



The Consumer Voice in Europe

TTIP & HEALTH

BEUC position

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Summary

Pharmaceuticals and medical devices have been flagged as key areas that will be covered by the Trans-Atlantic Trade and Investment Partnership (TTIP) agreement. TTIP is expected to facilitate trade and investment by eliminating barriers posed by regulation and other rules. What would this mean for the health sector in Europe? Enhancing consumer safety should be the number one goal of regulatory cooperation in the health sector. To this end, BEUC welcomes the potential for:

- Mutual recognition of inspections of manufacturing plants based on principles and guidelines defined as “Good Manufacturing Practices” to achieve more effective use of resources;
- Reducing needless duplication of clinical trials to avoid exposing consumers to unnecessary risks;
- Upwards harmonisation of the technical requirements for the authorization of medicines and in particular for paediatric medicines, generics and biosimilars to improve patient safety and access to medicines;
- Convergence of systems for identifying medical devices (UDI) to improve traceability

To achieve these advances for consumers, past experience has shown that an all-encompassing agreement such as TTIP does not seem to be essential to promote regulatory cooperation. Moreover, attention must be paid to the following, potentially overshadowing, issues:

- EU governments should maintain full autonomy to make pricing and reimbursement decisions about pharmaceuticals and medical devices in the public interest;
- The EU recent progress on clinical trials transparency and the EU Clinical Trials Regulation should not be undermined by references to trade secrets and commercial confidentiality;
- TTIP should not lead to any extension of intellectual property rights and exclusivities applied to medicines in the EU.

1. Introduction

Pharmaceuticals and medical devices have been flagged as key areas covered by the Trans-Atlantic Trade and Investment Partnership (TTIP) agreement. TTIP is expected to facilitate trade and investment by eliminating barriers posed by regulation and other rules. What would this mean for the health sector in Europe? The European Consumer Organisation sees both potential benefits and risks for consumers in the TTIP deal.

Although this position paper focuses on the impact of TTIP on pharmaceuticals and medical devices in the EU, there are two overarching challenges that must be addressed if TTIP is to be beneficial to consumers. First, BEUC welcomes the recent transparency initiatives of the Commission that increased access to negotiating texts and information regarding the TTIP negotiations. BEUC calls for greater efforts in order to have public access to consolidated texts. Second, the Investor-to-State Dispute Settlement (ISDS) mechanism would allow foreign companies to sue a state that allegedly does not respect the provisions of the agreement under a supra-national arbitration system. ISDS has been used in Australia and Canada to sue governments taking public protection measures, such as introducing plain packaging for tobacco products or setting high standards for pharmaceutical patents. BEUC believes the ISDS mechanism is too flawed to be fixed and advises negotiators to find other means to protect foreign investments. [Read BEUC's position paper.](#)

2. Existing regulatory cooperation without TTIP

It is noteworthy that in many aspects of pharmaceutical regulation and investment, the EU and the USA are already engaged in global or bilateral cooperation. The Transatlantic Administrative Simplification Action Plan¹ signed in 2007, aims to remove administrative burdens to the interaction between EMA and FDA. These Agencies share information on market authorisation procedures, changes to market authorisations and post-authorisation surveillance for products under review both in the USA and in the EU, through:

- The exchange of assessment reports and review documents;
- Regular videoconferences on specific topics and classes of medicines, such as oncology, orphan medicines, paediatrics, vaccines, blood products, pharmacogenomics, advanced therapies, veterinary medicines and biosimilar medicines;
- Ad hoc teleconferences between USA and EU experts.

The two Agencies have developed common procedures for Good Manufacturing Practice² and Good Clinical Practice inspections and for applications for orphan designation. They also share information on pharmacovigilance, scientific advice, biomarkers, inspection planning and reporting and preparedness for pandemic influenza. Moreover, the confidentiality agreements between the EU and the FDA were extended in 2005 and again in 2010. They are now effective for an indefinite period without the need for further renewal.

¹ http://ec.europa.eu/health/files/international/doc/eu_fda_action_plan_200806_en.pdf

² http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/12/WC500118766.pdf

Therefore, an all-encompassing agreement such as TTIP does not seem to be essential to promote regulatory cooperation.

