

Eye on the Ball

Medicine regulation – not IP enforcement – can best deliver quality medicines

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An AIDS patient holding drugs provided through the Thai government treatment programme.
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Poor-quality, or ‘substandard’, medicines threaten patients and public health in developing countries. Prioritization of medicines regulation by developing-country governments, with the technical and financial support of rich countries, is badly needed. Under the guise of helping to address dangerous and ineffective medicines, rich countries are pushing for new intellectual-property rules and reliance on police – rather than health regulatory – action. This approach will not ensure that medicines consistently meet quality standards. Worse, new intellectual property rules can undermine access to affordable generic medicines and damage public health. Developing countries must improve medicines regulation – not expand intellectual-property enforcement – in order to ensure medicine quality.

Summary

Access to medicines at affordable prices is critical to the enjoyment of the human right to health. Lower prices require the implementation of pro-access policies that include the promotion of generic competition. However, medicines cannot be selected on the basis of price alone. To ensure that only safe, effective, and quality products are on the market, effective regulation is necessary.

There is a significant difference between rich and poor countries in their ability to regulate the quality of medicines. In developed countries, national drug-regulatory authorities (DRAs) authorize medicines for use on the basis of their demonstrated safety, efficacy, and quality. Following authorization, or 'registration', health authorities monitor the market in order to detect and remove any poor-quality, falsified, or unregistered medicines. Rich countries expend significant resources on the protection of patients.

In contrast, for many reasons, a large number of developing countries are not able to regulate medicines effectively. This is principally due to a lack of money, equipment, and trained personnel. The poorest countries are unable even to maintain a registry of medicines, and therefore cannot effectively monitor which products are on the market. The World Health Organization (WHO) estimates that approximately 30 per cent of countries fall into this category.

In the absence of effective medicines regulation, poor-quality, or 'substandard', medicines, together with falsified, or fake and falsely labelled, medicines, may be widely traded and consumed. Although the prevalence of substandard and falsified medicines in developing-country markets is unknown, due to a lack of complete and reliable data, anecdotal evidence suggests that substandard medicines are widely available in some markets. The consumption of poor-quality or falsified medicines has devastating consequences for patients and for public health.

Substandard medicines do not meet the scientific specifications for the product as laid down in the WHO standards. They may contain the wrong type or concentration of active ingredient, or they may have deteriorated during distribution in the supply chain and thus become ineffective or dangerous. Falsified medicines are intentionally misrepresented to consumers. They may be fake in terms of composition or they may be falsely labelled, meaning that the information provided about the product is inaccurate.

In the interests of individual patient safety and public health in general, the capacity of developing-country DRAs to regulate medicines should be strengthened. A commitment to providing reliable and affordable medicines, together with the provision of universal health services and medicines, should be embedded in national policies and strategies to improve health-care infrastructure. The capacity of DRAs to properly enforce medicines regulations must be assured.

While many rich countries invest in this approach, a number of them are also pressuring developing countries to embrace the flawed argument that stricter enforcement of intellectual property (IP) is the best remedy to protect patients from poor-quality medicines. This argument is based on the fact that one class of medicines that should be removed from the market ('counterfeits') is the result of a type of IP infringement: criminal trademark infringement. Yet evidence suggests that the vast majority of substandard and falsified medicines are unrelated to criminal trademark infringement. Stringent IP enforcement measures only target counterfeit medicines, and cannot be relied upon to ensure that the much broader categories of substandard and falsified medicines are removed from the market.

Rich countries and some members of the multinational pharmaceutical industry propose the enactment of additional IP enforcement rules to fight broadly defined 'counterfeit' medicines. These rules have been and will be introduced in developing countries through numerous channels, including the recently completed Anti-Counterfeiting Trade Agreement (ACTA), bilateral and regional trade agreements, and technical assistance. The proposed new rules would be implemented on the basis of expansive definitions of 'counterfeit' which include medicines that do not infringe any IP, including substandard medicines and also legitimate, quality generic medicines. In some jurisdictions, the term 'counterfeit' has been redefined such that governments are obligated to use both existing and proposed IP and law enforcement measures to restrict access to lawfully-available generics together with true counterfeit products.

The new IP enforcement rules threaten public health and access to medicines. They create new barriers to the production of and trade in quality generic medicines, which are a lifeline for millions of patients in poor countries. The seizures of at least 19 shipments of generic medicines in transit through the EU, intended for patients in developing countries, provide a stark example of the consequences of these new IP enforcement measures.

Developing-country governments are under pressure to emphasize IP enforcement in order to ensure that medicines are safe and of quality, rather than public-health measures that are most appropriate to this objective. A WHO-led initiative, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), is contributing to the confusion surrounding the definition of counterfeit medicines and what should be done about them. IMPACT proposes an expansive definition of counterfeit medicines that confuses counterfeits and generic medicines, and overemphasizes police action to ensure the safety and efficacy of medicines. At the same time, the multinational pharmaceutical industry has exerted pressure on individual countries, such as Kenya and Thailand, to change their national laws and law enforcement priorities in ways that endanger access to generic medicines.

Instead of expanding IP enforcement, developing countries should remain focused on public-health measures to ensure that all medicines within their borders meet acceptable standards of quality. In addition to the long-term goal of building competent national DRAs that can

effectively develop and enforce medicines regulations, governments should consider (depending on national circumstances): regional information sharing, harmonizing aspects of regulation and registration, and continuing a reliance on WHO prequalification, as well as co-operation with more advanced country regulators. The WHO Good Governance for Medicines (GGM) anti-corruption task force has a part to play, and the Medicines Transparency Alliance, a new multi-stakeholder initiative, shows promise.

Such efforts bear no relationship to IP and, in fact, efforts to improve public health can be undermined by inappropriate IP enforcement policies that reduce generic competition and therefore drive up the price of medicines. High medicine prices are often a key factor that pushes low-income households to buy medicines from unregulated outlets, where they may be cheaper but of inadequate quality or falsified.

Many developing-country officials have fiercely resisted pressure to accept the new IP enforcement measures. They must be supported by civil society in continuing to do so. In addition, the following actions would do much to ensure that people in low-income countries have access to quality medicines.

Developed-country governments should:

- Expand funding and support for national and regional initiatives that increase the ability of DRAs in developing countries to protect their populations from harmful products. This includes building rigorous quality-assurance and pharmacovigilance functions, and expanding funding and support for WHO normative and technical work, including the WHO Prequalification Program.
- Ensure the consistent application of quality control for all medicines procured with the use of donor funds, and the regular and transparent publication of quality-testing results.
- Stop pursuing TRIPS-plus enforcement measures (intellectual property rules that exceed minimum obligations under global trade rules) through internal regulations, multilateral trade initiatives, bilateral trade agreements, or through technical assistance.

Developing-country governments should:

- Prioritize the expansion of public health-care infrastructure and invest in DRA capacity together with the provision of free essential medicines. Some functions of national DRAs should be co-ordinated among groups of countries where there is a rationale and the will to do so.
- Use new public and private investment to tighten the regulation of retail pharmaceutical outlets and to stop the sale of falsified and substandard medicines through informal and unqualified vendors.

- Promote generic competition in national medicines policies, including implementation of TRIPS flexibilities in national laws.
- Reject initiatives modelled on ACTA, and any other TRIPS-plus enforcement initiatives.

The World Health Organization should:

- Prioritize the WHO's comprehensive programme of work which underpins access to affordable, quality medicines for its Member States, including expansion of capacity and adequate funding to provide technical assistance to countries; support for the achievement of stronger national DRAs; and investment in and expansion of the WHO prequalification programme.
- WHO should disband IMPACT. WHO should also acknowledge that IMPACT has created unnecessary confusion, particularly through the misuse of the term 'counterfeit' to refer to substandard and falsified medicines that are unrelated to criminal trademark infringement, and through use of an IP framework to evaluate the public-health problem of unsafe medicines.
- Support countries in implementing TRIPS safeguards and flexibilities, and reject TRIPS-plus IP measures that could undermine access to medicines.

Pharmaceutical companies should:

- Adhere consistently to WHO quality standards. Companies must not produce substandard medicines for export to low-income countries, and they must fulfil their responsibility to declare to purchasers the full provenance of products openly and transparently.
- Recognize the damage inflicted on public health as a result of the confusion of quality with intellectual-property issues in initiatives such as IMPACT, and correct this fundamental error in their public statements and documents.

Global access to safe, effective, and quality medicines is grossly unequal. People in poor countries lack access to medicines for many reasons, which include high prices and inadequate health-care infrastructures. Generic competition has significantly reduced the cost of treatment for many illnesses and has substantially improved access. However, there is still much work to be done.

Even when medicines are available and affordable, they may be unsafe, ineffective, or falsified, or all of these things in various combinations. Consumption of such products can cause prolonged illness and death, and can undermine public health by inducing drug resistance and reducing patient confidence in medical services.

An estimated 90 per cent of patients in developing countries buy their medicines out of pocket,¹ purchasing them where they are most affordable. Often this means buying medicines from unregulated shops, where products may be of poor-quality or falsified. In some countries, in the absence of effective regulation, buying from regulated pharmacies does not offer an assurance of quality or safety. In contrast, rich countries maintain strict oversight of the trade in medicines, so that only safe, effective, and quality products are available through licensed outlets.²

Building effective regulation of medicines in developing countries is a major challenge, because resources and technical expertise are scarce, and many pressing health needs compete for priority. The WHO estimates that 30 per cent of countries have inadequate medicines regulation or none at all.³

Rich countries could play a critical role in supporting low-income countries with appropriate financial and technical resources to build pharmaceutical services that would include domestic and (as appropriate) regional regulatory capacity. Yet some rich countries are diverting attention from such actions and are using the real problem of poor-quality medicines to justify measures that favour their own economic interests.

These countries advocate stronger enforcement of intellectual property (IP) rules as a means to protect consumers in developing countries, even though they rely primarily on strict standards of quality assurance and pharmacovigilance⁴ to ensure the quality of medicines in their own jurisdictions. The proposed IP enforcement rules exceed countries' obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and create barriers to affordable, generic medicines.

In addition, policymakers in the US and the EU, alongside members of the multinational pharmaceutical industry, have focused mostly on tackling 'counterfeits' when fashioning international approaches to identify and eliminate poor-quality medicines. 'Counterfeit' products

are defined under global trade rules as products that result from one type of IP infringement: criminal trademark infringement. World Trade Organization (WTO) rules require that countries use IP enforcement to remove such products from their markets. Proponents of stricter IP enforcement have sought to expand the definition of 'counterfeit' to include products that do not infringe any IP, including poor-quality medicines, falsified medicines, and even legitimate generic medicines.

IP is an ineffective framework for addressing most problems of medicine quality, including many cases of criminal falsification. Stringent IP enforcement is a blunt instrument that cannot replace effective quality-assurance standards and pharmacovigilance by a drug regulatory authority (DRA).

Moreover, TRIPS-plus IP enforcement measures are counterproductive to the goal of improving health in developing countries. By creating barriers to the production of and trade in generic medicines, they will reduce or eliminate competition from lower-cost, quality medicines. As a result, drug prices will remain out of reach for millions of people. In addition, if generics are driven from the market, demand for cheaper, poor-quality and fake medicines will likely increase.

The negative consequences of TRIPS-plus IP enforcement rules far outweigh any contribution that they could make to improve the safety of the medicine supply chain. Developing countries should continue to resist pressure to institute these rules, and should remain focused on public health measures to ensure medicines are safe, effective, and of quality.

2

Medicines remain out of reach for billions of poor people

Millions of people suffer or die needlessly each year because they cannot obtain life-saving medicines.

