



Medicine being sold at a local market in Mozambique. (Photo: Tineke D'haese/Oxfam)

# TRADING AWAY ACCESS TO MEDICINES – REVISITED

How the European trade agenda continues to undermine access to medicines

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Insufficient innovation and a lack of access to affordable medicines are major barriers to achieving the right to health in low- and middle-income countries. The lack of a vaccine or treatment for the deadly Ebola virus highlights the need for new ideas of how to finance pharmaceutical research and development (R&D). Trade policies should not be used as a tool to defend the status quo, which rewards research with monopolies. Instead, innovative models that create new, affordable medicines should be supported. Members of the new European Parliament and EU Member states must ensure that the incoming European Commission defends a trade and R&D model that is coherent with its development and public health objectives. This should begin by ensuring that the 'regulatory harmonization' to be enshrined in the Transatlantic Trade and Investment Partnership will not lock in regulations that serve corporate over public interests, and set new global standards that will later be imposed on developing countries.

# SUMMARY

The failure of the current pharmaceutical research and development (R&D) system is revealed by the World Health Organization (WHO) alert about the lack of effective medicines to address antimicrobial resistance<sup>1</sup>, and the absence of a treatment for the deadly Ebola virus that is ravaging communities in West Africa at the time of writing.

While low- and middle-income countries (LMICs) have been suffering from a lack of access to medicines for years, European public health systems have become unable to bear the burden of expensive new medicines. The rise of non-communicable diseases (NCDs) is affecting all people, but is more acutely hitting developing countries that are still struggling with the unfinished business of communicable diseases. Meanwhile, European health systems, badly hit by austerity measures, are under pressure to deliver more with less money, against a backdrop of rising medicine prices.

The European Union (EU) could play a leading role in improving pharmaceutical innovation and access to medicines around the world. However, the European Commission (EC) has implemented a trade agenda that favours the commercial interests of the multinational pharmaceutical industry over the health of people in LMICs. Such trade policies have triggered an outcry from European citizens, experts and organizations, who are asking for the public interest to be prioritized in trade discussions.

Unfortunately, the EC appears to remain deaf to this call, and is currently negotiating the highly controversial Transatlantic Trade and Investment Partnership (TTIP), a free-trade agreement (FTA) that could negatively impact European citizens including via increasing medicine prices. That the TTIP is being negotiated behind closed doors, and has been captured by the industrial lobby, is to the detriment of the public interest.

It is time for the Directorate-General for Trade (DG-Trade) in the EC to change its approach to trade and innovation, and put people's health before multinational companies' profits.

## **The increasing disease burden on LMICs**

One third of the world's population – over 2 billion people – do not have regular access to the essential medicines that they need.<sup>2</sup> Nowhere in the world is the lack of access more problematic than in LMICs, where new or adapted medicines and vaccines to treat some of the world's deadliest diseases are unavailable or unaffordable. Although treatment for HIV/AIDS has improved, in LMICs, about 7 million people still do not have access to anti-retroviral medicines. This problem will only worsen, given that the 35 million people who are infected with HIV will need treatment at some point.<sup>3</sup> Similarly, 75 percent of the estimated 150–180 million people infected with hepatitis C live in LMICs. A new hepatitis C treatment (sofosbuvir, marketed as Sovaldi) recently came onto the market at the prohibitive price of \$84,000 for a 12-week treatment.<sup>4</sup> NCDs, such as

cancer and diabetes, are also increasing suffering throughout the developing world. Making generic medicines widely available is key to meeting these challenges.

## **Generic competition**

Although generic competition would be the most effective way to lower medicine prices in a sustainable way, patents and other forms of intellectual property (IP) protection impede this, and keep prices high. The governments and citizens of LMICs cannot cope with the high prices of needed medicines without sacrificing other basic necessities.<sup>5</sup> Even a slight price increase may result in life-saving medicines becoming unaffordable for the many.<sup>6</sup>

## **Global intellectual property rights**

The patent system, globalised under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),<sup>7</sup> is the dominant incentive framework for the development of new medicines. Given that its incentive structure is driven by profits, the system favours commercial interests over public health concerns, and tends to prioritise short-term maximisation of returns to shareholders. It does not focus on producing medicines that actually meet public health needs (e.g. antibiotics) at a price that societies can afford in the long term.<sup>8</sup> Lower-income countries lacking profitable pharmaceutical markets suffer the most from this system.<sup>9</sup>

## **New innovation models**

Evidence suggests that stronger IP protection does not lead to greater innovation and affordable prices.<sup>10</sup> Therefore, public institutions and even some parts of the pharmaceutical industry are exploring new approaches to biomedical innovation, such as collaborative and open knowledge. Meanwhile, the EU and the WHO have recognised the need for new approaches to innovation that do not rely on the patent system, and break the link between the costs of R&D and the price of medicines.

## **The EU trade agenda**

In its trade policies, however, the EU continues to push for a range of IP measures that support the pharmaceutical industry's commercial interests, and damage opportunities for innovation and access to medicines in LMICs. These measures include:

1. Introducing TRIPS-plus provisions, i.e. rules included in trade agreements that exceed WTO obligations;
2. Exerting pressure on LMICs to prevent the use of TRIPS public health safeguards and flexibilities to reduce medicine prices;
3. Using technical assistance programmes to further export excessive IP standards.

## Growing medicine inequalities in the EU

The ongoing Transatlantic Trade and Investment Partnership (TTIP) negotiations between the EU and the US are considering a number of clauses that could negatively affect Europe's public health. EU health systems which are already impacted by the high prices of new medicines and austerity measures can no longer bear huge medicines costs. TTIP could worsen this already sensitive situation.

### At odds: the EU's trade, health and development policies

The EU, under the Treaty of Lisbon, has committed to the principle of 'health in all policies',<sup>11</sup> which guarantees that a 'high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities'.<sup>12</sup> The Treaty also stipulates that all external policies of the EU should be coherent with its development objectives.<sup>13</sup>

Despite this, DG-Trade, lobbied by the pharmaceutical industry, implements policies that reverse those that improve access to medicines in LMICs, as well as in the EU, in contradiction to the EC's pro-public health policies. Such activities have provoked an outcry from the EP, academics, civil society and some trade partners,<sup>14</sup> and led to harsh criticism from UN commissions and the Vatican.<sup>15</sup>

### Recommendations to improve innovation and reduce medicine prices

Oxfam International and Health Action International Europe demand a U-turn on trade and R&D policies over the next five years. DG-Trade should stop considering trade policies as a tool to protect the commercial interests of EU industries, and collaborate more closely with other Directorate-Generals and EU institutions to ensure coherence with public health and development objectives. EU institutions and Member states should honour their commitments to ensure access to medicines and needs-driven innovation by promoting alternative R&D models.

To improve innovation and access to medicines, Health Action International and Oxfam International recommend that:

1. **The EU ensures its trade policy aligns with its development and (global) health objectives.** In particular it should:
  - a. Not introduce TRIPS-plus and investment protection measures in FTAs that are detrimental to access to medicines, and/or which limit the public-health policy space.
  - b. Actively support governments that make use of legal TRIPS safeguards and flexibilities to protect and promote public health.
  - c. Ensure that the TTIP agreement does not jeopardise access to medicines in Europe and beyond.

*Among the most damaging concessions developing countries make in regional and bilateral agreements are those enhancing the monopolies on life-saving medicines, which reduce access and affordability and those that provide excessive legal rights to foreign investors, limiting the policy space for nations to promote sustainable and inclusive development.*

Holy See, statement to 9th WTO Ministerial Conference in Bali, 3–6 December 2013<sup>16</sup>

**2. The EU supports generic competition to allow broad access to medical products in LMICs.** In particular it should:

- a. Engage in meaningful technology transfer with least-developed countries.
- b. Encourage companies to join the Medicines Patent Pool.
- c. Ensure that the Global Fund to Fight AIDS, Tuberculosis and Malaria continues to use generic medicines and support UNITAID work to make quality medicines and diagnostics available and affordable

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

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

# 1 INTRODUCTION

At least one third of the world's population lacks regular access to essential medicines.<sup>17</sup> This is in part due to the high prices of a number of existing patented medicines (eg. cancer medicines). High medicine prices can be a significant barrier to treatment, or create difficult choices for poor households that must choose whether to pay out-of-pocket for their medicines, or buy other basic necessities such as food instead.

