
Resolution on Medicinal Products and Medical Devices in the Transatlantic Trade and Investment Partnership Agreement (TTIP)

Introduction

The World Health Organisation (WHO) defines **health technologies** as including: ‘*devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives*’.¹ Medicines and medical devices play an important role in improving health outcomes and improving the quality of life of patients. However, providing affordable and equitable access to quality, safe and effective health technologies is increasingly a challenge both in the EU and the US and may be further challenged by provisions in TTIP.

TTIP should respect the principle of Universal Health Coverage and must ensure coherence between public health and trade in the field of health technologies. It should not reinforce the monopoly power of pharmaceutical corporations, or their ability to withhold information on medicine safety and efficacy. Nor should it limit the freedom of national governments to tailor decisions on pricing and reimbursement to ensure affordability, or to revise current intellectual property protection terms to spur affordable access to important drugs.

It is important to stress in the context of health technologies that trade agreements should not undermine the treatment and protection of sensitive health data.²

TACD Recommendations on Medicines

Investment protection

Recommendation 1: Referring to the concerns expressed by TACD, in light of the Eli Lilly case³ the exclusion of any form of investment protection measures is relevant in the context of health technologies.

Regulatory cooperation

Recommendation 2: With regard to regulatory cooperation on human medicines, there is no need for a specific annex on regulatory cooperation in TTIP.

Recommendation 3: However, if such an annex is included, it is essential that provisions on regulatory cooperation in TTIP should explicitly protect the EU’s exercise of the precautionary principle and

¹ World Health Organisation. Health topics: Technology, Health. Available at: http://www.who.int/topics/technology_medical/en/ (accessed 8 June 2016)

² See the TACD Resolution on Data Flows in the Transatlantic Trade and Investment Partnership <http://www.consumersinternational.org/media/1396104/tacd-resolution-on-data-flows-in-the-transatlantic-trade-and-investment-partnership.pdf>

³ See the TACD Resolution on Investor-State Dispute Resolution in the Transatlantic Trade and Investment Partnership <http://test.tacd.org/wp-content/uploads/2014/01/TACD-TTIP-Resolution-on-Investor-State-Dispute-Resolution-in-the-Transatlantic-Trade-and-Investment-Partnership.pdf>

similar US safeguards, and essential that the primary aim of regulatory cooperation on medicinal products is stated to be improving health outcomes and reducing health inequalities.

Pricing and reimbursement

Recommendation 4: Pharmaceutical pricing and reimbursement – including enhanced transparency and/or improved procedural rights in relation to these decision making processes - must be excluded explicitly from TTIP as the current rights and processes are sufficient.

Intellectual property

Recommendation 5: Intellectual property rights (IP) and related exclusivities for health technologies must be explicitly excluded from all relevant sections of TTIP.

Recommendation 6: If IP provisions and related exclusivities on health technologies are included in TTIP, they should not:

- regulate the standards or entrench established practices for granting patents on pharmaceuticals, in particular on secondary patenting and other patentability standards.
- strengthen or entrench the terms and scope of data or marketing exclusivity on pharmaceuticals, including particularly in the area of biologics.

Safeguarding access to information on development of health technologies, including clinical trial data

Recommendation 7: Ongoing EU commitment to increased transparency of clinical trials data of pharmaceuticals must be firmly restated in TTIP.

Recommendation 8: TTIP should not include trade secret protection.

Recommendation 9: If trade secret protection is included, safeguards and exceptions should be in place to ensure that data in the public interest, and in particular information related to safety, efficacy and development of medicines, cannot be protected as trade secrets.

Recommendation 10: If confidentiality provisions to facilitate information exchange between medicines regulators across the Atlantic are included, TTIP needs to:

- stipulate that access to information to be shared between EU/US regulators – even if marked commercially confidential – can always be requested, and should always be granted, if there is an overriding public interest in disclosure.
- stipulate that EU/US regulators will always request all data needed for a comprehensive assessment of marketing authorisation directly from the applicant, even if the data has already been obtained from other sources through this information exchange.

