

Trading Away Access to Medicines

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

EMBARGOED UNTIL 00:01 HRS GMT TUESDAY 20 OCTOBER 2009

Insufficient innovation and a lack of access to affordable medicines are major barriers to achieving the right to health in developing countries. The European Commission (EC) could play a leading role in working with developing countries to improve innovation and access to medicines. Instead, the EC has implemented a trade agenda that favors the commercial interests of the multinational pharmaceutical industry over the needs of people in developing countries. At the same time, the EU has failed to commit sufficient resources towards medical innovation that meets developing countries' public health needs. These policies undermine the efforts of the EC to improve access to health care. Oxfam International and Health Action International Europe urge Member States and the European Parliament to use their powers to ensure that the incoming Commission radically reforms its policies on trade, in order to ensure coherence with development objectives in the field of health. In addition, all European donors should review their policies to maximise access to medicines in developing countries.

Summary

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.¹ 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.² Non-communicable diseases (NCDs) have unleashed a new epidemic of suffering across the developing world.³ 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.⁴ 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.⁵

The patent system, globalized under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),⁶ 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.⁷

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.⁸

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.⁹ 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.¹⁰ 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,¹¹ 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.¹² 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.¹³

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,¹⁴ civil society groups,¹⁵ and inter-governmental organizations.¹⁶ 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.¹⁷

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.¹⁸ 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.¹⁹ EU Member States must act to hold the EC accountable when the EC fails to uphold these principles.
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 EU's 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

Introduction

The right to health is broadly recognized by governments and international organizations in constitutions and international treaties.²⁰ Yet approximately two billion people lack regular access to essential medicines in developing countries, in part due to high prices of existing patented medicines.²¹ High medicine prices can be an absolute barrier to treatment, or create difficult choices for poor households that must either pay out-of-pocket for their medicines, or buy other basic necessities instead, such as food. The cost of medicines represents the greatest share of health care expenditures for people in poor countries. Expenditures on pharmaceuticals range from 10 to 20 percent of expenditures on health in the richest countries and 20 to 60 percent in poorer countries.²² Unlike many rich countries, most developing countries lack universal health insurance. Across Asia, medicines comprise between 20 and 80 percent of out-of-pocket health care costs.²³ In Peru, where 70 percent of expenditures on medicines are paid for out-of-pocket, only 52 percent of the population has health insurance, and coverage mostly excludes those below the poverty line.²⁴ Additionally, innovation is inadequate for medicines needed to address diseases disproportionately affecting people in developing countries, leaving many people without effective treatment.

In recent years, progress has been made to improve innovation and access to medicines. In 2001, all World Trade Organization (WTO) Member States signed the Doha Declaration on Trade Related Aspects of Intellectual Property Rights (TRIPS) and Public Health, recognising concerns about the effects of intellectual property (IP) rules on generic competition, a proven mechanism to reduce medicine prices. The Declaration affirms that IP rules should not prevent countries from taking measures to protect public health.²⁵ Lower prices for medicines, achieved through generic competition, have enabled 4 million people to start treatment for HIV and AIDS.²⁶ Moreover, developing countries, such as Thailand, have used WTO rules to reduce medicine prices and provide free, public-sector treatments for HIV and AIDS, cancer, and cardiovascular disease.²⁷

Efforts to encourage R&D into diseases that disproportionately affect developing countries are encouraging. Some product development partnerships (PDPs) suggest a pipeline of promising medicines and vaccines that could deliver new treatments for neglected diseases, while innovative financing mechanisms have introduced incentives to encourage private sector R&D for the same purpose.²⁸ In addition, new models of innovation and access such as patent pools and prize funds have been tabled. These could generate technologies that meet the health needs of developing countries.²⁹

The European Union, under the present Treaty and under Lisbon, commit to the principle of 'Health in all Policies',³⁰ which guarantees that a 'high level of human health protection shall be ensured in the

definition and implementation of all Union policies and activities.³¹ The Treaty also stipulates that all the European Union's external policies should be coherent with the EU's development objectives. Yet the European Union, led by the European Commission, particularly the Directorate-General (DG) Trade, is acting in ways that will reverse progress made by many towards achieving better access to medical products in developing countries. Instead of implementing coherent policies to improve public health, the EU has introduced policies and practices that undermine access to affordable medicines by strengthening IP protection in developing countries to advance the interests of multinational pharmaceutical companies.

EU trade policies therefore undermine the obligations that EU Member States assumed under the Doha Declaration on TRIPS and Public Health, their commitments in numerous World Health Assembly (WHA) resolutions, and their responsibilities to reach the Millennium Development Goals (MDGs) by 2015. These commitments established a moral obligation among EU Member States to protect public health and promote development. Member States should ensure that this stance is reflected in trade policies implemented by the European Commission.

Member States should ensure that aid and trade policies promoted by the Commission are coherent and complementary, and not only benefit EU citizens, but also meet the needs of people in developing countries. They should speak up to correct the double standard whereby the EU allows policies that promote commercial interests to undermine its development activities on global public health.

Towards a new consensus on innovation and access

In 1995, all countries agreed to the TRIPS Agreement, which imposed a global system of IP rules, including patent protection for medicines for at least twenty years. The TRIPS Agreement was a major victory for rich countries and the pharmaceutical industry at WTO negotiations. It represented the single greatest expansion of intellectual property protection in history. Developing countries voiced serious concerns that the new IP rules would delay competition from generic medicines, resulting in higher prices that would have disastrous consequences for millions. Developing countries have also found that the administrative costs to implement TRIPS have been particularly costly.³²

Safeguards under the TRIPS Agreement to protect public health, also known as TRIPS flexibilities, were designed to guard against the high prices of patented medicines; provide exceptions to patent monopolies; and ensure early onset of generic competition once medicine patents expire. In the decade that followed the passage of the TRIPS Agreement, the multinational pharmaceutical industry has fought persistently to limit the ability of developing countries to use these safeguards and flexibilities, which they argue 'steal' their innovation and reduce incentives for new R&D that could benefit developing countries. While a few developing countries have managed to use these flexibilities on a limited basis, the efforts of the multinational pharmaceutical industry have historically been bolstered by the US government. It has engaged a variety of strategies to apply pressure on developing countries to prevent them from using the safeguards and in order to introduce additional IP protections.

Time for a new approach?

Since TRIPS, the rationale for the IP policies promoted by the pharmaceutical industry has lost credibility. Instead, there is a growing consensus among developing countries, civil-society groups, and inter-governmental organisations that IP rules should be sufficiently flexible to meet public health needs,³³ and that alternatives to a patent-based system are needed to stimulate therapeutically valuable innovation.³⁴ The prices of old and new anti-retroviral medicines indicate the need for a different model (see Box 1).

Box 1: Successes and challenges with HIV and AIDS treatment

Prices of anti-retroviral (ARV) medicines have fallen dramatically due to generic competition, which has reduced prices for 'first-line' ARV medicines from \$10,000 per patient per year to less than \$80 for the lowest-price

combination.³⁵ But new ARVs, protected by patents and other forms of IP, cost between five and ten times as much as first-line medicines.³⁶ In the absence of price competition, they are likely to remain unaffordable. UNITAID, the global purchasing facility, has identified the high price of new anti-retroviral medicines and the lack of innovation for new formulations and combinations as two key barriers to scaling up HIV and AIDS treatment across the developing world.³⁷ UNITAID is working to create a market for these products, so that prices decrease while availability improves.

Developing countries now face a growing burden from non-communicable diseases (NCDs) as well as from infectious diseases. The WHO estimates that over 80 per cent of all deaths from NCDs today occur in developing countries. It is clear that, in order to meet health needs in these countries, all disease groups need to be addressed.

The fact that global IP protection does not deliver innovation that addresses the needs of developing countries has become undeniable. The WHO Commission on Intellectual Property, Innovation and Public Health, in a landmark report, asserted that 'for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to the market.'³⁸ Increasing levels of IP protection, it continued, will not reverse the neglect of R&D, noting that 'there is no evidence that the implementation of the TRIPS Agreement in developing countries will significantly boost R&D in pharmaceuticals on Type II, and particularly Type III diseases.'³⁹ Insufficient market incentives are the decisive factor.⁴⁰ IP rules can in fact, inhibit innovation, as excessive patenting of both compounds and research tools hinders follow-on public and private research.

