FATAL FLAWS
How Kenya's 2008 Anti-Counterfeit Act could endanger access to medicines

A Médecins Sans Frontières briefing document
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Key sections of The Anti-Counterfeit Act must be clarified or amended if Kenyan patients are to continue accessing quality medicines at affordable prices.

MSF began treating people living with HIV/AIDS with antiretroviral (ARVs) medicines in Kenya in the end of 2001. MSF currently provides antiretroviral treatment to more than 140 000 HIV-positive adults and children in 30 countries, including Kenya.

MSF is able to treat people living with HIV/AIDS in Kenya because it can access quality generic medicines at affordable prices.[1] Although a number of ARVs are protected by patents in Kenya,[2] importation of more affordable generic versions of ARVs has been possible through the use of a pro- public health provision of the 2001 Industrial Property Act (Section 58.2 of 2001 IP & Regulation 37 of 2002 Industrial Property Regulations. Kenya's pro-public health provisions of the 2001 Industrial Property Act have been hailed by many as an essential mechanism that has allowed thousands of Kenyans to have access to life-saving medicines.

In 2008 Kenya introduced a new law, the Anti – Counterfeit Act. The objective of the Anti-Counterfeit Act 2008 (The Act) is "to prohibit trade in counterfeit goods, to establish the Anti-Counterfeit Agency, and for connected purposes".

MSF previously raised concerns along with Kenyan civil society groups, during the drafting of the Act, that provisions within it risked putting an end to the pro-public health importation or production of quality affordable generic medicines in Kenya and threatened ongoing efforts to ensure access to essential medicines for all Kenyans.[3]

While some amendments were made to the Act during the drafting stages, a number of sections of the Act still contain overbroad enforcement provisions, dangerous ambiguities in definitions and their misinterpretation would be detrimental to access to medicines.

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[1] ARVs used in MSF projects have all been prequalified under the WHO Prequalification Project or validated internally by MSF's own quality validation system.
[2] 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
[3] MSF briefing document October 2008 'Fatal Confusion: How Kenya's 2008 Anti- Counterfeiting Bill endangers access to medicines.

On 8th July 2009, three people living with HIV (the petitioners) supported by the Kenya Treatment Access Movement (KETAM) filed a petition with the Constitutional Court challenging the constitutionality of the Kenya Anti-Counterfeit Act 2008 (The Act). The petitioners want the Constitutional Court to declare the Act unconstitutional on grounds that its application and enforcement, particularly clauses 2, 32 and 34, will deny them access to affordable life-saving generic medicines necessary for the treatment of HIV and Aids, and therefore undermine their right to life, enshrined in the Kenyan constitution.

On 8th March 2010 there will be a preliminary hearing for an injunction. The petitioners in the case are seeking an injunction to stop the application of these clauses of the Act until the full constitutional case is heard and decided. The hearing will also seek permission to add interested parties to the case.

Definition of Counterfeiting

The petitioners are concerned that the Act's definition of counterfeiting is vague and ambiguous and risks including approved quality generics as counterfeit goods**.**

The Definition

Section 2 of the Act defines counterfeiting as

> "counterfeiting" means taking the following actions without the authority of the owner of 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;
>
> b) the manufacture, production or making, whether in Kenya or elsewhere, the subject matter of that intellectual property, or a colourable imitation thereof so that the other goods are calculated to be confused with or to be taken as being the protected goods of the said owner or any goods manufactured, produced or made under his licence;
>
> c) the manufacturing, producing or making of copies, in Kenya or elsewhere, in violation of an author's rights or related rights;
>
> d) in relation to medicine, the deliberate and fraudulent mislabelling of medicine with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging; (emphasis added**)**
>
> Provided that nothing in this paragraph shall derogate from the existing provisions under the Industrial Property Act.
>
> "counterfeit goods" means goods that are the result of counterfeiting, and includes any means used for purposes of counterfeiting;

The definition has been amended during the passage of the Act with the addition of a specific reference to medicines 2(d). It is still incomplete. Read together the definition is still vague and has not sufficiently excluded the application of the Act to legally manufactured generic drugs. While there is a reference to the Industrial Property Act 2001, it fails to clarify its application in so far as the Industrial Property Act allows exceptions necessary to make available generic drugs in Kenya.