According to the WHO, an estimated two billion people lack regular access to medicines, a fact which constitutes one of the most serious global public-health problems.⁵ A combination of factors is responsible, including high prices, poverty, lack of public health-care infrastructure, and inadequate government resources in developing countries. In 2009, total pharmaceutical per capita spending ranged from \$434.70 in rich countries to just \$7.70 in poor countries.⁶

90 per cent of people in poor countries are not covered by public or private insurance schemes and must therefore pay for their medicines out of pocket. In poor countries, medicines can account for as much as 80 per cent of a family's spending on health.⁷ In these circumstances an illness in the family can bring economic devastation.

Policies that promote affordable prices mean that more people can be treated using available resources, and thus a greater number of lives will be prolonged and saved. Because quality generic products often cost a fraction of the price of their brand-name equivalents, promoting generic competition is crucial to improving public health.

Generic medicines are therapeutically equivalent to 'originator' products. Generics manufacturers have lower levels of R&D investment to recuperate, although their production costs – which include payment for expensive active pharmaceutical ingredients (APIs) – may be high. Because they face fierce competition from other generics companies in developing countries, their prices can be close to the marginal cost of production. The major generics companies have become sophisticated producers of new formulations of medicines and can produce medicines on a large scale, which enables them to charge low prices.

Generic competition has been demonstrated to reduce the price of medicines in a sustainable way. The entry of a second generic competitor reduces prices to around 50 per cent of the branded product.⁸ As additional generics manufacturers enter the market, the price continues to fall and can reach 20 per cent, or less, of the price of the originator product. Robust competition among multiple generics producers resulted in a steep decline in the price of first-line HIV treatment between 2000 and 2010: from \$15,000 to \$67 per patient per year (see Figure 1).⁹

Figure 1. Price reductions in anti-retroviral medicines due to generic competition (2000–2010)

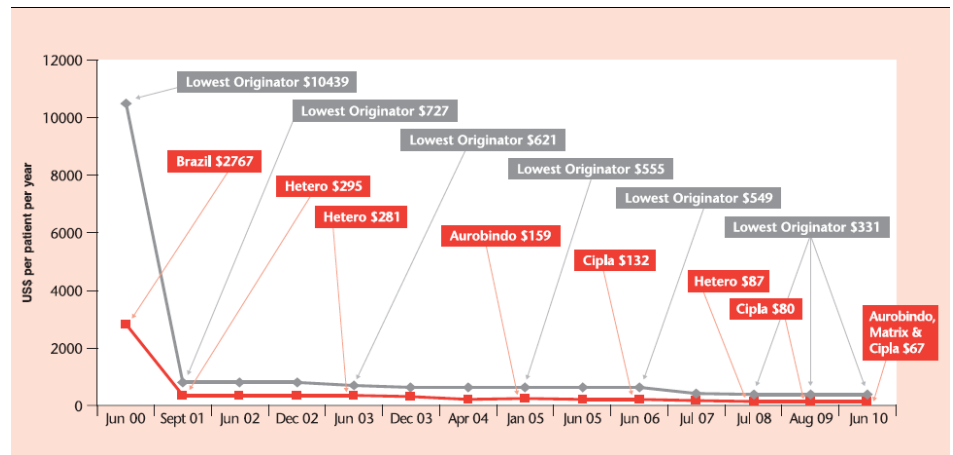


Figure courtesy of Médecins Sans Frontières - Untangling the Web (<http://utw.msfaccess.org/>)

Millions of people living with HIV and AIDS in developing countries have obtained treatment because structured financing and a functioning market have made low prices possible. Expanded access went hand in hand with the development of user-friendly fixed-dose combinations by generics manufacturers. However, two in three adults in need of immediate treatment – more than 14 million people – still lack access to anti-retroviral (ARV) medicines.¹⁰ And millions of patients still lack access to medicines for a range of other infectious and non-communicable diseases.

Intellectual-property rules and affordable medicines

In 1994, the TRIPS Agreement emerged as part of a package of new WTO trade rules. TRIPS set out minimum standards for IP protection that all WTO Member States must enact in their national legislations. Under TRIPS, developing countries agreed to apply patent protection to all products, including medicines, for twenty years. This was the single largest expansion of IP in history.

The new TRIPS standards constituted a major concession by developing countries – and a future threat to development and public health. In particular, the extended patent protection delays generic competition, thereby enabling multinational drug companies to continue to charge high prices. These high prices may be affordable to economic elites, but they exclude access for poor people and governments of low- and middle-income countries.

In response to this threat, developing countries insisted on the inclusion of safeguards and flexibilities in TRIPS that would enable them to reduce medicine prices when necessary to protect public health. Subsequent reductions of medicine prices were achieved in large part due to the existence and use of TRIPS safeguards and flexibilities. The Doha Declaration on TRIPS and Public Health, agreed by all WTO Member States in 2001, reaffirmed the right of countries to use TRIPS safeguards and flexibilities, and confirmed the primacy of public health over the enforcement of IP rules for medicines.¹¹

In the face of pressure by developed countries and multinational pharmaceutical companies, developing countries have used TRIPS safeguards to obtain access to quality medicines at prices that their populations can afford. Thailand has used compulsory licensing to reduce the prices of key patented medicines to treat HIV and AIDS, cancer, and heart disease.¹² India has used the flexibility in TRIPS to promote public health by enacting strict patentability criteria in its national laws. On the basis of such criteria, it has rejected frivolous patents that would have delayed the market entry of generic medicines.

For over a decade, rich countries have pressured developing countries to expand and intensify their enforcement of IP and, recently, they have justified these efforts based on the need to protect patients against poor-quality or falsified medicines. However, IP enforcement is not the best way to address the problem of unsafe medicines. This approach can only catch, at best, a limited subset of dangerous or ineffective products. Most problems of quality are unrelated to IP infringement and many falsified medicines do not infringe trademarks.

Developing countries should focus on investments in regulatory capacity and on strategies to improve access to health care, including medicines. Such efforts bear no relationship to IP and, in fact, efforts to improve public health can be undermined by inappropriate IP policies that drive up the price of medicines. High medicine prices are often a key factor that pushes low-income households to buy medicines from unregulated outlets,¹³ where they may be cheaper but of inadequate quality or falsified.¹⁴

3

Twin priorities: price and quality

Delivering generic or branded medicines for public health requires that products are of quality, safe, effective, and affordable. Policies that deliver affordability and access can help to reduce demand for medicines from unreliable sources, which may be unsafe or ineffective. In addition, affordable prices reduce the financial incentive for criminal elements to produce and trade falsified medicines.

Governments must ensure that medicines are registered and regulated by a competent DRA, as products purchased in unregulated outlets are more likely to be poor-quality or falsified.

Box 1. Medicines registration

Every country needs an effective DRA which ensures, among other things, that only medicines that are demonstrated by the manufacturer to be safe and effective are for sale. Registration of medicines, also known as marketing authorization, coupled with enforcement measures to ensure that only registered medicines are traded, are fundamental to medicines regulation.

A functioning DRA 'registers' a medicine following evaluation of scientific data submitted by the manufacturer, demonstrating the safety and efficacy of the product, together with confirmation of the manufacturer's compliance with Good Manufacturing Practice (GMP). GMP is a system of quality assurance which applies to the entire manufacturing process. It is complemented by standards for distribution, dispensing, and the provision of information for patients, known as Good Distribution Practice (GDP) and Good Pharmaceutical Practice (GPP).

Registration is valid only in connection with a specific manufacturer and a particular product, whether this is made by the originator or by a generic company. Without marketing authorization, a product cannot be lawfully sold in that country.

Once an originator product has been approved, a generic version may subsequently be registered on the basis of an abbreviated process in which the generic manufacturer demonstrates 'bioequivalence'. The generic manufacturer need not submit the full range of test data demonstrating that the product is safe and effective; this information has already been provided by the originator manufacturer.

The generic manufacturer must prove that its product has equivalent therapeutic effect, is safe and effective, and interacts with the body in the same way as the originator product – in other words, that it is ‘bioequivalent’. The generic manufacturer must also demonstrate compliance with GMP. Once registered, the generic product may enter the market, provided that there are no IP barriers.

Harmonization of certain aspects of registration, among a group of countries within a region, could deliver efficiencies. But – although this is the objective of a number of regional co-ordination initiatives in Africa and elsewhere – the theory seems to be more straightforward than the practice. Other aspects of regulation and enforcement require effective capacity at the national level.

Governments have vastly different capacities to monitor the importation, production, distribution, sale, and use of medicines, and the safety and quality of medicines can differ significantly depending on the country. The poorest countries lack the resources to maintain even a registry of medicines, which is the cornerstone of medicines regulation. In markets where there is effectively no list of products that may be lawfully sold, it is impossible to ensure that only safe products of appropriate quality are available.

Weak regulatory capacity is associated with a higher prevalence of substandard medicines. Even where regulations exist on paper, the inability of regulators to enforce the regulations properly may result in the trade in and consumption of poor-quality (substandard) and falsified medicines. These two categories are defined and exemplified in Table 1.

Table 1: Medicines to keep off the market

Type	Definition	Example
<i>Substandard</i>	Does not meet scientific specifications for the product. Includes products that have become contaminated.	Drug with poor solubility, thus less readily absorbed by the body, due to failure to follow GMP.
<i>Falsified</i>	Fake: does not contain the correct type or concentration of active and/or other ingredients. Falsely labelled: true properties of the product do not correspond to the information provided.	Example of a fake medicine: product is presented as an antibiotic but does not contain any antibiotic. Examples of a falsely labelled medicine: package says produced in EU, but the product was actually made in Kenya; or, the package misrepresents the manufacturer.

Substandard medicines are products that do not meet the relevant scientific specifications, in terms of ingredients and composition. The WHO defines such products, in part, as ‘pharmaceutical products that do not meet their quality standards and specifications’.¹⁵ This paper considers products that do not meet WHO specifications to be substandard, even if they comply with local standards.

Several types of quality problems have been confirmed in medicines distributed in poor countries: the wrong type or concentration of active ingredients; the wrong type or concentration of inactive ingredients; poor stability; poor dissolution; poor-quality packaging and/or labelling; and contamination. These deficiencies have been documented in relation to medicines produced and sold in a number of developing countries.¹⁶

Poor quality can result from a variety of problems, such as the use by a manufacturer of a poor-quality active pharmaceutical ingredient (API); the use of poor-quality or wrong inactive ingredients; contamination or poor handling of medicines during production or distribution; failure to sell medicines prior to expiration; and the failure by a manufacturer to follow GMP.

Failure to fully comply with GMP may be unintentional, due to human error, or due to negligence. In some cases, it may be deliberate. A manufacturer may cut corners in order to save costs, or may outsource to manufacturers that do so. This may be done in order to meet the price or other specifications of a tender, or simply to increase profits. Certain manufacturers that have been deemed ‘GMP-compliant’ in the country where they operate maintain separate production lines, producing products of lower quality for export to countries with low standards and weak regulatory capacity.¹⁷

Falsified medicines are medicines for which the identity, source, or history of the product is misrepresented.¹⁸ Such products may be falsified, or fake, in terms of composition and ingredients, or they may be falsely labelled.

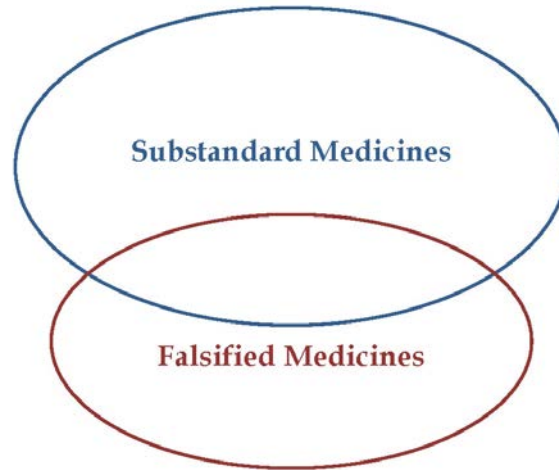
Fake products lack sufficient quantities of the correct ingredients, or contain the wrong ingredients. They may contain dangerous ingredients, or they may be safe to consume but ineffective. They are sold with the intention to defraud.