Medicines for neglected diseases account for only one per cent of new chemical entities reaching the market.⁴¹ Although the WHO declared Tuberculosis (TB) a 'global emergency' in 1993, therapies to treat the disease have advanced little in over nearly two decades.⁴² Similarly, the dearth of new antibiotics should be viewed against the backdrop of an alarming rise in resistant infections worldwide that threaten global public health. In general, levels of innovation by the pharmaceutical industry have been disappointing.⁴³

In recognition of this situation, all countries, including EU Member States, agreed to a comprehensive 'Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property' at the WHA in May 2008.⁴⁴ The strategy promotes measures to increase access to medicines, while exploring new approaches to innovation, including some that are outside an IP-based system.

3

Innovation and access within Europe

The EU, aware of increased global competition, and in particular from emerging economies such as India, has taken steps to protect its innovative research-based industry. These measures lead to higher medicine prices in developing countries. Yet Member States and the European Commission also defend the interests of European citizens by protecting them from over-charging by the pharmaceutical industry.

Improving the affordability of medicines within the EU

Many EU Member States use price controls and generic prescribing and dispensing to reduce prices and ensure access to medicines for their populations.⁴⁵ Although there are 27 different pharmaceutical systems across the EU, 24 out of 27 have price controls,⁴⁶ and nearly all have introduced mechanisms to protect vulnerable groups from excessive out-of pocket payments.⁴⁷

The Commission has also played a role in attempting to ensure fair play through an inquiry initiated by DG Competition in 2008, when it investigated delayed entry of generic medicines into European pharmaceutical markets. The inquiry revealed that IP systems, while playing a role in innovation, contain perverse incentives and are often abused. Over the period 2000–07, generic entry of a large number of medicines was delayed by up to seven months each, costing Europe three billion euro.⁴⁸ Strategies to delay generic competition included:

- Patent clusters (individual medicines can be covered by almost 100 patent families, resulting in 1,300 patents or pending applications in all of the Member States);
- Originator-initiated litigation against generics companies;
- Originator-initiated injunctions to delay entry of generic medicines;
- Bilateral settlements between originator and generic companies which limit generic entry of medicines;
- Life-cycle patent management and secondary patenting of medicines; and
- Interventions in proceedings for marketing authorisation of generics.

The report's findings indicate that the current incentive system for pharmaceutical companies is deeply flawed. For originator companies, it is more attractive to invest in marketing and litigation practices than to invest money into R&D.⁴⁹

DG Competition has suggested measures to curtail these practices that

include: prohibiting or curtailing third-party interventions that lead to delays in generic marketing approval for medicines; expediting generic marketing approval and enforcing deadlines; strengthening automatic pricing and reimbursement rules; penalising originator companies who question the quality of equivalent generic products; and recommending obligatory generic prescribing. These proposals indicate that the Commission is serious about ensuring that IP rules do not endanger access to medicines when its own governments or citizens are paying the bills.

Supporting innovation in Europe

The European Commission has led on a European initiative to foster European R&D through the Innovative Medicines Initiative (IMI), a public-private partnership with the European Federation of Pharmaceutical Industries and Associations (EFPIA). The objective of IMI is to develop knowledge sharing, tools, and methods that will facilitate the development of better medicines.⁵⁰ The IMI has a budget of two billion euro for the period 2009–13, with half of the funds coming from the EU and the pharmaceutical industry providing the rest.

In September 2009, the IMI announced a call for proposals for a second round of funding – with nearly 80 million euro from the EU budget. This second round includes funding opportunities to improve R&D for cancer and for other diseases that have high value for the industry. To date, there appears to be no assurance that this initiative connects with health needs in developing countries.⁵¹ Yet the European Parliament and individual Member States have repeatedly indicated that they support strategies that have a vision beyond Europe's interests.

Member States seem to have the political will to ensure that the prices of medicines do not compromise access to medicines within their borders, and are prepared to negotiate with the pharmaceutical industry to this end. Furthermore, the EC has developed initiatives to promote access and innovation in the EU, including explicitly curtailing excesses of the IP system. This stands in sharp contrast with DG Trade's policy towards other countries and reeks of an unjust double standard.

IP and trade: a boon for the pharmaceutical industry

Until recently, the US government was willing to impose sufficiently strict levels of IP protection (TRIPS-plus rules) on developing countries in order to serve the interests of the originator pharmaceutical industry. TRIPS-plus rules exceed minimum WTO obligations and create new barriers that impede access to medicines in developing countries.⁵² However, recent changes to US trade policy have left the multinational pharmaceutical industry without a reliable partner. The evidence indicates that the EU has stepped in to fulfil this role, imposing demands that exceed those previously pursued by the US government.⁵³ So far, this new role has not been countered by strong opposition from the EU Member States.

How EU Trade policy harms access to medicines

Competence to formulate and implement EU trade policy, including on IP, is delegated to the European Commission on behalf of EU Member States, including external IP policy. The strategy paper 'Global Europe',⁵⁴ aimed at maximising the competitiveness of European companies abroad, provides the framework within which the EU pursues its IP policy. To this end, the EU has focused on extending monopoly protection for patented medicines in developing countries, while limiting the ability of developing countries to use TRIPS safeguards to protect public health. Strategies used by the EU include free trade agreements, bilateral pressure, and enforcement rules.

In its defence, the European Commission likes to mention its adherence to the Doha Declaration on TRIPS and Public Health, as well as a tiered pricing policy to improve access in developing countries.⁵⁵ Yet its reference to the Doha Declaration is often an empty gesture, as it does not overcome its parallel efforts to impose stringent IP rules upon developing countries. These parallel efforts run directly counter to the spirit and intent of the Doha Declaration. Furthermore, tiered or differential pricing, while supported by Oxfam as one measure to improve access, has been barely used by pharmaceutical companies, and there is no consensus that tiered pricing can ensure sustainable access, by itself, in the long term.⁵⁶

1 Free Trade Agreements (FTAs)

Having failed to introduce stricter IP rules at the WTO, the pharmaceutical industry now relies heavily on litigation, lobbying, FTAs, and other agreements⁵⁷ to impose TRIPS-plus rules in developing

countries. A series of bilateral and regional FTAs with such rules is another means of pushing for upward harmonization of stringent IP rules globally.

As recently as 2004, EU Member States were adamantly against FTAs with TRIPS-plus rules. At the 2004 World AIDS Conference, the French President, Jacques Chirac, declared that efforts by the USA to sign an FTA with Thailand would severely affect access to anti-retroviral medicines and was 'tantamount to blackmail'.⁵⁸

Yet the EU has now evolved into a champion of these same agreements, pursuing regional and bilateral FTAs with developing countries such as Colombia, Peru, India, the Central American trading bloc, and the ASEAN⁵⁹ countries.

In these negotiations the EU has attempted to implement the following TRIPS-plus provisions:⁶⁰

- Significantly enhancing protection for clinical trial data by providing up to 11 years of exclusive use of such data to obtain marketing approval (also known as data exclusivity⁶¹), effectively prolonging monopoly protection for medicines;⁶²
- Extending patent monopolies through supplementary protection certificates (SPC) (also known as patent extensions);⁶³
- Introducing enforcement measures which potentially obstruct the import, transit, or export of legitimate generic medicines.⁶⁴

The EU has also failed to make any commitments, through FTAs or otherwise, on promoting technology transfer to developing countries.⁶⁵

The European Commission has defended its approach to FTAs by noting its implementation of the 'Paragraph 6 Amendment' of the Doha Declaration on TRIPS and Public Health and its inclusion of the Paragraph 6 amendment in the IP chapter of FTA texts. The Paragraph 6 Amendment was intended to find an appropriate solution to ensure that countries with insufficient or no domestic manufacturing capacity could import generic medicines under a compulsory license. This has been deemed mostly unworkable, and a 'solution wrapped in red tape'. In fact, the Paragraph 6 Amendment, despite its implementation in the EU since 2006, has not been used once in the EU, and has only been used once through Canadian legislation, to export anti-retroviral medicines to Rwanda.⁶⁶ The Amendment is not a substitute for generic production of medicines, and generic medicines exported under Paragraph 6 cannot be exported to developing countries that do not qualify as LDCs.

IP rules in EU FTAs have provoked fierce resistance. Recently, the Andean community trade negotiation fell apart when Ecuador and Bolivia left the negotiation due in large part to concerns that strict IP rules would restrict access to medicines. Nevertheless, the EU has pressed on with negotiations to enforce strict IPRs with the remaining Andean countries.⁶⁷

Developing countries are right to be concerned. Prospective and

retrospective impact studies confirm that TRIPS-plus rules threaten access to affordable medicines. Over time, these measures will have dramatic public health consequences in developing countries. See Box 2.

