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PATIENTS MUST COME BEFORE PROFITS IN EU TRADE POLICIES

Leïla Bodeux – Oxfam Solidarité



INTRODUCTION

Health is a basic right. International treaties and agreements oblige countries to guarantee that everyone can exercise this right. Is the right to health, however, compatible with economic interests? What are the impacts of free trade agreements on the healthcare of countries in the South with whom the European Union has concluded and/or is negotiating an agreement?

These policy briefs from the North-South working group of the Action Platform Health and Solidarity and the working group on Social Determinants of Health of Be-cause Health focus on various aspects of the impact international trade policy has on health. The policy briefs examine the following topics: international trade policy and the right to health in relation to (1) intellectual property rights (TRIPS), (2) decent work and (3) universal health coverage.

ABSTRACT

For years the EU has been at the front to negotiate Free Trade Agreements (FTA) with trade partners which promote the economic interests of the pharmaceutical industry lobby at the detriment of public health and more specifically access to medicines and new technologies in low- and middle-income countries. In these FTA, the European Commission (EC) tries to push for far-reaching intellectual property (IP) and investment provisions, putting states at the mercy of big companies. These attempts risk undermining efforts being done in other sectors by the European Union (EU) to promote development and health. Since 2013, the EC has embarked on the sensitive negotiation of the Transatlantic trade and investment partnership (TTIP) with the United States. Access to medicines and health is here again threatened.

The EC considers strict IP rules as a tool to incentivize and reward innovation and to boost EU's "knowledge economy". But this Research and development (R&D) model produces expensive medicines, and fails to deliver treatments for diseases that are not enough profitable, as the glaring example of Ebola has shown. Trade policies should not be used as a tool to defend commercial interests at the expense of the public interest. Members of the European Parliament (EP) and EU Member states must ensure that the EC defends a trade and R&D model that is coherent with its development and public health objectives.

1 Why generic medicines play a key role

Worldwide, over 2 billion people do not have regular access to the essential medicines that they need, expensive prices being one of the barriers for low and middle income countries (LMICs).¹ Furthermore LMICs are facing a double burden of disease: the unfinished agenda of infectious diseases such as HIV, hepatitis C or malaria combined with the rising burden of non-communicable diseases (NCDs) such as cancer, diabetes, and cardiovascular diseases. The World Health Organization (WHO) estimates that over 80 percent of all deaths from NCDs today occur in LMICs.² Making generic medicines widely available is key to meeting these challenges.

The 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)³ sets global standards for the protection of intellectual property (IP) rights under the auspice of the World Trade Organisation (WTO). It grants a 20 years patent

protection for new inventions: during this time lapse, the patent owner enjoys market exclusivity for its product. As such generic medicines (which are bioequivalent cheaper copies of one medicine) cannot enter the market. Consequently, these provisions keep prices high and have generated for years concerns regarding the impact on access to affordable treatment and the subsequent economic burden that falls on already stretched national health services.

This led to the adoption in 2001 of the Doha Declaration on TRIPS and Public Health which affirms that the WTO rules on IP should not prevent countries from taking measures to protect public health.⁴ Such measures are known as 'TRIPS flexibilities'.

Generic competition has proven to be the most effective way to lower medicines prices in a sustainable way. The impressive fall of anti-retroviral

(ARV) medicines prices is a telling example. Today, first-line ARV treatment is available for slightly less than \$100 per person per year, which is a 99 percent decrease since 2000, when treatments that were still under patent were priced at more than

\$10,000.⁵ LMICs, such as Thailand, Ecuador and India have effectively used TRIPS flexibilities to enable generic competition and reduce medicine prices. It is paramount that trade policies do not hinder the use of these flexibilities.

2 Trade policies detrimental for access to medicines in developing countries

WHO Director-General Margaret Chan warns about the implications of trade policies for health

'In my view, something is fundamentally wrong in this world when a corporation can challenge government policies introduced to protect the public from a product [tobacco] that kills. Some Member states have expressed concern that trade agreements currently under negotiation could significantly reduce access to affordable generic medicines. If these agreements open trade yet close access to affordable medicines, we have to ask: Is this really progress at all, especially with the costs of care soaring everywhere?'⁶

a) Prices of medicines risk skyrocketing in the name of stricter IP protection

For years, Western governments, hand in hand with the pharmaceutical industry, have sought to impose stricter IP standards than what WTO foresees (called 'TRIPS-plus' provisions) and to restrict the legitimate use of TRIPS flexibilities through the negotiation of Free Trade Agreements (FTA). These concern LMICs and trading blocs such as Central America, MERCOSUR, the Andean Community, Thailand or India. India is nicknamed the 'pharmacy of the developing world'⁷ because its balanced IP system allows it to play a key role in the production and the export of generic medicines bound to developing countries, providing for instance over 80 percent of the world's generic anti-retroviral medicines. The enforcement of stricter IP provisions in India would thus directly threaten access to affordable generic medicines for millions of patients around the world.

