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India-led BRICS Opposes UN Arm's Move on Model Drug Law

Soma.Das1@timesgoup.com

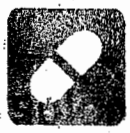
New Delhi: India has spearheaded a move by BRICS countries to oppose a United Nations agency's move to float without consultations with member states a model law on fraudulent drugs that has raised fears of genuine generic drugs trade getting disrupted.

An expert group within UN Office on Drugs and Crime (UNODC) had last week held closed-door meetings in Vienna to firm up a model law prescribing harsh penalties for 'falsified' drug-related crimes. The draft is expected to serve as a model for member countries to adopt and implement, but it has revived fears about seizures of Indian-made generics, as happened in 2008 when many shipments were confiscated at European Union ports.

BRICS' STAND

The permanent missions of BRICS countries – including Brazil, India, Russia, China and South Africa – stationed in Vienna shot off a joint letter last Wednesday to the UN body questioning the mandate under which it was drafting such a model law, the basis of selection of the countries, NGOs which make up the expert group and the source of funding of these meetings.

As per the letter reviewed by **ET**, the grouping believes a resolution passed in 2011 doesn't give UNODC the mandate to start such expert-level consultations and develop a model law on fraudulent medicine. The BRICS nations also urged the UN arm to consult member states before proceeding further. As one of the largest generic drugs suppliers globally, India may face direct consequences but it is not part of this expert group. Brazil, China and South Africa are not members of the expert group either. Among developing countries, the expert group is understood to have members from health ministries of Nigeria, Niger and Cambodia. UNODC's senior expert Karen Kramer did not respond to ET's queries sent on Friday. The definition of 'falsified' drugs has long remained contentious, creating situations wherein legitimate generics in one country could be labelled fake drugs in another, particularly because trademark and patent infringements are country specific violations. The confusion prompted a series of in-transit seizures of generic drugs by custom officials at EU ports in 2008, shipped from India and headed for South American and African markets where they were legitimate generics.



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The seizures were based merely on suspicion of patent and trademark violations of countries where the ships had docked in transit.

The late November draft of the proposed model law by UNODC does not explicitly exclude IPR-related violations while defining "a fraudulent medical product" and gives nations the flexibility to define it.

"UNODC has unwisely erred in its latest draft model law by including intellectual property. The attempt to copy a diluted version of European law and pass it off as a UN model law for the world is sickening and beneath the dignity of the UN. India is justified to protest in the strongest terms possible," said Amir Attaran, professor, University of Ottawa.

Attaran was till recently working with the UNODC to draft this model law, but his version was discarded by the group in favour of one written by Irish expert group. Attaran's version excluded international transit of unregistered medicines from the purview of drug related crime, and said that no prosecution should be undertaken merely because a medicine is generic or violates intellectual property laws.

Domestic drug industry executives who reviewed the draft model law for ET said this could spark EU-like seizures and potentially disrupt the trade of legitimate generic drugs.

Indian Pharmaceutical Alliance (IPA), a grouping of top Indian drugmakers, wrote to various government departments – of pharmaceuticals, health, external affairs and commerce – on Monday, urging them to oppose the UN move by building a coalition of like-minded countries. "It (the draft model law) empowers member states to define 'fraudulent medical products' in their legislation, seize them even in transit and criminally prosecute the manufacturer, distributor and agent. Thus, a legitimate generic can be treated as a 'fraudulent' product, depending on the definition adopted by it," said IPA's secretary general DG Shah.

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