Market Access

Factors Supporting a Sustainable European Biosimilar Medicines Market

PROJECT SUMMARY FOR EXTERNAL COMMUNICATION

A study undertaken by GfK Market Access on behalf of the European Biosimilars Group, a sector group of EGA, about the future sustainability of the biosimilar medicines market

Prepared for the European Generic medicines Association

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1 THE BENEFITS OF A SUSTAINABLE BIOSIMILAR MEDICINES MARKET

A sustainable biosimilar medicines market will:

- Deliver major benefits and opportunities for the four key stakeholder groups – Physicians, Payers, Patients, and Industry
- Deliver significant cost savings (at all budgetary levels in the funding flow – National, Regional, Local) and opportunities to reduce financial deficits
- Deliver the opportunity for more patients to have access to better healthcare (treatment options) and improve patient access to innovative medicines
- Allow more patients to be treated at earlier stages of disease, when clinically appropriate
- Provide an environment that is attractive for continued investment in innovation (R&D), by both originator and biosimilar medicines companies, with consequent improvement of healthcare and health outcomes
- Make a significant contribution to the sustainability of National Healthcare Systems (NHS) and the consequent contribution to economic growth and the maintenance of employment

2 EXECUTIVE SUMMARY

Biosimilar medicines provide a major opportunity for cost savings throughout Europe by making a significant contribution to the sustainability of National Healthcare Systems (NHS) whilst improving patient access to innovative medicines in both the short and long term. However, in order to deliver these benefits it is imperative that the biosimilar medicines market remains sustainable.

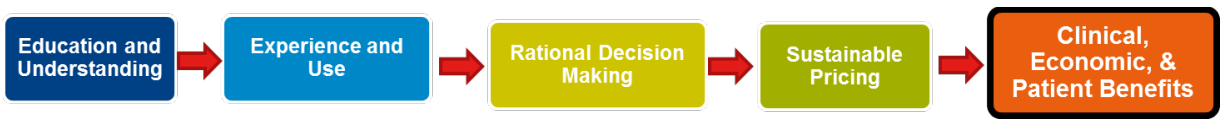
A sustainable biosimilar medicines market is one which is attractive and delivers continuing benefits to four key stakeholder groups (Physicians, Payers, Patients, and Industry) in BOTH the short and long term. The concepts of "attractiveness" and "benefit" differ amongst stakeholders, but potentially include: opportunities to treat more patients with appropriate therapies (Physicians), cost savings and financial sustainability of healthcare systems (Payers), improved access to medicines (Patients), and a reasonable return on investment with the continued attractiveness of R&D investment in new medicines development (Industry).

Policy development to establish and maintain a sustainable biosimilar medicines market requires holistic understanding of the dynamics of the market from all stakeholder perspectives, common shared understanding amongst all stakeholders of the comprehensive benefits that biosimilar medicines offer, and rational decision-making aligned with this shared understanding.

Policies and approaches in isolation (relating to Pricing, Switching, Substitution, Indication Extrapolation, Evidence Development, Clinical Guidelines, and Biosimilar Assessment & Access Decisions) are important building blocks for a sustainable market. However, it is the effect of policies in combination ("policy collision") that will deliver, or possibly fail to deliver, a sustainable market.

Four elements, considered holistically, provide a "**Sustainability Policy Framework**" for the biosimilar medicines market:

1. Education and Understanding
2. Experience and Use
3. Rational Decision-making
4. Sustainable Pricing



All four elements are required for sustainability. They are synergistic and are not independent of one another. Sustainable pricing policies in the absence of education, understanding, and experience, and rational decision-making in the absence of a differentiated value proposition, will lead to an unsustainable biosimilar medicines market.

3 OBJECTIVES AND SCOPE OF STUDY

The objectives of the study were:

- To establish the key policy areas that will drive the establishment of a sustainable biosimilar medicines market
- To develop a high-level, transparent understanding of the interactions and dynamics within and between policy areas
- To identify a set of policy measures that should be implemented by politicians (National and European level) and other stakeholders that would contribute to the growth of the biosimilar medicines market
- To outline the benefits that these will bring, with particular focus on the benefits for European National Health systems (increased savings to the National Health systems whilst treating more patients) and the economy (growth impact and job creation)

The study was undertaken across 7 countries: France, Germany, Hungary, Italy, Poland, Spain, and the UK. Conclusions are based on in-depth contributions from 71 experts and policy influencers at the National and Regional levels (some who influence pan-European policies), and from multiple stakeholder groups - Physicians, Payers, Pharmacists (hospital and retail), Patients, and Industry. **As a consequence, the resultant insights reflect the different perspectives of multiple stakeholders**.

Quantitative modelling was based on 3 representative, but significantly different, biologic products (Herceptin®, Avastin® and Humira®) in the EU5, and dynamics were based on a Delphi panel of expert opinions. The five forces of supplier power, buyer power, impact of new entrants, impact of substitutes, and competitive rivalry were addressed. A ranking of the attractiveness of various policy combinations from a sustainability and benefit perspective was made based on a biosimilar medicines market **"Sustainability Index"** (*see appendix*) and the calculation of the magnitude of the benefits (cost savings, additional patients treated) that the policy combination was likely to produce.