Falsified labelling¹⁹ involves incorrect product information, labelling that mimics the product information of a different producer, and labelling that does not reflect the contents of the product.²⁰

Since patients buy products on the basis of trust, misleading labels and goods undermine their rights as consumers, and damage the reputations of legitimate manufacturers. Falsification must be properly policed and all falsified products should be kept off the market. In many jurisdictions, there are long-standing criminal sanctions that punish the deliberate production and trade in falsified medicines.

It is important to note that not all substandard medicines are the result of falsification (see Figure 2).

Figure 2. Some substandard medicines are also falsified, and vice-versa



Although there is abundant anecdotal evidence that both substandard and falsified medicines are widely available in developing countries, the relative scale of each category has not been reliably measured. It is generally thought that substandard products are a more serious problem than falsified products in poorer countries, in part because there are fewer purchasers with enough money to make trade in falsified medicines profitable.²¹

The few studies that have attempted to quantify the problem of poor-quality medicines have estimated prevalence levels as high as 44 per cent.²² However, there are numerous concerns about the reliability of such studies, partly because many have conflated substandard medicines with falsified medicines, or confused substandard medicines with medicines that infringe IP.²³

Better data regarding the prevalence of medicines that are substandard, falsified, or both, in specific countries and for particular products, would help to support rational policymaking and the development of effective strategies to fight such products.

Regulation to ensure safety, efficacy, and quality of medicines

Effective medicines regulation

An effective DRA is a core component of a functioning health-care system. The overall objective of a DRA is to ensure that only safe, effective, and quality medicines are imported, manufactured, traded, and consumed. To achieve this, appropriate regulations must be in place and must also be properly enforced.

The WHO defines a DRA as a network that administers the spectrum of drug-regulatory activities, including at a minimum the following functions:²⁴

- Marketing authorization (registration) for new products and management of variations of marketing authorization;
- Quality-control laboratory testing;
- Monitoring of adverse reactions to medicines;
- Provision of medicines information and promotion of rational use;²⁵
- Good Manufacturing Practice (GMP) inspections and licensing of pharmaceutical establishments, including manufacturers, wholesalers, and distribution channels;
- Enforcement operations, including risk-based inspections; and
- Monitoring the utilization of medicines.

There is no one path to effective medicines regulation, and policies must be adapted to reflect the national context and sometimes also the regional context. Nonetheless, countries should aim to achieve WHO standards in relation to the above functions.

Box 2. Regulation by a 'stringent regulatory authority': the FDA

Together with the European Medicines Agency (EMA) and a number of other 'advanced' DRAs, the US Food and Drug Administration (FDA) is considered to be a 'stringent regulatory authority' that is effective in carrying out the tasks listed above.²⁶ FDA drug regulation works, first, by preventing medicines that have not been demonstrated to be safe and effective from entering commerce; and, second, by identifying and removing any medicines that are not safe, effective, and

of the required quality, together with falsified products, from the market. The FDA is tasked with evaluating and monitoring medicines in line with the health needs and priorities of the US, which differ from those in other countries.

The FDA system combines close scrutiny of applications for registration, including inspections of manufacturing sites in the US and abroad, with several post-marketing surveillance systems and appropriate sanctions.²⁷ The reporting of adverse drug events is mandatory for manufacturers and voluntary for public-health professionals and consumers. All pharmaceutical establishments are licensed and monitored. This type of system is very expensive to operate; in 2009, the FDA spent more than \$1 billion on regulating medicines.²⁸

Even this well-resourced system faces challenges in ensuring the safety of all products on the market. With regard to falsified medicines, there are reportedly increased efforts to introduce falsified medicines into legitimate channels of commerce in the US and other developed countries. By focusing on investigating and dismantling illicit diversion networks, which introduce falsified products into regulated distribution networks, the FDA claims that it has been able to prevent 'most' of these products from reaching consumers.²⁹

With regard to the quality of medicines, trade in substandard medicines is an on-going concern for US regulators. Recently, the multinational pharmaceutical company Glaxo Smith-Kline (GSK) reached a \$750m settlement with the US Department of Justice (DOJ) in connection with the US-based distribution and manufacture of several contaminated and substandard medicines over a period of several years.³⁰ GSK is not alone: multi-million-dollar settlements are reached between pharmaceutical manufacturers and the DOJ each year, in relation to failures to comply with US quality standards and other regulations.³¹

Challenges to effective regulation in developing countries

Medicines regulation in the poorest parts of the world is dangerously deficient, although a number of developing countries have started to make initial crucial investments.

The WHO estimates that as much as one-third of the countries in the world have either very limited drug-regulatory capacity or none at all.³² At a 2009 meeting, African regulators noted that an estimated 63 per cent of the 46 countries in sub-Saharan Africa had minimal medicines-regulatory capacity and that 30 per cent had no DRA.³³ Under such circumstances, poor-quality and falsified products are able to enter the market, with grave consequences for patients and for public health.

A 2009 study organized and carried out by the WHO, the Drug Quality and Information Program, USAID, and the US Pharmacopeia ('the QAMSA Study') evaluated the quality of certain key anti-malarial

medicines in ten sub-Saharan African countries.³⁴ The results were alarming. Of the medicines sampled in Senegal, 44 per cent were substandard. In Madagascar and Uganda, 30 and 26 per cent of the samples, respectively, were substandard – although in Uganda the samples procured from the public sector were free from quality problems.³⁵

There are numerous financial and technical challenges to improving the quality and safety of medicines in poor countries. Above all, the government authorities that are responsible for keeping poor-quality medicines off the market are chronically under-funded. A lack of adequate, trained human resources is also a serious problem. In Lesotho, for instance, there are only 21 trained pharmacists, just three of whom work in the public sector.³⁶ In Belize, there is only one inspector, working in the absence of any formal registration process for medicines.³⁷ Many countries do not have an operational national quality-control laboratory for testing medicines as part of quality assurance.

Low salaries, lack of incentives, or poor morale may lead to high turnover among DRA staff and thus undermine the effectiveness of the regulatory authority.³⁸ In addition, these difficulties can lead to corruption, resulting in registration of medicines that have not been demonstrated to be safe and effective, or in insufficient inspection of pharmaceutical establishments. Corruption has been identified by the WHO as a major impediment to ensuring access to quality medicines; its 'Good Governance for Medicines' programme is making some progress towards addressing this challenge through the voluntary participation of governments.³⁹

Other, systemic factors can also work against the development of effective medicines-regulatory capacity. Countries facing a health crisis such as HIV and AIDS may respond by adopting a quality-assurance system for medicines and diagnostics that is specific to that crisis. Over time, the system may become the basis for general medicines regulation, even though it was not designed to cover a broad spectrum of diseases, products, and regulatory activities.

In some countries there is no regulation, simply because no laws have been enacted to mandate it. Without any legislative mandate to regulate medicines, health authorities cannot set up basic administrative processes to identify which medicines may be lawfully sold in the country. In many countries, regulations are in place but are not enforced. Under such conditions, the pharmaceutical market is a free-for-all, with ineffective monitoring, or no monitoring at all, of what is produced, imported, and traded.

In addition to regulatory capacity, the quality of medicines may be affected by how medicines are procured for patients in developing countries. The Global Fund applies high quality standards to procurement and actively seeks to strengthen national health systems, allocating funds for this purpose.⁴⁰ Other procurement agencies and donors do not consistently apply quality-assurance requirements for

drug purchases. In some cases, donors demand low medicine prices without having the technical expertise or capacity to adequately define quality-assurance requirements. This sometimes leads donors to procure low-quality medicines.⁴¹

What can be done?

Brazil developed into a middle-income economy over a decade ago, and thus is not typical of the low-income countries that have very little or no drug regulatory capacity. Nevertheless, it is an encouraging fact that, in a relatively short time, beginning in the late 1990s, it created a national regulatory structure for medicines. Today, it has an extensive system of drug regulation in place, including registration, quality assurance, inspections, pharmacovigilance, monitoring of clinical trials, and oversight of marketing practices.⁴² Critically, this quality-assurance system together with policies to promote access and affordability were put in place simultaneously.

Box 3: Upgrading regulatory capacity in Brazil

Less than 15 years ago, oversight of medicines by the Brazilian government was very limited. Registration rested exclusively on a review of paperwork by officials at the Ministry of Health. No additional evidence was requested from applicants and manufacturing sites were never inspected. The only condition applied to registration of a medicine in Brazil was that the product had to be registered in another country.

In the late 1990s, Brazil developed and began implementing a strategy to build effective medicines-regulatory capacity. Facilities for testing and quality assurance were established throughout the country. The National Health Surveillance Agency – known by its Portuguese acronym ‘ANVISA’ – was created in 1999 to oversee the registration (which, ANVISA ruled, must be renewed every five years) and regulation of medicines.⁴³ Extensive post-marketing surveillance at the national, regional, and municipal levels was put in place,⁴⁴ along with a system for licensing pharmaceutical entities, including the entire distribution network. Wherever possible, the agency’s policies and regulations were modelled on WHO norms and guidelines.⁴⁵ The stated objective of ANVISA is to ‘promote and protect public health’.⁴⁶

When ANVISA was created, the Brazilian government was also enacting new legislation to promote generic competition and access to affordable generic medicines.⁴⁷ ANVISA’s mandate – to ensure the safety, efficacy, and quality of medicines – was considered complementary to measures to promote access.⁴⁸ In other words, quality and affordability were considered to be two sides of the same coin.

Few developing countries could create an agency like ANVISA in less than 15 years. Many low-income countries will need to build regulatory capacity by starting with the creation of a legal basis for regulation, then adding administrative procedures for registering medicines and monitoring what is in the market. More sophisticated quality control,

together with a more complete system of risk-based inspections, pharmacovigilance, and oversight of clinical trials and marketing practices, can be added later, as capacity evolves. Between these two extremes, many developing countries are striving successfully to improve their national drug-regulatory systems.

In 2002, Tanzania implemented a novel approach to targeting trade in illicit medicines.⁴⁹ The Ministry of Health created a database of unregistered medicines and then began checking it against the products for sale in outlets across the country. Inspectors invited pharmacies found to be selling unregulated medicines to co-operate with the authorities' efforts to track the source of such products. Those who refused faced well-publicized closures. A public-information campaign generated public support for this programme.⁵⁰

Parallel to government regulation, multi-stakeholder initiatives, such as the Medicines Transparency Alliance (MeTA), can contribute to improving the quality of medicines.⁵¹ MeTA aims to generate information about the pharmaceutical sector, in order to enhance the quality of medicines. In seven pilot countries, MeTA established councils which included health authorities, local and sometimes international pharmaceutical companies, and civil-society groups. Participants started exchanging information about products in the market, based on their shared interest in targeting trade in substandard and falsified products and in strengthening the pharmaceutical sector in their countries.

MeTA monitoring is new, having been introduced only in 2008 and 2009. Nonetheless, a 2010 evaluation noted positive policy and business-practice changes in the Philippines, Jordan, and Peru, which appeared to result at least in part from the programme.⁵²

Regional co-ordination of medicines registration and regulatory activities is another approach to overcoming resource constraints. Regional co-operation can help participating countries to share expertise and experience, support each other in implementing national drug strategies, and, ultimately, avoid duplication, thereby making the best use of scarce regulatory resources. Such co-ordination could also provide a regional focal point for certain types of capacity-building assistance.

Regional initiatives are at different stages in economic groupings in Asia, Latin America, the Caribbean, and Africa.⁵³ In Africa, the East African Community (EAC) and Southern African Development Community (SADC) are pursuing harmonization, supported by a new initiative called the African Medicines Registration Harmonization Initiative (AMRHI). The WHO participated in the launch of AMRHI in 2009, together with donor partners and the New Partnership for Africa's Development (NEPAD).⁵⁴ The goal of AMRHI is to foster regionalization of certain aspects of medicines regulation within economic groupings in Africa.