Poorer countries' government spend a much greater proportion of their health budget on medicines than wealthier countries; expenditures on pharmaceuticals worldwide range from 8.7 percent to 67 percent of total health expenditure.<sup>18</sup> Governments in developing countries cannot pay such high prices without sacrificing other basic necessities.<sup>19</sup>

Unlike many wealthier countries, most low- and middle-income countries (LMICs) lack universal health coverage. This means that the burden of health expenditure falls upon individuals and household. Across Asia, medicines comprise between 20 and 80 percent of out-of-pocket healthcare costs;<sup>20</sup> in China, for example, they make up over half.<sup>21</sup> Across South America, out-of-pocket spending on health has increased over the last decade;<sup>22</sup> in Ecuador and Argentina respectively, 49 and 62 percent of healthcare costs are paid out-of-pocket.<sup>23</sup> An average of 70 percent of healthcare costs in India is paid out-of-pocket.<sup>24</sup> Worldwide, 150 million people each year face catastrophic healthcare costs because of direct payments, while 100 million are pushed into poverty – the equivalent of three people every second.<sup>25</sup>

In the European Union (EU), citizens are also facing problems in accessing affordable medicines. European public health systems are no longer capable of carrying the financial burden of expensive new medicines. The financial crisis has exacerbated this situation.

In 1994, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was adopted and subsequently became part of World Trade Organization (WTO) rules. TRIPS imposed a system of global intellectual property (IP) rules, including a minimum 20-year patent term for medicines. It was a major victory for the pharmaceutical industry, representing the single greatest expansion of IP protection in history. During the negotiations, developing countries consistently voiced concerns over the effects of new IP regimes on the cost of medicines, and demanded safeguards and flexibilities.

In recent years, concerns about the effects of expanded patent protection on generic competition and affordable treatment have been recognised, and there have been international efforts to improve access to medicines. In 2001, the WTO ministerial conference adopted the Doha Declaration on TRIPS and Public Health. It affirms that the WTO rules on IP should not prevent countries from taking measures to protect public health.<sup>26</sup> Such measures are known as 'TRIPS flexibilities'.

Medicines for HIV illustrate the numerous problems with strict IP protection, the positive role of generic competition in decreasing prices, and the importance of allowing LMICs to use TRIPS flexibilities to enhance competition (see **Box 1**).

#### **Box 1. Successes and challenges with HIV treatment**

The prices of anti-retroviral (ARV) medicines have fallen dramatically due to generic competition. Today, first-line ARV treatment is available for slightly less than \$100 per person per year, which is a 99 percent decrease since 2000, when treatments that were still under patent were priced at more than \$10,000. Generic competition has already led to a 75 percent drop in the price of second-line treatment since 2006.<sup>27</sup>

However, the lowest priced 'second-line' treatments, to which most patients must switch at some point, is still more than double the average cost of first-line treatments. Newer medicines still have an astronomically high price because generic competition is mostly blocked by IP protection.<sup>28</sup> At the same time, new WHO treatment recommendations have considerably increased the number of people that need treatment.<sup>29</sup>

Ensuring affordability is not only crucial for access to HIV/AIDS treatments. LMICs are facing a double burden of diseases: the unfinished agenda of infectious diseases such as HIV, hepatitis C, malaria, children's pneumonia and tuberculosis, combined with the rising burden of non-communicable diseases (NCDs) such as cancer, diabetes, and cardiovascular diseases. The World Health Organization (WHO) estimates that over 80 percent of all deaths from NCDs today occur in LMICs.<sup>30</sup> Today, 70 percent of deaths caused by cancer occur in Asia, Central and Latin America, and Africa.<sup>31</sup>

Generic competition has proved to be the most effective strategy in pushing down low prices. LMICs, such as Thailand, Ecuador and India, as well as a number of least developed countries (LDC), have effectively used TRIPS flexibilities to enable generic competition and reduce medicine prices.<sup>32</sup>

In the decades that followed the implementation of TRIPS, however, the multinational pharmaceutical industry has fought persistently to limit LMICs from using TRIPS flexibilities. Companies argue that these flexibilities 'steal' their innovation, despite the fact that such measures are entirely legitimate and legal under WTO rules, and that many EU countries have used the very same TRIPS flexibilities to protect public health and correct anti-competitive practices by the same companies.<sup>33</sup>

A variety of strategies have been used to apply pressure on LMICs to not use TRIPS flexibilities, and/or to introduce additional IP protections, called 'TRIPS-plus' provisions. In particular, EU-US trade policy has been used to keep pushing a range of TRIPS-plus IP measures that support the commercial interests of the pharmaceutical industry, while damaging opportunities for innovation and access to medicines in LMICs.

## 2 A DIFFERENT INNOVATION MODEL

From a public health perspective, this harmful EU trade agenda is indefensible. This is especially true since there is increased recognition that excessive IP protection does not necessarily result in biomedical innovation that responds to global public health needs.<sup>35</sup>

### AN R&D SYSTEM THAT WORKS FOR THE RICH

With the patent system's traditional reliance on high monopoly prices to provide incentives for research and development (R&D), innovation is generally lacking where there is no profitable market (see **Box 2**). For example, although the WHO declared tuberculosis a 'global emergency' in 1993, it was only at the end of 2012 that the first new drug in 50 years received accelerated approval for use in treating multi-drug resistant tuberculosis.<sup>36</sup>

*'IP rights are irrelevant for stimulating innovation in the absence of a profitable market. For diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating research and development (R&D) and bringing new products to the market. Increasing levels of IP protection will not reverse the neglect of R&D.'*

World Health Organization<sup>34</sup>

#### **Box 2. How the IP-driven R&D system excludes the majority of the world**

*'So now, is this going to have a big effect on our business model? No, because we did not develop this product for the Indian market, let's be honest. I mean, you know, we developed this product for Western patients who can afford this product, quite honestly.'*

This comment by Marijn Dekkers, the chief executive officer of pharmaceutical giant Bayer, illustrates the fundamental flaws of the current biomedical innovation model. He made this comment in response to the Indian government's decision in 2013 to grant a compulsory licence on Bayer's cancer medicine. At \$69,000 per year, the drug was too expensive for most people in India. The licence allows for the generic version to be sold at less than 4 percent of Bayer's price.

The quote illustrates that current IP-related R&D incentives lead to the exclusion of the majority of the world's population from new medicines.

In addition, Marijn Dekkers referred to this compulsory licence as '*essentially theft*', illustrating the fact that the pharmaceutical industry does not accept governments' use of available legal means to provide access to medicines for their citizens.<sup>37</sup>

The statistical finding that only 10 percent of the world's R&D expenditure for health is devoted to diseases that primarily affect the poorest 90 percent of the global population has become a symbol of the current R&D crisis. In fact, 'neglected diseases'<sup>38</sup> receive a meagre two percent of the annual \$160 billion spent globally on R&D.<sup>39</sup>

The current Ebola crisis in West Africa poses fundamental questions about the way that R&D is financed. While Ebola is a highly infectious and

lethal virus, its outbreaks happen in Africa. However, pharmaceutical companies are not interested in the R&D of medicines or vaccines for markets that will not produce high profits. It is only now with the threat of widening spread that companies have started or resumed research – mostly funded by public money from the US.

An alarming WHO report launched in April 2014 warns the world of the devastating consequences of antimicrobial resistance, including antibiotic resistance, if no concrete action is taken urgently. Growing resistance to antibiotics has been noted in various countries, and means that common infections that have been treatable for decades will be able to kill again.<sup>40</sup> The dearth of new antibiotic treatments due to the lack of market incentives is another demonstration of the flaws of the current R&D system.<sup>41</sup>

Monopoly patent protection often results in high prices for new medicines once developed; a new Hepatitis C treatment recently came onto the market at the prohibitive price of \$1,000 per pill, or \$84,000 for a 12-week treatment, which triggered outcries and debate throughout the world.<sup>42</sup>

## BOOSTING OR LIMITING INNOVATION?

Although pharmaceutical companies claim that IP is the engine for innovation, the European Commission (EC) recognises that IP protection can, in fact, inhibit innovation because excessive patenting of both compounds and research tools hinders follow-on public and private research.<sup>43</sup> Even if the current R&D model has produced many key medicines, levels of innovation have still been disappointing for diseases across the world.<sup>44</sup> The promise that the current patent system would encourage massive investment in R&D driven by public health needs has failed to materialise.<sup>45</sup>

Companies have gradually shifted their business model from focusing on therapeutic innovation towards marketing schemes, expanding patent protection, litigation against competitors and the development of ‘me too’ medicines of little therapeutic advantage while pulling out of key areas of R&D.<sup>46</sup>

The practice of ‘evergreening’, which refers to the myriad ways in which companies use the law to extend their IP monopoly protection, is an example of the focus on extending patent protection and retrieving revenues from existing products.<sup>47</sup>

The shrinking of pharmaceutical companies’ development pipelines has resulted in fewer innovative medicines of added therapeutic value reaching the market. Out of 97 new medicines or indications of a known medicine in 2010, only four provided a therapeutic advantage.<sup>48</sup> The number of new medicines coming onto the market has been low in recent years.<sup>49</sup>

