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DRUG QUALITY

Indian firms, checkers need to do more'

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New Delhi, 14 December

Last year around this time, India-made medicines were losing sheen the world over, due to constant alerts from international drug regulators.

The situation remains quite the same. Indian generic drug makers continue to make headlines for all the wrong reasons. Against that backdrop, the Drug Controller General of India (DCGI), is struggling to ensure quality in the domestic market.

Faced with criticism on many fronts, DGCI feels India is still not equipped to match the standards practised in the US, the world's largest drug market. Incidents such as the Chhattisgarh sterilisation tragedy, followed by the Punjab eye cataract mishap, have added to the worsening view of Indian health care.

The American drug regulator's India team was at the DCGI office in the capital last Thursday, to discuss issues concerning domestic drug companies.

"There are issues but we (DCGI) have to work with them (American regulators) to improve the situation. We have communicated this to them and our first priority is safety and wellness of patients," Drug Controller General G N Singh said.

He said the situation has to be viewed from an Indian perspective, rather than a direct comparison with developed markets. "Regarding GMP (good manufacturing practices), we have told states to strengthen practices to ensure safety of patients. Some of the 'Bimaru' states (a term for undivided UP, MP, Bihar and Rajasthan) have to step up but there are others like Maharashtra and Gujarat which are doing a better job," he said.

It should, however, be also noted that several drug makers' units in Maharasthra and Gujarat have continuously received warnings and import ban orders from the American regulator, the Food & Drug Administration (FDA).

Indian drug makers were again under the spotlight recently after a Bloomberg report surfaced, claiming a top pharmaceutical company had deleted its test lab data to pass the FDA tests. Indian drug makers continue to come out with statements claiming continuous coordination with the American regulator. While the FDA tightening its stand on generic drug makers, Indian stakeholders feel adequate resources are lacking to improve GMP in India. "It's a challenge to meet international standards. The number of officer under Indian regulators are also less, compared to foreign counterparts," said V K Subburaj, the government's secretary for pharmaceuticals, at a conference on Friday. The Indian regulator has 1,200-1,500 officers; the FDA has close to 13,000. Experts believe 20,000 officers would be required to adequately inspect all drug facilities. India has a little over 10,000 manufacturing units for drugs.

When asked on the action regarding Ranbaxy Laboratories, whose India factories are all now barred from exporting to the US market, Singh said, "We have worked with them silently and they have improved."

Experts say the Indian regulator has been late to crack the whip on domestic companies for compromises in manufacturing practices.

PILL REQUIRED

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Regulatory