STATEMENT

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Corporate interests should not trump access to medicines for EU citizens in secret TTIP negotiations

AMSTERDAM—As the European Union (EU) and the United States (US) continue the fourth round of Transatlantic Trade and Investment Partnership Agreement (TTIP) negotiations in Brussels this week, Health Action International is gravely concerned. Against the already grim background of austerity measures and public health cuts, the European Commission may be about to enter into a secretive trade deal that will sacrifice even more of EU citizens' health for the benefit of multinational industry profits.

A 2013 letter from the Pharmaceutical Research and Manufacturers of America (PhRMA) to US trade negotiators clearly shows that what pharmaceutical companies seek to gain in these negotiations may seriously jeopardise the affordability of medicines in the EU.[i] The US has proved to be prone to adopting key elements of the PhRMA wish list in the past, as similar policies have been pushed by the US in previous trade negotiations.[ii]

TTIP COULD HARM AFFORDABILITY OF MEDICINES FOR EU CITIZENS

Faced with a financial and economic crisis and ever-increasing healthcare expenditures, EU Member States are struggling to continue to provide universal access to medicines for their citizens. New patented medicines are becoming increasingly expensive and the rise in expenditure on patented medicines has even outpaced the savings brought through the use of generics.[iii]

Countries hardest hit by the crisis, including Portugal, Spain and Greece, have been forced to dramatically cut pharmaceutical spending.[iv] The effects of these budget cuts on access to medicines and health services are already visible: In Greece more than 6000 children are now without vaccination.[v] Other countries, including Germany, are taking bold measures to contain medicines prices and amend their reimbursement policies to ensure their citizens will continue to have access to medicines in the long term.[vi]

Taking into account the PhRMA wish list and US demands in previous trade negotiations, and well within the Commission's negotiating mandate, TTIP can harm the affordability of medicines for EU citizens in several ways:

- ***Delay the availability of cheaper generic medicines in the EU.*** *Extending or expanding intellectual property (IP) monopoly protection through patent linkage, convergence of patent standards and strong IP enforcement measures will increase costs of medicines and health care services for EU governments and citizens. The Commission should not to include any substantive and enforcement provisions on IP that go beyond the already high standard of protection in the EU.*

- ***Limit the public availability of crucial safety and efficacy data regarding medicines.*** *Safety and efficacy of medicines data is crucial for evidence-based medicine and the protection of public health. Denying or limiting public access to information will cause irreparable harm to the health of EU citizens.[vii] The Commission should ensure that nothing in TTIP will impair EU developments in the new EU Clinical Trials Regulation and at the European Medicines Agency to move towards proactive public access to crucial medicines safety and efficacy data.*

- ***Give pharmaceutical companies a bigger 'say' in EU Member States' pricing and reimbursing decisions.*** *Providing the pharmaceutical industry with an increased 'voice' in EU*

Member States pricing and reimbursement policies will jeopardise the freedom of Member States to tailor these policies to ensure long-term, sustainable access to medicines for their citizens. The Commission and Member States should resist any US demand for such an increased 'voice' in EU Member States' pricing and reimbursement policies.

- ***Enable pharmaceutical companies to sue EU Member States over their pharmaceutical policies.*** *The proposed investment chapter, and, in particular, the inclusion of IP as an investment and the investor to state dispute settlement (ISDS) mechanism, seriously threatens the possibility for EU Member States to take measures to regulate for health and reduce the costs of medicines. The Commission should exclude IP from the definition of 'investment' and exclude the ISDS mechanism from the investment chapter.*

PUBLIC INTEREST AND CONSUMER ORGANISATIONS SHUT OUT OF NEGOTIATIONS

The PhRMA wish list also poses serious concern because of the sheer imbalance in access and influence on the EU and US trade agenda by corporations, as opposed to public interest groups. Corporate Europe Observatory (CEO) reported that in 2013, the European Commission held 130 'stakeholder meetings' on TTIP. Of these 130 meetings, 119 were with large corporations and their lobby groups.[viii] Also on the US side, corporations form the large majority of direct advisors on US trade policy priorities.[ix]

Because of this imbalance in access to policy-makers, it is crucial for public interest and consumer organisations to have access to draft negotiating texts during TTIP negotiations. If public interest and consumer organisations are not aware of what is negotiated, they cannot engage in the public debate and scrutinise and counterbalance the likely corporate-driven agenda of the EU and US.

