be imposed in emergency cases; such limit is not in force at the moment. From time to time, there might be imposed statutory price cut off (i.e. 5 % cut applied twice in 2006 or as in 2009 for generic products).

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

It is not a legal obligation but it is a widespread choice in order to remain competitive on the market. In fact, for “Class A” products, the patient that wishes to buy the branded product has to pay the difference between the price of the branded and the price of the generic medicinal product.

## 7 Other Types of price control

Does your jurisdiction control any of the following prices:

### 7.1 Full line or other wholesaler selling price

### 7.2 Pharmacy selling price

It controls both of them, through a system of margins for manufacturers, wholesalers and pharmacies, calculated on the sale price (VAT excluded), pursuant to article 1.40 of Law no. 662/1996, as amended by Law Decree no. 78/2008, as follows:

- manufacturers 66,65%,
- wholesalers 3%



- pharmacies 30,35%

As to Generics, pursuant to Law Decree no. 39/2009, as follows:

- manufacturers 58,65 %,
- wholesalers 6,65 %
- pharmacies 26,7 % (mandatory margin)

The remaining 8% is shared between wholesalers and pharmacists, pursuant to free competition principles.

## 8 Reimbursement – general principles and Transparency directive compliance

**8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?**

The reimbursement framework is national and publicly funded through the national healthcare system, - and locally, by the regional healthcare systems -, in compliance with the Fundamental Levels of Health Care, set out by the law (LEA, Livelli Essenziali di Assistenza Sanitaria). In case of generics or biosimilars, the patient that wishes to buy the branded product has to pay the difference between the price of the branded and the price of the generic medicinal product. .

**8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

The reimbursed products are included in the Prontuario Farmaceutico Nazionale or PNF. AIFA may further limit reimbursement of a product included in the PNF, for example to specific indications, populations of patients or care facilities, issuing the so-called “note”.

It has to be pointed out that Regions do have a concurrent power in managing the local healthcare expenditure and they may further limit the reimbursement status of a product in the light of the local patients' needs as well as of the regional financial situation. In fact every Region has a list of reimbursable drugs at a regional level PTR (Prontuario Terapeutico Regionale). Regions have the power to decide the partial or total exclusion from the reimbursement of a medicinal product listed in Class A, in the light of a comparison between the evolution of its pharmaceutical expenditure and the planned expenditure cap.

**8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

It is up to AIFA, therefore at national level, granting a product the reimbursement status, which is officialised by means of the same determination setting out the product's price, published on the Official Gazette. Then, as said, Region may then further limit terms and conditions of reimbursement at local level.

**8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

Please, see answer to questions 4. HTA is becoming of more and more essence in the reimbursement assessment, both at national and regional level.

**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

No they can't. Doctors must abide by the Prontuario Farmaceutico Nazionale and the Prontuario Farmaceutico Regionale.

## 9 Reimbursement – Administrative Arrangements

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

Please see answer to questions 5.

## 10 Reasons for decisions on Pricing and Reimbursement

**The Transparency Directive 89/105/EEC requires Member State authorities to provide a “statement of reasons based on objective and verifiable criteria” in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it if price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.**

**10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

As said, in the P&R negotiation procedure, a product undergoes the review of two Committees (Technical-Scientific Committee and P&R Committee) which do report their assessment in the minutes of the meeting. The minutes are accessible to the interested company. To the contrary, the final decision of AIFA is not motivated since it merely officialises terms and conditions already agreed upon.

**10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

In general, the Committees' decisions are sufficiently reasoned so to allow Companies to submit objections or counterarguments. However, please consider that the Committee's assessments cannot be judicially challenged, since they do not have the nature of final determination, which is the necessary requirement triggering a party's interest to stand before the Administrative Courts. Companies may challenge the final determination of AIFA, although it happens rarely.

## **11 Reconsiderations / Appeals**

**11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

Once the AIFA determination has been published on the Official Gazette, the only remedy is to challenge the decision before the Administrative Court of Lazio. However, the case is quite unrealistic: as a matter of fact, when the proposed conditions are not satisfying, the company usually refuses the agreement and, as a consequence, the product is automatically classified in class C (non-reimbursable products). The P&R negotiation can be started again at any time.

**11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

The time limit to appeal the AIFA determination to the Administrative Court of Lazio is 60 days from the publication on the Official Gazette.

**11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

We are not aware of any reported judgments in which the authorities have been successfully challenged in the national courts in relation to reimbursement policies or decisions relating to specific products.

## **12 Unlicensed products and off-label use**

**12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?**

Product supplied under compassionate use cannot be charged, rather it can only be supplied for free. To the contrary, the off-label use is reimbursable only in the following cases: (i) the off-label use of the product is listed in the 648/96 list, i.e. officially acknowledged by AIFA, which also determines price and reimbursement conditions; or (ii) if the off label is allowed under the "Di Bella" law (i.e. on named patient basis; under practitioner's responsibility), then the product is reimbursed only if the patient is hospitalized.

**12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?**

Off-label use is only licit insofar it results from a prescription. Please see answer under 12.1 above.

## **13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.**

It can happen in particular cases (for example orphan drugs or medicines for treating cancer) that the P&R negotiation with AIFA is driven by criteria and methods such as: Cost-sharing, risk-sharing, payment by results. In these cases the reimbursement is conditioned by the reaching of determined goals. AIFA set up a register (Registro dei Farmaci Oncologici sottoposti a Monitoraggio - RFOM) to collect information on the cost-effectiveness ratio of the medicines included into such reimbursement schemes.

- 14** Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).

Besides the determination of the margins reserved to each player of the supply chain (including pharmacists) the law determines the pay-back which pharmacists are entitled to whose amount varies depending on the final price of the product.

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# Latvia

## **1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied**

**Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?**

Latvia restricts its policy of price regulation to the distribution level, keeping the manufacturing level basically without any restrictions.

The medicines outside (i) the reimbursement system (below 8) or (ii) other public funding systems are subject to a specific price notification procedure. A manufacturer intending to launch certain medicine in Latvia must notify in advance the selling price to the State Agency of Medicine („Agency”).

The restrictions relates to the sales price of the wholesalers and the retail pharmacies. The Governmental Regulations provide formulas with the correction rate of the manufacturer's price, used for calculation of the maximum permitted wholesale or retail price. As well, the Agency publishes on its website the maximal price of the medicine permitted for the retail in the pharmacies.

### **1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met.”**

Price notification relates both to prescription-only and non-prescription medicines whether on patent or off-patent. There are no exceptions for medicinal products not containing NAS.

### **1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other “lifestyle” medicines).**

As described, the price notification does not relate to reimbursable medicines. For pricing principles of the reimbursable medicines see below 8.

### **1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.**

As described, the price notification requirements do not apply for supplies to the publicly funded medical entities (state or municipally funded hospitals, out-patient clinics), or, (upon the centralized supplies) to the National Health Service Upon the public procurement one of two selection

criteria may be used for choosing the best tender- (i) the lowest price; or (ii) the economically most advantageous tender, where other factors along the price may be considered (like offered terms of supply, operational and other costs and their effectiveness, the quality of medicines etc.).

These factors must be specifically expressed in the tender rules and objectively comparable or assessable. The buyer must indicate (i) all evaluation factors in the order of their significance, (ii) the proportion and numerical value of the factors, (iii) the selection algorithm of a tender; and (iv) how each of those factors will be evaluated.

The economically most advantageous tender is compulsory selection criteria upon specific types of the procurement.

Depending on the type of the procurement, the parties may also agree on particular price during negotiation, e.g. for purchase of orphan medicines.

In addition, the medicines intended for state funded in-patient treatment (i) must have the lowest costs of treatment comparing to other medicines with equal therapeutic efficacy and side effects, or (ii) if having higher costs of treatment, the advantages of medicines in the sense of therapeutic efficacy and side effects have been proved to a specific group of patients. The list of such medicines including their price is determined by the NHS. The hospitals requiring a broader or more specific range of the medicines must elaborate the list of additionally usable medicines to be examined by the NHS. The Medicines may be included in the Additional List if they have costs of treatment (i) commensurable with the state budget funding for the in-patient services of the hospital; and (ii) lowest comparing to other medicines with equal therapeutic efficacy and side effects.

#### **1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

Price notification relates to OTC medicines, however there are no specific provisions comparing to the medicines supplied otherwise.

#### **1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

Price notification relates the generics, however there are no specific provisions comparing to the patented products. There is no distinction between an originator and a generic in determination of maximum allowed wholesale or retail price mark-up. The patent position does not affect the price of a generic. However, the national Association of International Research-based Pharmaceuticals Manufacturers has called on the authorities to limit the inclusion of generics in the state reimbursement system, and instead to facilitate the entrance of innovative medicinal products into market.

#### **1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

Price notification relates to the biosimilar products.

#### **1.7 Orphan Medicinal Products.**

Price notification relates also to the orphan products. However, product specific provisions relates only to public tender process being outside the pricing notifications requirements (see above 1). For the purchase of orphan medicines ordinary the negotiated procedure without publishing a contract notice is applied, where a sole exclusive supplier is invited to tender and the price and other purchase conditions are being agreed during negotiations.

#### **1.8 Parallel imports from another Member State.**

The medicines supplied in parallel imports procedure are also subject to the price notification.

#### **1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

Price notification requirements are not product specific.

## **2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

As described above 1, a manufacturer or a marketing authorization holder intending to launch certain medicine in Latvia must notify in advance the selling price to the Agency. In turn, the medicines under the reimbursement system are subject to reimbursed price determination process (see below 8) instead of the price notification requirements.

## **3 Other Financial controls relating to supply**

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

There are no financial restrictions in addition to those mentioned above 1.

## 4 Pricing Criteria

**For those products identified in the answer to Q1 for which a price must be agreed:**

### 4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?

The international reference pricing is one of criteria to determine the price of reimbursable medicine. The price of the medicine to be included in the Latvian Reimbursement List must not exceed respective price (sales price used by the manufacturer) in Estonia, Lithuania, and the third lowest price among Denmark, Czech Republic, Rumania, Slovakia and Hungary. The applicant must inform the NHS on respective price in those countries, and it may be examined by the NHS.

Therefore international reference pricing and other described criteria are relevant only for the medicines under for the reimbursements system. On the other hand the medicines outside the reimbursement system our subject to a specific price notification procedure, where price is regulated only at the distribution level. That means that outside the reimbursement system the manufacturer can freely determine manufacturer's price since the law limits only the surcharges in the sales price of the wholesalers and the retail pharmacies.

### 4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?

Information on clinical and cost effectiveness of the medicines to be included in the reimbursement system must be provided under the law.

- 4.2.1 The therapeutic category reference pricing is a significant criterion in respect to the reimbursement system. For example, in Latvia the Reimbursement List "A" includes the medicines having alternatives with the equivalent therapeutic value. To include the medicine in the reimbursement system, in addition to the international pricing criteria the price must be compared among the medicines having the equivalent therapeutic value. That is, the price is compared:
- 4.2.1.1 among the medicines with the same non-proprietary name (active substance) having the same route of administration of the medicine Then it is assumed that the medicines have the same therapeutic value, unless the clinical trials have proved the opposite; and
- 4.2.1.2 for certain diseases- among the medicines with the same pharmaco- therapeutic group (3 to 5 levels of ATC code ), if the therapeutic value for the treatment of the respective disease has been

proved. The value for the treatment of the respective disease must be based on scientific data, as well as local and international treatment guidelines.

- 4.2.2 The medicines under the reimbursement system are also subject to the pharmacoeconomic analysis. The NHS must compare the costs of the medicine applied for reimbursement system with the costs of respective alternatives. An applicant must provide pharmacoeconomic calculations according to specific guidelines, if (i) a new non-proprietary name is being included in the Reimbursement Lists or (ii) the conditions of the reimbursement must be reconsidered or (iii) the medicine is applied for Reimbursement List B (for description of lists see below 8).

The analysis must include the calculation of the costs for one unit of an additionally obtained result of therapeutic efficiency (incremental cost-effectiveness ratio), as well as proved cost-efficiency of the medicinal products for the treatment of a particular disease or a target group of patients.

Three types of pharmacoeconomic analyses can be applied- (i) cost minimization analysis; or (ii) cost effectiveness analysis; or (iii) cost utility analysis (only additionally to the cost effectiveness analysis).

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

Within the price notification system a manufacturer or a MA holder must inform:

- the Agency on the manufacturer's sales price of the medicine prior its launching in the Latvian market; and
- the Agency and the wholesalers on the planned changes in the manufacturer's price not later than 30 days before the new price is applied. Although the manufacturer must justify the increase of the price in 15 days upon inquiry of the Agency, such justification has only informative purpose, as could not be actually examined by the authorities- the manufacturers are not disclosing the formation of the price of the particular medicine, as well as the gained profit.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

Ordinary they are reviewed once per year, however, there are no strict time limits.

**6.2 What controls apply to the right of company to:**

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 adobe?**

As described in 5.2 above, the justification of the increase has only informative purpose, as could not be actually examined by the authorities- the manufacturers are not disclosing the formation of the price of the particular medicine, as well as the gained profit.

- **Reduce the price generally or for a period?**

The price reduce is not limited.

**6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?**

The law does not determine overarching price freeze.

**6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?**

No, outside the reimbursement system such obligation does not exist. The base price is established only for reimbursable medicines.

Regarding reimbursable medicines the entrance of generics into the market affects the originator's prices. The prescription of the cheapest equivalent is mandatory.

A doctor must indicate in the prescription only a non-proprietary name of a medicine provided for the respective diagnose, if the patient will receive the reimbursable medicines for the particular diagnose for the first time. In turn, the pharmacy must offer and sell the cheapest medicine from the medicines with same non-proprietary name. If the sold medicine will not give the expected therapeutic effect, then the doctor will be entitled to prescribe the next cheapest medicine of the same non-proprietary name.

If the patient has already started the treatment with one of the reimbursable medicines and, upon update of the list of reimbursable medicines, another equivalent becomes the cheapest, then the patient is entitled to continue use of the initial medicine, but must cover the price difference.

It is advised by the Competition Authority also in respect to non-reimbursable medicines to provide that the doctors must indicate in prescriptions only the non-proprietary name. So the manufacturers would no longer have a reason to invest so much money on doctor-focused marketing, which also increases the cost of medicines. Such rule may serve as a precondition for increasing the number of cheaper generics entering the market. The national Market Surveillance Report following the EU sector inquiry promotes removal of restrictions of distribution of generics. If the prescriptions will refer only to the non-proprietary name instead of the product name, then the price competition between manufacturers will be strengthened and, in turn, the distributors' competition for the doctors' choice

(that might not be motivated by the price of equivalent medicine) could be eliminated.

**7 Other Types of price control**

**Does your jurisdiction control any of the following prices:**

**7.1 Full line or other wholesaler selling price**

Yes, as described the Governmental Regulations provides formulas with the correction rate of the manufacturer's price, used for calculation of the maximum permitted wholesale price.

**7.2 Pharmacy selling price**

Yes, the Governmental Regulations provides formulas with the correction rate of the manufacturer's price also for calculation of the maximum permitted retail price.

**8 Reimbursement – general principles and Transparency directive compliance****8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?**

Solely the prescription-only medicines are subject to the reimbursement system. The medicines conforming to certain criteria, applied to the Reimbursement List and selected by the NHS are subject to the reimbursement. A separate application must be filled.

Reimbursement List A includes the medicines with equivalent efficiency.

Reimbursement List B includes the medicines which have no alternatives with equivalent efficiency within the Reimbursement Lists.

Reimbursement List C includes the medicines with costs for treatment of one patient yearly which exceeds ca. EUR 4 268,62 and which costs partially will be covered by the manufacturer itself for certain number of patients. The number is determined by the NHS according to several criteria, and it could not be less than 10% from the expected patients to be reimbursed by state or 10% from the expected turnover of the respective medicines to be reimbursed by state.

The medicines under Reimbursement Lists A, B or C are reimbursed by 100%, 75% or 50% depending on respective diagnose according to the Latvian Government Regulations.

Reimbursement List M includes the medicines for children until age of 24 months (covered 50%) and for women be-



ing pregnant or being within 42 days after the child-birth (covered 25%).

**8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

A positive list exists. In turn, the homeopathic medicines are clearly excluded from the reimbursement system. In addition, the insufficient state budget resources are one of the reasons for not inclusion of the particular medicine in the reimbursement system. There are several cases where patients have challenged even before a constitutional court the refusal to reimburse certain medicines, however, the court has recognized the lack of state funds as justified reason for refusal.

**8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

The reimbursement status is subject to formal approval by the NHS. Additional local or regional reassessment is not provided.

**8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

The NHS takes the decision. For criteria, including the clinical and cost effectiveness, see above 4.2.1 and 8.1

**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

As mentioned, a doctor must indicate in the prescription only a non-proprietary name of a medicine provided for the respective diagnose, if the patient will receive the reimbursable medicines for the particular diagnose for the first time. In turn, the pharmacy must offer and sell the cheapest medicine from the medicines with same non-proprietary name. If the sold medicine will not give the expected therapeutic effect, then the doctor will be entitled to prescribe the next cheapest medicine of the same non-proprietary name.

If the patient has already started the treatment with one of the reimbursable medicines and, upon update of the list of reimbursable medicines, another equivalent becomes the cheapest, and then the patient is entitled to continue use of the initial medicine, but must cover the price difference.

## **9 Reimbursement – Administrative Arrangements**

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

The marketing authorization holder or the wholesaler must apply to the NHS and provide information inter alia on the medicine, the manufacturer's price and expected reimbursement base price, the manufacturer sales price in Estonia, Lithuania, Denmark, Czech Republic, Rumania, Slovakia and Hungary, the respective disease, the patient target group, clinical trials, pharmacoeconomical analysis (above 1), expected number of patients, to whom the applicant will partially cover the costs, if the medicine is applied for above List C, etc.

The NHS takes the decision in 180 days, excluding the period given for the applicant to submit additional requested information, and the period between issuance of the invoice and reception of the payment for respective services of the NHS.

## **10 Reasons for decisions on Pricing and Reimbursement**

The Transparency Directive 89/105/EEC requires Member State authorities to provide a “statement of reasons based on objective and verifiable criteria” in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it if price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.

**10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

Yes, such reasoning is mandatory.

**10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

As it is seen from the case law developed by courts, the reasoning in general was sufficient and therefore recognized also by the courts.

## 11 Reconsiderations / Appeals

### 11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?

The applicant is entitled to appeal the respective decision of the NHS to the Ministry of Health within a month.

### 11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?

In turn, decision of the Ministry of Health may be appealed to the Administrative court again in a month.

### 11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?

The courts have reviewed the compliance of the decisions of the NHS on refusal to include in the particular reimbursement list certain medicines. The case law has been developed regarding the evidences on the therapeutic value of the treatment among the medicines with the same pharmaco-therapeutic group or non-proprietary name. According to the court it must be presumed that the medicines having the same non-proprietary name have the equal therapeutic effectiveness, thus having the ground to be included in the Reimbursement List A. The opposite- that the therapeutic effectiveness of particular medicine is not equal and differs from the medicines with the same non-proprietary name already included in the list A (and that the new applied medicine therefore is subject to the reimbursement List B), must be proved by the manufacturer with the results of the clinical trials in respect to the effectiveness or the side effects.

## 12 Unlicensed products and off-label use

### 12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?

The reimbursement and price control in such case is provided subject to general criteria described in 4.2.1 and 8.1 above.

### 12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?

In general, the reimbursement of particular medicine is linked with particular diagnosis defined by the Governmental Regulations. The reimbursement for off-label use are provided by the NHS only for individual patients on the grounds of statement by the doctors' consilium only in two exceptional cases- (i) if the treatment by respective medicine for non-listed diagnosis is vitally required; or (ii) the respective diagnosis is listed, but the reimbursement list does not include any respective medicine for approved indications.

## 13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.

Patient access schemes or other special schemes are not used.

## 14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).

The pharmacists do not have pay-back or claw-back obligations.

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He obtained LL.M. degree from Latvian University. Renars Gasuns lectures at Riga Graduate School of Law on introduction to Latvian law and publishes in various areas of life science law.

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# Lithuania

## **1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied**

**Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?**

Controls on pricing are generally differentiated on the basis of whether their cost is compensated by the Government ("reimbursable" products) or not ("non-reimbursable" products)

Prices of products from both categories must be approved ex ante (with certain exceptions such as non-substitutable products or orphan products).

### **1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."**

Prescription products may be reimbursable or non-reimbursable (see above). In both cases, the maximum price must be determined before entry into the market.

Non-reimbursable products that may not be substituted by any other products, and which have been put on a list handled by the Ministry of Health, may however be marketed before declaring the acquisition price.

The above distinction is not made for reimbursable products.

### **1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).**

Non-reimbursable prescription and non-prescription drugs are not distinguished in terms of pricing controls. See non-reimbursable products above.

### **1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.**

Products supplied to hospitals or clinics are not distinguished in terms of pricing. Pricing is controlled by establishing a maximum price, therefore price competition below that maximum price in supplying products by tender is still possible.

#### **1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

Non-prescription products may be reimbursable or non-reimbursable (see above). In both cases, the maximum price must be determined before entry into the market.

#### **1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

Price controls are applied to all medicinal products, including generics, as described above.

#### **1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

Price controls are applied to all medicinal products, including biosimilar products, as described above.

#### **1.7 Orphan Medicinal Products.**

Non-reimbursable prescription products imported for use of a specified patient under responsibility of a specified doctor ("named medicinal products") are excluded from pricing controls.

#### **1.8 Parallel imports from another Member State.**

Price controls are applied to all medicinal products, including those imported in parallel, as described above.

#### **1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

See answers above.

## **2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, if so, by which agencies of government. Under what specific legislation are these decisions made?**

Maximum price of non-reimbursable products is determined by adding the acquisition price and a surcharge not higher than the level determined by a Government decision (No. 257 of 10 March 2010). The size of the surcharge is dependent on the acquisition price range.

Maximum price of reimbursable products is determined under a separate legal basis: by reference to Order of the Minister of Health (No. V-267 of 6 April 2010) and associated legal acts.

Although pricing controls for reimbursable and non-reimbursable products are treated under distinct legal bases and distinct procedural rules, both processes are generally supervised by the Ministry of Health (and its subsidiary agencies such as the State Pharmaceutical Control Authority), with the addition of certain agencies overseeing social security funds insofar as reimbursable products are concerned.

## **3 Other Financial controls relating to supply**

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

There are no such specific measures. However, MA holders' financial stability is taken into consideration when deciding questions regarding reimbursable products.

## **4 Pricing Criteria**

**For those products identified in the answer to Q1 for which a price must be agreed:**

#### **4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?**

Yes. There are 8 reference States: Bulgaria, Czech Republic, Estonia, Latvia, Poland, Romania, Slovakia and Hungary. The pharmaceutical manufacturers aren't If the product is not sold in any of the reference States, the price in the State where the product is manufactured is submitted.

The price of a product in the reference States is declared by the applicant.

#### **4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?**

Reference to the largest already existing retail price of a product is made when calculating the basal price for reimbursable medicines.

There is no set requirement to provide information on clinical and cost-effectiveness when determining price, but there are such requirements when a product is considered for reimbursement.

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

For non-reimbursable products, the MA holder must submit his declaration of the acquisition price and prices in reference States between February 1 and March 1 each year. The declared acquisition price is then announced publicly, and becomes effective within 14 days. If the declared acquisition price exceeds the average price from the reference States, a special Negotiation Committee is called to discuss reduction of the acquisition price.

Regarding reimbursable products: requests to determine a price for the following year must be submitted from November 15 until December 15. Requests regarding the present year are to be submitted from January 15 until February 1. The requests are processed within 15 business days, and in case any deficiencies have arisen, they are returned to the applicant within 3 business days. Decisions must be adopted within 90 days of a correct application being submitted. A negative decision is presented to the applicant within 14 days.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

On an annual basis.

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 above?**

Increases of the price of reimbursable products must be assessed by the Negotiation Committee. The Committee will refuse a price increase unless there is no possibility to otherwise insure continuity of patient treatment.

Additionally the Committee will refuse a price increase:

- if the increase will result in an increase of expenses incurred by the State social security fund (and a substitute product is available which would allow avoiding such consequences),
- if the increase would overall result in decreased availability of the medicine.
- **Reduce the price generally or for a period**

There are no restrictions to reduce the price, but there are also no special rules for only temporary reductions.

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

There are no price freezes currently in effect.

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

If the product is non-reimbursable, the entry of a generic product to the market does not affect the price, of the branded product. However, the entry of a generic product within the last 5 years may affect calculation of the price for reimbursable products.

## 7 Other Types of price control

**Does your jurisdiction control any of the following prices:**

### 7.1 Full line or other wholesaler selling price

Yes, separate surcharges applicable for distribution (determining the wholesale price) are applied.

### 7.2 Pharmacy selling price

Yes, separate surcharges applicable for pharmacies (determining the retail price) are applied.

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

100 %, 90 %, 80 % or 50 % of base price of medicinal products included in one of the following lists may be reimbursed in Lithuania:

- List of diseases and reimbursable medicines for treatment thereof (list "A");
- List of reimbursable medicines (list "B");
- Reimbursable aid equipment (list "C")
- List of centrally paid medicinal products.

The base price of the products included in the above lists are reimbursed for persons insured by compulsory health insurance from the budget of Compulsory Health Insurance Fund (the CHIF), part income of which consists of the insurance contributions. As mentioned above, the cost of the product is reimbursed in part, i.e. only the so-called

base price of the product is reimbursed. Base price is a part of the retail price at which the medicinal products are sold in pharmacies. Therefore, difference between the retail and the base price of the product has to be paid by the patient. Depending on the disease and social group (e.g. pensioners, children), 100 %, 90 %, 80 % or 50 % of the base price of medicinal products can be reimbursed.

Medicinal products may also be included in the List of Reserve Medicines. These products are not actually reimbursed. However, they may later be moved to either list A or list of centrally paid medicinal products and thus reimbursed.

**8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

Lithuania applies the rule of a “positive list”. As mentioned in question No. 8.1., there are four lists in Lithuania which include the products that may be reimbursed.

The above lists are approved by the Minister of Health of the Republic of Lithuania.

**8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

Whether the product will be reimbursed or not, depends on whether it is included in the list as referred to in Q 8.1 above. The lists are approved and reassessed at the state level.

**8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

When responsible authorities, described in the below Q 9 are including medicinal products in the list, the following is taken into account:

- drug’s medical benefits
- pharmacoeconomic indicators based on pharmacoeconomic analysis carried out;
- impact of product’s compensation to the CHIF.

When determining medical benefits of the product, various aspects are evaluated. Such aspects include for example product’s efficacy and safety, its place in the disease treatment regimen compared to other reimbursable me-

dicinal products and alternative treatments for disease, difficulty of the disease for the treatment of which the product is intended to, pathogenetic, symptomatic or prophylactic effects of the drug, information of clinical trials on the product from published scientific articles. In case product’s medical benefits and pharmacoeconomic indicators are lower than those of other products included in the list, the product is not reimbursed. Also, in case the applicant fails to prove that its medicinal product is more effective or safer than the cheapest reimbursable product of the same indication and pharmacoeconomic group, the product is not reimbursed.

**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

Lithuanian laws do not provide for such a doctors right. They may only prescribe products that are already included in either List A, B, C or list of centrally paid medicinal products.

## **9 Reimbursement – Administrative Arrangements**

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

Applicant (i.e. MA holder or its representative, personal health care institution, distributor, aid equipment producer or its representative, associations of doctors or organization of patients) wishing for a disease, medicinal product or aid equipment to be included in the list, must submit to the Ministry of Health an application of an established form with accompanying documents. The Minister of Health composes a special commission (the “Commission”) to examine the applications. Various institutions (e.g. the State Medicines Control Agency, State Patient Fund, Department of Pharmacy, etc.) provide the Commission with necessary information on the product, reimbursement of which is applied for. The mentioned information must be provided to the Commission in writing within 50 days. Not later than within 10 days after information from all necessary institutions is received, the Commission performs preliminary assessment after which the Commission either (i) asks for additional information from the applicant, (ii) terminates the assessment of application (in case the application does not meet the requirements applicable) or, (iii) in case the application meets the applicable requirements, decides to include the disease, medicinal product or aid equipment in a respective list. In the latter case the drafts of lists A, B, C and centrally paid medicinal products are prepared and submitted to the Minister of Health for approval. The named decision

of the Minister of Health to approve the drafts of lists is considered as final decision.

## **10 Reasons for decisions on Pricing and Reimbursement**

The Transparency Directive 89/105/EEC requires Member State authorities to provide a “statement of reasons based on objective and verifiable criteria” in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it if price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.

### **10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

Yes. As referred to in Q 9 above, the decisions of the Commission are based on opinions and information of various institutions as well as legal requirements. If the Commission or the Minister of Health adopt a negative decision, such decision must be based on verifiable criteria, include reasoning, motives as well as procedure and deadlines for appeal.

### **10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

Practice on this issue is still inconsistent.

## **11 Reconsiderations / Appeals**

### **11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

In case the applicant is dissatisfied with the decision on the Commission as referred to in Q 9 above, it may appeal the decision to a special Committee of Appeal, formed by the Minister of Health. The decisions may be appealed within 10 working days from the receipt of the decision. The Committee of Appeal must examine the claim within 30 working days.