Box 2: Public health impacts of free trade agreements		
FTA	Source	Public health impact
EU–Colombia FTA*	IFARMA prospective study commissioned by HAI Europe.	By 2030, patent term extensions could result in an increase of nearly \$280m in expenditures for medicines. Data exclusivity rules could result in an increase of more than \$340m of expenditures on medicines. Patent extensions and data exclusivity might jointly result in an increase in expenditure of more than \$620m. Increased expenditures of this magnitude would be equivalent to the expenditure on medicines of more than five million Colombians belonging to the poorest quintile in the country. ⁶⁸
US–Jordan FTA	Oxfam International	Data exclusivity for medicines resulted in significant delays to introducing generic competition for 79 per cent of medicines examined in the study. This led to between two- and ten-fold price increases for key medicines to treat cardiovascular disease and cancer. The availability of generic equivalents would have reduced expenditures on medicines by at least an estimated \$6.3–\$22.05m during the study period from mid-2002 to 2006.
US–Guatemala FTA (CAFTA)	Centre for Policy Analysis on Trade and Health	An FTA signed between the USA and Guatemala, Honduras, Nicaragua, El Salvador, Costa Rica, and Dominican Republic has led to significant delays in generic competition in Guatemala for medicines needed to treat major causes of morbidity and mortality, including diabetes, heart disease, pneumonia, and HIV and AIDS. This led to increases in medicine prices ranging from 2 to 58 times the cost of the generic equivalent. Delays in generic competition resulted in the introduction of generic competitors in the USA prior to their introduction in the Guatemalan market.

* Prospective impacts of the EU–Peru FTA, employing the same methodology, are similar to findings in Colombia. These studies were commissioned during the EU–Andean community trade negotiations. After objections by an alliance of Latin American and European civil society,⁶⁹ and the countries in question, TRIPS-plus rules have been modified to reduce public health impacts on negotiating partners.

Furthermore, strict IP rules that exceed minimum WTO obligations have limited or no economic benefits for poor countries as innovation-based economies tend to grow through imitation at lower levels of economic development.⁷⁰ Historically, developed countries only implemented the IP rules the EU seeks to impose on developing countries once they had attained far higher levels of economic

development.⁷¹

Impacts of new FTAs can extend beyond the borders of those countries that sign an agreement. An EU agreement with India would be particularly harmful, because India plays a key role as the 'pharmacy of the developing world', exporting 67 per cent by volume of the medicines its generic companies manufacture to developing countries, and providing over 80 percent of the world's generic anti-retroviral medicines. If India signed an FTA with the EU containing the harmful demands indicated above, access to medicines in poor countries would be in jeopardy. Not least affected would be EU Member States and the EU, which purchase key medicines for HIV and AIDS destined for developing countries through bilateral and multilateral financing instruments.

2 Bilateral pressure to eliminate TRIPS flexibilities

The EU introduced a 'Watch List' in 2006, emulating the US 'Special 301 Watch List', which is used to pressure developing countries that fail to comply with high levels of IP protection as preferred by the EU. The EC is using the Watch List to pressure countries with which it intends to conclude trade agreements. It does this by noting the alleged deficiencies in those countries' IP frameworks that could be remedied through an FTA. The list is currently being updated, and will provide a term for rights-holding companies to charge countries that are, in their judgment, not doing enough to enforce IPRs.⁷² Other bilateral pressure is also applied. Though specifically permitted by the TRIPS Agreement and reaffirmed in the Doha Declaration, compulsory licences are vehemently opposed by pharmaceutical companies, and governments daring to issue such licences are censured. By issuing a compulsory licence, a government authorises the production and marketing of a cheaper generic version of a patented medicine on the condition that an authorised generic firm pays a licence fee to the patent holder. A compulsory licence, or even the mere threat of one, will typically cause substantial decreases in the price of a given medicine. Yet few countries use compulsory licensing, despite high medicine prices, for fear of retaliation. Prior efforts by Thailand⁷³ and Brazil to use compulsory licensing were met with pressure by both developed countries and the multinational pharmaceutical industry.⁷⁴ The European Commission's recent effort to curtail Thailand's use of compulsory licensing is an example of such pressure (see Box 3).

Box 3: EC pressure on Thailand's use of compulsory licensing

Thailand has used compulsory licensing to reduce high medicine prices and expand treatment for cancer, HIV and AIDS, and cardiovascular disease through the country's public health system. Without lower prices, neither the government nor most of its citizens would be able to purchase these medicines. Multinational companies, the USA, and the EC have placed co-ordinated pressure on the Thai government to abandon its efforts. The previous EC Trade Commissioner, Peter Mandelson, wrote to the Thai Minister of Commerce to complain about the Thai government's use of compulsory licences.⁷⁵ Since then, the EC has entered into FTA

negotiations with Thailand (as part of ASEAN) with the intention to introduce TRIPS-plus rules that would delay generic competition and prevent the Thai government from using public health safeguards, such as compulsory licensing. The bilateral pressure exerted by the EC seems to have had the desired effect. Currently, the new Thai government is considering reforms to its IP policy that would scale back many of the gains of recent years.⁷⁶

3 The IP enforcement agenda

Rewarding pharmaceutical companies under the guise of promoting patient safety

The EU is taking the lead in a global offensive to increase enforcement of IP under the banner of combating counterfeiting through new global rules that could, if implemented, seriously undermine access to affordable generic medicines.⁷⁷ Under the TRIPS Agreement, enforcement of IP is to a large extent left to the discretion of each WTO member. Yet the EU, alongside others, is seeking to introduce an international regulatory framework for enforcement.⁷⁸ Cynically, the European Commission has sought to justify new enforcement measures by claiming that the new rules will save lives in poor countries by halting the trade in 'counterfeit' medicines.⁷⁹ In reality, enforcement rules could undermine efforts to identify and remove dangerous medicines in developing countries. Scarce resources could be directed to enforce IP rules on behalf of pharmaceutical companies, instead of being used to ensure quality of medicines.⁸⁰

The deliberate confusion surrounding counterfeits and generics

The WHO defines counterfeit medicines as deliberately mislabelled products with respect to identity or source. If a medical product is not mislabelled, it is not a counterfeit.⁸¹ As such, counterfeit medicines are often, but not always, medicines that wilfully infringe a trademark, which is a type of IP distinct from a patent. It is not the IP status of a medicine that determines the quality or safety of a medicine.⁸²

Arresting the trade in counterfeit medicines is a legitimate aim, and counterfeit medicines do pose a threat to public health. However, the issue of counterfeiting has been conflated with the wider issue of quality and safety. The dominant threat to public health in developing countries is the broader problem of sub-standard, adulterated, and contaminated medicines that can be either branded or generic medicines.⁸³ This problem cannot be adequately addressed by only policing mislabelled medicines. Halting the trade in unsafe and dangerous medicines requires better regulation of the pharmaceutical supply chain from producer to end user, for which it is particularly important to strengthen drug regulatory authorities in developing countries.⁸⁴

However, the European Commission now asserts that it is necessary to review all legitimate generic medicines of guaranteed quality for infringements of the Community's IP rules, to ensure the medicines are safe.⁸⁵ With this approach, the EU has opened the door to state-

sponsored harassment of the legal trade in quality generic medicines. The approach championed by the European Commission supports only the narrow interests of the multinational pharmaceutical industry and ignores major and legitimate concerns put forward by developing countries, civil-society groups, and pharmaceutical experts.

Seizing generic medicines intended for developing countries

To strengthen its own enforcement regime on IP, the EC has implemented regulations that empower customs officials to seize medicines suspected of infringing its IP rules.⁸⁶ Under the TRIPS Agreement, IP rules are defined at the national level by each country consistent with minimum obligations under WTO rules.⁸⁷ By applying EC rules at the border via the enforcement agenda, the EC is imposing its internal IP standards on the rest of the world. In doing so, the EC is obstructing commercial channels for generic medicines across the world, which has enormous consequences for public health.

In particular, an EU customs regulation, amended in 2003, expanded the authority of customs officials beyond trademarks and copyright infringement to include patent infringement.⁸⁸ Thus, under the amended regulation, customs officials, at the behest of pharmaceutical companies, make patent (and trademark) assessments at the border for medicines that are either being imported, exported or are 'in-transit' through an EU port. These measures, justified as a way to curb counterfeiting and the spread of dangerous medicines, in effect place border and customs officials at the service of the multinational pharmaceutical industry – enforcing IP on its behalf. This channels state resources towards the enforcement of all IP, irrespective of whether the IP claim is legitimate in the first place. Although companies are entitled to pursue legitimate concerns with respect to IP violations, it should be their responsibility to do so through the courts in the country of origin or destination.

