



## **FATAL CONFUSION**

### **How Kenya's 2008 Anti-Counterfeit Bill endangers access to medicines**

#### **A Médecins Sans Frontières briefing document**

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*The draft 2008 Anti-Counterfeit Bill must urgently be amended, if Kenyan patients are to continue accessing quality medicines at affordable prices.*

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MSF began treating people living with HIV/AIDS with antiretroviral (ARVs) medicines in Kenya in the end of 2001. MSF currently treats 140,000 patients in 27 countries, including Kenya.

MSF is able to treat PLHA in Kenya because it can access quality generic medicines at affordable prices.<sup>1</sup> For instance, MSF uses a generic fixed-dose combination of stavudine + lamivudine + nevirapine for first-line treatment which costs US\$ 109 per patient per year, when the same triple therapy available from patent-holding originator companies costs US\$ 331.<sup>2</sup>

Although a number of ARVs are protected by patents in Kenya,<sup>3</sup> importation of more affordable generic versions of ARVs has been possible through the use of a public health provision of the 2001 Industrial Property Act (Section 58.2 of 2001 IP & Regulation 37 of 2002 Industrial Property Regulations).

This pro-public health provision has come under attack several times since 2001 through legislative measures such as amendments in Parliament. Civil society in Kenya has always followed these closely and has succeeded in protecting the flexibilities that exist.

Today, access to quality affordable generic medicines is once again under threat with the draft 2008 Anti-Counterfeit Bill. The Bill risks putting an end to the importation or production of quality affordable generic medicines in Kenya.

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<sup>1</sup> ARVs used in MSF projects have all been prequalified under the WHO Prequalification Project or validated internally by MSF's own quality validation system.

<sup>2</sup> See Untangling the Web of Antiretroviral Prices. 11<sup>th</sup> Edition, Médecins Sans Frontières, July 2008, p.49. Accessible at <http://www.accessmed-msf.org/main/hiv-aids/untangling-the-web-of-antiretroviral-price-reductions-11th-edition/>

<sup>3</sup> See "Drug Patents under the Spotlight – Sharing practical knowledge about pharmaceutical patents", Médecins Sans Frontières, June 2004, pp.30-31. Accessible at: [http://www.accessmed-msf.org/fileadmin/user\\_upload/medinnov\\_accesspatents/Drug%20patents%20under%20the%20spotlight\\_UK.pdf](http://www.accessmed-msf.org/fileadmin/user_upload/medinnov_accesspatents/Drug%20patents%20under%20the%20spotlight_UK.pdf)

## **The Bill's definition of counterfeiting is misguided**

The objective of the 2008 Anti-Counterfeit Bill, submitted to the Parliament of Kenya, is “to prohibit trade in counterfeit goods, to establish the Anti-Counterfeit Agency, and for connected purposes”.

Section 2 of the Bill defines counterfeiting 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— (a) 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 definition of “counterfeiting” is much wider than other existing definitions. As such, it would likely include under the definition of ‘counterfeits’ legally manufactured generic medicines of approved quality, such as generic medicines prequalified under the World Health Organization Prequalification Programme<sup>4</sup> - such as some of the very ones imported by MSF to treat people living with HIV/AIDS in Kenya.**

The World Health Organization (WHO) defines a counterfeit medicine as “a medicine, which is deliberately and fraudulently mislabelled 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.”<sup>5</sup>

Similarly, the European Union defines counterfeit goods as “goods, including packaging, bearing without authorization a trademark identical to the trademark validly registered in respect of the same type of goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the trademark-holder's rights.”<sup>6</sup> The World Trade Organization's agreement on intellectual property rights (TRIPS) includes a similar definition of counterfeit trademark goods.<sup>7</sup>

According to these three definitions, counterfeiting results mainly from a trademark infringement, where the counterfeiter deliberately and fraudulently aims at confusing the source or identity of the counterfeit good. In other words, counterfeiting can target generic products in exactly the same way as products under patent, as WHO's definition notes.

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<sup>4</sup> <http://healthtech.who.int/pq/>

<sup>5</sup> [http://www.who.int/impact/impact\\_q-a/en/index.html](http://www.who.int/impact/impact_q-a/en/index.html)

<sup>6</sup> Article 2(a) of Council Regulation EC No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:196:0007:0014:EN:PDF>

<sup>7</sup> Footnote 14 of TRIPS Article 51: “counterfeit trademark goods” shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation.

But in Kenya's 2008 Anti-Counterfeit Bill, there is a risk that all generic products could fall under the definition of counterfeiting, when counterfeits are described as "substantially similar copies of the protected goods." Adopting the Bill could thus mean banning the importation of generic versions of medicines patented in Kenya. The consequences on access to life-saving medicines such as the antiretrovirals nevirapine or lamivudine, for example, both patented in Kenya, and on the sustainability of AIDS and other treatment programmes that rely on generic production or importation would be devastating.