It is important that donors continue to support both national and regional capacity building in order to protect the integrity of drug supplies – although it is also salutary to remember that creating harmonization of drug regulations in Europe through the EMEA took many years.

The WHO should take the lead in co-ordinating capacity-building activities, based on its mandate to act as the global arbiter of international health standards. WHO norms should be the basis for all technical assistance to DRAs. Its prequalification programme is well regarded by Member States and helps promising manufacturers in developing countries to improve compliance with international (WHO) quality standards, in keeping with strategies to support quality local production. It also provides training for inspectors from developing countries.

Box 4: The WHO Prequalification Program

The WHO Prequalification Program (PQP) aims to ensure that diagnostics, medicines, and vaccines for high-burden diseases, such as HIV and AIDS, meet global standards of quality, safety, and efficacy. By identifying appropriate-quality medicines for purchase by donors and procurement agencies, the programme contributes to the optimal use of health resources and to improved health outcomes.

The prequalification process consists of a transparent and scientifically sound assessment, including dossier review, testing to ensure that products are consistently of the appropriate quality, and site visits to manufacturers. Products that meet WHO specifications are placed on a registry of ‘prequalified’ products.

Initially, PQP focused only on medicines to treat HIV and AIDS, tuberculosis, and malaria. In 2006, the programme was extended to cover medicines and products for reproductive health. Since 2001, the PQP has prequalified more than 240 medicines for priority diseases.

Every year, billions of US dollars’ worth of medicines are purchased by or through international procurement agencies, such as UNICEF, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and UNITAID, for distribution in resource-limited countries. The WHO list of prequalified medicinal products is used by these international procurement agencies to purchase diagnostics, medicines, and vaccines. Increasingly countries with insufficient regulatory capacity are also relying upon the WHO Prequalification Program to source medicines, and drug regulators from low-income countries benefit from hands-on training by participating in PQP activities.⁵⁵

Bilateral capacity-building can help to upgrade technical capacity in low-income countries. The Promotion of Quality Medicines (PQM) project, which is funded by USAID and implemented by the US Pharmacoepia, assists countries to monitor and improve the quality of medicines.⁵⁶ Assistance may also come from representatives of

stringent regulatory authorities, but should not be aimed at harmonizing technical standards for medicines registration beyond WHO standards.⁵⁷ Medicines regulation is not a one-size-fits-all process. It should be carried out in line with the public-health needs and priorities of each country, on the basis of WHO recommendations.

Another way that stringent regulatory authorities may contribute to better quality of medicines in developing countries is through registration by reference. Under this approach, DRAs in developing countries register products on the basis of approval by stringent regulatory authorities. Regulatory authorities using this approach should ensure that manufacturers provide additional data as appropriate, to demonstrate that the medicine is adapted to the needs of the place where it will be consumed. However, low-income countries cannot rely exclusively on this approach, since not all manufacturers of quality, low-cost products register their medicines in developed countries.

IP enforcement cannot solve public-health problems

In recent years, numerous policy makers in the US and the EU have emphasized criminal IP infringement as a key factor behind the proliferation of poor-quality medicines.⁵⁸ However, such products are frequently produced and traded without infringing IP regulations.

Rich countries propose the enactment of stringent anti-counterfeiting legislation – often integrated into IP enforcement measures – combined with tough police action as the way to keep poor-quality and falsified medicines off the market.⁵⁹ But relying on IP enforcement to ensure quality is a flawed approach, not least because poorly conceived anti-counterfeit laws and regulations can undermine public health by targeting legitimate generic medicines.⁶⁰

A functioning DRA protects the public from poor-quality and falsified medicines much more comprehensively than IP enforcement. Resources should be used to build the capacity of DRAs in developing countries to institute and enforce strong quality standards for medicines. Anti-counterfeit actions based on trademark enforcement should be narrowly targeted and supplementary to regulation by health authorities.

What is a ‘counterfeit’ product?

‘Counterfeit’ products result from one type of IP infringement: criminal trademark infringement. A trademark is any sign, including words, names, letters, and numerals, used to identify a product or service. Examples of trademarks include the Apple computer logo, and the Coca Cola brand name. Trademarks are used to distinguish a product or service from the products and services offered by other companies. Trademarks are a distinct type of IP protection, separate from other types of IP, such as patents and copyright.

The TRIPS Agreement defines ‘counterfeit trademark goods’ 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.⁶¹ Article 61 of TRIPS says that criminal counterfeiting activities involve trademark infringement that is wilful and carried out on a commercial scale. Criminal trademark infringement, or counterfeiting, can be distinguished from so-called ‘civil’ trademark infringement in that it involves the intentional misrepresentation of the product as the trademarked article, when in fact it is an unauthorized copy.

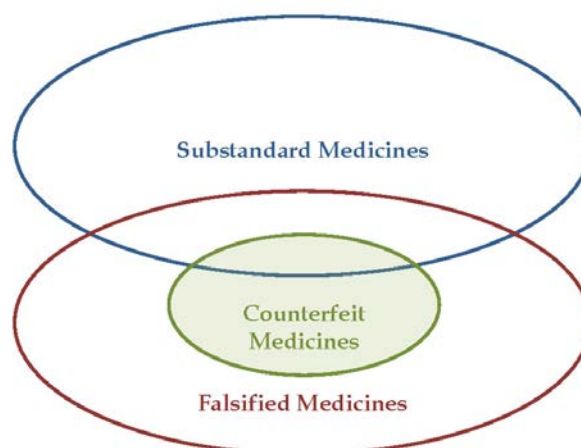
Under the TRIPS Agreement, WTO Member States are required to criminalize counterfeiting, together with copyright piracy, in their national legislations. Countries have some flexibility in that they may define 'wilful' and 'commercial scale' as they deem appropriate to their national contexts, provided that they comply with the minimum obligations in Article 61.⁶² This flexibility, which was recently confirmed by a WTO panel, is reflected in the differences across jurisdictions as to what constitutes criminal trademark infringement, or counterfeiting.⁶³

Criminal trademark infringement is different from the types of civil trademark infringement that may occur during the normal course of business.⁶⁴ Companies in the pharmaceutical sector regularly dispute whether the names, packages, or trade dress of competing branded or generic products are similar to the extent that they might create confusion for the consumer and therefore infringe a trademark.⁶⁵ Often, any existing similarity is unintentional. For instance, if two medicines containing the same active pharmaceutical ingredient are named after the scientific name for that substance, the International Non-Proprietary Name (INN), the products' names may be very similar. This may give rise to a dispute. This type of dispute is resolved in civil (not criminal) proceedings, in accordance with national laws.

Although it is well-known to IP practitioners, the term 'counterfeit' has little meaning in the context of public-health discussions.⁶⁶ Whether a falsely labelled, substandard, or unregistered product is also the result of wilful trademark infringement on a commercial scale, as criminalized under the TRIPS Agreement, is irrelevant from the perspective of public health.⁶⁷ IP enforcement measures that target the products of criminal trademark infringement fail to catch most poor-quality and falsified medicines; they cannot replace medicines regulation by a DRA.

Use of the term 'counterfeit' has persisted in forums including the WHO, leading to use of the wrong framework – an IP rather than public-health framework – to address poor-quality and falsified medicines. This derives from the limited overlap between products that are falsified and products that are the result of criminal trademark infringement, or 'counterfeiting'. In other words, a product that is falsified may also infringe a trademark. And, to the extent that a falsified product may also be substandard, i.e. have the incorrect type or concentration of ingredients, a product may be falsified, counterfeit, and substandard simultaneously (see Figure 3).

Figure 3. Limited overlap between counterfeit medicines, falsified medicines, and substandard medicines



Rich countries and the pharmaceutical industry have exploited this overlap in an attempt to blur the lines between health issues and IP issues. Concerns about poor quality and the need to protect patients from products that are dangerous or ineffective have been used to justify expanded criminal and civil enforcement of trademarks, as well as other forms of IP.

The 'anti-counterfeit' measures proposed by rich countries in various forums, which focus on IP, constitute a flawed approach to ensuring medicine quality. Anti-counterfeit actions that focus on IP enforcement address only a slice of the problem of unsafe or ineffective medicines. Figure 3 illustrates that anti-counterfeit interventions (which target the shaded area) only address a subset of the broader problem of poor-quality and falsified medicines. Not all falsified medicines are counterfeit, and not all falsified or counterfeit medicines are substandard. Moreover, stricter IP enforcement measures undermine access to legitimate generics which, in turn, drives demand for cheaper products that may be of inadequate quality or falsified.

Action should focus on identifying and removing poor-quality and falsified medicines from commerce. DRAs should lead efforts to keep these products out of the market, using targeted measures that do not undermine access to legitimate generic medicines. Separately, true 'counterfeit' medicines must also be removed from the market; these products may be dangerous or ineffective, and they undermine consumers' rights and the reputation of legitimate manufacturers.

Misrepresenting data to push for anti-counterfeit action

The proponents of strong IP enforcement routinely confuse falsification, IP infringement, and failure to meet GMP and other quality standards.

Data generated by the Pharmaceutical Security Initiative (PSI) are often cited in discussions about poor-quality and falsified medicines.⁶⁸ This

initiative, which was founded by security experts from originator pharmaceutical companies, tracks trade in falsified products, which it calls 'counterfeits', together with incidents of theft and the illegal diversion of 'genuine pharmaceutical products'. PSI relies on a broad definition of 'counterfeits' that encompasses more than products resulting from the criminal infringement of trademarks.⁶⁹ PSI data do not track the prevalence of poor-quality medicines. PSI figures – even if they were published – would thus be of limited usefulness in determining the relative prevalence of poor-quality and falsified medicines.

In addition, WHO statistics regarding the prevalence of falsified medicines have been misrepresented. In 2003, the organization estimated that 200,000 deaths could be prevented annually if anti-malarial medicines were consistently of acceptable quality, and if dosing was optimal.⁷⁰ On the basis of this calculation, some began stating that 200,000 deaths annually result from the consumption of falsified anti-malarial medicines. Seeking to distance itself from this distorted version of its calculation, the WHO stopped using the figure. However, it continues to be cited in news and other reports as the number of annual malaria deaths linked to fake medicines.⁷¹ Reliable and complete data about the impact of poor-quality and falsified anti-malarial and other medicines on patients and public health is not available.

The WHO has also distanced itself from other statistics, such as its 2003 estimate that 10 per cent of medicines traded globally are falsified.⁷² This figure was challenged and, in 2006, the WHO, together with the WHO-led anti-counterfeiting initiative IMPACT (International Medical Products Anti-Counterfeiting Taskforce), admitted that the figure was 'not supportable'.⁷³ Nonetheless, it continues to be cited by other groups.

In 2006, the WHO (and IMPACT, which is discussed in greater detail below) communicated a new, dubious statistic: approximately 30 per cent of medicines in developing countries are falsified.⁷⁴ IMPACT relied exclusively on anecdotal evidence, such as news reports and statements by unnamed government officials, to support this figure, which has never been substantiated on the basis of data.⁷⁵ Nonetheless, it continues to be cited by organizations such as the OECD and the UK Medicines and Healthcare Products Regulatory Authority (MHRA).⁷⁶

A particularly arbitrary approach to estimating the prevalence of counterfeit products, including medicines, is the 'rule of thumb' that was developed by the International Chamber of Commerce.⁷⁷ According to this rule of thumb, counterfeit products account for 5–7 per cent of total world trade. This approach had been used for nearly a decade by researchers when it was strongly criticized by the OECD and the US Government Accountability Office as unsupported.⁷⁸

Poorly conceived statistics do not support developing-country governments in addressing the safety, efficacy, and quality of medicines, or in targeting public-health resources in the most cost-

effective manner. Additional, reliable data about the prevalence of poor-quality and falsified medicines is urgently needed, both to fashion effective public-health solutions and to avoid use of inappropriate approaches to medicines quality assurance that focus on IP enforcement. Better information systems that improve understanding of the prevalence of poor-quality and falsified medicines, and monitor this, are needed, especially at the national level.

