PRESS RELEASE

Is TTIP prescribing more expensive medicines for Europe?

Brussels, 24th May 2016. Today, the European Commission released its proposal for an annex to the Transatlantic Trade and Investment Agreement (TTIP) on medicinal products. [1] [2] The proposal fails to answer essential questions about affordability of medicines, trade secrets and clinical trials transparency:

Affordability of medicines

The European Commission maintains that closer cooperation on trade in medicines in TTIP will lead to cost savings for pharmaceutical companies. However, it is not clear that any cost savings will translate to lower prices of medicines for national health services and patients. This is essential in the context of prohibitively expensive and rising medicines prices in Europe, which have been highlighted by the Council and the WHO as a major public health issue and are the major barrier between patients and their treatment. [3] [4]

Nina Renshaw, EPHA Secretary-General said, "*EPHA calls on the Commission to present evidence that TTIP will actually lead to lower prices for medicines in Europe, rather than a convergence with the even higher prices that are today's reality in the USA. Affordability of medicines should be included as a key objective in line with the commitment in the proposal to ensure a high level of protection of public health. Unless more affordable medicines are assured, the European Commission should not proceed with negotiations on this chapter*."

Clinical trials data and commercial confidentiality vs. public interest

The proposal includes provisions to facilitate the exchange of confidential and trade secret information related to the authorisation of medicinal products. Information not in the public domain that is shared between regulatory agencies will not be publicly disclosed by the other party.

It appears that pharmaceutical companies are pushing for clinical trial data to be included in the definition of 'confidential and trade secret information' and seeking to undermine the EU Clinical Trials Directive. If clinical trial data were included, then key data about efficacy and complications may be withheld from health professionals and the public. This would imply that commercial interests are put ahead of public health and undermine the progress on clinical trials transparency made over the last 4 years by the European Medicines Agency (EMA), European Parliament and Member States on the publication of clinical data for human medicines. [5] [6]

Questionable value added through including medicinal products in TTIP

There are no tariff barriers to trade in medicinal products, and the US Food and Drug Administration (FDA) and EMA have been engaged in technical cooperation for many years. In the context of already close cooperation, the added value of TTIP in this sector is not evident.

EPHA Policy coordinator for Trade, Zoltan Massay-Kosubek said, "*An additional system of regulatory cooperation as the Commission proposes, including the creation of a transatlantic Working Group, is likely to create an even more opaque regulatory system, an additional administrative burden, and unnecessary use of resources by both regulatory agencies and other stakeholders.*"

Notes to editor:

[1] This is the initial proposal for legal text for inclusion in TTIP for consideration by the US Trade Representative. The actual text in the final agreement will be a result of negotiations between the EU and US. http://trade.ec.europa.eu/doclib/press/index.cfm?id=1230

[2] http://trade.ec.europa.eu/doclib/docs/2016/may/tradoc_154582.pdf

[3] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52014XG1206(03)

[4] 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

[5] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf

[6] http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32014R0536

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