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## Indian exporters breathe easy as East African nations reject draft

Posted: Sun, Feb 21 2010. 10:12 PM ISTgf

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The new legislation in East Africa was mainly aimed at stopping affordable generic drugs from India  
Mumbai: In a move that spells relief for Indian generic drug manufacturers, at least five East African countries—Uganda, Tanzania, Rwanda, Burundi and Sudan—have refused to endorse a proposal by the

### GENERIC VS COUNTERFEIT

- A generic drug is generally defined by credible agencies such as WHO and US Food and Drug Administration (FDA) as a drug which is produced and distributed without patent protection. It must contain the same active ingredients as the original formulation
- Counterfeit medicines are medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source
- Generic competition and differential pricing can contribute substantially to the affordability of medicines in low-income countries
- Kenya passed the anti-counterfeiting law in 2008 in line with the East African Community proposal, which doesn't clearly differentiate a quality generic drug from counterfeit or spurious

Source: WHO, US FDA and Mint research



East African Community (EAC) to introduce an anti-counterfeit products law.

Photo: Pradeep Gaur/Mint

The law, which could have potentially blocked exports of generic drugs from India because of a lack of clarity on what is counterfeit, had worried the Indian drug industry ever since the 2007 draft proposal by the EAC. East African countries together contribute almost one-fifth of India's Rs40,000 crore drug exports.

Kenya passed a similar law in 2008 that Uganda had used as a model for its own draft Bill last year, and which was due for implementation this year. The Ugandan Bill has now been sent back for review, George Baguma, a representative of an East African drug industry group, wrote in an email.

The East African states have “refused to endorse the draft proposal and have demanded that the definition of generics be what WHO (World Health Organization) stipulates”, said Baguma, who is also a director of Ugandan generic drug firm **Quality Chemicals Industries Ltd.**

*Mint* reported last week about Indian drug manufacturers' concerns over the impending East African legislation. In the past, some consignments from Indian drug makers—among them Cipla Ltd, Dr Reddy's Laboratories Ltd, Ind-Swift Laboratories Ltd, and Lupin Ltd—en route to African and Latin American countries were stopped at European ports on the grounds that they either violated patents of multinational companies, or by being labelled spurious.

The Indian drug industry raised the issue of the East African draft proposal with the governments involved as well as the World Health Organization through the Indian government.

“It is true (that) there are ‘forces’ trying to push it (the anti-counterfeit Bill), but we are all aware. We have also formed an association of pharmaceutical manufacturers in the EA region made up of 5 countries,” Baguma wrote in an email.

Amar Lulla, joint managing director of Cipla, India’s largest generic drugs exporter, called the development “great news”.

“India should take lessons from the East African move and a recent Brazilian law against multinational drug lobby’s conspiracy to block quality generic drugs,” he said.

P.V. Appaji, executive director of Pharmaceutical Export Promotion Council, or Pharmexcil, a government body under the commerce ministry, had earlier told *Mint* that the new legislation in East Africa was mainly aimed at stopping affordable generic drugs from India, a key supplier of such drugs to the global market.

Domestic lobby groups for the Indian drug industry such as the Indian Pharmaceutical Alliance (IPA) and Indian Drug Manufacturers Association, as well as individual companies, had also launched awareness programmes in East Africa to educate patients and non-governmental organizations (NGOs) there about the effect of laws such as the anti-counterfeit draft proposal on access to affordable essential medicines. It is currently also devising a publicity campaign in those countries.

Last year, IPA suggested a seven-point action plan to the Indian government to discourage East African governments from adopting policies that could hit drug exports from the nation.

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