



## **Patients first: access to safe, quality and effective drugs**

The forthcoming 63<sup>rd</sup> World Health Assembly (WHA) will discuss 'counterfeit medical products'.

When drawing up policy recommendations on this issue, it is essential that Member States adopt measures that address public health problems and that counter-productive and harmful solutions are not adopted out of confusion. Yet recent interventions in this domain have centred on applying an intellectual property (IP) framework – that of trademark counterfeiting – to address what is fundamentally a public health problem. Relying on measures that merely enforce intellectual property is a poor framework for protecting public health. This approach has skewed the response to the fake medicines, and has led to inappropriate and harmful solutions being promoted that fail to ensure patients have access to safe, quality and effective medicines and create barriers to access to medicines.

Before addressing potential solutions, three often overlapping but distinct problems need to be borne in mind.

The first aspect is the deliberate falsification of medicines. Fake medicines are those that are deliberately and fraudulently mislabelled, giving a false representation of identity and/or source, so that people will think they are legitimate medicines. They may have incorrect or correct amounts of ingredients or wrong ingredients altogether. In addition, fraud in the area of medicines also occurs when companies are marketing products making false claims regarding medical properties and engage in deliberate suppression of data.<sup>1</sup> Trade in fake medicines is encouraged when quality affordable medicines are not available and where pharmaceutical circuits are not secured.

The second aspect is the question of poor quality or substandard medicines. Substandard medicines are genuine drugs produced by legitimate originator and generic manufacturers, which do not meet the standards set for them with regards to quality, strength, purity and packaging. These problems are in general linked to a lack of expertise and inadequate production infrastructure affecting adherence to international Good Manufacturing Practice standards.

Although distinct, both problems of substandard medicines and fake medicines need to be addressed as a public health problem. Médecins Sans Frontières (MSF) has witnessed first-hand the problems of fake medical products and when we find them we report them.<sup>2</sup> At the same time MSF experience from over 70 countries indicates that substandard medicines are by far the more widespread public health problem in the developing countries in which we work.<sup>3</sup>

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<sup>1</sup> Pharma Fraud. See wikipedia definition. [http://en.wikipedia.org/wiki/Pharma\\_Fraud](http://en.wikipedia.org/wiki/Pharma_Fraud)

<sup>2</sup> Pécoul B., Chirac P., Trouiller P., Pinel, J. (1999) Access to essential drugs in poor countries. A lost battle? JAMA, 281: 361-367.

<sup>3</sup> J.-M. Caudron, N. Ford, M. Henkens, C. Mace, R. Kiddell-Monroe and J. Pinel. Substandard medicines in resource-poor settings: a problem that can no longer be ignored. Trop Med and Int Health, Vol. 13 no 8 pp

The true extent of the problem of fake medicines is unknown.<sup>4</sup> Purported data conflate various terms (substandard, counterfeit etc) and thus give a wrong impression about the size of the problem. It is important for countries to review data and focus policy efforts and resources on the public health problems they face with regards to substandard and fake medicines. Many national legislations already have provisions that allow authorities to take actions against fake drugs but drug regulatory agencies remain weak in many countries (see below).

The third aspect is the broader policy context of both health and economic interests that impact on access to medicines. Here, conflicting interests are at stake. Genuine drug manufacturers want to sell safe medicines; they have a business interest to fight fake medicines because a fake harms the reputation of the genuine product. Brand name companies also have an interest to limit generic competition through increased intellectual property enforcement. Conflicting interests also exist within Western governments as health ministers concerned about medicines safety may diverge from trade ministers focused on promoting trade interests, in particular through increased IP enforcement.

In such a context, the concern about fake medicines has regrettably been used to promote trade agendas and divert attention where action is most needed to ensure patients receive safe, effective and quality drugs, in particular in the strengthening of pharmaceutical market regulation and control by the national drug regulatory agency. Some of the recent measures designed to fight against counterfeits, including domestic legislation in some WHO Member States, have been shown to be directly harmful to access to medicines (see below).