No internal mechanisms apply for appeal of price determination.

### **11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

Decision of the Minister of Health may be appealed to the court of administrative jurisdiction within one month after the decision was adopted.

### **11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

There is no case law in Lithuania on this matter.

## **12 Unlicensed products and off-label use**

### **12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?**

Products that are not registered in the Republic of Lithuania may be included in the list A or list B when (i) the term of registration of the product included in the list A or list B expires and the product is thus excluded from the list of registered products or when (ii) there are no registered products that could provide emergency medical aid or effectively treat the patients. In such case general rules for inclusion in the lists apply.

### **12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?**

As described in the above Q 8.1, in general, only the products included in one of the above lists may be reimbursed. Each list provides not only for the catalogue of medicinal products but also for prescribing conditions which must be strictly adhered to in order for products to be reimbursed. The only exception is made to medicinal products that are included in the list A and that are for treatment of orphan diseases. Such products may be prescribed for unapproved indication, dosage, etc. and will still be reimbursed.

## **13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.**

Outside of reimbursement under the general rules, persons having extremely rare diseases (orphan diseases) may apply for compensation of their medicine to a special



Concilium of doctors. Extremely rare diseases are defined as exceptional occurrences (diseases and conditions) which are not possible to be foreseen generally. The question of reimbursement is then decided upon by the National Health Insurance Fund. This question is treated as an exceptional matter, although a negative answer must still be duly motivated.

**14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

Lithuanian laws do not provide for any such pay-back / claw-back provisions. Under Lithuanian laws, pharmacists conclude reimbursement agreements with the National Health Insurance Fund. Once a month pharmacies submit to the National Health Insurance Fund invoices showing all reimbursable products dispensed. Based on these invoices, the National Health Insurance Fund fully compensates the agreed reimbursement price, i.e. the base price of the products as referred to in Q 8.1.

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### **Monika Rudyte**

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Monika Rudyte has joined the bnt attorneys-at-law Vilnius team in 2011, right before she obtained her Master of Laws degree in Vilnius University. The Lithuanian office of bnt attorneys-at-law was founded in 2004. Since then an excellent team of lawyers has been offering legal services to foreign and Lithuanian corporate clients. She has now been working with bnt attorneys-at-law Vilnius for almost four years as an Associate Attorney. Monika Rudyte specializes in and supports local and international clients in life sciences as well as in legal matters on various industry and regulatory matters. Her expertise includes day-to-day employment law matters, data protection, food & beverages, advertising and entertainment issues, health, medical & pharmaceutical and other International & EU regulatory affairs.

# Luxem- bourg

## **1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied**

**Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?**

In Luxembourg, the Minister in charge of social security policy (hereinafter the "Minister") decides on prices for all products which are considered and defined as "medicines".

In accordance to the Article 2 of a "Règlement Grand-Ducal" (hereinafter "RGD") of December 1st, 2011 on criteria, conditions and procedure for the pricing of medicinal products for human use, the MA holder is authorized to commercialize a product only after having received the approval of the price by the Minister.

### **1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."**

Initial pricing approval is required for medicines which are defined as follows: "Any substance or composition presented for treating or preventing the human diseases and any drug substance or composition which may be prescribed to human beings in order to making a medical diagnosis or establishing, correcting or modifying humans psychological functions and with a marketing authorization in accordance with the legal provisions in force."

### **1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).**

No reimbursement will occur by the National Health Fund named "Caisse Nationale de Santé" (hereinafter "CNS") for medicines prescribed for personal convenience, or for esthetic reasons.

### **1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.**

Where a product is supplied to hospitals, the price of the product is fixed by the Minister if it is considered as "medicine". All products registered as medicines under its "national number" are controlled by the Ministry of Social Security. The price fixed for those products is the ex-factory price which refers to the cost that the manu-

facturer charges for a distributor or others to purchase directly from the source.

#### **1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

Regarding the reimbursement, OTC products are non-reimbursed except where there is a prescription delivered by a physician.

#### **1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

**In relation to the price:**

In Luxembourg, the Direction of Health of the Health Ministry established, on basis of an international scientific classification (ATC) in accordance to the World Health Organization (WHO), a list of groups of products, called generic groups. These groups contain the same active substance which is not anymore protected by a patent.

This list is updated monthly and reported to the CNS which is the national system of health insurance in Luxembourg. The Department of Health admits substitution products with the same qualitative and quantitative composition in active substance having the same pharmaceutical form.

**In relation to the reimbursement:**

In Luxembourg, since 1st October 2014, the pharmacist must inform the patient that a generic drug is on the market. The generic product is substitutable and belongs to a group of alternative drugs. The substitutable medicines are listed by the Direction of Health.

Based on this list, the CNS fixes for all alternative products the basis of reimbursement and sets a reference amount on which the participation of the patient is established. The list of all the groups of drugs subject to a reimbursement basis is published in the Memorial ([www.legilux.lu](http://www.legilux.lu)). If the patient refuses the generic product, he must pay the difference that is not supported by the CNS.

#### **1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

Waiting for confirmation from Luxembourg authorities.

#### **1.7 Orphan Medicinal Products.**

In Luxembourg, the access to orphan medicinal product may be possible before marketing authorisation is granted where a compassionate use or a nominative base of patient authorization is submitted to the administration authority.

In conformity with the List 9 of the CNS's Bylaws (hereinafter the "Bylaws"), point 9, products considered as orphan products by the market authorization are subject to prior approval by the "Contrôle médical, de la sécurité sociale", which is a state administration under the Minister's au-

thority (hereinafter "Contrôle médical") to be reimbursed provided the conditions of the marketing authorisation are fulfilled.

Orphan medicinal products which are exclusively used in hospitals are, following positive mention by the Commission, registered on the list of admitted products and their prices are free.

#### **1.8 Parallel imports from another Member State.**

For a commercialisation in Luxembourg, all medicinal products require a prior authorisation ("Autorisation de Mise sur le Marché") (article 22 (1) of the "Code de la sécurité sociale" (hereinafter « CSS »)).

The sole exception to the necessity of a prior Luxembourgish authorisation is a European authorisation delivered by the EMEA ("Agence Européenne pour l'Evaluation des Médicaments") which is valid in all the Member States.

## **2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

In principle, there is no relationship between Pricing and Reimbursement. Nevertheless, the Ministry of Social Security sets forth a positive list and, based on this one the CNS will reimburse or not. Furthermore, the normal rate of reimbursement is 80% of the public pricing.

These rates are set up by the Bylaws of the CNS.

## **3 Other Financial controls relating to supply**

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

In accordance to the article 14 of the RGD of December 1st, 2011 on criteria, conditions and procedure for the pricing of medicinal products for human use, the pharmacist trade margin is also regulated as follows:

- 50 % of the acquisition price (if price is equal to or below EUR 50,-);
- 15 % of the acquisition price (if price is higher than EUR 50,-), within the limit of EUR 250,-.

## 4 Pricing Criteria

For those products identified in the answer to Q1 for which a price must be agreed:

### 4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?

Like in the majority of European countries, the external reference pricing (ERP) is applied in Luxembourg market products (publicly reimbursed medicines, prescription-only medicines, innovative medicines). The reference price is calculated on the lowest price per basket.

Since Luxembourg does not have pharmaceutical industries, the international pharmaceutical industry decides on the supply circuits of the Luxembourg market. Therefore, almost 80% of the products covered by health insurance are imported from Belgium.

For that reason, the public prices practiced in Luxembourg are directly derived from the Belgian retail prices.

### 4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?

In accordance to the article 14 of the RGD of December 1st, 2011 on criteria, conditions and procedure for the pricing of medicinal products for human use, the price of a product shall be determined as follows:

Pharmacy purchasing price + pharmacist trade margin + 3% VAT rate

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

In accordance with Article 5 of the RGD of December 1st, 2011 on criteria, conditions and procedure for the pricing of medicinal products for human use, an application to approve the price of the product shall be introduced by the marketing authorization holder to the Minister.

Once the request fulfils all the requirements, the competent authority shall provide an official acknowledgement of receipt and the decision on the applicable price shall be communicated within 90 days from the delivery receipt.

In case of insufficient information, the Minister shall notify within 15 days the missing information required and act his decision 90 days after reception of the information.

The approval decision shall enter into force on the first day of the month following the date of the decision.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

There is no review of the price imposed on a regular basis.

### 6.2 What controls apply to the right of company to:

There is no specific control. The claimant who wants to increase or reduce the price of a medicine shall fill in the special form concerning the prices' request.

In the context of an increase, the claimant shall provide supporting documents (increase of the raw material or production price).

- Increase its price and are the criteria applied for approval different from these given in the answer to 4 above?
- Reduce the price generally or for a period?

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

No.

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

There is no legal obligation, nevertheless in order to optimize the competition in the market, when a generic product enters the market, the price industry is in fact forced to match the prices of the generic product.

## 7 Other Types of price control

Does your jurisdiction control any of the following prices:

### 7.1 Full line or other wholesaler selling price

In Luxembourg, the proportion of pharmacy sales originated directly from Full Line wholesaler represents 80% (Source: Authors' compilations from GIRP Member Database, 2010).

### 7.2 Pharmacy selling price

Luxembourg has different wholesale margins for different classes of drugs, depending on the country of origin (especially margins applied to Belgian imports).

The margin applied in Luxembourg is linear referring to a flat rate regardless of price.

In 2007, the average of the pharmacy margin was between 46.7 % (local and Belgian imports) and 50.6 % (Others imports) of the PRP

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

The system is based on percentage co-payments, i.e. a cost sharing in the form of a set proportion of the cost of the product. Therefore, the patient will pay a certain fixed proportion of the cost of a product with the third party payer (CNS) paying the remaining proportion.

In Luxembourg, the health care system works on a reimbursement basis whereby you submit receipts for consultations, treatment and medicines to the CNS for reimbursement at the appropriate rate, which varies from 80 to 100 per cent. Where the reimbursement is not full, the patient is subject to co-payment.

### 8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?

The products which are provided in pharmacies open to the public are reimbursed where there is a positive list published in the Memorial. The decisions on whether or not a product (a category or a specific product) shall be listed or excluded fall under the Bylaws and come within the competency of the “Direction de la Santé, Division de la pharmacie et des médicaments” and the “Contrôle médical”.

In accordance to the article 100 of the Bylaws, the products, which are listed and reimbursed, are classified in three different classes of reimbursement. For each class there is a specific rate applied to the public prices.

- (a) The standard rate of 80% applies to all products which are in the positive list and not covered by a specific provision of the Bylaws
- (b) Preferential rate of 100% applies to medicinal products for specific therapeutic indication, usually whose containing a single active substance and used to address the long term illness considered as irreplaceable and may produce extra participation inappropriate to the protected person (list 2 Bylaws).
- (c) The reduce rate of 40% applies to others products with therapeutic indication (list 5 Bylaws)

### 8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?

Generally, the product types identified as subject to reimbursement controls in the answer to Q1 does not require a formal approval or a recommendation for their reimbursement. There is no local or regional reassessment.

Nevertheless the different rates abovementioned, the rates of 40% or 80% may be increased to 100% in three cases (lists 3 & 4 Bylaws):

- (a) Products known to be particularly expensive and irreplaceable appearing on a special list, which are fully covered and subject to prior authorization by the “Contrôle médical”.
- (b) Products which are in principle subject to normal or reduced rate when these products are used by protected persons.  
These protected persons are the persons subject to:
  - Treatment of a long and costly illness;
  - Treatment of serious illness needed irreplaceable and expensive products;
  - Home care treatment further to hospitalization where it generated an inappropriate participation for the patient;
  - Where products are given intravenously prescribed further to hospitalization where it generated an inappropriate participation for the patient.
- (c) Products delivered in case of hospital treatment.

### 8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?

Where a reimbursement shall be subject to prior authorization, the “Contrôle médical” is competent. The decision is based on the medical file of the patient establish by the attending physician who specifies the products for which the preferential rate of reimbursement is requested. In virtue of article 105 of the Bylaws, another criteria of the decision is the accordance of the prescription with the characteristics of the medicine which were approved for the marketing authorisation.

### 8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a

particular patient in a way that allows reimbursement of the product cost in whole or in part?

We refer to the response to question 8.4 above.

## 9 Reimbursement – Administrative Arrangements

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

In the case of a litigation between the CNS and a patient, the “Commission de surveillance” has competence. An appeal can be introduced against the decision of the “Commission de surveillance” in front of the “Conseil Arbitral des Assurances Sociales”.

The timeline for the reimbursement is depending of the procedure and cannot be estimated.

An agreement on the reimbursement may still occur but there is no specific procedure and no timeline.

## 10 Reasons for decisions on Pricing and Reimbursement

**The Transparency Directive 89/105/EEC requires Member State authorities to provide a “statement of reasons based on objective and verifiable criteria” in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it if price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.**

**10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

In virtue of article 97 of the Bylaws, a medicine is included into the list of products covered by CNS if it complies with the conditions set by the article 22 § 1 alinea 5 (medicine with marketing authorisation), and article 22 §3 (medicine automatically registered on the positive list in reason of the public interest and the public health) of the CSS. Then the decision is based on objective criteria (marketing authorisation), but may be based on the expert opinions or recommendations (public interest and the public health).

**10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

We do not record any special complaint from companies.

## 11 Reconsiderations / Appeals

**11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

Price issues

In accordance to article 10 of the RGD, the decision to approve or reject the price is effective the first day of the month following the date of the decision. If the Minister decides not to approve the marketing of the product at the applicant’s proposed price, the decision shall contain a statement of reasons based on objective and verifiable criteria.

In addition, the applicant is informed of the available legal recourses and the time within which appeals must be submitted.

Reimbursement issues

In accordance to the article 418 of the CSS, the “Contrôle médical” is competent to:

- approve the covering of medical costs, provided it is prescribed by the laws , regulations or statutes, and monitoring ;
- give notice to the CNS’s request, particularly in terms of drugs referred to in Articles 22 , 22a and 22b and Caregiving

The Administrations are binding by the decision of the “Contrôle médical”, nevertheless they may request from the “Contrôle médical” the motivation of its opinion in order to rely on their position before the Arbitration Council and the Superior Council of the Social Security.

Notwithstanding the foregoing, independent experts may be established. If the opinion of the “Contrôle médical” is contradicted by medical report, the institution or the administration determines itself of the opportunity to appeal.

If for the same person there is conflict between the opinions, the case may be brought before the medical director of the “Contrôle médical” which sets forth the final opinion.

**11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

Dissatisfied applicant are not entitled to appeal to the Courts, as abovementioned it seems that the administration is the sole which is entitled to appeal such decision on reimbursement price.

**11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

We do not know that kind of procedure in our jurisdiction, and not all the judgements are automatically published.

## **12      Unlicensed products and off-label use**

**12.1** Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?

Not possible. We refer to point 1.8. of the present.

**12.2** Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?

**13      Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.**

No

**14      Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

No



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# Nether- lands

## 1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied

Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?

N/A

1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."

N/A

1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).

N/A

1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.

N/A

1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).

N/A

1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.

N/A

1.6 Biosimilar medicinal products (whether the first or subsequent available product)

N/A

1.7 Orphan Medicinal Products.

N/A

1.8 Parallel imports from another Member State.

N/A.

### **1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

For all prescription only medicinal products for which a marketing authorization has been granted, a maximum price can be established by the minister of Healthcare on basis of the “Wet geneesmiddelenprijzen” (the Act on prices of medicinal products). The price established by ministerial decree is the maximum price for which a medicinal product may be sold to a pharmacist: the price therefore regulates the relation between, in the end, the party who sells and delivers the product to the pharmacist, irrespective of whether or not that is the manufacturer, the importer or the wholesaler, and the pharmacist.

The maximum price is not linked to the reimbursement status. There is no requirement to obtain a reimbursement status but under the compulsory healthcare insurance in the Netherlands, without a decision on that status there is, in general, no place on the market for non-reimbursable medicinal products which are covered under the healthcare insurance. The reimbursement status is given, again, by ministerial decree, based on the “Zorgverzekeringswet” (the Healthcare Insurance Act).

Once the reimbursement status is established by means of a maximum reimbursement, this still does however not reflect the prices on the market. Healthcare insurers are entitled to select medicinal products that will fall under the cover of their healthcare insurance subject to the condition that of all active substances of medicinal products at least one product per active substance is available for the insured of said insurer. Healthcare insurers use different pricing tender procedures to select which medicinal products will be covered.

Please note that the reimbursement of pharmaceutical products in hospitals forms part of the overall reimbursement of the hospital care. Based on “de DiagnoseBehandelingsCombinatie (DBC)” (“the Diagnosis Treatment Combination”), the hospital charges one price for all stages from diagnosis by a medical specialist and possible hospital treatment, including the use of pharmaceutical products. This might be different however for “expensive medicinal products” such as new biological medicinal products for which an “add on” on the price can be given by the Dutch Healthcare Authority. The Authority’s policy however is aimed at stopping the possibility of the “add on”.

## **2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

The decisions are made separately on basis of the “Wet geneesmiddelenprijzen” and the “Zorgverzekeringswet”; both decisions however are taken by the minister of Healthcare.

## **3 Other Financial controls relating to supply**

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

No.

## **4 Pricing Criteria**

**For those products identified in the answer to Q1 for which a price must be agreed:**

### **4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?**

Yes: under the “Wet geneesmiddelenprijzen” the maximum price is established as the arithmetical average of the prices of the product in Belgium, Germany, France and the UK. The prices in those countries are established on basis of, for Belgium: the “Tarief voor Specialiteiten”, published by “de Algemene Pharmaceutische Bond (A.P.B.)” in Brussels, and for medicinal products administered in hospitals, the list known as “bijlage I van het K.B. van 21.12.2001”, published by “het Rijksinstituut voor ziekte- en invaliditeitsverzekering” in Brussels;

for Germany: the list published by “Informationsstelle für Arzneispezialitäten GmbH (IFA)” in Frankfurt am Main;

for France: the list known as “DATASEMP”, published by Vidal S.A. in Paris;

and for the UK: the “Dictionary of Medicines and Devices” published by National Health Service in London

### **4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?**

No other criteria apply, and no other information is required or supplied.

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

The decision of the minister of Healthcare is governed by the provisions of the "Algemene wet bestuursrecht" (The Act on administrative law). Under the applicable provisions of the Act a draft of the decision is published and concerned parties are allowed to present their view with respect to the draft decision. The decision is considered a decision on an application and therefore has to be given within 6 months from the date of the application.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

Twice a year, Farmatec (a division of the department of Healthcare) examines whether there is a cause to reassess the maximum prices and if so, it publishes a new, amended draft of the Regulations. Based on this draft, interested parties may express their opinions within six weeks. After that period, the Regulations will be changed. Interested parties may lodge an appeal against these changed Regulations.

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 adobe?**

None.

- **Reduce the price generally or for a period?**

None, however as the price is a maximum price, the company is free to set any price below the maximum and change it as often as necessary or wanted.

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

No.

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

No, at least no legal obligation. Under the reimbursement system, the limit for reimbursement however will change as a group of substitutable products will be established and the reimbursement limit will be set for that group which will be – in general – less than the price of the originator's product.

## 7 Other Types of price control

**Does your jurisdiction control any of the following prices:**

### 7.1 Full line or other wholesaler selling price

No, the provisions of the "Wet geneesmiddelenprijzen" apply to wholesalers as well, meaning that wholesalers are not entitled to sell a product for a price which exceeds the maximum price.

### 7.2 Pharmacy selling price

The pharmacy selling price is not governed by the "Wet geneesmiddelenprijzen" but the selling price is subject to the reimbursement price under the compulsory healthcare insurance system.

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

A medicinal product is part of the cover of the compulsory healthcare insurance once the minister of Healthcare has placed the product on the list of covered products as mentioned in Article 2.8, of the "Besluit zorgverzekering" (The Royal Decree on the healthcare insurance). The decision of the minister follows an application of the MA holder or its representative in the Netherlands. The application is made through a designated form which can be found on the website of Farmatec, the division of the department of Healthcare which prepares the decision: [http://www.farmatec.nl/doc/pdf/Farmatec%20aanvraagformulier%20GVS%20\(FA22.04\)\\_32299.pdf](http://www.farmatec.nl/doc/pdf/Farmatec%20aanvraagformulier%20GVS%20(FA22.04)_32299.pdf)

Once the medicinal product is placed on the list, a reimbursement limit is established, based on the fact whether or not the medicinal products is "onderling vervangbaar met" (substitutable by) other products on the list. Products are considered "substitutable" if (i) they can be used for the same medical condition, (ii) they have the same manner of administration and (iii) prescribed for the same age categories. If there is no substitute product, the minister will not establish a reimbursement limit: the limit de iure equals the maximum price set on basis of the "Wet geneesmiddelenprijzen". If there are substitute products, the reimbursement limit will be established on basis of comparison of prices as per October 1998 or, if no such prices are available on the lowest available market price published in the "Taxe" (the unofficial pricelist published by Z Index B.V.). Please note that the reimbursement limit and the price published in the "Taxe" do not reflect the

actual prices in the market but are, again, sort of maximum prices. The actual prices are the result of tendering procedures or civil law contracts between concerned parties on the market.

As long as the consumer price does not exceed the reimbursement limit, no additional payment of a patient is required. If however the consumer prices exceeds the reimbursement limit but is still under the maximum price based on the "Wet geneesmiddelenprijzen" an additional payment is required.

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**8.2 Does your jurisdiction purport to operate a "positive list" or "negative list" in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

As explained in our answer to question 8.2, the Netherlands has a positive list of products which may be reimbursed. It should be noted that health care insurers have the power to limit the cover: they may decide that only specific products are reimbursed as long as there is at least one product available for every active substance in the list of products by the minister of Healthcare.

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**8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

The reimbursement status is subject to formal approval based on an assessment by Farmatec, a division of the department of Healthcare.

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**8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

The decision on an application for a product to be put on the list of products as mentioned in Article 2.8 of the "Besluit zorgverzekering" is made by the minister of Healthcare as is the decision to establish a reimbursement limit.

The decision depends in part on whether or not a "substitute" product is already on the list. If so, the applicant only as to argue why the product should be clustered with the product already on the list. If not, the applicant has to provide a "pharmaco-economic" dossier following the guidelines of the "Zorginstituut Nederland", the adviser of the department on the merits of the product. The guidelines for pharmaco-economic research are published: <http://www.zorginstituutnederland.nl/binaries/content/>

<documents/zinl-www/documenten/rubrieken/pakket/pakketbeheer/0604-guidelines-for-pharmaco-economic-research/Guidelines+for+pharmaco-economic+research.pdf>

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**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

Yes, but only with respect to the decision of the healthcare insurer to limit the cover of the compulsory insurance; doctors have no power to override the list of products established by the minister.

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## **9 Reimbursement – Administrative Arrangements**

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

The decision of the minister is due within 90 days after a full and admissible application has been filed.

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## **10 Reasons for decisions on Pricing and Reimbursement**

The Transparency Directive 89/105/EEC requires Member State authorities to provide a "statement of reasons based on objective and verifiable criteria" in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it if price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.

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**10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

Yes.

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**10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

Yes.

## 11 Reconsiderations / Appeals

### 11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?

The applicant is entitled to express its view on the draft decision and this view has to be taken into account in the decision.

### 11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?

The decision is subject to judicial review; such a review may be asked in a procedure for interim measures. A decision in a procedure for interim measures is available within – in general – 6 to 8 weeks after the start of the procedure.

### 11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?

Yes. Preparation is key: the procedure should be won in the administrative phase as the judicial review is limited because of the margin of appreciation the courts leave the minister.

## 12 Unlicensed products and off-label use

### 12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?

Yes, costs made are reimbursed.

### 12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?

Yes, reimbursement for off-label use is only possible if the use meets the specific criteria in the decision of the minister of Healthcare as mentioned in Article 2.8, of the “Besluit zorgverzekering”. However, where the off-label use is not manifest, reimbursement will be based on the “labelled use”.

### 13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.

No.

### 14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).

No, pricing for pharmacists is not regulated anymore. The system works through the decision of the healthcare insurer which products are covered under the compulsory healthcare insurance.

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Recent work in the sector includes advising and litigating on clinical trials, licensing, parallel import, regulatory aspects of wholesaling and brokering of products, promotion, pricing and reimbursement, procurement of healthcare services and the qualification of healthcare insurers as "a body governed by public law" within the meaning of Article 1(9) of Directive 2004/18/EC.



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Recent work in the sector includes advising and litigating on clinical trials, licensing, parallel import, regulatory aspects of wholesaling and brokering of products, promotion, pricing and reimbursement, procurement of healthcare services and the qualification of healthcare insurers as "a body governed by public law" within the meaning of Article 1(9) of Directive 2004/18/EC.

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# Norway

## **1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied**

Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?

### **1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."**

The Norwegian Medicine Agency (NOMA) regulates maximum pharmacy purchasing price and the pharmacy mark-up for prescription-only products, whether on or off-patent.

### **1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).**

A maximum price must be obtained for all prescription only products.

### **1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.**

A maximum price must be obtained for all prescription only products.

### **1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

The price for medicinal products which are not subject to prescription (OTC-product) is not regulated

### **1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

Prices for generic prescription-only products cannot exceed the maximum market price of the original branded product. Further, a price model called the stepped price model (Trinnprismodellen) came into effect in January 2005. Under this scheme, a maximum reimbursement price is set for affected medicines (both branded and generics). The maximum reimbursement price level is automatically reduced in stages (steps) following patent expiry. The size of the price cuts depends on annual sales



prior to the establishment of generic competition and time since competition was established. NOMA decides what medicinal products shall be subject to the stepped price model.

Two criteria must be fulfilled for a product to be subject to the stepped price model:

- NOMA must have listed the original product and the generic product(s) as substitutable (placed on a substitution list)
- Stable generic competition must have occurred for the original product. Stable generic competition occurs when the products are placed on the substitution list and there are not documented any serious delivery issues related to the product.

The price is reduced by 30 % at the moment stable generic competition occurred, and 55 % 6 months after stable generic competition occurred. For medicinal products with sales of NOK 100 million or more within a 12-month period during the last 2 years before generic competition was established, the cut rate after 6 months is 75 %. The relevant regulation also gives NOMA the right to decide further price cuts 12 months after the last ordinary cut.

Within the step-price system there are no regulations of pharmacy mark-ups. Pharmacies therefore have a financial incentive to carry out generic substitution and dispense the cheaper product.

#### **1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

See answer to Q 1.2

#### **1.7 Orphan Medicinal Products.**

See answer to Q 1.2

#### **1.8 Parallel imports from another Member State.**

See answer to Q 1.2

#### **1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

N/A

## **2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?

NOMA is responsible for setting maximum prices on prescription-only-medicines. The NOMA also evaluates and decides whether a medicine should be reimbursed by the National Insurance Scheme. The pricing and reimbursement process is regulated in detail in Regulation No. 1839 of 18 December 2009 relating to pharmaceutical products (Legemiddelforskriften), Sections 12 and 14.

## **3 Other Financial controls relating to supply**

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

Pharmacy mark-ups for prescription-only-medicines are regulated (by decree) by NOMA. The established pharmacy mark-up is a maximum mark-up and is applied for all price-regulated medicines, including both reimbursed and non-reimbursed medicines. Since 1995 there has been no price control on OTC products by the authorities.

Every fourth year the NOMA performs an evaluation of the pharmacy mark-up.

Self-dispensing doctors, which are very few in Norway, may charge a mark-up of 10%.

## **4 Pricing Criteria**

**For those products identified in the answer to Q1 for which a price must be agreed:**

### **4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?**

Prices for products in other countries in the European Economic Area (EEA) serve as the main basis for price settlements. The price of a prescription-only medication in Norway is set as the mean of the three lowest market prices of the product in a selection of countries.

The reference countries that are included in the price comparison are: Sweden, Finland, Denmark, Germany, UK, Netherlands, Austria, Belgium and Ireland. In a situation where market prices exist in three or fewer of these countries, the price will be set as the average price of the existing prices.

### **4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?**

See answer to Q 4.1.

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

A pharmaceutical company can apply for preapproved reimbursement for a drug that has received marketing authorization. Applications are handled by NOMA.

The timeline until approval is normally 90 days.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

The marketing authorization holder and NOMA may initiate a reevaluation of the maximum prices. However, adjustments should normally not occur more frequently than once per year. NOMA reevaluates the maximum price for the active ingredients with the highest turnover. The purpose is to ensure that the maximum prices reflect the developments in European prices.

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 adobe?**

See Q 6.1.

- **Reduce the price generally or for a period?**

There are no limits in regards to price reductions.

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

No.

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

See Q 1.5 regarding the stepped price model.

## 7 Other Types of price control

**Does your jurisdiction control any of the following prices:**

### 7.1 Full line or other wholesaler selling price

Yes, see above regarding maximum prices.

## 7.2 Pharmacy selling price

Yes, see Q3.