A pharmaceutical sector enquiry by the Directorate General for Competition (DG-Competition) revealed the structural use of a toolbox of tactics by companies to delay generic competition, adding an additional cost to EU health systems of at least €3bn between 2000 and 2007.<sup>50</sup> During the same time period, pharmaceutical companies in the EU market spent around 23 percent of their turnover from prescription medicines on marketing, and only about 17 percent on R&D.<sup>51</sup> In 2012, EU pharmaceutical companies reported allocating only 15.1 percent of their net sales in 2011 to R&D.<sup>52</sup> Additionally, considerable amounts of funding for R&D come from public sources including financing basic research at universities - basically citizens pay for R&D through their tax.<sup>53</sup>

In short, the IP system is not producing the fruits of innovation required by society, and acts as a barrier for access to the products that it does produce. This has led to a broad recognition among public health academics, and civil society and intergovernmental organizations that IP rules should be sufficiently flexible to meet public health needs. Furthermore, alternatives to a patent-based system are needed to stimulate therapeutically valuable innovation.<sup>54</sup>

## NEW INNOVATION MODELS THAT BENEFIT ALL

New approaches to biomedical innovation are based on sharing knowledge and data, rather than shrouding it in secrecy and IP protection.<sup>55</sup> Increasingly, public and private R&D initiatives engage in collaborative and open forms of innovation that allow for open access to research results,<sup>56</sup> in which the outputs of research are considered public goods.

Collaborative networks and open research may be more efficient and deliver cheaper innovation.<sup>57</sup> New product development partnerships (PDPs) have suggested a pipeline of medicines that could deliver new treatments for neglected diseases, while financing mechanisms have introduced incentives to encourage private sector R&D for the same purpose.<sup>58</sup> In addition, new access and innovation models such as medicines patent pools,<sup>59</sup> open data pools and prize funds have been created or conceived. These could generate and ensure access to technologies that meet the public health needs of LMICs.<sup>60</sup>

Debates about alternative incentives for innovation in health products have taken place at the WHO for over a decade. In 2008, WHO Member state agreed to a comprehensive Global Strategy and Plan of Action on Public Health, Innovation and IP (GSPoA),<sup>61</sup> which promotes measures to increase access to medicines, while exploring new approaches to innovation. The WHO Consultative Expert Working Group on Co-ordination and Financing of Biomedical R&D (CEWG) was subsequently established to develop concrete recommendations for financing and coordinating new incentives for R&D to meet global health needs. This high-level expert group has emphasised the importance of 'delinking' the costs of R&D from the price of the end product as well as 'open knowledge innovation' (see **Box 3**).

In particular, the CEWG strongly recommends that WHO Member states begin negotiations for a multilateral global health R&D convention.<sup>62</sup> WHO Member states have also commissioned exploratory health R&D projects to try new innovation incentive models for R&D (see **Box 3** for examples). However, the projects selected have yet to prove that they will adequately embrace these new models.<sup>63</sup> At the 2014 World Health Assembly, the WHO secretariat was given a mandate to create a new pooled (voluntary) funding mechanism for health R&D.<sup>64</sup> Despite these developments, more ambitious discussions on health R&D funding are needed.

### **Box 3. Principles to ensure access and innovation**

**Open knowledge innovation** refers to research and innovation that generates knowledge that is free to use without legal or contractual restrictions. This paves the way for capacity building and transfer of technologies for developing countries, and enables others to build upon existing innovations to further their reach and potential, e.g. heat stable versions of products, or more effective combinations, etc. Open knowledge innovation also includes data transparency – requesting researchers to publish both positive and negative data sets, including clinical trial data.

**Delinkage** of the cost of R&D from the price of the medicine refers to mechanisms other than traditional reliance on monopoly protection and high prices to incentivise R&D. The aim is to develop needs-driven R&D, rational marketing, and the fair use of results and to enable affordable medicines' prices.

The EU has also committed to exploring alternative models in its development, innovation and health policy objectives. The 2010 EU Council Conclusions on Global Health promised '*to ensure that innovation and interventions produce products and services that are accessible and affordable*'.<sup>65</sup> These conclusions call for needs-driven innovation and further exploration of innovation '*de-linkage models*'. The EU's 2020 flagship proposal, the Innovation Union, speaks of introducing a more '*open approach to innovation*', '*increased open access to the results of EU financed research*' and the '*promotion of patent pools*', as well as '*innovation inducement prizes*'.<sup>66</sup>

Horizon 2020, the EU's €80bn research- and innovation-funding programme, adopted in 2013, would have been an excellent opportunity to reflect and implement these commitments. Some important steps have been taken, such as mandating open-access publishing, encouraging the broad dissemination of results and encouraging the use of prizes.<sup>67</sup> The EU has fallen short, however, on including meaningful priority-setting and access policies, such as non-exclusive licensing or substantial encouragement of data sharing and open knowledge innovation.

One European collaborative R&D initiative under Horizon 2020 is the Innovative Medicines Initiative (IMI). Its second phase (IMI2) is led by the EC to foster European R&D through a public-private partnership with the European Federation of Pharmaceutical Industries and Associations (EFPIA). The objective of IMI2 is to enhance knowledge sharing and create tools and methods that will facilitate the development of better

medicines.<sup>68</sup> Despite the large share of EU public funding,<sup>69</sup> priority setting within IMI2 remains largely driven by industry, which is problematic because companies make choices based on market opportunities to increase profits. In addition, IMI2 does not guarantee data sharing outside the project, nor affordable access to medicines. Therefore, while the initiative ensures EU public money contributes towards more efficient R&D, the benefits are still mainly privatised.<sup>70</sup>

The European Clinical Trials and Development Partnership (ECTDP) is another biomedical R&D initiative under Horizon 2020. It devotes significant financial resources to improving clinical trial capacity – a key component of biomedical R&D – in sub-Saharan Africa.<sup>71</sup> Some steps were taken to include affordability and the suitability of medicines in the design of the new EDCTP2. However, the EC resisted attempts by the European Parliament (EP) to include clear mandatory guidelines on access to results and knowledge sharing.

In summary, although the EU recognises the need for new approaches to biomedical innovation in its policy commitments, it is failing to make a real difference in supporting global calls for an improved system of biomedical innovation.

# 3 IP AND TRADE: WEALTH BEFORE HEALTH

## Box 4. WHO Director-General Margaret Chan warns about the implications of trade policies for health

In a 2014 address, the WHO's Director-General, Dr Margaret Chan, said:  
*'In my view, something is fundamentally wrong in this world when a corporation can challenge government policies introduced to protect the public from a product [tobacco] that kills. Some Member states have expressed concern that trade agreements currently under negotiation could significantly reduce access to affordable generic medicines. If these agreements open trade yet close access to affordable medicines, we have to ask: Is this really progress at all, especially with the costs of care soaring everywhere?'*<sup>72</sup>

Despite the negative implications of TRIPS on access to medicines, the EU and the US governments have been willing to impose even stricter levels of IP protection (TRIPS-plus rules) on LMICs in order to serve the interests of pharmaceutical companies that are mainly based in the USA and the EU. TRIPS-plus rules exceed minimum IP WTO obligations and create new barriers that impede access to medicines in developing countries.<sup>73</sup> Initially, the US mostly assumed this role, yet the EU has also stepped in line with the industry, imposing demands that, at times, exceed those pursued by the US government.<sup>74</sup> So far, such activity has not been countered by strong opposition from EU Member states. Despite strong criticism from civil society and a wide range of actors (see page 21), the EU is still concluding trade agreements containing more stringent IP protection with a range of countries and trading blocs.

## EU TRADE POLICY: DAMAGING IMPACTS ON MEDICINES

The competence to formulate and implement EU trade policy, including external IP policy, is delegated to the EC on behalf of EU Member states. In its trade agenda, the EU has focused on extending monopoly protection for patented medicines, using FTAs and bilateral pressure.

In its defence, the EC mentions its adherence to the TRIPS flexibilities according to the WTO Doha Declaration on TRIPS and Public Health<sup>75</sup>, as well as tiered-pricing policies to improve access to medicines in developing countries. Yet, its reference to the Doha Declaration is often an empty gesture, given that it does not supersede parallel efforts to impose more stringent TRIPS-plus rules upon developing countries that conflict with the spirit and intent of the Doha Declaration. Furthermore, tiered pricing has only been modestly used by pharmaceutical companies. Evidence shows that tiered pricing, in practice, is demonstrably less reliable and less effective than generic competition in sustainably achieving affordable prices for quality medicines (see **Box 5**).<sup>76</sup>

## Box 5. Tiered pricing and generic competition

**Tiered pricing** is the practice of selling medicines to different countries at different prices, depending on companies' pricing policies. Some companies classify countries according to the World Bank's income classification. This allows companies to maximise profits in all countries by setting prices they consider should be paid in each territory, which are not necessarily affordable for the majority of people in each country.<sup>77</sup> Therefore, tiered pricing does not necessarily reflect the true lowest price potential, and acts against generic competition.