TACD Recommendations on Medical Devices

Recommendation 11: The reduction of tariffs on medical devices (bringing these into line with pharmaceutical products where there are no tariffs) is welcome – provided that the reduction in tariffs is reflected in lower prices for purchasers and not higher profits for manufacturers.

Recommendation 12: With regard to regulatory cooperation on medical devices, there is no need for a specific detailed annex in TTIP.

Recommendation 13: However, if a detailed annex on medical devices is included, the primary aim of regulatory cooperation should be explicitly stated as improving health outcomes and reducing health inequalities, with increased trade a secondary aim.

TACD Recommendation on Direct-to-Consumer Advertising of Medicines and Health Technologies

Recommendation 14: Nothing in TTIP should affect the ban on direct-to-consumer advertising of medicines and health technology products in the EU, or limit the US from regulating or restricting direct-to-consumer advertising in the future. This must be explicitly stated in the final text of TTIP.

Background

Affordable medicines in TTIP

Affordability of Medicines in Europe

High medicines prices are a public health challenge in Europe acknowledged by EU decision makers. The June 2016 EU Council Conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States⁴ illustrate the serious concerns EU Member States have in relation to the high prices of medicines. It is indicative that for the first time, in these strongly-worded conclusions, the European Commission is mandated by the 28 EU Health Ministers to critically examine the suitability and impact of IP-related incentives on the quality of medical innovation, affordability, accessibility as well as availability of medicinal products in Europe. Moreover, orphan drugs which enjoy longer forms of patent protection are in the spotlight and EU Health Ministers may wish to consider a revision of the respective regulatory framework in the future “to ascertain correct application of current rules and fair distribution of incentives and rewards”. Furthermore, the European Parliament has recently again discussed the issue of high medicine prices and the need for reform.⁵ Also the recent WHO publication on “*Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research (2015)*”⁶ acknowledges high prices as a public health concern which affects sustainability and patient access to life saving medicines.

Affordability of Medicines in the US

High medicine prices are also an issue in the US, where one in five people has foregone filling a prescription due to high prices, medical illness and drug prices are the leading driver of personal bankruptcy, and payers ration treatment even for the most important medicines. A recent statement of WHO Director Margaret Chan with regard to the Trans-Pacific Partnership (TPP) stressed “*strikingly high prices, especially for new drugs for various cancer indications and for hepatitis C*”⁷ and she also referred to US cancer drugs.⁸

⁴ <http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-balance-pharmaceutical-system/>

⁵ See eg. 11 February 2015: <http://www.europarl.europa.eu/news/en/news-room/20150206IPR21208/MEPs-to-debate-access-to-medicines>

⁶ <http://www.euro.who.int/en/health-topics/Health-systems/medicines/publications2/2015/access-to-new-medicines-in-europe-technical-review-of-policy-initiatives-and-opportunities-for-collaboration-and-research-2015>

⁷ <https://twitter.com/who/status/659512771298656256>

⁸ <https://twitter.com/who/status/649321062866493440>

Medicine Prices on the Global agenda

In a similar spirit, the 32nd Session of the United Nations (UN) Human Rights Council adopted in July 2016 a resolution highlighting the correlation between patent-based monopolies or exclusivities and the challenges in accessing affordable medicines across the globe.

