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Summary

Trading Away Access to Medicines

How the European Commission's trade agenda has taken a wrong turn

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Access to medicines poses a critical challenge in developing countries, largely because prices are high, and new or adapted medicines and vaccines to address diseases of the developing world are lacking. More than 5 million people in low and middle income countries still lack access to the anti-retroviral medicines needed to treat HIV and AIDS. Non-communicable diseases (NCDs) have unleashed a new epidemic of suffering across the developing world. Pandemics are a serious threat in rich and poor countries alike, but while rich countries can stockpile medicines, these are often unaffordable for poor countries. Most people in developing countries pay for medicines out-of-pocket, so even a slight price increase can mean that life-saving medicines are unaffordable.

The patent system, globalized under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), is the dominant incentive framework for the development of new medicines, particularly where there is a profitable market. However this framework does not provide for innovation that meets health needs and added therapeutic value for use in countries where profitable markets do not exist.

Furthermore, patents (and other forms of intellectual property) for medicines delay competition by prohibiting low-cost copies (generic medicines). This results in higher prices for medicines that neither developing country governments nor poor people can pay without sacrificing other basic necessities, and has disastrous consequences for millions of poor people.

Developing countries have addressed some of the challenges created by the extension of the patent system under TRIPS. The Doha Declaration on TRIPS and Public Health was agreed in November 2001 by all World Trade Organisation (WTO) members. It provided assurance that intellectual property (IP) rules should not prevent governments from taking measures to protect public health, while also offering least-developed countries (LDCs) a transition period to 2016 to implement TRIPS. At the same time, the World Health Organization (WHO) has secured a mandate, based on the political will of governments and existing evidence, to examine and promote models of innovation that lie outside the patent system and that have the potential to generate health products appropriate for developing countries. These welcome shifts have occurred in spite of fierce resistance by the multinational pharmaceutical industry.

European Union (EU) Member States and the European Commission (EC) have taken some steps to improve access to health services,

including access to health technologies in developing countries. Within the EU, many EU Member States have policies in place to reduce medicines prices for their citizens, while the EC has launched an inquiry into the perverse incentives and abuse of the IP system by multinational pharmaceutical companies and the costs of these abuses for health systems and patients. The EC is also committing nearly one billion euro on behalf of Europeans to new research and development (R&D) aimed at generating new therapies.

Yet the EU is guilty of double standards, with the EU's trade agenda acting directly against these same objectives in developing countries. The EU is pushing a range of IP measures that would support the commercial interests of the pharmaceutical industry, while damaging the opportunities for innovation and access to medicines in developing countries. These measures include:

1. Introducing TRIPS-plus rules (IP rules that exceed obligations under WTO rules) through agreements, especially free trade agreements (FTAs) with developing countries.
2. Exerting bilateral pressure upon developing countries to prevent the use of TRIPS public health safeguards to reduce medicine prices.
3. Leading on a new global framework to enforce IP rules, within which elements of European legislation are resulting in the seizure of generic medicines in transit, intended for developing countries.

EU demands exceed those pursued by the previous United States government, whose IP policies were criticized for their negative effects on health in developing countries for many years by developing country trade negotiators and Ministers of Health, civil society groups, and inter-governmental organizations. Strict levels of IP protection imposed through EU trade policies will result in a vast increase of expenditure for medicines purchased by donors, developing countries, and households. India, which exports two-thirds of the affordable medicines its generic companies produce to developing countries, including over 80 percent of the world's generic anti-retroviral medicines, could face severe restrictions that would deny affordable medicines to millions of people in India and jeopardize exports of its generic medicines to the world's poorest countries.

European donors and the European Commission have taken some initiatives to promote innovation in developing countries. For example, the Commission has initiated a model programme to improve clinical trial capacity in developing countries, and it has introduced new regulations to ensure that studies are carried out in order to assure the safety of new paediatric medicines for children in all age bands. Yet overall, not enough has been done and the Commission has not contributed its fair share to stimulate innovation to address diseases that disproportionately affect developing countries. Its overall spending on R&D for innovation for developing countries is growing, but remains insufficient.

