



## EPHA Submission to the DG TRADE public consultation EU-US: Call for proposals for regulatory cooperation activities April 2019

### Medicines and medical devices, antimicrobial resistance and Digital Health in the EU-U.S. regulatory cooperation activities

Submission from European Public Health Alliance (EPHA)

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## 1. EU-U.S. regulatory cooperation and public health

The European Commission Directorate General for Trade (DG TRADE) is looking forward to receive comments from all interested stakeholder groups on potential areas for regulatory co-operation with the United States. In particular, comments in the areas of conformity assessment, dialogue on standards and regulatory cooperation in sectors.<sup>1</sup>

**Medicines and medical devices, antimicrobial resistance and Digital Health are identified public health aspects the European Commission should be aware of** in the context of the EU-U.S.: call for proposals for regulatory cooperation activities<sup>2</sup>.

## 2. Why are public health concerns relevant in the context of EU-U.S. regulatory cooperation activities?

**There is a need for policy coherence between public health and trade policies and technical discussion on regulatory cooperation is not an exception.** Throughout these expert discussions, and also in any potential trade negotiations, the EU should hold to its binding obligations under Article 168 TFEU and Article 35 of the Charter, to ensure that health aspects are taken into account (Health in all policies).

Therefore, there is a concern with regard to the Commission's language regarding "reduce administrative obstacles" and "slashing costs". This kind of language is predicated on the assumption that regulations are irritants to trade. However, regulations are not always arbitrary bureaucratic impediments to business, but rather measures designed to protect health and well-being, and this must be acknowledged and upheld by the EU.

Appropriate impact assessment – including health impacts – of any regulatory cooperation, including the benefits of existing regulations, should be a pre-condition for any kind of cooperation between the EU and any partner, including the United States. Before considering regulations as 'trade irritants' because of their costs, benefits of these regulations and standards – including health benefits - should be measured and taken into consideration.

<sup>1</sup> See pages 1 and 2 of the referenced 'Call for proposal' document.

<sup>2</sup> [http://trade.ec.europa.eu/doclib/docs/2019/march/tradoc\\_157722.pdf](http://trade.ec.europa.eu/doclib/docs/2019/march/tradoc_157722.pdf)



### 3. Regulatory cooperation in the health sector

#### I. Pharmaceuticals and medical devices

Concerns about the impact of trade on reforming the medical innovation model

The Doha Declaration on the WTO Agreement on Trade-Related Aspects of IPRs (TRIPs) and Public Health adopted on 14 November 2001 recognises concerns over the relationship between protection of Intellectual Property Rights (IPR) and the impact on medicine prices. The EU should continue to uphold this, and implement it in its trade negotiations.

There have already been [transatlantic health concerns](#)<sup>3</sup> raised about the impact of regulatory cooperation between the EU and US about human medicines and medical devices. Caution is needed as regards the scope and the content of any regulatory talks in the medicines field as there is an ongoing [European policy discussion](#)<sup>4</sup> both in the Council and the European Parliament about the suitability of the Intellectual Property-related incentives in medical innovation therefore questioning the current innovation model<sup>5</sup> <sup>6</sup>.

**The regulatory cooperation around medicines should be considered in the context of the ongoing debate of reforming the current medical innovation model.** The UN Secretary-General established [the High-Level Panel to](#) propose solutions for addressing the incoherencies between international human rights, trade, intellectual property rights and public health objectives. The High-Level Panel on Access to Medicines report “Promoting innovation and Access to Health Technologies was published in September 2016 and called for a new deal to close the health innovation and access gaps. The report points out that for decades, many international treaties and national constitutions have enshrined the fundamental right to health and the right to share in the benefits of scientific advancements. The misalignment between the right to health on the one hand, and intellectual property and trade on the other, fuel this tension.<sup>7</sup>

**The intention of the EU to avoid discussing Regulatory Cooperation or Good Regulatory Practices patents or intellectual property rights with the US is welcome, and EPHA would encourage the Commission to resist any US pressure to do so.** The wider context of regulatory cooperation is the negotiating mandate of both the EU and the U.S. negotiators. Given that [the USTR negotiating mandate](#)<sup>8</sup> includes that ‘*Procedural Fairness for Pharmaceuticals and Medical Devices: - Seek standards to ensure that government regulatory reimbursement regimes are transparent, provide procedural fairness, are non-discriminatory, and provide full market access for U.S. products*’ a cautious approach is needed from the EU, as similar language was [incorporated into TPP](#) (in Chapter 26 on Transparency and Anti-Corruption, Annex A), notably Article 3e)<sup>9</sup> which prescribes a review mechanism that allows pharma companies to challenge decisions not to reimburse pharmaceuticals/medical device.