In November 2015, the UN Secretary-General Ban Ki-Moon launched a High-Level panel on Access to Medicines (N HLP) to “review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.” The final report⁹ calls for public health assessments to be done with every free trade negotiation to assess the possible impact on public health, and for the creation of public health patentability criteria. **Intellectual property rights and in particular patents and related market and data exclusivities**, have a direct impact on pricing of new health technologies, and in particular the unaffordably high prices that may limit equitable access to medicines in the EU and US. Accordingly, it is crucially important that no provisions in TTIP worsen the already unsustainable IP regime in the EU and US, or restrict the political space for future action to work towards a more equitable framework for IP related to pharmaceuticals. The US and the EU take different approaches to pharmaceutical IP, though the ultimate result is the same – long periods of market exclusivity for new medicines which are sold at high prices. This leads to significant profits for the manufacturer and high costs for healthcare systems, and can result in limiting access to medicines for patients or increased out-of-pocket payments. The median period of market exclusivity for top-selling medicines in the US between 2000 and 2011 was 12.5 years.¹⁰ The top selling medicine of all time, Pfizer’s Lipitor (atorvastatin), raised \$125bn over the 14.5 years that it was sold under patent – with the overall cost-savings from the expiry of the patent and generic atorvastatin availability to the US healthcare system projected to reach \$4.7bn annually by 2014.¹¹ Sofosbuvir is a genuine example of the challenge of high medicine prices in Europe with the 12-weeks treatment course being priced 41,680 euros to French Social Security whereas the Indian generic version is sold at 220 euros.¹² These are just a few examples of the excessively high costs of the current approach to IP for healthcare systems and the exorbitant returns that flow to pharmaceutical companies. Prices are set in a way that bears no relation to the cost of R&D or production, but rather according to the maximum of what we will pay to care for our sick, while the real costs of R&D remain unknown.¹³ It is therefore essential that the policy space to work towards a more equitable IP regime for pharmaceuticals, both globally and with regard to EU Member States and the US, is protected. Confirming or acknowledging current standards or practices on IP by means of an international trade agreement will block the possibility to change these practices in the future. Accordingly, **IP and related exclusivities for health technologies must be explicitly excluded from the final text of TTIP.**

⁹ <http://www.unsgaccessmeds.org/final-report/>

¹⁰ Wang B et al. Variations in time of market exclusivity among top-selling prescription drugs in the United States. *JAMA Internal Medicine* 2015; 17(4):635-37. Available at <http://archinte.jamanetwork.com/article.aspx?articleid=2109854> (accessed 8 June 2016)

¹¹ Jackevicius CA et al. Generic atorvastatin and health care costs. *New England Journal of Medicine* 2012; 366(3):201-204. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3319770/> (accessed 8 June 2016)

¹² <http://hepcoalition.org/news/press-releases/article/hepatitis-c-gilead-patent-on-sofosbuvir-partially-maintained-following-mdm>

¹³ Sell, D. (2013) ‘GlaxoSmithKline’s Andrew Witty says \$1 billion price tag for drug development is a “myth”’, *Philly.com*, 15 March [Online]. Available at:

www.philly.com/philly/blogs/phillypharma/GlaxoSmithKlines-Andrew-Witty-says-1-billion-pricetag-for-drug-development-is-a-myth.html (accessed 15 August 2016).

TTIP could give the pharmaceutical industry undue influence in governments' decisions on pricing and reimbursement. It could weaken the negotiating power of governments to make medicines affordable for patients, by imposing cumbersome procedural requirements on public authorities seeking to take cost-containment measures, potentially including excessively exacting cost-benefit analysis. Even if provisions only seem to deal with transparency of proceedings or procedural issues, they could interfere with adopting measures necessary to protect public health and ensure affordable access to medicines out of fear for costly legal battles. **TTIP should therefore not contain any provisions on pricing and reimbursement.**

Clinical trials data transparency is a crucial element of ensuring patient safety. By making all data from all clinical trials publicly accessible, healthcare decision-makers will have access to the complete picture on patient benefits and risks – ensuring that prescribing decisions can be made in patients' best interests. It also allows researchers to more accurately compile the data from different trials on the same intervention to show whether a treatment is ineffective or unsafe, and leads to cost-savings from avoiding government procurement of ineffective medicines and unnecessary duplication of research efforts. The EU has recently harmonised trade secret protection through the new Trade Secrets Directive. This paves the way for the EU to discuss trade secrets as part of TTIP. The new EU Directive's broad definition of what constitutes a "trade secret," and its lack of clarity on exceptions to unlawful use or disclosure, create legal uncertainty. It is therefore **important that trade secret protection is not harmonised across the Atlantic in TTIP.** Any negative consequences that may arise from such harmonised trade secret protection will then be difficult to repeal or mitigate through democratic processes.

