

Keys to Improving Access & Innovation of Needed Medicines

Medicines are crucial to improving our health and well-being. But in the European Union (EU), sky-rocketing costs for new patented medicines combined with shrinking healthcare budgets are jeopardising affordable access to them. At the same time, in Europe, despite strong intellectual property (IP) protection and continued strengthening of market monopolies, there has been a striking lack of medical innovation. Only a few new medicines that address priority public health needs and show true therapeutic added value have been brought to market in the last decade.

The situation requires immediate policy intervention at international, national and regional levels. New policies and mechanisms that contribute to affordable access to medicines and their rational use are needed. And good governance of medicines policy, which involves independent and democratic processes, is also required to make the system more transparent, accountable and effective.

Health Action International urges governments to implement the following recommendations to address current access to medicines shortfalls.

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Support needs-driven, open models of innovation that can bring more affordable medicines.

1

Critically examine the impact of the current over-protection and misuse of intellectual property (IP) and related rights for pharmaceutical products to ensure availability and affordability of medicines that meet priority health needs.

Today's patent system is out of balance. In the European Union (EU), on top of the 20-year patent protection period, additional market exclusivity, data exclusivity, and supplementary protection certificates (SPCs) delay price-lowering generic competition. Despite continued strengthening of market exclusivities for pharmaceutical companies in Europe, there has been a striking lack of truly valuable medicines being brought to market over the last decade. In a review of newly patented medicines brought to market between 2000 and 2013, the independent drug bulletin, *La Revue Prescrire*, found that that only 9 percent of the medicines offered an advantage compared to existing products on the market.¹ At the same time, companies are pulling out of research and development (R&D) for new antibiotics when society needs them most, and investment in neglected diseases remains poor.

The current biomedical innovation model, based on patent monopolies, relies on high prices of resulting medical technologies. This incentive model steers research efforts towards markets that guarantee high prices and speedy recovery of assumed investment. For example, despite the urgent need for new antibiotics, no new class of truly valuable antibiotics has been introduced on the market since the 1980s. Originator companies have gradually shifted their focus from needs-driven innovation towards market driven innovation, promotion, wide patenting, litigation against competitors and the accelerated development of 'me too' medicines of little therapeutic advantage. The practice of 'evergreening', which refers to the numerous ways in which pharmaceutical companies use the law to extend their patent monopoly protection, is an example of the industry's focus on extending protection and retrieving revenues from existing products. Another area of concern is orphan drugs, which benefit from supplementary protection and are often high priced.²

2

Make full use of the opportunity offered by Horizon 2020 and EU Member State biomedical R&D funding programmes to explore the 'delinkage' of R&D costs from the final price of medicines.

Consensus is growing among experts for the adoption of alternative models to finance R&D so critical health needs are prioritised and medicines are suitable and affordable. 'Delinking' the cost of R&D from the price of the medicine is essential to create incentives for needs-driven R&D, rational marketing and use of results. It also allows for structural affordable access to medicines. This is possible because the recoupment of R&D costs is no longer dependent on the sales revenue of the product. This replaces the traditional incentive expectations of high monopoly medicine prices through patents. Examples of incentive models that embrace the concept of delinkage include some of the Product Development Partnerships, such as the Drugs for Neglected Diseases initiative (DNDi). Another tool is offering mid-term or end-stage prizes.

3

Ensure that innovation and biomedical knowledge, derived in whole or in part from publicly-funded health R&D, results in medical products that are appropriate, affordable and accessible at prices that reflect the public contribution. This is particularly the case for Horizon 2020 (including the European and Developing Countries Clinical Trials Partnership and the Innovative Medicines Initiative).

To achieve this, the EU and Member States need to attach conditions to public funding of biomedical R&D that mandates non-exclusive or equitable licensing, open data and affordable access to resulting medicinal products.