### **Definitions**

At the core of the problem is the use of the overly-broad term 'counterfeit medicines', which is creating confusion. Overbroad definitions of counterfeit medicines conflates IP issues with public health problems. Adopting such definitions can prevent countries from taking measures to protect access to safe and affordable medicines. As such, it is useful here to state what should not be considered as counterfeit:

**Counterfeits and trademarks.** The term counterfeit is defined in the TRIPS Agreement in the context of trademarks, which are a form of intellectual property concerning the use of brand names, logos, packaging, etc.

Under TRIPS, countries are obliged to criminalise wilful cases of trademark counterfeiting on a commercial scale. But the World Trade Organization notes that "trademark counterfeiting" is different from "trademark infringement" and that this difference needs to be acknowledged in measures to fight against counterfeiting - this means that trademark infringement disputes when companies may contest that competitors are using over-similar names or packaging cannot be considered as trademark counterfeiting.<sup>5</sup>

Civil trademark disputes will likely remain a common occurrence in the pharmaceutical field as companies will often choose brand names for medicines that sound inevitably similar, in that they are derived from the drug's international non-

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1062-1072 August 2008. Available from: [http://www.msfacecess.org/fileadmin/user\\_upload/key-publication/Trop\\_Med\\_and\\_Int\\_Health\\_vol\\_13\\_Substandard%20Meds.pdf](http://www.msfacecess.org/fileadmin/user_upload/key-publication/Trop_Med_and_Int_Health_vol_13_Substandard%20Meds.pdf)

<sup>4</sup> Medicines: Counterfeit Medicines. World Health Organization Factsheet. Available at: <http://www.who.int/mediacentre/factsheets/fs275/en/>

<sup>5</sup> For a discussion of the distinction between civil and criminal aspects of trademark disputes and its relevance to medicines, see Public Citizen Comments to the Office of the United States Intellectual Property Enforcement Coordinator, Peter Maybarduk for Public Citizen, 29 March, 2010, *available at*: <http://www.wcl.american.edu/pijip/go/maybarduk03282010>;  
Also see: Defining 'Counterfeit Medicines' from the Perspective of Public Health. WHO SEARO 2008

proprietary name (INN). Likewise, as originator pharmaceutical companies are increasingly seeking trade dress<sup>6</sup> protection on various non-functional aspects of medicines, such as pill colour and shape, civil disputes over such matters will continue to arise.

Regardless of whether such disputes are ultimately found to infringe a valid trademark in civil litigation proceedings (and companies have the right to pursue these problems in the court), they are not the basis on which to define if a medicine is counterfeit or not. However, adopting an overly-broad definition that would consider such factors as similar name, colour or shape as proof of counterfeit would likely hinder access to legitimate, safe, effective and affordable generic medicines.

In addition, while criminal trademark counterfeiting is part of the problem of fake medicines, it does not cover other very important aspects of faking, such as using incorrect amounts of active pharmaceutical ingredients, or using the wrong ingredients altogether.

**Counterfeits and patents.** Patents have nothing to do with counterfeit. It is therefore important, as with civil trademark infringements, that patent infringements are never considered counterfeit and are removed from the ambit of any proposed anti-counterfeiting legislation.

### **The impact of over-broad definitions of 'counterfeit' on access to medicines<sup>7</sup>**

The dangers of over-broad definitions are illustrated by the recent use of customs regulations in the EU, originally introduced to combat trademark infringements, but which have since been expanded to cover other IP infringements, including patent infringements, all in the name of medicines safety.

These rules have in fact prevented the timely access to life-saving medicines. For example, several shipments of generic medicines being shipped from India to Brazil, Colombia, Ecuador, Peru, Venezuela, Mexico and Nigeria (procured by international drug purchasing agency UNITAID) have been detained whilst in transit in the Netherlands, on the grounds of patent infringement in the EU. The logistical operations of MSF and other humanitarian agencies, which consolidate procurement supplies in the EU en route to other countries, could be harmed by customs officials' enforcement of this type of regulation.