<sup>3</sup> [http://tacd.org/wp-content/uploads/2016/12/TACD-Resolution-TTIP-medicines-medical-devices\\_-Final.pdf](http://tacd.org/wp-content/uploads/2016/12/TACD-Resolution-TTIP-medicines-medical-devices_-Final.pdf)

<sup>4</sup> <https://epha.org/dutch-pharma-policy-a-groundbreaking-presidency/>

<sup>5</sup> <https://epha.org/scientists-voice-concerns-about-adaptive-pathways/>

<sup>6</sup> <https://epha.org/scientists-voice-concerns-about-adaptive-pathways/>

<sup>7</sup> <http://www.unsgaccessmeds.org/final-report>

<sup>8</sup> [https://ustr.gov/sites/default/files/01.11.2019\\_Summary\\_of\\_U.S.-EU\\_Negotiating\\_Objectives.pdf](https://ustr.gov/sites/default/files/01.11.2019_Summary_of_U.S.-EU_Negotiating_Objectives.pdf)

<sup>9</sup> <https://ustr.gov/sites/default/files/TPP-Final-Text-Transparency-and-Anti-corruption.pdf>



### *Regulatory cooperation on medicines and medical devices*

Plans to expand the scope of the US-EU pharmaceutical GMP Mutual Recognition Agreement to include veterinary drugs, must include clear protections against the spread and development of Antimicrobial Resistance (AMR). This cooperation must not undermine the prudent use of antibiotics in the veterinary, agriculture and aquaculture sectors. The European Commission should strive to achieve the adoption of successful best practices and legislation on AMR as a public health concern, and cooperate with the US in this regard.

Although there may be benefits from close collaboration between regulators in the EU and US, this is already taking place at a technical level and the strength of collaboration has been increasing in recent years. Therefore, there may be limited scope to expand, or formalise regulatory cooperation in this area.

## **II. Antimicrobial Resistance and antibiotic research and development**

In accordance with the [European One Health Action Plan against Antimicrobial Resistance \(AMR\)](#), EPHA would welcome strengthened ongoing collaboration on AMR within the Transatlantic Task Force on Antimicrobial Resistance (TATFAR) which includes the EU, the US, Canada and Norway. Moreover, it is important that the EU promotes international regulatory convergence between the European Medicines Agency and other regulatory agencies such as the US Food and Drug Administration (FDA) on development plans for new antimicrobials.

One of the pull mechanisms to incentivise biomedical innovation concerning new antibiotics is the granting of additional monopoly protection through the extension of IP or related exclusivities. Transferrable IP rights, which has become common practice in the US, is thought to overcome the risk of further incentivising antibiotic sales as companies receive the right to extend their monopoly protection for another product upon successful development of a new antibiotic. However, for antibiotic R&D, EPHA considers this measure inappropriate as it does not delink development costs from the price of the new product. Therefore, it cannot be used to set conditions to make global access and conservation a requirement. The US Generating Antibiotics Incentives Now (GAIN) Act, offers five additional years of market and data exclusivity for the development of new antibiotics. This has resulted in limited antibiotic innovation and increased costs for patients. In addition, it does not address the principles of affordability, accessibility and conservation of new antibiotics.

EPHA calls upon the European Commission to continue to defend EU standards and EU policies on AMR in these trade negotiations, including encouraging the US to align itself with the EU ban on the use of antibiotics as growth promoters in food-producing animals as well as enforcing this EU ban as a conditionality to all food imports from the US. An AMR cooperation article could also be explored in trade agreements.