Currently, European taxpayers pay multiple times for their medical tools (funding and infrastructure for early research, as well as clinical trials, various tax and other incentives, price monopolies with limited to no price regulation, and acceptance to pay high prices down the line). All in all, about 80 percent of all funds for basic research³ for medicines and about 30 to 40 percent of all R&D for global health is publicly funded.⁴

Crucially, and placing a double burden on tax-payers, EU and Member State public R&D funding programmes do not attach any real conditions concerning public access to all research results or proper reflection of the share of public funding received in the price of medicines developed down the line.

RESEARCH & DEVELOPMENT

4

Constructively engage in the World Health Organization's (WHO) Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) to address common critical problems in global biomedical R&D, such as the lack of coordination, the need to globally agree on priority setting, and to build norms that guide different R&D initiatives on affordable access to results and early data sharing.



Debates about alternative incentives for innovation in medicinal products have taken place at the WHO for over a decade. In 2012, the CEWG was established to develop concrete recommendations for financing and coordinate new incentives for R&D to meet global health needs. In particular, the CEWG strongly recommends that WHO Member States begin negotiations for a multilateral global R&D convention.⁵ This instrument will allow for international coordination on health R&D to be improved and a public fund for sustainable and equitable resource distribution to be established. It would also ensure that R&D results financed by this instrument are global 'public goods' (not constrained by IP rights), widely accessible and affordable.

ENDNOTES

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Clinical Review & Education Article

"Unintended Consequences of Expensive Cancer Therapeutics—The Pursuit of Marginal Indications and a Me-Too Mentality That Stifles Innovation and creativity" (2014) by Tito Fojo, Sham Mailankody and Andrew Lo. Link: <http://nfrank.info/site/ckfinder/userfiles/pdf/Unintended%20Consequences%20of%20Expensive%20Cancer%20Therapeutics.pdf>.

Website

"Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines", based on the book by public health advocate, Ellen 't Hoen. Link: www.accesstomedicines.org

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"Prizes for Innovation of New Medicines and Vaccines" (2009) by Tim Hubbart and James Love. Link: <http://lawecommons.luc.edu/cgi/viewcontent.cgi?article=1111&context=annals>

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AMR Control Article

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"Trading Away Access to Medicines—Revisited" (2014) by Health Action International and Oxfam International (pp. 8-12). Link: <http://haiweb.org/wp-content/uploads/2015/09/Trading-Away-Access-to-Medicines-Revisited.pdf>

Webpage

"Overview of Decisions at WHO Regarding the CEWG Process" by the World Health Organization. Link: www.who.int/phi/cewg/en/

Ensure that information that is in the public interest, such as medicines safety and efficacy data, is publicly disclosed, and increase transparency of research and development costs.

1

Ensure that the transparency provisions of the European Union's (EU) 'Clinical Trials Regulation' and the European Medicines Agency's 'Access to Documents' policies are implemented in ways that put people's health ahead of commercial interests.

The EU's Clinical Trials Regulation has become, in many ways, an international benchmark in the field of trial data transparency. The new rules mandate prospectively all trials in Europe to be registered prior to their start in a public database and the publication of summary results and clinical study reports within specific timelines. Notably, the Regulation considers that clinical trial data disclosure should be the rule, and confidentiality the exception. But for this principle to be upheld, the Regulation must be implemented in ways that maximise data transparency.¹ The definition of commercial confidentiality must be narrow and should never apply when there is an over-riding public interest in disclosure. In addition, any anonymisation techniques to safeguard the protection of personal data need to preserve the clinical utility of the reports. The same principles should apply when implementing the European Medicines Agency's access to documents policies (e.g., Policy 0043 on access to documents, Policy 0070 on the publication of clinical data and EudraVigilance access). We also call upon regulators in Europe to follow the World Health Organization's recommendations to ensure publication of unreported clinical trials conducted in the past.²

2

Do not classify information that is in the public interest as a trade secret.

