

EMPTY GESTURES: THE EU'S COMMITMENTS TO SAFEGUARD ACCESS TO MEDICINES



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INTRODUCTION

Health Action International (HAI) and Médecines Sans Frontières (MSF) welcome the revision of the European Union's (EU) trade and investment policy. This is an excellent opportunity for the European Commission (Commission), European Parliament and EU Member States to develop a comprehensive access to medicines policy that is consistent across all relevant policy areas.

The revision should ensure that future trade and investment agreements reinforce public health in developing countries. The starting point of the new trade and investment strategy should therefore be the treaty-bound obligation of the EU to ensure policy coherence for development of all EU policies¹.

In its recent strategy on intellectual property (IP) enforcement in third countries, the Commission went beyond discussing IP enforcement issues, and also outlined the cornerstones in its approach to access to medicines and EU trade². HAI and MSF commend the Commission for explicitly recognising the need to address access to affordable, safe and effective medicines. However, looking at the Commission's current access to medicines commitments in more detail, these have proven to be empty words and gestures, contradicted and undermined by a long history of including substantive damaging TRIPS-plus provisions in EU free trade agreements, and other damaging EU trade policies.

This report identifies the contradiction between the Commission's stated commitments to ensure access to medicines and the EU's trade policy. It also provides a series of recommendations that would enable the Commission and EU to achieve its access to medicines commitments and broader development and public health objectives. Commissioner Malmström's trade policy review is a welcome opportunity to identify and adopt the necessary corrective measures to ensure that the EU's trade policy supports, instead of undermines, access to medicines.



1 FLAWED & LIMITED DATA UNDERPINNING POLICY CHOICES

In 2010 the consultancy firm, Analysis for Economic Decisions (ADE), carried out an independent evaluation of the previous EU IP enforcement strategy in third countries. One of ADE's key criticisms was that the IP enforcement strategy was based on a 'hard-line approach', which did not take into account a development perspective, including the detrimental effects of strengthening IP enforcement measures on local societies³. Additionally, the ADE evaluation noted that "a very substantial gap remains in data and information about the scope of the [IP enforcement] problem," and that "there is very little, if any, reliable statistical evidence on the overall economic and social impact of IPR [intellectual property rights] infringements"⁴.

When the Commission published an update of its 2004 strategy to enforce IP in third countries⁵ in 2014, it attempted to address this 'lack of data' critique. For this purpose, it had ordered a joint report by the Office for Harmonisation of the Internal Market (OHIM) and the European Patent Office (EPO)⁶. The findings of this report claim that IP-intensive sectors account for 39% of the overall EU gross domestic product (GDP) and up to 35% of jobs in the EU. European institutions have used these numbers widely to justify continued focus on increasing IP protection. While the two numbers may be correct, the report does not actually demonstrate that these sectors account for 39% of GDP and 35% of all jobs because they are IP intensive. The authors themselves prudently acknowledge the lack of causal link between the two⁷. Therefore, the critique made by the ADE review remains valid: There is still "very little, if any, reliable statistical evidence on the overall economic and social impact of IPR infringements"⁸.

HAI and MSF agree that more data is needed, particularly on the negative impact of excessive IP enforcement on public health⁹. The Commission too eagerly uses the flawed OHIM/EPO report as evidence to justify its hard-line approach to strengthening IP protection and enforcement. HAI and MSF therefore fear that 'better data' for the Commission simply means data that supports an already defined political line on strong IP – without consideration of any negative impacts this may have, including on public health, in third countries.

2 NEGATIVE IMPACT OF STRONG IP ON ACCESS TO AFFORDABLE MEDICAL TOOLS IN LOW- & MIDDLE- INCOME COUNTRIES

In 1994 the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) imposed a system of global IP rules on all WTO Member States. TRIPS obliged many countries to introduce or increase monopoly patent protection periods for pharmaceutical products. Despite the clear negative consequences that TRIPS had on access to medicines (such as HIV treatment in African, Asian and Latin American countries), the EU has since pushed for low- and middle-income countries (LMICs) to adopt even stricter levels of IP protection (TRIPS-plus rules) through bilateral and regional free trade agreement negotiations, IP dialogues and watch lists¹⁰.

TRIPS-plus rules exceed minimum WTO obligations and threaten access to affordable medicines. The damaging public health consequences of TRIPS-plus rules for people living in LMICs have been documented in numerous studies. For example, an impact assessment study demonstrated that an up to ten-fold price increase for key medicines occurred in Jordan when the United States imposed the TRIPS-plus rule of data exclusivity¹¹.

In addition, the Commission has pushed for stronger investment protection under EU free trade agreements since 2011, including investor-state dispute settlement (ISDS). Using ISDS, pharmaceutical companies can sue a government arguing that legitimate and WTO-compliant government measures to promote access to medicines will damage their IP-protected investments¹².

The lack of access to medicines is no longer just a problem in developing countries. European Member State governments currently face a looming access to medicines crisis as they struggle to afford new medicines with excessive price tags. Moreover, despite strong IP protection and continued strengthening of market monopolies in Europe, there has been a striking lack of medical innovation. Only few truly valuable medicines have been brought to market over the last decade¹³. With this in mind, the EU should seriously question whether strengthening IP protection and enforcement for pharmaceuticals through bilateral trade agreements is truly in the public interest.