The new powers have led to seizures of legitimate generic medicines in transit through the EU and intended for developing countries, to treat diseases such as HIV and AIDS, cardiovascular diseases, and common infections. The seizures are a chilling illustration of the possible consequences of border measures implemented on a global scale (see Box 4).

Box 4: Seizures of legitimate generic medicines intended for poor countries

Since late 2008, customs officials in the Netherlands and Germany have seized 19 shipments of legitimate generic medicines. Of the shipments, 18 were legally manufactured and exported from India (and one shipment from China) and intended for developing countries where they could be legally imported.⁸⁹ Patents did not exist on the medicines in either the country of origin or destination. These shipments were seized as a result of national implementation of the EU regulation. Even though the medicines were in transit, and thus not intended for domestic consumption in the EU, border officials in both countries seized the medicines because they violated IP

protections in the EU. Medicines that were seized included a cardiovascular disease medicine (Losartan) intended for Brazil,⁹⁰ and a key anti-retroviral medicine, (Abacavir) intended for Nigeria. The anti-retroviral medicine was produced in India and paid for by UNITAID, a medicine purchasing facility funded in large part through aid from the UK and through an airline tax levied in France.⁹¹ After public outcries and pressure by the countries in question, the batch of Losartan was eventually sent back to India, while the batch of Abacavir was released and sent on to Nigeria.

These seizures have generated condemnation from civil society groups, inter-governmental organisations, and UNITAID. The Indian government has indicated that it is likely to file a complaint before the WTO Dispute Settlement Body to declare the EU anti-counterfeiting regulation illegal.⁹² EU Member States have expressed concern. The Dutch government has been particularly vocal towards the Commission, as nearly all seizures of medicines intended for developing countries have occurred at its main airport.

Initially, the response of the EC was of measured defiance, with DG Trade going so far as to say that other countries should be 'grateful to the EU for saving lives'.⁹³ More recently, the EC has signalled that it may be willing to change its approach.⁹⁴

Globalising enforcement rules

The EU is aggressively seeking to extend TRIPS-plus rules globally by exporting its IP enforcement measures through FTAs with developing countries – via efforts at multilateral organisations like the WHO and the World Intellectual Property Organisation (WIPO), and separately through the negotiations of the Anti-Counterfeit Trade Agreement (ACTA). The implementation of these measures will force developing countries to channel government resources into protecting the trademarks and patents of multinational pharmaceutical companies. As such, enforcing private rights will place a significant burden on developing countries and impede countries seeking to address more pressing public policy priorities.⁹⁵ Generic companies would be less able to challenge frivolous patents and would fear seizures of their medicines. Under such a framework, the position of the IP rights-holder would be strengthened, to the detriment of generic competitors, effectively leading to extended monopolies for medicines in developing countries.

As part of a broader framework, and as mentioned earlier, the EU is pursuing ACTA, which is currently a pluri-lateral trade negotiation between 12 countries and the EU Member States, represented by the EC and the EU presidency. The Agreement has the express purpose of developing and implementing a multilateral IP enforcement scheme. The ACTA 'Key Elements Under Discussion'⁹⁶ concerning injunctions, border measures, criminal penalties, and enforcement practices suggests the Agreement may seek to introduce the same policies that have obstructed and deterred legitimate generic competition within the borders of the EU. This would include introducing criminal and financial penalties for violations of patents, and even go so far as to

hold manufacturers of active pharmaceutical ingredients (APIs) liable for counterfeiting and enforcement violations. However, verifying the true intent, scope, and purpose of ACTA is impossible, because all negotiating parties, including the EU, refuse to release the text to public scrutiny.

Where is the dissent?

The EU's IP policies promoted by DG Trade undermine the efforts of other Directorates within the European Commission, and the efforts of EU Member States at a national level, to promote access to health care in developing countries. Yet, even as the actual and potential harm to these policies continues to grow, concerns by EU Member States and other Directorates within the Commission, with few exceptions, remain muted.

In recent years, Oxfam International has applauded the efforts of the Commission to strengthen health care systems in developing countries (the EU is a major funder of health care in developing countries). As part of the EU development agenda, its funding contributes to financing health-sector and general budget support. Such policies enable governments to expand public health services for poor people. Sector budget support also strengthens governments' capacity to plan and implement national priorities and recurrent costs such as recruiting and paying salaries for health workers – a key strategy to ensure access to medicines. The EU has also contributed to donors' co-ordination mechanisms at the country level via sector wide approaches (SWAPs). This leads to the pooling of donor resources to ensure improved funding for public health services, including medicines. The funds from the EU budget also contribute to financing the Global Fund to fight HIV/AIDS, TB and Malaria, which funds two-thirds of global Malaria and TB programmes, including paying for medicines. Alongside these efforts, EU Member States have implemented programmes to improve access to medicines in developing countries.⁹⁷

In general, despite these strong financial commitments to global health, trade policies that would ensure access to medicines have not yet followed. In recent months, DG Development has led efforts to define policies on the EU's role in Global Health which should include recommendations on how to improve internal and external coherence related to trade and access to medicines. The European Parliament, through resolutions, recommendations, and letters, has communicated its concerns on trade agreements and access to medicines in developing countries.⁹⁸

Yet, no groundswell of action has followed. Only a few Member States have repeatedly voiced concern (including the Netherlands, Finland and the UK⁹⁹). Without pressure from Member States for the DG Trade to change course, the steady march towards stricter IP rules in developing countries will continue unabated, with potentially devastating consequences for people living in poverty.

R&D: The positive, the inadequate, and the harmful

EU policies and those of Member States to improve innovation in order to meet health needs in developing countries are a mixed bag of positive, inadequate, and harmful policies and practices.

The positive: R&D programmes have improved innovation for developing countries

Despite an overall shortfall in financing for R&D for developing countries (see below), the financial disbursements that the EU has made are often spent on valuable and effective programmes. For instance, Oxfam International has previously lauded the European Clinical Trials and Development Partnership (ECTDP) for devoting financial resources (200 million euro) to improving clinical trial capacity – a key component of medical R&D – in sub-Saharan Africa.¹⁰⁰

The EU has also taken crucial steps to improve the safety of children's medicines with respect to studies that relate dosages to age and weight. The lack of such studies has resulted in doctors and nurses having to split adult tablets into fractions, with the consequence of harmful under- and over-dosing to children, based on little more than guesswork on the part of the prescribers.¹⁰¹

To address this deficiency, in 2007, the European Medicines Regulatory Agency required that all new products submitted for licensing in the EU must go through clinical trials in children.¹⁰² The implications of the new rules should not be underestimated, as studies must be done in all age and weight bands. This is a very considerable undertaking, which involves substantial extra costs. However, the regulation compensates companies by allowing an extended patent term.¹⁰³ Extended patent protection can lead to delays in generic competition, thus reducing access in developing countries.

The inadequate: EU financial contributions for R&D fall short

Over the last decade, some avenues to improve R&D for poor people have emerged, including: PDPs, which are funded by a mix of public and private resources; clinical trial and manufacturing facilities in developing countries; and basic academic and laboratory research.

In gross terms in 2007, according to a recent report released by the

George Institute, the EU spent approximately \$121m on R&D, while both the Commission and EU Member States collectively invested nearly \$385m.¹⁰⁴ While this is seemingly a considerable sum of money, it is still insufficient, especially when compared with annual financial contributions by the USA and even the Gates Foundation.¹⁰⁵ Although recent studies have demonstrated that the EU is more productive than the USA in terms of overall R&D for medicines, funding for neglected diseases still lags far behind. Insufficient funding has immediate implications for global health. Recent figures from the Treatment Action Group indicate a global funding shortfall of nearly \$800m per year for TB R&D.¹⁰⁶ Under-funding of PDPs may mean that, 'the eight or nine drugs that PDPs might be expected to bring to market in the next five years will stay where they are – in the pipeline.'¹⁰⁷

The harmful: The EU is impeding progress at the WHO to explore new models of innovation which meet health needs in the developing world

In 2006, the WHO launched a process to develop a public health consensus among all Member States to improve both innovation and access to medicines, especially in developing countries. At the 2008 World Health Assembly (WHA), Member States agreed on a Global Strategy and Plan of Action that would mandate WHO to address critical barriers to innovation and access in developing countries. At times during negotiations, the EU played an unconstructive role. It opposed reaffirmation of the Doha Declaration on TRIPS and Public Health, or that public health must be prioritized over commercial interests. It also wanted to prevent the WHO from asserting that middle-income and developing countries shall have the right to implement TRIPS flexibilities to either import or produce generic versions of new medicines.¹⁰⁸ Finally, at the 2008 WHA, the EU blocked inclusion of WHO as a stakeholder for the design of a new Essential Health and R&D treaty that seeks to enhance standard-setting for global health and to explore new models of financing and innovation.¹⁰⁹

Conclusion and recommendations

An emerging consensus requires governments to promote and protect the right to health, including the provision of essential medicines. This responsibility cannot be traded away to accommodate the commercial interests of multinational pharmaceutical companies.