### **Counterfeit and substandard medicines: distinct problems that require distinct solutions**

Like other actors in the field of public health, MSF teams are faced with the problem of medicines that do not meet international standards for quality, in many countries where we work.<sup>8</sup>

According to the WHO, 'substandard drugs are genuine drug products which do not meet quality specifications set for them.' Similarly, the United States Pharmacopoeia defines a substandard product as a 'legally branded or generic product, but one that does not meet international standards for quality, purity, strength or packaging'.<sup>9</sup>

However acute the problem of counterfeit medicines, poor quality drugs with detrimental consequences on public health result mainly from **substandard**, rather than **counterfeit** medicines. Indeed Médecins Sans Frontières has recently highlighted the dangers of confusing the two issues:

"Substandard medicines represent a far larger risk to public health than counterfeit medicines. However, with some exceptions, substandard and counterfeit drugs are regularly conflated and confused.... Determining whether a medicine is counterfeit is problematic, yet the few published reports that did differentiate between the two problems have found that **the majority of poor quality drugs were genuine, but substandard drugs, and not the result of counterfeiting....** Because substandard drugs are frequently portrayed as a consequence of counterfeiting, it is hardly surprising that the majority of international attention and action is directed at the latter. This is partly because counterfeit drugs undermine the markets of pharmaceutical companies who put significant energy into tackling the problem".<sup>10</sup>

Fighting against counterfeit drugs alone through legal actions entirely fails to address the issue of genuine (i.e. non-counterfeit) but substandard medicines. The focus of attention should rather be on the detection and removal of poor quality medicines, whether they are counterfeit or not, while at the same time assisting legitimate manufacturers to improve the quality of their pharmaceutical production.

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<sup>8</sup> J.-M. Caudron, N. Ford, M. Henskens, C. Mace, R. Kiddell-Monroe and J. Pinel, *Substandard medicines in resource-poor settings: a problem that can no longer be ignored*. Tropical Medicine and International Health, volume 13 no 8 pp 1062–1072 August 2008.

[http://fieldresearch.msf.org/msf/bitstream/10144/37334/1/Caudron\\_substdmeds\\_TMIH2008.pdf](http://fieldresearch.msf.org/msf/bitstream/10144/37334/1/Caudron_substdmeds_TMIH2008.pdf)

<sup>9</sup> Smine A (2002) Malaria Sentinel Surveillance Site Assessment. Mekong Region. United States Pharmacopoeia, Rockville, MD.

<sup>10</sup> Ibid 8.

Intellectual property rights (including patents, trademarks, copyright,) are clearly distinct from quality control issues when related to medicines. In its current form, the 2008 Anti-Counterfeit Bill confuses these issues in such a manner that it is difficult to distinguish one from the other. As such, legally manufactured and/or imported generic medicines of approved quality may be erroneously interpreted as counterfeits because of the provisions of this Bill.

Trade in counterfeit medicines is encouraged when quality affordable medicines are not available. If people cannot afford the medicines they need, or if they are not available, they tend to seek relief in the informal circuit. Expensive products are more attractive to potential counterfeit manufacturers than affordable products.<sup>11</sup> One effective measure to combat counterfeiting is to ensure the availability of quality drugs at affordable prices.

## **Conclusions**

- **By erroneously extending the definition of counterfeit products to potentially include legally-manufactured generics, the 2008 Anti-Counterfeit Bill risks banning the importation of and hindering access to life-saving essential medicines, such as those used by Médecins Sans Frontières to treat people living with HIV/AIDS**
- **By confusing the issues of counterfeit medicines and substandard medicines, the 2008 Anti-Counterfeit Bill is attacking the wrong problem and does nothing to improve the quality of medicines, which is a far greater public health problem.**

**Médecins Sans Frontières therefore recommend the 2008 Anti-Counterfeit Bill be amended to ensure that whatever measures are taken to combat counterfeit do not hamper in any way trade in and access to generic medicines of assured quality.**

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<sup>11</sup> Counterfeit Pharmaceuticals in Canada, Criminal Intelligence Service Canada - [http://www.cisc.gc.ca/pharmaceuticals/pharmaceuticals\\_e.html#1a](http://www.cisc.gc.ca/pharmaceuticals/pharmaceuticals_e.html#1a)

“New, expensive medicines such as hormones, corticosteroids, cancer drugs or anti-retrovirals are the most frequently counterfeited medications in industrialized countries. Other commonly counterfeited types of drugs in industrialized countries are: psychotropic drugs which include opiate-based pain-killers, tranquillizers, stimulants and depressants.”