Because it relies on overly-broad definitions, the Kenya 2008 Anti-Counterfeit Act also risks that legally manufactured generic medicines of approved quality may erroneously be interpreted as counterfeit goods. The Act thus has the potential to seriously endanger access to generic medicines, such as those used by MSF and other treatment providers in Kenya. Public health groups are now seeking a judicial review on the grounds that the legislation contravenes their 'right to life' under the Kenyan Constitution. It is critical that the Act be revised.<sup>8</sup>

Similar legislation is under consideration in Uganda (reportedly with funding by the EU)<sup>9</sup> and at the regional East African Community level, and national legislation is also expected to be tabled in other countries.

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<sup>6</sup> Trade dress is a legal term of art that generally refers to characteristics of the visual appearance of a product or its packaging (or even the design of a building) that signify the source of the product to consumers. Trade dress is a form of intellectual property.

<sup>7</sup> For further analysis of these issues, see Public Citizen's documents on enforcement at [www.citizen.org](http://www.citizen.org)

<sup>8</sup> Fatal Flaws: How Kenya's 2008 Anti-Counterfeit Act could endanger access to medicines. MSF March 2010. [http://www.msfastcess.org/resources/key-publications/key-publication-detail/index.html%3ftx\\_ttnews%5Btt\\_news%5D=1602&cHash=60c0ded677](http://www.msfastcess.org/resources/key-publications/key-publication-detail/index.html%3ftx_ttnews%5Btt_news%5D=1602&cHash=60c0ded677)

<sup>9</sup> EU Implicated in Controversial Counterfeiting Bill. The Lancet. Volume 375, Issue 9723, Page 1335, 17 April 2010 <http://www.thelancet.com/journals/lancet/article/PIIS0140673610605600/fulltext?rss=yes>

In addition, a variety of other initiatives exist.<sup>10</sup> The secretive Anti-Counterfeiting Trade Agreement (ACTA) is currently being negotiated by a number of countries, outside the United Nations multilateral institutions. Its title is misleading as it does not just apply to counterfeits but it seeks to create a common standard for enforcement for all IP rights. The intention is to complete negotiations by the end of 2010. Once agreed, there will be a push to get other countries to join even though they have not been part of the negotiations.

After concerns about lack of transparency, it has finally been agreed to release official versions of the text on 21 April 2010.<sup>11</sup> MSF is concerned that key elements under discussion concerning injunctions, border measures, criminal penalties and enforcement practices may obstruct and deter legitimate generic competition.<sup>12</sup> All the provisions of the agreement must be reviewed to ensure that they do not have such an effect, and public interest groups must be provided with open and transparent means to provide their views to negotiators.

### **What is WHO's role?**

As the leading agency for health, WHO's various interventions to fight against fake and substandard medicines must focus on public health concerns.

The first of these interventions is norm-setting. Norm-setting in the area of medicines is the mandate of WHO and its Member States, and a definition of the public health problems of fraud in the area of medicines must be established. WHO must ensure that its work in this area is determined by public health concerns only. For this reason, the International Medical Product Anti-Counterfeit Taskforce (IMPACT) creates concern. Created in 2006, it includes various stakeholders, including the private sector, but lacks a mandate from WHO's governing bodies and presents serious conflicts of interest. WHO is hosting IMPACT and documents carry both WHO and IMPACT logos; this has created confusion between the work of WHO and IMPACT.

While WHO needs to distance its work from an IP enforcement agenda, it must provide technical advice to those Member States and institutions that have or are seeking to introduce general IP laws, to avoid threatening access to medicines. WHO must speak out against the threats posed to public health and access to medicines in general and to generics in particular, from overly-broad definitions of counterfeit goods in domestic legislation.