Developing countries are facing increased risks to public health which include: a worsening burden of infectious diseases such as HIV and AIDS, TB, and pneumonia; an increasing challenge from NCDs; and continuing prevalence of untreated neglected diseases.

With the change of Commission, these realities provide the context for a re-examination by the EU as to the incoherence of its trade policies with development objectives. Where these policies favour the Union's interests at the expense of the health of poor people in developing countries, the policies of the EU must change.

For the EU to curb IP abuses by the pharmaceutical industry within the Union while pressing for more onerous IP protection in developing countries, amounts to an unacceptable double standard. The EU is imposing a trade agenda that enables pharmaceutical companies to strengthen their monopoly powers, resulting in delayed generic competition and higher medicines prices in developing countries. This is inconsistent with its own development agenda, which has a long and successful record of support for health care in developing countries, backed by the European Parliament and the Member States.

These policies also undermine the obligations undertaken by the EC and Member States when they committed themselves to reaching the MDGs, the Doha Declaration on TRIPS and Public Health, and the WHO Global Strategy and Plan of Action. They are inconsistent with the spirit and substance of much beneficial assistance to the health of people living in poor countries. And they go some way towards negating the political and financial support that EU Member States and the EC itself have contributed to improve innovation and access in developing countries.

Furthermore the EU is not committing sufficient resources to catalyze medical innovation on behalf of developing countries and is cynically blocking progress at WHO to build a political consensus towards new models of innovation that could address urgent health needs in developing countries.

Member States and the European Parliament must use their powers to ensure that the new European Commission radically reforms its policies. To accomplish these reforms, 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.¹¹⁰ EU Member States must act to hold the EC accountable when the EC fails to uphold these principles.
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.

Notes

- ¹ WHO (2006) 'WHO, Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Right, Innovation, and Public Health', Geneva: WHO, p 21–4.
- ² 'More than 4 million HIV-positive people now receiving life saving treatment', UNAIDS at http://www.unaids.org/en/KnowledgeCentre/Resources/FeatureStories/archive/2009/20090930_access_treatment_4millions.asp, accessed 8 October 2009.
- ³ The World Health Organization now estimates 80% of all deaths from non-communicable diseases occur in developing countries today. See WHO, 'Chronic diseases and their common risk factors', www.who.int/chp/chronic_disease_report/media/Factsheet1.pdf.
- ⁴ R. Syal (2009) 'Swine Flu could kill millions unless rich nations give 900 million pounds', *The Guardian*, 20 September 2009 at <http://www.guardian.co.uk/world/2009/sep/20/swine-flu-costs-un-report>.
- ⁵ G. Velásquez, Y. Madrid, and J. Quick (1998) 'Health Reform and Drug Financing, Selected Topics', *Health Economics and Drugs*, DAP Series no.6., WHO/ DAP/98.3, Geneva: WHO, p14.
- ⁶ Agreement on Trade Related Aspects of Intellectual Property Rights, Annexure 1C to the Marrakesh Agreement Establishing the World Trade Organisation, signed in Marrakesh, Morocco, on April 15, 1994, (TRIPS), Articles 28.1 a and b.
- ⁷ P.Trouiller et al (2002) 'Drug Development for Neglected Diseases: A Deficient Market and a Public Health Policy Failure', *The Lancet* 359 (2002), p. 2188.
- ⁸ WHO (2006) *op. cit.*, p. 102 (2006).
- ⁹ WTO (2001) World Trade Organisation, Ministerial Conference fourth session, Doha, November 9–14, 2001, 'Declaration on the TRIPS Agreement and Public Health', adopted on 14 November 2001, WT/MIN/01/DEC/2.
- ¹⁰ WHA (2008) United Nations World Health Assembly, 'Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property', WHA 61.21 (24 May 24 2008), Element 5.
- ¹¹ OBIG, PPRI report, Vienna 2008, p XVI, <http://ppri.oebig.at/index.aspx?Navigation=r%7C2%7C0->
- ¹² Final Report pharmaceutical sector inquiry, DG Competition 2009: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>
- ¹³ See IMI Press Release 17 July 2008, <http://www.medicalnewstoday.com/articles/151253.php>
- ¹⁴ See 'Declaration of Ministers of South America over Intellectual Property, Access to Medicines and Public Health', Geneva, 23 May 2006. The Ministers of Health were from Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay, and Venezuela at: lists.essential.org/pipermail/ip-health/2006-May/009594.html. See also Gabarone Declaration, 2nd Ordinary Session of the Conference of African Ministers of Health, Gabarone, Botswana, 10–14 October 2005, CAMH/Decl.1(II), lists.essential.org/pipermail/ip-health/2005-October/008440.html.
- ¹⁵ See also MSF (2004) 'Access to Medicines at Risk Across the Globe', Briefing Note, MSF Campaign for Access to Essential Medicines, May 2004, www.accessmed-msf.org/documents/ftabriefingenglish.pdf
- ¹⁶ See WHA 56.27, May 2003, www.who.int/gb/ebwha/pdf_files/WHA56/ea56r27.pdf and also see 'Public Health, Innovation and Intellectual Property Rights', World Health Organization, April 2006 – for example, see recommendation 4.21 at www.who.int/intellectualproperty/report/en
- ¹⁷ Ellen t' Hoen (2009) 'The Global Politics of Pharmaceutical Monopoly Power', AMB, pXVII.
- ¹⁸ Louise van Schaik (2009) 'The European Union, A Healthy Negotiator? A study on its unity in external representation and performance in the World Health Organization', Clingendael: Netherlands Institute of International Relations, 5 May 2009, p 21–30.
- ¹⁹ 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
- ²⁰ See, for example, International Covenant on Economic, Social and Cultural Rights (ICESCR) 1966, Council of Europe; The European Social Charter, October 18, 1961; African Charter on Human and People's Rights, June 27, 1981; New Ecuadorian Constitution 2008; New Bolivian Constitution, 2009.
- ²¹ UK Department for International Development (2004) 'New Alliance to Improve Access to Medicines in Developing Countries', at <http://www.dfid.gov.uk/Media-Room/Press-releases/2008/New-alliance-to-improve-access-to-medicine-in-developing-countries/> (accessed on 8 October 2009). See also World Health Organization (2004) 'World Medicines Situation', Chapter 7 (Access to Essential Medicines).
- ²² WHO (2004) *op. cit.*, Chapter 5: <http://hinfo198.tempdomainname.com/medicinedocs/library.fcgi?e=d-0edmweb--00-1-0--010---4---0--0-10l--1en-5000---50-about-0---01131-00115ERnz+VC9ee84d640000000436f372a-0utfZz-8-0-0&a=d&c=edmweb&cl=CL2.1.6&d=Js6160e.7>.
- ²³ E. Van Doorslaer et al. (2005) 'Paying out of pocket for health care in Asia: Catastrophic and poverty impact', Equitap Project: Working Paper #2, May 2005. In India, 80 percent of out of pocket expenditures on health are for medicines. See http://www.whoindia.org/LinkFiles/Commission_on_Macroeconomic_and_Health_Access_to_Essential_Drugs_and_Medicine.pdf
- ²⁴ G. Valladares Alcalde (coordinator), R. Cruzado Ubillús, J. Seclén Palacín, Z. J. Pichihua Serna (2005) 'Evaluación de los potenciales efectos sobre acceso a medicamentos del Tratado de Libre Comercio que se negocia con los Estados Unidos de América', Lima: Health Ministry, April 2005. Also in: http://www.forosalud.org.pe/estudio_minsa_evaluacion_efectos_del_tlc_en_medicamentos.pdf.
- ²⁵ 'Doha Ministerial Declaration on the TRIPS Agreement and Public Health', WT/MIN(01)/DEC/W/2, 14 November 2001
- ²⁶ See Fn. 2.
- ²⁷ Thailand has issued a series of white papers explaining the merits of compulsory licensing to expand health care in the country. See ICTSD (2007) 'Thailand responds to compulsory licensing critics', April 2007 at <http://www.iprsonline.org/ictsd/news/bridges11-2.pg17.pdf>.
- ²⁸ Mary Moran, 'A Breakthrough in R&D for Neglected Diseases: New Ways to Get the Drugs we Need', Plos Med: 2(9) at <http://www.plosmedicine.org/article/info:doi%2F10.1371%2Fjournal.pmed.0020302>.
- ²⁹ The Expert Working Group, formed under auspices of the World Health Organization Global Strategy and Plan of Action, is considering a number of innovative financing mechanisms and new models of research and development that could improve innovation and access. For more information, see http://www.who.int/phi/R_Dfinancing/en/index.html.
- ³⁰ Ministry of Social Affairs and Health (Finland) and European Observatory on Health Systems and Practice (2009) 'Health in all policies: Prospects and Potential' at http://ec.europa.eu/health/ph_information/documents/health_in_all_policies.pdf (accessed 8 October 2009).
- ³¹ Public Health is currently dealt with in Article 152 of the EC Treaty and will be dealt with in Article 168 of the Lisbon Treaty. <http://www.eph.org/a/336>
- ³² Lisa Foreman (2008) "'Rights" and wrongs: What Utility for the right to health in reforming trade rules for medicines?', Toronto, p 48. <http://www.hhrjournal.org/index.php/hhr/article/viewFile/80/148>
- ³³ *Ibid*, p40–5.
- ³⁴ WHO Expert Working Group on Research and Development, http://www.who.int/phi/R_Dfinancing/en/index.html
- ³⁵ 'AIDS, drug prices and generic drugs', at <http://www.avert.org/generic.htm>.
- ³⁶ All-Party Parliamentary Group on AIDS (2009) 'The Treatment Time Bomb: Report of the Enquiry of the All Party Parliamentary Group on AIDS into long term access to HIV medicines in the developing world', July 2009.
- ³⁷ See: <http://www.unitaid.eu/en/The-Medicines-Patent-Pool-Initiative.html>
- ³⁸ WHO (2006), *op. cit.*, p.22.
- ³⁹ **Type I diseases** are incident in both rich and poor countries, with large numbers of vulnerable population in each. Examples of communicable diseases include measles, hepatitis B, and Haemophilus influenzae type b (Hib), and of non-communicable diseases (e.g. diabetes, cardiovascular diseases, and tobacco-related illnesses). Many vaccines for Type 1 diseases have been developed in the past 20 years, but have not been widely introduced into the poor countries because