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

NOMA produces a list of medicines which are preapproved for reimbursement – the “reimbursement list” (NO: “Blå resept-listen”). Products may be included on the reimbursement list on the basis of a reimbursement application to the NOMA, who decides whether the pharmaceutical product in question is to be included on the list. In order for a product to be included on the reimbursement list, the product must be used for the treatment of severe and prolonged illnesses. When constructing the application, the applying company needs to follow the Norwegian guidelines for pharmaco-economic evaluations when applying for reimbursement. A price application may be submitted in parallel (a fixed initial maximum price is a prerequisite for reimbursement). The time allocated to the NOMA for dealing with both pricing and reimbursement is 180 days. If the NOMA has questions regarding the application, the company has a maximum of three months to answer.

Generally speaking the Norwegian reimbursement system may be characterised as disease and consumption based. Whether a pharmaceutical product is reimbursed and the amount of reimbursement depends on the following criteria:

- the illness must as a main rule be considered serious and chronic, for which long-term medication (more than three months per year) is necessary;
- the annual consumption no co-payment above an annual ceiling of NOK 1,880 / € 240; low income pensioners and children under 16 are exempt from co-payment.

Reimbursement is provided only for “long-term” medication for chronic diseases, defined as more than three months’ of medication per year. In general the reimbursement programme does not cover short-term therapy (e.g. antibiotics for pneumonia). Over-the-counter (OTC) products are in general exempt from reimbursement.

The Norwegian Health Economics Administration (HELFO) may upon application from the patient decide on reimbursement for individual patients for pharmaceuticals/indications not included on the reimbursement list.

**8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

Positive list.

**8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

See Q 8.1

**8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

See Q 8.1

**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

Where several similar products exist, the prescribing physician shall as the main rule prescribe the cheapest product containing the relevant active ingredient, provided that the products are considered medically equivalent. However, the physician may in certain cases choose to prescribe another product if there are compelling reasons for the opt-out.

## 9 Reimbursement – Administrative Arrangements

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

The marketing authorization holder can apply for pre-approved reimbursement and inclusion on the reimbursement list. The application is handled by NOMA. NOMA assesses the application. In order for a reimbursement application to be granted, four criteria must be met:

- The drug is to be used in the treatment of serious diseases or risk factors with high probability of leading to, or exacerbating serious illness.

- The illness or risk of disease as mentioned above will necessitate or risk repeated treatment over a long period of time.
- The drug has a scientifically well documented and clinically relevant effect in a defined and appropriate patient population.
- Costs related to the use of the drug are reasonably related to the drug’s therapeutic value and costs associated with alternative therapies (cost-effectiveness).

NOMA also considers the budgetary implications. If drug costs after granting reimbursement are below the so-called “bagatelle” threshold, then the NOMA evaluates and makes a decision. However, if drug costs are above this limit, NOMA sends the case to the Ministry of Health and Care Services (HOD) who in turn forward it for political consideration and decision-making.

Applicants must pay a fee for processing the application.

NOMA will approve or reject the application within 180 days. NOMA requests for supplementary information, the time limit is increased beyond the 180 days.

## 10 Reasons for decisions on Pricing and Reimbursement

The Transparency Directive 89/105/EEC requires Member State authorities to provide a “statement of reasons based on objective and verifiable criteria” in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it if price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.

**10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

Yes.

**10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

Yes.

## 11 Reconsiderations / Appeals

**11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

The decision may be appealed. Appeals are decided by the Ministry of Health. The deadline for appeal is three weeks from notice of the decision.

**11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

Yes.

N/A

**11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

N/A

## **12 Unlicensed products and off-label use**

**12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?**

Unlicensed products may be reimbursed on a case by case basis.

**12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?**

Reimbursement is decided on a case by case basis.

**13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.**

N/A.

**14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed**

**reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

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# Poland

## 1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied

**Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?**

There is no requirement to obtain price approval during the market authorization proceedings or during a certain period of time following the issue of marketing authorization. Generally, Polish law clearly differentiates marketing authorization from reimbursement/pricing. The latter is decided upon in separate proceedings and by different regulator (MA – Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products / reimbursement and pricing – Minister Zdrowia (Ministry of Health)). The reimbursement and pricing procedures may be applied only to a product, which has been authorized to market. A natural consequence is that these procedures cannot precede the granting of marketing authorization, i.e. proceedings relating to such authorization or run parallel to such proceedings.

There is also no requirement to obtain price approval before placing a product on the market or within certain period of time following such placement.

### 1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."

N/A

### 1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).

N/A

### 1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.

A maximum price must be obtained for all prescription only products.

### 1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).

N/A

- 1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

N/A

- 1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

N/A

- 1.7 Orphan Medicinal Products.**

N/A

- 1.8 Parallel imports from another Member State.**

N/A

- 1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

N/A

## **2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

Please see replies to Q1.

## **3 Other Financial controls relating to supply**

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

If the question is related to issues addressed in Q1 then the answer is "no".

If this is a general question, then yes – there are certain restriction related to supply of reimbursed products. Any entity applying for reimbursement of its product must make a commitment in writing that it will ensure the continuous supply of the reimbursed product. The annual amount of supply must be stated too. Failure to comply may result in the reimbursement decision being annulled.

## **4 Pricing Criteria**

**For those products identified in the answer to Q1 for which a price must be agreed:**

- 4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?**

If the question is strictly related to issues addressed in Q1 then the answer is "no".

If this is a general question then yes – the applicant must provide the maximum and minimum prices for the product in EU/EFTA countries in the reimbursement application. This information must cover one year before the date of filing. The same information is later one of basis of negotiating reimbursement price with the regulator, as well as one of criteria taken in consideration by the regulator when making the final decision on the product's price in the certain areas of treatment (e.g. rehabilitation, psychiatry).

- 4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?**

The remaining criteria include for instance:

- maximum and minimum price for the applied product in Poland during one year preceding the filing of reimbursement application;
- discounts/rebates and price agreements in EU/EFTA countries;
- the cost of therapy with applied product, as compared to the cost of using other medical procedures and/or technologies, which may be replaced with the applied product;
- impact of potential reimbursement on the budget of the state;
- counterbalancing the interest of patients and manufacturers/distributors of drugs;
- applicant's R&D and investments in Poland.

## **5 Pricing control timelines**

- 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?**

A drug may obtain the reimbursed status only throughout a specific administrative proceedings carried out by the Minister of Health. The pricing is decided upon in the same proceedings. In principle the proceedings is instigated by filing a detailed application, which must contain e.g. – apart from regular information related to the drug (name and address of the applicant, name of the drug, EAN, MA

number) – a proof of drug's availability in trade, an obligation to ensure the drug's continuous supply, proposed price, proposed RSS (if any is to be applied), information on the product's maximum and minimum price in Poland and EU/EFTA (see Q4 above), information on daily and average cost of therapy, information on standard duration of therapy, information on patent protection and data/market exclusivity.

The exception from the said principle is off-label reimbursement, where the regulator passes the reimbursement decisions ex officio.

The proceedings lasts 180 days, yet may be prolonged in some cases, e.g. when the application needs supplementing or explaining.

There are two institutions supporting the MoH in passing the decision. One is Economic Committee (Komisja Ekonomiczna) which negotiates the price related issues with the applicant, as well as the medical indications in which the product is to be reimbursed and potential RSS. The other is the Agency for Medical Technologies Assessment (AOTM), which provides general recommendation as to whether the product should be reimbursed or not and provides in depth analysis with respect to therapy cost issues, including but not limited to the therapy cost/therapy effects ratio.

The list of reimbursed products is published every two months along with medical indications, degree of reimbursement and prices.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

There is generally no practice of reviewing the prices. The reimbursement decisions are fairly short (2 years in principle) and the price related aspects and the price itself are thoroughly reviewed during the proceeding before passing the reimbursement decision. There is rarely a need to change the price, and if there is – the applicant may move to the MoH to increase or decrease the price.

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 above?**

N/A.

- **Reduce the price generally or for a period?**

There are no specific new criteria regarding the increase or decrease of price. An application must be filed in this respect and the criteria taken into consideration by the regulator are roughly the same as in case of first decision on reimbursement and pricing.

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

No.

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

No. There is a different mechanism however. If given product is reimbursed for the first time for certain medical indication, all products reimbursed afterwards – irrespective whether original or generic – will not have the reimbursement price higher than 75% of the first product's price.

## 7 Other Types of price control

**Does your jurisdiction control any of the following prices:**

### 7.1 Full line or other wholesaler selling price

Polish jurisdiction imposes a fixed ex-factory price, a fixed wholesale price (including margin) and fixed pharmacy price (including margin). An exception is sale of drugs to hospitals, where the price remains officially decided by the regulator, but is maximum and not fixed. This allows the hospitals to purchase drugs at lesser prices.

### 7.2 Pharmacy selling price

It's a fixed price. The pharmacy cannot offer any discounts to the patients. See also above.

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

Polish reimbursement system is exclusively national, with the reimbursement decided by central administration body (see response to Q1) and financed from the state budget. The reimbursed drugs are available to patients who are subject to the national health insurance. This condition is met by all employees, as such insurance is a mandatory element of employment, and most of remaining citizens, as they may obtain national insurance voluntarily and usually do, as the insurance is a condition of receiving free medical services.

The reimbursement system involves co-payment by the patients in principle. This is so called "pharmacy reim-



bursement" which aims at making the drugs available to patients in pharmacies at lower prices than regular (three thresholds depending among others of the type of drug and duration of treatment – lump sum of (PLN 3,20), 30% reimbursement and 50% reimbursement). There are also certain forms of reimbursement where patients receive the drugs free of charge. These mainly apply to various aspects of inpatient care, such as certain treatment programs (e.g. sclerosis multiplex) or chemotherapy.

**8.2 Does your jurisdiction purport to operate a "positive list" or "negative list" in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

Polish jurisdiction purports to use the positive list. Although the reimbursement is granted via individual decisions, a list of all reimbursed products is published every two months. You may see an example here:

[http://www.bip.mz.gov.pl/\\_data/assets/pdf\\_file/0008/23795/Zalacznik-do-obwieszczenia.pdf](http://www.bip.mz.gov.pl/_data/assets/pdf_file/0008/23795/Zalacznik-do-obwieszczenia.pdf)

**8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

N/A

**8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

The reimbursement decision is passed by Minister of Health. HTA plays important role in the proceedings, however only with respect to a product that is to be the only one reimbursed for given medical indication. In such case the application must contain e.g. a clinical analysis made on the basis of a systematic review and comparison to other medical procedures used in given medical indication and an economic analysis from the perspective of state budget and hospitals. The application and enclosed analysis are reviewed by a specialized agency (AOTM, see reply to Q5), and its assessment and recommendations play important role in the process of passing the reimbursement decision. As for other criteria please see replies to Q4.

**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a**

**particular patient in a way that allows reimbursement of the product cost in whole or in part?**

No. The doctors may only choose to prescribe the drug at full cost. They may not cause the drug to be reimbursed or change the degree of reimbursement.

## 9 Reimbursement – Administrative Arrangements

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

Polish reimbursement proceedings are a bit specific in this respect. They involve negotiations of the price, where the applicant and the regulator exchange the arguments and attempt to reach an agreement on the final level of the price. Yet the negotiations are not binding to the regulator and the price is being finally set in the reimbursement decision. It all is a routinely part of reimbursement procedure, which should end within 180 days from filing for reimbursement.

## 10 Reasons for decisions on Pricing and Reimbursement

The Transparency Directive 89/105/EEC requires Member State authorities to provide a "statement of reasons based on objective and verifiable criteria" in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it if price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.

**10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

In principle yes.

**10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

In principle yes.

## 11 Reconsiderations / Appeals

### 11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?

The applicant may move to the Minister of Health for reconsideration of the reimbursement decision. These are not court proceedings. Generally speaking it's a repetition of first instance proceedings in merits, with the main focus on charges set forth in the motion for reconsideration.

### 11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?

Yes. The deadline is 30 days from receiving the MoH second instance decision (11.1 above).

### 11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?

There have not been numerous judgments yet, as the Reimbursement Act is a fairly new one (entry to force as of 2012). Those that we know refer mostly to various formal issues and do not have any specific meaning to the practice of reimbursement in Poland.

## 12 Unlicensed products and off-label use

### 12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?

The unlicensed products may be reimbursed on the basis of an individual decision of the regulator (Minister of Health). The key differences with respect to regular reimbursement procedure are that:

- the proceedings is instigated on patient's motion and not MAH' or its representative's;
- there are no price negotiations. The product is made available to the patient at lump sum price (PLN 3,20);
- the proceedings are short and cannot exceed 30 days.

### 12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?

We would not call it a restriction, but off-label reimbursement procedure differs from regular reimbursement procedure and the prerequisites for granting reimbursement to off-label use are more strict. For instance:

- the regular reimbursement procedure is instigated on application, whereas off-label reimbursement decisions are always passed ex officio;
- the off-label reimbursement must be necessary to save health or life, meaning that there must be no alternative medical procedure financed from the state budget that might be applied instead of the product that is to be reimbursed.

## 13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.

We are not aware of any such schemes or agreements.

## 14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).

Pharmacists are not subject to pay-back scheme as described in the question. Yet they must ensure that persons requesting reimbursed products have proper prescription and must provide to the regulator reports from sale of reimbursed products. The regulator may control the pharmacies and their reports. In case of any defaults or discrepancies the pharmacies may be obliged to pay damages equal to unjustified reimbursement.

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Bartosz Kaczmariski is a partner to Brudkowski&Wspolnicy and the head of the firm's life sciences/pharma practice. His expertise and key areas of specialization involve various regulatory matters related to pharmaceutical companies operations, including market access, pricing, distribution and advertising, as well as contentious matters, including but not limited to unfair competition and patent infringement disputes. Mr. Kaczmariski has also been advising client in intellectual property matters and is regularly representing companies in disputes over reputable trademarks infringement.

# Portugal

## **1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied**

Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?

### **1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."**

All prescription-only branded products, whether on patent or off-patent or containing a new active substance are always required to obtain approval of the price. Following that if the MAH requires it can apply for reimbursement status.

### **1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).**

As long as these products are prescription-only, they are always required to obtain approval of the price, even though reimbursement status will not be requested afterwards.

### **1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.**

Two situations must be distinguished: (i) if prescription-only products supplied to hospitals or clinics are of restrict prescription and for EXCLUSIVE hospital use, price approval is not required; (ii) if prescription-only products supplied to hospitals or clinics are able to be used / supplied to the patient out of hospitals, price approval is always required. In one case or another, supply to the hospitals will commonly be subjected to a tender process that forces the price – even if price is established – to decrease.

### **1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

Two situations must be distinguished: (i) if the applied OTC products supplied have reimbursement status –either prescription-only or prescription-free – they must obtain in advance price approval [and, of course, reimbursement status]; (ii) if they do not have reimbursement status, and are prescription-free, their price is free, not requiring any

price approval, but being subjected to administrative supervision for possible “speculative” or “exaggerated” price under free competition/anti-trust rules.

### **1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

As long as the generic medicinal product is prescription-only or prescription-free but with reimbursement status, price approval is always required.

### **1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

New general regulation on pricing is being studied and planned. For now, they are mainly subject to pricing/reimbursement under specific payment schemes to treat particular diseases subjected to contractual terms agreed with the Medicinal Products Authority, which are then subjected to annual review and, sometimes, to forced reductions of price due to volume of sales exceeded.

### **1.7 Orphan Medicinal Products.**

Subject to pricing/reimbursement under specific payment schemes agreed between the MAH and the authorities, which are then subjected to annual review and, sometimes, to forced reductions of price due to volume of sales exceeded.

### **1.8 Parallel imports from another Member State.**

The maximum public price of sale must be at least 5% lower than the maximum public price for sale practiced for the same/or identical/or essentially identical medicinal product with MA in Portugal. In case there is no comparative product in Portugal, it must be 5% lower than the average price in the three reference countries used for Portugal, or, in case this may not be possible, 5% lower than the average price in the majority of countries possible to elect. In case none of these criteria may work, at least 5 % lower than the price in the country of origin.

### **1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

## **2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

In Portugal, pricing and reimbursement are elements dealt with separately, but recently all the process is centralized within the Medicinal Products Regulatory Authority – INFARMED.

(i) First step - Pricing – request delivered to INFARMED which consults the price with another agency - the General Directorate on Economic Activities [DGAE] – before granting approval. The approved price is subject to the pricing system based on the average of the three prices (Slovenia, France, Spain);

(ii) Second step- Reimbursement – requested to INFARMED under an administrative power of delegation issued by the Ministry of Health, any reimbursement decision being subject to periodical review.

In terms of legislation, pricing is mainly subject to Decree-Law 112/2011 of 29th November, including all legal alterations inserted up to now; and reimbursement legislation is mainly subject to Decree-Law 48-A/2010 of 13th May, including all legal alterations inserted up to now.

## **3 Other Financial controls relating to supply**

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

The pricing system essentially establishes a maximum price of sale to the public/retail which is then still subject to a lower therapeutic reference price for the purpose of reimbursement. The maximum price of retail is regulated including (i) the warehouse price (price at the stage of manufacturing or import) (ii) the wholesaler margin (iii) the retailer margin (iv) and taxes applied, establishing the maximum margins for marketing the medicinal product. The wholesalers and retailers margins are fixed and regulated in reference to the ex factory price: the higher the price at the stage of manufacture/import the lower are the margins applicable to wholesale and retail. The MA holder may practice any prices lower than the maximum retail price approved and offer within distribution any discounts/rebates, but only over the portion of the price which is not subject to reimbursement.

In addition to individual price control on wholesale/retail margins, the global profit for some products is frequently controlled by subjecting its reimbursement approval to a reimbursement agreement with discriminated conditions, namely:

- limited duration term for the reimbursement;
- limited term for reimbursement which may only be renewed subject to additional cost-effectiveness

and therapeutic studies and/or a certain decrease of sale price;

- maximum sales limit to be reimbursed: when exceeded, the MA's holder shall have to reimburse the NHS for the amount of reimbursement exceeded.
- dynamic variation and reduction of the price in reference to any foreseen requirements.

## 4 Pricing Criteria

**For those products identified in the answer to Q1 for which a price must be agreed:**

### 4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?

The maximum retail price is fixed under the reference countries system. The final maximum retail price of the medicinal product cannot exceed (i) the average price calculated by comparing the warehouse prices practiced on the 3 reference countries for the use of the same medicine presentation and dosage or similar pharmaceutical specialty, (ii) exclusive of taxes in those countries; (iii) adding to it the marketing margins (wholesale/retail) and taxes to be practiced in Portugal.

Currently, Portugal's reference countries are Spain, France and Slovenia.

### 4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?

There is also in place in Portugal a therapeutic reference pricing lower than the retail maximum price, and that reference pricing is the one relevant to obtain reimbursement. "Reference Price" means the value

Over which the State reimburses the price of medicines included in each of the homogeneous groups according to the level or reimbursement system applicable to them. "Homogeneous group" being the set of drugs with the same qualitative and quantitative composition in active substances, dosage and route of administration, with the same pharmaceutical form or equivalent dosage forms, in which it's included at least one existing generic medicinal product in the market (are still part of the same homogeneous group of medicines those which, while not meeting those criteria, are still part of the same therapeutic group or subgroup, and are considered therapeutic equivalents).

The Reference Price is the average price of the five lowest prices effectively charged and practiced (which may be lower than the maximum retail prices approved) of medicinal products within each homogeneous group. The calculation is based on 5 different prices, which may cor-

respond to more than five medicinal products, whether generic or not.

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

In summary, the request duly drafted and instructed in accordance with all legal requirements and INFARMED's instructions is delivered at INFARMED, and in case there's no opposition from the General Directorate on Economic Activities [DGAE] the price approval should be obtained within 30 days. In principle, the absence of any express decision within 30 days may cause the tacit approval of the proposed price.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

The maximum retail price is at least subject to annual review. Exceptional reviews may also occur for motive of public interest. On what regards the therapeutic reference price system, the five lowest prices by products of homogeneous group are reviewed quarterly for purposes of establishing the reimbursement on the class of medicinal products with 95% reimbursement (patients with special arrangements).

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 above?**

A review or alteration for increase is possible subject to the reference/country criteria or therapeutic reference pricing explained above in the answer to question 4.

- **Reduce the price generally or for a periodd**

The MA holder may at any moment reduce the price effectively practiced in reference to the maximum retail price fixed, but when a reimbursed medicinal product is involved this alteration should coincide with the first day of the month. Any price alteration is subject to a prior notice of 20 days.

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

The Portuguese government has established in several annual agreements since 2012 with the Pharma Industry the objective of freezing and stabilizing the annual expenditure of the NHS on medicinal products on a maximum

of 2.000 million euro, and therefore in 2014 the so called «special contribution of the pharmaceutical industry» has been agreed on the amount of 160 million euros, to be returned to the State and to the NHS hospitals, divided between all pharma companies depending on the volume of sales/cost each represented to the NHS.

#### **6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?**

No. When a first generic product enters the market the obligation on a lower price is imposed on the generic product and not on its branded originator.

However, if it does not automatically affect the list price that can be charged for the originator, it may automatically affect its margin or percentage of reimbursement, or even its reimbursement at all, depending on the change caused by the generic to the therapeutic category reference price.

## **7 Other Types of price control**

Does your jurisdiction control any of the following prices:

### **7.1 Full line or other wholesaler selling price**

Yes. The wholesaler margin is controlled within the maximum retail price approved: it may go from 2,24% + € 0,25 [on products which ex factory/warehouse price is equal or lower than € 5,00] to 1,18% + € 3,68 [on products which ex factory/warehouse price is higher than € 50,00]; always being included in such retail maximum price.

### **7.2 Pharmacy selling price**

Yes. The pharmacy margin is also controlled within the maximum retail price approved: it may go from 5,58% + € 0,63 [on products which ex factory/warehouse price is equal or lower than € 5,00] to 2,66% + € 8,28 [on products which ex factory/warehouse price is higher than € 50,00]; always being included in such retail maximum price.

## **8 Reimbursement – general principles and Transparency directive compliance**

### **8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?**

The Portuguese reimbursement system is controlled, regulated and financed at central/national government level, without any intervention from any other local authorities, apart from the intervention of the special regions/gov-

ernments of Madeira and Azores islands on some of the regional financing of their health public systems.

Apart from specific medicinal products for specific chronic diseases (e.g. cancer, diabetes etc.) which are free of any charge to the patient, the reimbursement system always involves a minimum of at least 5% or 10% co-payment from the patient at the time of dispensing with the remainder of the charges levied and assumed by the NHS.

The reimbursement system distributes medicinal products under 4 levels of reimbursement, corresponding to the fraction of the reference price bear by the State: A – 90%; B – 69%; C – 37% and D – 15%.

An extraordinary level of 95% reimbursement level is established to support pensioners with lowest income.

### **8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

The Medicinal Products Regulatory Authority – INFARMED – publishes and updates periodically on its website:

- A list of products with reimbursement status – by year and month;
- A list of products which have lost reimbursement status – by year and month;
- The evaluation reports on which basis reimbursement was either approved or denied.

Lists of substances/products with 100% reimbursement for specific chronic diseases are subjected to particular legal or administrative acts also published and periodically reviewed.

### **8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

Reimbursement status is subject to a technical analysis followed by a recommendation which must then be the object of a formal approval by the executive board of the Medicinal Products Regulatory Authority by delegation of administrative power from the Ministry of Health, in case of generics, or by the Ministry of Health in the case of the other medicinal products. There is no local or regional reassessment.

### **8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made**

### **locally or in other Member States in respect of the same product?**

The Ministry of Health, with the collaboration of the Medicinal Products Regulatory Authority, delivers any reimbursement decision in general. For generic medicinal products the decision lies with the Medicinal Products Regulatory Authority.

Therapeutic value and cost-effectiveness analysis, whether made locally or in other Member States in respect of the same product are valued by its quality on decreasing levels of importance, as follows:

- (a) Systematic reviews and meta-analysis of controlled and randomized clinical trials, well-designed and well-executed;
- (b) Clinical trials randomized, controlled, well-designed and executed;
- (c) Almost experimental studies, well designed and executed, and clinical trials not randomized (when circumstances prevent the realization of controlled clinical trials), observational studies prospective and retrospective (cohort and case-control);
- (d) Experts opinions.

#### **8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

Doctors cannot override the reimbursement or non-reimbursement status. On the other hand, Doctors at NHS hospitals are subject to a National Therapeutic Formulary which limits their right to prescribe to certain classes of medicinal products.

## **9 Reimbursement – Administrative Arrangements**

### **What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

The MA holder, upon obtaining price approval, requests the reimbursement by drafting the necessary templates and supplying all attachments legally required, including the necessary technical and scientific elements, which are filed at the Medicinal Products Regulatory Authority – INFARMED – that shall instruct and conduct all the administrative procedure.

In the first 20 days, Infarmed shall verify the regularity and formal sufficiency of all documents presented. After the internal study and analysis performed by Infarmed, this Authority shall present a project of decision to be submitted to the Ministry of Health, either proposing the

approval of reimbursement or its refusal. In case of generic products the decision lies with Infarmed.

The deadline for the decision of a request for reimbursement is 75 working days for generics and 90 working days for the other medicinal products.

The time count is suspended whenever the applicant is requested to present and file additional elements or additional information.

## **10 Reasons for decisions on Pricing and Reimbursement**

**The Transparency Directive 89/105/EEC requires Member State authorities to provide a “statement of reasons based on objective and verifiable criteria” in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it if price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.**

### **10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

Yes. In principle, the reasoning is supported by the expert opinions or recommendations that they have relied upon in reaching a decision otherwise the decision would be invalid for lack of fundamentals.

### **10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

Sometimes is not sufficient to contradict the technical merits presented by the applicant, but it is highly limited and difficult to challenge the merits of an administrative decision in the special jurisdiction of administrative courts. The main grounds for an appeal lie mainly on invoking breach of fundamental formalities of the administrative procedure or being able to prove a total lack of fundamentals of the negative decision.

## **11 Reconsiderations / Appeals**

### **11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

In principle, every administrative prospective decision is subject to a prior written hearing of the applicant. After the decision is rendered, if unfavorable to the applicant notwithstanding its arguments at such hearing, it must be



challenged in court because it is a final and vertical administrative act which does not depend from the supervision/control of any other administrative entity.

**11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

All administrative acts are subjected to judicial review by violation of law or violation of legal formalities or legal requirements in the Administrative Courts (judicial discussion of the merits of the administrative decision is however of very limited success). The general time bar to challenge an administrative act is 3 months counting from its notification.

**11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

The Portuguese case law on these matters is very scarce.

**12 Unlicensed products and off-label use**

**12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?**

There is no reimbursement or pricing control over off-label prescribed use of medicinal products.

**12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?**

No. The off-label use is not illegal neither restricted. Such use lies entirely on the doctor's and on his hospital's clinical committees' responsibility.

The Medicinal Products Regulatory Authority refuses to issue any regulation on off-label use or based on off-label use, only highlighting the responsibilities of the pharmaceutical and ethical committees in each clinical institution and the necessity of an informed consent by the patient

**13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go**

**beyond the controls identified in the answer to question 1.**

Yes. There are special reimbursement schemes designed for cancer, HIV, diabetes, rheumatic diseases, rare diseases and other chronic diseases or specific groups of patients which medicines are subject to specific pricing and reimbursement schemes and are in some cases only dispensed through hospital pharmacy.

**14 Are pharmacists subject to any annual or other pay-back/claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

No, the State option was to reduce the margins of the pharmacists, in such a way that the pharmacies business is facing serious solvency problems. The option for pay-back/claw-back was basically directed to the pharmaceutical industry.

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## CONTRIBUTOR

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### **Antonio Borges**

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António Borges is a Partner at Lopes Dias & Associados since 2004, and a practicing lawyer since 1999.

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He has substantial experience representing and assisting pharmaceutical and health technology clients in all regulatory matters, distribution contracts, IP litigation, public procurement procedures and administrative courts litigation.

# Slovenia

## **1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied**

Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?

Yes, MA holder is obliged to apply for price prior to launch of product reimbursed from public funds.

### **1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."**

Yes, price approval is required for both patent and off-patent products.

### **1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).**

No. Price approval is not required if reimbursement is not sought for such product.

### **1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.**

Yes, price approval is required for all such products.

### **1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

Yes, price approval is required in case such products might also be prescribed under health security system and reimbursed from public funds (irrespective of the fact they are in most times paid by patients).

### **1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

Yes, price approval is required for all generic products reimbursed from public funds.

### **1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

Yes, required for all biosimilar products.

### 1.7 Orphan Medicinal Products.

Yes

### 1.8 Parallel imports from another Member State.

Yes

### 1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.

Price approval is also required for the so called essential/ indispensable medicinal products (currently valid list here: [http://www.jazmp.si/fileadmin/datoteke/dokumenti/SFE/Seznam\\_NPZ-JAZMP-0141014.pdf](http://www.jazmp.si/fileadmin/datoteke/dokumenti/SFE/Seznam_NPZ-JAZMP-0141014.pdf)).

## 2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

The price approval is dealt with the Medicines Agency - Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices – JAZMP ("Agency") under the Rules on determining the prices of medicinal products for human use (Official Gazette of RS, no. 102/10, 6/12, 16/13, 71/13, 17/14). Reimbursement is granted by the Sick Fund - Health Insurance Institute of Slovenia (ZZZS) under the Rules on classification of medicines on the list (Official Gazette of RS, no. 53/13).