The European commission (EC) negotiates FTA on behalf of European union (EU) Member states and tries to push for the following standards:

- **Extending monopolies through (1) patent-term extensions** beyond the 20-year period provided for by the TRIPS agreement and **(2) data exclusivity**. The former extends the monopoly protection by

several years (5 to 10 years depending on the provision).⁸ The latter involves significantly enhancing the protection for clinical trial data (which must be submitted to the drug regulatory authority in order to obtain marketing approval for a medicine), by providing up to 11 years of exclusive use.⁹ This prolongs monopoly protection for medicines even in cases in which patents do not exist.

- **Introducing IP enforcement measures that strengthen the IP protection** of rights holders and obstruct the import, transit or export of legitimate generic medicines,¹⁰ delaying henceforth their availability. For example, European customs seized at least 19 generic medicine shipments from India and Brazil in transit through the EU to developing countries in 2008 and 2009. Despite the rejection by the European Parliament (EP) of the controversial anti-counterfeiting trade agreement (ACTA) - which contained problematic IP enforcement measures-, the EU is still attempting to incorporate similar provisions in FTAs and in EU legislation.¹¹

The following prospective and retrospective impact studies confirm the risks TRIPS-plus rules represent for access to medicines for developing countries, which directly contradicts EU's commitment to the Doha Declaration.

ETA	PUBLIC HEALTH IMPACT
UE - Colombia	By 2030, patent-term extensions could increase expenditure on medicines in Colombia by nearly \$280m; data-exclusivity rules could result in an increase of more than \$340m. ¹²
US - Jordan	Data exclusivity resulted in significant delays to the introduction of generic competition for 79 percent of medicines examined in the study. The availability of generic equivalents would have reduced Jordan expenditures on medicines by between \$6.3m and \$22m between mid-2002 and 2006. ¹³
US - Thailand	A macro-economic model measured the impact of data exclusivity and patent extension proposals on the pharmaceutical market and access to medicines: Medicines' prices would increase by 32 percent by 2027. ¹⁴

b) When investment prevails over health

Another tool the EC used in FTAs to protect its industry is investment provisions such as the investor-to-state dispute settlement (ISDS). This highly controversial mechanism gives foreign investors the right to sue governments in secret arbitration tribunals claiming huge financial compensation if laws, policies, court decisions or other actions interfere with expected profits from investments, even if these government actions are in accordance with the public interest.

Companies could for instance sue a government for using TRIPS flexibilities to promote access to medicines. ISDS henceforth creates a “chilling effect”¹⁵ and risks putting off states from regulating to protect public health because of the fear of being sued. In 2013, the US-based pharmaceutical company Eli Lilly accused Canada of violating its obligations to foreign investors under the North American Free Trade Agreement (NAFTA), by allowing Canadian courts to invalidate patents for two of its drugs and is demanding \$500 million in compensation.¹⁶

3 Watch out for our medicines in TTIP !

LMICs are not alone in trading their public health for free trade: the Transatlantic trade and investment partnership (TTIP) currently in negotiation between the EU and the United States poses several threats for public health at the benefits of multinational industry. Besides, TTIP provisions would be used as global standards to be imposed on other countries -including developing countries- in later stages.¹⁷

a) Stricter IP standards and medicines policies risk increasing health inequality

Public expenditure on pharmaceutical products increased on average by 76 percent across EU countries between 2000 and 2009 due to ageing populations and the increasing cost of medicines.¹⁸ Problems of affordability and availability of medicines in Europe have been exacerbated by the financial crisis, when several governments were forced to decrease health budgets in order to achieve ‘fiscal balance’, at the expense of the right to health. In this context, facilitating the entry into the market and the use of affordable generic medicines is crucial.

Leaked pharmaceutical industry “wish list” demonstrates however that the big pharmaceutical companies seek **stronger IP protections and harmonization on patentability standards**. Standards risk being aligned to the US ones, which are considerably lower. This means concretely more patents granted, less generic competition and higher prices for medicines and technologies. Furthermore, the pharmaceutical industry is also pushing to get more influence in EU Member states’ **medicines pricing and reimbursement policies**, which could challenge Member states’ sovereignty to take measures to control expenditure on medicines.¹⁹

b) Spotlight on ISDS

Both the USA and the Directorate-General for Trade (DG-Trade) which negotiates FTA on behalf of the EC and EU Member States are pressing for the agreement to include an ISDS. This mechanism (explained above) would allow companies to bring legal challenges against state measures like price

controls, reimbursement and therapeutic formulary decisions, marketing approvals and pharmacovigilance decisions, or stronger patentability standards. Hence, Accessibility and affordability of medicines in Europe

could be put in jeopardy. Moreover Including ISDS in TTIP is unjustified and unnecessary, given the high level of investment protection that the domestic EU and US legal systems already provide.