In addition, the EU and US are looking to include provisions, including provisions protecting confidential information from public disclosure, to facilitate information exchange between medicines regulators across the Atlantic. It is crucial that **all data relating to the development of medicines, and in particular all clinical trial data, is excluded from the definition of 'confidential information of commercial, technical or scientific nature' that is prohibited from public disclosure** once shared. (This does not refer to personal information regarding individual patients, which should be subject to appropriate protection.) As a minimum, this information should always be released if there is an overriding public interest in disclosure. Additionally, the ongoing EU commitment to increased transparency of clinical trial data should be firmly restated, and no restrictions should be imposed on similar moves in the US.

Medical Devices in TTIP

The reduction of tariffs on medical devices (bringing these into line with pharmaceutical products, where there are no tariffs) in TTIP is **welcome, provided** that the reduction in tariffs is reflected in lower prices for purchasers and not higher profits for manufacturers. This will lead to an increased availability of medical devices for patients, perhaps leading to improved health outcomes and reduced health inequalities.

Concerning regulatory cooperation on medical devices in TTIP, there is presently a high level of cooperation between the EU and US through the International Medical Device Regulators Forum (IMDRF). The proposed approach under TTIP is to build on progress made through the IMDRF in order to increase regulatory cooperation and further reduce non-tariff barriers to trade (NTBs). However, the presence of existing mechanisms for regulatory cooperation that are highly effective render a

detailed annex in this area redundant and therefore unnecessary. Ongoing collaboration through the IMDRF is the most appropriate route to increasing regulatory cooperation in order to achieve upward standardisation to the highest common safety standards, unencumbered by the timeline and additional provisions of a trade and investment treaty such as TTIP.

If such an annex is included in the final text of TTIP, it must be explicitly stated that the primary aim of regulatory cooperation is to improve health outcomes and reduce health inequalities. So far the primary aim of regulatory cooperation is stated in terms of increasing trade while maintaining existing protection and public health standards. Given the specific nature of medical devices to human health, a different goals statement is needed here to ensure that trade policy does not undermine public health policy. The primary aim of regulatory cooperation on medical devices should be explicitly stated as improving health outcomes and reducing health inequalities, with increased trade as a secondary aim. Clearly distinguishing means from ends will ensure that patient safety is not jeopardised in order to achieve a trade benefit.

Direct-to-consumer advertising of medicines and health technologies

As regards pharmaceuticals, direct-to-consumer advertising (DTCA) must be explicitly excluded. In the EU, advertising of prescription-only medicines is not allowed, but it is currently legal in the US. This leads to inappropriate demand for drugs from patients due to advertisements promoting consumption by over-emphasising benefits and minimising risks; promoting new drugs before risks are fully known; medicalising minor ailments and encouraging over-utilisation of drugs; and many other problematic results.¹⁴ In addition to this, by driving up marketing costs for pharmaceutical companies (reaching \$4.5bn in 2015), DTCA also raises the cost of medicines, which has already been noted to be a major public health challenge in the EU and the US. For these reasons, the American Medical Association has called for a ban on advertising prescription drugs and medical devices directly to consumers.¹⁵ The pharmaceutical industry has been lobbying for many years to try to remove the barriers to DTCA in the EU, and TTIP presents another opportunity for them to succeed ‘through the back door’.¹⁶ Accordingly, **TTIP should not contain any provisions on DTCA to protect patient safety and prevent higher medicines prices.**

Similarly, nothing in TTIP shall affect the full autonomy of the EU Member States or US States to prohibit direct-to-consumer advertising for medical devices. The ongoing prohibition on direct-to-consumer advertising for medical devices in the EU should explicitly be restated in TTIP.

¹⁴ Ventola CL. Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic? *Pharmacy and Therapeutics*. 2011; 36(10):669-674. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278148/> (accessed 8 June 2016)

¹⁵ Press Release. AMA calls for a ban on direct to consumer advertising of prescription drugs and medical devices, 17 Nov 2015. Available at <http://www.ama-assn.org/ama/pub/news/news/2015/2015-11-17-ban-consumer-prescription-drug-advertising.page> (accessed 8 June 2016)

¹⁶ Humphreys G. Direct-to-consumer advertising under fire. *Bulletin of the World Health Organisation*. 2009; 87(8):565-644. Available at <http://www.who.int/bulletin/volumes/87/8/09-040809/en/> (accessed 8 June 2016)