In the context of LMICs, however, TRIPS-plus provisions continue to be completely indefensible. These countries often lack a robust institutional framework of balancing institutions, such as government competition agencies, pricing policies and universal access to healthcare, to mitigate the impact of high medicine prices resulting from high levels of IP protection. In addition, because governments in LMICs have limited budgets to purchase medicines through public sector expenditures (even those that allocate a substantial percentage of expenditure towards health), healthcare services and medicines are often paid out of pocket. As a result, any increase in price can make essential and lifesaving medicines unaffordable for many people in these countries¹⁴.

3 A TRUE COMMITMENT TO ENSURING ACCESS TO MEDICINES?

In the following sections, we will compare the commitments outlined in the Commission's Communication on Trade, growth and intellectual property - Strategy for the protection and enforcement of intellectual property rights in third countries (2014), against the substantive provisions in EU trade agreements and policies to assess the validity of the claim that it promotes and protects access to medicines. (Full text Communication on page 12.)

EU CLAIMS "The EU ensures that any multilateral and bilateral agreements reflect these objectives."

FACT The Commission imposes TRIPS-plus IP rules in free trade agreements, which threaten access to affordable medicines.

The Commission has a long history of including TRIPS-plus IP rules for pharmaceuticals in its bilateral and regional trade negotiations. Examples include agreements with trading blocs (e.g., Central America and the Andean Community), countries (e.g., India, Thailand, South Korea, Vietnam and Canada) and EU neighbouring countries (e.g., Ukraine and Moldova)¹⁵. Prospective and retrospective impact studies confirm that these TRIPS-plus rules threaten access to affordable medicines¹⁶ and, over time, will be detrimental to public health in developing countries. The European Parliament has, on several occasions, opposed the inclusion of TRIPS-plus measures in free trade agreements—most notably, in its 2007 resolution on TRIPS and public health¹⁷. Recently, the European Parliament reiterated that full EU support for third countries' use of TRIPS flexibilities is essential¹⁸.

The inclusion of TRIPS-plus provisions in the negotiating text has caused immense public outcry in the EU free trade negotiations with India. More stringent IP rules in India would be particularly harmful because India has an invaluable role as 'pharmacy of the developing world' by producing quality, affordable generic medicines. As such, India provides over 80% of the world's generic antiretroviral medicines¹⁹. While some damaging IP provisions, such as patent-term extensions and data exclusivity, were removed from the negotiating text after strong civil society pressure, excessive IP enforcement provisions and the inclusion of IP in the definition of 'investment' under the ISDS mechanism remain serious concerns²⁰. As reports about the resumption of negotiations have recently emerged, the removal of the TRIPS-plus enforcement clauses and the exclusion of IP from the scope of ISDS are imperative to safeguard the lifeline of affordable generics from India for millions of patients in developing countries.

The Commission is also proposing TRIPS-plus measures in other trade negotiations, such as those with Thailand. These demands are met with strong opposition from local civil society and the government of Thailand²¹.

EU CLAIMS "The EU supports the Doha Declaration on TRIPS and Public Health."

FACT The Commission's reference to the Doha Declaration is an empty gesture.

The WTO Ministerial Conference adopted the Doha Declaration on TRIPS and Public Health in 2001. The Doha Declaration affirms that WTO rules (TRIPS) on IP should not prevent countries from taking the necessary measures to safeguard public health²². Such measures are known as 'TRIPS flexibilities'.

All EU free trade agreements include a standard reference to confirm its adherence to the Doha Declaration in the preamble. Yet, such a reference is an empty gesture if, at the same time, the substantive provisions of the agreement include TRIPS-plus provisions that impact the price of medicines. In addition, the Commission uses other areas of its trade policy to pressure countries to refrain from making full and legitimate use of TRIPS flexibilities. This includes placing third countries on trade watch lists for fully legitimate exercise of TRIPS flexibilities.

TRIPS-plus measures, as they relate to pharmaceuticals, directly contradict the spirit and intent of the Doha Declaration on TRIPS and Public Health.

EU CLAIMS "The EU supports developing countries in implementing TRIPS and uses TRIPS flexibilities in appropriate cases, such as health emergencies."

FACT By introducing an inappropriate and narrow interpretation of TRIPS, the Commission does not respect the freedom of other countries to implement TRIPS and use its flexibilities to protect public health as they see fit.

The Doha Declaration is very clear when stating that nothing in TRIPS should prevent countries from taking measures to protect public health²³. This means that countries have the full freedom to implement TRIPS and make use of TRIPS flexibilities as they see fit for public health purposes. The qualification by the Commission that use of TRIPS flexibilities should be restricted to "appropriate cases, such as health emergencies" is simply an attempt to limit countries' freedom to use these flexibilities and directly contradicts WTO norms.

This statement and the following three examples of Commission practices show how the EU interferes with other countries that attempt to use TRIPS flexibilities to protect public health:

A The EU puts countries using TRIPS flexibilities on a 'priority country list'.