The EU has obstructed progress on measures at the WHO that would explore new models of R&D to address essential public health needs in developing countries. Without innovation to address these needs, many millions of men, women, and children will continue to wait for solutions that fail to materialise.

The incoming European Commission provides an opportunity to bring much needed coherence to EU policies – a chance to ensure that it no longer takes with one hand what it gives with the other.

At present, EU policies on innovation and intellectual property diminish other investments that the EU and Member States are making to improve health care in developing countries. This makes a mockery of the Commission's own drive to demonstrate policy coherence across its own institutions, and ignores the political will of many stakeholders, including some Member States of the EU.

While the EC has led in the implementation of these policies, Member States, with few exceptions, have stood by silently as the EC has implemented its damaging IP agenda internationally.

In order to improve innovation and access to medicines for developing countries, Oxfam International and Health Action International recommend the following:

1. The European Commission and EU Member States should honour commitments under the MDGs, the Doha Declaration on TRIPS and Public Health, and relevant World Health Assembly (WHA) resolutions on innovation and access to medicines, including full implementation of the WHO 'Global Strategy and Plan of Action'.
2. The EU should ensure its trade policy is in line with its development objectives, including specifically enhancing access to health care and access to medicines. This includes ensuring that trade rules, whether multi-lateral, regional, or bilateral, exclude essential public services such as education, health, and water and sanitation from liberalization commitments. EU Member States must act to hold the EC accountable when the EC fails to uphold these principles.[1]
3. With respect to IP:

- The EU and Member States should not misuse FTAs to introduce TRIPS-plus IP rules in developing countries to extend monopoly protection and introduce new enforcement measures, which limit access to medicines.
- The European Commission should stop exerting pressure on governments that attempt to introduce safeguards and flexibilities to protect and promote public health.
- The European Commission should amend its counterfeiting regulation to ensure it does not have a detrimental impact on developing countries, by excluding border measures for violations of pharmaceutical patents, especially for medicines in transit.

- The EU should ensure that the Anti-Counterfeiting Trade Agreement (ACTA) does not set a new global standard for intellectual property rules (IPR) that impedes access to medicines in developing countries. Therefore, the EU should ensure that patents are excluded from any agreed framework.
- The European Commission and Member States should identify and support other measures to improve access to generic medicines in developing countries, including the UNITAID patent pool for HIV and AIDS medicines.

4. With respect to R&D:

- European donors, including the Commission, should scale up financial contributions to R&D to address diseases that disproportionately affect people living in developing countries, especially through alternative funding mechanisms that promote therapeutic innovation.
- The EU should also support Product Development Partnerships (PDPs) that are designed to deliver affordable and effective new products, and it should continue building R&D capacity in developing countries.
- The EU should support the implementation of the World Health Organization's Global Strategy and Plan of Action (GSPA) on Public Health, Innovation and Intellectual Property, and support the Expert Working Group in its efforts to explore new models of innovation that increase both innovation and access.
- The European Commission should take appropriate measures to ensure that specific initiatives such as the Innovative Medicines Initiative (IMI) meet real health needs, and that both the IMI and the EUs regulation on children's medicines can also be to the benefit of developing countries.

Acronyms

ACTA	Anti-Counterfeiting Trade Agreement
EU	European Union
EC	European Commission
DG	Directorate General
FTA	Free Trade Agreement
IMI	Innovative Medicines Initiative
IP	Intellectual Property
IPRs	Intellectual Property Rights
MDG	Millennium Development Goal
NCD	Non-communicable disease
LDCs	Least developed countries
TRIPS	Trade Related Aspects of Intellectual Property Rights
WHO	World Health Organization
WTO	World Trade Organization
WIPO	World Intellectual Property Organization

1. This briefing paper focuses primarily on European Union intellectual property and innovation policy and its consequences for health care in developing countries, and does not discuss in any detail existing EU trade policy on liberalization of essential services. Oxfam remains seriously concerned that liberalization of essential services will have negative consequences for access to education, health, and clean water and sanitation in developing countries. For more information, please see: Oxfam International (2008) 'Partnership or Power Play?' http://www.oxfam.org/en/policy/bp110_EPAs_europe_trade_deals_with_acp_countries_0804

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