European Commission

Towards an EU-US trade deal
Making trade work for you

The Transatlantic Trade and Investment Partnership (TTIP) Regulatory Issues

EU position on pharmaceutical products

1. Introduction

The final report of the US - EU High Level Working Group on Jobs and Growth of February 2013 highlights that as regards regulatory aspects TTIP should contain in addition to cross-cutting disciplines and TBT plus elements provisions concerning individual sectors.

This paper presents an approach under TTIP on pharmaceutical products and contains preliminary ideas that build on the outcome of consultations carried out in preparation of the TTIP and existing cooperation between EU and US regulators in this area.

Regulatory cooperation between EU and US in the pharmaceutical area, supported by certain existing confidentiality arrangements, is very well established both at bilateral level as well as at multilateral level, notably via the International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use.

TTIP could reinforce existing collaborative processes on pharmaceuticals by:

- establishing bilateral commitments that would facilitate pharmaceutical products authorization processes and optimise agencies' resources (notably with respect to Good Manufacturing Practices (GMP) inspections and exchange of confidential information)

- fostering additional harmonization of technical requirements in new areas or in areas where the need to improve harmonization at bilateral or international level has been identified (e.g. biosimilars, paediatrics, generics, terminology)

- reinforcing joint approaches on scientific advice and evaluation of quality by design applications.

The proposed actions should enable a more efficient and focused use of the resources of the regulators, facilitate building on the best available regulatory practices, and reduce unnecessary duplications (including with respect to clinical trials) for the benefit of patient safety, innovation and greater cost-effectiveness.

They would be compatible with the EU regulatory framework for medicines and with the EU approach on mutual recognition of GMP inspections already adopted in agreements with third countries.

2. Possible elements for pharmaceuticals provisions in TTIP

2.1. GMP inspections

Both Parties should explore possibilities for the recognition of each other's Good Manufacturing Practices (GMP) inspections carried out in the EU and the US and in third countries.

An advantage of this approach would be that US Food Drug Administration (FDA) and EU Member States would allow a better use of the inspection resources by avoiding the current overlap of inspections of third countries facilities and EU and US facilities which have been already inspected by one of the Parties.

This would significantly strengthen the already existing bilateral collaboration that is currently limited to major incidents. In addition, this approach would entail significant cost savings for the industry.

A rigorous assessment of the respective GMP systems in view of determining their equivalence should take place. In addition, provisions on the exchange of confidential/trade secret information should be in place for such approach to function.

2.2. Exchange of confidential information and trade secret information

Both Parties should explore possibilities for allowing the exchange of confidential information and trade secret information between EU Member States/EU institutions and FDA. This approach would apply not only to GMP and other inspection reports but also to data and information on marketing authorizations applications.

TTIP could entail legal provisions allowing the exchange of confidential information in the horizontal chapter as well specific confidentiality provisions in the pharmaceuticals annex.

Innovative approaches from industry could greatly contribute to the realisation of this objective.

2.3. Harmonisation of requirements for the authorisation of biosimilars

Both Parties could commit on converging systems for the authorisation of biosimilars. FDA and the European Medicines Agency (EMA) are expected to pursue their scientific exchanges which contribute to the development or review of their respective guidelines.

In the context of the current development of the authorisation system for biosimilars in the US, an advantage of this approach would be the potential increase of approved biosimilars in the US and limit the number of diverging requirements to demonstrate the quality, safety and efficacy of these products.

In addition, US and EU could shape the international approach for the review/authorization of biosimilars.

2.4. Collaborating in generics authorisation systems

Both Parties could explore the possibility to streamline authorisation systems for generics including the development or review, if need be, of respective guidelines in particular as regards bioequivalence, biowaivers and the use of reference medicines.

2.5. Revising requirements for paediatrics authorization

Both Parties could work towards the revision of ICH guidelines on paediatrics in particular by agreeing on clinical studies design (paediatric investigation plans, data collection for small clinical trials with particular interest to treat rare diseases, template for information for benefit risk assessment) and by mutually accepting clinical studies.

In addition, both Parties could agree on a common format and compatible timing for submission of the paediatric investigation plan.

2.6. Terminology for pharmaceutical products

Both Parties could work towards the implementation of a harmonized terminology for pharmaceutical products (unique identification of medicinal products and substances, pharmaceutical forms, routes of administration, etc.).

This approach would improve the information flow between enterprises and regulators and between regulators of both Parties.

2.7. Bilateral cooperation on joint assessment approaches

Both Parties could commit to continue existing cooperation on 'parallel scientific advice' (joint discussion between EMA, FDA and applicant/sponsor of scientific issues during the development phase of a new product) and existing cooperation on 'parallel evaluation on quality by design applications' (joint list of questions to the applicant and harmonized evaluation of the applicant's responses).

This approach has the advantage of optimizing product development and avoiding unnecessary clinical trials/testing replication, optimising agencies resources (sharing assessment reports/authorization decisions) as well as important costs savings for industry.

Provisions on the exchange of confidential/trade secret information or industry readiness to allow such exchange should be in place to allow such approach to function.