

India combats confusion over counterfeit drugs

India is taking steps to reverse anti-counterfeiting measures in some east African nations that could stop the importation of generic drugs made in the country. *Patralekha Chatterjee reports.*

India, the leading supplier of low-cost generic drugs to Africa, has begun fighting back to counter the confusion surrounding counterfeit drugs in the region. A raft of new and proposed anti-counterfeit laws could potentially deprive Africa of affordable, essential medicines.

The immediate cause of concern is Kenya's Anti-Counterfeit Act 2008, which came into effect in July, 2009. The new law, which ostensibly seeks to clamp down on fake products, blurs the distinctions between generic, substandard, and counterfeit drugs, argue critics, including Médecins Sans Frontières (MSF). MSF depends mostly on low-cost generic versions of essential medicines to treat patients around the world.

"The definition of counterfeits in Section 2 of the new Kenyan law (Anti-Counterfeit Act, 2008) can be interpreted to refer to generics as counterfeits as they are considered to be substantially similar goods", Allan Maleche, a lawyer and member of Kenya Ethical Legal Network on HIV and AIDS told *The Lancet*.

Kenya's new law could become a template for other countries in east Africa. The draft east African policy on anti-counterfeits and anti-piracy

has provisions similar to the Kenyan legislation with regard to generics; Uganda has a draft Anti-Counterfeit Goods Bill; and Tanzania, Rwanda, and Burundi are discussing these issues.

India has asked Kenya to make changes to its anti-counterfeit law passed last year that could make generic drugs exported by Indian companies into the country illegal.

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In addition to sustained dialogue with Africa's health ministers and other officials, India's riposte, over the next few months, will include advertisements in the African mass media and interactive meetings with journalists and industry in several African countries to counter the confusion about generic drugs, said Padmanabhuni Venkata Appaji, executive director of Pharmexcil, a body set up by India's Commerce Ministry.

The developments in east Africa are occurring against a worrying backdrop. Amar Lulla, joint managing director of Indian drug company Cipla, sees the recent anti-counterfeit initiatives in Africa as part of a campaign inspired by an embattled big pharma fighting to preserve market share for brand name drugs. Cipla is one of the world's largest producers of generic medicines.

"There have been attempts in recent times to stretch the meaning of counterfeits at the local and global level", said intellectual property lawyer Peter Munyi, partner in the law firm Sisule Munyi Kilonzo and Associates based in Nairobi.

However, despite the disturbing trends, all is not bleak. Besides

continuing to publicly question whether the purported aim of tackling the problem of bad quality and substandard products, including medicines, can be achieved using intellectual property based laws and policies, African activists and lawyers are taking their battle to the courtroom.

A petition has been filed in Kenya by three people living with HIV/AIDS challenging the constitutionality of the anti-counterfeit legislation. The three petitioners want the Court to declare the anti-counterfeit law unconstitutional on the grounds that it will deny them access to affordable life-saving generic medicines and therefore rob them of their right to life. However, "at this point it is not clear when the suit will come up for hearing", Munyi told *The Lancet*.

In the current scenario, a Ugandan model holds out hope for other African nations, said Cipla's Lulla. The Ugandan model refers to Quality Chemicals Industries (QCIL), a Ugandan pharmaceutical company that has just started producing much-needed drugs to treat HIV/AIDS and malaria—Africa's two biggest killers. The factory is now in advanced preparatory stages for WHO pre-qualification. "Cipla has been involved with the QCIL venture from the start, providing technological know how and expertise. We have been educating Ugandan health officials, sensitising public opinion in Uganda about the differences between substandard, counterfeit and spurious drugs. We are also in touch with international NGOs [non-governmental organisations], such as Oxfam and MSF, who are fighting for access to quality medicines at good prices", says Lulla.

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African nations are trying to introduce laws to fight the importation of fake drugs