of cost.

Type II diseases are incident in both rich and poor countries, but with a substantial proportion of the cases in the poor countries. HIV/AIDS and tuberculosis are examples: both diseases are present in both rich and poor countries, but more than 90 percent of cases are in poor countries.

Type III diseases are those that are overwhelmingly or exclusively incident in developing countries, such as African sleeping sickness (trypanosomiasis) and African river blindness (onchocerciasis). Such diseases receive extremely little R&D, and essentially no commercially based R&D in rich countries. When new technologies are developed, they are usually serendipitous, as when a veterinary medicine developed by Merck (ivermectin) proved to be effective in control of onchocerciasis in humans.

Type II diseases are often termed *neglected diseases* and **Type III** diseases very *neglected diseases*. WHO (2006) *op. cit.*, p13

⁴⁰ WHO (2006) *op. cit.*, p.85.

⁴¹ Neglected diseases are defined by WHO as those that 'affect almost exclusively poor and powerless people living in rural parts of low-income countries'. They include leishmaniasis, onchocerciasis, Chagas disease, leprosy, TB, schistosomiasis, lymphatic filariasis, sleeping sickness, and dengue fever. P. Hunt (2007) 'Neglected Diseases: A human rights analysis', World Health Organization. Available at: www.who.int/tdr/publications/publications/pdf/seb_topic6.pdf (last accessed October 2007).

⁴² 'Preventing and managing M/XDR – TB: a global health imperative', 1 April 2009 at http://www.who.int/dg/speeches/2009/mxdr_tb_prevention_20090401/en/index.html

⁴³ A survey published in France in April 2005, concluded that 68 percent of the 3,096 new products approved in the country between 1981 and 2004 brought 'nothing new' over previously available preparations. See: 'A review of new drugs in 2004: Floundering innovation and increased risk-taking', *Prescrire International* 2005 14:76 pp68–73. Similar data in Canada and in the USA indicate declines in innovation. See also: M. Barer, P. Caetano, C. Black, S. Morgan, K. Bassett, J. Wright, R. Evans (2005) 'Breakthrough drugs and growth in expenditure on prescription drugs in Canada', *British Medical Journal*, 2005 331:815-16 and Research and development in the pharmaceutical industry', Congress of the United States, Congressional Budget Office, October 2006.

⁴⁴ WHA (2008) *op. cit.*

⁴⁵ Several (EU) countries have introduced prescription guidelines in order to promote an appropriate and economic prescribing of pharmaceuticals. In most countries, these guidelines are indicative; obligatory prescription guidelines are in place in Austria, Germany, Hungary, Norway and Slovakia. For instance, the "Guidelines on Economic Prescribing" in Austria, which apply for the outpatient sector, provide that in case of several similar therapeutic options being available a physician has to choose the most cost-effective one.', OBIG, PPRI report, Vienna, 2008 p100.

⁴⁶ *Ibid.* p XVI at <http://ppri.oebig.at/index.aspx?Navigation=r%7C2%7C0->

⁴⁷ In the European Union, pricing and reimbursement of pharmaceuticals is primarily a national competence, and, as a result, 27 different pharmaceutical pricing and reimbursement systems are in place in the enlarged European Union. There is a strong connection between pricing and reimbursement at EU level. In many EU countries price controls are only applicable to reimbursable medicines. The most common price control policy is statutory pricing, where authorities set the price on a regulatory, unilateral basis. In a few countries pharmaceutical prices are negotiated between the manufacturer (or wholesaler) and the government authority. UK has no direct price control, but the prices of NHS pharmaceuticals are indirectly controlled via a profit control scheme. Twenty-two PPRI countries apply external price referencing (international price benchmarking). Another common pricing procedure is with equivalent or similar products within the same country (internal price referencing). OBIG (2008), *op. cit.*, p XIII-XVI.

⁴⁸ Executive Summary p 8, Final Report pp 81–94. The Commission noted that on entry to the market, generic versions are 25 percent less expensive than originator versions. After two years in the market, generic medicines are cheaper on average by 40 per cent, due to competition. These savings translate across to the health system: average savings are estimated to be almost 20 percent after the first year, and 25 percent after the second year. The main emphasis in the inquiry dealt with a sample of ~219 medicines set to expire between 2000 and 2007. These medicines represent 47 percent of overall turnover of prescription medicines: EU (2007) (P150–2 of Final Report, p4 of Executive Summary and; 'Antitrust: shortcomings in pharmaceutical sector require further action – frequently asked questions', available at <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/321&format=D OC&aged=0&language=EN&guiLanguage=en>)

⁴⁹ See HAI Europe Response, Amsterdam, 31 January 2009 at <http://www.haiweb.org/29072009/31%20Jan%202009%20HAI%20Europe%20Response%20to%20DG%20Competition%20Consultation.pdf>