## 3 Other Financial controls relating to supply

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

As a rule, the Sick Fund would require a discount on the officially approved price in order to list the product on the reimbursement list. This normally takes form of an agreement on discounted price for the relevant product(s) and only occasionally in a form of financing risk sharing, claw-back or alike.

## 4 Pricing Criteria

**For those products identified in the answer to Q1 for which a price must be agreed:**

### 4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?

- the approved price of an original product shall not exceed 100% of the lowest of the prices for the same product in Germany, France and Austria ("reference price") increased for the wholesale margin which depends on the value, approx. 7% ("wholesale margin") – see below Q7.1;
- the approved price of a generic product shall not exceed 72% of the average of prices for the same product in Germany, France and Austria ("reference price") increased for the wholesale margin; If the generic product is marketed in only one reference country or if no generic medicinal product exists in reference countries, the price shall not exceed 68% of the reference price of the original medicinal product;
- the approved price of a bio-similar product shall not exceed 92% of the reference price.

### 4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?

Registered products with the same active substance would, as a rule, be listed on the Interchangeable Drugs List ("IDL") for which the Maximum Reimbursed Value ("MRV") would be defined, usually at the price of the cheapest product in each IDL group. The products with prices higher than MRV would have to be co-paid by patients.

In early 2014 the Sick Fund also formed several therapeutic groups for which they apply a similar principle as for IDL products; they would define a reference product for the therapeutic group and would set the MRV at the price of such product. Higher-priced products would be subject to co-payment. Currently there are therapeutic groups formed for the following products: proton pump inhibitors, lipid-lowering drugs, ACE inhibitors, drugs with acetylsalicylic acid 100 mg, imatinib products, triptan products, glaucoma treatment products.

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

MA holder shall apply for the price by an application filed with the Agency. The Agency shall approve the price

within 90 days from receipt of complete application. In case they fail to meet the deadline the price as suggested in the application is presumed approved.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

MA holder is obliged to resubmit prices twice a year, i.e. by end of March and by end of September in order to reflect eventual price changes in reference countries. The Agency normally issues price approvals in 30-45 days from receiving such resubmissions.

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 above?**

Companies have the right to apply for Exceptionally Higher Price ("EHP") which exceeds the price calculated under criteria set out in Q4 above. EHP may be approved for a maximum of 1 year provided that the applicant successfully proves benefits for public health obtained by such product.

- **Reduce the price generally or for a period?**

Theoretically companies have the right to reduce the officially approved price generally or for a limited period of time, however this is never used in practice. Companies would always tend to keep the official price (which is publicly displayed on Agency's website and serves for reference pricing in other countries) at the maximum allowed level and would rather consider offering discounts to the Sick Fund since such discounted prices would not get disclosed to public.

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

No.

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

Please see Q4.2. No direct obligation is imposed, however when a first generic enters the market the Agency would form an IDL and would assign MRV for the group of product with the same molecule. In case the MA holder of the original product does not lower its price to the level of MRV, its product will be subject to co-payment by patients.

## 7 Other Types of price control

**Does your jurisdiction control any of the following prices:**

### 7.1 Full line or other wholesaler selling price

Wholesale margins are set by law and calculated as a sum of a fixed and a variable part per the following formula:

Wholesale margin = 0,50 EUR + MIN (ExMan Price \* 1.1; 27,00 EUR)

### 7.2 Pharmacy selling price

Pharmacies sell medicinal products at officially approved prices (see Q4.1) or discounted prices (see Q3) increased for the wholesale margin (see Q7.1) and VAT (9,5%). Pharmacies are paid a fee (directly from the Sick Fund) for each dispensed box of Rx product (currently 1,72 EUR).

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

The reimbursement process is conducted on a national level by the Sick Fund (one institution for the whole country). The reimbursement procedure starts with an application filed by the applicant. A successful application would result in listing of the product on either "positive list" or "intermediate list".

There are three levels of reimbursement by the compulsory health insurance:

- 100% reimbursement for medicines on the positive drug list applied in prevention and in therapy of the specified groups of insured persons and of the diseases and health;
- 70% reimbursement for all other medicines on the positive drug list;
- 10% reimbursement for the medicines on the intermediate drug list.

Medicines applied in prevention and in therapy for certain groups of insured persons (children under 18 years, students, pregnancy and motherhood) and medicines for the treatment of most important contagious diseases including AIDS and STD's, diabetes mellitus, major psychiatric diseases, epilepsy, muscular dystrophy, multiple sclerosis and psoriasis are eligible to be listed on a positive list.

In practice the additional voluntary health insurance scheme (held by more than 90% of population) covers the price difference for reimbursed medicines (up to 100 %).

There are no other charges (participation). There are no social criteria for exemption of co-payments.

**8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

See Q8.1!

**8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

Reimbursement status is confirmed by an administrative decision issued by the Sick Fund.

**8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

A reimbursement application shall include documentation which allows the Sick Fund to assess the following criteria for reimbursement:

- Significance of medicinal product in terms of public health;
- Health care programme implementation priorities;
- Therapeutic significance of the medicinal product;
- Relative therapeutic value of a medicinal product;
- Assessment of pharmacoeconomic data on the medicinal product;
- Evaluation of ethical aspects;
- Health care programme priorities; and
- Data and assessments from reference sources.

As indicated above one of the criteria applicable is also comparative data from reference sources (other countries).

**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

No

## 9 Reimbursement – Administrative Arrangements

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

Reimbursement status is granted by an administrative decision issued by the Sick Fund. The Sick Fund shall issue the decision on reimbursement no later than within 90 days of receiving the complete application. This deadline can be extended only in case the Agency has determined the price prior to the expiry of 90 days. The process of determining the price and the process of reimbursement may together not last more than 180 days.

## 10 Reasons for decisions on Pricing and Reimbursement

The Transparency Directive 89/105/EEC requires Member State authorities to provide a “statement of reasons based on objective and verifiable criteria” in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it if price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.

**10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

Reimbursement decisions would as a rule rely on the opinion of the Reimbursement Committee, a 16-members advisory body which opines on the criteria as indicated in 8.4 above. Apart from these we are not aware that the Sick Fund would rely on any other opinion in reaching the reimbursement decision.

**10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

In general the companies complain about non-transparency of the reimbursement process and low level of arguments put forward in the proceedings. In practice companies generally claim the only issue in discussions with the Sick Fund is the price they are prepared to offer in order to get reimbursement, and the main criteria applicable is the health budget impact. As explained below, there are almost no court cases in relation to reimbursement decision and therefore deficiency in reasoning has not yet been challenged in front of a court.

## 11 Reconsiderations / Appeals

### 11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?

The applicant may lodge an appeal against an unfavourable pricing or reimbursement decision with the Ministry of Health. The appeal may be filed within 30 days from receipt of the decision and has no suspensive effect.

### 11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?

The applicant may further challenge an unfavourable decision of the Ministry of Health in an administrative dispute in front of the Administrative Court of Slovenia. The timeframe for filing the action is 30 days from receipt of decision and again it has no suspensive effect.

### 11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?

Companies very rarely decide to challenge pricing and reimbursement decisions and hence no practical implication derive from jurisprudence.

## 12 Unlicensed products and off-label use

### 12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?

No, the costs of such products is not reimbursed. The sponsor of a compassionate use programme must provide a statement that the product is made available to the compassionate use programme free of charge, thereby the sponsor shall bear any cost of supply of such product, including the costs of wholesale distribution of the medicinal product in the programme;

### 12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?

There is a general requirement that reimbursed medicines are prescribed in line with indications as stated in SmPC, however there is impression that products are also prescribed off-label and such prescribing is tolerated by the Sick Fund.

### 13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.

No such agreements are in place. For example, orphan products are subject to the same reimbursement application procedure as all other products.

### 14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).

No, there are no pay-back/claw-back obligations imposed on drug suppliers in Slovenia.

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Tomaž Ilešič is a partner in Law firm Rojs, Peljhan, Prelesnik & Partners, the largest Slovenian law firm in terms of the number of fully qualified attorneys specializing in commercial and corporate law. Tomaž has joined the firm in 2001 after having successfully completed master studies at College of Europe, the court traineeship and the state bar exam. He has considerable experience in healthcare law and has developed broad-based expertise through working with a range of major pharmaceutical companies. He provides advice across the full range of regulatory matters. He focuses in representation of clients in front of regulatory authorities and advising to domestic and foreign clients, also in several local attention-grabbing cases.



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# Spain

## **1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied**

Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?

### **1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met.**

Yes, prescription-only branded products must obtain a prior approval of their price and reimbursement.

### **1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other “lifestyle” medicines).**

No prior approval is required though the selling price is notified by the laboratory to the Ministry of Health, Social Services and Equality (hereinafter “Ministry of Health”). Health authorities may object to the notified price for reasons of public interest. At the time of writing, a new Regulation on Pricing and Reimbursement of Medicinal Products is being developed, and such notification process is likely to be developed.

### **1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.**

Yes, prescription-only products for hospital use must obtain a prior approval of their price and reimbursement though such price is considered a maximum price which can be held (i.e. decreased) within the framework of negotiations or can be offered in a tender held by the hospital.

### **1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

No prior approval is required though the price is notified to the National Health System. In Spain, OTC products are normally non-prescription products.

### **1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

Yes, generic medicinal products must obtain a prior approval of their price if they are financed. If they are not publicly financed, their price is notified to the authorities.

#### **1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

Yes, biosimilar medicinal products must obtain a prior approval of their price if they are financed. If they are not publicly financed, their price is notified to the authorities.

#### **1.7 Orphan Medicinal Products.**

Yes, orphan medicinal products must obtain a prior approval of their price and reimbursement to the extent they are financed.

#### **1.8 Parallel imports from another Member State.**

Yes, parallel import products must obtain a prior approval of their price and reimbursement to the extent they are financed.

#### **1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

In Spain, the public financing of medicinal products is subject to the system of reference prices as provided for in Article 93 of Law 29/2006, dated July 26 on the Rational Use of Medicines and Medical Devices ("Law 29/2006") and further developed in Royal Decree 177/2014, dated March 21, governing the system of reference prices and homogenous groups of medicines within the National Health System ("Royal Decree 177/2014"). The reference price is the maximum amount with which the medicinal product's presentations included in each of the groups are financed, provided that they are prescribed and dispensed with public funds.

The reference price is set forth once a year (via an administrative Order) following certain criteria (see our response to question 6.4). The prices of the medicinal products within each group are automatically reduced to the reference price. For products which are granted a marketing authorization and are adscribed to a group subject to reference pricing, the intervention of the Interministerial Price Commission of Medicines (see our response to question 2) is not necessary, as the reference price directly applies to the product.

Article 93 bis of law 29/2006 provides as well for a system of "selected prices" for medicinal products within the system of reference pricing which comply with certain criteria, though this has not been developed hitherto.

Article 90.6 of Law 29/2006 provides that the prices of financed medicines shall generally be lower than the price for the same medicines when they are not financed. This provision, as well as the above-mentioned referring to the system of "selected prices" should be developed

in the new Regulation on Pricing and Reimbursement of Medicinal Products which is currently under discussion.

## **2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

The authorization (or a refusal of the inclusion in the funding) is granted by the General Directorate on Basic Services Benefit of the National Health System (hereinafter "DGCB") in the case of medicinal products which may be financed by the National Health System (hereinafter "NHS"). The authorization of a maximum price and whether a medicinal product is to be reimbursed (and at which price) or not by the NHS is dealt with together, and does not imply a separate application. This does not mean that all prescription products are reimbursed: the final decision shall depend on whether the requirements set forth in Articles 89.1 and 89 bis of Law 29/2006 are met. The dossier of the price is dealt with by the Interministerial Price Commission of Medicines ("CIPM"), though the price and reimbursement decision is finally approved by the DGCB.

In the case of generic products, the price is directly approved by the DGCB (and does not go through the CIPM), as long as the applicant requests a price which is at least 40% lower than the price of the original medicinal product.

The pricing and reimbursement decisions are governed by Articles 89 to 90 bis of Law 29/2006.

## **3 Other Financial controls relating to supply**

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

There are several controls which have historically affected the price of products in Spain. From 2006 the following apply:

- Contribution to the NHS by sales volume to the NHS which shall amount to 1,5% of such sales for sales up to 3 million Euro and 2% onwards (6th Additional Provision of Law 29/2006). This is extended to sales of medicines for hospital use by Royal Decree-Law 16/2012, 20 April, on urgent measures to ensure the sustainability of the National Health System

and improve the quality and safety of its benefits (hereinafter, "RD 16/2012").

Contributions made by laboratories may benefit from a deduction up to 25% depending on their classification within the Profarma programme (classification granted according to their commitment to R&D).

- Royal Decree-Law 4/2010, established a general reduction in the price of generic medicinal products of 30%, fixing a minimum price of 3,12 Euro.
- Pursuant to Royal Decree-Law 8/2010, a general reduction in the price of financed medicinal products of 7.5% (limited to 4% in the case of orphan drugs) was imposed. Generics and medicinal products included within the reference pricing system are not affected by this deduction.
- Royal Decree-Law 9/2011 increases the former discount to 15% for those medicines which have no generic or biosimilar authorized in Spain, if they have been 10-11 years financed with public funds, except for medicines covered by a product patent within the European Union.

## 4 Pricing Criteria

**For those products identified in the answer to Q1 for which a price must be agreed:**

### 4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?

Yes, currently the most commonly used criterion is that of European reference prices and, specifically, the lowest price of a product in Europe. Although this has been common practice for a long time it has not been referred to in regulations until the approval of Royal Decree 177/2014. The application of the European reference price affected by the mentioned Royal Decree 177/2014 only covers products included in the system of reference prices, the price of which has been fixed following certain specific criteria (as a correction of the minimum and weighed average prices recognized for certain presentations). In the event that (i) such minimum threshold or the weighted reference price have been applied and (ii) the same presentation is commercialized in a Member State of the European Union and (iii) such presentation has a minor price than the established for Spain, the presentation in Spain shall be commercialized at the minor price or such European country.<sup>10</sup>

### 4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?

In theory, the criteria to be used by the CIPM for fixing the price of a medicinal product are set forth in Article 3 of Royal Decree 271/1990 governing the fixing of prices of medicinal products.

According to such regulation, the main criterion is the manufacturing cost plus a business profit. The cost is calculated by the analytical application of the full cost, including research and technological development. For the calculation of the cost several issues shall be taken into account: the level of activity, cost trends, sales volumes of the company, sales estimates, impact on cost structure for manufacturing. The business profit for each medicinal product is set at a percentage that is determined on an economic and financial report of the company.<sup>11</sup>

In order to make the price consistent with the existing products in the market, Royal Decree 271/1990 contemplates certain corrective factors:

- The scientifically proven therapeutic utility provided by the product;
- The proportionality test that prevents that the treatment cost is disproportionate compared to other existing alternatives.

In practice, the calculation of the cost of production has proven to be difficult for several reasons, such as: (i) identifying transfer pricing (between parent and subsidiary companies) or (ii) the temporary assignment of research and development costs.

As a result:

(i) Although the CIPM continues to receive among the supporting documentation for decision-making, the cost analysis of the product, in practice it is not analyzed and does not add any value to the final decision.

(ii) In practice the cost criterion has been substituted by correcting mechanisms such as: (a) the therapeutic utility, (b) the cost of financing for similar therapeutic medicinal products and (c) the modulator factor of the minor price of the medicinal product which is being financed in the European environment. Thus, in practice, the most commonly used criterion is the criterion of European reference lowest price (see our response to question 4.1).

(iii) Additionally nowadays the criteria established in Article 89.1 and 89 bis of Law 29/2006<sup>12</sup> must also be taken into account.

The ongoing reform on pricing and reimbursement shall need to adapt the regulatory requirements to the new criteria set forth by the recent amendments of Law 29/2006 and the consolidated practice of the health authorities. It is likely, though, that the authorities shall continue to have very wide discretionary powers to weigh each of the concurring circumstances.

10. See our response to question 6.4.

11. This percentage is within a range annually established by the Delegate Commission of the Government for Economic Affairs, taking as baseline the financial situation of the pharmaceutical industry as a whole and the conjunctural forecasts of the financial policy.

12. See our response to question 8.1.

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

Once the Marketing Authorization and/or modification of the Marketing Authorization of a medicinal product has been granted by the Spanish Agency of Medicinal Products and Health Products (hereinafter, "AEMPS"), the Director of the AEMPS notifies the marketing authorization holder on even date that the decision granting the Marketing Authorization shall be handed over to DGCB for the purposes of proceeding ex officio to the Initiation of the Procedure of Price and Financing Agreement.<sup>13</sup>

After the Initiation of the Procedure of Price and Reimbursement Agreement by the DGCB aimed at deciding whether to include or exclude the authorized medicinal product within the pharmaceutical benefit, the DGCB shall ask the marketing authorization holder to make the financing price request. Two different situations might occur:

- The laboratory applies for a given price between the period that goes from the date of notification of the Marketing Authorization and the date of notification of the Agreement of Initiation of the Procedure, in which case the DGCB shall order its accumulation to the procedure in order to decide on the inclusion or exclusion of the authorized medicinal product.
- The laboratory applies for a given price once the DGCB has reported the Initiation of Procedure Agreement.

The laboratory generally provides, in addition to the price request, certain documentation that is relevant to the assessment of the request (e.g. cost analysis, proforma invoice, cover letter, etc.).

After the submission of the request and unless there is an error/lack of documentation, etc. which shall be remedied, and typically following an informal negotiation with the applicant, the price is discussed within the CIPM.

The DGCB issues a draft decision which indicates if the medicinal product is included or excluded from the pharmaceutical benefit and, in the event of inclusion, the corresponding price.

The applicant shall respond to the draft stating whether or not it agrees with the proposed price.

After this process, a final decision from the DGCB is issued.

The average time for obtaining the final decision on the price and financing ranges from 8 months to 1 year. For generic products, the procedure is considerably simpler and faster (3-4 months).

Laboratories seeking to market their medicinal products outside the scope of reimbursement of the NHS (or excluded from reimbursement) must submit an application form before the DGCB communicating that they have obtained the Marketing Authorization and the price at which they will sell it. The DGCB may object, within a

term of one month, to the price proposed for reasons of public health.

Non-reimbursable medicinal prices may be commercialized by a simple notification of the price to the authorities. Nevertheless, it is provided that the DGCB may object as well on public interest grounds.

The procedure is likely to change and be clarified after the developing legislation regarding Pricing and Reimbursement is enacted.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

Prices may be reviewed ex officio or upon request in accordance with the provisions of Article 91 of Law 29/2006, according to which the price of a medicinal product can be modified if required by changes in the economic, technical and/or health circumstances, or in the evaluation of its therapeutic utility.

A revision ex officio typically occurs in the event of approval of a new indication which is likely to increase the number of prescriptions.

In addition to such individualized review, the Council of Ministers, with the prior agreement of the Government Commission for Economic Affairs, may globally revise or set the conditions for periodic review of industrial prices or, where applicable, of the retail prices, to all or a portion of medicinal products included in the pharmaceutical benefit of the NHS.

Finally, an annual review of reference prices is made by means of a ministerial order.

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 above?**

The same criteria described in answer to question 4 are applied. In practice, regarding reimbursed medicines the possibility to increase prices relates to those which have been in the market for a very long time because their prices are largely outdated.

As for non-reimbursed medicines, the company is able to notify the increase to the authorities.

- **Reduce the price generally or for a period?**

The company has the right to request for a reduction of price of its products but normally such reductions are not limited in time. The approval of the health authorities must always be obtained with respect to reimbursed medicines.

13. The procedure is similar when a company notifies to the AEMPS its intention to commercialize a centrally approved medicinal product.

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

In practice prices are currently frozen.

In addition, as stated in our response to question 3, Royal Decree-Law 4/2010, Royal Decree-Law 8/2010 and Royal Decree-Law 9/2011 established general reductions in the price of certain medicinal products.

These are, in theory, transitory measures to cope with the financial difficulties, though no review date has been set.

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

According to Article 93 of Law 29/2006 and Royal Decree 177/2014, when a presentation of a generic or biosimilar medicinal product<sup>14</sup> enters the market all financed medicinal product presentations that have the same active ingredient and the same route of administration form a group<sup>15</sup> for the purposes of reference pricing. The reference price of each group is set forth once a year (via an administrative Order) and is the lowest costs per treatment per day within the presentations of a group. The prices of the remaining medicinal products of the group are automatically reduced to the reference price.

The mentioned Royal Decree also provides that in certain cases (presentations of medicinal products with special dosages of active ingredient, of use in serious pathologies or when its prices have been revised by lack of profitability) where the resulting price by application of the reference price system does not guarantee its economic viability, a weighted reference price shall be applied. The Royal Decree further establishes a minimum threshold of 1,60 Euro as reference price. In the event that (i) such minimum threshold or the weighted reference price have been applied and (ii) the same presentation is commercialized in a Member State of the European Union and (iii) such presentation has a minor price than the established for Spain, the presentation in Spain shall be commercialized at the minor price or such European country.

## 7 Other Types of price control

Does your jurisdiction control any of the following prices:

### 7.1 Full line or other wholesaler selling price

Royal Decree 823/2008, dated May 16, establishing the margins, deduction and discounts corresponding to the

14. Notwithstanding, when there is no generic or biosimilar medicinal product, a group for the purposes of reference prices shall also be created when the medicinal product or its main active ingredient has been authorized at least ten years in advance in Spain or in another Member State, provided there exists a medicinal product different than the innovator and its licenses.

15. The presentations indicated for paediatric treatments as well as those for medicinal products of hospital use including clinical packaging, shall constitute independent groups.

distribution and dispensing of medicinal products for human use sets forth the margin of the wholesaler when distributing medicinal products, as follows:

- Laboratory selling price equal or inferior to 91,63 Euro: the margin shall be 7,6% of the selling price of the distributor (taxes excluded);
- Laboratory selling price exceeding 91,63 Euro: the margin shall be 7,54 Euro per package;
- Clinical packages shall be charged with a margin of 5% of the selling price of the distributor (taxes excluded);

### 7.2 Pharmacy selling price

The same Royal Decree 823/2008 sets forth the margin of the pharmacist when dispensing medicinal products as follows:

- Laboratory selling price equal or inferior to 91,63 Euro: the margin shall be 27,9% of the selling price to the public (taxes excluded);
- Laboratory selling price exceeding 91,63 Euro up to a maximum of 200 Euro: the margin shall be 38,37 Euro per package;
- Laboratory selling price exceeding 200 Euro up to a maximum of 500 Euro: the margin shall be 43,37 Euro per package;
- Laboratory selling price exceeding 500 Euro: the margin shall be 48,37 Euro per package;
- When the products dispensed are financed by the NHS, Royal Decree 823/2008 establishes a scheme of deductions considering the total monthly invoice of each pharmacy office.
- Clinical packages shall be charged with a margin of 10% of the selling price to the public (taxes excluded);

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

The inclusion of medicinal products within the NHS is made possible through the selective and indiscriminate funding of medicinal products, taking into account the criteria set out in paragraph 3 of Article 89.1. of Law 29/2006, July 26, of Guarantees and Rational Use of Medicinal Products and Sanitary Products (hereinafter, Law 29/2006):

- Seriousness, duration and after effects of the various pathologies for which they are indicated;

- Specific needs of certain groups;
- Social and therapeutic value of the medicinal product and incremental clinical benefit considering its cost-effectiveness;
- Rationalization of public expenditure for pharmaceutical benefit and budgetary impact on the NHS;
- Availability of medicinal products or other therapeutic alternatives for the illnesses at a lower price or inferior treatment cost; and
- Degree of innovation of the medicinal product.

Furthermore, Article 89 bis of Law 29/2006 provides that other criteria, such as the social and therapeutic value of the medicinal product and its incremental clinical benefit considering its cost-effectiveness as well as the rationalization of public expenditure for the pharmaceutical benefit and budgetary impact on the NHS shall be considered.

The decision on the reimbursement condition of a medicinal product is made at the national level though the involvement of the Autonomous Communities (i.e. Spanish regions) is ensured by its representation within the CIPM, by including two rotary representatives of the regions. Autonomous Communities, who are supporting within their budget the impact of paying for medicinal products are trying to introduce elements of price control (for instance in Andalusia or Valencia) but these efforts are being contested in the courts by the central government to the extent they are considered as exceeding their attribution.

As for co-payment, Article 94 and 94 bis of Law 29/2006 govern the co-payment related to pharmacy offices and outpatient dispensing by hospital pharmacy services.

The contribution to be made at the time of dispensing the medicinal product shall be proportional to the level of income. Generally, a percentage of user contribution of between 10% and 60 % of retail price plus VAT (RP) is fixed, as appropriate:

- 60% of RP: For users and their beneficiaries whose annual income is equal to, or exceeds € 100,000 set in the general taxable base and savings tax base of the Personal Income Tax.
- 50% of RP: For individuals who have the status of active insured and their beneficiaries whose annual income is equal to, or exceeds €18,000 and lower than €100,000 set in the general taxable base and savings tax base of the Personal Income Tax.
- 40% of RP: For individuals who have the status of active insured and their beneficiaries provided that they are not included in the previous sections.
- 10% of RP: For individuals who have the status of insured as Social Security pensioners and their ben-

eficiaries, except those individuals included in the first section.

#### Contribution ceilings

Notwithstanding the above, in order to ensure continuity of chronic treatments and ensure a high level of equity to pensioner patients with long-term treatments, a particular rule is established, whereby the overall percentages referred to above will be subject to maximum caps in certain cases (Art. 94 bis.6 Law 29/2006), amongst which are the following:

- Reduced contribution medicinal products: 10% of RP of medicinal products belonging to ATC reduced contribution groups, with a maximum expressed in €, to be updated, automatically, every January according to the evolution of Consumer Prices Index of the previous twelve months.<sup>16</sup>

The Ministry of Health has set a classification for these medicinal products. There are three categories: (i) medicinal products for the treatment of chronic or serious diseases, classified in the therapeutic groups or subgroups contained in the current regulations and in accordance with the established conditions, (ii) effects and accessories (medical devices) belonging to the groups which have been established by regulations and (iii) medicinal products funded by the NHS through the official prescription provided by the System, to patients who suffer from HIV / AIDS.

It should be noted that for reduced contribution medicinal products, the ceiling of contribution is fixed in € 4.26 per package for the year 2015.

- Pensioners (and their beneficiaries):<sup>17</sup>
  - € 8.23 per month for those who have an income below € 18,000.
  - € 18.59 per month for those with an income between €18,000 and €100,000
  - € 61,75 per month for higher incomes.

Article 94 Bis.7 of Law 29/2006 provides that the amounts paid over the limit will be subject to reimbursement by the relevant Autonomous Community, on a maximum six-monthly-basis.

#### Exempt contributions

Law 29/2006 sets out circumstances in which users and beneficiaries are exempt from contribution:

- Individuals affected with toxic syndrome and individuals with disabilities in the cases specified in their specific regulations.
- Individuals receiving social integration income.
- Individuals receiving non-contributory pensions.
- Unemployed individuals who have lost their right to receive unemployment benefits while the situation persists.

16. Decision of December 15, 2014, of the DGCB, whereby the maximum amount corresponding to medicinal products belonging to the ATC reduced contribution groups is updated, and the maximum monthly contribution limits for individuals who have the status of insured as Social Security pensioner and their beneficiaries in outpatient pharmaceutical services are established.

17. Updated amounts by Decision December 15, 2014, of the DGCB, see footnote 7.

- Individuals with treatments derived from labour accidents and professional diseases.

The level of contribution of mutual entities and passive classes of the General Mutual State Civil Servants, of the Social Institute of the Armed Forces and the Judicial General Mutual will be, as hitherto, 30%.

By contrast, hospitalized patients do not have to contribute to the cost of the medicinal products which are being administered to them (although a legal provision has been adopted establishing their contribution for hospital use medicines, the mechanisms to apply this have not been developed yet).

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**8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

In Spain, there are both a “positive list” that includes **categories** of reimbursable prescription medicinal products and “negative list” that includes **certain categories of medicinal products and lists** of medicinal products that are excluded from the pharmaceutical benefit.

To be a part of the “positive list”, prescription medicinal products shall have to meet the criteria set out in Article 89.1 of Law 29/2006<sup>18</sup>. In addition to the criteria set forth in such Article 89.1, in the decision to include a medicinal product within the NHS, a cost-effectiveness analysis and the budgetary impact are taken into account together with the innovation component, the prognosis and the therapeutic outcome of the intervention and its contribution to the sustainability of the NHS if, for a given healthcare outcome, it contributes positively to Gross Domestic Product. For the innovators, return mechanisms are also mentioned by the law (linear discounts, price reviews)<sup>19</sup>.

