POSITION STATEMENT

18 February 2016

Why You Should Be Concerned About TTIP and Access to Medicines

Both the European Union (EU) and the United States (US) are confronted with increasingly high medicine prices. European Member States are facing a looming access to medicines crisis as they struggle to afford new, patented, high-priced medicines. The Transatlantic Trade and Investment Partnership Agreement (TTIP), now under negotiation, could hamper needed changes towards affordability, needs-driven innovation and alternative incentive structures.

Affordability of medicines is essential to assure equitable access to healthcare. Unfortunately, European Commission position papers and pharmaceutical industry filings with the Commission and the US Trade Representative indicate threats to affordable medicines under consideration in TTIP negotiations. The Trans-Pacific Partnership (TPP) trade agreement recently negotiated by the US also contains provisions that will be devastating for people's health in countries from Chile to Vietnam[i].

The Dutch EU Presidency has questioned the excessive intellectual property (IP) rights protections that are now at the disposal of the pharmaceutical industry. The Health Minister has clearly stated that a new balance must be found to achieve affordable and sustainable access to medicines. Many of the provisions foreseen for TTIP will put industry interests ahead of patients' health. If adopted, they will make it impossible for governments to make certain changes later on.

TTIP could restrict national pricing and reimbursement decisions

TTIP could offer the pharmaceutical industry a much bigger say 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 that attempt to enact cost-containment measures, potentially including cost-benefit analysis[ii].

TTIP may expand monopolistic intellectual property (IP) practices

TTIP could further extend monopoly periods derived from patents and market exclusivity rules and delay price-lowering generic competition. The agreement is likely to lock into place the worst rules from each side of the Atlantic, and block the path toward future cost-cutting reforms[iii].

TTIP will enshrine trade secrets regulations

The EU is about to adopt a Directive that aims to harmonise trade secrets protection rules amongst EU Member States. The Directive extensively refers to an IP framework, threatening citizens' freedom of expression and right to know[iv]. It will likely restrict access to information that is in the public interest, such as medicines safety and efficacy data[v], as well as technical know-how to enable generic competition[vi]. In effect, the scope of IP protection would be widened. In the US, negotiations for new rules on trade secrets are also underway. The objective down the line is to include trade secret protection in TTIP, enshrined as an international benchmark.

TTIP regulatory cooperation mechanism could pave the way for more corporate influence

EU–US working groups for ongoing bilateral coordination on IP and pricing and reimbursement decisions established under TTIP would have the ability to influence domestic medicines policy. A complex institutional infrastructure for regulatory cooperation in the context of an agreement meant to reduce barriers to trade will, in practice, inevitably lead to more possibilities for industry to influence national pharmaceutical policies[vii].

The inclusion of any investor-state dispute settlement mechanism in TTIP could jeopardise public health

The inclusion of investor-state dispute settlement in any form—whether it is based on the US Model Bilateral Investment Treaty or the European Commission's "Investment Court System" proposal—in TTIP would allow foreign companies to extra-judicially challenge legislative, administrative measures, and even judicial decisions taken by a government to safeguard public health and other public interest concerns[viii].

TTIP may set global standards that would harm public health in lower- and middle-income countries

TTIP could harm patients in low- and middle-income countries (LMICs) where resources are more constrained. TTIP may include EU–US cooperation agreements against policies that developing countries use to access affordable generics. Many LMICs have fewer institutions to balance IP monopolies and rally against high prices. This could lead to health systems being even less able to provide care and treatments to patients due to a lack of funds[ix].

Co-signatories:

Health and Trade Network (www.healthandtradenetwork.org)
European Public Health Alliance (www.epha.org)
STOPAIDS (www.stopaids.org.uk)
Wemos (www.wemos.nl)
Health Projects for Latvia (www.healthprojects.lv)
Déclaration de Berne – Berne Declaration (www.ladb.ch)
EKPIZO (www.ekpizo.gr)
PRAKSIS (www.praksis.gr)
Access, France
Verein demokratischer Pharmazeutinnen und Pharmazeuten (www.vdpp.de)
The International Society of Drug Bulletins (www.isdbweb.org)
Salud por Derecho (www.saludporderecho.org)
Medicines In Europe Forum (www.prescrire.org/Fr/1/507/49248/3234/ReportDetails.aspx)
Universities Allied for Essential Medicines (www.uaem.org)

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ENDNOTES

[i] Médecins Sans Frontières (MSF) - Open Letter to ASEAN Governments - Don't trade away health:

[ii] EU-Korea FTA - Annex 2-D Pharmaceutical products and medical device: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2011.127.01.0001.01.ENG
TPP: Threats to Affordable Medicines: http://www.citizen.org/documents/TPP-IP-Factsheet-December-2015.pdf
How the TTP endangers Access to Affordable Medicines: http://www.citizen.org/documents/how-tpp-endangers-access-to-medicines.pdf

[iii] Big Pharma´s leaked wish list for TTIP EU-US trade pact: http://tacd-ip.org/archives/1138
A civil society response to the Big Pharma Wish list: http://commonsnetwork.eu/wp-content/uploads/2014/03/A-Civil-Society-Response-to-the-Big-pharma-wish-list_Nov2014.pdf

[iv] CEO et al. European civil society organisations call for the rejection of the EU Trade Secrets Directive. Press release, 27 January 2016 http://corporateeurope.org/power-lobbies/2016/01/european-civil-society-organisations-call-rejection-eu-trade-secrets-directive

[v] De Pracontal, M. Essai clinique de Rennes: des scientifiques réclament la transparence. Mediapart.fr, 26 January 2016. https://www.mediapart.fr/journal/international/250116/essai-clinique-de-rennes-des-scientifiques-reclament-la-transparence

[vi] EU trade secrets directive threat to free speech, health, environment and worker mobility: http://haieurope.org/wp-content/uploads/2015/03/Statement-updated-on-trade-secrets-directive.pdf

[vii] One might think the EC is close to pharma but it is incomparable to the US where pharma has determining voice in policy making, especially in trade. Any US influence in our EU policies through working groups, in the area of pharmaceuticals, effectively will mean pharmaceutical industry influence.

[viii] The inclusion of investor-to-state dispute settlement (ISDS) in Transatlantic Trade and Investment Partnership (TTIP) would undermine public health:
http://trade.ec.europa.eu/doclib/docs/2015/may/tradoc_153458.pdf

[ix] Big Pharma´s leaked wish list for TTIP EU-US trade pact (footnote iii)