The new EU Trade Secrets Directive provides a broad understanding of what constitutes a trade secret and enables companies to use legal remedies against anyone in society who, in the company's opinion, has unlawfully acquired trade secret information. This could restrict access to information in the public interest, such as crucial technical know-how to enable generic competition, or to medicine safety and efficacy data. Although the Directive states that it will not affect the application of public disclosure obligations by the EU and national institutions, the implications of this provision in real practice remain uncertain. Regulatory agencies could take a safe course of action—to avoid litigation—and consider information that is important from a public health perspective as commercially confidential. Trade secret protection and commercial confidentiality has long been a recurring argument by the pharmaceutical industry to justify restrictions on data disclosure.⁴ In fact, the trade secrets argument was used recently by the company sponsoring a clinical trial in France in which one person died and others were injured.⁵

Since the Directive sets minimum standards, Member States should refrain from strengthening trade secret protection, and instead adopt necessary steps to ensure that information that is in the public interest can be publicly disclosed. The EU should also refrain from including trade secret protection in the Transatlantic Trade and Investment Partnership (TTIP). Unforeseen negative consequences that arise from trade secret protection will then be nearly impossible for governments to repeal through democratic processes.

3

Address the ongoing problematic ‘information asymmetry’ between EU Member State governments and pharmaceutical companies. Without transparency of research and development (R&D) costs by originator companies and information on the actual prices paid for medicines across EU Member States, any discussion about sustainable medicine prices remains impossible. To achieve this:

A. Increase transparency of EU and Member State spending on biomedical R&D by declaring any support, including all research funding and infrastructure, as well as clinical trial set up and implementation, various tax benefits and other incentives.



About 80% of all funds for basic research for medicines and about 30 to 40 percent of all R&D for global health is publicly funded.⁶ There is a need to better track public funding of biomedical R&D to ensure a proper reflection of the share of public funding received in the price of medicines developed down the line.

B. Support price transparency by establishing a publicly accessible EU database where governments publish the actual price of medicines, including discounts and rebates.



The ‘real’ prices paid by governments are neither retrievable nor comparable (often due to secrecy clauses in contracts). Without knowing when rebates, discounts and pay-back mechanisms have been applied, it is impossible for national purchasers, whether public or third party, to be empowered in price negotiations and make well-informed decisions about procurement prices. A recent article in *The Lancet Oncology* highlighted the risk of overpaying for 16 selected cancer medicines caused by the lack of information on real prices paid (including discounts).⁷

C. Demand full transparency of actual R&D costs from the pharmaceutical industry by, for example, making disclosure of R&D costs a pre-condition for health technology assessment (HTA) and reimbursement.



The real costs of R&D remain unknown. Even the director of GlaxoSmithKline, Sir Andrew Witty, called the “\$1-billion estimate [of R&D costs] one of the greatest myths of the industry”.⁸ What we do know is that the pharmaceutical industry is the most profitable in the world.⁹ In 2010, pharmaceutical-related R&D spending by the private sector was less than 8 percent of global sales.¹⁰ And from 2005 to 2014, American pharmaceutical companies spent more money on buying back shares and paying out dividends than on R&D.¹¹

Estimates from the industry and independent analysts vary greatly. According to the pharmaceutical industry, it costs US\$1.2–2.6 billion to bring a new medicine to market¹²; however, the Drugs for Neglected Diseases initiative (DNDi), a non-profit organisation that develops new medicines, says it costs much less—€100–150 million (approximately US\$113–169 million), excluding in-kind contributions from partners¹³. If they acted together, EU Member States, which represent about 27 percent of the global pharmaceuticals market, could pressure industry to become more transparent.

ENDNOTES

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- ⁹ Anderson, R. (2014, November). Pharmaceutical Industry Gets High on Fat Profits. *BBC News*. Link: www.bbc.com/news/business-28212223.
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Research Report

"Access to High-priced Medicines in Hospital Settings in Europe: A Study in Four European Countries" (2016) by Kathi Hawlik and Aliénor Devalière, Health Action International. Link: <http://haiweb.org/wp-content/uploads/2016/04/Access-to-High-priced-Medicines-in-the-Hospital-Sector.pdf>

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BioSocieties Article

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Ensure that marketing authorisation procedures for medicines uphold patient safety and assess therapeutic advance.