The “negative list” stems from Article 89.2 of Law 29/2006, which states the products that are not considered necessary to meet the basic health requirements of the Spanish population and, therefore, they are not included within the pharmaceutical benefit:

- Non-prescription medicinal products
- Medicinal products that are not used for the treatment of a clearly determined pathology
- Cosmetics
- Dietetic products
- Mineral Waters
- Elixirs
- Toothpastes
- Medicinal products indicated in the treatment of less severe syndromes and/or symptoms

- Medicinal products that do not respond to current therapeutic requirements (unfavorable benefit / risk relation for the diseases for which they are indicated).
- Other similar products

On the other hand, Royal Decree 1348/2003 sets forth a list of categories of products excluded from reimbursement on the basis of their ATC classification. This Royal Decree has been amended by a Decision dated August 2, 2012 and a Decision dated February 18, 2013 (which contains a list of products excluded from reimbursement and, as the case may be, the indications that remain reimbursed).

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**8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

Reimbursement is subject to a formal approval of the DGCB.

Subsequently, there may be a regional reassessment (the powers to do so are under discussion in the courts, see our response to question 8.1) as well as a review on a hospital-by-hospital basis. In the later case, the grounds for such reassessment are more solid, since the law establishes that hospitals have certain powers to select the medicines they need to provide their services.

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**8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

We refer to our responses to questions 2 and 8.1. For new chemical entities and other medicines for which it is considered convenient, the AEMPS prepares a Therapeutic Position Report (“TPR”) which studies the compared efficiency and safety of the product and use criteria. Despite the fact of not being binding, it is intended to provide more insight to the product and homogeneity amongst the different Autonomous Communities. The TPR is a useful tool for the DGCB to determine the price level and the reimbursable condition of the new chemical entities. TPR shall include the budgetary impact and the financial assessment of the medicine once the pricing and reimbursement decision has been issued.

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**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

For non-reimbursed products it is not possible to obtain reimbursement by means of the intervention of a doctor.

18. See answer to question 8.1.

19. See Article 89 bis of Law 29/2006.

The doctor may prescribe a specific product included in the reference price system or an homogenous group <sup>20</sup> (instead of the general rule of prescription by active ingredient) as long as the principle of greater efficiency for the system is respected.

As for hospital use products, although doctors may override the guidelines adopted by the relevant hospitals, they are being put bureaucratic (difficulties in filing the requests, labor objectives) and legal obstacles to direct their prescription towards “eligible” medicinal products pursuant to the hospital guidelines.

## 9 Reimbursement – Administrative Arrangements

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

Reimbursement does not imply a separate application from the pricing decision and the failure to issue a decision involves the denial of the request (negative effects). This implies that applicants do not enforce the recognition effects (positive effects) of pricing decisions (as we mentioned pricing and reimbursement are dealt within the same procedure) and that negotiations can last months or even years.

## 10 Reasons for decisions on Pricing and Reimbursement

**The Transparency Directive 89/105/EEC requires Member State authorities to provide a “statement of reasons based on objective and verifiable criteria” in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it fr price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.**

**10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

The reasoning provided by the Spanish authorities within the formal decision is normally scarce. Expert opinions are normally included in the administrative dossier (available to the applicant) but not attached to the final decision.

20. For purposes of dispensing and substitution rules, the DGCB, publishes monthly on its website, together with the Nomenclator of pharmaceutical products of the NHS, information on homogeneous groups presentations of medicinal products and medical devices.

In each homogeneous grouping of medicinal products are integrated the presentations of the medicinal products financed with the same/s active ingredient/s in terms of dosage, content, pharmaceutical form or group of pharmaceutical form and route of administration, which can be exchanged when dispensed.

**10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

The level of reasoning is normally sufficient to understand the grounds of the decision and thus appeal it. Companies tend to decide not to appeal the administrative authorities' decisions based in the perception that a court shall probably not overrule a decision issued by an expert/technical body, but normally not because of the lack of reasoning of the decision.

## 11 Reconsiderations / Appeals

**11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

As regards the available appeals against a pricing/reimbursement decision issued by the DGCB, the decision may be appealed (“Recurso de Alzada”) within one month from the day after the notification of the decision (if it is express) or three months (if it is tacit).

Such appeal may be filed before: (i) the authority who issued the pricing decision (DGCB) or (ii) to the superior authority, that is, the General Secretariat of Health and Consumption.

Once the appeal has been filed, the deadline for issuing and notifying the decision on the same is 3 months. If after the deadline no decision is issued, it will be assumed, through the negative (administrative) silence, that the appeal has been dismissed (except if the previous decision was tacit, in which case the silence is positive).

The dismissal of the above-mentioned appeal puts an end to the administrative procedure.

**11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

When the administrative procedure has ended, in order to appeal this decision, a judicial contentious-administrative appeal shall need to be filed before the competent court within two months from the day following the notification or publication of the act that puts an end to the administrative proceeding (if the challenged decision is express), or within six months (if it is a tacit decision).

**11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

Despite the fact that a laboratory is naturally reluctant to challenge the decisions of the authorities in court, there is



a number of judgments against pricing policies or individual decisions. In case of a favorable decision for the company, in practice, the court's decision is issued a long term after the company's request and thus the laboratory shall be compensated for the damages caused in addition to, in certain cases, the amendment of the relevant regulation. Such compensation is often implemented by means of a negotiation with the relevant administration.

## 12 Unlicensed products and off-label use

### 12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?

The supplier of the product under such circumstances may charge for providing the product and this is not subject to any pricing restrictions.

Recently, in order to control the public hospital's expenditure in this context, a provision has been adopted (though further development is pending) whereby public administrations shall have to communicate the Ministry of Health the units of foreign medicines consumed (Article 15.1. of Royal Decree 177/2014).

### 12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?

In principle, no. Nevertheless, the authorities may choose to require an extra control ("visado") for the dispensing of such products or decide to amend the price of the product.

## 13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.

Within the recent years, examples of risk-sharing agreements negotiated directly with specific hospitals or the central or regional government have proliferated in Spain. These may adopt various forms:

(a) Charging less for the first treatment cycles until completing, for example, a quarter of the duration of the treatment as set out in the Summary of Product Characteristics. At that stage, the continuity or not of the formula established in the agreement is evaluated.

(b) Charging a conventional price until an acceptable cost / effectiveness ratio is proven according to predefined criteria.

(c) Charge a fixed amount per patient regardless of the required dosage.

(d) Charge a fixed amount per year regardless of the volume of treated patients.

The Autonomous Community of Catalonia has been a pioneer in such agreements, while developing several pilot programs between CatSalut and certain laboratories and issuing Guidelines setting forth the applicability criteria for such agreements in May 2014.

Although risk-sharing agreements are confidential as to their content, there is a campaign to raise awareness of this type of agreement. Therefore, certain details of the same are being made public.

Another practice to lower the effective price paid by NHS without having an impact on the original list price is the change in the status of certain medicinal products (such as oncology or biological products), making them "hospital use" products, which determines that they are normally acquired via tenders (and therefore, below the list price).

## 14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).

Yes, pharmacists are subject to a scale of deductions depending on their aggregate turnover on products dispensed which are funded by the NHS, according to Royal Decree 823/2008, dated May 16, establishing the margins, deduction and discounts corresponding to the distribution and dispensing of medicinal products for human use. Pharmacies not reaching a certain turnover are exempt.

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Since 2005 he has been considered by the Chambers & Partners legal directory as one of the best lawyers in Spain in the area of Life Sciences. The legal directory Best Lawyers, another of the most prestigious international publications, named him as the best lawyer in his speciality in 2014. The Legal 500 and PLC also consider him as one of the best lawyers in the area of Life Sciences in Spain.



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Both Chambers and Who is Who Legal selected her in 2014 as one of the most prestigious lawyers on regulatory advising to health and life sciences Industries.

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# Sweden

## 1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied

**Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?**

There is no general pricing control as such of medicinal products. Products can be placed on the market without a pricing decision. The timing of the application to be included in the reimbursement scheme is up to the MA holder.

The Swedish Dental and Pharmaceutical Benefits Agency (TLV) is responsible for the reimbursement scheme and the prices of products included in the reimbursement scheme. Although there is no formal requirement to obtain a decision before the products are placed on the market, in practice pharmaceutical companies will have difficulties selling products (other than OTC) without being a part of the reimbursement scheme. Our answers in these parts refer to the (optional) process of applying for subsidies and pricing for pharmaceutical products.

In general, the pharmaceutical benefits system for medicines is product-oriented. A medicine is granted either a general subsidy for all its approved fields of use (indications) or no subsidy at all. However, if there are special reasons, TLV may decide to include a medicine in the pharmaceutical benefits scheme only for a particular use or a specific patient group, a so-called restricted subsidy. TLV may also attach other special conditions to a subsidy decision. We have listed specific information for the different categories of products below.

### 1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."

N/A

### 1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).

N/A

### 1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.

Pricing is free for hospital pharmaceuticals and physicians have free prescription rights. However, County Councils

have during recent years increased their use of public procurements for all kinds of medicinal products, including those available only by prescription, although this is questionable under Swedish law. Also, it should be noted that even for hospital pharmaceuticals, many pharmaceutical companies are encouraged by clinics/hospitals to apply for subsidies, due to the structure of the system.

#### **1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

Public funding is generally only available for medicinal products available only on prescription (a few OTC products for chronic diseases/condition). OTC pricing is free.

#### **1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

An application for subsidy for a generic product is granted if the requested price is the same or lower than the current highest price and the generic product has been deemed substitutable with the originator product by the MPA.

#### **1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

N/A

#### **1.7 Orphan Medicinal Products.**

Some City Councils have initiated a "County Council Subsidy" for certain orphan drugs which have been denied entry into the national subsidy system of TLV.

#### **1.8 Parallel imports from another Member State.**

N/A

#### **1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

N/A

## **2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

The pricing and reimbursement elements for the products identified above are dealt with together by TLV. TLV is,

through the authorisation by the government, responsible for decisions regarding pricing and reimbursement of products within the Act of Pharmaceutical Benefits [SFS 2002:160].

The decisions of pricing and reimbursement made by TLV are made under the above mentioned legislations together with the Regulation with Instructions for the Swedish Dental and Pharmaceutical Benefits Agency [SFS 2007:1206]. TLV also issues regulations on certain details of the application process.

## **3 Other Financial controls relating to supply**

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

Not under the current system, the TLV however monitors cost increases for therapeutic areas. In a government report from 2013 it was proposed that the applicant also should be obligated to make a volume forecast, which if exceeded to a certain degree will open the pricing process again for the exceeding volume for a value-based assessment again, and in the end even an IRP. However, this proposal was not accepted.

## **4 Pricing Criteria**

**For those products identified in the answer to Q1 for which a price must be agreed:**

### **4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?**

IRP is not currently part of the criteria, but was proposed in the above mentioned government report. This was however also not implemented.

### **4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?**

Internal therapeutic category reference pricing is used, i.e. a number of reference products with the same indication is used as references for the new medicinal product.

The current system for when a price must be agreed uses a value based pricing/cost-effectiveness analysis, i.e. a calculating QALY (Quality Adjusted Life Years) in comparison to reference products decided by TLV, within

the therapeutic area. However, there is no requirement of information on cost-effectiveness.

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

An application to be included in the reimbursement scheme, including a proposed price, must be filed with the TLV. TLV will then verify the requested price through a cost-effectiveness/health technology assessment and decide the price. The TLV must give a decision within 180 days. Decisions of the TLV may be appealed within our administrative court system.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

There are no specific legislation regarding when or how often price determinations are reviewed. However, it is possible for TLV to independently decide when a price determination shall be reviewed.

It is also possible for the MA holder to request a review of a price determination. The MA applying for a change/review has the right for deliberation with TLV. If a deliberation is not asked for, the new price can be determined based on the available review.

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 above?**

It is possible for a MA to apply for an increase of price for a medicine in the reimbursement system, (but not under substitution rules). In order for an application for a price increase to be complete the MA must provide reasons that justify the price increase, information on prices and treatment costs of other comparable pharmaceuticals that are included in the benefit system and information on the desired implementation time of the changes applied for. An application for increasing the price of a product outside the substitutability system requires a well-founded justification. TLV has published general guidelines (LFNAR 2006:1) on grounds for price increase of pharmaceuticals.

A decision on price increase is reported within 90 days after the application was received by TLV. If the decision is not made within this time, the price applied for will be in effect.

It is also possible for a company to apply for a price change of a medicine within the boundaries of the generic sub-

stitution system. In this case, a correctly completed application is sufficient.

- **Reduce the price generally or for a period**

For a price reduction outside the substitution system, the company only has to send a correctly completed application to TLV. A decision on price reduction of a previously determined sales price is reported as soon as possible.

It should be noted that this applies to a general price reduction and not a reduction for a limited period of time.

Regarding a reduction of price within the boundaries of the generic substitution system, see the previous section.

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

There is currently no overarching price freeze for austerity or other reasons.

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

Generally not at product entry, no automatic regulatory mechanism exists. However, there is a maximum price obligation that can be decided by the TLV under certain conditions. If the price has sunk with 70 per cent of the price of the original product at the generic entry and a generic product has been available and sold for at least four months, the TLV can set a maximum price of 35 per cent of the original product price at the generic entry. Also, the Swedish model with substitution and a so called "product of the period" (where the TLV lists the cheapest product, which the pharmacies are obliged to dispatch unless the prescribing doctor has specifically prescribed a different product) normally gives a price pressure downwards, which of course becomes greater as more substitutable generic products enter the therapeutic area.

## 7 Other Types of price control

**Does your jurisdiction control any of the following prices:**

### 7.1 Full line or other wholesaler selling price

There is no control of full line or wholesaler selling prices. However, within the reimbursement scheme, TLV determines the buying-in price for pharmacies.

### 7.2 Pharmacy selling price

TLV determines the pharmacy selling prices for products within the reimbursement scheme. Products outside the reimbursement scheme are not subject to any price control.

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

The so called high-cost threshold for pharmaceuticals covers prescription pharmaceuticals, some OTC pharmaceuticals (mostly for chronic diseases/conditions) and certain expendable/consumable products within healthcare.

TLV is the government agency responsible for decisions concerning subsidies and price regulation of medicines and products included in the pharmaceutical benefits scheme. TLV also determines which dental treatments and medical devices should be included in the high-cost protection scheme and decides how much pharmacies should charge for those medicines included in the pharmaceutical benefits scheme by setting the purchase and sale price for pharmacies.

The pharmaceutical benefits system for medicines is product-oriented. A medicine is granted either a general subsidy for all its approved fields of use (indications) or no subsidy at all. However, if there are special reasons, TLV may decide to include a medicine in the pharmaceutical benefits scheme only for a particular use or a specific patient group, a so-called restricted subsidy. TLV may also attach other special conditions to a subsidy decision.

The so called high-cost threshold for prescription pharmaceuticals is designed in steps, beginning from the first purchase of a pharmaceutical within the high cost threshold and twelve months onward. The patient pays the full price for pharmaceuticals within the high-cost threshold up to SEK 1,100. For the patient's costs up to SEK 1,600, the patient pays 50 % of the full cost, the other 50 % is reimbursed from public funds. Up to SEK 2,050 of the patient's cost, the patient pays 25 % of the cost for pharmaceuticals and finally up to SEK 2,200, the patient pays 10 % of the full cost for pharmaceuticals within the high-cost threshold. Over SEK 2,200, all costs for pharmaceuticals are fully covered by public funds, until the twelve month period since the first purchase has expired.

### 8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?

Products included in the reimbursement scheme are placed on a positive list, “opt in”. If there are special reasons, TLV

may decide to include a medicine in the pharmaceutical benefits scheme only for a particular use or a specific patient group, a so-called restricted subsidy. TLV may also attach other special conditions to a subsidy decision.

### 8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?

Reimbursement status is the subject of a formal approval made by TLV. A reimbursement status can be reviewed by TLV on its own initiative. TLV can then decide whether or not a product should retain its reimbursement status. The TLV allows the county councils' pharmaceutical benefits group, to issue reports on the applications it receives. The county councils' also procure hospital pharmaceuticals independently, based on the MPA's decisions on exchangeability.

### 8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?

TLV decides whether or not a product should be eligible for reimbursement status and included in the high-cost threshold. The final reimbursement decision is made by TLV's board of experts, the Pharmaceutical Benefits Board.

It is the company applying for reimbursement that is responsible for demonstrating that the medicinal product meets applicable legal requirements. A medicinal product must be approved by the Swedish Medical Products Agency or the European Commission in order to be sold in Sweden.

Three basic principles form the basis for TLV's decision on reimbursement status. The first is cost-effectiveness where two or more alternative treatments are compared. Calculations, as an example, may be based on whether a new medicine which is more expensive – but also better than its alternative – is worth the price tag. The result is normally documented in QALYs. If the cost per QALY gained is under a certain level, then the new medicine is considered cost-effective.

The second is the societal perspective, which means that the analysis of direct costs also takes productivity costs into account for sick leave or increased productivity if the patient can start work again.

The third principle is based on an ethical platform and relates to human value together with human needs and solidarity.

### **8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

There are no possibilities for doctors to override a formal decision of reimbursement by the TLV. Instead, every prescriber is responsible for making sure that the prescription meets the requirements for reimbursement.

It is however possible for TLV to determine a restricted reimbursement. Then the medicine is only included in the high-cost threshold for a certain area of users or a specific patient group. The reasons for restricted reimbursement could be that a medicine is only cost-effective for one limited and specific group of patients or a medicine is only cost-effective within one of several possible areas of use. A further reason may be that some patients may lack treatment options because they are unable to take a certain medicine or a certain dosage form.

## **9 Reimbursement – Administrative Arrangements**

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

A new application for subsidy shall be handled within 180 days, from the application is complete. A "stop-the-clock" procedure is utilized. TLV sometimes agrees to initiate the investigation despite the application being incomplete in parts (for example, if the approval of the Medical Products Agency or EMA was not provided yet).

The pharmaceutical company must submit an application for pricing and reimbursement. TLV selects a medical reviewer, a health economist and a legal adviser who process the application. One of them is the responsible investigator for the application. A copy of the application is sent to the county councils' pharmaceutical benefits group, who issue a report on the application. The TLV will evaluate the suggested price and whether the product should be included in the benefits system at such price.

Within the TLV, the Pharmaceutical Benefits Board, a panel of experts, then make the final decision of whether or not the pharmaceutical product will be subsidized or not.

A decision on a price increase has to be made within 90 days after the application is received by TLV. Decisions on price cuts will be reported as soon as possible.

## **10 Reasons for decisions on Pricing and Reimbursement**

**The Transparency Directive 89/105/EEC requires Member State authorities to provide a "statement of reasons based on objective and verifiable criteria" in respect of**

**a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it if price is defined in chapter 6, section 7 of the Health Insurance Act and refusal criteria in section 5 of the same chapter.**

### **10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

Yes, a decision by the TLV is supported by collected expert opinions and committee statements, to which not only a general reference is made in the decision if particular notice or weight has been given any of these.

### **10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

Yes. It is often the detailed reasoning which gives a company the basis for an appeal.

## **11 Reconsiderations / Appeals**

### **11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

If a company does not agree with a decision on subsidisation and price, the decision can be appealed against at the general administrative court, which is the Administrative Court in Stockholm.

### **11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

Yes. The appeal must be sent to TLV (not to the court) and must be received by TLV within three weeks after the applicant received the decision. TLV then forwards the appeal to the court.

### **11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

Due to a government drive for savings, court procedures have increased with regard to pricing and reimbursement over the last 3-4 years.

There is an ongoing case which tests the maximum QALY possible for a reimbursed product, i.e. challenging the principle of solidarity with regard to diseases that are severe, chronic and fatal. The question is whether or not

a very limited patient group should not have access to a certain medicinal product within the reimbursements system since it's QALY is about five times higher than the highest QALY for a broad patient group with a severe and often fatal disease (certain cancer). The case was won in the first instance by the company challenging the decision by the TLV not to include the product in the reimbursement system.

There are also various cases challenging the reference products use by the TLV and a principle from these cases are that the reference product must be actively used in the general treatments of the healthcare system, and not only being available on the Swedish market.

Otherwise the most discussed cases have been around the question whether or not it is possible or not for Swedish county councils/regions to negotiate discounts on prices for products that are within the reimbursement system (thus making the prices set by the TLV only applicable to retail pharmacies and not the national medicinal product market as a whole) and whether such an action should be setup in a public procurement or not. It has been decided by the courts that negotiating such a discount agreement is not an action that will have to be arranged through public procurement. The other question is still ongoing, since the case is awaiting leave to appeal at the Supreme Administrative Court but in the Administrative Court of Appeal held in its judgment that the pricing by the TLV is national on the whole market for products within the reimbursement system, thus making discount agreements illegal for such products.

## **12      Unlicensed products and off-label use**

### **12.1    Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?**

TLV refers to non-approved medicines that are sold based on a special permission by the MPA (license) on a named patient basis as licensed medicines. Generally, the same procedures apply for new licensed medicines as for applications for subsidy for a new original pharmaceutical. For licensed medicines that have lost a previous marketing authorisation, TLV must review the circumstances concerning the medicine. If the price for the medicine remains the same, the review for this medicine can be simplified if TLV previously has approved the subsidy.

### **12.2    Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?**

In principle, no. Nevertheless, the authorities may choose No, not in general. TLV may in attach special conditions to a subsidy decision, as is the case when the product

is granted a restricted subsidy for a particular use or a specific patient group. We are not aware of such kinds of restrictions for off-label use.

## **13      Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.**

As mentioned above, certain county councils/regions have a local reimbursement system, for certain products that are not part of the national reimbursement system, for example due to the TLV deciding that the QALY of the product is too high. For certain orphan medicines, the county councils/regions also enter into so called solidarity agreements, for example if a certain rare disease is more prevalent in certain areas of the country, all regions share the cost of those patients.

## **14      Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

No, the Swedish system is not set up in such way.



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Lindahl's life sciences group is one of Sweden's most prominent in terms of both expertise and capacity and is top rated by international legal publishers year after year. The group consists of a large number of specialists, which means that we possess the cutting-edge expertise required to provide advice in the sector.

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# Switzerland

## 1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied

Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?

General remark: A product may be placed on the market as soon as it has obtained Marketing Authorization (MA). There is no legal obligation to obtain approval of price before launch of placing on the market. However, a product is only reimbursed after it has obtained a price from the competent authority (which is different from the authority that grants the MA). The approval of price takes place only after MA has been granted. The answer to the following questions is therefore "yes" for all questions with the exception of question 1.2.

### 1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."

Yes.

### 1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).

No.

### 1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.

Yes.

### 1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).

Only if reimbursement will be sought.

### 1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.

Yes.

### 1.6 Biosimilar medicinal products (whether the first or subsequent available product)

Yes.

**1.7 Orphan Medicinal Products.**

Yes.

**1.8 Parallel imports from another Member State.**

Yes.

**1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

None.

## **2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?

Pricing and reimbursement elements are dealt with together. The competent authority is the Federal Office of Public Health. The specific legislation is the Law on Health Insurance and its Ordinances.

## **3 Other Financial controls relating to supply**

Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?

In the event that the total sales are not known and may not be estimated at the time of first launch and the product has a high price, the authority may set a sales cap and oblige the company to transfer sales above such sales cap to a general account of the health insurances. But there is no explicit legal basis for such sales cap and it is an exemption in order to guarantee the cost effectiveness of the product.

## **4 Pricing Criteria**

For those products identified in the answer to Q1 for which a price must be agreed:

### **4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?**

The ex-factory price in Switzerland must not be higher than the average ex-factory price (minus VAT) in the following countries: Germany, Netherlands, Denmark, UK, Austria and France.

The official price in the foreign country has to be confirmed by the company's affiliate in this country and refer to the package with the highest sales. The exchange rate between Switzerland and the foreign country is fixed and published by the competent authority.

There should be additional countries in future, namely Belgium, Finland and Sweden. The coming into force of this new regulation is not determined at the date of finishing this questionnaire.

### **4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?**

Beside price comparison with foreign countries, the price of a product, whose price is determined and approved for the first time, is compared with the price of other medicinal products with the same indication or similar mode of action (so called therapeutic cross comparison).

The therapeutic cross comparison is repeated on the occasion of the three-year price examination only if the product is not in the market abroad and the comparison with the price in foreign countries therefore not possible or if the price of less than three foreign countries is known.

## **5 Pricing control timelines**

### **5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?**

The MA holder has to obtain MA first. He may then apply for a price by sending the request. The competent authority has published a hand-book describing in detail the procedure and the necessary documentation (so called hand-book for the specialty list). If there are no questions and the company agrees on the price, the procedure takes about 4-6 months, depending on the meeting dates of the commission. However, if there are discussions on the price, the procedure may take longer.

## **6 Prices increases and reductions**

### **6.1 How often are price determinations ordinarily reviewed?**

Every three years

**6.2 What controls apply to the right of company to:**

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 adobe?**

The price may only be increased if the last price examination took place at least two years ago and the comparison with the price in foreign countries shows that the price in Switzerland is lower than the average price in foreign countries.

- **Reduce the price generally or for a period?**

A company may reduce the price at any time.

**6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?**

No.

**6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?**

There is no explicit legal obligation to lower the price when a generic enters the market, but the competent authority examines the price of the branded product at the time of patent loss and the price has then to be lowered in general.

There is a legal provision that the patient has to contribute to the costs with 20% instead of 10% in the event that there are reimbursed generics in the market and the patient prefers to obtain the original product (except if the original product is needed from medical reasons). This higher co-payment leads in general to a "voluntary" price reduction of the MA holder of the original product.

**7 Other Types of price control**

**Does your jurisdiction control any of the following prices:**

**7.1 Full line or other wholesaler selling price**

N/A.

**7.2 Pharmacy selling price**

The Swiss jurisdiction controls the ex-factory price and the so called public price. The latter is the maximum price which may be reimbursed by the health insurance.

**8 Reimbursement – general principles and Transparency directive compliance****8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local govern-**

**ment? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?**

The Swiss system of reimbursement is national and based on an obligatory insurance. The list of medical services, medicinal products and medical devices which are subject to reimbursement is defined by the authorities. Only listed products may be reimbursed by the obligatory insurance. The insurance system involves a so called franchise of at least CHF 300 which means that the first CHF 300 per year have to be paid by the patient. As soon as the amount of the franchise is reached, the insurance reimburses the services at 90%. The patient has to co-pay 10% of the services and products up to a certain amount which is defined in an Ordinance. This amount is at CHF 700 per year for the time being. As soon as the amount of co-payment is reached, the obligatory insurance pays for all services and products.

Beside the obligatory insurance there are private and additional insurances which cover costs that are not covered by the obligatory insurance. However, the listed services and products are sufficient, it is not necessary to enter into a private and additional insurance in order to have one's disease treated in a sufficient way.

**8.2 Does your jurisdiction purport to operate a "positive list" or "negative list" in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

With regard to medicinal products, Switzerland has no negative list but a positive list which is exclusive. Products which are not included must not be reimbursed in general. There are often limitations defined which restrict reimbursement to a certain amount.

With regard to medical services there is an assumption that any medical service is effective, appropriate and economic and has to be reimbursed. If there are clinical trials and other evidences for its therapeutic effectiveness and cost effectiveness it may be included in a list. This list is kind of a positive list, but it is not exclusive.

**8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

Reimbursement is subject to a formal approval. This approval will be reassessed every three years. The reassessment is based on a comparison with the price of the same product in foreign countries. Due to changes in the exchange rate between Swiss Francs and Euro, the prices are in general lowered after the three year evaluation.

#### **8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

The competent authority is the Federal Office of Public Health.

Health technology assessments do not play a big role for the time being. It is planned to consider them to a greater extent in future.

#### **8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

Doctors may not override the formal decision themselves, but they may send a request for reimbursement to the health insurance of the patient. The decision on reimbursement is with the health insurance. However, since March 2011, there is a provision in the Ordinance on Health Insurance according to which the health insurance has to reimburse hors-list products or off-label use if certain conditions are met (there has to be life-threatening disease or severe and chronic invalidity, the product has to have a high therapeutic benefit and there must not be an alternative treatment approved and reimbursed). It is up to the health insurance how much of the price of such medicinal products are reimbursed. The rest has in general to be taken over by the Marketing Authorization holder of the product.

## **9 Reimbursement – Administrative Arrangements**

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

The MA holder has to send a request. The competent commission has 5 to 6 meetings per year. After its assessment, the Federal Office of Public Health has to decide on reimbursement and potential limitations. It then enacts an injunction with its decision. This injunction is subject to appeal.

The timelines depend on the meeting dates. In general, the procedure takes some months, depending also whether the MA holder accepts the price or starts discussions with the Federal Office of Public Health.

## **10 Reasons for decisions on Pricing and Reimbursement**

The Transparency Regulation 89/105 requires Member State authorities to provide a “statement of reasons based on objective and verifiable criteria” in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it from reimbursement (negative lists).

#### **10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

Yes, the decisions are accompanied in general by the reasoning of the external commission which assesses the request. The injunction with the price has to be motivated as well.

#### **10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

The reasoning is in general rather short, but in general sufficient for an appeal.

## **11 Reconsiderations / Appeals**

#### **11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

There is an appeal to the Federal Administrative Court (1<sup>st</sup> instance), followed by an appeal to the Supreme Court (2<sup>nd</sup> instance).

#### **11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

Yes, the decision is subject to appeal to the Courts. The deadline for submitting the appeal is thirty days without possibility to extend this deadline. The decision of the 1<sup>st</sup> instance takes for the time being about 1½ to 2 years, sometime longer.