'TRIPS-plus' IP enforcement rules threaten public health

IP enforcement under the TRIPS Agreement

The TRIPS Agreement defines 'counterfeit' products and sets out the types of IP enforcement measure that WTO Member States are obliged to enact.⁷⁹ Such measures are aimed at permitting 'effective action' against infringement of the intellectual property covered by TRIPS, including the prevention of imminent infringement and deterrence of further infringement.⁸⁰

TRIPS imposes limitations and safeguards on the enforcement of IP by government officials. For instance, the only types of IP infringement that must be criminalized under TRIPS are 'wilful trademark counterfeiting' and 'copyright piracy on a commercial scale'.⁸¹ In addition, TRIPS requires that actions taken against goods suspected of infringing IP be justified on the basis of evidence and that Member States provide for the indemnification of owners and importers of goods that are unjustifiably targeted.⁸² Article 41 requires that all enforcement procedures be applied in 'such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse'.

A WTO panel recently confirmed that Member States may implement the TRIPS-enforcement provisions as appropriate to their national contexts.⁸³ Least-developed countries do not have to implement TRIPS patent rules related to pharmaceuticals until at least 2016 and can request extended timelines for implementing TRIPS-enforcement obligations.⁸⁴

What TRIPS-plus IP rules are being proposed?

Requiring WTO Member States to enforce their obligations under TRIPS may not seem unreasonable. However, rich countries are proposing 'enforcement' measures that would modify and extend IP protection beyond the global standards in the TRIPS Agreement. They have pursued these new rules via multi-lateral and bilateral trade agreements, anti-counterfeiting conventions, and national legislation.

Such 'TRIPS-plus' enforcement rules erect new barriers to the development and distribution of generic medicines, as follows:

- They introduce new measures that enhance the ability of companies to enforce IP rules, regardless of the impact on public welfare, including health.

- They expand substantive monopoly rights that various industries, including the pharmaceutical industry, can enforce to secure greater market share and profits.
- They shift the burden of enforcement from the private sector (such as the pharmaceutical industry) to the public sector (regulatory agencies, customs and border officials, and patent offices). This includes granting *ex officio* authority to customs officials to seize and potentially destroy suspected goods, on their own initiative.

The proponents of TRIPS-plus IP enforcement have also sought to expand the definition of ‘counterfeit’ products, together with the type and scope of anti-counterfeit measures, and to modify law enforcement priorities to emphasize fighting counterfeit goods. The combination of an expansive definition and broader anti-counterfeit measures enables customs and other officials to take action against a broad category of products, at the direction of pharmaceutical or other IP-reliant companies. Often this category of products includes legitimate generic medicines produced by competitors.

Proponents of stricter IP enforcement have pushed to include civil trademark infringement – and even patent infringement – in the definition of ‘counterfeit’. In some instances, they have sought to define ‘counterfeit’ so broadly as to include any product with a name, trademark, size, shape, or colour that is ‘confusingly similar’ to a branded product.⁸⁵ Often, this may include lawfully-available generic medicines that are not intended to deceive consumers.

The types of new rules that have been proposed to target ‘counterfeits’ would enhance the ability of companies to aggressively defend, even abuse, IP.⁸⁶ These new rules include extended border measures, third-party and/or intermediary liability, heightened damages for IP owners, and the elimination of limitations and exceptions for injunctions.

These measures, which are described in more detail in Annex A, would seriously upset the already uneasy balance in the TRIPS Agreement between the protection of IP, on the one hand, and competition and the public interest, on the other.

The leading role of the EU

Alongside the various individual developed countries that have pursued stricter IP enforcement, the EU stands out for the intensity with which it has championed TRIPS-plus enforcement rules, and for its role in expanding the scope of these enforcement rules so that they have a direct, detrimental impact on poor people’s access to affordable medicines.⁸⁷

The EU’s pursuit of TRIPS-plus enforcement rules is part of a broader strategy, elaborated in the strategy paper, ‘Trade, Growth and World Affairs’, which explicitly champions strict IP enforcement as critical to safeguarding and enhancing the competitiveness of European businesses.⁸⁸

Some of the problems with the international approach adopted by the EU stem from an internal regulation that the EU has championed abroad: EU Customs Regulation 1383/2003.⁸⁹ This regulation enables customs officials to apply border measures to detain imports, exports, and in-transit goods, including pharmaceuticals, which are suspected by customs officials of infringing any type of IP (patents, trademarks, or copyrights). Regulation 1383/2003 has been used to prevent the international movement of generic medicines through the use of border and customs actions within the EU.

EU Regulation 1383/2003 is inconsistent with Article 41 of the TRIPS Agreement, which requires that Member States avoid the creation of IP-related barriers to legitimate trade, and it has been challenged at the WTO on the basis of this and other provisions. Nonetheless, the EU has sought to export this regulation globally in trade negotiations, in discussions at the WHO, and through bilateral technical assistance, backed by funding, to poor countries.⁹⁰

Public-health consequences of stricter IP enforcement

TRIPS-plus IP enforcement measures disrupt the production and distribution of generic medicines in different ways:

- **Heightened damages for IP infringement** and the **elimination of limitations and exceptions for injunctions** discourage generics manufacturers from challenging tenuous monopolies held by multinational drug companies in various jurisdictions.
- **Third-party and intermediary liability**, broadly defined, can hold the suppliers of active pharmaceutical ingredients (APIs), who are responsible for providing bulk ingredients used by manufacturers to produce medicines, accountable for IP violations that occur downstream. This could discourage API suppliers from openly selling the basic ingredients which generics manufacturers need to formulate medicines. Distributors, shippers, procurement agents, and other actors in the supply chain could also be affected.
- **Expanded border measures** grant draconian powers to customs officials to seize and even destroy products, including legitimate generic medicines.

The consequences of TRIPS-plus enforcement measures have become particularly apparent following application by the EU of Customs Regulation 1383/2003. The EU has claimed repeatedly through press statements and announcements that the new regulation will halt the flow of unsafe medicines into the EU and also into developing countries.⁹¹ Although the Customs Regulation could be used to eliminate some unsafe medicines, it is written too broadly. It has often been applied to products other than counterfeits, undermining the free movement of quality generic products intended for consumption in developing countries.

Box 5: Seizures of generic medicines in transit through the EU

In 2003, the EU revised its internal customs regulation. The new regulation – Regulation 1383/2003 – expanded the powers of border officials within the EU.⁹² This regulation directs border officials to seize counterfeit products, products that may infringe patents, and products that may be contested under a civil trademark-infringement dispute (wherein one party alleges that a competing product is ‘confusingly similar’ to its own product’s registered trademark). Regulation 1383/2003 has been the object of international scrutiny since 2008 and is currently under revision by the EU.⁹³

This broadly-written law, once enforced, has had a serious, damaging impact on trade in affordable medicines. In particular, European customs officials started seizing shipments of generic medicines en route from India and China to other developing countries. Over a period of 12–18 months, at least 19 shipments of legitimate generic medicines, in transit through the EU, were seized or temporarily detained by customs officials for alleged infringement of patent rights.⁹⁴ In one case, the consignment was seized under the ‘confusingly similar’ trademark-infringement standard.⁹⁵ All of these actions resulted from the misguided use of border measures by customs officials against legitimate generic medicines that were deemed to infringe patents or trademarks within the EU.

Some seizures were done at the behest of multinational pharmaceutical companies seeking to enforce their IP rights within the EU.⁹⁶ In other cases, customs officials used their own independent authority to seize products that they deemed to infringe IP rights.⁹⁷ In each case, the medicines did not infringe any IP in the country of origin or in the recipient developing countries.

Many of the seized medicines were of considerable public-health importance, including medicines to treat cardiovascular disease or HIV and AIDS. In one case, Dutch authorities seized a generic version of *abacavir*, a key second-line anti-retroviral medicine that had been purchased by UNITAID, the international UN medicines-purchasing facility.⁹⁸ The medicine was being shipped from India to Nigeria, using logistical support offered by the Clinton Foundation. Approximately four months later, these life-saving medicines finally reached the HIV and AIDS patients they were intended to treat.⁹⁹

In seizing in-transit medicines with no connection to the EU market, the EU has sought to impose its domestic, TRIPS-plus standards of IP enforcement on the exporting and importing countries. The TRIPS Agreement does not require the detainment of in-transit goods, or even the checking of the IP status of products that are in transit.¹⁰⁰ As long as Regulation 1383/2003 remains in place, it will be risky for generics manufacturers to ship their products through the EU, often the cheapest route.

Developing countries are right to reject TRIPS-plus IP enforcement

Rich countries have pursued TRIPS-plus enforcement rules through an array of trade agreements, conventions, technical-assistance programmes, and internal measures. In some instances, they have been supported in these efforts by developing countries, but, overall, developing countries continue to fiercely resist. Civil-society organizations and officials in rich and poor countries are persuading developing countries – and, in some cases, developed countries – to oppose TRIPS-plus IP enforcement rules, and anti-counterfeiting measures that negatively impact public health.

EU pressure for TRIPS-plus IP enforcement

The EU has not yet modified Regulation 1383/2003, despite the demonstrated consequences for public health and increased pressure from trading partners.

In 2010, India and Brazil initiated a dispute before the WTO against the EU.¹⁰¹ In their complaints, the countries separately alleged that Regulation 1383/2003 violates several WTO rules, including rules in the TRIPS Agreement, and that it conflicts with the EU commitment to prioritize public health under the Doha Declaration on TRIPS and Public Health. In 2010, the countries began consultations with the aim of finding a negotiated resolution to the dispute. In December 2010, the EU and India announced that an agreement had been reached which would satisfy India's concerns and enable it to withdraw its WTO complaint, although the agreement would require approval of the European Parliament.¹⁰² Brazil has yet to reach an agreement with the EU and has indicated that it will pursue the dispute until this barrier to trade in affordable medicines is removed.

Other developing countries have also opposed the EU approach to IP enforcement, refusing to include rules inspired by Regulation 1383/2003 in free-trade agreements with the EU. For example, the Andean countries that completed negotiations for a free-trade agreement with the EU refused to include new border measures that would have jeopardized access to affordable medicines. India, which is concluding a free-trade agreement (FTA) with the EU, has resisted efforts to introduce stricter IP provisions, including new enforcement measures.¹⁰³

The EU also did not succeed in exporting its approach to IP enforcement in other trade agreements – notably the Anti-Counterfeiting Trade Agreement.

The Anti-Counterfeiting Trade Agreement

The Anti-Counterfeiting Trade Agreement (ACTA) is a pluri-lateral treaty which introduces new TRIPS-plus standards of IP enforcement.¹⁰⁴ Proponents claim that ACTA protects consumers from 'dangerous counterfeit goods', including pharmaceuticals.¹⁰⁵ It is primarily an agreement among developed countries; just two developing countries – Morocco and Mexico – participated in the talks.

Many developing countries have been highly critical of ACTA, in forums including meetings of the WTO TRIPS Council, throughout 2010.¹⁰⁶ Despite this opposition, the negotiating countries persisted in their negotiations, reaching final agreement on the text in December 2010. Signatories are expected to ratify ACTA in 2011. It is expected that the ACTA signatories will either encourage additional developing countries to sign up to ACTA, or will force them to adopt ACTA rules by incorporating identical provisions in FTAs.

