



POLICY BRIEF



In the Initiative for
Supporting Strategic Leadership in Global Health
Diplomacy in East, Central and Southern Africa (1)
Brief produced by EQUINET: SEATINI. TARSC May 2011



Preventing substandard, spurious medicines and protecting access to generic medicines in Africa

Recent developments at national and international levels with regards to anti-counterfeiting legislation and actions have raised debate about such laws not undermining TRIPS flexibilities and access affordable generic drugs. At the same time, countries importing medicines seek measures to protect against substandard imports. The 2011 World Health Assembly resolved that a working group review WHO policy on counterfeit, falsified and substandard medicines, and its relationship with IMPACT. This policy brief addresses definitions of counterfeit, substandard and generic medicines, as fundamental to progress in such review. It points to the separate measures and mandates needed to combat firstly fraudulent trade mark and intellectual property (IP) infringement in counterfeit medicines by IP authorities, secondly to ensure that any anti-counterfeit measures protect TRIPS flexibilities, including for access to generic medicines; and thirdly to ensure that national drug regulatory authorities ensure that substandard medicines do not compromise health.

Debates and concerns over counterfeit and substandard medicines

In 1985 in Nairobi, a Conference of Experts on the Rational Use of Drugs considered, among other things, the role WHO could play in assessing the extent of counterfeiting. In 1988, a World Health Assembly (WHA) Resolution (41.16) called for WHO to initiate programmes to prevent and detect the export, import and smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations (Clift 2010). This led to the launch in 2006 of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT).

IMPACT: In February 2006, the WHO launched the International Medical Products Anti-Counterfeiting Taskforce to build coordinated networks across and between countries to halt the production, trading and selling of counterfeit medicines. It is a partnership comprised of all the major anti-counterfeiting players, including international organizations, non-governmental organizations, enforcement agencies, pharmaceutical manufacturers' associations and drug regulatory authorities. It includes representatives from: Interpol, Organization for Economic Cooperation and Development (OECD), World Customs Organization, World Intellectual Property Organization, World Trade Organization, International Federation of Pharmaceutical Manufacturers' Associations, International Generic Pharmaceuticals Alliance, World Bank, European Commission, Council of Europe, ASEAN Secretariat, International Pharmaceutical Federation, International Council of Nurses, World Medical Association, and Pharmaciens sans Frontières. IMPACT has five working groups in areas where action is needed to combat the spread of counterfeits: legislative and regulatory infrastructure, regulatory implementation, enforcement, technology and communication (Clift 2010)

Customs authorities in Germany and the Netherlands in 2008 and 2009 seized generic medicines that were mostly destined for Africa and Latin America from India. The seizures were done under the auspices of an EU regulation (1383/2003) introduced in 2003 that permitted action against goods infringing intellectual property rights, including goods in transit on the grounds that the medicines were suspected of infringing Netherlands intellectual property law, even though they were not patented in India nor the destination countries (Oxfam International and HAI Europe 2009). This sparked debate globally and concern that mixing counterfeit and generic medicines would undermine access to essential drugs, especially for poor people in low income countries (The Economist 2010).

This concern was heightened when anti-counterfeit laws proposed or enacted in East Africa seemed to not make a distinction between generic drugs and counterfeits, eroding the gains that developing countries have achieved under the TRIPs negotiations at the World Trade Organisation (WTO). For example the Kenyan Anti Counterfeit Act of 2008 has been challenged in a constitutional court for threatening the importation or manufacturing of cheap generic medicines, thus denying Kenyans their constitutional right to life. This is because of a wide definition of counterfeiting as, "*(t)aking the following actions without the authority of the owner of any intellectual property right subsisting in Kenya or elsewhere in respect of protected goods, (such as) the manufacture, production, packaging, re-packaging, labelling or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods*" that does not specifically exclude generic medicines (Médecins Sans Frontières 2008).

Brazil, India and other low and middle income producer countries raised these issues at the WHO Executive Board meeting in January 2009 and at a meeting of the WTO TRIPs Council in 2009. At the 63rd WHO World Health Assembly in May 2010, member states noted that counterfeiting, an infringement of intellectual property laws, was being mixed with issues of substandard medicines, and that counterfeit laws were being used as a barrier to generic medicines. Member states resolved that the Director General (DG) establish a working group to review WHO policy on counterfeit, falsified and substandard medicines, and review its relationship with IMPACT (WHO Resolution WHA63(10) 2011).

At the same time, countries importing medicines, such as many in Africa, remained concerned at what measures would be put in place to protect against substandard medicines. Substandard medicines are a problem in Africa. A recent WHO survey found for example that almost 30% of sampled anti-malarial medicines from Cameroon, Ethiopia, Ghana, Kenya, Nigeria and Tanzania failed to meet international quality standards. Many medicines had not been registered with the national medicines regularity authority, suggesting that the pharmaceutical market in Africa may be "vulnerable to penetration by products whose properties are unknown." (WHO AFRO 2010)

There are thus four issues at stake: How to regulate and prevent the deliberately illegal infringement of intellectual property rights in counterfeit products; secondly how to regulate and ensure that imported or produced drugs are not substandard; and thirdly how to ensure that measures for dealing with counterfeits and substandard medicines do not compromise implementation of the TRIPs flexibilities and access to generic medicines. A fourth issue, WHO's relationship with IMPACT is important but not covered in this brief.

Counterfeits, substandard medicines and generics

To date the working group set up at the 2010 WHA has met once in February/ March 2011. This meeting highlighted the divergent views amongst members. One area of contention was in agreeing on a standard and universally acceptable definition of counterfeit medicines.