**Generic competition** for new medicines under patent is enabled by governments using TRIPS flexibilities. It has been central to improving the affordability of medicines in developing countries. A recent study found that the US President's Emergency Plan for AIDS Relief (PEPFAR) has saved \$943m since 2005 by buying generic, rather than tiered-priced, HIV medicines.<sup>78</sup>

In 2013, the Secretariat of the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM) proposed establishing a 'blue ribbon task force' on tiered pricing for middle-income countries. There has been an effective opposition to this move mainly by civil society organizations. The GFATM currently purchases generic medicines; switching to generally more expensive tiered-pricing products would be a regressive step, because agencies and governments would get less value for their money. In response to the criticism of this policy, the GFATM changed its plans to focus on the problem of the lack of donor funding for health programs in middle-income countries. There are other ways that the GFATM can contribute to sustained low prices for new medicines, such as pooling LMIC demand, and supporting countries to use TRIPS flexibilities to encourage generic competition.

The strengthening of IP protection and enforcement to supposedly foster innovation is indefensible in the context of LMICs. These countries often lack a robust institutional framework to mitigate some of the impact of high prices, such as effective government competition agencies, pricing policies, or universal access to healthcare.

## 1 Trade agreements

Having failed to introduce stricter IP rules at the WTO, the pharmaceutical industry now relies heavily on litigation, lobbying and trade agreements<sup>79</sup> to impose TRIPS-plus rules to extend their monopoly protection periods. Upward harmonisation of stringent IP rules globally is pursued through bilateral and regional FTAs. Such has been the case with trading blocs like Central America, MERCOSUR, the Andean Community, and with countries such as India, Thailand, South Korea, Canada and the EU's neighbour's Ukraine and Moldova.

In these negotiations, the EU attempts to impose several of the following TRIPS-plus provisions:<sup>80</sup>

- a) **Extending monopolies through data exclusivity and patent-term extensions.**
- b) **Introducing IP enforcement measures** that strengthen the IP protection of rights holders, to the detriment of generic competitors.

**c) Investment measures** that can undermine governments' public health policies protecting access to affordable medicines.

Strict IP rules that exceed minimum TRIPS obligations have limited or no economic benefits for poor countries because technological capacity for innovation tends to grow through imitation at lower levels of economic and technological development.<sup>81</sup> Historically, developed countries only implemented the IP rules that the EU now seeks to impose on developing countries once they had attained far higher levels of economic development.<sup>82</sup> Retaining the flexibility to prioritise national development objectives over IP protection has facilitated the development of robust generic industries in India and Brazil.

The impact of new FTAs can extend beyond the borders of the signatory countries. For example, more stringent IP rules in India would be particularly harmful for access to medicines in poor countries because India plays a key role as the 'pharmacy of the developing world'. India produces a large number of high-quality, affordable generic medicines, and provides over 80 percent of the world's generic anti-retroviral medicines.<sup>83</sup> Implementing TRIPS has already severely limited India's role in providing affordable generics for poor people, and a harmful FTA with the EU would worsen the situation.

Countries have found that the implementation of the IP rules in TRIPS has been particularly costly.<sup>84</sup> The implementation of additional IP measures will force countries to channel significant government resources into protecting the trademarks and patents of multinational pharmaceutical companies. As such, over-enforcing private rights will place a significant burden on developing countries and impede their ability to address more pressing public policy priorities.<sup>85</sup>

**Impact of patent-term extensions and data exclusivity**

Patent-term extension or supplementary protection certificates (SPC) extend patent monopolies beyond the 20-year period provided for by the TRIPS agreement. Data exclusivity involves significantly enhancing the protection for clinical trial data, by providing up to 11 years of exclusive use of such data, which must be submitted to the drug regulatory authority in order to obtain marketing approval for a medicine.<sup>86</sup> This prolongs monopoly protection for medicines even in cases in which patents do not exist.<sup>87</sup>

Prospective and retrospective impact studies confirm that TRIPS-plus rules threaten access to affordable medicines and have dramatic public health consequences for developing countries (see **Table 1**).

**Table 1. Public health impacts of FTAs**

FTA	Source	Public health impact
<i>EU–Colombia FTA</i>	IFARMA prospective study commissioned by Health Action International (HAI) Europe <sup>88</sup>	By 2030, patent-term extensions could increase expenditure on medicines in Colombia by nearly \$280m; data-exclusivity rules could result in an increase of more than \$340m. <sup>89</sup>
<i>US–Jordan FTA</i>	Oxfam International <sup>90</sup>	Data exclusivity resulted in significant delays to the introduction of generic competition for 79 percent of medicines examined in the study. This led to price increases of between two- and ten-fold for key medicines to treat cardiovascular disease and cancer. The study estimates that the availability of generic equivalents would have reduced Jordan expenditures on medicines by between \$6.3m and \$22m between mid-2002 and 2006.
<i>US–Thailand FTA</i>	University of Bangkok prospective impact study <sup>91</sup>	A macro-economic model measuring the impact of data exclusivity and patent extension proposals forecasted that all scenarios demonstrated a negative impact on the pharmaceutical market and access to medicines. Medicines' prices would increase by 32 percent and the domestic pharmaceutical market would contract of \$3.3m by 2027.

## b) IP enforcement: a threat to generic competition

Far-reaching IP enforcement potentially 'chills' generic competition because it creates a high level of legal uncertainty for generic competitors. Moreover, enforcement can also obstruct the import, transit or export of legitimate generic medicines.<sup>92</sup> The EU has been a frontrunner in increasing IP enforcement standards,<sup>93</sup> and is trying to export its enforcement regulations to the rest of the world.<sup>94</sup>

For example, generic companies will be more likely to face expensive and time-consuming litigation, less able to challenge frivolous patents, and more likely to see their medicines wrongfully seized.<sup>95</sup> This all delays or prevents the availability of affordable medicines. Scaled-up enforcement provisions can therefore expand the monopoly power of IP rights holders, while removing protections against the abuse of that power and further undermine the balance between IP protection and public health.<sup>96</sup>

One practical consequence of enforcement was the seizure by European customs of at least 19 generic medicine shipments from India and Brazil in transit through the EU to developing countries in 2008 and 2009. The medicines were lawfully produced and could be lawfully sold in their countries of destination, yet allegedly violated IP provisions in effect in Europe.<sup>97</sup> The seizures provoked public outcry and a WTO dispute by India and Brazil against the EU.<sup>98</sup> The EU's DG-Competition, in its 2009 'Pharmaceutical Sector Inquiry', also reported that IP enforcement

measures were often abused by originator companies to delay generic entry of a large number of medicines.<sup>99</sup>

The anti-counterfeiting trade agreement (ACTA)<sup>100</sup> combined all the problematic elements of the EU's IP enforcement agenda. By aiming to set a global standard on IP enforcement, albeit under the banner of preventing bad quality medicines, this agreement threatened access to medicines as well as a range of civil liberties.<sup>101</sup> Despite the rejection of ACTA by the EP and several EU Member states, the EU is still attempting to incorporate ACTA-like provisions in FTAs and in EU legislation. With the review of EU customs regulations and the recast of the EU trademark package, there was and is again a strong push to expand IP enforcement measures in in-transit areas, conflating counterfeiting products with generic medicines.<sup>102</sup>

#### **Box 6. The flawed link between combating counterfeits and IP enforcement**

**'Substandard medicines'** do not meet the scientific specifications for the product. **'Falsified medicines'** may be fake in terms of composition and/or labelling.

**'Counterfeit trademark goods'** are defined by TRIPS as *'goods that bear, without authorization, a trademark that is identical to, or which cannot be distinguished in its essential aspects from, a registered trademark'*.<sup>103</sup> Article 61 of TRIPS states that criminal counterfeiting activities involve trademark infringement that is wilful and carried out on a commercial scale.<sup>104</sup>

Counterfeiting is therefore a very specific term which should not be conflated with other types of IP infringement or legitimate generic medicines.

However, many rich countries are pressuring developing countries to embrace the flawed argument that stricter IP enforcement is the best remedy to protect patients from poor-quality medicines. Evidence suggests, however, that the vast majority of substandard and falsified medicines do not constitute IP infringement. Therefore, IP enforcement does not address the real public health problem of bad quality medicines, which should be tackled by strengthening **drug regulatory authorities**.<sup>105</sup>

Introducing new IP enforcement rights (e.g. in in-transit areas) will increase the risk of abuse and over-enforcement by rights holders and deter generic competition, as it has been shown above.