3. Mutual recognition of Good Manufacturing Practices can enhance efficiency and safety

Currently, European and American authorities conduct inspections of companies' facilities on their territories and third countries to check compliance with good manufacturing practices (GMP) and verify the quality of products. Closer cooperation between EMA and FDA could avoid duplicating such inspections, thereby more effectively using resources.

EMA does not currently have an operational Mutual Recognition Agreement with the USA for Good Manufacturing Practices. However, Mutual Recognition Agreements do not require a partnership such as TTIP, as the EMA already maintains agreements with Australia, Canada, Israel, Japan, New Zealand and Switzerland³.

The formal recognition of manufacturers quality management system audits (QMS) could also reduce costs for inspections for medical devices. However, the EU and the US are already working together in the international initiative 'Medical Device Single Audit Programme - MDSAP' and developed the concept of "single audit" by which, when auditing a facility, QMS auditors check compliance with the requirements of several jurisdictions at the same time.

4. Harmonised requirements for the authorization of medicines can reduce needless duplication of clinical trials and facilitate access to medicines

The upwards harmonisation of the technical requirements to demonstrate quality, safety and efficacy of medicines can facilitate the recognition of clinical trials on both sides of the Atlantic, saving resources and sparing more patients from the risky process of experimenting with medicines. This is particularly important especially with regard to medicines for children. In this respect BEUC would support the revision of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines on paediatrics as, at the moment, there are some differences in the conduct of paediatrics trials that make it difficult to compare data and mutually accept studies. BEUC also supports the convergence of the systems for the authorization of biosimilars and generics.

³http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000248.jsp&mid=WC0b01ac058005f8ac

5. Medicines and medical devices pricing & reimbursement have no place in an EU-US trade deal

EU governments should maintain full autonomy to make pricing and reimbursement decisions about pharmaceuticals and medical devices in the public interest. BEUC welcomes the EU commitment indicating that “neither TTIP nor any other EU trade deal would affect EU governments' right to decide how much people have to pay or how they're reimbursed”. However further clarification is needed with regard to the reference to the transparency of decision making⁴. While we support the principle that regulatory decisions should be made in a “clear and open way”⁷, we oppose the inclusion of an Annex on transparency and procedural fairness provisions similar to those introduced in the Korea-US⁵ and Australia-US agreements.

BEUC supports balanced stakeholder involvement in decision making at all levels. At the same time, BEUC finds that local, national and European fora are better suited to such exchanges that impact on European consumer protection, rather than an EU-US trade partnership. Expanding the role of stakeholders through the mandatory exchange of information can increase the pressure on decision makers, particularly from foreign investors. Indeed, corporate pressure has played an influential role in past decisions to reimburse unproven medicines at the cost of consumers and EU health systems⁶.

6. Safeguard progress on access to clinical trials data

The newly adopted European Regulation on clinical trials (n. 536/2014) and the new EMA policy on publication and access to clinical trials data⁷ put Europe at the fore front with regard to regulatory transparency and accountability. European consumers expect that the EU's high standards for clinical data disclosure are upheld by TTIP. In this context BEUC welcomes the EU commitment⁷ not to negotiate - neither in TTIP nor in other EU trade deals – any rules that will impact “in any way” the EU Regulation on clinical trials.

With regard to the exchange of information about the safety, efficacy and quality of medicines between EMA and FDA, BEUC supports the highest possible level of information sharing and the narrowest definition of commercial confidentiality and trade secrets. According to EU law, any information received or held by the EMA will be subject to European legislation on Access to Documents (Regulation n. 1049/2001) and Data Protection (Directive n. 95/46/EC).

⁴ http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153010.4.7%20Pharmaceuticals.pdf

⁵ Final Text of the Pharmaceuticals and Medical Devices chapter in the KORUS FTA https://ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file899_12703.pdf

⁶ Van Herck, P., Annemans, L., Sermeus, W., & Ramaekers, D. (2013). Evidence-based health care policy in reimbursement decisions: lessons from a series of six equivocal case-studies. *PloS one*, 8(10), e78662.

