European Federation of Pharmaceutical Industries and Associations

TTIP and healthcare

EFPIA Position – TTIP Stakeholder meeting 27 May 2015

Introduction

Europe and the United States account for more than 80% of global sales of new medicines, 75% of global R&D in life sciences, and create and sustain over 1.5 million direct jobs.[1] The Transatlantic Trade and Investment Partnership (TTIP) would boost the world's largest trading relationship, spur transatlantic investment in life sciences, and foster research cooperation, resulting in improved healthcare and facilitated patient access to innovative medicines on both sides of the Atlantic.

This paper aims to highlight the key priorities of the pharmaceutical industry in TTIP. EFPIA supports an ambitious and comprehensive agreement, which addresses regulatory convergence, intellectual property protection and provides for greater market access.

Regulatory convergence

TTIP is a unique opportunity to create greater compatibility between EU and US regulatory systems, ultimately benefiting patients, science and the economy. The EU and U.S. can work together to eliminate and reduce duplicative and burdensome processes, submissions, evaluations, testing and inspections, without lowering the strong regulatory systems for approval of medicines. This would free up resources to invest in research and innovation, especially to the benefit of small- and medium-sized companies (SMEs). Through regulatory convergence, patients would be able to benefit from more efficient processes by getting quicker access to new medicines.

To this end, EFPIA proposes the following issues to be addressed in TTIP:

- **Mutual recognition of GMP (Good Manufacturing Practice) inspections**

  Mutual recognition of GMP inspections through TTIP could reduce duplicative inspections of manufacturing sites on both sides of the Atlantic by 40%. This would generate significant cost-savings, not only for industry, but also for regulators, who may need to focus on higher risk countries.

[1] The pharmaceutical industry in figures, edition 2014, http://www.efpia.eu/uploads/Modules/Mediaroom/figures-2014-final.pdf

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- **Common procedures and timing for paediatric plans**

  Through the creation of common procedures and timing for submitting paediatric plans, TTIP could reduce unnecessary and duplicative testing on children, and accelerate the delivery of new paediatric medicines.

- **Establishment of a harmonised list of clinical trials results data fields**

  Harmonisation of the list of clinical trial results data fields is a technical measure that would address the duplicative submissions of summaries of clinical trials in the EU and U.S. It would reduce the often substantial resources needed to introduce identical results into two different systems.

- **Establishment of a harmonised approach to post-approval variation submissions for CMC (chemistry, manufacturing and control) changes**

  The EU and U.S. operate similar concepts for the submission of CMC changes, but there remain significant differences regarding the type of change, the content and necessary pre-approval of the submission, which complicates the handling of such changes and hinders continuous process improvements. The establishment of a harmonised approach would reduce the administrative burdens for both companies and regulatory agencies.

Intellectual Property (IP)

TTIP can ensure a commitment to shared IP principles that uphold the strong IP-protection already in place in both the EU and the U.S. In order to ensure competitiveness, both IP systems should remain open to adaptation in order to spur research and innovation in new medicines and treatments.

To this end, EFPIA proposes the following issues to be addressed in TTIP:

- Joint commitment to existing high-level standards of IP protection and enforcement and establishment of **joint high-level IP principles** to be used as a point of reference in future bilateral and multilateral fora.

- Joint commitment to support the existing cooperation between patent offices and their work towards substantive patent law harmonisation, including a **grace period.**

- Provide for effective patent enforcement opportunities by supporting the eventual introduction of an **Early Resolution Mechanism**

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Market Access

TTIP can help promote fair, predictable and transparent policies on pricing and reimbursement processes. **A pharmaceutical annex in TTIP**, consistent with the annex already in place in the EU-Korea FTA and in line with the EU Transparency Directive, could promote principles around transparency in pricing and reimbursement processes, and reflect the value new medicines can bring to patients, healthcare systems, and society.

For more information about the potential benefits of TTIP to patients, healthcare, science and business, please see our paper at:
http://www.efpia.eu/uploads/Modules/Documents/ttip_benefits.pdf

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