#### **c) Investment measures at the expense of health**

Under investment provisions proposed by the EU, pharmaceutical companies can claim that governments' health regulations undermine enjoyment of their IP-related 'investments'. This would undermine governments' ability to issue regulations to protect public health and promote access to medicines. The investor-to-state dispute settlement (ISDS) provisions proposed in FTAs give foreign investors the right to sue governments for compensation if laws, policies, court decisions or other actions interfere with expected profits from investments, even if these government actions are in accordance with the public interest. This could lead to companies suing governments for using TRIPS flexibilities to promote access to medicines. Such ISDS procedures would take place in secret arbitration tribunals outside the realm of national laws or judicial oversight.<sup>106</sup>

In 2013, US-based pharmaceutical company Eli Lilly accused Canada of violating its obligations to foreign investors under the North American Free Trade Agreement (NAFTA), by allowing Canadian courts to invalidate patents for two of its drugs. Eli Lilly is claiming indirect (regulatory) expropriation and a violation of minimum standards of treatment, and is demanding \$500 million in compensation for the invalidation of two patents, as well as challenging Canada's legal doctrine for determining a patent's validity.<sup>107</sup> This case clearly demonstrates that a pharmaceutical company is able to challenge states' routine patent validity decisions under ISDS, pursuant to investor rights in a FTA.

Other means used by rich countries to restrict TRIPS flexibilities are explained in the following sections.

## 2 Pressure on LDCs to implement the TRIPS agreement

Under TRIPS and the Doha Declaration, least developed countries (LDCs) benefit from a transition period to implement TRIPS due to their special needs and economic situation. In June 2013, the TRIPS Council reached a decision to push the TRIPS implementation deadline back from July 2013 to July 2021.<sup>108</sup> LDCs requested this extension for good reason; the time-limited transition period was insufficient for the majority of them to achieve the necessary technological transformation and capacity building. Also, evidence does not support the assumed proposition that "*heightened IP protections have had a positive impact on foreign direct investment, local innovation, technological capacity building, or even development more broadly in LDCs*".<sup>109</sup> Indeed, IP provisions are more likely to undermine technological development and nascent industries in LDCs.<sup>110</sup>

The lack of rational justification for forcing LDCs to adopt TRIPS rules is widely recognised, even by the pharmaceutical industry.<sup>111</sup> The EU however, throughout months of behind-the-scenes negotiations, consistently sought to undermine both the requested duration of the transition period and LDCs' freedom to determine levels of IP protection that would be optimal in light of their special circumstances.

The EU's position becomes even more problematic in light of the fact that developed countries have failed to facilitate meaningful technology transfer as agreed under TRIPS.<sup>112,113</sup> Under TRIPS, developed country WTO Member states are required to provide incentives to induce technology transfer to LDC Member states, to enable them '*to create a sound and viable technological base*'.<sup>114</sup> Instead, the EU and the USA mainly use technology transfer in tandem with technical assistance programmes, as a route to export their IP standards.<sup>115</sup>

LDCs are not the only ones under pressure regarding IP rights. LMICs have also been attacked for legally using TRIPS flexibilities, such as compulsory licences to allow generic competition to decrease medicines' prices.

### **3 Compulsory licenses and other TRIPS flexibilities under pressure**

The TRIPS agreement allows a government under certain circumstances to issue a compulsory license, which is an authorization to use the patent of a rights holder in order to produce and market a cheaper generic medicine without the right holder's authorization.<sup>116</sup> In exchange, the authorised generic firm must pay a licence fee to the patent holder. A compulsory licence, or even the mere threat of issuing one, will result in a substantial decrease in the price of a medicine. Compulsory licensing of IP-protected technologies is a tool that is also frequently used by western economies, including EU competition agencies.<sup>117</sup>

Using compulsory licenses is one of the flexibilities foreseen in the TRIPS agreement which has been reaffirmed by the 2001 Doha Declaration on TRIPS and Public Health that confirmed that countries are free to determine the grounds for granting compulsory licences<sup>118</sup>.

Many LDCs have used TRIPS flexibilities to lower medicine prices, and several middle-income countries – including Thailand, Brazil and Ecuador – have used compulsory licences to lower the prices of essential medicines.<sup>119</sup> Although most licenses were used for HIV treatments, some have concerned drugs to treat cancer and cardiovascular diseases, as was the case in Thailand. More recently, India and Indonesia issued compulsory licenses to ensure access to treatment for NCDs, including patented cancer treatments. Currently, civil society organizations are urging the governments of LMICs, which have to deal with 73 percent of all hepatitis C patients globally, to use compulsory licences to lower the price of new and exorbitantly priced treatments.<sup>120</sup>

However, efforts to use compulsory licences, especially by middle-income countries that have the capacity to manufacture medicines, such as Thailand<sup>121</sup>, Brazil, Ecuador and India, have been met with strong pressure from western governments and the pharmaceutical industry.<sup>122</sup>

In another effort to apply bilateral pressure on countries that fail to comply with high levels of IP protection, the EU introduced a 'Watch List' in 2006, emulating the US 'Special 301 Watch List'. This list, which is part of the EC's 'Strategy for the Enforcement of IP in Third Countries', highlights the alleged deficiencies in those countries' IP frameworks that could be remedied through FTAs.<sup>123</sup> In the EC's evaluation of the IP Enforcement Strategy, it was noted that this Strategy and the negotiation of ACTA were largely based on a hard line approach and did not take much account of the emerging development agenda.<sup>124</sup>

In spite of this, the EC released on July 2, 2014 an action plan to bolster the enforcement of IP rights in its internal market and a revised strategy to enhance IP rights standards in third countries. The latter considers trade relations with third countries as one of the channels for improving IP rights, and envisages financial sanctions for countries repeatedly infringing these rights. Such sanctions could even include restricting third countries' participation in, or funding from, specific EU-funded programmes.<sup>125</sup> The fact that the EC is persisting in this tough approach is very worrying for developing countries.

# DEMOCRACY AT RISK IN EU TRADE POLICY

The EU's demand that FTAs include stricter IP rules has provoked fierce resistance; the EU has had to accept the embarrassing rejection of ACTA by the EP in July 2012 and its inability to impose certain TRIPS-plus provisions in several bilateral negotiations. In negotiations with the EU, the Indian government – under strong pressure from local and international civil society groups, the media and its own generic medicine industry – largely rejected the EU's IP demands. In 2009, trade negotiations with the Andean Community fell apart when Ecuador and Bolivia left the negotiations, partly because of concerns that strict IP rules would restrict access to medicines. Nevertheless, the EU pressed on with negotiations to enforce strict IP standards with the remaining countries: Peru and Colombia.<sup>126</sup> The South American trading bloc, MERCOSUR, in negotiations with the EU, refused to use the standard EU text as a starting point, and proposed a different approach to the role of IP provisions that prioritised social welfare. Negotiations with this regional bloc have stalled, although bilateral negotiations with Ecuador and Brazil are slowly progressing. In current negotiations with Thailand, the EU is again attempting to impose strict IP rules for medicines.<sup>127</sup>

Multi-sectorial stakeholders, e.g. public health NGOs, experts<sup>128,129</sup>, the Vatican<sup>130</sup> and UN bodies<sup>131,132</sup>, recognise the link between TRIPS-plus provisions and poor access to medicines. The EP, through resolutions, recommendations and letters, has communicated its concerns about trade agreements and access to medicines in developing countries.<sup>133</sup> Academics and civil society representatives have spoken in a single voice on the ineffectiveness of greater IP protection for needs-driven and affordable innovation in medicine. Despite this opposition, the EU's IP policies – promoted by DG-Trade – continue to undermine the efforts of other DGs within the EC and Member states to promote access to healthcare in LMICs.

For example, Oxfam and Health Action International recognise the contributions from the EU and its Member states to the financing of the GFATM, which funds two thirds of global malaria and tuberculosis programmes. Alongside these efforts, EU Member states have implemented other programmes to improve access to medicines in developing countries.<sup>134</sup> As part of the EU development agenda, the EC's funding contributes to financing countries' health sectors and general budget support. Such policies enable governments to expand public health services for people living in poverty. It is shameful that EU trade policies undermine all these accomplishments.

DG-Trade seems to remain deeply convinced of the need to impose stricter IP protections, even in the field of medicines, purportedly to 'save' the EU knowledge economy. Rather than changing its policies or engaging in meaningful dialogue on the health impact of EU trade policy, DG-Trade has publicly identified social media as the main reason for ACTA's failure.<sup>135</sup> This response reflects DG-Trade's lack of will to truly

take into consideration concerns expressed by civil society, especially when it comes to IP measures and the pharmaceutical industry

DG-Trade's rigid position in support of strong IP protection is not surprising when considering the amount of corporate lobbying activity. The pharmaceutical industry spends more than €40m annually to influence decision making in the EU, employing an estimated 220 lobbyists.<sup>136</sup>

These numbers keep increasing, as the US-based pharmaceutical industry lobby (PhRMA) is also establishing a firm presence in Brussels.