4 SUSTAINABILITY POLICY FRAMEWORK

A European biosimilar medicines industry based on stakeholder and policy alignment within the four elements of the "Sustainability Policy Framework" will be sustainable and deliver significant benefits to all stakeholders. Within each of the elements there are key concepts that must be considered.

Education and Understanding

- There is a need for **clear** information from **unbiased** sources, that is non-promotional, targeting doctors, other healthcare professionals, payers and patients
- Education is required on the **scientific concept of biosimilar medicines**, their approval process, and their safety and efficacy
- Stakeholders require an appreciation for the fact that **biosimilar medicines are not generic medicines**. The development and manufacturing processes of biosimilar medicines are more complex and much more expensive than of chemical small molecule medicines.

Experience and Use

- Accelerated **experience and uptake of biosimilar medicines** will be important for short term benefit (to payers, physicians, patients, and biosimilar companies) and the long term sustainability of the market and healthcare systems
- Physician (and other stakeholder) **confidence and trust should be established** via encouraging and incentivising appropriate early use, and encouraging the collection and publication of Real World Evidence (RWE) (*see appendix*)
- In the long term, provided that patient benefit is core to the decision, and once confidence and trust have been established, the following approaches would also be supportive of the **biosimilar medicines industry sustainability**:
    - **The Physician should always be involved in both procurement and utilisation decisions**
    - **Procurement and utilisation policies should evolve to include multi-stakeholder input and agreement. Such policies should be evidence-based and risk-minimised**
        - **Early Use:** predominantly a physician driven decision
        - **Intermediate Use:** physician/pharmacist/payer driven decision (multi-stakeholder approach)
        - **Well Established Use:** predominant pharmacist/payer driven decision
    - **Procurement and utilisation policies should be transparent to all stakeholders, not be driven by consideration of cost alone, or be influenced by consideration of pharmacist remuneration**
- The fundamental concept of "Indication Extrapolation," which is at the core of biosimilar regulation, should be clearly **communicated and explained to all stakeholders in a context and language that provides complete understanding**

Market Access

Sustainable Pricing

- Policies that maintain and **encourage competition** favour sustainability
  - Ensure regulation does not create an uneven playing field with Biosimilar A being treated differently to Biosimilar B, as fair competition requires a level playing field.
- Avoid pricing and procurement policies that drive prices to levels that **threaten the financial viability** of the biosimilar medicines industry and **undermine continued investment** by the pharmaceutical industry in future innovation (R&D). Situations where, in the longer term, all stakeholders eventually lose via:
  - Negative impact on **innovation** (lower pricing reference point for future advanced innovative therapies, making investment in future innovation in the therapy area less commercially attractive)
  - Reduced **return on investment** (ROI) for the biosimilar medicines industry, reducing attractiveness of investment in the next wave of biosimilar medicines, consequently threatening continuity of the cost saving and patient access benefits delivered by biosimilar medicines

Rational Decision Making

- Pricing, procurement, positioning, and utilisation decision-making processes of National Healthcare Systems should be **transparent** and should **not delay time to pricing, reimbursement or access**
- Pricing approval and market access (including access to National and Regional tenders) should be as close as possible to the date of biosimilar marketing authorisation
- Biosimilar medicines should not require a Health Technology Assessment (HTA) in situations where assessment of the biosimilar medicine is futile and does not add value
  - In situations where an originator (reference product) has not been recommended for reimbursement, or restricted to a conditional recommendation, or patient access has been denied on economic grounds by the HTA body, the policy should not exclude an HTA assessment of the biosimilar medicine if there is reasonable chance that it will be able to demonstrate cost-effectiveness

- Pricing, procurement, positioning and utilisation decision-making should **encourage**:
  - Recognition of the value of differentiated “Product Offerings” (e.g. Drug delivery, Value-Added Services, Point of Care)
  - Recognition of the value of differentiated “Pricing Propositions” (e.g. innovative contracting agreements and economic predictability)
  - Recognition of the value of outcomes data to Payers (economic), Physicians (clinical), and Patients

- Encourage stakeholder collaboration (e.g. Payers co-funding the generation of relevant outcomes data)
- Look at cost in the context of additional factors (e.g. outcomes and service provision) and apply weights in procurement decisions to reflect factors other than price.

