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## Preventing substandard, falsified medicines and protecting access to generic medicines in Africa

*Anti-counterfeiting laws and actions have raised concern about such laws and actions not undermining the flexibilities in the World Trade Organisation TRIPS agreement to protect access to affordable and generic medicines. At the same time, importing countries need measures to protect against substandard imported drugs. The 2011 World Health Assembly resolved that a working group review World Health Organisation (WHO) policy on counterfeit, falsified and substandard medicines, and WHO's relationship with IMPACT. This policy brief defines counterfeit, substandard and falsified medicines. It points to the separate measures and mandates needed to combat each: for dealing with fraudulent trade mark and intellectual property (IP) infringement in counterfeit medicines by IP authorities, for ensuring that any anti-counterfeit measures protect TRIPS flexibilities, including for access to generic medicines; and for national drug regulatory authorities to ensure that substandard and falsified 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, WHO's role in assessing the extent of counterfeiting of medicines. In 1988, a World Health Assembly (WHA) Resolution (41.16) called for WHO to initiate programmes to detect and prevent the export, import and smuggling of falsely labelled, spurious, counterfeited or substandard medicines. In 2006, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) was launched. In 2008 and 2009, customs authorities in Germany and the Netherlands seized generic medicines from India that were mostly destined for Africa and Latin America. The seizures were done under the auspices of a 2003 EU regulation (1383/2003) that permitted action against goods infringing intellectual property rights, including goods in transit, if the medicines were suspected of infringing Netherlands intellectual property law, even if they were neither patented in India nor the destination countries (Oxfam International and HAI Europe 2009). This sparked debate and concern that confusing counterfeit with generic medicines could undermine access to essential drugs, especially for poor people in low income countries.

This concern was further increased when anti-counterfeit laws proposed or enacted in East Africa seemed to not make a

**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)

distinction between generic drugs and counterfeit medicines, eroding the gains that developing countries have achieved



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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 manufacture or importation of lower cost generic medicines, thus denying Kenyans their constitutional right to life. This interpretation arises due to a wide definition of counterfeiting in the Act 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”*. This does not specifically exclude generic medicines.

Brazil, India and other middle and low 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 and falsified medicines, and that counterfeit laws were posing a barrier to access 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 its relationship with IMPACT (Resolution WHA63(10) 2011).

At the same time, countries importing medicines, including many in Africa, were still concerned to have measures that would protect against the substandard medicines that pose 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 of these sampled medicines had not been registered with the national medicines regulatory 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 deliberate illegal infringement of intellectual property rights in counterfeit products;
- How to regulate and ensure that imported or produced drugs are not substandard;
- 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, and fourthly,
- WHO’s relationship with IMPACT. This last issue is important but not covered in this brief.

### **Counterfeits, substandard medicines and generics**

At the time of printing this leaflet the working group set up at the 2010 WHA had met once in February/ March 2011. The meeting raised divergent views on the issue, including 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 labelled 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),

While the contents of counterfeit medicines may or may not include harmful toxic substances or inactive, ineffective preparations, as a trademark infringement, their source is always unknown, and thus information on their content unreliable. This is always illegal. Substandard products do not meet the standards or quality set by the relevant authority. They may be genuine medicines produced by legitimate



manufacturers, but do not meet the quality specifications that the producer defines. They are not the result of deliberate criminal activity, although they may lead to treatment failure or death. Falsified medicines may falsely represent their contents, without misrepresenting their source or identity (WHO 2005, 2011).

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. 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, and also provides measures to facilitate access to generic medicines, such as government-use order and parallel importation. Because generic medicines are in general 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.

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, and 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 national drug regulatory authorities and improving 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 the 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, and these should have the legal mandate, autonomy and institutional capacity to ensure compliance with standards of quality, safety and efficiency; to prevent and control the manufacture



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and distribution of substandard, spurious, falsely labelled, medical products and, together with port authorities, to block their import and export.

Counterfeit laws should thus not seek to take over this role of national drug regulatory authorities 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 WHO Working Group requested the 64th meeting of the World Health Assembly (WHA) in May 2011 to consider extending the period set out in WHA63(10) in order to allow the Working Group to complete its work after engaging in further deliberations. The WHA agreed to extend the period of the working group to allow the member states to narrow their differences..

As they engage in further deliberations on this issue, 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.

The review of IMPACT activities is not covered in this brief. Most developing countries have, however, welcomed the fact that IMPACT has moved out of the WHO premises and is now operating from Italy. This is a step to ensuring the separation of intellectual property matters from the discussion on substandard drugs, and the adoption of a universally agreed definition of counterfeit medicines.

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