1

Demand strong evidence of medicines' benefits and harms for marketing

The requirement of comprehensive and solid evidence about benefits and harms to inform marketing authorisation decisions should be the foundation of pharmaceutical regulation. However, there is an increasing tendency to lower regulatory standards by allowing smaller trials, surrogate endpoints and placebo comparisons.^{1 2 3} Low evidence requirements lead to poorly evaluated medicines entering the market with very weak benefit-harm balance and little or no therapeutic advance.⁴ Regulators should instead publish scientific guidelines that help align drug development decisions with public health needs, demand robust evidence on benefits and harms as a condition for medicines' approval and favour the demonstration of a medicine's added therapeutic value when compared to the best proven intervention. This is regulation for innovation.

2

Early approval of medicines through the envisaged adaptive pathways paradigm is not the adequate solution to improve access to safe and effective medicines. Expedited approval mechanisms should only apply in situations of true unmet medical need and in ways that uphold patient safety.

The European Union's regulatory framework for pharmaceuticals provides for some specific procedures for the early approval of new medicines (i.e., 'accelerated assessment', 'approval under exceptional circumstances' and 'conditional marketing authorisation'). Under expedited approval schemes, medicines are often evaluated on the basis of less comprehensive data, leading to greater uncertainty about a therapy's true effects. Because of inherent concerns about patient safety of early approval of medicines, such mechanisms should be confined to situations of true unmet medical need (e.g., a medical condition that has a significant effect on a person's quality of life or leads to serious morbidity or mortality and for which there is no adequate medical treatment available).⁵ All marketing authorisation decisions should be informed by clinically-relevant outcomes and uphold patient safety. A revealing study by researchers from the Mario Negri Institute shows, however, that the benefit-risk profile of medicines that have been subject to conditional approval is rarely reassuring.⁶ This signals a need to strengthen the marketing authorisation system. Emerging proposals for further flexibility of the system, such as the so-called 'adaptive pathways' paradigm^{7 8}, raise serious concerns from a health perspective⁹:

- the scope for early approval of medicines is broadened;
- the burden of proof is shifted significantly from the pre- to the post-marketing phase;
- emphasis is placed on observational studies at the expense of randomised controlled trials;
- the involvement of health technology assessment bodies in the provision of parallel scientific advice is enhanced to ensure that lower levels of evidence are accepted by all parties and there are early agreements to reimburse medicines with an uncertain benefit-harm balance.

3

Enforce rigorous and proactive pharmacovigilance requirements, including the application of dissuasive sanctions when companies do not comply with post-marketing requirements.



Sound pharmacovigilance frameworks are of paramount importance to identify medicine-induced harms and to protect patient safety. Data collection is even more relevant for medicines that are authorised early. In such cases, authorisation is usually granted under the requirement that companies conduct further studies with a defined timeframe; however, companies often do not honour pharmacovigilance commitments and regulators fail to perform a proper oversight.^{10 11 12 13} Regulatory agencies must be stringent about companies' conduct of post-marketing studies by applying sanctions in non-compliance situations. Regulators must also effectively respond to medicine safety issues as soon as these are detected. Further efforts are needed to increase awareness about the importance of spontaneous reporting among healthcare professionals and patients and optimal reporting mechanisms must be ensured.¹⁴

ENDNOTES

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Policy Brief

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Enable effective price control mechanisms and reimbursement policies that contribute to the affordability of medicines.

1

Facilitate the exchange of European Union (EU) Member States' best practices in health technology assessments (HTAs) through, for example, EUnetHTA, as well as co-operation in price negotiations and procurement to support equitable access to medicines.



HTA is an important tool for the sustainability of healthcare systems. Cooperation on HTA at the EU level should strive to find synergies that enhance the quality of assessments and preserve high standards.

Joint price negotiation and procurement schemes at regional and national levels can contribute to more affordable medicine prices. We highly recommend increased voluntary joint initiatives in this area, such as the pilot launched by the Belgian and Dutch governments.

2

Favour the reimbursement of medicines with added therapeutic value.



