Annex III

INITIAL POSITION PAPER

PHARMACEUTICALS IN TIIP

INTRODUCTION

The final report of the US - EU High Level Working Group on Jobs and Growth (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.

The purpose of this paper is to present some possible elements for a TTIP annex on pharmaceutical products. It is based on ideas put forward by EU and US industry and builds on existing cooperation between EU and US regulators in this area. It is anticipated that stakeholders will continue to support the process and could play an active role towards the implementation of some of the identified objectives.

Regulatory cooperation between EU and US in the pharmaceutical area supported by existing confidentiality arrangements is very well established both at bilateral level as well as at multilateral level via ICH (International Conference on Harmonization 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 reliance on each other's GMP inspections results 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).

POSSIBLE ELEMENTS FOR A PHARMACEUTICALS ANNEX IN TTIP

GMP inspections

Both Parties could explore possibilities for the improvement of the recognition of each other's GMP inspections carried out in third countries and inspections carried out in EU and US territory.

An advantage of this approach would be that FDA and EU Member States would be able to focus their resources on inspecting high risk areas (which are located outside EU and US) instead of spending resources on inspecting third countries facilities and EU and US facilities which have been already inspected by one of the Parties. In addition, this approach would entail significant cost savings for the industry.

Although the EU has functional MRAs or equivalent in place with Canada, Japan, Switzerland, Australia, New Zealand and Israel, between the EU and US a more flexible approach could be taken.

Therefore, in TTIP, a system based on mutual reliance on each other's GMP inspections (instead of legally binding mutual recognition) could be envisaged. Such approach should include progressive targets that would contribute to confidence building.

Provisions on the exchange of confidential/trade secret information should be in place for such approach to function.

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.

Establishing functioning systems for the authorisation of biosimilars

Both Parties could commit on establishing functioning systems for the authorisation of biosimilars. The FDA could benefit from the experience of EMA that has already completed opinions on 16 biosimilars. FDA and EMA are expected to pursue their scientific exchanges which contribute to the development or review of their respective guidelines. In particular, a formal acceptance of comparative clinical trials based on reference medicines sourced in the EU or US or in third countries should be envisaged.

An advantage of this approach would be the potential increase of approved biosimilars in both markets. In addition, US and EU could shape the international approach for the review/authorization of biosimilars.

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) and by mutually accepting clinical studies. In addition, both Parties should agree on the timing for data submission.

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.

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 would have the advantage of optimizing product development and avoiding unnecessary clinical trials/testing replication, optimising agencies

resources (sharing assessment reports/authorisation 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.

NEXT STEPS

Taking into account that the objective of the current paper is to present a first analysis of possible elements for a TTIP annex on pharmaceutical products, the first negotiation meetings could aim at:

- discussing how to combine health regulators' agendas (focus on protecting human health) with more general competitiveness objectives (increased trade, growth and jobs);
- calling on stakeholders to see how they can best support these objectives;
- identifying common goals and possible scope of commitments;
- deciding on whether the identified goals should be achieved at bilateral level or at multilateral level (e.g. ICH) and within which time frame;
- discussing the best tools to achieve in a pragmatic way the goals (e.g. GMP recognition vs. reliance on GMP results);
- determining what type of deliverables can be expected within TTIP in the short and medium term;
- discussing implementing measures and what type of resources (financial, human, legal) will be necessary to put in practice TTIP commitments.