- ⁵⁰ Fact Sheet: IMI Joint Undertaking.
- ⁵¹ An 'innovative' medicine may be considered innovative from a commercial point of view because it will sell and enjoys patent protection. From a medicinal or public health perspective, however, a product might not be innovative at all, because it adds little therapeutic value when compared with similar existing medicines.
- According to the US Food and Drug Administration (FDA), 487 new products received market authorisations in the USA between 1998 and 2003, of which 78% were by and large similar to previously authorised medicines. Only 14% displayed a marked therapeutic improvement. (FDA Report, quoted in *Neue Züricher Zeitung*, 14/15 May 2005). For example, most new cancer drugs generate large revenues at high prices, but have not proved to be clinically superior to existing ones. (Donald Light (2009) 'Global Drug Discovery: Europe Is Ahead', *Health Affairs* 28: 5 (2009): w969–w977 (published online 25 August 2009; 10.1377/hlthaff.28.5.w969), pw974-975
- ⁵² See Oxfam International Briefing Paper No. 102, 'All Costs, No Benefits: How the US–Jordan FTA affects access to medicines', at http://www.oxfam.org/en/policy/bp102_jordan_us_fta.
- ⁵³ European Commission (2004) *Strategy for the enforcement of intellectual property rights in third countries*, p10, http://trade.ec.europa.eu/doclib/docs/2004/november/tradoc_120025.pdf
- ⁵⁴ See: http://ec.europa.eu/trade/issues/sectoral/competitiveness/global_europe_en.htm.
- ⁵⁵ Council Regulation (EC) 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines: 'The purpose of this Regulation is to achieve the objectives of the " Programme for Action: Accelerated action on HIV/AIDS, malaria and TB in the context of poverty reduction" by setting up a system enabling pharmaceutical producers to sell developing countries essential medicines at reduced prices while ensuring that these products do not find their way back to the EU. The ultimate goal is to give the developing countries greater access to the essential medicines they need to fight the major communicable diseases', http://europa.eu/legislation_summaries/development/sectoral_development_policies/l21166_en.htm
- ⁵⁶ Oxfam response to EC working document on Tiered Pricing, 2003: <http://www.oxfam.org.uk/resources/policy/health/downloads/tiered.pdf>
- ⁵⁷ Traditionally, the Community practice of negotiating economic agreements has been one of getting commitments for adhering to or for adopting multilateral treaties that protect intellectual property, see Xavier Seuba (2009) 'Health Protection in the European and Andean Association Agreement', HAI Paper series, January 2009 p5.
- ⁵⁸ Michael, Wines et al. (2004) 'Early tests for U.S. in its global fight on AIDS', *New York Times*, July 14, 2004 at <http://www.nytimes.com/2004/07/14/world/early-tests-for-us-in-its-global-fight-on-aids.html>.
- ⁵⁹ Association of South East Asian Nations, www.aseansec.org.
- ⁶⁰ HAI Europe Policy Brief 'Protecting Access to Medicines in EU Trade Agreements: The Andean region', May 2009 at <http://www.haiweb.org/03052009/1%20May%202009%20Policy%20Brief%20EU-Andean%20Trade%20Agreements%20Access%20to%20Medicines%20in%20jeopardy.pdf>
- ⁶¹ Data exclusivity creates a new system of monopoly power, separate from patents, by blocking the registration and marketing approval of generic medicines for five or more years, even when no patent exists. Drug regulatory authorities are prevented from using the clinical trial data developed by the originator company to establish the safety and efficacy of a medicine in order to approve the marketing of a generic medicine that has already been shown to be equivalent to the original one. This delays or prevents generic competition. The TRIPS Agreement protects only 'undisclosed data' to prevent 'unfair commercial use'. It does not confer either exclusive rights or a period of marketing monopoly. Data exclusivity prohibits generic competition for a specified period of time. The alternative would be for generic manufacturers to repeat clinical trials of drugs to prove their safety and efficacy. However, giving placebos when the safety and clinical validity of the medicine being tested is already established is unethical.
- ⁶² Xavier Seuba (2009) *op. cit.*, pp 48–50.
- ⁶³ The extension will be equal to the time elapsed between the filing of the application for a patent and the date of the first market authorisation, Seuba (2009).
- ⁶⁴ Xavier Seuba (2009), *op. cit.* pp36–53. See also: Carlos Correa, *The Push for Stronger Enforcement Rules: Implications for Developing Countries*, ICTSD, Intellectual Property and Sustainable Development Series, February 2009
- ⁶⁵ Xavier Seuba (2009) *op. cit.* In terms of i) guaranteeing access to innovative products, ii) fostering technological development in developing countries or iii) prioritising the higher social good, such as human health and technology dissemination. Basically there is nothing in these proposals that would enhance technology flows from

Europe to these countries.

See also: Carlos Correa (2009) 'Negotiation of a free trade agreement European Union-India: Will India accept TRIPS-PLUS protections', June 2009 BA University, Oxfam Germany, and EED, http://www.oxfam.de/download/correa_eu_india_fta.pdf

- ⁶⁶ Médecins Sans Frontières (2006) 'Neither Expeditious, Nor A Solution: The WTO August 30th Decision is Unworkable', Geneva/Montreal, August 2006.
- ⁶⁷ For various policy briefs and material tracking these negotiations see http://www.haiweb.org/02_focus_b.htm
- ⁶⁸ The impacts presented in this study are calculated based on the 'Guide for estimating the impact of changes in intellectual property rights (IPR) on access to drugs' 4, prepared by the World Health Organisation and the Pan American Health Organisation – WHO/PAHO. This guide describes the IPRIA (Intellectual property rights impact assessment) model. The IPRIA has been applied in different contexts to various countries, and the most recent applications have been carried out within the framework of a consortium of organizations including the WHO, the PAHO, the World Bank Institute and the International Centre for Trade and Sustainable Development (ICTSD), who have refined the methodology. Some of the applications carried out are: Colombia (2005, 2006, 2007), Guatemala (2005), Costa Rica (2005), Bolivia (2006), Costa Rica (2008), Dominican Republic (2008), Uruguay and Argentina. See http://www.haiweb.org/02_focus_b.htm.
- ⁶⁹ CAN-EU ALLIANCE for Access to Medicines is a coalition that started in 2008 during the negotiations of the Association Agreement between the Andean Community and the European Union. Latin American civil society, led by Mision Salud, called in the help of European civil society out of concern for IP demands and their experience with the US FTA. NGOs included are: AISLAC, Mision Salud, RED GE, IFARMA, HAI Europe, EPHA, Oxfam International, Evert Vermeer Stichting, RED CAN EU, MSF, and Farmamundi.
- ⁷⁰ The role of technology in development follows a fairly standard path, described by one UN report as 'a developed, innovating "North" and a developing, imitating "South"'. All countries initially grow by imitating and adapting existing technologies. As they approach the global 'technological frontier', they move into innovation. One of the reasons why countries such as China or India, that are in 'catch-up' mode, grow so much faster than the industrialised countries is that adapting existing technologies is much easier than creating new ones.
- ⁷¹ Historically, IP legislation has followed development: as countries have grown richer, and as they evolve from imitation to innovation, they have introduced more stringent IP laws. Chemical substances remained un-patentable until 1967 in West Germany, 1968 in the Nordic countries, 1976 in Japan, 1978 in Switzerland, and 1992 in Spain (by which time, their chemical industries had established themselves). This pattern was broken over the past twenty years by a combination of new institutions such as the WTO and regional trade agreements, and an extraordinarily aggressive campaign by large corporations and their home-country governments.
- ⁷² See European Commission (2008) 'Survey on Enforcement of Intellectual Property Rights in Third Countries'. Among the countries listed are: China, Russia, Ukraine, Chile, Turkey, Thailand, Malaysia, Indonesia, the Philippines, Vietnam, Brazil, Argentina, Paraguay and Korea. http://europa.eu.int/comm/trade/issues/sectoral/intell_property/survey_en.htm (3/2008).
- ⁷³ See numerous documents explaining Thailand's experience with compulsory licensing, including Government White Papers, at http://www.wcl.american.edu/pijip/thai_comp_licenses.cfm.
- ⁷⁴ Matthew Flynn (2007) 'Brazil's Use of Compulsory Licenses for AIDS Medicines', University of Texas at Austin, August 2007, pp15–20.
- ⁷⁵ A. Bounds (2007) 'Thais warned on drug pricing pressure', *Financial Times*, August 9, 2007.
- ⁷⁶ M. Macaan-Markar (2009) 'Threats to generic drugs policy alarms activists', Inter Press Service, August 21, 2009.
- ⁷⁷ Carlos Correa (2009), 'The Push for Stronger Enforcement Rules: Implications for Developing Countries', ICTSD, Intellectual Property and Sustainable Development Series, February 2009; 'Impact of the EU-CAN Trade Agreement concerning Access to Medicines', Bogota: Ifarma, July 2009, pp 32–8.
- ⁷⁸ C. Correa (2009) *op. cit.*
- ⁷⁹ 'It is important to allow the customs authorities to control goods in transit suspected to infringe IP rights so that they can stop the traffic of potentially dangerous products, such as fake medicines'; 'a significant and worrying level of trade in illegal medicines indicating a potentially serious public health and safety issue, which fully justify the control of medicines in transit suspected to infringe IP rights'. (Ip-health) 'Intervention by European Commission at the TRIPS Council (Dutch Seizures)', at <http://lists.essential.org/pipermail/ip-health/2009/March/013528.html>.
- ⁸⁰ C. Fink (2009) 'Enforcing Intellectual Property Rights: An Economic Perspective',

ICTSD, Intellectual Property and Sustainable Development Series, February 2009.

⁸¹ The WHO states that 'counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.', see www.who.int/impact

⁸² 'Importantly, for the WHO, counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals. Substandard pharmaceuticals are products whose composition and ingredients do not meet the correct scientific specifications and which may be either ineffective or dangerous to the patient. It is therefore a public health problem that has a limited relationship with trademark law and a very marginal relationship with patent law. As it has been demonstrated elsewhere, only one percent of 'counterfeits' are exact copies of original products and could, in consequence, and assuming that the original product was patented, imply a patent infringement. The rest of cases involve trademark violations and much more importantly, quality shortcomings. This is reason why it must be stressed that originator companies and some developed countries have misplaced intellectual property at the centre of the debate.' From: Xavier Seuba (2009) *op. cit.*, p24.