The Commission recently established special advisory groups to advise on public interests.[x] This limited group of public interest experts may have access to the negotiating texts, but will not be allowed to share this with other people in their own organisations, let alone third parties. This secret and limited process of arbitrary access, conditioned upon signing non-disclosure agreements to block public debate, does not enhance openness and transparency in a meaningful way.

Without real transparency of the negotiations, TTIP will result in a trade agreement pieced together in an undemocratic and opaque process without real representation of public interests and consumer groups. The Commission should make negotiating texts available in such a way that parliamentarians, public interest groups and other stakeholders can provide meaningful input.

Health Action International strongly urges the European Union to consider the impact that IP, regulatory and investment provisions within TTIP could have on the public health and socioeconomic development of EU Member States. The health of EU citizens must not be traded away in exchange for multinational pharmaceutical industry profits.

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Health Action International (HAI) is an independent, global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy.

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Endnotes

[i] See comments PhRMA submitted to the Office of the US Trade Representative, available at: www.regulations.gov/contentStreamer?objectId=09000064812d9cad&disposition=attachment&contentType=pdf

[ii] Key elements of this PhRMA wish list, including IP demands and an increased voice for pharmaceutical companies in governments' pricing and reimbursement decisions, were proposed by the US in the context of US trade negotiations with South Korea and in the Trans Pacific Partnership (TPP) Agreement.

[iii] Guiseppe Carone et al. Cost-containment policies in public pharmaceutical spending in the European Union. Economic Papers 461, European Economy, September 2012. pp. 41–42.

[iv] Christine Leopold. Pharmaceutical policy measures implemented in response to the recession in Europe 2012–2013. Presentation May 2013. Available at: http://haieurope.org/wp-content/uploads/2014/02/Christine_Leopold-Pharmaceutical_policy_measures_implemented_in_response_to_the_recession_in_Europe_2012-2013.pdf

[v] Euractiv. Doctors say thousands of Greek children unvaccinated. 10 December 2013. Available at: www.euractiv.com/health/doctors-thousands-children-greec-news-532216

[vi] For example, Germany implemented changes to its reimbursement policy, which now takes into account the cost/benefit compared to existing treatments before treatments can be successfully reimbursed. Germany also recently announced that it will publish previously secret information on discounts that it receives from the pharmaceutical industry on the publicly listed medicines prices. Such price transparency is crucial because it empowers pricing officers when they are negotiating prices and can lower the price that patients and consumers pay. (For more information on price transparency, see Health Action International's consultation response to the European Union Transparency Directive, available at: http://haieurope.org/wp-content/uploads/2012/01/25-May-2011-HAI-Europe-Consultation-Response-Transparency-Directive.pdf)

Examples of press coverage of these changes:
Reuters. Germany's stance on pricing threatens drug firm profits. 18 February 2014. Available at: http://uk.reuters.com/article/2014/02/18/us-germany-drugs-analysis-idUKBREA1H09E20140218

Eyeforpharma. Pharma reimbursement in Germany: Through the eyes of a budget holder. 16 September 2013. Available at: http://social.eyeforpharma.com/market-access/pharma-reimbursement-germany-through-eyes-budget-holder

[vii] For more information, see Health Action International Europe's policy paper, 'Protecting citizens' health: Transparency of clinical trial data on medicines in the EU'. October 2013. Available at: http://haieurope.org/wp-content/uploads/2013/10/HAI_Protecting-citizenshealth-transparency-of-clinical-trial-data-on-medicines-in-the-EU.pdf

More information on Health Action International's work on access to medicines safety data available at: http://haieurope.org/work-areas/rational-use-of-medicines-2/the-patient-information-debate/

[viii] Corporate Europe Observatory. European Commission preparing for EU-US trade talks: 119 meetings with industry lobbyists. 4 September 2013. Available at: http://corporateeurope.org/print/trade/2013/09/european-commission-preparing-eu-us-trade-talks-119-meetings-industry-lobbyists

[ix] Washington Post. Industry voices dominate the trade advisory system. 27 February 2014. Available at: www.washingtonpost.com/wp-srv/special/business/trade-advisory-committees/index.html

[x] European Commission press release, Expert group to advise European Commission on EU-US trade talks. 27 January 2014. Available at: http://europa.eu/rapid/press-release_IP-14-79_en.htm