The Commission produces a 'priority country list'²⁴ to assess third countries' performance on IP protection and enforcement, which is based on the EU's interpretation of TRIPS. These country-specific reports outline the perceived deficiencies in these countries' IP frameworks, which the EU believes should be remedied. These lists put undue pressure on third countries to change their IP laws and practices. Closer examination of some countries' reports show that the Commission actually denounces IP measures that are perfectly legal under TRIPS and beneficial to public health²⁵. An example of such a measure is the use of compulsory licensing. A compulsory licence is a government-authorized licence to produce and market a cheaper generic version of a patented medicine often with the condition that the authorised generic company pays a small licence fee to the patent holder.

A compulsory licence, or the mere threat of issuing one, is an effective tool to ensure a substantial decrease in the price of a medicine. Many developing countries, including Thailand, Brazil and Ecuador, have used this instrument to lower medicines prices to meet public health needs²⁶. High-income countries, such as the United States, have also used compulsory licensing as a tool to negotiate a lower price for medicines²⁷.

Pointing to practices in Canada, Argentina, Brazil and India, the Commission has also put countries on its 'watch list' for using different and often stricter (but TRIPS-compliant) standards for granting pharmaceutical patents. These countries have adopted specific patent legislation aiming to prevent a widespread commercial practice known as 'evergreening' in which pharmaceutical companies obtain new patents for minor modifications of existing medicines that offer no additional therapeutic advances. Preventing such a practice by introducing stricter patentability criteria is perfectly legal under WTO law and very beneficial from a public health perspective because cheaper generics can enter the market faster. Moreover, it is desirable from a societal perspective to award real innovations and discourage over-investment in 'me-too' drug development.

B The EU pushes for TRIPS-plus measures in third country national consultation processes.

South Africa is currently implementing a much-needed patent law reform process and has published a new draft patent policy. The Commission has submitted its comments to the South African government and has argued in favour of introducing TRIPS-plus measures and against the use of TRIPS flexibilities as proposed in this draft policy²⁸.

Currently, one key challenge in South Africa is the lack of examination of patent applications. Instead, the current system allows pharmaceutical companies to obtain multiple patents for the same drug, even for subject matter that does not fall under the country's definition of what is patentable. This allows companies to extend the life of their patent monopolies, block competition from generic manufacturers, and charge inflated prices for medicines in the public and private sectors.

To remedy this, the draft policy from the South African Government notes that South Africa should set a higher standard for what is patentable. This means that patents should no longer be granted for simply combining existing medicines, or registering new uses for previously patented drugs. Additionally, the draft policy proposes the creation of a substantive patent examination system to better ensure that criteria for granting a patent are upheld.

The proposed South African draft policy could play a key role in ensuring that the five million HIV-positive people in South Africa can access the latest generation of anti-retroviral medicines. Yet, the EU argues in its submission that South Africa should consider TRIPS-plus measures, including patent term extensions, stronger IP enforcement and the introduction of data exclusivity. The South African government is under no legal obligation under TRIPS to implement any of these measures, which would increase medicine prices²⁹.

C The EU offers IP-related technical assistance to least-developed countries without sensitivity for the potential negative consequences.

The EU also uses technical assistance programmes as a way to export European IP standards, even to least-developed countries (LDCs), which are not obliged by WTO law (TRIPS) to implement these IP standards³⁰. This exception for LDCs exists specifically because excessive IP protection levels can create serious barriers to access to medicines and undermine technological development and emerging industries³¹. When the EU combines technology transfer with a package of IP-related technical assistance, it pushes countries to implement levels of IP protection that are wholly inappropriate for their level of socio-economic development.

For example, in Bangladesh, an LDC with an average income of little over US\$3 a day, the Commission implemented an IP programme worth €1.2 million³². Given its LDC status, Bangladesh is not obliged by the WTO to do so, and should therefore not spend scarce resources on implementing TRIPS IP provisions. It may be difficult for LDCs to refuse IP-related technical assistance, particularly if it is bundled with a large package of much-needed technology transfer. Unfortunately, the EU provides little transparency about the content of its IP programmes.

In 2010, the EU funded the drafting of Uganda's controversial IP Enforcement Counterfeit Goods Bill. This proposed law caused an outcry because it threatened access to life-saving generic medicines by defining counterfeiting so broadly that it criminalised the production and importation of generic medicines. The financing of this project was part of Uganda's implementation of the economic partnership agreement (EPA) between the EU and East African countries³³. Uganda, being an LDC, was (and still is) under no obligation to implement TRIPS, let alone implement TRIPS-plus IP enforcement standards as envisaged in the (now rejected) draft Counterfeit Goods Bill.

These examples show that there is a need for greater transparency in the EU's IP-related technical assistance programmes, as well as an urgent need to align EU trade policies with development objectives. It is important to clarify whether the EU IP support programmes also include training in the full use of all TRIPS flexibilities, including transition periods available to LDCs, compulsory licences, public health friendly patentability criteria, patent oppositions and limitations and exceptions to patents.