The pharmaceutical business model has long relied on the development of 'me-too' drugs that do not offer any real therapeutic advance, but are often marketed at a higher price.¹ In Spain, alone, pharmaceutical expenditure could have been cut by €70 million in 2014 had the reference medicine been prescribed in four therapeutic areas (i.e., depression, hypertension, high cholesterol and heartburn). This is due to the better relationship between cost and effectiveness found in treatments of reference.²

Reimbursement should be confined to medicines of added therapeutic value, and affordable prices are needed to enable universal access.

3

Only apply tiered pricing in very limited situations because it is not an effective tool to improve access to medicines.



Tiered pricing does not reflect the true lowest potential price of drugs nor provide the public health benefits of generic competition. It is first and foremost a commercial strategy that allows pharmaceutical companies to maximise their profits in all countries because prices are often determined according to the highest price a country or a segment of a country is prepared to pay. The arbitrariness and lack of transparency of industry-tiered pricing strategies is well illustrated by the fact that companies sell antiretrovirals in non-African countries at up to five times the amount of African countries with similar gross national incomes.³

Robust generic competition has continuously proven to be the most effective and sustainable way to improve affordability of medicines. Only in limited situations where a lack of robust competition exists, or for small or neglected markets, can tiered pricing play a role in improving access to medicines.

Generic competition can efficiently lower costs and reduce overall expenditure on medicines.

(In European countries, generics are, on average, three to four times cheaper than the respective off-patent originator brands. Prices tend to drop 25 percent a year after generic entry and 40 percent two years after entry.⁴)

4

Increase scrutiny of anti-competitive practices by pharmaceutical companies, such as blocking or delaying generic competition, and apply dissuasive sanctions.

Pharmaceutical companies try to prolong market exclusivity through evergreening, pay-for-delay deals, deregistering the originator medicine before generic entry and other activities. All strategies aim to exclude cheaper generics from the market. A pharmaceutical sector enquiry by the Directorate-General for Competition revealed the structural use of tactics by companies to delay generic competition, which added at least €3 billion more in additional costs to EU health systems from 2000 to 2007.⁵

In 2015, the Commission published its decisions on the Lundbeck, Fentanyl and Servier investigations with an analysis of agreements between originator and generic pharmaceutical companies that delayed the market entry of cheaper generic medicines. The Commission concluded that these practices have harmed patients, national health systems and taxpayers because prices for originator medicines could remain artificially high.⁶

5

Support legislation to facilitate Member States' uptake of generic medicines to decrease pharmaceutical expenditure.

Once generics are allowed on the market, Member States can enhance their uptake and use a thorough range of policies, including obligatory generic prescribing, international non-proprietary name (INN) prescribing, internal reference pricing, price capping, and tendering.⁷

6

Consider issuing compulsory licences to guarantee affordable access to high-priced life-saving medicines of assured safety and therapeutic added value.

A compulsory licence authorises the use of a rights holder's patent in order to produce and market a cheaper generic medicine without the right holder's authorisation. In exchange, the authorised generic company must pay a royalty to the patent holder.

Compulsory licensing for public health is specifically permitted by international law. Compulsory licensing of IP-protected technologies is a tool that is also used by EU competition agencies.⁸

ENDNOTES

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⁶ European Commission (June 15, 2016). Report on Competition Policy 2015, COM(2016) 393 final. 68-71. Link: <http://data.consilium.europa.eu/doc/document/ST-10587-2016-ADD-1/en/pdf>.

⁷ Carone, G, Schwierz C and Xavier A (2012) Cost-containment Policies in Public Pharmaceutical Spending in the EU, European Commission Economic Papers 461, (pp. 24-26, 33-37, 39-72). Link: http://ec.europa.eu/economy_finance/publications/economic_paper/2012/pdf/ec_p_461_en.pdf

⁸ See, for examples: J. Love (2014) "Recent European Union Compulsory Licenses", Research note, 1 March, http://keionline.org/sites/default/files/Annex_B_European_Union_Compulsory_Licenses_1Mar2014_8_5x11_0.pdf.