- Procurement decision-making should **avoid**:
  - Systems that distort the market or lead to an arguably unfair position of dominance (e.g. exclusive tendering policies)
  - Measures that lead to conflict between stakeholders (e.g. Physician / Pharmacist, Payer / Physician, Payer / Industry)

5 IMPACT OF POLICY ON THE SUSTAINABILITY OF THE BIOSIMILAR MEDICINES MARKET

The policies that make the **strongest contribution** to the sustainability of the biosimilar medicines market are those that:

- Increase prescriber confidence and trust (information, education, evidence)
- Encourage early use and experience
- Incentivise appropriate use of biosimilar medicines
- Promote competition
- Encourage transparent, multi-criteria decision-making with price as a major factor

Policies that **weaken / undermine** the sustainability of the biosimilar medicines market are those that:

- Lead to conflict between stakeholders (e.g. Physician/Pharmacist, Payer/Physician, Industry/Payer)
- Drive prices to levels that threaten the financial viability of the biosimilar medicines industry and make continued investment unattractive to both the pharmaceutical industry (future innovation) and the biosimilar medicines industry (new biosimilar medicines)
- Distort the market or lead to an arguably unfair position of dominance (e.g. exclusive tendering policies)
- Establish procurement/tender/contracting systems that are not transparent and in which the decision criteria are unclear to the participants
- Create an uneven playing field (e.g. mandatory price discounts that increase with order to market)

6 QUANTITATIVE IMPACT OF POLICY

Quantitative analysis indicated that the optimal policy combination consistent with a sustainable biosimilar medicines market was the same for all three products studied (Herceptin®, Humira® and Avastin®). This comprised of policies that promote:

- Intensive "understanding and education" programs
- Capturing and communicating Real World Evidence (RWE) in order to build confidence and trust (but not as a requirement for access)
- Incentivisation programs to encourage use and experience
- A sustainable competitive pricing environment with price levels consistent with financial viability and a fair return on investment
- Indication extrapolation is understood and accepted by all stakeholders - a valid regulatory concept applied to all medicinal products. Indication specific data in all of the reference indications is not a requirement at launch for access or utilisation (underpinned by education/understanding and RWE programs)
- Procurement and utilisation policy which involves multiple stakeholders, including physicians, in the choice of therapies available for patients, and how those therapies should be used within prescribing guidelines

The combination of these policies delivers greatest benefits across all stakeholder groups.

Typical benefits seen were:

Molecule	Cumulative 10 year Savings† (EU5)
adalimumab (Humira®)	26%
bevacizumab (Avastin®)	24%
trastuzumab (Herceptin®)	25%

Note: EU5 is composed of France, Germany, Italy, Spain, and the UK

Many of the patients who would benefit from anti-TNF treatment, but are currently denied on economic grounds, will benefit from anti-TNF biosimilar medicines. The research indicated that there is an upside potential for more patients to be treated if anti-TNFs are introduced earlier in the treatment algorithm.

There is a significant experience with bevacizumab in many tumour types and lines of therapy for which there is no licensure. This leads GfK to believe that there may be significantly more patients who may benefit from bevacizumab therapy due to the opportunity created by the arrival of biosimilar medicines.

The opportunity to treat more patients with trastuzumab is greater in countries like Poland and Hungary, where trastuzumab access and use is currently more restricted due to economic considerations.

† Bevacizuab (Avastin®) and adalimumab (Humira®) are currently licensed in a wide range of indications. Lower prices of an originator product in one indication, triggered by the entry of biosimilar medicines, will lead to cost savings in all the indications in which the originator product is licensed.

APPENDIX

BACKGROUND

The study was commissioned by the European Biosimilars Group (EBG), which is a sector group of the European Generic medicines Association (EGA). The vision of the EGA is to provide sustainable access to high quality medicines for all European patients. The EGA Member Companies' medicines underpin the economic sustainability of Europe's healthcare systems, enabling investment in new medicines that Europe's patients increasingly need. The EGA is determined to continue to work with Europe's policy makers, legislators and regulators to create the right environment to support and strengthen the economic sustainability of the industry, ensuring continued contribution to European patients and society.

DEFINITIONS

RWE – Real World Evidence: In addition to the standard safety monitoring requirements of licensure (PSUR) - Post Marketing studies, Observation of Use studies, Retrospective Chart Reviews, Prospective Registries, Drug Utilisation Audits (DUAs). Such studies should, where possible, capture outcomes data. Such studies should NOT be a requirement for access, but should be considered "facilitators" for developing early experience, confidence and trust.

Sustainability Index: The "Sustainability Index" is a simplification of the "Efficiency Frontier" approach, well documented in Economic Theory. Scores are allocated for each stakeholder group: Red = 0, Amber = 1, Green = 2, where the colour represents the attractiveness of a policy or policy combination from the perspectives of the stakeholder group. The perfect policy combination would be one that scores green with all stakeholders (Physicians, Payers, Patients, Originator Product and Biosimilar manufacturers) giving a sustainability score of 10 (= 5*2). The sustainability score is calculated for all scenarios. This is then expressed as a fraction of 10. This number (between 0 and 1) is the "Sustainability Index". The higher the sustainability index, the more sustainable the biosimilar medicines market. It is used to identify the most attractive policy combination(s) that would deliver continuing benefits to the key stakeholder groups in BOTH the short and long term.

THIRD PARTY LIABILITY DISCLAIMER

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In reading, interpreting, and implementing any recommendations from this report, consideration should be given to ensuring compliance with all relevant EU and National regulations and laws including, but not limited to, competition, pricing, collusion, and market dominance.

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