The concepts counterfeit and substandard medicines are not interchangeable. Counterfeit medicines are products that are presented in such a way as to look like a legitimate product although they are not that product. In legal terms and under Article 51 of the TRIPs Agreement, this is a trademark infringement. They are the result of deliberate criminal activity and infringement of patent law. In 2010 WHO defined counterfeit medicines as "*... deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.*" (WHO 2010), Counterfeit medicines may include contents that range from harmful toxic substances to inactive, ineffective preparations, both of which can lead to treatment failure and possibly death. In every case, the source is unknown, its content unreliable and it is always illegal. (WHO, 2011).

Substandard products do not meet the standards or quality set by the relevant authority. While these may be genuine medicines produced by legitimate manufacturers, they do not meet the quality specifications that the producer defines (WHO, 2005). They are not the same as counterfeits in that they are not the result of deliberate criminal activity, but they may lead to treatment failure and possibly death.

Generic drugs, are legitimately produced medicines that are the same as original brand name products with the same active ingredients but that are manufactured “without a licence from the innovator company and marketed after the expiry date of the patent or other exclusive rights” (www.who.int/trade/glossary/story034/en/index.html). The Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement provides in Article 31 that countries may make national laws that allow them to grant licenses to other producers for the production of a patented medicine if the patent owner cannot provide it at a reasonable price or in sufficient quantities. The agreement also offers authority for government-use order and parallel importation. Because generics are in general a lot cheaper than patented products, they have played a role in widening access to essential medicines. They are neither counterfeit nor substandard.

Counterfeits, generic medicines and intellectual property rules

African and other developing countries fought very hard at the WTO TRIPs negotiations to find a permanent solution to the public health problems associated with access to essential medicines especially for the treatment of HIV/AIDS, malaria and TB. The 2001 WTO ministerial meeting in Doha, Qatar produced a declaration which provided that the TRIPs Agreement “*can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, access to medicines for all.*” (Article 4). This gave the countries the authority to use flexibilities in the TRIPs Agreement in the interest of public health. These flexibilities include, among others:

- Providing for **compulsory licensing** or the right to grant a license, without permission from the license holder, on various grounds including public health
- Providing for **parallel importation** or the right to import products patented in one country where the price is less
- Providing for early working, known as the Bolar Provision, allowing generic producers to conduct tests and obtain health authority approvals before a patent expires, making cheaper generic drugs available more quickly at that time (Musungu et al 2004).

This landmark decision by the WTO membership, the same member states as in WHO, gives legal authority for the production of generic drugs within the precincts of rules set. A further provision in 2003 (termed the ‘Paragraph 6’ system), allowed countries to export medicines to countries without manufacturing capacity, if the latter had issued a compulsory licences for them. While the amendment of the TRIPs Agreement by WTO members, as agreed in 2005, is yet to take effect, a number of countries have now used the flexibilities to increase access to medicines, moreso parallel importation than compulsory licensing.

Given this background, there is need to draw a line between counterfeit medicines, produced as an infringement of IP laws, from generic medicines, produced and exported/ imported under the TRIPs flexibilities. Counterfeit laws should in their legal definitions exclude generic medicines covered by the flexibilities for public health provided in patent law.

Counterfeits and substandard medicines

Strengthening the national drug regulatory authorities and pharmacovigilance offers one of the best policy options for dealing with medicines that are substandard or falsified, and IP and port authorities should not diminish or replace the role of national drug regulatory authority in dealing with all matters to do with falsified, substandard medicines. Countries need to ensure the quality, efficacy and safety of drugs, beyond the IP issues covered in the TRIPs agreement, and to ensure that the medicines exported or imported are not substandard. These issues are dealt with through national Medicines Regulatory Authorities. The necessary global guidance, resources and national laws should be put in place to

ensure that countries have the legal mandate, autonomy and institutional capacity in their regulatory authorities to ensure compliance with standards of quality, safety and efficiency; and to effectively control the manufacture and distribution of substandard, spurious, falsely labelled, medical products and, together with port authorities, their import and export.

Counterfeit laws should thus not seek to take over national drug regulatory authorities roles in ensuring safety, quality and efficacy. Port authorities should work with the drug regulatory authority in ascertaining if imported drugs are substandard, and seek court orders to seize products alleged to be substandard on the basis of information provided by the drug regulatory authority.

Next steps

The May 2011 WHA will consider the issue and the work of the working group. Member states, and particularly those from Africa, will need to ensure that solutions such as use of TRIPs flexibilities to allow for the manufacture and importation of cheaper generic drugs are not renegotiated at WHO. South-South alliances forged by African countries with emerging economies like Brazil, India and China with regards to the manufacture of generic drugs will be important for ensuring vigilance on maintaining and implementing TRIPs flexibilities.

At the same time, countries need to ensure that substandard medicines are not produced, exported or imported, and to recognise the public health consequences of this. Separate to debates on IP protection, the same alliance should support African countries, who are the main importers of medicines, to focus working group and Assembly outputs on the global guidance, mechanisms and resources needed by drug regulatory authorities and for pharmacovigilance.

While the review of IMPACT activities is not covered in this brief, it would need to be done taking into account such principles, understanding of counterfeit, substandard and generic medicines and separation of issues and mandates.

Further information and resources

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Author: R Machedmedze Technical edit: R Loewenson, Peer review: P Nyagura
Produced May 2011 with support from Rockefeller Foundation

Cite as: SEATINI (2011) Preventing substandard, spurious medicines and protecting access to generic medicines in Africa Policy brief, EQUINET, ECSA HC Harare