Pharmaceuticals in TTIP

Making sure European patients can get the medicines they need

In this chapter, we want to:

- make it easier and cheaper to sell some US medicines on the EU market, and EU medicines in the US
- support each other as we develop regulations in new areas.

Reasons for negotiating pharmaceuticals

We already work together a lot with the US in the area of pharmaceuticals - for example, we have already removed tariffs.

This is also valid for regulations. We still have, however, some work ahead of us. With TTIP, we can strengthen this collaboration and make a difference for consumers and the industry.

More specifically, we want to:

- make the access to complex medicines easier and cheaper for patients – TTIP could foster the development and approval of generics (biosimilars) of biological medicines, such as vaccines and insulin
- improve and speed up the way generic medicines are approved, including the rules on what information needs to be submitted to EU and US authorities in this process
- make sure that special medicines for children or other speciality products, like medicines for rare diseases, are available for the patients that need them.

EU goals

In this part of the agreement, we want to:

- recognise each other's Good Manufacturing Practice (GMP) inspections of manufacturing plants, so we don't unnecessarily do the same work twice
- exchange information between regulators - this helps them when they have to decide whether or not to approve new medicines
- work together on our requirements for approving 'biosimilars' - products similar to already-licensed biological medicines, such as vaccines
- streamline systems for authorizing generic drugs
- strengthen our collaboration under the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (**ICH)**
- pave the way for **closer EU-US collaboration** in areas not covered or insufficiently covered internationally
- support the joint development of compatible regulations on innovative areas not yet fully regulated.
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Sensitive or controversial issues

In this area, some issues are sensitive or controversial.

Here's a summary of some key issues and what we're doing to address each one.

Sensitivity/concern	EU response
1. Drug costs and reimbursement	
TTIP will change the way public authorities decide on the pricing or reimbursement of medicines.	EU Member States will continue to take decisions on the pricing and reimbursement of medicines. This will not change with TTIP nor with any other trade agreement. Those decisions only have to follow some transparency principles as set out in Council Directive 89/105/EEC.
2. Release of data	
TTIP could undermine the policy of the European Medicines Agency on releasing data from clinical trials.	In October 2014, the European Medicines Agency published its final policy on publication of clinical data. TTIP will have no influence on this policy nor on the Regulation on clinical trials (Regulation No 536/2014) that enters in force in May 2016.
3. Intellectual property (IP)	
There will be more protection of intellectual property rights (IPR) – meaning medicines will be more difficult to get and more expensive.	Both the EU and US have a solid and comprehensive IPR system which allows innovation companies to thrive and to remain among the most competitive in the world. We will not negotiate any IP rules that change this delicate balance or put more strain on already stretched national health budgets.