EU CLAIMS "The EU has adopted rules on tiered pricing.

FACT The anti-diversion mechanism established in the EU tiered pricing regulation has only been used by one company and has not significantly contributed to improving access to affordable medicines in LMICs.

The Commission refers to Council Regulation (EC) 953/2003: To Avoid Trade Diversion into the EU of Certain Key Medicines (EU Tiered Pricing Regulation)³⁴. This regulation is currently under review because it has only been used by one company since its inception in 2001. Importantly, this regulation has not contributed in any significant way to improving access to affordable medicines in LMICs³⁵.

Pharmaceutical companies increasingly use 'tiered pricing' strategies to show their commitment to access to medicines. This refers to the practice of selling drugs to different countries at different prices depending on their economic status. However, it is a misconception that tiered pricing is the most effective access to medicines strategy. It is first and foremost a commercial strategy that allows pharmaceutical companies to maximise their profits in all countries, because prices are determined according to the highest price a country, or a segment within a country, is prepared to pay. Moreover, for many medicines, including cancer medicines, pharmaceutical companies do not provide any access programmes³⁶.

While emerging upper-middle classes are now firmly on the pharmaceutical industry's radar as promising growth markets, tiered pricing strategies that target these discrete populations of high-income patients are particularly harmful when deployed in middle-income countries. Under tiered pricing regimes, these countries, home to 73% of the world's poor³⁷, are being charged prices that only a fraction of the population can afford, while the poorest and most vulnerable people are left behind.

When tiered pricing is applied to low-income countries, they also lose out. This is because tiered pricing does not reflect the true lowest potential price of drugs, nor provide the public health benefits of generic competition. Robust generic competition has continuously proven to be the most effective and sustainable way to improve affordability of medicines in developing countries³⁸. Only in limited situations where a lack of robust competition exists, or for small or neglected markets, can tiered pricing have a role to play in improving access to medicines.

The fact that the Commission, so far, has used the EU Tiered Pricing Regulation as an example of its efforts to promote access to medicines demonstrates that public health objectives and impact studies of EU trade policies are not guiding its current access to medicines policies.

EU CLAIMS "The EU is a major contributor to health-related aid."

FACT The EU is in dire need of a comprehensive, overarching access to medicines policy, which encompasses all relevant policy areas, such as public health, development, research and trade to ensure that its health-related aid is not undermined.

The Commission states that it is a major contributor to health-related aid. However, policy coherence for development is clearly lacking between EU health-related development goals and trade policies. The conflicting interests between supporting and protecting public health in partner countries and promoting the European pharmaceutical industry's interests in free trade agreements and European partnership agreements have largely proved to favour the latter. While health-related aid from the EU can provide substantial benefits to public health systems and capacity building around the world, high medicine prices can seriously undermine the benefits that such assistance may create.

The EU urgently needs a comprehensive, overarching access to medicines policy that encompasses all relevant policy areas, including public health, international development, research and trade. This will ensure that the economic interests of the EU do not undermine, or take primacy over, the protection of public health in developing countries and beyond.

Unprecedented: Commission considers cutting ‘non-complying’ countries off from EU-funded programmes.

It is worrying to see that the Commission interprets sound policy coherence as restricting or ending participation or funding in specific EU-funded programmes if a third country consistently “breaches” IP rights. Moreover, it is doubtful whether such a unilateral penalty system is supported under WTO rules³⁹.

In general, no country can, nor should, impose penalties on other countries based on a unilateral interpretation of TRIPS.

EU CLAIMS

“Indirect benefits that can exist on health and safety from eliminating IPR infringing goods should also not be underestimated.”

FACT

IP is inappropriate for, and irrelevant to, combatting the broader and more significant categories of substandard and falsified medicines.

Here, the Commission refers to claims that IP enforcement is an effective tool for removing falsified and substandard medicines from the market. This is, however, a misconception. IP enforcement does not address health and safety concerns of substandard and falsified medicines. It can, however, create unnecessary barriers to access to affordable generic medicines.

It is important to clarify that ‘falsified medicines’ refer to mislabelling of ingredients, while ‘substandard medicines’ are medicines that do not meet applicable safety, efficacy and quality standards. Neither of these two categories have anything to do with IP infringement. ‘Substandard medicines’ are genuine medicines that are produced by authorised manufacturers, but do not meet quality specifications. They can therefore be both originator and generic medicines and an IP enforcement framework has no relevance or use for combatting substandard medicines⁴⁰.

Crucially, the term ‘counterfeit’, which may involve commercial trademark disputes, should not be used in relation to medicines because it is an overly-broad term that conflates IP issues with quality assurance and regulatory problems. The Commission’s conflation of the various categories in the above statement wrongly asserts the relevance of IP enforcement when addressing the problem of ‘substandard’ and ‘falsified medicines’. Unfortunately, the Commission uses its trade relations with LMICs to push them to embrace the flawed argument that stricter IP enforcement is the best remedy to protect patients from poor-quality medicines.

Instead, the Commission should use more accurate and precise terms, such as ‘falsified’ or ‘substandard’, for medicines. It should also address the problems they separately poses through improved regulatory measures in exporting and importing countries.