⁷ http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000_555.jsp&mid=WC0b01ac0580607bfa

7. No extension of the intellectual property protection that keeps medicines prices high

The EU already has 20 years of patent protection and a number of other exclusivities granted to certain medicinal products. In general, longer patent protection or exclusivity delays competition from generics and keeps medicines prices high, at the expense of the healthcare system and, ultimately, the consumer.

TTIP should not lead to any extension of the intellectual property rights and exclusivities already applied in the EU. BEUC notes that existing EU laws, notably the Bolar exemption in Directive 2004/27/EC⁸, must be respected by TTIP. Concerning intellectual property protection, BEUC welcomes the EU's commitment "not to negotiate anything in TTIP which would ... increase costs for EU countries' national health systems, which are already stretched"⁹.

8. No US-style medicines promotion

The EU and the USA take different approaches to the promotion of pharmaceuticals. Given TTIP's ambitions to enhance regulatory cooperation, it must be said that TTIP needs to be in line with Directive 2001/83/EC on medicinal products for human use, which prohibits advertising of prescription medicines and governs the acceptable role of industry in information production and dissemination to patients¹⁰.

9. Safer medical devices

BEUC supports the main elements of possible cooperation in the medical devices sector as outlined in the EU position on medical devices in TTIP¹¹, including the recognition of manufacturers quality management system (QMS) audits (see also point 3), convergence of system for identifying and tracing medical devices (Unique Device Identification – UDI) and of models form marketing submission (Regulated Product submission). However we regret that the harmonisation of the approval system of devices in the EU and the USA is ruled out. European consumers are often considered as 'guinea pigs' for medical devices, especially in comparison to consumers in the United States¹². Many products used in Europe were never approved in the USA as they were considered dangerous and ineffective¹³. While in the USA high risk devices are subject to a form of marketing authorisation and are assessed by the Food and Drug Administration on the basis of valid clinical evidence to prove their safety and effectiveness, in Europe they can enter the market after a CE certification by private companies

⁸ Directive 2004/27/EC Article 10(6).

⁹ http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153010.4.7%20Pharmaceuticals.pdf

¹⁰ Directive 2001/83/EC Articles 86-90.

¹¹ http://trade.ec.europa.eu/doclib/docs/2015/april/tradoc_153349.4.5%20Med%20devices.pdf

¹² It is worth noting that only one in five of the 8.500 medical devices companies in Europe have approached the USA market. In addition, more devices of a particular type are often marketed in Europe compared to the US, e.g. 28 drug eluting stents are CE marketed while only five obtained FDA approval.

¹³ Unsafe and ineffective devices approved in the EU that were not approved in the US, Food and Drug Administration, May 2012.

called “notified bodies” on the basis of limited evidence and often without significant studies in humans^{14,15}.

European consumers should not be involuntarily partaking in what is effectively a large, uncontrolled experiment¹⁶. The current system is unethical and exposes consumers to unjustified risks. BEUC considers TTIP as a useful opportunity for an upward harmonisation of safety requirements for medical devices in Europe. When finalising the long awaited Regulation on medical devices that has been pending since 2012, EU legislators should ensure European consumers are granted the same level of protection as their American counterparts.

10. Health services should be excluded from TTIP

According to Article 168 of the Treaty the management, organisation and delivery of health care is a sole responsibility of Member States and it should remain as such. On several occasions EU negotiators¹⁷ confirmed that health services will be exempt from TTIP. Rather than an exemption BEUC calls for a hard exclusion or a “carve out” of health services from the scope of application of TTIP.

END

¹⁴ D. Kramer et. Al, Regulation of Medical devices in the United States and European Union, New England Journal of Medicine, March 2012.

¹⁵ D. Zuckerman et al., Public health implications of differences in USA and European Union regulatory policies for breast implants, Reproductive Health Matters, 2012.

¹⁶ Dispositifs médicaux: le patient sert de cobaye, Test-Achats, Test-Santé n. 106, Décembre 2011.

¹⁷ http://trade.ec.europa.eu/doclib/docs/2014/july/tradoc_152665.pdf
http://europa.eu/rapid/press-release_STATEMENT-15-4646_en.htm