#### **11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

There were only very few court procedures so far because the authority has withdrawn the suspensive effect of the appeal in the past regularly. This behaviour has been successfully challenged in 2012 (for the first time since a long time) and it is assumed that there will be more appeals in future due to the suspensive effect.

Since there are only a few decisions for the time being, No.  
there are no practice or practical effects of them.

## **12      Unlicensed products and off-label use**

### **12.1    Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?**

The costs may be reimbursed for off-label use of a product which is reimbursed for the approved indications as well as for a product which is approved by Swissmedic but not reimbursed, provided that such product is of high therapeutic value and against a disease which would be life-threatening or leading to severe and chronic invalidity for the patients without treatment. The health insurance decides on the costs or part of the costs which it covers.

### **12.2    Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?**

See section 12.1 above.

## **13      Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.**

No.

## **14      Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

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## CONTRIBUTOR

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Ursula Eggenberger Stöckli studied pharmacy at the Swiss Federal Institute of Technology (ETH) in Zurich and worked for 2 years in a public pharmacy and 10 years as a pharmacist in the pharmaceutical industry. She then studied law and was admitted to the bar. Since 2000 she has worked as an attorney-at-law specializing in pharmaceutical and healthcare law. Ursula Eggenberger Stöckli advises her clients, which are pharmaceutical companies of any size, in all matters of pharmaceutical and healthcare law. She has been a partner with Bratschi Wiederkehr & Buob Ltd. since 2005. Her main focus is on advising her clients, but she also represents them before the courts and the authorities. Besides this, she regularly publishes articles and gives further education presentations in the field of her specialization.

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# Turkey

## **1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied**

**Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?**

In accordance with Article 4 of the 'Notification Regarding the Pricing of Medicinal Products for Human Use' (dated June 30, 2007 and numbered 26568), the license holders shall file with the Ministry of Health the Price Declaration Form along with the other documentation (which may be required depending on whether the product is an original or a generic product). For the original products; the price declaration form as well as the documenting indicating the product's price in reference countries shall be submitted to the Ministry.

### **1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met."**

Initial pricing approval is required for products that do not have similar (the same pharmaceutical form of the same active substance(s) in a form with a different unit amount of raw material and/or different number of units per package) or fully equivalent products (whose active substance(s), pharmaceutical forms, unit amounts of raw material and packaged quantities are the same) in Turkey. Products containing "new active substance(s)" are not subject to a special regulation.

### **1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other "lifestyle" medicines).**

Abovementioned products are not subject to a different regulation.

### **1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.**

For purchasing medicinal products by hospitals; the applicants shall participate in government tenders by following the procedures in accordance with Public Procurement Law no. 4734. Even though the participating conditions are determined separately for each tender, business experience certificate, which shows that the bidder has experience on the area and participated in a similar tender before, is usually requested. However, tender only determines which



company will supply products to hospitals. Products will be priced as it is set out in 1.1.

#### **1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

As per article 5/c of 'Notification Regarding the Pricing of Medicinal Products for Human Use'; the cheapest reference pricing system (of the Decision of the Council of Ministers, with No. 2007/12325, Regarding the Pricing of Pharmaceuticals for Human Use) shall not be implemented for non-prescription drugs. However the price of these products cannot be set by manufacturer itself, it is also set with Ministry of Health the Price Declaration Form. Even though there are different pricing criteria for generic, original, twenty year old or co-marketing drugs, these different criteria are not taken into consideration while pricing OTC products. The price cannot be higher than the highest ex-factory price for such product currently applicable in the reference countries.

#### **1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

Generic products must be priced at a predetermined percentage of the original product.

Please be informed that in Turkish Law there is no explicit provision for market exclusivity.

#### **1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

In accordance with 'Notification Regarding the Pricing of Medicinal Products for Human Use'; bio-similar product means a non-generic product, similar to the biological/biotechnological reference drug having the same potency and used to treat the same condition. While pricing bio-similar products, 100% of the price of the lowest priced biosimilar product marketed in the reference countries, including the countries of manufacture and import, shall be regarded. Where the product concerned is not marketed in these countries, then 100% of the lowest price applied in other EU Member States shall be regarded.

#### **1.7 Orphan Medicinal Products.**

In accordance with "Notification Amending the Notification on the Pricing of Medicinal Products for Human Use" orphan medicinal products (i.e. orphan drugs) means the drugs used for treating a fully characterized disease whose incidence is so low that it affects less than 1 out of every 100,000 persons in a country. The lowest pricing system is not applicable for orphan medicinal products. The maximum price for orphan medicinal products is the reference price which is determined with formal documents provided from importing and manufacturing country. Parallel imports from another Member State.

Turkish law does not allow the parallel import of medicinal products. Import of a medicinal product can only be conducted by a licence holder, since a custom control certificate is required to import medicinal products, and such certificates are only issued in the name of the licence holder.

#### **1.8 Parallel imports from another Member State.**

There is no any other special regulation apart from before mentioned products.

#### **1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

There is no any other special regulation apart from before mentioned products.

## **2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

In the Turkish pharmaceutical industry, state is the legislator and the largest drug buyer at the same time. Duties such as licensing and pricing are conducted by General Directorate of Pharmaceuticals and Pharmacies ('IEGM') under the Ministry of Health of Turkey, while main drug reimbursement is carried out by Turkish Social Security Institute ('SSI').

Pursuant to Notification Amending the Notification on the Pricing of Medicinal Products for Human Use, the Ministry of Health exerts strict control over the pricing in the pharmaceutical sector by determining the innovator's base price on the first product to enter the market (i.e. original product) based on the price of the product in other countries (see Question 4.1). Subsequent generic entrants to the market must price their product at a predetermined percentage of the original product. In that respect, the Ministry of Health applies a reference pricing system to determine the prices of original and generic products.

A Price Evaluation Commission is formed with the participation of the representatives from the Ministry of Health, Ministry of Finance, State Planning Organization, Undersecretariat of Treasury and Directorate of Social Security Authority.

The Code of Social Security Institution (dated May 16, 2006 and numbered 5502) combined all social security institutions under the roof of the Social Security Institution (SSI). Along with the code, a list was published to

indicate the pharmaceutical products to be reimbursed. Any product that is not included in the list will not be subject to reimbursement.

New products entering into the market for the first time can be subjected to reimbursement upon approval of the Reimbursement Committee, which gathers at least quarterly to discuss and update the list indicating the molecules to be reimbursed.

### 3 Other Financial controls relating to supply

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

Pursuant to article 7 of Pharmaceuticals and Medical Preparations Law no.1262, the controlling authority for pricing of medicinal products is the Ministry of Health which does its share of task by Cabinet Decrees.

As we have mentioned previously, Price Evaluation Commission is formed with the participation of the representatives from the Ministry of Health, Ministry of Finance, State Planning Organization, Undersecretariat of Treasury and Directorate of Social Security Authority. Therefore, Ministry of Finance, State Planning Organization and Undersecretariat of Treasury impose on the MA holder or his distributor or local representative in a roundabout way.

## 4 Pricing Criteria

**For those products identified in the answer to Q1 for which a price must be agreed:**

### 4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?

Turkey uses a reference pricing system for originator products (Decree Regarding the Pricing of Medicinal Products for Human Use dated 30.06.2007, numbered 2007/12325). The price for an originator product is determined according to the lowest ex-factory price among five EU countries (Current reference countries are France, Spain, Italy, Portugal and Greece). The reference countries may change and the number of reference countries may increase up to 10, provided that four months prior notification is given to industry.

If there is no ex-factory price available for a product in the reference countries, the price is calculated by deducting mark ups and VAT from the pharmacy retail price. In cases where the ex-factory price of a product is lower in the country of origin (for products imported into the

reference countries), the price in the country of origin is taken as the reference price. If the product is available in only one of the reference countries, the ex-factory price in that country is taken as a reference. In cases where the product is not authorized in any of the reference countries, the cheapest ex-factory price in any other EU Member State is taken as a reference.

### 4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?

There are no other criteria for pricing of medicinal products for human use.

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

As we have explained before in A1, the MA holder or his representative shall apply to the Ministry of Health along with the Price Declaration Form. Applicant must have access to the database to have the form. Therefore, the applicant must have an ID and password which is provided by IT department of General Directorate of Pharmaceuticals and Pharmacy.

The applications to obtain an initial price shall be concluded within 60 days. Applications (other than for the purposes of obtaining an initial price, i.e. amendments to the price agreed) shall be concluded within 10 days.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

As per Article 10 of the Notification, the Price Evaluation Commission will hold ordinary meetings once every three months. In its ordinary meetings, the Commission shall evaluate the prices of pharmaceuticals for human use in accordance with changes in economic indicators and make proposals to the Ministry of Health for the increase, reduction or preservation of the price of pharmaceutical products.

The Committee shall meet to decide drug price increases, decreases or maintenance of current price levels, and to set the "Euro value for the period" and the "Euro value band for the period", both used during setting of drug prices. The lower limit of the Euro value band for the period shall be the Euro value for the period, and its upper limit 10% above the aforesaid lower limit. Any variations in the exchange rates within 5% below the lower limit and

5% above the upper limit of the Euro value band for the period shall not provide rationale for changing the prices.

In case a variation occurs in the currency exchange rates beyond the lower or upper limit of the Euro value for the period, the Ministry will call on the Price Assessment Committee to convene extraordinarily within no more than five working days to reassess the drug prices. If an agreement cannot be reached during this meeting, the Committee shall set and announce the new values during a final meeting which it shall hold within no more than 10 working days.

## **6.2 What controls apply to the right of company to:**

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 adobe?**
- **Reduce the price generally or for a period?**

All kinds of changes in prices of medicinal products for human use are under the control of Ministry of Health. Companies may not increase or reduce the price of the medicinal product by themselves.

The reduction shall be announced within 3 months, if the rate of reductions in reference prices exceeds 3% in total (including 3%). The changes to occur in the approved sale price to wholesalers in Turkey due to the change of reference price or reference country shall not be reflected on the price until they exceed 3%. The Ministry shall announce the change in the reference price on the official web site of the General Directorate within 7 days as of the notification date of the company. In the announcement, the new reference price, the date of modification and the relevant reference country shall be specified. Companies manufacturing or importing generic products are obliged to apply to the Ministry within 7 days of the announcement, so as to obtain a new price. In case of a delay, the price shall be reduced ex-officio. In order to prevent any disruption due to official holidays, validity date shall be announced in advance.

## **6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?**

There is no current price freeze in Turkey for medicinal products for human use.

## **6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?**

As per Article 4 of the Notification, "for products which are currently on the market and assigned a Ministry-approved price, or for which a pricing application has been submitted for the first-time; the "ex-factory price" of an original product may not exceed the reference price until a generic is launched; furthermore the "ex-factory price" of

an original whose generic has been authorized and placed on the market shall be no more than 60% of the reference price as registered in the Ministry of Health's database. The ex-factory price of a product, whose original is unavailable in Turkey, shall be equal to 60% of the reference price as registered in the Ministry of Health's database. For the original product's price to be posted as 60% on the official website, the product should be licensed (sales). Information derived from generally accepted databases may be admissible in connection with any objections raised on the grounds of market unavailability of a product. Such objections must be raised and concluded within 5 working days after the announcement of the new price. An "ex-factory price" up to 60% of the reference price of the original may be assigned to all generics, starting with the first one."

This means that until a generic is launched companies may request up to a maximum of 100% of the reference price for original products. However, the price of the original product with a generic product that has been licensed and placed on the market shall not exceed 60 percent of the base price registered under the Ministry of Health database.

The method of evaluating when to substitute prescribed pharmaceuticals (i.e. branded products) with non-prescribed products (i.e. generic products) is determined by protocols assigned by SSI, Ministry of Finance and Turkish Pharmacists Association. On the other hand, as mentioned by the Turkish Competition Authority in the April 20, 2009 dated decision for Sanofi Aventis; the current practice in the market is for pharmacists to provide pharmaceutically equivalent generic products instead of the prescribed product. As a matter of fact, it is an established practice for the pharmacists to direct customers to the lower priced equivalent generic product by indicating that they have the option to pay the extra price from the reference price determined by the Ministry of Health for the original product or buy the generic product which is within the reference price determined. There are two legal bases for such application, first of all it is accepted that the generic product is the exact subsidiary of the original product and secondly, it is the practice of SSI and Ministry of Finance which together holds approximately 80% of the pharmaceutical purchase in the Turkish market.

## **7 Other Types of price control**

**Does your jurisdiction control any of the following prices:**

### **7.1 Full line or other wholesaler selling price**

### **7.2 Pharmacy selling price**

Wholesaler selling price and pharmacy selling price are also under control of the Ministry of Health. According to the product's sale price to wholesalers, wholesaler and pharmacy profits shall be added separately to the figures corresponding to each tier established in the Decision so

as to designate the wholesaler and pharmacy sale prices. The public sale price including VAT shall be designated by adding the VAT to the pharmacy price.

Wholesalers' and pharmacies' profit rates to be applied in the designation of public sale prices of products are determined in the Notification.

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?

As indicated before, there is a list for products to be reimbursed which is published by SSI. Any product that is not included in the list will not be subject to reimbursement. The list is updated frequently. New products entering into the market for the first time can be subjected to reimbursement upon approval of the Reimbursement Committee, which gathers at least quarterly to discuss and update the list indicating the molecules to be reimbursed.

The Reimbursement Commission consists of doctors, pharmacists, public health experts, economists, statisticians, specialists, pharmacologists and biostatisticians who evaluate applications for reimbursement and amend the list of pharmaceuticals to be reimbursed according to the Directive on the Procedure and Principles of Practice of the Reimbursement Committee.

The Communiqué on Health Implementations published by the SSI provides that the basic discount applicable to the generic and original products (on reference price) shall be at a rate of 11%. The Communiqué also stipulates the terms of reimbursement for pharmaceutical products.

As per the amendments to the relevant Communiqué on April 4, 2012, the following additional discount rates shall apply:

- 1. 29 percent until reference price is determined (a total of 40 percent) and 17 percent after the reference price is determined (a total of 28 percent) for products which have been released to the market before August 1, 1987 (twenty year products) and have a warehouse sale price of 6.79 TL and above.
- 30 percent for original products of which generics have not been launched to the market (a total of 41 percent).
- 17% for original products of which generics have been launched to the market (a total of 28%).
- 17 percent for generic products (a total of 28 percent).

Pursuant to Article 6.4.1 of the Communiqué on Health Implementations, the provisions for lowest reference pricing and price ratio (Question 6.4) shall not be applied to non-prescribed products and/or products that are not within the list of products to be reimbursed. These products will be evaluated without differentiating whether they are original, twenty year, co-marketing or generic. Regardless, the price shall not be higher than the official highest warehouse sales price in the reference countries.

### 8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?

The Commission is responsible for issuing the positive list of reimbursable drugs and meets every two months. The positive list is unified for all health insurance funds. It is brand-based, meaning that every new generic has to apply for inclusion in the positive list. The list defines the reference prices for reimbursement. Bargaining over prices appears to take place in the commission: manufacturers sometimes offer higher rebates than the statutory 4% for drugs less than 6 years old and 11% for drugs older than 6 years, in order to get on the list.

There are two separate positive lists; one covering green card holders, civil servants, military staff, and the other covering self-employed workers and farmers, private and public sector workers and retired civil servants entered. According to SSI, the two lists are identical.

### 8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?

A Medical and Economic Evaluation Commission operating under the main commission (the Reimbursement Commission) represents the technical expertise needed to assess the dossiers submitted by industry (see Question 9). It prepares the decisions of the main commission and makes recommendations for inclusion of new drugs into the reimbursement list. However, the main commission does not always follow the recommendations of the technical commission. The Reimbursement Commission reviews data on efficacy, safety, clinical benefit and pharmacoeconomics as a basis for their decision.

### 8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made

**locally or in other Member States in respect of the same product?**

Answered above.

**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

It is not possible for doctors to override a formal decision of the Reimbursement Commission. Even though the decisions of the commission can be subject to objections, special needs of a particular patient are not considered as a valid ground for objection.

## **9 Reimbursement – Administrative Arrangements**

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

For original products, it is mandatory that a pharmacoeconomic dossier is prepared including the information showing the new treatment is cost-effective in comparison with alternative treatments. Two commissions operate for the evaluation of such dossiers. The first is the Medical and Economic Evaluation Commission (MEEC). The MEEC assesses all applications and declares its decision. The second commission is the Reimbursement Commission (RC). The RC finalizes the decision declared by MEEC. Both the MEEC and RC consist of SSI and the Ministry of Finance officers. The difference is that the RC is formed of general managers and deputy managers of each institution and the MEEC is formed by technical staff from each institution. Each commission accepts application four times in a year. Assessment takes approximately three to four months. ("The waiting period").

As for generic product reimbursement coverage; the same application is submitted without cost-effectiveness analysis and a waiting period until the decision is finalized

Original products must provide a discount of 11% to be listed in the positive list. The said discount rate is for the first year; and it will be increased to 23% in the following year. Generic products must provide a discount of 23% in the first year.

## **10 Reasons for decisions on Pricing and Reimbursement**

**The Transparency Regulation 89/105 requires Member State authorities to provide a "statement of reasons based on objective and verifiable criteria" in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered**

**by a national health system (positive lists) or a decision to exclude it from reimbursement (negative lists).**

**10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

**10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

Commissions do not provide a statement of reasons for refusal to approve a price or include a product in positive list.

## **11 Reconsiderations / Appeals**

**11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

If the applicant is not satisfied with the determination on price or reimbursement status, the applicant may apply for reconsideration.

For price status, manufacturers and importers may apply before the Ministry of Health, when any revision is required. The applicant is obliged to document the information required for pricing and the procedure has to be completed within 90 working days following the application date. Decisions on price adjustments, after the initial price determination, have a 10 day deadline.

Relevant person in the case of refusal of the application shall make an objection to the commission, against the Reimbursement Commission decisions, within two months following the publish date or the notification date of given decision. Medical and Economical Evaluation Commission or Remuneration Commission examine the objection pursuant to examination and application calendar stated in article 6 of the Directive, for once only, if appropriate by receiving opinion from the technical commission.

**11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

There is no special procedure to appeal the decisions with regard to pricing and/or reimbursement. However, in theory, the decisions are made by administrative authorities, they are administrative decision and accordingly the persons concerned may bring directly a full remedy action or a full remedy action together with an annulment action to the Council of State and/or the Administrative Courts.

**11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions**

**and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

We are not aware of court orders for pricing and reimbursement issues.

## **12 Unlicensed products and off-label use**

### **12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?**

In Turkey, compassionate use (CU) programmes started in 2006. Patients suffering from a serious or urgent life-threatening disease, which have not responded to currently licensed and available medicinal products, or been enrolled in related clinical studies and who need access to products that are unlicensed in Turkey, but which are licensed/not licensed in other countries, can apply to CU programmes. These were described with the last guidelines of the Compassionate Use for Humanity Program in 2009.

However, costs of compassionate use products are not reimbursed by SSI. Pursuant to Guideline on the Compassionate Use Program, the therapeutic program where the physician has indicated that it provides benefit to the patient cannot be terminated unilaterally by the company. The company shall be responsible for procuring the drug until it receives registration in Turkey. In case it is requested by the company and approved by the Pharmaceutical General Directorate, the relevant company may continue to procure the drug until it is included into the reimbursement list.

### **12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?**

Off-label use is forbidden for curable diseases with approved indications. However; in case of treatment options that provide significant advantages in line with scientific data, demand for off-label use of drugs is reviewed by the Turkish Drug and Medical Device Institution.

Application forms shall bear the signature and stamp of the physician who monitors and treats the patient. Application form cannot be edited by patients, relatives, pharmacists or other parties. The applications for off-label use of drugs to be held in the electronic application system is planned by the Institution. The Institution will not accept the applications which are not made in the electronic system as of 01.01.2015.

The patient needs to have a severely disabled health status, i.e. life-threatening/debilitating condition with an approved diagnosis in order to start on an off-label treatment.

### **13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.**

There are not any special schemes for controlling the reimbursement price.

### **14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

Pharmacies receive their income from social security funds (reimbursement for patients that come with a covered prescription) and from private out-of-pocket payments from patients. They have to pay for drugs with 3 months maturity term, unless the wholesaler offers more generous payment terms as an incentive. Payment from SSI is received usually after 6 months.

In addition to their official income, pharmacies receive promotional (free) products from wholesalers for which they get full reimbursement – generating significant additional profits. The offer of free goods creates a strong incentive to recommend specific brands for purely commercial reasons and runs contrary to the intended cost containing effect of the generic substitution policy.

The system that pharmacies use to process dispensing of reimbursed products is based on an online connection to a server at SSI that checks every entry and clears or rejects it. If for example a patient has received a four week prescription for an antihypertensive, the next prescription will only be cleared after a reasonable time interval. This is an effective measure to reduce system abuse. Pharmacists cut off the bar code part of the package and submit it to SSI together with the prescription as proof that the drug has been dispensed.

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# Ukraine

The healthcare system of Ukraine is declared to be completely state-funded which means that public sector procurement is formally dominating compared to out-of-pocket purchase. However, there is around 90 per cent of retail sale of medicines and only up to 10 per cent are purchased for state and local budgets' funds (public procurement). As of today no coherent or well-structured reimbursement scheme exists. Only pilot projects on reimbursement in respect of certain medicinal products started to emerge in 2012. Besides, purchase of medicinal products in Ukraine is arranged based on different positive lists (e.g. list of medicines which may be publicly procured) and on the requirement to declare wholesale price (price of imported product or price of manufacturer) of medicinal products which are procured for public funds or are reimbursed under pilot projects. An important issue of Ukrainian market of medicinal products is that majority of them are imported from other countries and as of today there are no effective mechanisms to tackle negative impact of currency fluctuations on pricing and reimbursement schemes. All the prices are declared in Ukrainian currency – hryvnia.

## 1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied

**Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?**

As of today Ukrainian legislation does not impose an obligation of MA holders to obtain approval of the price and/or reimbursement status of medicinal products before they are placed on the market. There are two exceptions: 1) medicinal products procured for public funds and 2) medicinal products included into pilot projects on price' reimbursement in respect of antihypertensive and insulin products.

In case MA holder plans to sell medicinal products for public funds, he is obliged to declare the wholesale price in advance.

In terms of the pilot projects, antihypertensive products (included to the respective list of INNs) are subject to wholesale price' declaration before they are placed on the market (the requirement is valid until December 31<sup>st</sup>, 2014 but is likely to be extended). The same requirement will apply to insulin products starting as of January 1<sup>st</sup>, 2015.

### 1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of



**NAS is applied and how it is determined whether that definition is met.”**

Not required, unless they are purchased for public funds or included to the range of products approved by pilot projects.

**1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other “lifestyle” medicines).**

Not required, unless they are purchased for public funds or included to the range of products approved by pilot projects.

**1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.**

The wholesale price of any medicinal product (both prescription-only and OTC products) to be supplied to hospitals or clinics and for which a tender process will be applied has to be preliminary declared by the MA. It should be mentioned that only medicinal products included into the pre-approved by government list may be supplied to publicly funded hospitals and clinics (the “Procurement List”).

**1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

Not required, unless they are purchased for public funds.

**1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

Not required, unless they are purchased for public funds or included to the range of products approved by pilot projects.

**1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

Not required, unless they are purchased for public funds or included to the range of products approved by pilot projects.

**1.7 Orphan Medicinal Products.**

Not required, unless they are purchased for public funds.

**1.8 Parallel imports from another Member State.**

Not applicable for the reason that Ukraine is not a Member State and parallel import is not possible due to regulatory requirements.

**1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

As a clarification, pilot projects on reimbursement include the following medicinal products:

the pilot project on hypertension disease concerns medicinal products of 10 INNs and their combinations in the form of tablets and capsules;

the pilot project on diabetes concerns all insulin products.

**2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

There is no reimbursement element in respect of products purchased for public funds. Furthermore, as of today no reimbursement mechanism is implemented in respect of insulin medicinal products. Thus, only price' declaration is required before any product may be supplied for public funds or an insulin product is placed on the Ukrainian market (the requirement regarding insulin products will start to apply as of January 1st, 2015). The approval of wholesale price is made by the Ministry of Healthcare of Ukraine (the “MoH”) in accordance with the Procedure for Declaration of Wholesale Prices on Medicinal Products and Medical Devices approved by the Resolution of the Cabinet of Ministers of Ukraine (the “CMU”) dated 2 July 2014 No. 240 (the “Procedure for Price' Declaration”). The State Inspection of Ukraine on Prices' Control is involved to the price' approval procedure as an expert institution which verifies the calculation of the declared wholesale price. It should be noted, that under the decision of the CMU the State Inspection of Ukraine on Prices' Control will be liquidated in the nearest time and another state authority will be entrusted with verifying the calculation.

The price approval for antihypertensive medicinal products that fall under the regulation of the pilot project is also conducted by the MoH under the Procedure for Price' Declaration. Their reimbursement element is dealt with separately by the MoH in accordance with:

- The Procedure for Partial Reimbursement of Price of Medicinal Products for Treatment of Persons with Hypertension Disease, approved by the Resolution of the CMU dated 5 September 2012 No. 907; and The Procedure for Calculation of Marginal Level of Wholesale Prices on Medicinal Products for Treatment of Persons with Hypertension Disease and Comparative (Referential) Prices on Such Products,

approved by the Order of the MoH of 29 May 2012 No. 394.

### 3 Other Financial controls relating to supply

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

In regard of medicinal products that are:

- (i) included into pilot projects, or
- (ii) purchased for public funds, or
- (iii) included to the National List of the Main Medicinal Products and Medical Devices (save for narcotic, psychotropic medicinal products, precursors and medical gases) and Mandatory Minimum Assortment of (Socially Significant) Medicinal Products and Medical Devices for Pharmacies, adopted by the MoH,

marginal wholesale and retail mark-ups are established ranging from 10% to 25%.

Control over compliance with requirements listed above is vested in State Inspection of Ukraine on Prices' Control.

It should be additionally noted that, according to the recent practice, the Antimonopoly Committee of Ukraine (an authority in charge of antitrust and competition) within investigations on competition/antitrust violations tends to control "fairness" of the profit margin received by business entities operating on the market. In our opinion, this is obviously out of scope of the Committee's competence.

### 4 Pricing Criteria

**For those products identified in the answer to Q1 for which a price must be agreed:**

#### 4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?

Yes, there are elements of international reference pricing in Ukraine.

Within the scope of pilot projects reference prices are calculated based on the prices in Bulgaria, Moldova, Poland, Slovakia, Czech Republic and Ukraine. "Additional" reference countries (when respective medicinal product is not available in the countries above) are Latvia, Hungary and Serbia.

For medicinal products that may be purchased for public funds the reference price is calculated based on the prices

in Ukraine, Bulgaria, Moldova, Poland, Slovakia, Czech Republic, Latvia, Hungary, Serbia and the country of origin of the respective medicinal product.

The price of a product in reference countries is determined according to prices reflected on official web-sites of the Ministries of Health or other authorized state bodies which maintain registers of prices on medicinal products.

#### 4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?

Information on clinical and cost-effectiveness is not required in terms of defining pricing regulations.

### 5 Pricing control timelines

#### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

Under the Procedure for Price' Declaration MA holder or his representative shall submit declaration of wholesale price' change to the MoH along with substantiation of price change, reference on level of wholesale prices on the medicinal product in reference countries and in Ukraine, copy of marketing authorization for the medicinal product and power of attorney of the representative translated into Ukrainian and duly certified (or copy thereof duly certified). All documents must be submitted in two copies. One copy of submitted documents is sent by the MoH to the State Inspection of Ukraine on Prices' Control within 5 business days following the date of registration of applicant's documents in the MoH. The State Inspection of Ukraine on Prices' Control shall determine whether calculation of price submitted for declaration is economically reasonable. The State Inspection of Ukraine on Prices' Control must give its conclusion within 10 business days. Violation by the applicant of the Procedure for Prices' Declaration or unsubstantiated change of wholesale price may result in refusal to issue the conclusion. The MoH approves the order on declared change of wholesale price and enters it into the register of prices within 5 business days following the date of receipt of the conclusion of State Inspection of Ukraine on Prices' Control. Therefore, the stipulated timeframe for declaration of price' change constitutes 20 business days from the date of registration of submitted to the MoH documents. In practice the MoH rarely complies with the stipulated terms of price' change approval and a timeframe of up to two months may be expected.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

MA holders or their representative are entitled to declare change of wholesale price only once per calendar month and only due to changes in conditions for manufacture and trade in medicinal products which are independent from commercial activity of the applicant.

Maximum wholesale prices on medicinal products engaged in pilot project on treatment of hypertension are reviewed once a year based on official index of consumer prices on medicinal products calculated and regularly published by the State Statistics Service of Ukraine.

The pilot project on medicinal products for treatment of diabetes will not start until December 1st, 2014, and respective details on frequency of maximum wholesale prices' review are not yet adopted.

