

India may join group with good drug manufacturing norms

Will help sort out the problems exporters face in different countries

OUR BUREAU

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To help pharmaceutical exporters meet numerous manufacturing and inspection requirements being put in place by buyer countries, India is considering joining a group of 41 countries that have good manufacturing practice (GMP) standards for drugs.

Eyes PICs

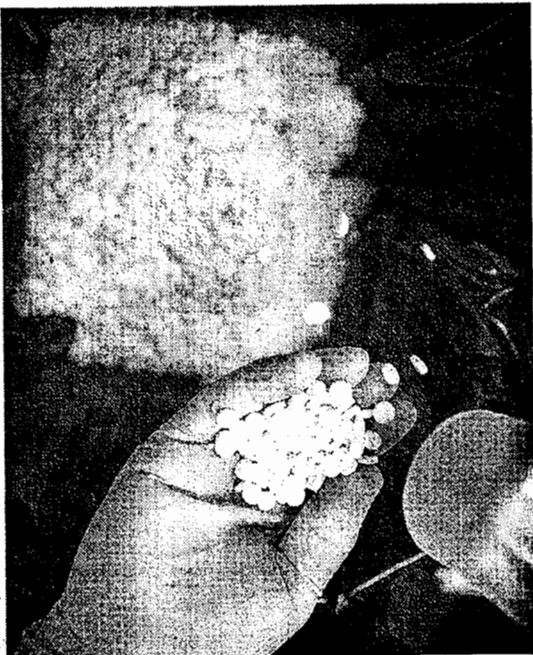
The Pharmaceutical Inspection Cooperation Scheme (PICs) — which includes Canada, Australia, European, African countries and the US — is an informal cooperative arrangement between regulatory authorities in the field of Good Manufacturing Practice (GMP) of medicinal products. The Health Ministry

and the Commerce Ministry are examining the option of joining PICs. We feel that the problems exporters face in terms of meeting different GMP and inspection procedures in different countries will be sorted out if we join PICs," said PV Appaji, Director-General, Pharmexcl.

If for some reason India cannot become a member of PICs, exporters should make sure they follow the practices and regulations specified by the group, Appaji added.

Pharma exports

Indian pharmaceutical exports posted a negligible increase to \$14.8 billion in 2013-14 against \$14 billion in the previous year, as exports from big players such as Ranbaxy and Wockhardt took



a hit due to quality issues raised by the US Food and Drug Administration (USFDA).

Exporters also faced restrictions in countries such as Brazil

and Russia which recently placed their own plant audits for exporters which added to the cost and time. "Even if Indian exporters are in compliance

with USFDA norms, a large number of countries have started insisting on their own plant audits. We have to have common standards and practices," said Ashutosh Gupta, Chairman, Pharmexcl.

IPHEX 2014

To help build familiarity between Indian drug regulators and their counterparts in other countries, India has invited regulators from 25 countries to participate in the global pharmaceutical exhibition — IPHEX 2014 — in Mumbai from May 21-23.

Over 500 buyers from 110 countries are likely to participate in the exhibition which is expected to generate a business of ₹2,000 crore.

"We want the regulators from various countries to meet our industry and our regulators as a confidence building measure," Gupta added.

Regulatory