The conflation of categories has also been instrumental for the introduction of new and stronger TRIPS-plus IP enforcement rights (e.g., in the in-transit area at the border) on medicines in the EU, which increases the risk of abuse and over-enforcement by rights holders and potentially deters generic competition. Plenty of evidence exists of IP rights holders using strong IP enforcement rights to deter such competition. This was acknowledged by the EU Directorate-General for Competition in its 2009 Pharmaceutical Sector Inquiry⁴¹.

EU customs officials have previously seized medicines in transit in the EU on the grounds of alleged patent (or in one case in Germany, trademark) infringement in the EU, even though both the sending country (particularly, India) and the receiving country did not have patents on the relevant product⁴². Such seizures of goods-in-transit represent an unacceptable expansion of the territorial enforcement of a patent (or trademark) that limits the free movement of generic medicines and generic competition. IP enforcement on goods in transit—even if limited to criminal trademark infringement (counterfeits)—bears the risk of impeding generic competition and does not address the real problem of falsified and substandard medicines.

The seizure of legitimate generic medicines through border enforcement measures is a typical example of misusing TRIPS rules in the name of combating counterfeit medicines⁴³. Legitimate generic medicines could therefore be at risk of seizure in the EU based merely on suspicions of IP infringement, particularly given that EU customs officials often act on the request of rights holders.

Many originator and generic medicines carry similar brand names derived from the international non-proprietary (INN) name of the medicine. In addition, generic medicines often have similar shapes and colours as the originator. Regardless of whether similarly named, colored or shaped generic versions of medicines are ultimately found to infringe a valid trademark in civil litigation proceedings, they need not, and indeed should not, be confused with counterfeit medicines.

HAI and MSF are therefore disappointed that the EU plans to introduce additional border measures with respect to trademarks. This will further increase the risk of confusing legitimate generic medicines with what the EU calls counterfeit medicines. These measures will increase the risk of wrongful seizures and can create unnecessary barriers to access to affordable medicines for patients in developing countries⁴⁴.



CONCLUSION & RECOMMENDATIONS

In the upcoming revision of its Trade and Investment Policy, the EU must ensure that its public health, development, research and trade policies are consistent with, and beneficial for, access to affordable medicines for citizens in the EU and low- and middle-income countries alike. To achieve this, the EU should:

- ▶ **Develop a comprehensive access to medicines policy** that ensures that its trade policy is consistent with its development, research and global health goals. In particular, the EU should:
 - ▶ **Not use free trade agreements with LMICs to introduce TRIPS-plus IP rules** that extend monopoly protection, nor introduce new IP enforcement rules or investment protection to the detriment of access to medicines.
 - ▶ **Support LDCs' request for an extension of the TRIPS transition period** until LDCs graduate from being LDCs. The EU should also support LDCs' request for a waiver of Article 70.8 and Article 70.9 of the TRIPS Agreement for the duration of the TRIPS transition period.
 - ▶ **Support generic competition to allow broad access to medicines in LMICs.** In particular, the EU should actively support governments that use available legal measures, including TRIPS safeguards and flexibilities, to protect and promote public health. The EU should immediately stop targeting countries, like India, that have implemented progressive TRIPS-compliant IP policies that promote access to medicines through its watch list of 'priority countries'.
 - ▶ **Refrain from implementing financial sanctions,** as envisaged in its new strategy on IP Enforcement in Third Countries, upon countries that make use of WTO-compliant rules.

- ▶ **Engage in meaningful technology transfer** that allows developing countries to build a sound technology base. It must not offer these programmes in tandem with IP-related technical assistance.
- ▶ **Provide full transparency of the content of its IP-related assistance** programmes for LMICs. It should also ensure that parallel IP assistance efforts do not undermine health-related development projects.
- ▶ **Avoid using the term 'counterfeit' when discussing concerns about the quality, safety and efficacy of medicines.** The EU should instead focus upon the categories of substandard and falsified medicines and ensure the right tools are used to combat concerns with these categories. In particular, the Commission should acknowledge that IP enforcement does not address concerns with substandard and falsified medicines, whether branded or generic. The EU should instead address such issues via improved and strengthened regulatory oversight of quality standards. The EU should expand its support and collaboration with the WHO pre-qualification program, which has been crucial to increasing the quality of low-priced medicines in LMICs.
- ▶ **Ensure transparency in the development of its trade and investment agenda.** If public interest and consumer organisations are not aware of what is negotiated, they cannot engage in public debate and scrutinise the EU trade and investment agenda. Without real transparency of negotiations, EU trade agreements are pieced together in an undemocratic and opaque process and lack real representation of public interests and consumer groups. HAI and MSF commend the Commission's commitment to greater transparency of EU positions, specific legal proposals, and negotiating texts in the TTIP negotiations. At a minimum, the same commitment to increased transparency should apply to all other trade negotiations undertaken by the Commission. However, more needs to be done to ensure real representation of public interests and consumer groups. The Commission should make negotiating texts available in such a way that elected parliamentarians, stakeholders and informed citizens can provide meaningful input.
- ▶ **Generate more data of better quality on the economic and social impact of IP protection and enforcement**—particularly, on the potential negative impact of high levels of IP enforcement on generic competition and public health.
- ▶ **Use the ongoing review process of the EU Tiered Pricing Regulation to repeal this Regulation** unless it can be amended in close collaboration with the DG Devco and DG Santé (Directorates-General for 'International Cooperation and Development' and 'Health and Food Safety') to codify full EU support for the use of all measures countries have at their disposal to ensure affordable access. This includes stimulating generic competition, compulsory licensing and other key TRIPS safeguards and flexibilities, voluntary licensing, transparent price negotiations, price disclosure and (only in limited and clearly defined circumstances) the use of tiered pricing.

