

Drug cos may have to swallow stricter manufacturing rules

Himani Chandna

■ himani.chandna@hindustantimes.com

NEW DELHI: With domestic drug-makers frequently running into regulatory hurdles overseas, the government is looking to make the manufacturing process more stringent by adopting international standards.

Fearing hit on export of drugs, which constitutes about 20% of India's total outbound shipments, the commerce ministry is mulling to become a part of a multinational regulatory regime — Pharmaceutical Inspection Cooperation Scheme (PICS) — under which India will adopt global standards on drug inspections and manufacturing.

However, the move, which will help exporters gain access to newer markets, will also require better skilled workers at the units.

"We are planning to graduate

HEAVY DOSAGE

- PICS, headquartered in Geneva, consists of 45 drug importing countries
- It prescribes two international instruments for member countries and their pharmaceutical authorities for 'active and constructive cooperation' in the field of good manufacturing practices

to the next level of inspections and manufacturing standards. But for that, the primary priority is to improve the skill sets in pharma sector across roles," said GN Singh, Drug Controller General of India. "Under Prime Minister Narendra Modi's 'Make in India' initiative, the move will help exporters gain access to international markets

by adopting global standards prescribed by PICS".

"We are currently evaluating the standards that we are expected to follow by PICS and hence collating the perspectives from industry bodies," Singh added.

Small and medium-sized pharma companies are, however, wary of the stricter standards, and fear that adoption of such norms will drive up costs.

"Being a part of the new system could make it smoother for Indian firms to access lucrative export markets. However, we have not firmed up our mind yet," said Dara Patel, secretary-general, Indian Drug Manufacturers' Association, the largest pharma group, which has over 800 members. "We have given our perspective to the ministry that we need to gear up our capabilities first and then go ahead with such stringent standards."

Regulatory