DG-Trade should no longer be the only DG to set the trade and IP agenda, and should stop using trade policies to advance the interests of EU industry alone, without taking into consideration its impact on the public interest. Other DGs of the EC, the EP and EU Member states should ensure that public health, development and trade policies promoted by the Commission are coherent and complementary, and benefit EU citizens as well as people in developing countries. The principle of '*policy coherence for development*', enshrined in the Lisbon Treaty, should be implemented to ensure that no EU policies contradict the objectives of EU development policies.<sup>137</sup>

# 4 RISE OF HEALTH INEQUALITY IN EUROPE

## THE EU STRUGGLES TO KEEP HEALTH FOR ALL

The affordability and availability of medicines is increasingly a problem in the EU, and has been exacerbated by the financial crisis. Public expenditure on pharmaceuticals increased on average by 76 percent across EU countries between 2000 and 2009.<sup>138</sup> Costs are rising faster than Member states' GDP, mainly due to ageing populations and the increasing cost of medicines (see **Chapter 1** for more on this topic).<sup>139</sup>

Unnecessary delays in the entry of generic medicines onto the market further affect the affordability of medicines. In EU countries, generic medicines are, on average, a third to a quarter of the price than their respective off-patent originals.<sup>140</sup> Prices tend to drop by 25 percent a year after generic entry to the market, and by 40 percent per year from two years after entry.<sup>141</sup>

New patented medicines introduced on the market are increasingly expensive and form the key drivers of increases in expenditure. The rise in expenditure on patented medicines outpaces the savings brought through the use of generic medicines.<sup>142</sup> More than 100 influential oncologists have recently described current prices of cancer medicines as: '*astronomical, unsustainable and even immoral*'.<sup>143</sup> When Gilead announced that its new hepatitis C treatment, sofosbuvir (Sovaldi), would be priced in the US at \$84,000 for a standard 12-week course of treatment, there was a public outcry. The company sold \$2.27bn of Sovaldi in the first quarter of 2014 alone.<sup>144</sup>

At the same time, EU Member states' healthcare budgets are being cut, and there is increasing pressure to make treatment more efficient, while maintaining high levels of quality.<sup>145</sup> For example, in April 2014, the UK's National Institute for Health and Care Excellence (NICE) rejected ado-trastuzumab emtansine (Kadcyla), a new breast cancer medicine from Roche, whose treatment course cost £90,831 per patient, because it was too expensive for the National Health Service (NHS).<sup>146</sup>

This unsustainable situation risks polarising European society and reinforcing inequality in access to healthcare. There is a risk that only those wealthy enough to pay will be able to benefit from the latest treatments.

The high costs of medicines, in combination with concerns about innovation and delayed generic entry to the market, are a source of serious concern for the EC. The 2009 DG-Competition Inquiry report into the pharmaceutical sector found that an excessive focus on IP litigation

was hampering generic competition and weakening innovation in Europe.<sup>147</sup> DG-Competition should take bold and effective actions to stop and sanctions these abuses.

**Box 7. The financial crisis and austerity measures threaten access to medicines in Europe**

Following the financial and economic crisis, the majority of EU Member states have made policy adjustments in order to reduce health costs. The most worrying consequence of this is the increase in co-payments by patients, and medicine shortages in some countries, which lead to a reduction in access and an increase in inequality.

Measures imposed by the Troika (EU, IMF, European Central Bank) on Member states that have loans, force governments to decrease health budgets as a percentage of GDP in order to achieve 'fiscal balance'. Access to medicines is an essential element of the right to health that has been undermined on such occasions.

These developments, together with austerity measures undermining social protection systems, have led to serious problems for access to medicines in the most hard-hit countries, such as Spain, Portugal and Greece. In Greece, for example, widespread medicine shortages have been reported in pharmacies, as wholesalers turn to markets with higher profits.<sup>148</sup>

## BIG PHARMA PROFITS IN TTIP

The TTIP agreement that the EU is now negotiating with the US does not bode well for access to medicines. In the midst of controversies around EU's democratic deficit, trade policies and the capture of EU institutions by industrial lobbies<sup>149</sup>, TTIP represents a huge threat to European public health systems and the public interest for the benefit of multinational industry's profits.

Leaked pharmaceutical industry "wish list" demonstrates that the originator industry seeks harmonization on patentability standards, as well as a 'voice' in EU Member states' pricing and reimbursement policies.<sup>150</sup> The US government has made similar demands in previous and ongoing trade agreements with the EU.<sup>151</sup> As the US has lower patentability standards, this would effectively lead to more patents in the EU, which would in turn lead to less generic competition and more expensive medicines.<sup>152</sup> Granting even stronger IP protection would also seem contrary to DG-Competition's findings about the abuse of monopoly power by originator companies. Moreover, increased influence for companies in how medicine price and reimbursement policies are set would challenge Member states' sovereignty to take measures to control expenditure on medicines.<sup>153</sup> This could have, for example, weakened recent policies by Member states that cut medicine prices to curb spending in times of austerity. It could also harm Germany's recently revised reimbursement policy, which takes into account the costs/benefit ratio of new patented medicines in relation to existing treatments.<sup>154</sup>

#### Box 8. TTIP: A threat to EU citizens' health

TTIP provisions would harm the affordability of medicines for EU citizens by delaying the availability of cheaper generic medicines, as well as keeping medicine prices high.

Several provisions would result in **stronger IP protections**, linking pricing and reimbursement decisions to the market value of patented pharmaceutical products – as already included in some FTAs (e.g. US-South Korea, EU-South Korea) – and giving companies the power to intervene in government decision-making.

In addition, TTIP represents a real threat to the **public's access to clinical trial data** through the IP and regulatory cooperation chapters.<sup>155</sup>

Both the USA and the DG-Trade are pressing for the agreement to include an ISDS. This would allow US pharmaceutical companies to sue EU Member states, and potentially claim millions of dollars in compensation, by arguing that government measures to promote access to medicines will negatively affect future earnings on their IP or other investments in the EU.<sup>156</sup> Such legal challenges could be brought against measures like price controls, reimbursement and therapeutic formulary decisions, marketing approvals and pharmacovigilance decisions, or stronger patentability standards.

The potential for US pharmaceutical companies that invest in the EU to use this form of arbitration against EU Member states (or EU companies against the USA) and challenge pro-public health measures is evidenced through suits recently brought forward by major US, Canadian and French companies under ISDS provisions in other investment treaties.<sup>157</sup>

Including ISDS in TTIP is unjustified and unnecessary, given the high level of investment protection that the domestic EU and US legal systems already provide. Using ISDS to restrict countries' legitimate rights to implement specific health measures poses a considerable threat to the ability to address the issue of accessibility and affordability of medicines in Europe.

Furthermore, TTIP poses a threat for access to medicines beyond the EU and the US since it could set a new global standard for strict IP protection they will surely seek to impose on developing countries through future trade deals.<sup>158</sup>

# 5 CONCLUSION AND RECOMMENDATIONS

The right to health requires governments to promote and protect access to needed medicines. This responsibility must not be traded away to accommodate the expanding monopoly power of multinational pharmaceutical companies.

The balance between protecting commercial interests and public health interests has been lost. New medical technologies come at a tremendous cost to health systems and patients, and the percentage of pharmaceutical expenditure as a part of total health budgets has been rising steadily. Increasing IP protection has not led to more innovation, since the IP-based model is critically flawed in its ability to promote innovation that addresses priority public health goals. As a result, pharmaceutical companies have failed to deliver medicines that people need at a sustainable price for health budgets worldwide. Even in the EU, the affordability and availability of medicines are in jeopardy.

Unfortunately, the EU's trade policy agenda does not reflect the recognition that excessive IP protection results in increased medicine costs and hampers biomedical innovation. Decreasing levels of innovation have led companies to retain and strengthen monopoly power over their products and to look for higher revenues in LMICs by leveraging that power, which in turn hampers generic competition and limits access for poor populations. EU trade policy is one avenue through which companies attempt to export stronger IP rules.

EU trade policies are harming access to medicines across the world. The EU is not doing enough to explore new models of innovation to address urgent health needs and deliver innovation at a sustainable cost. Resistance against those EU trade policies that undermine health and development commitments undertaken by the EU and Member states is now coming from many angles.

TTIP which will be in the spotlight for quite some time risks increasing medicine prices in Europe and increasing the financial burden on already strained health systems. In addition, TTIP intends to become the global standard that will apply to other trade agreements across the world. It is time for the EU to amend its trade and innovation policies to better serve the public interest in Europe and the world.

