



PHARM 658

PHARMACEUTICAL COMMITTEE
26 March 2014

Subject: Transatlantic Trade and Investment Partnership (TTIP)

Agenda item 5b

The fourth round of TTIP negotiations took place in Brussels between 10 and 14 March 2014. The discussions were largely devoted to the possibilities to strengthen collaboration on GMP inspections and possible objectives for the TTIP and beyond. Further exchanges of information, notably on current experience of collaboration and on the EU system are due to further inform this priority topic.

An in-depth exchange of views took also place regarding the exchange of commercially confidential information amongst regulators as well as the transparency on clinical trial data. It was in particular the opportunity for the EU to address questions regarding the state-of-play of the ongoing EMA reflections regarding pro-active release of information of clinical trials. Each party outlined its views towards the inclusion of Biosimilars and Generics. The US request to include Price and reimbursement in the negotiations was also discussed.

Both parties supported the ongoing EMA-FDA collaboration in the context of the Quality by Design Pilot or parallel scientific advice. In the same way, both parties supported the ICH ongoing work on harmonisation of paediatrics trial design, data collection for small clinical trials with particular interest to treat rare disease, and template for information for benefit-risk assessment. The possibilities to align the timing of submission of the paediatric investigation plans were also discussed.

More detailed information will be provided orally during the meeting.

A Line-To-Take regarding the TTIP that was shared with Inspectorates during their last meeting on 21 February 2014 is provided in annex.

Action to be taken:
For Information

ANNEX

TTIP and Medicinal products

Scene Setter

The Transatlantic Trade and Investment Partnership (TTIP) is a trade agreement that is presently being negotiated between the European Union and the United States.

It aims at removing trade barriers in a wide range of economic sectors to make it easier to buy and sell goods and services between the EU and the US.

On top of cutting tariffs across all sectors, the EU and the US want to tackle barriers behind the customs border – such as differences in technical regulations, standards and approval procedures. These often cost unnecessary time and money for companies who want to sell their products on both markets. The sector of medicinal products is amongst the priorities for greater regulatory convergence.

The identification of the priority topics for the negotiations in the different sectors has been supported by public consultations that took place in the context of the High Level Working Group on Jobs and Growth which prepared the TTIP negotiations. The various contributions to these consultations (including the ones of the pharmaceutical industry) can be found on the following webpage: http://ec.europa.eu/enterprise/policies/international/cooperating-governments/usa/jobs-growth/index_en.htm.

The TTIP negotiations will also look at opening both markets for services, investment, and public procurement. They could also shape global rules on trade.

More information on the TTIP can be found on the website of DG TRADE: http://ec.europa.eu/trade/policy/in-focus/ttip/#what_is_ttip

line to take

- To indicate that you are aware of the ongoing trade negotiations between the EU and the US. These negotiations are led by the Commission. The position of the EU is developed in close collaboration with Member States.
- To inform that until now, as regards pharmaceuticals, the negotiations have been largely devoted to an exploratory phase aiming to identify priority topics for the TTIP negotiations.
- To underline that there substantial cooperation is already ongoing between EU and the US on pharmaceuticals. For example, ICH has been established for 20 years or refer to the joint programs or pilots involving FDA, EMA and Member States.

- In the same way than past and current collaboration, the TTIP negotiation will aim at providing requirements which ensure a high level of protection of public health while avoiding unnecessary duplication of tests or clinical trials.
- To stress that, against this background, the trade negotiations should be seen as an opportunity to strengthen and formalise existing collaboration. It has thus a clear health dimension and should contribute by joining forces to a better use of the resources of authorities which is also in the interest of the patient.
- To indicate that the first priority identified for the TTIP by both the EU and the US is strengthening the collaboration on GMP inspections.
- The EU has already a long experience with Mutual Recognition Agreements with Several Partners (Japan, Canada, Switzerland, Australia, New Zealand) and recently the ACAA with Israël. An MRA was even concluded in 1999 with the US but did not come in operation. The US has also the willingness to increase collaboration for a better oversight of the global supply of medicinal products and recent US law (FDASIA) facilitate the recognition by FDA of foreign governments. Discussions are thus ongoing in view of establishing a system which would allow both parties to rely/recognise their inspections. The next step will be to elaborate a process to assess the equivalence of both systems. Close collaboration between the Commission, EMA, and the inspectorates from Member States will be needed in this process.
- Several other topics are also under considerations under the TTIP. Those are notably opportunities for collaboration on generics, biosimilars in view to ensure similar requirements for authorisation that could pave the way for further development of international guidelines, or streamlining requirements regarding paediatrics.