The initial ACTA negotiating text contained a broad range of TRIPS-plus enforcement measures that would have seriously harmed public health. In particular, the EU tried repeatedly to include border regulations in the ACTA text based on which all parties would use enhanced border measures to seize any in-transit products suspected of infringing IP, including patents. The EU was ultimately unsuccessful in inserting an obligation for countries to maintain such far-reaching border measures in relation to patents.

The final ACTA text still contains many TRIPS-plus enforcement measures, despite improvements made to the earlier negotiating texts.¹⁰⁷ It provides for extended border measures which could allow for: the seizure of legitimate medical products; heightened damages for IP infringement; rules that limit the discretion of judges who wish to avoid imposing injunctions; and rules enabling third-party enforcement measures.¹⁰⁸ Furthermore, ACTA contains few public-interest safeguards.

ACTA will erect new barriers to affordable medicines. It would have been far more onerous from a public-health perspective but for the efforts of civil-society groups worldwide, which expressed their serious concerns regarding ACTA as it evolved.

The International Medical Product Anti-Counterfeit Taskforce (IMPACT)

IMPACT is an anti-counterfeit taskforce which includes the WHO, the multinational pharmaceutical industry, Interpol, the European Commission, various inter-government organizations, and representatives of the health-care sector.¹⁰⁹ Its mandate is to raise awareness and develop 'global solutions to this global problem' of 'counterfeit medical products'.¹¹⁰

Although IMPACT recommendations are not legally binding, they may be incorrectly perceived as endorsed by the WHO, due to the participation of the latter in the taskforce. Because countries look to the WHO for expert advice on public-health issues, this misperception could result in IMPACT's recommendations having considerable influence.

The origins of IMPACT can be traced to a meeting organized by the WHO and the International Federation of 1992 Pharmaceutical Manufacturers and Associations (IFPMA) to address the problem of counterfeit medical products.¹¹¹ Founded officially in 2006, IMPACT has never been approved by the World Health Assembly (WHA), the governing body of the WHO. Its legitimacy has been called into question by a number of Member States and civil-society groups on this basis, and also in relation to perceived conflicts of interest among its participants. Many developing countries, together with civil-society groups, have aggressively sought to arrest the progress of IMPACT.¹¹²

IMPACT participants and the WHO Secretariat, including the Director-General, insist that it is purely a public-health initiative with no link to IP or IP enforcement.¹¹³ However, recommendations emanating from IMPACT bear a strong resemblance to measures proposed by rich countries and the multinational pharmaceutical industry elsewhere to advance TRIPS-plus enforcement rules.

IMPACT's work rests on the foundation of expanding the definition of a 'counterfeit medical product'. The current IMPACT definition (see Annex 2) includes elements from both civil and criminal trademark law, in addition to public health. This expansive definition could extend the reach of proposed IMPACT anti-counterfeiting measures to cover generic medicines that are legally available.¹¹⁴ For instance, a generic with a trade name that is based on the INN and therefore similar to the name of a competing product could be targeted as a counterfeit on the basis of the IMPACT definition and the enforcement measures in 'Principles and Elements for National Legislation Against Counterfeit Medical Products'.¹¹⁵ On the basis of 'Principles and Elements...', the manufacture, distribution, and possession of affordable generic versions of life-saving medicines could be considered criminal offences.¹¹⁶

At the WHA in 2010, developing countries succeeded in putting IMPACT on hold. They won the adoption of WHA Resolution A63/23, which requires the formation of an inter-government commission to: (a) evaluate the relationship between IMPACT and the WHO, including whether this partnership should continue; (b) define the WHO's role in promoting access to medicines; and (c) define the WHO's role in promoting medicine quality, safety, and efficacy.¹¹⁷ This resolution explicitly states that all these issues should be examined, 'excluding trade and intellectual property issues'.

This inter-government commission is scheduled to meet for the first time in March 2011. The stakes are high, especially considering the impact that WHO guidelines have upon national-level measures to improve quality assurance.

Pressure for anti-counterfeit action in East Africa

At the national level as well, the wrong framework – an IP framework – is being used to address quality assurance. In 2008, Kenya enacted the ‘Anti-Counterfeit Act’, with the encouragement and under the influence of a variety of TRIPS-plus IP enforcement supporters, including the multinational pharmaceutical industry and IMPACT representatives.¹¹⁸ Supporters of the law lauded the bill as a public-health measure that would protect consumers by removing counterfeit medicines from the market.¹¹⁹

This law highlights the risk posed by an expansive definition of ‘counterfeit’, combined with TRIPS-plus IP enforcement measures. The law defines ‘counterfeiting’ very broadly as ‘taking the following actions without the authority of the owner of any intellectual property right subsisting in Kenya or elsewhere in respect of protected goods [...]’.¹²⁰ As a result, generic medicines that are legally available in Kenya and do not infringe any IP rules in Kenya can be targeted as counterfeit products because they infringe IP rights held by someone anywhere in the world.

The implications are enormous. Under this law, Kenya would have to enforce patents held in other countries on all medicines – even if the medicine is not patented in Kenya. This would delay generic competition, while doing nothing to improve the quality or safety of medicines in the country. Moreover, since patents are national and many companies may not apply for patents in Kenya, this is likely to increase greatly the proportion of medicines in Kenya that have a generic-excluding monopoly. This law also burdens the Kenyan DRA with IP enforcement tasks, thereby straining scarce resources that should be dedicated to ensuring safety, efficacy, and quality.

Following the passage of the Kenyan counterfeiting law, people living with HIV and AIDS challenged it before Kenya’s Constitutional Court in July 2009.¹²¹ The complainants argued that, because it would undermine their access to affordable generic ARVs, the law conflicts with the right to life enshrined in Sections 70 and 71 of Kenya’s Constitution. In April 2010, the Court suspended the law’s application to medicines, pending its final decision. The Court agreed with the complainants that its application to medicines could lead to irreparable harm, including loss of life.¹²²

Beyond these efforts in Kenya, local civil-society groups will need to monitor anti-counterfeit initiatives across sub-Saharan Africa. The Ugandan ‘Counterfeit Goods Bill’, also justified as a measure to protect health, is being drafted. It contains an expansive definition of ‘counterfeit’ that is based on the definition used by IMPACT, which could result in the targeting of legitimate generics.¹²³ Problematic anti-counterfeit legislation is also under consideration at the EAC level.¹²⁴ EAC legislation could affect access to generic medicines in Kenya, Uganda, Rwanda, Tanzania, and Burundi – regardless of policies at the national level.¹²⁵ Other African countries are considering enacting national anti-counterfeit legislation, including Zambia and Malawi.

Industry activism in Thailand

The push for stricter levels of enforcement at the national level is not exclusive to Kenya and other parts of sub-Saharan Africa.

In Thailand, extensive lobbying by the multinational pharmaceutical industry (represented locally by the industry group, PReMA) nearly succeeded in pushing the Thai government to introduce new IP enforcement standards at the national level. In particular, the pharmaceutical industry pressured the government to introduce anti-counterfeit measures that would require customs officials to seize medicines if they seem 'confusingly similar' to a medicine marketed by a multinational drug company in the country.¹²⁶

Adoption of this standard would result in the seizure of lawfully-available generic medicines that, unlike true counterfeit products, are not intended to deceive consumers. The proposed standard would erase the divide between civil and criminal trademark infringement, which ultimately distinguishes commercial disputes from criminal investigations of fraudulent manufacturers.

Thai civil-society groups, through advocacy and the provision of strong evidence against the proposed changes, convinced the government to resist industry pressure. The Thai government has not amended its customs laws. Parallel to this endeavour, PReMA also lobbied the Thai Commerce Ministry to introduce several TRIPS-plus IP measures through a Memorandum of Understanding (MOU) between several government agencies and PReMA, which would require the enactment of TRIPS-plus IP measures.¹²⁷ PReMA claims that the MOU is necessary to protect Thai consumers from falsified medicines.¹²⁸

Box 6: TRIPS-plus Memorandum of Understanding in Thailand

The multinational pharmaceutical industry, through PreMA, has sought the enactment of TRIPS-plus standards through the negotiation of a MOU. This effort was promoted as necessary to protect the public from dangerous counterfeit products.

In August 2007, a draft MOU aimed at curbing the production, sale, import, and export of 'counterfeit' medicines was developed by the Ministry of Commerce (in response to lobbying by PreMA) and shared with other Thai government agencies. The MOU contained an extremely broad definition of 'counterfeit' which included falsified and substandard medicines, along with medicines infringing a patent. It also required the enactment of extensive border measures, patent linkage, and other TRIPS-plus IP rules. The Thai DRA, the Food and Drug Administration (FDA), refused to consider the MOU.

After a change of government in early 2008, PReMA modified the title of the MOU, and again requested that the government sign it. A number of government agencies agreed to sign, but the FDA still refused to sign the MOU, due to the anticipated impact on public health.

In 2010, PReMA, together with the Department of Intellectual Property within the Ministry of Commerce, began bombarding the public with warnings about counterfeit goods, arguing for stricter IP enforcement to address this danger. PReMA organized numerous conferences on counterfeit medicines and revived the MOU, again pressuring the government, and particularly the FDA, to sign it.

Although civil-society groups have consistently fought efforts to get the government to sign this MOU, they were unable to prevent the government from signing a modified text in 2010. The modified version contains a less expansive definition of counterfeit, and it does not require patent linkage or other TRIPS-plus concessions. The government has promised that it will involve civil-society groups if it modifies any existing legislation on these issues.

Finally, there are concerns that the US government, which placed Thailand on the Priority Watch List of its 2010 Special 301 Report, will use an out-of-cycle review of Thailand's IP law to pressure the Thai government to amend both its IP regulations and customs law, in line with PReMA's primary policy objectives.

Conclusion and recommendations

Too many people in poor countries suffer needlessly because the medicines that are available to them are not safe, effective, and of the appropriate quality.

Rich countries make massive investments in their DRAs, which enables them to effectively screen medicines and remove any products that are unfit for therapeutic use. Developing countries, in contrast, lack the financial and technical resources to provide the same protection to their populations. Donors must provide the necessary resources to help to bridge this international gap in medicines regulation, and developing countries must prioritize the development of national medicines-regulatory capacity and, where appropriate, regional coordination.

In addition, developed countries, on behalf of industries that rely on IP as their 'competitive advantage', must stop using legitimate concerns about the quality of medicines in developing countries to pursue an array of stringent new IP enforcement measures. Such measures threaten to undermine generic competition, with grave consequences for patients and public health.

Developing countries should use international forums – such as the WHA and the G-8 – to press developed countries to modify their approach to IP enforcement. They should make clear that new IP standards will be acceptable only if developed in concert with their priorities, including the protection of public health. And they should ensure that TRIPS flexibilities and safeguards have been implemented in their national legislations.

At the national level, continued efforts by civil society are critical, but will not be sufficient on their own. Increased vigilance by health authorities is also needed. In Kenya and Uganda, the lack of involvement by health officials in the process of drafting anti-counterfeit legislation is one of the key reasons why harmful laws were developed.¹²⁹ This contrasts with the process in Thailand, where the health authorities, working with civil-society groups, engaged with the Ministry of Commerce to avert modification of Thai customs regulations.

As in developing countries, it is critical that developed-country health and other officials – particularly in the US and at the European Commission – ensure that the IP enforcement policies promoted by trade officials are coherent with broader approaches to development around the world.

Oxfam recommends the following policies and actions to ensure that people in developing countries can access affordable medicines that are safe, effective, of the appropriate quality, and not falsified.

Developed-country governments should:

- Expand funding and support for national and regional initiatives that increase the ability of DRAs in developing countries to protect their populations from harmful products. This includes building rigorous quality-assurance and pharmacovigilance functions, and expanding funding and support for WHO normative and technical work, including the WHO Prequalification Program.
- Ensure the consistent application of quality control for all medicines procured with the use of donor funds, and the regular and transparent publication of quality-testing results.
- Stop pursuing TRIPS-plus enforcement measures through internal regulations, multilateral trade initiatives, bilateral trade agreements, or through technical assistance.

