

# TTIP and healthcare

## Separating Fact from Fiction

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.<sup>1</sup> The Transatlantic Trade and Investment Partnership (TTIP) could significantly **boost the world's largest trading relationship**, spur transatlantic investment in life sciences, and **foster research cooperation**, resulting in improved healthcare and **enhanced patient access to innovative medicines on both sides of the Atlantic**. TTIP also has the potential to set global standards in key areas.

Despite the potential benefits of this opportunity, questions have been raised about the TTIP, its provisions relating to life sciences, and the role of the pharmaceutical industry. This document aims to address some of the myths, and to highlight the benefits of increased transatlantic cooperation through the TTIP.

**Myth** *The TTIP is negotiated in secret, allowing it to be driven by the interests of multinational companies.*

**Fact** The EU and the US have both provided **transparency** during the TTIP negotiations through public consultations and regular

stakeholder engagement. In the EU, an Advisory Group (like the International Trade Advisory Committees in the US) with representatives of industry, trade unions, consumer groups and NGOs has been formed, through which the members can provide input on negotiating proposals. Cecilia Malmström, the European Commissioner for Trade, has also launched a TTIP transparency initiative as a response to public demand in the EU.<sup>2</sup>

**Myth** *The TTIP will reduce regulatory standards to the lowest common denominator on either side of the Atlantic.*

**Fact** The pharmaceutical industry strongly supports upholding the high regulatory **standards** already existing on both sides of the Atlantic, which facilitate the delivery of safe,

high quality medicines to patients. There is no intention to lower regulatory standards. Our industry wants to see the optimisation of the regulatory systems and resources already in place. For example, both the FDA (U.S. Food & Drug Administration) and the EMA (European Medicines Agency) currently inspect the same manufacturing sites and use comparable standards. With greater regulatory convergence, medicines could be approved more quickly, benefiting patients by speeding up access to medicines, without diminishing their quality or safety.

**Myth** *The pharmaceutical industry attempts to limit clinical trials transparency through TTIP.*

**Fact** The pharmaceutical industry is committed to sharing its clinical trial data through responsible reporting and publication of clinical research and safety information. In January

2014, EFPIA and PhRMA adopted clinical trial data sharing principles with member companies committing to make clinical trial results public and share data with researchers. Responsible data sharing protects **patient privacy**, maintains the integrity of the regulatory review process, and preserves incentives for biomedical research.

In TTIP, the pharmaceutical industry would welcome the harmonisation of the list of clinical results data fields, a technical measure which would make reporting of results easier, reduce costs and allow faster access to the information.

Myth

*The pharmaceutical industry's asks in TTIP will create longer monopoly periods, higher prices and less generic competition.*



Fact

Intellectual property (IP) protection is not intended to hinder access to and distribution of medicines to patients. Both the EU and the US already have high standards of

IP. TTIP has the potential to provide greater alignment between the two and to establish minimum **common benchmarks** without reducing the existing level of protection and ensuring sustainable research of new medicines in the future. Indeed, without IP, some of the most important medical breakthroughs would not have been and will not be possible; neither would generic medicines be on the market. IP protection is not about limiting generic competition, but about giving companies incentives to invest in researching and developing new medicines – a lengthy, high-risk, and resource-intensive process.

Myth

*The TTIP will undermine Member States' national competence on pricing and reimbursement*



Fact

TTIP will not impact national governments' decision-making powers for **pricing and reimbursement** of pharmaceuticals. TTIP can underscore the importance of

transparent processes for pricing and reimbursement on both sides of the Atlantic, consistent with existing legislation and trade agreements.

Myth

*ISDS (Investor State Dispute Settlement) provisions will hamper government policy space and regulatory freedom. The pharmaceutical industry will use ISDS provisions to undermine national health policies.*



Fact

Investors need to be sure that they will be **treated fairly**, and in the same way as domestic companies, when investing abroad. Investment agreements aim to do just that, and offer a platform for addressing serious cases that cannot always be

solved through domestic courts. For instance, the ISDS mechanism might be used to address a case of direct expropriation by the host country without proper compensation. Investment protection provisions have been included in the many investment treaties that the U.S. and the EU's Member States already have in place.<sup>3</sup>

The track record of these existing treaties has shown that investment protection does not exempt foreign firms from the host country's laws and regulations. It also does not curtail a sovereign government's ability to pursue legitimate policy objectives, including those related to national health policies. Given this, the use of an ISDS mechanism in TTIP could not change social security systems or national health legislation, nor could an ISDS tribunal challenge a Member State's right to regulate in this field.<sup>4</sup>

On the EU side, the Commission has released the results of the investment protection and ISDS consultation, which called for improvements in certain areas. EU authorities have stated that the final TTIP investment chapter will be consistent with EU law.

Myth

*TTIP will affect the ability of national health services to provide publicly funded health services, and will open the possibility of privatisation of health services.*



Fact

It has been clearly stated that there are no provisions envisaged in TTIP that would affect the ability of national authorities to provide **publicly funded health services**.

TTIP will not affect the rights of Member States to organise their own healthcare systems and provide healthcare services: this falls within national competences of the Member States. In all recent trade agreements, the EU has excluded publicly funded health services from the scope of services commitments.

1 *The pharmaceutical industry in figures, edition 2014*, <http://www.efpia.eu/uploads/Modules/Mediroom/figures-2014-final.pdf>

2 <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1205&title=Opening-the-windows-Commission-commits-to-enhanced-transparency-in-TTIP>

3 [http://trade.ec.europa.eu/doclib/docs/2013/november/tradoc\\_151916.pdf](http://trade.ec.europa.eu/doclib/docs/2013/november/tradoc_151916.pdf) and [http://trade.ec.europa.eu/doclib/docs/2014/march/tradoc\\_152290.pdf](http://trade.ec.europa.eu/doclib/docs/2014/march/tradoc_152290.pdf)

4 [http://trade.ec.europa.eu/doclib/docs/2014/july/tradoc\\_152665.pdf](http://trade.ec.europa.eu/doclib/docs/2014/july/tradoc_152665.pdf)