The EU needs to adopt a comprehensive approach to ensure sustainable access to affordable health technologies for people inside and outside the EU. Its competition, R&D and trade agendas should all be tailored to serve this goal. DG-Research and the DG for Health and Consumers need to further explore alternative biomedical innovation models. DG-Competition should be robust in addressing the abuse of strong IP provisions identified in its 2009 Pharmaceutical Sector Inquiry report. Most importantly, DG-Trade should no longer be the only DG to set the trade and IP agenda, and should broaden its vision of the purpose of EU trade going beyond simply protecting

the commercial interests of EU industry. To achieve this, other DGs, the EP and EU Member states should oversee trade negotiations more closely to make sure that trade policies do not undermine public health. The current narrow approach is harmful for people at the other end of the trade policies, as well as for European citizens.

More specifically, Health Action International and Oxfam International recommend that, in order to improve innovation and access to medicines:

1. **The EU should ensure its trade policy aligns with its development and (global) health objectives.** In particular it should:
  - a. Not misuse FTAs to introduce TRIPS-plus IP rules that extend monopoly protection and enforcement policies to the detriment of access to medicines.
  - b. Not include investment protection measures in FTA and bilateral investment treaties, including ISDS mechanisms, which limit public health policy space.
  - c. Actively support governments that make use of legal TRIPS safeguards and flexibilities to protect and promote public health. LDCs should not be required to implement TRIPS.
  - d. The EU should ensure that the TTIP agreement with the USA does not jeopardise access to medicines or limit public health policy space in the EU, and does not restrict the use of TRIPS flexibilities.
  
2. **The EU should support generic competition to allow broad access to medical products in LMICs.** In particular it should:
  - a. Engage in meaningful technology transfer that allows LDCs to build a sound technology base.
  - b. Encourage companies to join the Medicines Patent Pool to enable generic companies' medicines production.
  - c. Ensure that the GFATM continues to pursue a policy that encourages the procurement and use of generic medicines and support UNITAID work to make quality medicines and diagnostics available and affordable.
  
3. **The EU and its Member states should support the exploration of new models of innovation** that increase both innovation and access to, and incorporate conditions and guidelines for, biomedical R&D grants that promote the sharing of knowledge and are responsive to public health needs. They should do this by:
  - a. Supporting the implementation of the WHO's GSPoA.
  - b. Constructively engaging in the process to develop a Biomedical R&D Convention at the WHO.
  - c. Ensuring that innovation and biomedical knowledge derived in whole or in part from EU publicly funded health R&D, such as Horizon 2020 (including the EDCTP and the IMI), results in public goods and medical products that are suitable, affordable and accessible.

The newly elected EP should make the most of the tools at its disposal to improve access to medicines for all citizens, in Europe and in LMICs, and make sure that EU trade policies do not undermine the right to health and access to medicines. Their new legislative mandate represents a great opportunity for the EU institutions to ‘act, react and impact’, as the EP elections’ campaign invited citizens to do.

## ACRONYMS

ACTA	Anti-Counterfeiting Trade Agreement
ARV	Antiretroviral
CEWG	Consultative Expert Working Group on Research and Development: Financing and Coordination
DG	Directorate-General
EC	European Commission
EDCTP	European and Developing Countries Clinical Trials Partnership
EFPIA	European Federation of Pharmaceutical Industries and Associations
EP	European Parliament
EU	European Union
FTA	Free trade agreement
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GSPoA	Global Strategy and Plan of Action on Public Health, Innovation and IP
IMI	Innovative Medicines Initiative
IP	Intellectual property
ISDS	Investor-state dispute settlement
LDC	Least developed country
LMIC	Low- and middle-income countries
NAFTA	North American Free Trade Agreement
NCD	Non-communicable disease
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PEPFAR	US President's Emergency Plan for AIDS Relief
PDP	Product development partnerships
R&D	Research and development
SPC	Supplementary Protection Certificate
TRIPS	Trade-Related Aspects of Intellectual Property Rights.
TTIP	Transatlantic Trade and Investment Partnership
WHA	World Health Assembly
WHO	World Health Organization
WTO	World Trade Organization

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- <sup>81</sup> The role of technology in development has been explained by UNIDO 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 that countries such as China and India can grow much faster than industrialised countries is that adapting existing technologies is much easier than creating new ones.
- United nations industrial development organization (2006), 'The Role of Intellectual Property Rights in Technology Transfer and Economic Growth: Theory and Evidence', working paper, [http://www.unido.org/fileadmin/user\\_media/Publications/Pub\\_free/Role\\_of\\_intellectual\\_property\\_rights\\_in\\_technology\\_transfer\\_and\\_economic\\_growth.pdf](http://www.unido.org/fileadmin/user_media/Publications/Pub_free/Role_of_intellectual_property_rights_in_technology_transfer_and_economic_growth.pdf)
- <sup>82</sup> 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 respective chemical industries had become established). This pattern has been broken over the past twenty years by a combination of new institutions, such as the WTO and regional trade agreements, and an aggressive campaign by large corporations and their home-country governments.
- <sup>83</sup> MSF (2012) *op. cit.*
- <sup>84</sup> J. Finger and P. Schuler (1999) 'Implementation of the Uruguay Round Commitments: The Development Challenge', *World Bank Development Research Group, Working Paper 2215*, <http://elibrary.worldbank.org/doi/pdf/10.1596/1813-9450-2215>
- L.Foreman (2008) "'Rights" and wrongs: what utility for the right to health in reforming trade rules for medicines?', *Health Human Rights* 10(2):37–52, p.48
- <sup>85</sup> C. Fink (2009) 'Enforcing IP Rights: An Economic Perspective', [http://www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=129546](http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=129546)
- <sup>86</sup> Data exclusivity creates a new system of monopoly power, separate from patents, by blocking the registration and marketing approval of generic medicines, even when no patent exists. The duration of data exclusivity varies in each country. Drug regulatory authorities are prevented from using clinical trial data developed by originator companies 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. 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. Also repeating clinical trials add to the costs of generic medicines.
- <sup>87</sup> X. Seuba (2009) *op. cit.*, pp 48–50.
- <sup>88</sup> IFARMA (2009a) 'Impact of the EU-Andean Trade Agreement on Access to Medicines in Colombia', [http://www.haiweb.org/04102010/29\\_Mar\\_2010\\_Report\\_IFARMA\\_Impact\\_Study\\_Colombia\\_EN.pdf](http://www.haiweb.org/04102010/29_Mar_2010_Report_IFARMA_Impact_Study_Colombia_EN.pdf)
- The prospective impacts of the EU–Peru FTA, assessed using 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 groups, and the governments of the countries in question, TRIPS-plus rules have been somewhat modified to reduce public health impacts on negotiating partners. See: IFARMA (2009b) 'Impact of the EU-Andean Trade Agreement on Access to Medicines in Peru', <http://haieurope.org/wp-content/uploads/2010/12/11-Nov-2009-Report-IFARMA-Impact-Study-on-EU-Andean-Trade-Agreement-in-Peru-EN.pdf>
- <sup>89</sup> *Ibid.*
- <sup>90</sup> Oxfam (2007) *op. cit.*
- <sup>91</sup> Kessomboon, Nusaraporn et al. (2010) 'Impact on Access to Medicines from TRIPS-plus: A case study of Thai-US FTA', *The Southeast Asian Journal of Tropical Medicine and Public Health* 41(3):667–677
- <sup>92</sup> X. Seuba (2009) *op. cit.* pp36–53.
- C.Correa (2009a) 'The Push for Stronger Enforcement Rules: Implications for Developing Countries', Centre for Interdisciplinary Studies on Industrial Property and Economics, University of Buenos Aires, [http://mercury.ethz.ch/serviceengine/Files/ISN/102258/ichaptersection\\_singledocument/0e](http://mercury.ethz.ch/serviceengine/Files/ISN/102258/ichaptersection_singledocument/0e)

