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STRICTER STANDARDS

Drug regulator seeks to amend pharma manufacturing laws

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After facing heat from the American and European counterparts over quality issues, the Indian drug regulator is set to draft an amendment to existing pharmaceutical manufacturing laws to bring them on par with international standards.

The Drug Controller General of India (DCGI) will move a proposal before the government within the next six months to amend the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, in an attempt to raise drug manufacturing standards in line with those recommended by the World Health Organization (WHO).

"We have decided to revisit the present laws and bridge the gap between Indian manufacturing practices and the WHO good manufacturing practices (GMPs)," said G.N. Singh, the drug controller general of India. "The new standards in India will be up to the global marks."

DCGI will be evaluating the regulations and GMPs in the US, Europe, Canada, Japan and Australia as part of this process.

Several Indian drug makers, such as Sun Pharmaceutical Industries Ltd, Wockhardt Ltd, RPG Life Sciences and Polydrug Laboratories, have come under the scanner of the US Food and Drug Administration (USFDA) in recent years over a range of issues, including production quality, sanitation standards and alleged data manipulation. Ranbaxy was one of the companies than came under US regulatory heat as it had products from the company's facilities in Toansa, Paonta Sahib, Dewas and Mohali in India barred. Generic giant Sun Pharma also came under fire after a USFDA ban on its plant at Karkhadi in Gujarat.

According to the department of pharmaceuticals, the number of Indian manufacturers following WHO GMPs is 10-15%. "Out of around 8,000 manufacturers in India, only a few are following the WHO guidelines," Singh said.

US and European Union sanctions have hurt India's image as an inexpensive and reliable supplier of generic drugs in international markets. India's pharmaceutical exports totalled about $15.3 billion in 2014-15, marginally up from the previous year's $14.84 billion.

"India has become a pharmacy of the world. So, we cannot live in isolation and will have to meet their expectations. Our system is in the process of improving," Singh said.

As per the WHO website, GMPs includes factors such as sanitation and hygiene, qualification and validation, self-inspection, quality audits, suppliers' audits, prevention of cross-contamination and bacterial contamination during production, training employees and personal hygiene.

"The quality of Indian products is definitely lower. There are companies in India that have separate plants for India and for the US. If higher standard becomes mandatory, local manufacturers will feel the brunt and naturally prices of products will go up," said Hemant Bakhru, a pharmaceuticals analyst at UBS Securities in Mumbai.

To meet higher standards, drug makers will have to invest money, a matter of concern to some sections.

"Such sort of a regulation would mean that the small and medium units will have to bear the brunt. If the regulations are in place, it will demand an additional investment of ₹5 crore more for new testing facilities and machine upgradation," said Sudesh Kumar, executive secretary of the Confederation of Indian Pharmaceutical Industry (CIPI).

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