ANNEX

Excerpt from Communication on: Trade, growth and intellectual property - Strategy for the protection and enforcement of intellectual property rights in third countries, European Commission, 2014.

2.2.7. The challenges of access to medicines

Access to affordable, safe and effective medicines is crucial to all countries, and the challenge is particularly large when it comes to LDCs and developing countries. Recognising this, the **EU is a major contributor to health-related aid** – e.g. the Global Fund to Fight AIDS, Tuberculosis and Malaria and other key organisations³⁷. It also initiated the European and Developing Countries Clinical Trials Partnership (EDCTP) to accelerate the clinical research development process for medicines against neglected diseases related to poverty.

The role of IP in access to medicines has been highly debated. As a recent WHO-WTO-WIPO study notes, the «lack of access to medical technologies is rarely due to a single isolated factor»³⁸. There are many factors affecting access (explained in more detail in the accompanying Commission Staff Working Document (SEC(2013)30)), but mostly unrelated to IPRs, such as lack of access to quality health care, poor infrastructure, lack of distribution and supply systems, and lack of quality control. Still, IPRs may affect the price of medicines.

The challenge is to come up with a broad response to this complex and multifaceted problem and to ensure affordable access to medicines without undermining the incentives needed for continued pharmaceutical research. It should be noted that generic medicines play an important role and should not be equated with counterfeit³⁹ medicines.

The EU addresses these IPR challenges, in line with a European Parliament resolution⁴⁰, through policies intended to reduce obstacles to trade in both innovative and generic medicines, while also promoting innovation and curbing trade in counterfeit and falsified medicines that can be dangerous for patients⁴¹. In particular, the EU:

- ensures that any multilateral and bilateral agreements reflect these objectives; 4
- supports the Doha Declaration on TRIPS and Public Health (implemented through Regulation 816/2006); 4
- has adopted rules on 'tiered pricing'^{42,43,44} and harmonised clinical trial exceptions⁴⁵. 7

The Commission is also looking into ways of improving its support for developing countries implementing the TRIPS Agreement – including its flexibilities in appropriate cases, such as health emergencies. 5

SEE COMMENTS ON PAGE :



37 Including GAVI, WHO, UNICEF.

38 Promoting Access to Medical Technologies and Innovation. Intersections between public health, intellectual property and trade, Trilateral study by WHO, WIPO and WTO, Geneva, 2012.

39 It is worth noting that certain concepts such as standard, spurious or falsified medicines do not entail any IPR aspects – see related WHO discussion at apps.who.int/gb/ssffc/pdf_files/A64_16-en.pdf

40 European Parliament Resolution of 12 July 2007, B6-0288/2007.

41 Counterfeit drugs kill, final brochure WHO and IMPACT, Updated May 2008, www.who.int/impact/FinalBrochureWHA2008a.pdf

42 Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines, OJ L135/5, 3.6.2003.

43 I.e. prices enabling exporters to deliver essential medicines to poor countries at prices only slightly above their own production costs.

44 The EU will initiate an evaluation of Regulation 953/2003 in 2014.

45 The EU introduced a 'Bolar-type exemption' in Directive 2004/27/EC.

ENDNOTES

1 Consolidated version of the Treaty on the Functioning of the European Union, article 208-212, OJ C 326, 26.10.2012,

2 Communication on Trade, growth and intellectual property - Strategy for the protection and enforcement of intellectual property rights in third countries, European Commission, 2014, http://trade.ec.europa.eu/doclib/docs/2014/july/tradoc_152643.pdf.

3 Evaluation of the IPR enforcement strategy in third countries, 2010, p.53 & 65, Analysis of Economic Decisions; http://trade.ec.europa.eu/doclib/docs/2010/november/tradoc_147053.pdf.

4 Ibid, p. 64.

5 Strategy for the enforcement of intellectual property rights in third countries (2005/C 129/03)

6 Intellectual property rights intensive industries: contribution to economic performance and employment in the European Union Industry-Level Analysis Report, A joint project between the European Patent Office and the Office for Harmonization in the Internal Market, September 2013.

7 Ibid, p. 18.

8 Evaluation of the IPR enforcement strategy in third countries, 2010, p.64, Analysis of Economic Decisions; http://trade.ec.europa.eu/doclib/docs/2010/november/tradoc_147053.pdf.