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"The Doha Declaration on the TRIPS Agreement and Public Health" by the World Health Organization. Link: http://www.who.int/medicines/areas/policy/doha_declaration/en/

Research Paper

"Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing" (2011) by Carlos M. Correa. Link: <http://apps.who.int/medicinedocs/documents/s21395en/s21395en.pdf>

Ensure the independence, transparency and accountability of decision-making processes and bodies.

1

Implement robust conflict of interest policies in regulatory decision-making bodies, such as drug regulatory agencies, health technology assessment bodies, price and reimbursement committees, and ethics committees.

Conflict of interest policies for board members, staff and consulted experts must be registered in a publicly available database. Sound restrictions regarding involvement with the activities of the organisation must also be applied to avoid situations in which private interests could obstruct/interfere with the public interest. Conflict of interest policies should be guided by a precautionary principle and be applied both at an individual and organisational level (e.g., patient and healthcare professional organisations funded by the pharmaceutical industry). Evidence shows that funding from the pharmaceutical industry to patient organisations can influence their policy positioning.¹ It is also important to ensure that drug regulatory agencies and health technology assessment bodies are financially independent from the pharmaceutical industry. The high reliance on industry fees by the European Medicines Agency (83 percent of its budget) raises concerns.^{2 3}

2

Make policy decision-making processes transparent and inclusive of civil society representatives.

The exercise of public health policy, either at the European Union, international, national, or local level, should allow for public scrutiny and enhance citizens' trust in the system. Public institutions should implement access to document policies that maximise data transparency. Decision-making processes should also facilitate the involvement and input of civil society (e.g., through public consultations, involvement in working groups, invitations to speak at relevant events). A mandatory registration of lobbying organisations and activities (e.g., list of meetings with public officials) should also be requested in a publicly accessible database.

ENDNOTES

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³ HAI, ISDB, MIEF (2015). Health Groups Call on European Medicines Agencies to Address Independence and Transparency Problems. Press release. Link: <http://haiweb.org/publication/health-groups-call-on-european-medicines-agencies-to-address-independence-and-transparency-problems/>.

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Safeguard the provision of independent information on medicines.

1

Ensure that information provided to healthcare professionals and consumers about health, diseases, diagnostics and therapeutics is evidence-based and not guided by promotional strategies.

Pharmaceutical promotion does not lead to net improvements in prescribing, but can jeopardise good clinical practice.^{1 2 3} In general, regulations on pharmaceutical promotion are not strong enough and rely too heavily on self-regulatory bodies, such as industry associations, for the control of promotional activities. The process of self-regulation is, in itself, a conflict of interest and is inherently flawed. There is often a gap between the standards reported in industry codes of conduct and the actual behaviour of the pharmaceutical industry.⁴ The regulation and monitoring of pharmaceutical promotion should be government-led. Government-led pre-vetting and monitoring should be intensified and effective enforcement ensured. Patients and healthcare professionals must be effectively protected from promotional materials for medicines. It is also critically important to provide independent education to medical students and healthcare professionals about the impact of pharmaceutical promotion on prescribing and dispensing practices and how to critically appraise pharmaceutical marketing.^{5 6}

2

Support the disclosure of payments from the pharmaceutical industry to healthcare providers.

Transparency of financial links between the pharmaceutical industry and healthcare providers helps expose pharmaceutical promotional practices⁷ and can discourage healthcare professionals from entering into conflicting situations. Transparency also empowers patients. Preferably, transparency initiatives that disclose financial links should be government-led rather than driven by the pharmaceutical industry. The scope of disclosure should cover benefits, agreements and fees for service. Breach of law by companies should be faced with dissuasive sanctions.