### *Conformity assessments*

EPHA calls for the precautionary principle to be the central organising principle regarding conformity assessments for medicines and medical devices. Public health must remain the utmost concern in this rather than cost reduction. Reducing the cost of conformity assessments cannot be at the expense of consumer safety. The EU and US should



guarantee the impartiality, independence and technical competence of conformity assessment bodies.

### **III. Digital Health**

Ensuring that similar high standards of data protection, patient safety and service quality will be adopted on both sides of the Atlantic represents a worthy aspiration. , However, the inclusion of digital health in a future EU\_US trade agreement would be undesirable given European health systems' orientation towards striving for universal access to quality healthcare for all, which makes them less compatible with the commercial imperatives guiding many of the Silicon Valley players currently expanding their activities in the health sector by offering digital health technologies.

While developments such as mHealth, Big Data and Artificial Intelligence hold many opportunities for improving individual and population health, the experience of the eCommerce sector – marked by major breaches of privacy and data security – demonstrates that prudence is of the utmost importance when it comes to gathering, storing, processing and analysing personal data in a cross-Atlantic or even global context.

Health data being particularly sensitive, the potential consequences of such breaches are very serious as they put patient safety at risk, threaten livelihoods and compromise quality access to healthcare for all in Europe. European health systems should not be infiltrated by the marketing objectives of private IT companies whose “personalised” health offers are available only for the few; rather, Europe’s future digital health policy should be driven by the actual needs of European patients, healthcare professionals and citizens.



## About EPHA

EPHA is the main public health NGO engaging with [international trade at the European level](#)<sup>10</sup>. This is reflected in the fact that EPHA is the only health NGO member of **the European Commission's Expert Group on Trade**<sup>11</sup>, which regularly meets to discuss the latest developments in trade negotiations and policy, and to enable stakeholders to give input to the European Commission.

### EPHA's work to mainstream public health in international trade

EPHA's work on trade issues dates back to 2013, beginning with advocacy around the Transatlantic Trade and Investment Partnership (TTIP) negotiations, which, at that time, was high on the EU agenda. As the EU holds the exclusive right to negotiate trade deals on behalf of the Member States, Brussels is the centre of European trading decisions. Although international trade might seem unrelated to public health, the way in which trade of alcohol, food and tobacco has developed, as well as the way in which rules regarding regulatory cooperation, investor protection rules limiting the health policy space, intellectual property rights, public procurement and public services clauses are set, has resulted in trade having a wide-ranging impact, affecting many areas of health directly. To highlight this impact, at the 11th July 2018 meeting<sup>12</sup> of the Trade Expert Group, EPHA requested the opportunity to present the EPHA Risk Register covering the EU's negotiations with **Latin America (Mercosur, Mexico, Chile)**<sup>13</sup>, under the agenda point on Mercosur negotiations. EPHA's contribution focused on the relationship between trade and tobacco-related health problems as well as the importance of health impact assessments of trade agreements. Based on the Latin America Risk Register EPHA has developed a general risk register which includes recommendations for future EU trade agreements to protect health.

EPHA also elaborated on [the health impacts of TTIP](#)<sup>14</sup> and the EU-Canada equivalent, the Comprehensive Economic and Trade Agreement (CETA). EPHA was one of the health members of the now-frozen TTIP advisory group, while the declaration attached to [CETA mentions public health several times](#)<sup>15</sup>. The EPHA publication 'The unhealthy side effects of CETA' is available [here](#)<sup>16</sup>

<sup>10</sup> <https://epha.org/trade-and-health/>

<sup>11</sup> <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3556>

<sup>12</sup> <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeeting&meetingID=4050>

<sup>13</sup> <https://epha.org/unhealthy-trades-the-side-effects-of-the-european-unions-latin-american-trade-agreements-report/>

<sup>14</sup> <https://epha.org/?s=TTIP>

<sup>15</sup> <https://epha.org/ceta-and-health/>

<sup>16</sup> <https://epha.org/wp-content/uploads/2016/12/EPHA-Booklet-The-unhealthy-side-effects-of-CETA.pdf>