9 Seuba, Xavier, Joan Rovira, and Sophie Bloeman. 2010. Welfare Implications of Intellectual Property Enforcement Measures. PIIJP Research Paper no. 5. American University Washington College of Law, Washington, DC <http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1005&context=research>.

10 Trading Away Access to Medicines - Revisited, Joint paper by Health Action International Europe and Oxfam, 2014, p. 13-19, available at: <http://haieurope.org/wp-content/uploads/2014/09/Trading-Away-Access-to-Medicines-Revisited.pdf>.

11 World Health Organization, World Intellectual Property Organization and World Trade Organization, Promoting Access to Medical Technologies and Innovation Intersections between public health, intellectual property and trade, 2012, http://www.who.int/phi/promoting_access_medical_innovation/en/; and Oxfam International Briefing Paper No. 102: All costs, no benefits: How TRIPS - plus intellectual property rules in the US-Jordan FTA affect access to medicines, Oxfam International (2007) available at: http://www.oxfam.org.uk/resources/issues/health/downloads/bp102_trips.pdf; 'A Trade Agreement's Impact on Access to Drugs' (2010), Ellen R. Shaffer and Joseph E. Brenner, CPATH, www.healthaffairs.org/IFARMA; Impact of the EU Andean Trade Agreements on Access to Medicines in Peru, November 2009, HAI Europe. <http://haieurope.org/wp-content/uploads/2010/12/11-Nov-2009-Report-IFARMA-Impact-Study-on-EU-Andean-Trade-Agreement-in-Peru-EN.pdf>.

12 For a more in-depth analysis of ISDS and Access to Medicines please consult HAI Europe submission to the EU Consultation on ISDS in TTIP and its implications for health: http://trade.ec.europa.eu/doclib/docs/2015/may/tradoc_153458.pdf.

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15 Specific free trade agreements concluded by the EU that contain TRIPS-plus measures: EU-Colombia FTA, EU-Peru FTA, EU-CARIFORUM FTA, EU-Singapore FTA, EU-South Korea FTA, EU-Canada FTA, Ukraine and Moldova AA. Free trade agreements currently under negotiations where the EU has proposed TRIPS plus provisions, or where we know or expect the EU to propose TRIPS plus: EU-India FTA, EU-Thailand FTA, EU-Vietnam FTA, EU-MERCOSUR, EU-Myanmar BIT and TTIP.

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22 The Doha Ministerial Declaration on the TRIPS Agreement and Public Health', November 2001, WTO

23 Ibid, Paragraph 4: "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."

24 Commission Staff Working Document: Report on the protection and enforcement of intellectual property rights in third Countries, Brussels, 5.2.2013, SWD(2013) 30 final: http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150789.pdf.

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30 Under TRIPS and the Doha Declaration, least developed countries are not required to implement TRIPS. In June 2013, the TRIPS Council reached a decision to further extend the deadline of July 2013 for these countries to implement TRIPS.

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'Global Academics' Expert Letter on LDC Extension', April 29, <http://infojustice.org/archives/29438>.

32 Table with an overview of EU Support in the Field of IP provided by DG Trade: http://trade.ec.europa.eu/doclib/docs/2006/august/tradoc_129556.pdf.

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34 Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines; <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32003R0953>

35 See the Commission's assessment report, 2005: [http://trade.ec.europa.eu/antitrade/diversion_html/SEC\(2005\)0896.pdf](http://trade.ec.europa.eu/antitrade/diversion_html/SEC(2005)0896.pdf); See also Politico's media coverage: <http://www.politico.eu/article/big-pharma-shuns-drugs-plan-for-worlds-poorest/>.

36 <http://apps.who.int/medicinedocs/documents/s21758en/s21758en.pdf>.

37 Middle Income Countries Overview, The World Bank: <http://www.worldbank.org/en/country/mic/overview>.

38 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: see MSF (2013) 'Untangling the web of Antiretroviral Price Reductions', 16th edition, http://www.msf.org/sites/msf.org/files/msf_access_utw_16th_edition_2013.pdf;

39 The assessment of TRIPS compliance by Member States shall only be conducted by following the multilateral mechanisms and procedures set forth under TRIPS Council and WTO rules. Strengthening multilateral trading system and preventing unilateral actions has been one of the founding principles and objectives of WTO. For instance, the preamble of TRIPS has emphasized 'the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures'.