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- <sup>93</sup> EU enforcement legislation formulated in European Directive 2004/48/EC (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:195:0016:0025:en:PDF>), and European Regulation 1383/2003 (<http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32003R1383>).
- <sup>94</sup> C. Correa (2009a) *op.cit.*
- <sup>95</sup> X. Seuba, J. Rovira and S. Bloemen (2010) 'Welfare Implications of IP Enforcement Measures', *PIJIP*, Research Paper no. 5. American University Washington College of Law, Washington, DC., [http://digitalcommons.wcl.american.edu/do/search/?q=author\\_iname%3A%22Seuba%22%20author\\_fname%3A%22Xavier%22&start=0&context=973062](http://digitalcommons.wcl.american.edu/do/search/?q=author_iname%3A%22Seuba%22%20author_fname%3A%22Xavier%22&start=0&context=973062)
- <sup>96</sup> S. Musungu (2012) 'Anti-counterfeit Laws and Public Health: What to Look Out for', UNDP discussion paper, <http://www.undp.org/content/dam/undp/library/hiv aids/English/UNDP%20Discussion%20Paper%20-%20%28revised%29.pdf>
- <sup>97</sup> HAI Europe (2009a) 'Dutch seizure puts pressure on access to medicines in developing countries', press release, 6 February, <http://haieurope.org/wp-content/uploads/2010/11/6-Feb-2009-Press-release-Dutch-seizure-of-generic-medicines.pdf>  
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- <sup>98</sup> WTO (2010) 'Dispute Settlement: Dispute DS408, European Union and a Member states – Seizure of Generic Drugs in Transit', [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds408\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm)
- <sup>99</sup> EC (2009) *op. cit*
- <sup>100</sup> ACTA was negotiated between the EU, US, Mexico, Japan, Australia, Canada, Japan, Morocco, New Zealand, Singapore and South Korea.
- <sup>101</sup> For a detailed analysis of the potential impact of ACTA on access to medicines, see: HAI Europe (2012a) 'ACTA and Access to Medicines: A Flawed Process, flawed rationale and flawed agreement', policy brief, <http://haieurope.org/wp-content/uploads/2012/02/27-Feb-2012-HAI-Europe-Policy-Brief-AC TA-and-Access-to-Medicines.pdf>
- <sup>102</sup> HAI Europe, MSF and Oxfam (2013) 'Position paper on the recast of the EU Trademark package', [http://haieurope.org/wp-content/uploads/2013/11/Nov-2013-Joint-position-paper-EU-Trade-mark-package-MSF\\_OXFAM\\_HAI-3.pdf](http://haieurope.org/wp-content/uploads/2013/11/Nov-2013-Joint-position-paper-EU-Trade-mark-package-MSF_OXFAM_HAI-3.pdf).  
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- <sup>103</sup> WTO (1994), *op.cit.*, art 51, footnote 14
- <sup>104</sup> WTO (1994) *Ibid*, art.61
- <sup>105</sup> For an overview of the issue, see: J. Brant and R. Malpani (2011) 'Eye on the ball: Medicine regulation – not IP Enforcement – can best deliver quality medicine', Oxfam International Briefing Paper, <http://policy-practice.oxfam.org.uk/publications/eye-on-the-ball-medicine-regulation-not-ip-e nforcement-can-best-deliver-quality-121411>, p. 22-26
- <sup>106</sup> The Commission recently announced revisions to the proposed investment chapter in TTIP that would allegedly reduce this risk. These amendments, however, still leave considerable room for interpretation about what grounds companies can use to sue EU Member state governments for their health regulations. This uncertainty is unacceptable when it potentially limits the ability of governments to regulate in the interest of public health. This is exacerbated because the interpretation will be determined in secret by arbitration tribunals outside national judicial systems.
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- <sup>108</sup> WTO (2013) 'Extension of the transition period under art.66.1 for least developed country members', Decision of the Council for TRIPS, 11 June 2013, [http://www.wto.org/english/tratop\\_e/trips\\_e/ldc\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/ldc_e.htm)
- <sup>109</sup> For an overview of the evidence, see: B. Baker (2013) 'Global Academics' Expert Letter on LDC Extension', April 29, <http://infojustice.org/archives/29438>
- <sup>110</sup> *ibid.*
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- <sup>112</sup> WTO (1994) *op.cit.*, art. 66.2.  
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- <sup>114</sup> WTO (1994) *op.cit.*, art. 66.2
- <sup>115</sup> X. Seuba (ed.) (2013) 'Propiedad Intelectual, competencia y aspectos regulatorios del medicamento', *PUJ-ICTSD*, pp. 42-43  
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- <sup>117</sup> J. Love (2014) 'Recent European Union Compulsory Licenses', research note, 1 March, [http://keionline.org/sites/default/files/Annex\\_B\\_European\\_Union\\_Compulsory\\_Licenses\\_1\\_Mar2014\\_8\\_5x11\\_0.pdf](http://keionline.org/sites/default/files/Annex_B_European_Union_Compulsory_Licenses_1_Mar2014_8_5x11_0.pdf), annex B to 'KEI's comments to the US special 301 watch list', <http://keionline.org/node/1976>  
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- See also comments from US PhRMA submitted to the Office of the U.S. Trade

Representative (USTR): J. Taylor (2013) 'Re: Request for Comments Concerning the Proposed Transatlantic Trade and Investment Partnership, 78 Fed. Reg. 19566 (Apr. 1, 2013), open letter, <http://www.regulations.gov/contentStreamer?objectId=09000064812d9cad&disposition=attachment&contentType=pdf>

<sup>151</sup> Key elements of this industry wish list, including IP demands and an increased voice for pharmaceutical companies in governments' pricing and reimbursement decisions were included by the US in its FTA with South Korea and have been tabled by the US in its trade negotiations for the Trans Pacific Partnership agreement (TPP).

<sup>152</sup> L. Genovesi (2013) 'La aplicación industrial y la utilidad como requisitos de patentabilidad: diferencias y semejanzas. Consecuencias de su aplicación', in X. Seuba (ed.) *Propiedad Intelectual, Competencia, Aspectos Regulatorios del Medicamento*, Bogotá: PUJ-ICTSD, 2013.

<sup>153</sup> For a detailed analysis, see: Commons Network, HAI et al. (2014) 'The Trans Atlantic Trade and Investment Partnership (TTIP): A Civil Society response to the Big Pharma Wish list', joint position paper, [http://www.prescrire.org/Docu/DOCSEUROPE/20140324CivilSocietyResponseBigPharmaWishList\\_final.pdf](http://www.prescrire.org/Docu/DOCSEUROPE/20140324CivilSocietyResponseBigPharmaWishList_final.pdf)

<sup>154</sup> Commons Network, HAI et al. (2014) *ibid*.

For more information on Germany's pricing policy, see: S. Fernando and J. Smith-Parker (2012) 'Germany's new drug reimbursement process picks up industry resistance, potential for minor alleviation by authorities', *Financial Times*, 17 July, <http://www.ft.com/intl/cms/s/2/906e131a-d057-11e1-99a8-00144feabdc0.html#axzz2vZH6LTqs>

In the EU, pricing and reimbursement of pharmaceuticals is primarily a national competence. There is a strong connection between pricing and reimbursement at the 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 unilateral basis. In a few countries pharmaceutical prices are negotiated between the manufacturer (or wholesaler) and the government authority.

S.Vogler (2008) 'Pharmaceutical pricing and reimbursement information report', report commissioned by EC, DG Health and Consumer Protection and the Austrian Federal Ministry of Health, Family and Youth, p XIII-XVI, [http://ec.europa.eu/health/ph\\_projects/2004/action1/docs/action1\\_2004\\_frep\\_05\\_en.pdf](http://ec.europa.eu/health/ph_projects/2004/action1/docs/action1_2004_frep_05_en.pdf)

<sup>155</sup> The European federation of pharmaceutical industries and associations (EFPIA) and the US pharmaceutical industries organisation (PhRMA) have developed joint principles for 'responsible data sharing,' which basically maintain the current status quo, by using 'commercial confidentiality' agreements as barriers to transparency. Moreover, welcoming the new EU Directive proposal on trade secrets published end of November 2013, EFPIA calls for clinical data to fall into the definition of trade secrets. Enshrining such an 'aligned approach' in the TTIP would lock in the status quo for EU and US law, and undermine efforts by the European Medicines Agency (EMA), EP and Member states to disclose clinical trial data for public health reasons. In practice that could mean that any information which is "unfavourable" for a drug (lack of efficacy, harms) could be considered confidential because its publication will definitely mean a commercial disadvantage.

See Commons Network, HAI et al. (2014) *op.cit*.

<sup>156</sup> CEO, S2B and TNI (2013) 'A transatlantic corporate bill of rights: Investor privileges in EU-US trade deal threaten public interest', <http://corporateeurope.org/sites/default/files/attachments/transatlantic-corporate-bill-of-rights-oct13.pdf>

Commons Network, HAI et al. (2014) *op. cit*.

<sup>157</sup> R. Ugarte, F. Stirnimann and D. Bentolila (2013) 'Pharmaceuticals: a new frontier in investment treaty arbitration', *Global Arbitration Review*, 6 September, <http://globalarbitrationreview.com/news/article/31867/pharmaceuticals-new-frontier-investment-treaty-arbitration>

<sup>158</sup> C. Gerstetter, M. Mehling, A. Eberle and K. Salès (2013) 'Legal implications of the EU-US trade and investment partnership (TTIP) for the *Acquis Communautaire* and the ENVI relevant sectors that could be addressed during negotiations', EP Directorate General for Internal Policies, [http://www.europarl.europa.eu/RegData/etudes/etudes/join/2013/507492/IPOL-ENVI\\_ET\(2013\)507492\\_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/etudes/join/2013/507492/IPOL-ENVI_ET(2013)507492_EN.pdf)

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