Developing-country governments should:

- Prioritize the expansion of public health-care infrastructure and invest in DRA capacity together with the provision of free essential medicines. Some functions of national DRAs should be co-ordinated among groups of countries where there is a rationale and the will to do so.
- Use new public and private investment to tighten the regulation of retail pharmaceutical outlets and to stop the sale of falsified and substandard medicines through informal and unqualified vendors.
- Promote generic competition in national medicines policies, including implementation of TRIPS flexibilities in national laws.
- Reject initiatives modelled on ACTA, and any other TRIPS-plus enforcement initiatives.

The World Health Organization should:

- Prioritize the WHO's comprehensive programme of work which underpins access to affordable, quality medicines for its Member States, including expansion of capacity and adequate funding to provide technical assistance to countries; support for the achievement of stronger national DRAs; and investment in and expansion of the WHO prequalification programme.
- The WHO should disband IMPACT. WHO should also acknowledge that IMPACT has created unnecessary confusion, particularly through the misuse of the term 'counterfeit' to refer to substandard and falsified medicines that are unrelated to criminal trademark infringement, and through use of an IP framework to evaluate the public-health problem of unsafe medicines.
- Support countries in implementing TRIPS safeguards and flexibilities, and reject TRIPS-plus IP measures that could undermine access to medicines.

Pharmaceutical companies should:

- Adhere consistently to WHO quality standards. Companies must not produce substandard medicines for export to low-income countries, and they must fulfil their responsibility to declare to purchasers the full provenance of products openly and transparently.
- Recognize the damage inflicted on public health as a result of the confusion of quality with intellectual-property issues in initiatives such as IMPACT, and correct this fundamental error in their public statements and documents.

Annex 1

Review of TRIPS-plus IP enforcement measures

Below is an overview of the types of TRIPS-plus enforcement measures that have been proposed by rich countries as part of their push for stricter IP enforcement.

Extended border measures

Under TRIPS, countries are required to have in place border measures for imports, such as product suspensions, that can be used under specific circumstances to prevent the entry of counterfeit trademark and pirated copyright goods into commerce.¹³⁰ These measures are aimed at targeting criminal activities. Member States are not required to provide for action against ‘in-transit’ or export goods in their national law. These are goods passing through on their way to their country of destination.

On the basis of TRIPS-plus IP enforcement measures, countries have sought to use border measures to arrest the movement of goods that would infringe patents and/or trademarks if brought to market in the country of transit, and to require countries to take action against goods that are in transit. Generic medicines that are in transit could be seized under such provisions, even if they are lawfully available in the country of manufacture and the country of destination.

Lawful generic products that are deemed ‘confusingly similar’ to their branded counterpart could also be at risk for seizure, whether in transit or intended for export from the generic-producing country. For example, in May 2009, the equivalent of 76,000 courses of the generic medicine Amoxicillin was seized in Frankfurt airport en route from India to Vanuatu on grounds of suspected civil trademark infringement, on an *ex officio* basis by German customs officials, on the grounds that the medicine was ‘confusingly similar’ to a branded product. The consignment was released three weeks later after GSK informed the German customs authorities that there was no trademark infringement.¹³¹ GSK is the former patent holder for ‘Amoxil’, a brand-name amoxicillin. There was no valid reason for detaining these medicines, because the name ‘Amoxicillin’ is an INN, which cannot be trademarked. According to sources, no checks of the quality of the products were made prior to seizure or release.

Extension of third-party and/or intermediary liability

Proponents of TRIPS-plus enforcement have sought to arrest the production of competitors’ products by making the manufacturers of raw materials liable for counterfeiting if their products are incorporated

into a final counterfeit product. Third-party liability also affects others involved in the 'channels of commerce', including distributors/shippers, procurement agents, and purchasers and regulators.

Under current proposals, severe penalties could be imposed on third parties whose products are incorporated not only in counterfeit products, as defined under TRIPS, but also in products that infringe a patent or a trademark (under a civil infringement standard). Penalties would apply even where a product is incorporated without the knowledge of the inputs manufacturer, through the normal stream of commerce.

If applied to manufacturers of APIs, these efforts could hinder their supply to generic manufacturers. API manufacturers may not be willing to risk penalties if their products are incorporated into generic medicines which, under the new expansive definitions, could be considered counterfeit products. APIs are key building blocks of medicines, and the quality of the API has a direct impact on the quality of the final medicine. Hindering the supply of APIs to generics producers would significantly undermine production of quality, affordable medicines.

Heightened damages for IPR owners

New enforcement rules would alter how courts calculate damages for IP infringement, resulting in much higher penalties for manufacturers who are found to have infringed a patent or other IP. Generics manufacturers regularly and aggressively challenge patents of branded manufacturers, by introducing follow-on versions of their products or through legal action. Heightened damages for IPR owners make this substantially more risky and would discourage potential competitors from aggressively opposing patents of branded manufacturers. Some countries have even gone so far as to propose criminal penalties for patent infringement, even though patent infringement is driven by commercial disputes between competitors.

Elimination of limitations and exceptions for injunctions

In recent years, courts have been more willing to force parties to settle patent disputes by requiring the infringing party to pay a licence fee to the patent holder in lieu of imposing an injunction. An injunction is a court order to cease an activity that is perceived to infringe an IP. Fewer injunctions encourage patent holders to more openly license IP to competitors to produce low-cost products. This could, in the long term, induce pharmaceutical companies to issue increased voluntary licences to generics companies to produce low-cost versions of medicines for specific markets. The enforcement agenda has sought to partly or absolutely forbid judges to avoid imposing injunctions in IP-infringement disputes.

Imposition of barriers to parallel trade

Parallel importation is permitted under Article 6 of the TRIPS Agreement; this was reaffirmed under the Doha Declaration on TRIPS and Public Health. Parallel importation is a process by which a country imports a patented product that is sold in another country at a cheaper price. This process is carried out based on domestic laws that provide for the 'international exhaustion' of IP rights, meaning that IP rights are considered to expire once the product has been placed on the market somewhere in the world. It is recommended that countries enact the international exhaustion of rights regime in their domestic laws since this allows them to parallel import patented products from the most affordable global source. Parallel importation has been used to obtain dramatically lower prices for medicines in rich and poor countries.

New TRIPS-plus IP enforcement rules confuse the difference between trade in counterfeit goods and the importation of legitimate medicines at a lower price using parallel importation. For example, IP enforcement rules have defined 'counterfeit medicines' to include products that would normally be characterized as legal parallel imports. In particular, model laws have defined counterfeit goods to include 'any goods which are made, reproduced, put into circulation or otherwise used in breach of the IP laws and without the consent of the rights holder or a person duly authorized to do so by the rights holder'.¹³² Under TRIPS, once goods are put into circulation, countries with measures that permit parallel importation can import these products without the consent of the rights holder. Under the enforcement regime, these goods, even after being placed into circulation, cannot be used by a third party without the consent of a rights holder.

Ex officio border measures, which empower customs officials to seize goods that are suspected of infringement, may similarly lead to confusion between legitimate parallel imports and goods suspected of being counterfeit. Officials may confuse a product that is legitimately moving through a grey channel of commerce with a counterfeit good.

Shifting enforcement burdens to the government

While public laws provide for patent, trademark, and copyright protection and enforcement, it is generally the responsibility of private parties to identify alleged infringements and to bring legal actions in response. Enforcement measures contemplated by rich countries shift the burden of private rights enforcement to the public, namely government authorities. The capture of public resources for private ends is not only tangential to the legitimate public goal of protecting consumers from unsafe and ineffective products, but it also comes at significant financial cost to taxpayers and diverts considerable law-enforcement resources from other priorities. By placing responsibility upon public actors – including drug-regulatory agencies and customs officials – it creates additional barriers to the movement of legitimate competitor products at these agencies, since the presumption of public authorities will always be weighted towards protection of IP on behalf of rights holders, in lieu of their traditional function of ensuring that consumers are not harmed by unsafe and ineffective products (which has no relationship to the protection of IP).

Annex 2

Current IMPACT definition of a 'counterfeit medical product'

The term 'counterfeit medical product' describes a product with a false representation – see Note (a) below; of its identity – Note (b); and/or source – Note (c). This applies to the product, its container or other packaging, or labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components – Note (d) – with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.

Violations or disputes concerning patents must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorized for marketing in a given country but are authorized elsewhere are not considered counterfeit. Substandard batches of legitimate medical products, or quality defects, or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting.

Notes:

- (a) Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behaviour shall be considered during the legal procedures for the purposes of sanctions imposed.
- (b) This includes any misleading statement with respect to name, composition, strength, or other elements.
- (c) This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder, or steps of distribution.
- (d) This refers to all components of a medical product.

Source: World Health Organization IMPACT meeting at Hammamet, December 2008.

Notes

All URLs were last accessed December 2010

- 1 WHO publication 'Equitable Access to Essential Medicines: A Framework for Collective Action', WHO, March 2004. http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.4.pdf
- 2 Availability of safe, effective, quality medicines does not mean that people in developed countries do not purchase treatment outside of the regulated distribution network. Increasingly, people in rich countries are purchasing medicines from internet pharmacies, particularly so-called lifestyle medicines. See for example: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm109018.htm>

See also: <http://www.who.int/mediacentre/news/releases/2006/pr69/en/index.html>
- 3 WHO publication 'Effective Medicines Regulation: Ensuring Safety, Efficacy and Quality', WHO, November 2003. <http://apps.who.int/medicinedocs/en/d/Js4921e/>
- 4 Pharmacovigilance (PV), according to the World Health Organization, is defined as: 'the science and activities relating to the detection, assessment, understanding and prevention of adverse drug effects or any other drug-related problem.' The WHO also states: 'The aims of PV are to enhance patient care and safety in relation to the use of medicines, especially with regard to the prevention of unintended harm, to improve public health and safety in relation to the use of medicines by the provision of reliable, balanced information resulting in more rational use of medicines; and to contribute to the assessment of the risk profile of medicines, thus encouraging safer and more effective use of medicines.' See: http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/index.html
- 5 WHO publication 'Equitable Access to Essential Medicines: A Framework for Collective Action', WHO, March 2004. http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.4.pdf
- 6 MDG Taskforce Report (2010), 'The Global Partnership for Development at a Critical Juncture', United Nations, New York. http://www.un.org/esa/policy/mdggap/mdggap2010/mdg8report2010_engw.pdf
- 7 Report of the Commission on Macroeconomics and Health from the Ministry of Health and Government Welfare, Government of India, p.74. <http://www.who.int/macrohealth/action/Report%20of%20the%20National%20Commission.pdf>
- 8 US Food and Drug Administration, 'Generic Competition and Drug Prices'. <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm>
- 9 <http://utw.msfacecess.org/background/challenges>
- 10 Medecins Sans Frontieres, 'AIDS Progress Under Siege; The Emergency is Far from Over'. http://utw.msfacecess.org/background/aids_progress_under_siege

See also: UK All-Parliamentary Group on AIDS, 'The Treatment Timebomb', July 2009. <http://www.aidsportal.org/repos/APPGTimebomb091.pdf>
- 11 'The Doha Declaration on the TRIPS Agreement and Public Health', November 2001. http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
- 12 The Thai Government issued three compulsory licenses in 2006 and 2007. On 26 January 2007, it issued compulsory licenses for the heart disease drug Clopidogrel (Sanofi-Aventis' Plavix) and for the HIV/AIDS drug, Lopinavir/Ritonavir (Abbott's Kaletra). On 29 November 2006, it issued a compulsory license for the HIV/AIDS medicine, Efavirenz (Merck Sharp and Dohme's Stocrin).