### 6.2 What controls apply to the right of company to:

- **Increase its price and are the criteria applied for approval different from these given in the answer to 4 above?**

N/A

- **Reduce the price generally or for a period?**

In respect of products described in Q.1 MA holder may increase the wholesale price only after declaring wholesale price' change in accordance with the Procedure for Prices' Declaration. Besides, MA holder should take into account that change of price may only be declared due to certain reasons which need to be substantiated by the applicant, namely: changes of conditions of manufacturing and sale of medicinal products which are independent from the business activity of the MA holder.

Furthermore, the wholesale price' change declared by an applicant may not exceed the maximum price determined according to applicable reference pricing rules as described in Q. 4 above.

In case of price' reduction there are no price controls applied and medicinal products may be sold at any prices lower than the declared level.

### 6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?

No, there is no mechanism for medicinal products' price' freeze in Ukraine.

### 6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?

No, there is no such requirement in Ukrainian legislation.

## 7 Other Types of price control

Does your jurisdiction control any of the following prices:

### 7.1 Full line or other wholesaler selling price

Yes. Any wholesaler must comply with the requirements as to marginal supply mark-ups which are up to 10% of wholesale prices for medicinal products:

- included into pilot projects;
- included into the National List of Main Medicinal Products and Medical Devices (Save for Narcotic and Psychotropic Drugs, Precursors, and Medical Gases) and the Mandatory Minimum Assortment of (Socially Oriented) Medicinal Products and Medical Devices for Pharmacies;
- which are purchased for public funds.

### 7.2 Pharmacy selling price

Yes. Any pharmacy must comply with the following requirements as regards marginal trade (retail) mark-ups:

- For medicinal products engaged in hypertension pilot project the marginal mark-up constitutes 25% of purchase price;
- For medicinal products included into the diabetes pilot project, medicinal products that may be purchased for public funds, and medicinal products included into the National List of Main Medicinal Products and Medical Devices (Save for Narcotic and Psychotropic Drugs, Precursors, and Medical Gases) and the Mandatory Minimum Assortment of (Socially Oriented) Medicinal Products and Medical Devices for Pharmacies, marginal trade (retail) mark-ups differ based on purchase prices for such products as follows:

Purchase price, UAH (appx. € as of 23.09.2014)	Trade (retail) mark-up to the purchase price, %
Up to 100 inclusive (6 €)	25
From 100 to 300 inclusive (6-17 €)	23
From 300 to 500 inclusive (17-29 €)	20
From 500 to 1000 inclusive (29-58 €)	15
Over 1000 (58 €)	10

## 8 Reimbursement – general principles and Transparency directive compliance

### 8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local govern-

**ment? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?**

As of today Ukrainian legislation does not provide for a general reimbursement system in respect of medicinal products. However, there are two particular approaches to reimbursement of the cost of medicinal products: 1) “privileged prescriptions” and 2) pilot projects.

“Privileged prescriptions” provide for full or 50% reimbursement of the cost of medicinal products included to the Procurement List to certain groups of population and in case of certain types of diseases. For instance, children up to three years old, veterans, persons suffered from Chernobyl disaster are entitled to free of charge medicinal products, while children aged 3 to 6 years, handicapped (since childhood) persons of 1 and 2 group are entitled to purchase medicinal products at the 50% price. Besides, persons suffering from certain diseases are also entitled to free of charge medicinal products, inter alia, diabetes, tuberculosis, HIV-AIDS, certain orphan diseases etc. Such reimbursement is funded by state or local budgets’ funds.

Reimbursement in the framework of pilot projects (as of today effective for medicinal products to treat hypertension and planned for medicinal products to treat diabetes) is based on national legal framework and state budget funding.

Hypertension pilot project involves co-payment as all medicinal products engaged in the project are divided into three groups:

- (i) Medicinal products, 90% of price of which is reimbursed
- (ii) Medicinal products, less than 90% of price of which is reimbursed (the amount of reimbursement is calculated in accordance with specific formula)
- (iii) Medicinal products, the price of which is not reimbursed

The patient pays the difference in the retail price and reimbursement price established by the MoH.

For diabetes pilot project rules regarding reimbursement procedure are not adopted yet.

**8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

There is a “positive list” including international non-proprietary names of medicinal products to treat hypertension. The MoH maintains the respective register which includes trade names of medicinal products subject to reimbursement mentioning the respective reference price and marginal prices for package and dosage form unit. As

regards diabetes pilot project, the rules for reimbursement of insulin medicinal products’ price are not adopted yet.

**8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

Reimbursement status is subject to formal approval by the MoH based on applicable regulations, not being subject to any local or regional reassessment.

**8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

The decision on reimbursement status is made by the MoH. The sole criteria for inclusion to any of the reimbursement groups for hypertension pilot project is correlation of the marginal price of the medicinal product with the marginal prices of other medicinal products with the same INN or with the prices of defined daily dose of respective medicinal product in reference countries. Health Technology Assessments are not yet implemented in Ukraine.

**8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?**

No, doctors are not able to override the reimbursement status of a medicinal product which is established in legislation.

## **9 Reimbursement – Administrative Arrangements**

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

No such procedure exists in Ukraine. Reimbursement has so far been implemented by regulatory acts of government in respect of certain products/diseases/groups of population. The provisions of such acts define which products shall be reimbursed and at which level. The MoH only implements such regulations without any discretion in terms of approving or disapproving decisions.

## 10 Reasons for decisions on Pricing and Reimbursement

The Transparency Regulation 89/105 requires Member State authorities to provide a “statement of reasons based on objective and verifiable criteria” in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it from reimbursement (negative lists).

### 10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?

As regards price’ declaration procedure the authority to refuse approval of the price proposed by an applicant is in fact vested with the State Inspection of Ukraine on Price’ Control. In case it refuses to approve the proposed price’ change it provides a “substantiated answer” to the MoH which informs the applicant in written form.

Concerning the reimbursement element, as explained in Q. 9 above no individual decisions in respect of each medicinal product are in fact adopted. Reimbursement status is awarded to products based on regulations adopted by the government. The reasoning for adoption of such regulations is provided together with their draft at the stage of drafting.

### 10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?

The Procedure on Price’ Declaration entered into force on 1<sup>st</sup> of August 2014 but the required subordinate rules have not entered into force yet (as of September 24<sup>th</sup>, 2014). Therefore no price approvals under the new procedure have been made as of today yet.

## 11 Reconsiderations / Appeals

### 11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?

There is no specific administrative procedure to challenge the decisions of the MoH regarding price or reimbursement status. Therefore, an applicant being refused has to submit a new price’ change declaration taking into account the reasoning why price approval was not awarded.

In practice, in case an applicant is not satisfied with the decision of the State Inspection of Ukraine on Prices’ Control in respect of the price’ change submitted for declaration he may address the MoH with counter-arguments in writing. In case an applicant believes that the MoH applied

regulations on reimbursement status incorrectly it may also send a letter to the MoH. Such letters are considered under the general legislation on requests from citizens within a month.

### 11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?

Yes. The timeframe for submitting the claim is six month following the day when the entity has become aware or was supposed to become aware of violation of its rights. However, applicants tend to avoid court disputes against the MoH on pricing and reimbursement questions.

### 11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?

Currently, we are not aware of any court practice regarding MoH’s decisions on pricing and reimbursement issues, probably for the reason that companies avoid litigation against the regulatory authority and attempt to settle disputes in amicable way.

## 12 Unlicensed products and off-label use

### 12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?

As mentioned above, there is no general reimbursement system for medicinal products in Ukraine. Within the framework of pilot projects reimbursement is only applicable to medicinal products holding marketing authorisation in Ukraine.

### 12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?

Off-label use is not applicable in terms of pilot projects on reimbursement for the reason that they concern specific diseases and specified medicinal products only.

## 13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go

**beyond the controls identified in the answer to question 1.**

In Ukraine there is no practice regarding any special schemes or patient-access agreements that go beyond legislative provisions identified in the answer to Q.1.

- 14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

No, there is no such legislation adopted in Ukraine yet. Each pharmacy shall draw up a register of dispensed medicinal products that includes international non-proprietary name as well as trade name of the product, dosage, pack size, number of the units in the pack, the amount of dispensed packs, reference price, the name of the medical institution where the prescription was issued, the sum to be reimbursed. The abovementioned register shall be submitted each month to state authorities which administer government subsidies for reimbursement in full in case all documents are filled in and submitted correctly and in accordance with the established requirements.

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# United Kingdom

## 1 Products having a marketing authorisation under EU law to which pricing / reimbursement controls are applied

**Is there a requirement in your jurisdiction imposed on the MA holder or his distributor or local representative to obtain approval of the price and/or reimbursement status of the following category of products before they are placed on the market or within a stated period from launch?**

The Secretary of State's powers in relation to the control of prices of medicinal products in the UK are set out in the National Health Service Act 2006 and subordinate legislation. In relation to branded health service medicines, these powers are exercised through the voluntary Pharmaceutical Price Regulation Scheme ("PPRS") and the alternative statutory scheme.

The PPRS is a voluntary scheme agreed between the Department of Health and the Association of the British Pharmaceutical Industry ("ABPI") under Section 261 of the National Health Service Act 2006. It has existed in various forms since the late 1950s and has been renegotiated about every 5 years. The current version of the PPRS is the 2014 scheme. Historically the PPRS has sought to control profit on sales to the National Health Service ("NHS") rather than prices per se, although more recently that situation appears to have changed.

The statutory scheme, under Sections 262-264 of the 2006 Act, is currently set out in the Health Service Branded Medicines (Control of Prices and Supply of Information) No.2 Regulations 2008, as amended. The statutory scheme is applicable only to prescription only medicines. All companies supplying branded health service medicines, who are not members of the PPRS, are automatically subject to the statutory scheme.

### 1.1 Prescription-only branded products whether on patent or off-patent. If initial pricing approval is only required for products that do not contain a New Active Substance, explain what definition of NAS is applied and how it is determined whether that definition is met.

Formal price approval is required in the UK for first marketing of:

- (a) new branded, health service medicines (as defined below) that do not contain a new active substance, supplied by companies who are members of the PPRS 2014; and
- (b) all new branded, prescription-only, health service medicines supplied by companies who are members of the statutory scheme, even if they contain a new active substance.

A "health service medicine" is a medicinal product used to any extent for the purposes of the NHS in the UK or for



services provided pursuant to the public health functions of the Secretary of State. A “branded medicine” is any medicinal product for which a marketing authorisation has been granted and to which a specific or brand name has been applied, that enables the product to be identified without reference to the generic title/INN.

New products introduced by PPRS member companies following the grant of an EU or UK new active substance marketing authorisation are generally subject to free pricing, as are new products based on the same active substance that are line extensions authorised within 5 years of grant of the original marketing authorisation. The Department of Health will confirm the new active substance marketing authorisation status with the relevant licensing authority. The 2014 PPRS does not otherwise define “new active substance”.

The price of new branded NHS medicines supplied by PPRS member companies, which do not contain a new active substance, must be approved by the Department of Health prior to launch. In reaching its decision, the Department may take into account factors such as the following:

- The price of other presentations of the same medicine or comparable products;
- Forecast sales and the effect on the NHS drugs bill;
- The clinical need for the product; and
- Any exceptional costs.

If, following discussion, agreement on the price for a new product cannot be reached between the PPRS member company and the Department of Health, the dispute resolution procedure under the PPRS may be invoked (see Q 11.1).

With respect to new branded medicines launched in the UK by companies who are members of the statutory scheme, the Secretary of State is empowered to specify the maximum price at which that presentation may be supplied for the purposes of the NHS, by way of a direction to the relevant company. In determining the maximum price for a presentation, the Secretary of State will have regard to criteria including:

- The expected supplies of the presentation for health service purposes;
- The cost of therapeutically equivalent medicines;
- The cost of the presentation in other markets (if relevant);
- The costs of manufacture;
- The costs of research and development of the presentation;
- Whether the presentation contains a new active substance; and
- The likelihood of the presentation being supplied at a particular price (which appears to allow consideration of whether supplies will be subject to

competitive tender to hospitals or otherwise subject to discounting).

## **1.2 Prescription-only products, but not ones for which reimbursement will be sought under the national health / social security systems (e.g. private prescriptions for hair loss or other “lifestyle” medicines).**

Products that are not supplied, to any extent, through the NHS are technically not subject to price controls. However, this situation is unusual.

There are provisions under NHS legislation<sup>1</sup> (see Q 8.2) prohibiting the prescription of particular products by General Practitioners, either at all (“the black-list”) or for specific indications (“the grey-list”). Prescribers in secondary care are also generally expected to adhere to these restrictions, although there is no legal prohibition on prescription of such products in hospitals. The inclusion of particular products within black or grey-lists has generally been limited to particular (more minor) therapeutic areas or “lifestyle” drugs, such as those for erectile dysfunction or hair loss. Products that are black-listed for all indications and have no NHS usage, fall outside the PPRS and, therefore, those that are supplied by PPRS member companies do not require price approval. (The statutory scheme however does not exclude “black-listed” products, and prices are therefore subject to the direction of the Secretary of State, as described above.) No products have been added to the “blacklist” since 1997 and any addition to the existing list would require the enactment of amending regulations.

## **1.3 Prescription-only products to be supplied to hospitals or clinics and for which a pricing tender process will be applied, in any event.**

The PPRS and the statutory scheme control the maximum price which may be charged to the NHS for specific branded medicinal products (referred to as “the NHS List Price”). Many companies supply products to hospitals and clinics at prices below the List Price under competitive tenders. However, there is no exemption to the requirement to agree a maximum price simply because the product will be supplied under public procurement procedures.

## **1.4 Products to be supplied OTC (whether capable of prescription under national health/social security systems or not).**

The PPRS covers all branded medicines used to any extent for health service purposes, including medicines which may be supplied on prescription or purchased OTC. Accordingly, all such products are subject to the requirement to agree an NHS list price with the Department of Health unless it can be shown that a particular presentation will not be purchased by the NHS, for example because it is only purchased OTC. In these cases, where NHS reimbursement

does not arise, there are no limits on the prices which may be charged

The statutory scheme only applies to prescription only medicines.

### **1.5 Generic medicinal products whether supplied under their common (INN) name or as so called branded generics.**

The prices of branded health service medicines, whether an originator product or a generic, are controlled under the PPRS and statutory schemes.<sup>2</sup>

There is no requirement for the manufacturer to agree the price of a new non-branded generic medicine with the Department of Health. However, the Department of Health has entered into a voluntary price regulation scheme with the British Generic Manufacturers Association under section 261 of the NHS Act 2006 which is applicable to manufacturers of non-branded generic products. "Scheme M", which has some similarity to the PPRS, provides that manufacturers of who join the scheme may price freely, save that the price of a new generic product, may not exceed the price of the equivalent originator product (there is no requirement for the price to be lower than that for the originator medicine at generic entry) and so long as they provide information to Department of Health (which it then uses to determine the reimbursement price for such products).

There is currently no statutory scheme in existence for controlling the prices of non-branded generic products supplied by companies who are not members of Scheme M.

In practice, the amount that pharmacists will be reimbursed for dispensing a generic medicinal product indirectly controls prices, and the reimbursement price of a product that is widely available as a generic is likely to be limited by the price of other generic products on the market (see Q 8.4 below).

### **1.6 Biosimilar medicinal products (whether the first or subsequent available product)**

There are no particular requirements relating to the price of biosimilar products. However in view of the complex structures of biological products and the differences between an innovator product and a biosimilar, MHRA's current position is that such medicines should be prescribed by brand name. Accordingly, in circumstances where all biosimilar medicinal products are available on prescription only and will be branded, they will accordingly be subject to the PPRS or statutory scheme.

Biosimilars are not viewed as "new products" for the purpose of the PPRS and, accordingly, the Department of Health's agreement to the proposed price must be obtained. New biosimilar medicines, launched by companies who are members of the statutory scheme, are subject to a direction from the Secretary of State as to the maximum

price which may be charged, in the same way as other new branded medicines.

### **1.7 Orphan Medicinal Products.**

There are no particular requirements relating to the price of orphan medicinal products.

### **1.8 Parallel imports from another Member State.**

There are no particular requirements relating to the price of parallel imports.

### **1.9 Please add any additional other products or product types and distinctions considered relevant in your jurisdiction.**

N/A

## **2 Relationships between pricing and reimbursement of products with a marketing authorisation under EU law – general principles**

**For those products identified in the answer to Q.1 for which approvals are required, are the pricing and reimbursement elements dealt with together or separately and, of so, by which agencies of government. Under what specific legislation are these decisions made?**

There is no formal reimbursement step or "decision" that has to be undertaken in the UK. Once the price is notified or agreed (see Q1 above) the product may, in principle, be reimbursed, if prescribed. In practice, however, reimbursement is controlled through local formularies and national commissioning policies.

The National Institute for health and Care Excellence ("NICE") is required by the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013, to conduct appraisals of the clinical-effectiveness and cost-effectiveness of most new medicines and new indications (and existing products in some cases), following which it issues recommendations on usage of such products to treat NHS patients in England and Wales. (A comparable body issues recommendations in Scotland and one in Wales appraises products which have not been considered by NICE. NICE's recommendations are modified for local application in Northern Ireland.)

NICE seeks to make its recommendations available as soon as possible after product launch. While in theory, medicinal products may be reimbursed prior to issue of NICE recommendations, in practice, hospitals (or NHS Trusts which are responsible for them) and Clinical Commissioning Groups (responsible for care provided by General Practitioners in the community) are unlikely to include a new product on their product formularies until it has been appraised by NICE.

NICE's recommendations are characterised as "guidance"; however compliance with NICE's guidance is a standard to which NHS bodies are generally required to adhere and against which they are audited. Furthermore, NHS bodies have a legal obligation, to make funding available for all medicines recommended by NICE, as options for use where the treating doctor and patient consider such treatment to be appropriate. The right to receive treatment recommended by NICE is also confirmed in the NHS Constitution. In contrast, there is no obligation for NHS bodies to fund medicinal products which have not been recommended by NICE and accordingly such products are not generally included in local NHS formularies for routine prescribing.

### 3 Other Financial controls relating to supply

**Do your authorities also impose additional financial restrictions on the MA holder or his distributor or local representative relating to supply of medicines e.g. any element of control of profit made on supply of products within the national health / social security systems, that can result in additional controls and financial rebates independent of price control?**

The PPRS controls the prices of branded medicines in part by regulating the profits a company is permitted to make on sales to the NHS. The scheme sets a target rate of return on NHS sales, based either on total sales or capital. Where NHS sales exceed capital employed (as included in the scheme member's UK audited accounts) by a factor of 3.5 or more, that company will be assessed on a return on sales ("ROS") basis, with a target of 6%. In other cases, the assessment is based on return on capital ("ROC") with a target of 21%. A margin of tolerance of 50% is permitted around the target level of profit. However if a company exceeds the profit limit by more than the margin of tolerance ("MOT"), it will be required to do one or more of the following: (a) repay excess profits over and above the MOT; (b) reduce prices charged to the NHS, to bring profits down to an acceptable level based on available forecasts; (c) delay or restrict agreed price increases.

The 2014 PPRS introduced a budget cap on the total expenditure by the NHS on branded health service medicines supplied by scheme members. To the extent that actual measured spend by the NHS on PPRS medicines exceeds the allowed growth rate, member companies will be required to make PPRS Payments, retrospectively, to the Government to cover the overspend.

These provisions are not applicable to companies that are not members of the PPRS.

## 4 Pricing Criteria

**For those products identified in the answer to Q1 for which a price must be agreed:**

### 4.1 Is there any element of international reference pricing and, if so for what countries and how is the price of the product in the other countries determined?

There is no formal reference pricing assessment conducted in the UK. The criteria under the PPRS to be taken into account by the Secretary of State when approving prices for new products (which do not qualify as new active substances) do not include consideration of the price agreed in other EU or third countries. In contrast however, the statutory scheme does list "the cost of the presentation in other markets (if relevant)" as one of the criteria to be taken into account when agreeing a price for a new product with members of that scheme. No particular countries are specified.

As set out above, NICE (and equivalent bodies in the devolved countries) will perform a cost/benefit assessment of certain products to decide whether they should be recommended for use within the NHS. This may result in pressure for price reduction or the offer of patient access schemes, which could theoretically include arguments based on prices offered in other countries.

### 4.2 What other criteria are applied in law (and practice if different)? Please address in particular any substance or therapeutic reference pricing. Is information on clinical and cost-effectiveness required or normally supplied voluntarily?

In reaching a decision on the acceptability of a proposed price for a new PPRS product that does not contain a new active substance, the Department of Health may take into account the factors listed at Q 1.1 above, including "the price of other presentations of the same medicine or comparable products" (clause 7.22 of the 2014 PPRS). As part of its assessment, the Department of Health may request additional information from the PPRS scheme member.

Similarly, when determining the maximum price which may be charged for any new product supplied by a member of the statutory scheme, the Secretary of State may have regard to criteria listed in the 2008 Regulations (see Q 1.1 above) including "the cost of therapeutically equivalent medicines".

The PPRS provides that, when companies are exercising freedom of pricing in relation to any product granted a new active substance marketing authorisation, they are expected to price the product at a level that will subsequently be found to be cost-effective by NICE. Clinical and cost effectiveness is not otherwise taken into account in relation to price, and NICE does not have a direct role in setting price.

## 5 Pricing control timelines

### 5.1 What, in summary, is the administrative system for the MA holder or his representative obtaining a price and what are the timelines?

#### New branded medicines launched by companies who are members of the PPRS

PPRS members are required to give the Department of Health a minimum of 28 days' notice before the date of launch of a new branded health service medicine on the UK market. The company may not launch a medicine until it has received confirmation from the Department of Health either that it has freedom of pricing (for products with new active substances and line extensions for 5 years) or that the proposed price is acceptable (for all other products).

#### New branded, health service medicines launched by companies who are not members of the PPRS

The statutory scheme provides that the Secretary of State will issue a direction specifying the maximum price that may be charged for a new branded health service medicine. In practice, the relevant company will propose a price, and this is accepted or reduced by the Secretary of State taking into account the factors listed in Q.1.1. There is no specified timeline for the decision making process.

## 6 Prices increases and reductions

### 6.1 How often are price determinations ordinarily reviewed?

#### Products supplied by companies who are members of the PPRS

Prices are not reviewed under the PPRS. Previous versions of the PPRS imposed a mandatory price reduction on list prices over the course of the relevant scheme. However, this is not a requirement of the 2014 PPRS.

#### Products supplied by companies who are members of the statutory scheme

Prices are not reviewed per se. However, the statutory scheme imposes a mandatory price reduction on all products on the UK market at a specified date. The statutory pricing scheme has been periodically amended to change the level of discount. The current statutory pricing scheme is applicable from 1 January 2014, and requires that a 15% price reduction is applied to all products that were on the UK market on 1 December 2013.

### 6.2 What controls apply to the right of company to:

#### Increase its price and are the criteria applied for approval different from these given in the answer to 4 above?

#### Products supplied by companies who are members of the PPRS

No scheme member may increase the NHS list price of a relevant medicinal product without the Department's prior approval. Where a company wishes to increase the price, it should give the Department not less than 8 weeks' notice. This notice should state the amount of the proposed increase and the reasons in sufficient detail to satisfy the Department that the increase is justified. The Department will only agree a price increase if the scheme member's estimated and forecast profits for the current and following finance years are below 50% of the target level. No scheme member will be awarded a price increase within 12 months of a previous agreed increase.

Any removal of discounts in secondary care should not increase net costs to the NHS. Therefore, where a company wishes to remove discounts offered to hospitals/ NHS Trusts in respect of a PPRS product, in all or most of the UK (excluding those in the context of competitive tenders), the company must notify the Department of Health 28 days in advance, stating what counterbalancing measures are proposed. The Department may reject the proposals where it concludes that the removal of discounts and counterbalancing measures are not cost-neutral.

In addition, the PPRS allows price-neutral modulation (increasing some prices and reducing others) across a company's product portfolio (measured by reference to NHS list prices in primary care and average selling prices in secondary care). NHS list prices may be increased through modulation to a level no greater than 20% above the level that existed on 31 December 2013, subject to the agreement of the Department. Companies must ensure that the overall cost to the NHS following price modulation is unchanged, e.g. the effect on the NHS is cost neutral.

The PPRS also allows "flexible pricing", where a scheme member can apply for an increase (or decrease) to a product's original list price where (i) there is significant new evidence in relation to an existing indication, which has the potential to significantly change the expected value to NHS patients when compared with the value at the original review of the medicine; or (ii) a significant new indication is proposed. This recognises that the initial launch price of a medicine may not fully reflect its longer-term value to patients, and so the price can be adjusted as new evidence or data are developed. This mechanism only applies to medicines that are subject to a NICE appraisal, and a review by NICE is required to determine whether the revised price provides value to the NHS. However, this mechanism has not been used by any pharmaceutical company since its introduction in the 2009 PPRS, and the approach of the Department of Health (and NICE) to requests for a price increase, and the level of evidence required, is uncertain. The 2014 PPRS, therefore, acknowledges that the provisions may need to be reviewed if there are no applications within two years of the commencement of the 2014 scheme.

#### Products supplied by companies who are members of the statutory scheme

Under the statutory scheme, the Secretary of State may either on his own motion, or on the application of a manufacturer, increase the maximum price of a medicinal product. Any such application by a manufacturer must state the reasons for the application and be accompanied by audited accounts for the last accounting year, showing, in respect of branded medicines:

- (a) the supplies of those medicines to the NHS;
- (b) promotion costs with respect to those medicines;
- (c) research and development costs;
- (d) non-recurring operational costs;
- (e) any other costs; and
- (f) total profit after interest charges and taxation.

The Secretary of State then has 90 days to make a decision, or notify the applicant of any additional information required.

#### **Reduce the price generally or for a period**

##### **Products supplied by companies who are members of the PPRS**

Scheme members may make temporary reductions to the NHS list price (and subsequently increase the price to a level no more than the price before the reduction) without agreement of the Department. However, companies must inform the Department at least 21 days before the changes take effect, and provide information on the existing and new prices, and the expected duration of the reduction.

##### **Products supplied by companies who are members of the statutory scheme**

A company is free to reduce prices as it wishes, as long as the mandatory price reduction in the legislation is met.

#### **6.3 Are product prices currently subject to any overarching price freeze for austerity or other reasons and, if so, is there a set review date?**

There are no price freezes as such. However, as indicated above (Q 6.1), the statutory scheme imposes a mandatory price reduction on all branded health service medicines supplied by statutory scheme members which were available on the UK market on 1 December 2013. Save for the limited circumstances described at Q 6.2 above, the PPRS permits no price increases unless these occur in the context of price-neutral modulation.

#### **6.4 When a first generic product enters the market, is there any obligation imposed on the branded product originator to lower his price?**

No; the obligation is simply that the price of the generic should not exceed the price of the originator product. Depending on the extent of generic competition, an innovator company may reduce its price in order to retain a proportion of the market. Where generic competition becomes more intense (e.g. where the market for the prod-

uct is larger), there is likely to be a progressive 'ratchet' down of price after generic entry.

## **7 Other Types of price control**

### **Does your jurisdiction control any of the following prices:**

#### **7.1 Full line or other wholesaler selling price**

In 2005, the Department of Health has entered into a voluntary price regulation scheme with wholesalers, known as "Scheme W". Similar to Scheme M for generic manufacturers, wholesalers of generic medicinal products are allowed to price freely, save that the price cannot exceed the price of the equivalent originator product, and so long as they provide information to Department of Health.

#### **7.2 Pharmacy selling price**

Medicines prescribed for NHS patients and dispensed in a retail pharmacy will be charged to the patient at the flat prescription charge rate (see Q 8.1 below). The pharmacist is reimbursed by the NHS Business Services Authority at the rate specified in the Drug Tariff (a monthly publication, specifying the amounts to be paid to contractors for providing relevant services) described at Q 8.3 below.

For products subject to patent protection, the reimbursement price paid to the pharmacist is generally the NHS List Price (see Q.1).

There are no controls relating to the price of products supplied on an OTC basis or on private prescription (as opposed to NHS prescription).

## **8 Reimbursement – general principles and Transparency directive compliance**

### **8.1 Please provide a brief overview of the reimbursement framework i.e. is it national or local; is it based on insurance or funding by central or local government? Does it involve co-payment? Are costs met in part by prescription / dispensing charges levied on the patient at the time of dispensing?**

The UK's national healthcare system is the NHS. It provides healthcare that is free at the point of delivery, and is funded primarily through general taxation. Approximately 11% of the UK population also has private health insurance, which is generally used as an add-on to NHS treatment.

The Health and Social Care Act 2012 made major changes to the structure of the NHS in England. Central to these reforms was the creation of a new body, the NHS Commissioning Board (now known as NHS England) that has been given a wide range of responsibilities for the provision of healthcare. While the Secretary of State for Health remains ultimately responsible for the NHS, NHS England is now

responsible for allocating funding for most NHS services. The 2012 Act also introduced clinically led commissioning, whereby Clinical Commissioning Groups (“CCGs”) principally made up of general practitioners, commission the NHS services required by their local patient populations, from NHS Trusts and other providers.

The health services in each of the devolved countries in the UK (England, Wales, Scotland and Northern Ireland) are managed differently and are accountable to their respective government bodies.