4 The European commission on the wrong track

a) European democracy and coherence in jeopardy

The EU, under the Treaty of Lisbon, has committed to the principle of *'health in all policies'*,²⁰ which guarantees that a *'high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities'*.²¹ The Treaty also stipulates that all external policies of the EU should be coherent with its development objectives.²² But negotiations of TRIPS-plus and far reaching investment measures directly contradict these principles and efforts made by several Directorate-Generals to foster development and health. Several trade policies led to an outcry from the European Parliament, academics, civil society and some trade partners,²³ and harsh criticism from UN commissions and the Vatican.²⁴ This resistance has impeded the EU to impose certain TRIPS-plus provisions in several FTAs, such as the one with India, whose government was put under strong pressure from various actors. The South American trading bloc, MERCOSUR, refused to use the standard EU text as a starting point, and proposed an approach to IP provisions that prioritised social welfare. Nevertheless, in current negotiations with Thailand, the EU is again attempting to impose strict IP rules for medicines.²⁵

DG-Trade lacks the will to truly take into consideration concerns expressed by civil society, especially when it comes to IP measures and the pharmaceutical industry, which spends more than 40m annually to influence decision making in the EU, employing an estimated 220 lobbyists.²⁶ Academics and civil society representatives have spoken in a single voice on the ineffectiveness of the predominant IP-based Research and development (R&D) system. But this is falling on deaf ears and the EU keeps on promoting this R&D model in FTA.

b) A flawed R&D model that works for the rich

The current R&D model which relies predominantly on IP to boost innovation is failing in terms of public health. This system produces medicines with small or no therapeutic added value, high priced products and leaves diseases, which do not promise high economic benefits, such as neglected diseases, without any cures.²⁷ Companies are more and more focusing their business model on marketing schemes, patent protection, litigation against competitors and the development of *'me too'*²⁸ medicines of little therapeutic advantage while disinvesting in R&D for key diseases.²⁹ Only four out of 97 new medicines or indications of a known medicine in 2010, provided a therapeutic advantage.³⁰ A pharmaceutical sector



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enquiry by the Directorate General for Competition (DG-Competition) of the EC revealed the structural use of a toolbox of tactics by companies to delay generic competition, adding an additional cost to EU health systems of at least €3bn between 2000 and 2007.³¹ While the pharmaceutical sector justifies the exorbitant prices of many new medicines by the need to recoup R&D costs, figures show that the sector allocate as little as 15 percent of its net sales in R&D.³² A more accurate explanation to the skyrocketing prices can be found in the huge profits the sector reaps.

CONCLUSION

In short, the IP system is not producing the fruits of innovation required by society, and acts as a barrier for access to the products that it does produce. This is why IP rules should be sufficiently flexible to meet public health needs and alternatives to a patent-based system are needed. New approaches to biomedical innovation are based on sharing knowledge and data, rather than shrouding it in secrecy and IP protection should instead be supported by the EU. Unfortunately, the EU persists in presenting IP rights as a silver bullet to boost growth and is set to scale up its strategy to ensure that third countries implement high level of IP rights, as a Communication released in July 2014 revealed. Exclusion from EU-funded programs are even envisaged for the more resistant countries.³³

POLICY RECOMMENDATIONS

A dramatic shift in the way the EC is leading on trade policies is needed. DG-Trade should stop considering trade policies as a tool to protect the commercial interests of EU industries, and should collaborate more closely with other Directorate-Generals and EU institutions to make sure that trade policies benefit EU citizens as well as people in developing countries. EU institutions and Member states should honour their commitments to ensure access to medicines and needs-driven innovation by promoting alternative R&D models. The principle of 'policy coherence for development', enshrined in the Lisbon Treaty, should be implemented to avoid that EU trade policies contradict the objectives of EU development policies.³⁴ More specifically:

1. EU trade policies must be coherent with its development and (global) health objectives:

- a. Not introduce TRIPS-plus and investment protection measures in FTAs that are detrimental to access to medicines, and/or which limit the public-health policy space.
- b. Actively support governments that make use of legal TRIPS safeguards and flexibilities to protect and promote public health.
- c. Ensure that the TTIP agreement does not jeopardise access to medicines in Europe and beyond.

2. The EU supports generic competition to allow broad access to medical products in LMICs:

- a. Engage in meaningful technology transfer with least-developed countries to allow among others the local production of medicines .
- b. Encourage companies to join the Medicines Patent Pool. (A UN-backed organisation that aims to improve access to appropriate, affordable HIV medicines by opening the door to generic production through facilitation licensing of relevant patents)
- c. Ensure that the global health and medicines organisations such as the Global Fund to Fight AIDS, Tuberculosis and Malaria continue to use generic medicines and make quality medicines and diagnostics available and affordable.

3. The EU and its Member states support new models of innovation by:

- a. Supporting the implementation of the WHO's Global Strategy and Plan of Action on Public Health, Innovation and IP, and a Biomedical R&D Convention at the WHO.
- b. Ensuring that innovation and biomedical knowledge, derived in whole or in part from publicly funded health R&D, results in public goods and medical products that are suitable, affordable and accessible.

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