Finally, WHO and other agencies must strengthen activities to increase the capacity of national regulatory agencies to address issues of substandard medicines, including fake medicines. Approximately 20% of countries have fully operational medicines regulatory bodies while 30% have either no or very limited regulation capacity.<sup>13</sup> Member States must address the root problem of lack of adequate human and financial resources that hampers regulatory capacity – it is wrong to focus efforts solely on strengthening customs, when all the pharmaceutical circuit (from drug regulatory authorities to pharmacies) needs reinforcing.

Regulatory agencies need mechanisms for enforcement when fake medicines are detected. But enforcement without adequate regulatory capacity can be

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<sup>10</sup> See for example the Council of Europe's proposed Medicrime Convention, [http://www.coe.int/t/DGHL/StandardSetting/MediCrime/Default\\_en.asp](http://www.coe.int/t/DGHL/StandardSetting/MediCrime/Default_en.asp)

<sup>11</sup> Joint Statement on Anti-Counterfeiting Trade Agreement. European Commission - Trade. <http://trade.ec.europa.eu/doclib/press/index.cfm?id=550>

<sup>12</sup> Public Citizen comments to U.S. Intellectual Property Enforcement Coordinator. March 2010. <http://www.wcl.american.edu/pijip/go/maybarduk03282010>

<sup>13</sup> Effective medicines regulation: ensuring safety, efficacy and quality. WHO Geneva 2003. <http://apps.who.int/medicinedocs/pdf/s4921e/s4921e.pdf>

counterproductive, as enforcement agencies do not have competencies to assess drug quality.

**In light of the upcoming World Health Assembly, Médecins Sans Frontières therefore urges:**

- That the term 'counterfeit medicines' be abandoned to reduce current confusion and be replaced with a definition of the public health problems of fraud in the area of medicines, for example under the term fake medicines. A clear definition of the problem of fraud in the area of medicines can provide adequate grounds for actions by WHO and other agencies in this area, including international enforcement actions targeting criminal operations producing fake medicines.
- WHO to develop reliable, impartial empirical data on the prevalence of a variety of safety problems including substandard and fake medicines. This data can then inform rational decision on the allocation of public resources and to define the actions necessary.
- WHO to establish an independent process for providing guidance on appropriate measures to tackle fake medicines. WHO must clearly separate its activities and documents from IMPACT.
- Companies to be required to disclose information concerning potentially dangerous fakes of which they are aware.
- Member States to increase significantly the political priority given to improving national regulatory capacity to address substandard and fake medicines. The root problem of lack of human and financial resources must be tackled urgently. In addition, WHO's Prequalification Programme is a benchmark for the identification of quality essential medicines and has significantly improved access to quality HIV/AIDS, tuberculosis and malaria medicines over the past years. WHO and Member States must support its work.
- WHO and Member States to pursue measures that increase access to medicines as a core part of measures to tackle the trade of fake medicines. Trade of fake medicines is encouraged when quality affordable medicines are not available. If people had systematic access to affordable, effective medicines of assured quality, those engaging in fraudulent activities would have little space to operate.
- Member States to not pursue TRIPS+ intellectual property enforcement agendas. TRIPS+ agendas negatively impact access to affordable generic medicines.
- Member States to not compromise access to generic medicines through enforcement measures. New legislation is only warranted when public agencies are not yet empowered to take action against the problem of fake drugs. When introducing new legislation, anti-abuse provisions should be included in order to protect against the risk of overzealous enforcement that may endanger access to medicines.
- WHO to provide technical advice to those countries and institutions that have introduced or are seeking to introduce general intellectual property rules to avoid negative effects on access to medicines, including the removal of patents and civil trademark infringements in anti-counterfeits rules and measures. The discussion paper by SEARO region provides a useful first step on such advice.<sup>14</sup>

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<sup>14</sup> Defining 'Counterfeit Medicines' from the Perspective of Public Health. WHO SEARO 2008.

- WHO to speak out strongly against legislation or other measures that establish harmful barriers to trade in and availability of legitimate generic medicines.