

# 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.

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