The Ministry of Public Health and The National Health Security Office, Thailand, 'The 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand', February 2007. <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf>

Upon issuing its compulsory licenses, Thailand came under severe pressure, both from rich countries, especially the U.S. and the EU, and from members of the pharmaceutical industry, particularly Abbott Pharmaceuticals which chose not to register seven medicines on the Thai market, including a heat-stable version of Kaletra, a key second line HIV and AIDS medicine. The decision to not register the seven medicines was done directly in response to the issuance of a compulsory license. In particular, Abbott stated that because the Thai government 'decided not to support innovation by breaking the patents, Abbott will not submit applications or register new medicines and will withdraw current applications in Thailand until the government changes its position'. See: <http://www.medicalnewstoday.com/articles/65274.php> (accessed January 2011)
- 13 See Lauren M, Niens et al, 'Quantifying the Impoverishing Effects of Purchasing Medicines: A Cross-Country Comparison of the Affordability of Medicines in the Developing World', Plos Medicine 2010 at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000333>
- 14 See K. Outterson and R. Smith (2006), 'Counterfeit Drugs: The Good, the Bad and the Ugly', Alb. L.J. Sci. & Tech., Vol. 16, p. 537-537 at <http://www.publicknowledge.org/pdf/acta/outterson-20061229.pdf>
- 15 WHO '45th Expert Committee on Specifications for Pharmaceutical Preparations', October 2010. <http://www.who.int/medicines/services/expertcommittees/pharmprep/43rdpharmprep/en/index.html>. However, adoption of this definition has not been confirmed with WHO as of the time of publication.

- 16 J.M Caudron *et al*, 'Substandard Medicines in resource-poor settings', August 2008.
http://www.msf.org.za/docs/ScientificDocs/TMIH2008_Vol13_substandards.pdf
- 17 Ibid.
- 18 European Commission, 'Public Health – Falsified Medicines'. http://ec.europa.eu/health/human-use/quality/fake-medicines/index_en.htm
- 19 In some cases, a falsely labelled product may be safe, even effective, but misrepresented as the product of a different, well-known manufacturer.
- 20 In some instances, errors in labelling are unintentional due to a production error. The definition of 'falsified medicine' in this paper does not apply to falsification that is not deliberate.
- 21 J.M Caudron *et al*, 'Substandard Medicines in resource-poor settings', August 2008.
http://www.msf.org.za/docs/ScientificDocs/TMIH2008_Vol13_substandards.pdf
- 22 US Pharmacopedia/USAID (2009), 'Survey of the Quality of Selected Anti-malarial Medicines Circulating in Madagascar, Senegal, and Uganda', WHO, <http://apps.who.int/medicinedocs/en/m/abstract/Js17069e/>
- 23 J.M Caudron *et al*, 'Substandard Medicines in resource-poor settings', August 2008,.
http://www.msf.org.za/docs/ScientificDocs/TMIH2008_Vol13_substandards.pdf
- 24 World Health Organization, 'Marketing Authorization of Pharmaceutical Products with Special Reference to Multi-Source Generic Products: A Manual for a Drug Regulatory Authority', WHO/DMP/RGS/98.5 (1999).
http://apps.who.int/prequal/info_general/documents/WHO_DMP_RGS_98_5_R.pdf
- 25 Rational use of medicines requires that 'patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community'. WHO, 'Rational use of medicines', 2010.
http://www.who.int/medicines/areas/rational_use/en/
- 26 Global Fund, 'List of countries considered as Stringent Regulatory Authorities (SRA) from 1 July 2009', Stop TB Partnership, July 2008.
http://www.stoptb.org/assets/documents/gdf/drugsupply/List_of_Countries_SRA.pdf
- 27 Congressional Research Service papers regarding the FDA regulation of medical products are available at <http://opencrs.com>
- 28 FDA Budget Reports can be found at:
<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/2009FDABudgetSummary/default.htm>. The 2010 Budget Request for the FDA, which requested additional funds to regulate medicine quality, can be found at:
<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/ucm153154.htm>
- 29 Randall Lutter, 'Counterfeit Drugs', US Food and Drug Administration, November 2005.
<http://www.fda.gov/newsevents/testimony/ucm112670.htm>
- 30 US Department of Justice, 'GlaxoSmithKline to Plead Guilty & Pay \$750 Million to Resolve Criminal and Civil Liability Regarding Manufacturing Deficiencies at Puerto Rico Plant', Civil Division Office of Public Affairs, October 2010. <http://www.justice.gov/opa/pr/2010/October/10-civ-1205.html>, Glaxo Smith Kline plc, 'GSK completes previously reported settlement with U.S. Department of Justice regarding former manufacturing plant', October 2010. http://www.gsk.com/media/pressreleases/2010/2010_pressrelease_10116.htm
- 31 US Department of Justice, 'Justice Department Recovers \$2.4 Billion in False Claims Cases in Fiscal Year 2009; More Than \$24 Billion Since 1986', November 2009. <http://www.justice.gov/opa/pr/2009/November/09-civ-1253.html>
- 32 WHO, 'Effective Medicines Regulation: Ensuring Safety, Efficacy and Quality - WHO Policy Perspectives on Medicines', November 2003. <http://apps.who.int/medicinedocs/en/d/Js4921e/>
- 33 WHO/AFRO publication, 'First African Medicines Regulatory Authorities Conference - Final Report', WHO Regional Office Africa, 2009. <http://www.afro.who.int/en/clusters-a-programmes/hss/essential-medicines/programme-components/medicines-regulation-and-quality-assurance-systems.html>
- 34 US Pharmacopedia/USAID, 'Survey of the Quality of Selected Antimalarial Medicines Circulating in Madagascar, Senegal, and Uganda', WHO, November 2009.
<http://apps.who.int/medicinedocs/en/m/abstract/Js17069e/>
- 35 Ibid.
- 36 Communication with Wilbert Bannenberg on November 30, 2010. See also WHO, Country Health System Fact Sheet Lesotho, 2006 at
http://www.afro.who.int/index.php?option=com_docman&task=doc_download&gid=1663
However, the WHO study erroneously adds together pharmacists and pharmacy technicians.
- 37 Communication with the Belize Ministry of Health on November 16, 2010.
- 38 World Health Organization, 'Assessment of medicines regulatory systems in sub-Saharan African countries: An overview of findings from 26 assessment reports' (2010) at www.afro.who.int accessed January 2011. See also S. Ratanawijitrasin *et al*, 'Effective Drug Regulation: A multi-country study' (2002) at www.who.int

- 39 Good Governance for Medicines, WHO, <http://www.who.int/medicines/ggm/en/index.html>
- 40 The Global Fund to Fight AIDS, Tuberculosis and Malaria (2010), 'Pharmaceutical Systems Strengthening and Pharmacovigilance Information Note' at: http://www.theglobalfund.org/documents/rounds/10/R10_InfoNote_Pharma_en.pdf
- 41 J.M Caudron *et al*, *Op. Cit.*
- 42 See ANVISA website, <http://www.anvisa.gov.br/eng/institution/introduction.htm>
- 43 ANVISA was created on the basis of Law 9.782 of January 26, 1999. For more information about ANVISA's objective and activities, and the legislative basis for its work, see <http://www.anvisa.gov.br/eng/institution/introduction.htm>
- See also: <http://www.anvisa.gov.br/eng/ombudsman/pharmacovigilance/results.pdf>
- 44 See information regarding the 'SNVS - Sistema Nacional de Vigilância Sanitária' at ANVISA website, <http://portal.anvisa.gov.br/wps/portal/anvisa/agencia>
- 45 Presentation by ANVISA, India-Brazil-South Africa Conference on Counterfeit Medicines, Geneva, October 2010.
- 46 See ANVISA mission statement at ANVISA website, <http://portal.anvisa.gov.br/wps/portal/anvisa/agencia>
- 47 Review legislation related to the promotion of generic competition at ANVISA website, <http://www.anvisa.gov.br/eng/legis/index.htm#3>
- 48 Presentation by ANVISA, IBSA Conference on Counterfeit Medicines, October 2010.
- 49 See http://www.msh.org/seam/country_programs/3.1.4b.htm#top
- 50 See a full description of programs at <http://www.tfd.or.tz/addoprogramme.php>
- 51 MeTA website. <http://www.medicinestransparency.org/>
- 52 Ibid.
- 53 Suzanna Hill *et al*. (2004), 'Emerging Challenges and Opportunities in Drug Registration and Regulation in Developing Countries', DFID. <http://www.dfidhealthrc.org/publications/atm/Hill.pdf>
- 54 For information on AMHRI, see the website of the regional office of the WHO for Africa (AFRO). <http://www.afro.who.int/en/clusters-a-programmes/hss/essential-medicines/highlights/2514-african-medicines-registration-harmonization-amrh.html>
- 55 The WHO Prequalification database can be found at: <http://www.who.int/topics/prequalification/en/>
- 56 USAID, 'Growing Threat of Substandard and Counterfeit Medicines in Developing Countries Addressed by New SAID-USP Cooperative Agreement', October 2009. http://www.usaid.gov/press/releases/2009/pr091026_1.html
- 57 The one effort to harmonize standards for medicines registration at levels that may be inappropriate for developing countries is the International Conference on Harmonization (ICH). ICH is an initiative by regulators from 17 countries to harmonize technical standards for medicines internationally. Started in 1990, the ICH has been criticized for failing to consider the appropriateness of certain proposals, which would harmonize standards at levels exceeding WHO standards, to the health needs and resources of developing countries. See www.ich.org
- 58 See, for example: 'US pulls out all the stops to fight counterfeits' at <http://www.fiercepharmamanufacturing.com/story/us-pulls-out-all-stops-fight-counterfeits/2010-12-15>. See also: 'States clash over anti-counterfeiting agreement', <http://www.theglobalipcenter.com/news/states-clash-over-anti-counterfeiting-enforcement>; and http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146191.pdf
- See also 'Positive aspects of IP Rights: Providing guarantees regarding the quality and safety of products', http://trade.ec.europa.eu/doclib/docs/2009/january/tradoc_142108.pdf; and 'The Anti-Counterfeiting Trade Agreement (ACTA) Fact sheet', January 2009, http://trade.ec.europa.eu/doclib/docs/2009/january/tradoc_142039.pdf.
- 59 At the WTO TRIPS Council, the US and EU have frequently cited their concerns with unsafe medicines as a reason for stricter intellectual property rules. See <http://economictimes.indiatimes.com/news/economy/foreign-trade/US-EU-cite-safety-issue-in-defence-of-piracy-law/articleshow/6065596.cms>. See also Jonathan Lynn, 'States clash over anti-counterfeiting enforcement', June 9, 2010 at <http://www.reuters.com/article/idUSLDE6582GO20100609> (accessed January 2011). The US has also mentioned concerns with unsafe medicines in many policy statements justifying strict IP enforcement. For example, see: http://www.dhs.gov/ynews/releases/pr_1277230118250.shtm and http://www.whitehouse.gov/sites/default/files/omb/assets/intellectualproperty/intellectualproperty_strategic_plan.pdf. See also statements made by the U.S. under the Special 301 Report. The EU, when explaining what it does to combat fake medicines, sites its provisions on border measures under EU Regulation 1383/2003. See http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146191.pdf
- 60 Using IP enforcement to target poor-quality and falsified medicines is an approach that is at once both over- and under-inclusive. This approach is over-inclusive in that, on the basis of an expansive definition of 'counterfeit', it can target legitimate generics of proven quality, safety and efficacy. It is under-inclusive in that it excludes safety and quality concerns with 'originator' products, which do not come under scrutiny because

- they are protected by IP. See Public Citizen, Submission to United States Intellectual Property Enforcement Coordinator in regards to FR Doc. 2010-3539, March 28, 2010.
- 61 Footnote 14, WTO Trade Related Aspects of Intellectual Property Rights (*TRIPS Agreement*).
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