There is no system of co-payments for medicines supplied in hospitals. However, for products supplied in primary care, in the out-patient sector, patients must pay a fixed price for NHS prescriptions, unless they fall within one of the exempt categories (for example, children, the elderly and persons suffering from certain chronic diseases). The current prescription charge has been set at GB£8.20. In some cases this would exceed the price of medicine purchased pursuant to a private prescription.

## **8.2 Does your jurisdiction purport to operate a “positive list” or “negative list” in terms of products reimbursed i.e. is there an approved list or a list of products or categories of product that will not be reimbursed or only reimbursed where used for certain types of patient (e.g. products for erectile dysfunction due to surgery)?**

The UK operates a “negative list” system. Products listed in Schedule 1 or 2 of the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004/629 may not be prescribed by general practitioners using an NHS prescription form or may only be prescribed for the specified indications.

- Schedule 1 to these Regulations lists drugs and other substances not to be prescribed under the NHS (the “Black List”). This list can be found in Part XVIII A of the Drug Tariff. The UK has, in accordance with the Transparency Directive, notified the criteria for exclusion (e.g. on affordability/ cost grounds) to the European Commission.
- Schedule 2 lists drugs to be prescribed in certain circumstances under the NHS (the “Grey List”). It specifies groups of patients who may receive specific drugs for specific purposes. These drugs may not be prescribed to other types of patients or for different purposes. The list of drugs covered by Schedule 2 is usually referred to as the Selected List (previously the “Limited List”) and can be found in Part XVIII B of the Drug Tariff. If one of these drugs is prescribed, the doctor must endorse the face of the prescription with the reference “SLS”.

For completeness, while the UK has never purported to operate a positive list scheme and does not comply with the associated time-limits and other obligations under Article 6 of the Transparency Directive (89/105/EEC),

there is some Court authority for the proposition that NICE appraisals, with the associated obligation for NHS bodies to provide funding for products recommended by NICE, constitutes a positive list system (R on the application of Bristol-Myers Squibb Pharmaceuticals Ltd v. the National Institute for Health and Clinical Excellence [2009] EWHC 2722). This is a first-instance decision made without submissions by the parties on this issue and it is unclear whether it would be followed in future cases or upheld on appeal.

## **8.3 In respect of the product types identified as subject to reimbursement controls in the answer to Q1, is reimbursement status the subject of a formal approval or a recommendation only and, in either case, is this subject to any local or regional reassessment?**

There is no formal reimbursement step or “decision” that has to be undertaken in the UK.

### **Primary care/ community sector**

- Black- and Grey-listed products  
Save for black- and grey-listed products, described at Qs 1.2 and 8.4, there is no legal restriction on the medicinal products which may be prescribed by General Practitioners in primary care.
- Local formularies  
Individual CCGs prepare formularies, which seek to define the medicinal products prescribed by the General Practitioners for whom they are responsible. These local formularies are comprised of products recommended by NICE and those which have been assessed as clinically and cost-effective, based on local assessments. GPs are placed under substantial pressure to prescribe within the formulary and may be exposed to sanctions if they do not comply.
- Drug Tariff  
The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013/349 provide for the publication and maintenance of the “Drug Tariff”; similar regulations exist in Scotland and Northern Ireland.  
Pharmacies purchase medicinal products from wholesale distributors or directly from manufacturers; they are reimbursed by the NHS Business Authority for the products they dispense in the course of providing pharmaceutical services for the NHS, in accordance with the amounts set out at Part VIII of the Drug Tariff.

### **Secondary care/ hospital sector**

- The national tariff  
The Health and Social Care Act 2012 sets out a statutory basis for the “national tariff”, a set of prices for services carried out in NHS hospitals/ Trusts across the UK; this was subsequently introduced at

the end of 2013 and has operated from 1 April 2014. NHS Trusts are paid by CCGs based on procedures actually performed, and the cost of each procedure, including the costs of standard medicines required for the purposes of that procedure, is fixed by the national tariff (known as “currencies”). For high cost products, and new products that are not covered by existing currencies, the costs may be charged separately or the tariff is allocated an uplift, to cover the additional cost. The costs associated with the use of that product are negotiated separately, outside the national tariff system, by the relevant hospital/ NHS Trust and CCG.

The 2015/2016 national tariff has introduced the possibility for providers to opt-into an “Enhanced Tariff Option”, which will include a package of local variations and local pricing arrangements for certain services without a national price, including certain high cost medicines, previously excluded from the national tariff arrangements, with the aim of providing greater consistency and certainty for these services. So far, nearly all NHS providers have opted for this enhanced tariff.

- Hospital formularies

Like CCGs, NHS Trusts produce local formularies which determine the medicinal products generally available for NHS patients. Again, these are based on NICE guidance and, where NICE guidance is unavailable, on local assessment of cost-effectiveness. In contrast to General Practitioners, hospital prescribers are unable to prescribe outside the formulary, unless specific approval is given.

#### **8.4 Where a formal decision or recommendation on reimbursement is required, or occurs in practice, who makes the decision and what are the criteria applied? What role do health technology assessments of clinical or cost effectiveness play, whether made locally or in other Member States in respect of the same product?**

##### **Health technology assessments of clinical and cost effectiveness**

As set out above (Q2), NICE is required to carry out appraisals of most new products and new indications for existing products, and will issue recommendations based on an assessment of clinical and cost-effectiveness as to whether such products should be used to treat NHS patients. Cost-effectiveness is generally assessed by reference to the cost per quality adjusted life year gained (“cost per QALY”). NICE’s procedures state that products associated with an assessed cost per QALY of less than £20,000 will be recommended for use within the NHS. Over a threshold of £20,000 per QALY gained, products will be recommended based on consideration of a range of factors, including any uncertainty in relation to the conclusions reached, the innovative nature of the product

and whether all benefits associated with treatment have been adequately captured in the assessment of cost effectiveness. Over a cost per QALY threshold of £30,000, products will be recommended only in exceptional circumstances. For products which satisfy NICE’s “end of life” criteria (typically, certain cancer therapies) the benefits are weighted, giving an effective cost per QALY threshold of around £50,000.

NICE appraisals apply to products in both primary and secondary care and the resulting guidance determines whether the relevant product will be generally available to NHS patients.

##### **Primary Care**

- Black and Grey Lists

In contrast to NICE guidance, the Black and Grey-lists (Q 1.2) create a legal prohibition on prescribing of relevant medicines by General Practitioners to NHS patients. Decisions to add or remove products from these lists are based upon advice from within the Department of Health. Schedule 1 (drugs not to be prescribed) has not been amended since 1997. Schedule 2 (drugs to be prescribed in certain circumstances) has been amended many times. The criteria for inclusion on one of the lists are set out in Part XVIIIIC of the Drug Tariff as follows:

- medicinal products in seventeen therapeutic categories are excluded from prescription on the grounds that, on expert advice, they had no clinical or therapeutic advantage over other, cheaper, drugs, e.g. mild to moderate painkillers, indigestion remedies and cough and cold remedies.
- products considered as “borderline substances” which are not truly medicinal products with clinical or therapeutic value and are excluded from NHS prescription on that ground.
- as well as being freely available on sale over the counter to the general public, the cost to the NHS if the product(s) were to be supplied on prescription could not be justified at any price likely to be economic to the manufacturer, and that the supply of the product is not considered a priority for the use of the limited resources available to the NHS.
- products which nonetheless may meet a legitimate clinical or therapeutic need when properly prescribed, are subject to misuse by drug misusers, and such misuse, or the manner in which the product is administered by drug misusers, gives rise to the risk of physical or mental morbidity and alternative products are available to meet all legitimate clinical or therapeutic needs.
- a medicinal product or a category of medicinal products may be excluded entirely from supply on NHS prescription. It may alternatively be excluded except in specified circumstances, or except in relation to specified conditions or categories of condi-

tion, or specified categories of patient. A medicinal product or a category of them may be so excluded where the forecast aggregate cost to the NHS of allowing the product (or category of products) to be supplied on NHS prescription, or to be supplied more widely than the permitted exceptions, could not be justified having regard to all the relevant circumstances including in particular, the Secretary of State's duties and the priorities for expenditure of NHS resources.

- products which comprise an injection device pre-filled with a drug may be excluded from supply on NHS prescription if the same drug is available and can be used more economically in a container which may be used in conjunction with a refillable injection device.

#### – Drug Tariff

Pharmacists must submit NHS prescriptions that they have dispensed to the NHS Prescription Services, a service supplied by the NHS Business Services Authority. The NHS Prescription Services calculates how much pharmacists, GPs who dispense and appliance contractors should be paid as reimbursement and remuneration for medicines and medical devices dispensed to patients from NHS prescription forms, in accordance with the amounts specified in the Drug Tariff.

Part VIII of the Drug Tariff specifies three categories of medicinal products:

- (a) those which are readily available as a generic ("Category A") - price derives from monthly list price submissions by the major manufacturers and suppliers of generic products in England, namely AAH, Alliance Healthcare (Distribution) Ltd, Teva UK and Actavis;
- (b) those which are not readily available as a generic (normally because generic entry has been limited) ("Category C") - price is based on the price of a particular proprietary product; the Drug Tariff is annotated with an indication of which products forms the basis for the reimbursement price, and where this is absent, there is more than one product with a list price matching the reimbursement price; and
- (c) those which are readily available as a generic where the reimbursement price is based on pricing information submitted by manufacturers ("Category M") - price is determined by the Department of Health on the basis of pricing information submitted by manufacturers and wholesalers that are members of Scheme M (and an equivalent Scheme W for wholesalers) (which includes the volume sold and net income generated for each generic medicine), together with information from the NHS Business Services Authority on dispensing volumes.

Where medicinal products are not listed in Part VIII of the Drug Tariff (most medicines which are still subject to patent protection) or are prescribed by brand, the pharmacy contractor will generally be reimbursed at the manufacturer's list price.

#### Secondary care/ hospital sector

As indicated above, medicinal products used as standard therapy within the scope of routine NHS procedures are funded by CCGs as part of the national tariff within a standardised classification system.

Other medicines are supplied outside the national tariff arrangements through local, regional or national public procurement tenders. Products which do not meet public procurement thresholds are purchased under standard supply contracts.

Medicines in certain "specialised" areas are purchased under Specialised Commissioning arrangements developed at a national level by NHS England.

### 8.5 Where a formal decision or a recommendation is made, can doctors override that decision or recommendation applying their judgment on the special needs of a particular patient in a way that allows reimbursement of the product cost in whole or in part?

#### Primary care/ community sector

In primary care, the issue does not usually arise, as any prescribed product will be reimbursed at the price specified in the Drug Tariff, unless it is included in the Black or Grey Lists, in which case, it may be prescribed on a private prescription, paid for by the patient directly. Local formularies established by CCGs for the purpose of GP prescribing (Q 8.3), are not binding.

#### Secondary care/ hospital sector

In the hospital setting, clinicians, on behalf of their patients, are entitled to make a request (known as an Individual Funding Request) for treatment that is not routinely funded, where a case for exceptionality can be made out (i.e. where the patient's particular clinical circumstances fall outside the criteria set out in an existing commissioning policy).

## 9 Reimbursement – Administrative Arrangements

**What is the procedure and timeline for reaching agreement on the reimbursement price or a recommendation that the product should be reimbursed under national health / social security schemes?**

#### Black and Grey Lists

There is no specific procedure or timeline for amending these lists.

#### NICE Appraisals



As indicated above, most new medicinal products and new indications for existing products undergo appraisal by NICE. Such appraisal generally commences prior to grant of a marketing authorisation, although the appraisal committee will not meet to consider preliminary guidance until after CHMP has issued a positive recommendation (in the cases of applications under the centralised procedure) or a marketing authorisation has been granted. The process typically takes between 9 to 18 months to be completed.

Following NICE appraisal, NHS bodies are required to make funding available for the use of recommended medicinal products, usually within 3 months of guidance being issued. This should result in appropriate amendment of NHS Trust and CCG formularies within this timeframe. Conversely, products that, following appraisal, are not recommended by NICE are not expected to be the subject of routine commissioning.

Where products will not be appraised by NICE (generally because the expected budget impact is low) or where NICE appraisal has not yet been completed, commissioning policies may be developed either by CCGs at local level or by NHS England. The process followed in these cases is not uniform, but typically involves a form of assessment of cost-effectiveness.

### The Drug Tariff

The Drug Tariff (see Q 8.4) is produced monthly by the Pharmaceutical Directorate of the NHS Business Services Authority, and is supplied primarily to pharmacists, doctors surgeries and (twice yearly) to Nurse Prescribers. In relation to reimbursement prices of listed medicinal products, the following procedures and timelines apply:

- (a) Category A - prices are calculated using a weighted average formula, with AAH and Alliance Healthcare (Distribution) Ltd prices having twice the weighting of the prices from other suppliers. The suppliers submit their list prices to the Department of Health on a monthly basis and may result in changes to reimbursement prices, with the same degree of frequency.
- (b) Category C - prices are based on the list prices notified by the manufacturer. A price change up to and including the 8<sup>th</sup> of the month takes effect for prescriptions dispensed in the following month, and a change after the 8<sup>th</sup> will be applied to prescriptions dispensed one month later.
- (c) Category M - the Department of Health gathers information from manufacturers that are members of Scheme M (and an equivalent Scheme W for wholesalers) on volumes and prices of products, and from NHS Prescription Services on dispensing volumes, to set prices each quarter. The prices are adjusted every three months in light of the information received, and negotiations between manufacturers and the Pharmaceutical Service Negotiating Committee.

For product that are not specifically listed in the Drug Tariff (i.e. in Categories A, C or M), the pharmacist will be reimbursed at the manufacturer's list price.

The reimbursement price of all medicines dispensed by pharmacists is then reduced in accordance with a discount scale intended to reflect the average level of discount that pharmacists receive from their wholesalers and their assumed dispensing, in some cases, of cheaper parallel imports (see Q.14).

## 10 Reasons for decisions on Pricing and Reimbursement

**The Transparency Directive 89/105/EEC requires Member State authorities to provide a "statement of reasons based on objective and verifiable criteria" in respect of a refusal to approve a price proposed by the company or refusal to include a product in the list of products covered by a national health system (positive lists) or a decision to exclude it from reimbursement (negative lists).**

**10.1 In practice, do your authorities provide such reasoning supported (in the case of reimbursement decision) by the expert opinions or recommendations that they have relied upon in reaching a decision?**

### Pricing

The PPRS and the statutory scheme both set out the criteria that are taken into account when agreeing the price of a new medicinal product that is not subject to free pricing (see Q.1.1). However, while decisions issued by the Department of Health in relation to the prices of individual products include limited reasons (typically assertions based on the specified criteria) there is generally no attempt to explain the application of the criteria in the context of the evidence relating to that product.

### Reimbursement

Decisions relating to inclusion on the Black or Grey Lists are not accompanied by detailed reasons, although the criteria used to determine if a product should be included on one of these lists is set out in the Drug Tariff (see Q.8.4). Decisions to add or remove products from the Black or Grey Lists are based upon advice from within the Department of Health itself.

The national tariff and the Drug Tariff both set out details of the criteria taken into account and the basis for decision making (see Q.8.4) which enables decision-making on an individual drug level to be verified.

NICE guidance in relation to individual products, includes a summary of the evidence presented and the reasons for the recommendations made; the evidence relied upon for the purposes of guidance is disclosed, including any expert reports generated during the course of the appraisal process.

### **10.2 In your experience, is the level of reasoning viewed by companies as sufficient for their purposes including exercising rights of appeal?**

In general, the level of reasoning provided by NICE is detailed. Appeals are not uncommon, including where transparency of decision-making is viewed as insufficient.

However, in cases where NICE guidance is not available and decisions on NHS funding are, therefore, determined at local level by CCGs or by NHS England, the adequacy of reasoning is inconsistent and often inadequate.

## **11 Reconsiderations / Appeals**

### **11.1 What internal administrative appeal mechanisms exist if the applicant is dissatisfied with the determination of the authorities on price or reimbursement status?**

#### **Pricing**

Under the PPRS, if, following discussions with the Department, agreement cannot be reached on the price of the product, a company may refer the issue to the PPRS Dispute Resolution Panel. The Dispute Resolution Panel comprises a Chairman appointed by the Secretary of State (usually a qualified solicitor or barrister) and two members, one appointed by the Secretary of State and the other by the pharmaceutical industry body, the Association of the British Pharmaceutical Industry. The PPRS makes clear that the dispute resolution process under the scheme shall not entail any forfeiture of any other judicial remedy available to either party.

The Secretary of State's enforcement decisions under the statutory pricing scheme are subject to appeal to the NHS Medicines (Control of Prices and Profits) Appeal Tribunal (The Health Service Medicines (Price Control Appeals) Regulations 2000/124).

#### **Reimbursement**

Within NICE, an internal appeals procedure is available by which consultees (not competitor companies) may challenge guidance on limited grounds (procedural fairness, reasonableness and excess of powers). If an appeal is successful, the appraisal will be returned to the Appraisal Committee for further consideration.

#### **Local Formularies**

In general, local formularies issued by CCGs and NHS Trusts do not include an internal appeal route.

Where a clinician submits an individual funding request on behalf of a patient however, any refusal is generally subject to a review procedure.

### **11.2 Is a dissatisfied applicant also entitled to appeal any such decision to the Courts and, if so, what time limit, if any, applies?**

It is possible to bring administrative law proceedings, known as judicial review, challenging the process by which pricing and reimbursement decisions have been made. An application should be brought promptly, and in any case, within 3 months of the decision. There is no automatic right to judicial review, and all cases are subject to an initial permission stage, where the Court considers whether the applicant has raised a "prima facie case" and may proceed to a full trial. Permission to apply for judicial review is usually decided on the papers by the Court within 2 months of the application being made. However the overall procedure is likely to take at least 10 months before a decision is issued, although in some cases expedition may be possible.

Following success at judicial review, the Court will not generally substitute its decision for that of the relevant public body, but will simply return the matter for reconsideration, but following a correct procedure.

### **11.3 Have courts in your jurisdiction been engaged on pricing and reimbursement issues and decisions and, if so, what, in summary, are the main practical implications of these judgments for a pharmaceutical company?**

#### **Pricing**

Most challenges to pricing decisions of the Department of Health by PPRS member companies are brought via the internal dispute resolution procedure, rather than through the Courts. Where Court proceedings have been commenced, these have focussed on the interpretation of the PPRS (e.g. the price changes to be taken into account for the purposes of modulation (see Q 6.2)) rather than in relation to individual pricing determinations.

Traditionally, relatively few companies have participated in the statutory scheme. While therefore, the scheme provides an internal route for challenge to decisions of the Department of Health only in the context of enforcement action, we are not aware of any Court decisions following challenges by statutory scheme members.

#### **Reimbursement**

Legal proceedings have been commenced by (a) patients challenging local funding decisions; (b) companies challenging local funding decisions (e.g. formulary listings); and (c) stakeholders challenging decisions by NICE (or equivalent bodies in the devolved administrations).

Accordingly, proceedings may be brought against local NHS bodies by patients who have been refused access to a given product. These cases centre on two competing principles, namely the NHS's authority to decide what treatments should be funded in the context of limited resources and an obligation to meet its budget, and patients' entitlement to receive necessary clinical treatment for their condition. For example, the Court of Appeal has ruled that an NHS health body's policy to refuse funding for unlicensed Herceptin treatment save in exceptional

personal or clinical circumstances - but without taking into account the money available to the NHS health body - was irrational (*R (On the application of Ann Marie Rogers) v Swindon NHS Primary Care Trust & Secretary of State for Health* [2006] Lloyd's Rep Med 364). The Court stated: "Once financial considerations had been ruled out then the only concern which the [NHS body] can have must relate to the legitimate clinical needs of the patient". Accordingly because the relevant NHS body could not rationally make a difference between the cohort of patients who might benefit from Herceptin treatment and those who would not, it was irrational not to fund treatment for all patients who might benefit.

Companies have also challenged decisions by NHS bodies not to fund particular products or to prefer cheaper alternatives, although obtaining sufficient evidence of funding policies can be difficult. In 2012, Novartis challenged the decision of a group of several NHS health bodies to fund Roche's product Avastin as an alternative to Novartis' NICE-approved product Lucentis for patients with wet AMD; while the relevant formulations of Avastin were cheaper than Lucentis, they were unlicensed and there was limited evidence for ophthalmic administration. Ultimately, however, the policy to fund unlicensed Avastin was reversed against a background of concerns over legality, criticism by patient organisations, refusal by many ophthalmologists to prescribe Avastin (on the advice of the Royal College) due to liability concerns – and in circumstances where Novartis provided an enhanced discount for Lucentis. As a result Novartis' claim did not proceed to trial.

Given its key role in determining access to medicinal products by NHS patients, NICE's decisions have also been subject to challenge by way of judicial review. For example, in 2008 the Court of Appeal held that NICE's procedures were unfair, because a central part of the evidence relied upon for decision-making had not been disclosed to consultees to the appraisal (*R on the application of Eisai Ltd v National Institute for Health and Clinical Excellence (NICE)* [2008] EWCA Civ 438).

## 12 Unlicensed products and off-label use

### 12.1 Where unlicensed products are prescribed on a compassionate use or named-patient basis (and outside a clinical trial) are the costs reimbursed and, if so, is there any control over the level of price that may be charged?

There are no legislative provisions addressing this issue and the pricing of unlicensed medicines falls outside the control of the PPRS and the statutory scheme.

Historically unlicensed medicines could be priced at the discretion of the manufacturer. However from 1 November 2011, the Drug Tariff has been expanded to create a

new section on unlicensed medicines: Part VIIIB entitled "Arrangements for payment for Specials and Imported Unlicensed Medicines". This now sets limits on prices of a defined list of unlicensed medicines ("specials") when supplied on NHS prescription. The pricing of prescriptions for unlisted specials is restricted depending on how the product was sourced. Prescription of imported unlicensed medicines or products sourced in the UK from manufacturers holding a manufacturer's "specials" licence that are not listed individually in Part VIIIB attract reimbursement at the price endorsed on the prescription, and this must be the invoice price less any discount or rebate given to the pharmacist.

In general, unlicensed medicines dispensed in primary care are reimbursed in accordance with the above arrangements, although local formularies issued by CCGs may contain directions to General Practitioners on prescribing of such medicines. In secondary care, decisions on reimbursement of unlicensed products are made at the discretion of NHS England or individual NHS Trusts. However, from April 2014, the Department of Health has established the Early Access to Medicines Scheme ("EAMS") for products in phase II or III clinical trials which satisfy the designation of "promising innovative medicine". In accordance with these arrangements, any product supplied under an approved EAMS must be provided to the NHS free of charge.

### 12.2 Are there any restrictions on reimbursement for off-label use where such use is manifest from the prescription or other circumstances?

In secondary care, NHS Trusts may restrict the indications for which a product may be prescribed. NICE recommendations and patient access schemes (see Q13) may be limited to specific indications and these may, in practice, prevent off-label reimbursement. However, companies are also seeing cases where NHS Trust formularies list cheaper products for off-label indications, rather than a licensed alternative, in order to save on costs.

NICE guidance may also restrict the indications for which a product prescribed in primary care is recommended. However in practice, reimbursement in primary care is difficult to control. Pharmacy reimbursement is based on the product dispensed/used, and not the indication for which the doctor has prescribed the product, save for limited exceptions where a product is on the "Grey List" allowing NHS supply only for certain indications (see Q.8.2). In other circumstances, the product will be reimbursed under the normal rules, whether or not it is to be used for off-label use.

**13 Are there any special schemes or so-called patient access agreements that, in practice, control the reimbursement price for particular classes of products (e.g. orphan medicines or products for treating cancer) that go beyond the controls identified in the answer to question 1.**

The PPRS sets out a patient access scheme mechanism aimed at facilitating earlier patient access for medicines that are not, in the first instance, found to be cost effective by NICE, within a framework that preserves the independence of NICE. Such schemes, which may provide confidential discounts or involve outcomes based arrangements (e.g. cost per cure or rebates where a defined endpoint is not reached) have national application and must be approved by the Department of Health prior to implementation. These schemes are not limited to particular classes of products, although the PPRS recognises that they will be operable in primary care only rarely.

The Cancer Drugs Fund ("CDF") was established in 2011 in order to allow patients in England to access cancer medicines that are not routinely funded by their local NHS (either because they are not recommended by NICE or because they were not selected for NICE appraisal). The CDF is currently scheduled to continue until the end of March 2016. As a result of budget overspend, the allocation of funds to the CDF was increased in August 2014 and again in January 2015 and a new procedure was introduced, which added a crude measurement of cost to the previous requirement to conduct a form of assessment of cost-effectiveness, before cancer medicines would be included on the CDF List and routinely accessed by patients. This change in procedure, resulted in a number of products, previously included on the CDF List, being removed.

NICE has recently introduced a new procedure for the appraisal of Highly Specialised Technologies, indicated for very rare conditions (so-called "ultra-orphan" diseases), where a standard cost per QALY approach would produce results substantially in excess of the usual thresholds. While there is little experience of this procedure to date, it does not incorporate a standard cost-effectiveness assessment, although value for money and overall affordability are factors to be taken into account.

**14 Are pharmacists subject to any annual or other pay-back/ claw-back by the authorities of their aggregate turnover on products dispensed under the national health service/social security systems such that they**

**do not recover the full agreed reimbursement price per product for the units they have dispensed (e.g. to take account of any increase in margin they achieve by deep discounting by suppliers of generic medicines or dispensing of parallel imports).**

The price that a pharmacist is reimbursed for products that he dispenses on the NHS assumes that the pharmacy will have received a discount for the product from its distributor. The Department of Health expects pharmacists to receive these discounts in applying their discount deduction, or claw-back, to the amount of reimbursement provided for the products dispensed. This aims to ensure that the NHS obtains the "best deals" for supply of drugs and devices through NHS prescriptions. Clause 5B in Part I of the Drug Tariff specifically states:

"Payment for services provided by pharmacy contractors in respect of the supply of drugs, appliances and chemical reagents supplied against prescriptions at each separate place of business shall comprise:

(i) (a) The total of the prices of the drugs, appliances and chemical reagents so supplied calculated in accordance with the requirements of this Tariff.

LESS

(b) An Amount, based on the total of the prices at (i) (a) above, calculated from the table at Part V ("Deductible Scale")..."

The Deductible Scale in Part V sets out standard discount percentages based on the volume of combined monthly sales of all products. The level of discount was calculated based on a national survey of the average level of discounts offered to pharmacists, and does not relate to the actual discount received by a particular pharmacist. Therefore, the Department of Health assumes that a pharmacist will, on average, receive the level of discount set out in the Drug Tariff, and the reimbursement amount takes this discount into account. Pharmacists often purchase stock direct from pharmaceutical companies and wholesalers at lower prices and can, therefore, benefit from the marginal difference between the purchase price and the reimbursement price.

Some products are classified as "Discount Not Given" in Part II of the Drug Tariff, where it is acknowledged that due to the specific nature of the product, the pharmacist will not have received a discount for it, and therefore no deduction will be applied to the list price.

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Jackie Mulryne is an associate in the firm's London office and a member of the life sciences group. She advises clients in the biotechnology, pharmaceutical and medical device sectors and has a broad practice providing regulatory compliance and public policy advice. She advises on UK and EU law and has experience with a range of regulatory issues that arise throughout the product life cycle, including borderline classification, clinical research, authorisation, advertising and labelling and pricing and reimbursement. She has assisted a number of life science and medical device companies in developing and implementing cross-border regulatory action and compliance programmes.

Ms Mulryne advises on public and administrative law cases brought before the UK and European courts, including actions arising from the decisions of regulatory bodies, such as the Medicines and Healthcare products Regulatory Agency (MHRA), the European Medicines Agency (EMA) and the National Institute for Health and Care Excellence (NICE).

She trained at Arnold & Porter (UK) LLP and also spent time in the firm's Brussels office. She gained a Natural Sciences degree from Christ's College, Cambridge University and completed her Graduate Diploma in Law and Legal Practice Course at Nottingham Law School.



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Adela Williams is a partner in Arnold & Porter's London office. She is also medically qualified.

Her practice focuses on the regulation of medicinal products and medical devices in the UK and at EU level, particularly in relation to clinical trials, marketing authorisations and advertising, and promotional issues, including legal proceedings arising from the decisions of regulatory bodies.

She provides advice to clients in relation to pricing and reimbursement issues. This area of her practice involves consideration of both statutory and voluntary pricing regimes (PPRS) in the UK and representation at hearings before the PPRS dispute resolution panel. She also advises clients in relation to all stages of health technology appraisals by the National Institute for Health and Care Excellence (NICE), Scottish Medicines Consortium, and the All Wales Medicines Strategy Group and also in relation to assessments by the Cancer Drugs Fund. She frequently represents clients at NICE appeal hearings and has acted on behalf of the manufacturer company in two of the three applications for judicial review, brought against NICE in the Administrative Court.

She has substantial experience representing pharmaceutical and medical device clients in product liability litigation (unitary actions and group litigation) including claims involving unlicensed medicines in the research context as well as marketed products. Such litigation has often involved co-ordinating proceedings within the EU and advising on forum and other jurisdictional issues.



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