ENDNOTES

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- ² Wazana, A (2000). Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift? *JAMA*, 283(3):373-380. Link: <http://jama.jamanetwork.com/article.aspx?articleid=192314>.
- ³ World Health Organization & Health Action International (2009). Understanding and Responding to Pharmaceutical Promotion: A Practical Guide. Amsterdam, HAI. Link: <http://haiweb.org/wp-content/uploads/2015/05/Pharma-Promotion-Guide-English.pdf>.
- ⁴ Zetterqvist AV, Merlo J & Mulinari S (2015). Complaints, Complainants, and Rulings Regarding Drug Promotion in the United Kingdom and Sweden 2004–2012: A Quantitative and Qualitative Study of Pharmaceutical Industry Self-Regulation. *PLoS Med*, 12(2): e1001785. Link: <http://journals.plos.org/plosmedicine/article/asset?id=10.1371%2Fjournal.pmed.1001785.PDF>.
- ⁵ Mintzes B (2005). Educational Initiatives for Medical and Pharmacy Students about Drug Promotion. An International Cross-sectional Survey. World Health Organization and Health Action International, Geneva. Link: http://www.who.int/medicines/areas/rational_use/haipromosurvey.pdf.
- ⁶ Etain B, Guittet L, Weiss N, Gajdos V & Katsahian S (2014). Attitudes of Medical Students Towards Conflict of Interest: A National Survey in France. *PLoS ONE*, 9(3):e92858. Link: <http://journals.plos.org/plosone/article/asset?id=10.1371%2Fjournal.pone.0092858.PDF>.
- ⁷ Jones RG and Ornstein C (2016). Matching Industry Payments to Medicare Prescribing Patterns: An Analysis. *Pro Publica*. Link: <https://static.propublica.org/projects/d4d/20160317-matching-industry-payments.pdf?22>.

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“Conflict of Interest Policy Guide for Medical Schools and Academic Medical Centers” (2013) by Community Catalyst. Link: <http://www.communitycatalyst.org/initiatives-and-issues/initiatives/prescription-reform/conflict-of-interest-policy-guide>

Ensure that European Union (EU) trade and investment policy does not harm access to affordable medicines in the EU and low- and middle-income countries.

1

The EU should develop a comprehensive access to medicines policy that ensures that its trade policy is consistent with its development, research and public health goals.

The EU should stop exporting the current EU standard of pharmaceutical-related intellectual property (IP) protection through trade agreements at a time when EU governments are increasingly questioning the role of monopoly protections in medicines development and looking for alternative ways to encourage meaningful and affordable medical innovation.¹

To ensure policy coherence, 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, research and development and trade agendas should all be tailored to serve this goal. To achieve this, other directorates general, the European Parliament and EU Member States should oversee trade negotiations more closely to ensure that trade policies do not undermine health.

2

Ensure that the Transatlantic Trade and Investment Partnership (TTIP) does not harm people's health.

European Commission position papers and pharmaceutical industry filings with the Commission and the United States Trade Representative indicate threats to affordable medicines under consideration in TTIP negotiations. TTIP might add to existing monopoly protections for medicines, reinforce the current trend of industry to claim trade secret protection on medicines development information, limit the freedom of Member States to make decisions on pricing and reimbursement, and establish a global standard that is harmful for developing countries.

3

The EU should not use free trade agreements or other bilateral agreements with low- and middle-income countries to introduce Trade-Related Aspects of Intellectual Property Rights (TRIPS)-plus IP rules that extend monopoly protection.

In 1994, the World Trade Organization's (WTO) TRIPS Agreement 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 TRIPS-plus IP rules that exceed minimum WTO obligations. Prospective and retrospective impact studies confirm that these TRIPS-plus rules threaten access to affordable medicines and, over time, will be detrimental to public health in developing countries. Moreover, TRIPS-plus IP measures, as they relate to pharmaceuticals, directly contradict the spirit and intent of the Doha Declaration on TRIPS and Public Health.

4

The EU and EU Member States should actively support governments that use available legal measures, including TRIPS safeguards and flexibilities, to protect and promote public health.



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 health.¹ Such measures are known as 'TRIPS flexibilities'. Countries have the full freedom to implement TRIPS and make use of TRIPS flexibilities as they see fit for public health purposes. The EU states its support the Doha Declaration, but in practice, interferes with other countries that attempt to use TRIPS flexibilities to protect public health. (See further reading below.)

ENDNOTES

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