In addition the definition extends to protection of intellectual property rights 'whether in Kenya or elsewhere'. The section allows the holder of Intellectual Property Rights (IPRs) accrued elsewhere to enforce its rights in Kenya -- notwithstanding the existing laws in Kenya do not recognise those IPRs. This could allow a pharmaceutical company to seek to enforce a claim for patent or trademark infringement in Kenya even if the medicine was not protected by IPR rights in Kenya. This would mean, for example, that if a drug exported from India to Kenya which is not under patent in either country but is under patent in the US, could be prevented from entering Kenya on the basis of claim by the rights holder that it infringes their patent or trademark in the US.

By failing to provide a clear definition of counterfeit goods, the risk remains that legally manufactured generic medicines of approved quality, such as generic medicines prequalified under the World Health Organization Prequalification Programme[4] may be erroneously interpreted as counterfeit goods in this Act and thereby effectively prohibiting the importation and manufacturing of generic drugs and medicines- such as some of the very ones imported by MSF to treat people living with HIV/AIDS 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.

Overbroad Enforcement provisions

The wide and vague definition is coupled with overbroad enforcement provisions, which further threaten the importation of medicines.

Section 32 of the Act states:

> 32. It shall be an offence for any person to–
> (f) Import into, transit through, tranship within or export from Kenya, except for private and domestic use of the importer or exporter as the case may be, any counterfeit goods;

Section 34 states:

> **34.** (1) The owner of an intellectual property right, who has valid grounds for suspecting that the importation of counterfeit goods may take place, may apply to the Commissioner in the prescribed manner to seize and detain all suspected counterfeit goods which are–
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> Goods featuring, bearing, embodying or incorporating the subject matter of that intellectual property right or to which the subject matter of that right has been applied; and
>
> Imported into or enter Kenya during the period specified in the application:
>
> Provided that the period may not extend beyond the last day of the period for which that intellectual property right subsists.

As section 32 makes counterfeiting a criminal offence rather than a civil matter, it gives the power to police and border officials, in the first instance, to enforce the Act and interpret the wide and ambiguous definition of counterfeiting, including determining whether there is patent

[4] http://healthtech.who.int/pq/

infringement. This is not a question for customs officials or the police to answer and could result in wrongly identifying legally manufactured medicines as counterfeits.

As part of the enforcement provisions in the Act, section 34 further provides the power for customs officials to seize and detain suspected counterfeit goods (including medicines) that are either entering or leaving Kenya or for goods in transit through Kenya to neighbouring countries. The law is open to abuse so that legitimate medicines could be routinely seized or detained on suspicion of infringement—thus delaying supplies. Such seizures could lead to "stock outs" and potential interruption of health treatments both within Kenya and neighbouring countries that rely on importing generic medicines that transit through Kenya to treat their people.

The dangers of overbroad enforcement measures on the availability of generic medicines are illustrated by the recent controversial use of European Union customs rules based on the European Community's (EC) Council Regulation 1383/2003 and European Customs Code,[5] which contain similar provisions to section 34. Since late 2008, customs officials in EU countries have detained over 20 consignments of legitimate generic medicines transiting through the EU - including AIDS drugs [6] – enroute to treatment programmes In Africa and South America detained in transit through European countries based on the grounds of suspected EU patent or trademark infringements Even though the medicines were 'in-transit', and thus not intended for domestic consumption in the EU, and even though they are not protected by IP rights in the countries of export or import.

Based on the reality of the seizures of generic medicines in Europe and the lack of clarity in relation to the treatment of quality, affordable generic medicines in the Act there is a risk that such medicines could be seized at the port of Mombassa or at the border in Busi.

Conclusions

Ambiguities in the definition of counterfeit products to potentially include legally-manufactured generics and overbroad enforcement provisions, mean that the 2008 Anti-Counterfeit Act 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. It will also paralyse the use of the pro- public health provision of the 2001 Industrial Property Act.

Médecins Sans Frontières urges that the 2008 Anti-Counterfeit Act be clarified to ensure that measures taken to prevent counterfeit medicines to reach consumers, do not hamper in any way trade in and access to legitimate generic medicines.

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[5] The Regulation (available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:196:0007:0014:EN:PDF), sets out the conditions under which customs authorities may intervene in cases where goods are suspected of infringing IP rights as well as the procedures to be followed.. Also see the report by Mara, Kaitlin and William New, "Concerns Continue over Drug Seizures As Legality Debate Begins", Intellectual Property Watch, Geneva, 5 March 2009 available at http://www.ip-watch.org/weblog/2009/03/05/concerns-continue-over-generics-drug-seizures-as-legality-debates-begin/.

[6] http://www.unitaid.eu/en/20090304156/News/UNITAID-statement-on-Dutch-confiscation-of-medicines-shipment.html