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Govt to Persuade Unregulated Mkts to Accept Indian Pharma Manual

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Hyderabad: The Indian government is lobbying with certain unregulated markets to accept Indian Pharmacopoeia, realising that most domestic drug makers cannot upgrade their manufacturing facilities to global standards set by the US FDA for exporting medicines.

India's commerce ministry is in talks with at least 10 such unregulated economies and will have a detailed meeting with their regulators and enforcement authorities next month to impress upon them about the superior Indian drug standards. These countries include Vietnam, Cambodia, Myanmar, Iran, Ukraine, Belarus, Ghana, Nigeria, South Africa and Kenya among others.

A top commerce ministry official said a meeting of regulators and enforcement authorities of these 10 odd unregulated economies would take place at Mysore next month. "These markets are currently accepting either the British Pharmacopoeia (BP) or the United States Pharmacopoeia (USP) while sourcing medicines from India," director general of Pharmaceuticals Export Promotion Council (Pharmexcil) PV Appaji told **ET**.

"If we are successful in convincing these markets to accept the Indian Pharmacopoeia (IP), then it helps many Indian medicine manufacturers, which are solely following IP, to save significantly on time, packaging and other costs needed to adopt either BP or USP."

Pharmacopoeia is a set of standards and quality specifications for ingredients, preparation and dosage forms of medicines manufactured, sold, consumed and exported in a country. According to information on World Health Organisation's website, there are 140 independent countries that are currently adopting around 30 national and African, European and International Pharmacopoeias.

India exported around \$15.2 billion (approximately Rs 95,000 crore) of medicines last fiscal and these 10

unregulated markets accounted for nearly \$2 billion.

Appaji said the representatives of the regulators and enforcement authorities of these 10 countries would be participating in the ensuing Indian Pharmaceutical Congress at Mysore in December. "We have lined up an exclusive meeting on the sidelines of the Congress to discuss various regulatory issues, including the proposal to convince them to allow IP. If successful, it enables a number of domestic drug makers begin exports and thereby help the country significantly improve its overall exports."

India is looking at convening similar meetings with groups of various unregulated economies, based on the success of the proposed meeting with the 10 countries, said Appaji, Welcoming the idea of propagating the Indian Pharmacopoeia to the authorities in unregulated markets, SV Veeramani, president of the Indian Drug Manufacturers Association (IDMÅ), said, "Today, Indian Pharmacopoeia is no way less than BP or USP."

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