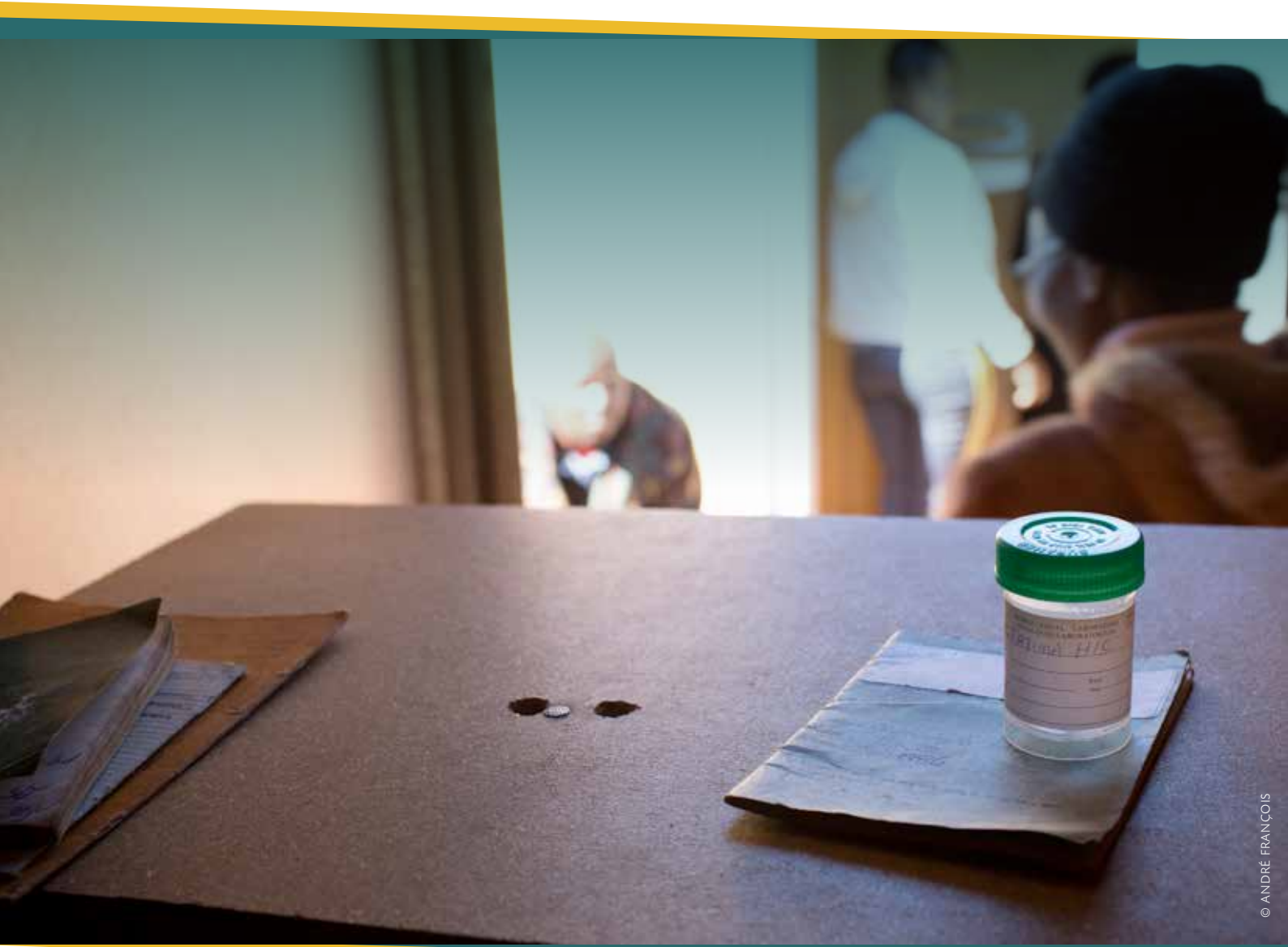
40 Ellen t' Hoen and Fernando Pascual, Counterfeit medicines and substandard medicines: Different problems requiring different solutions, Journal of Public Health Policy advance online publication 16 July 2015; doi: 10.1057/jphp.2015.22.

41 Strategies include excessive use of litigation, patent clusters, and practices like patent settlements (like pay for delay deals), as well as misleading claims by originators about inferior quality of generics in decisions on product authorization and pricing and reimbursement status and the launching of follow-on products in order to displace generic medicines based on the original product. See: Executive Summary Final Report DG Competition Sector Inquiry Summary, available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf, p. 9-17.

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43 While the TRIPS rules allow competent customs authorities to detain goods on the ground of IP infringement when a prima facie case is established, this is not reflected in the EU's regulations. Article 51 and 52 of TRIPS state that the right holder can apply for suspension of goods by providing adequate evidences and valid ground, under the law of the country of importation, to prove that there is a prima facie infringement of intellectual property. In another word, sufficient evidences to prove an obvious infringement under the rule of law of the importing country are required. On the contrary, EU regulations do not require the right-holder to provide such sufficient evidence, nor examining the case based on the law of the importing countries.

44 For a good overview of the issue, see: Oxfam Briefing Paper, 2 February 2011, Eye on the ball: Medicine regulation – not IP Enforcement – can best deliver quality medicines, p. 22-26, <https://www.oxfam.org/sites/www.oxfam.org/files/eye-on-the-ball-medicine-regulation-020211-en.pdf>.



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REVIEW OF THE EUROPEAN UNION'S TRADE & INVESTMENT POLICY, 2015



Health Action International (HAI) is an independent, global network committed to increasing affordable access to needed medicines and improving their rational use through research and advocacy.



In 1999, on the heels of Médecins Sans Frontières (MSF) being awarded the Nobel Peace Prize, MSF launched the Access Campaign. Its sole purpose has been to push for access to, and the development of, life-saving and life prolonging medicines, diagnostics and vaccines for patients in MSF programmes and beyond.

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