⁸³ WHO (2004) *op. cit.*, Chapter 9.

⁸⁴ Xavier Seuba (2009) *op. cit.*. See also: C Correa (2009) *op. cit.*

⁸⁵ See Fn 80.

⁸⁶ Customs Regulation EC 1383/2003.

⁸⁷ See TRIPS Agreement Article 1(1).

⁸⁸ Because of this original content, the regulation is still unofficially called 'counterfeits and piracy regulation', very much adding to the confusion around generics and counterfeits. Customs officials are not capable of testing for patent infringement, which needs laboratory tests, etc., see Xavier Seuba (2009) *op. cit.*

⁸⁹ M. Kaitlan (2009) 'Drug Seizures in Frankfurt spark fear of EU wide pattern', June 5, 2009 at <http://www.ip-watch.org/weblog/2009/06/05/drug-seizures-in-frankfurt-spark-fears-of-eu-wide-pattern/>

⁹⁰ 'Brazil, India denounce generic drug seizure', Reuters, January 30, 2009 at <http://www.reuters.com/article/GCA-Davos2009/idUSTRE50T27O20090130>.

⁹¹ A. Jack (2009) 'Dutch seizures of HIV drugs highlights patent friction', *Financial Times*, March 5, 2009 at http://www.ft.com/cms/s/0a0a0a9e-0928-11de-b8b0-0000779fd2ac,Authorised=false.html?_i_location=http%3A%2F%2Fwww.ft.com%2Fcms%2Fs%2F0%2F0a0a0a9e-0928-11de-b8b0-0000779fd2ac.html&_i_referer=http%3A%2F%2Fwww.keionline.org%2Ftaxonomy%2Fterm%2F258.

⁹² J.C. Mathew (2009) 'India may move WTO to protest drug seizures, Business Standard', October 9, 2009 at <http://www.business-standard.com/india/news/india-may-move-wto-to-protest-drug-seizures/365850/>.

⁹³ M. Kaitlin (2009) 'India may be nearing dispute settlement with EU over generic drug seizures', Intellectual Property Watch, August 28, 2009 at <http://www.ip-watch.org/weblog/2009/08/28/india-may-be-nearing-dispute-settlement-with-eu-over-generic-drug-seizures/>.

⁹⁴ 'EU will take steps to resolve drug seizure cases, says Ashton', The Economic Times, September 6, 2009 at <http://economictimes.indiatimes.com/News/Economy/Foreign-Trade/EU-will-take-steps-to-resolve-drug-seizure-cases-says-Ashton/articleshow/4977335.cms>.

⁹⁵ C. Fink (2009) *op. cit.*

⁹⁶ 'The Anti-Counterfeiting Trade Agreement – Summary of Key Elements Under Discussion,' April 6, 2009, available at: http://www.international.gc.ca/trade-agreements-accords-commerciaux/fo/intellect_property.aspx?lang=en&menu_id=7&menu.

⁹⁷ This includes strong public support from the British and French governments, including financial disbursements, to implement a UNITAID patent pool for HIV and AIDS medicines. The Dutch ministry of development traditionally has access to medicines as a priority policy.

⁹⁸ On July 12th, 2007 there was a European Parliament resolution on the TRIPS Agreement and access to medicines (P6_TA(2007)0353), urging the EC not to demand for TRIPS plus provisions.

The following recommendations were given to the EC by the EP in 2008 in the context of the negotiations with the Andean community: i) Using negotiating guidelines on development cooperation designed to achieve MDGS, including the protection of public health, ii) ensuring coherence of development policies in line with the principle enshrined in Article 178 of the EC Treaty, iii) granting high priority for greater access to education and health, iv) fostering regional integration by negotiating block by block, see X. Seuba, (2009) 'Protection Health in the EU Andean trade agreement', Hai paper series.

These recommendations are in conflict with the EC's stand on limiting TRIPS flexibilities and the one-sided perspective of IPR holders. Furthermore, the EC has engaged in bilateral agreements, excluding some of the Andean countries, as happened in the ACP countries. See P6_TA(2007)0080, http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007_0080+0+DOC+XML+V0//EN&language=EN

- ⁹⁹ In the Council Working Group C133 on trade matters, these countries have voiced concern over DG Trade's IP policy and its impact on access to medicines in developing countries.
- ¹⁰⁰ Oxfam International (2008) 'Ending the R+D Crisis in Public Health: Promoting Pro-Poor Medical Innovation' at <http://www.oxfam.org/sites/www.oxfam.org/files/bp122-randd-crisis-public-health.pdf>. See also www.edctp.com, and Naomi Antony: 'Clinical Trials in Africa Receive Funding Boost', 6 June 2008, available at: www.scidev.net/en/health/malaria/news/clinical-trials-in-africa-receive-funding-boost.html
- ¹⁰¹ 'Children being neglected in AIDS fight, says MSF', at <http://www.dwb.org/news/article.cfm?id=712%20&cat=field-news&ref=tag-index>.
- ¹⁰² See: <http://www.emea.europa.eu/htms/human/paediatrics/introduction.htm>.
- ¹⁰³ See <http://www.emea.europa.eu/pdfs/human/paediatrics/leaflet.pdf>.
- ¹⁰⁴ 'Neglected Diseases Research and Development: How much are we really spending?', G-Finder Report, The George Institute For International Health, 2008.
- ¹⁰⁵ *Ibid.*
- ¹⁰⁶ Treatment Action Group (2009) 'Tuberculosis Research and Development: A Critical Analysis of Funding Trends 2005-2007: An Update', at http://www.treatmentactiongroup.org/uploadedFiles/About/Publications/TAG_Publications/2009/2009%20TB%20web%20new.pdf. See also 'Cough Up for TB: The Underfunding of Research for Tuberculosis and other Neglected Diseases by the European Commission', Médecins Sans Frontières (2008).
- ¹⁰⁷ M. Moran, 'A Breakthrough in R&D for Neglected Diseases: New Ways to Get the Drugs we Need', Plos Med: 2(9) at <http://www.plosmedicine.org/article/info:doi%2F10.1371%2Fjournal.pmed.0020302>.
- ¹⁰⁸ Only concerted efforts from all developing countries ensured that WHO could address this critical public health issue. See Louise van Schaik (2009) 'The European Union, A Healthy Negotiator? A study on its unity in external representation and performance in the World Health Organization', Clingendael: Netherlands Institute of International Relations, May 5 2009, p 21–30.
- ¹⁰⁹ Not only could the EU's unpreparedness to explore alternative mechanisms for R&D undermine global health, but it could also damage public health objectives within the EU. Antibiotic resistance is an increasingly serious problem, and has been identified as a priority by the Swedish presidency. Antibiotic resistance poses many challenges, including the treatment of Tuberculosis (TB). One of the most pressing challenges is stimulating new TB diagnostics and medicines. The current diagnostic test for TB is not adequate, and this leaves many untreated, increasing the disease population. MSF has recently proposed a prize fund for TB diagnostics; the EC should be open to explore this alternative funding mechanisms for R&D. See 'Prize for TB low-cost point of care rapid diagnostic test', MSF at fieldresearch.msf.org/msf/.../TB%20and%20prize%20fund,pc,fj%5B1%5D.ppt -
- ¹¹⁰ 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

© Oxfam International and Health Action International October 2009

This paper was written by Rohit Malpani (Oxfam International) and Sophie Bloemen (HAI Europe), with writing assistance from Mohga Kamal-Yanni, Esme Berkhout and Philippa Saunders. HAI Europe and Oxfam acknowledge the assistance of Tim Reed, Martin Auton and Teresa Alves from Health Action International, Xavier Seuba from Pompeu Fabra University, Priti Radhakrishnan and Tahir Amin from the Initiative on Medicines, Access and Knowledge, Alexandra Heumber from Médecins Sans Frontières, and Elise Ford, David Hachfeld, Stephanie Burgos, Eve Odete and Jon Slater from Oxfam International in its production. It is part of a series of papers written to inform public debate on development and humanitarian policy issues. The full paper is available to download from www.oxfam.org.

The text may be used free of charge for the purposes of advocacy, campaigning, education, and research, provided that the source is acknowledged in full. The copyright holder requests that all such use be registered with them for impact assessment purposes. For copying in any other circumstances, or for re-use in other publications, or for translation or adaptation, permission must be secured and a fee may be charged. E-mail publish@oxfam.org.uk.

For further information on the issues raised in this paper please e-mail advocacy@oxfaminternational.org.

The information in this publication is correct at the time of going to press.

Oxfam International www.oxfam.org

Health Action International www.haiweb.org