Premium

Adopt WHO-standard good manufacturing practices: Govt sets deadline for pharmas

Companies with a turnover of over Rs 250 crore will have to implement the revised GMP within six months, while medium and small-scale enterprises with turnover of less than Rs 250 crore will have to implement it within a year, Union Health Minister Mansukh Mandaviya said on Wednesday.

Written by Anonna Dutt Follow
New Delhi | Updated: August 3, 2023 06:29 IST

"Those who do not comply with the direction will face suspension of licence and/ or penalty," he said.

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FOLLOWING RECENT incidents of several countries reporting deaths allegedly linked to "contaminated" India-manufactured drugs, the government has set a deadline for mandatory implementation of the Good Manufacturing Practices (GMP) which were revised in 2018, bringing them on par with World Health Organisation (WHO) standards.

Companies with a turnover of over Rs 250 crore will have to implement the revised GMP within six months, while medium and small-scale enterprises with turnover of less than Rs 250 crore will have to implement it within a year, Union Health Minister Mansukh Mandaviya said on Wednesday.

"Those who do not comply with the direction will face suspension of licence and/ or penalty," he said.

The decision is important as only 2,000 of the 10,500 manufacturing units in the country were found to be compliant with the global WHO-GMP standards, he said.

The move comes after a risk-based inspection of 162 such units and 14 testing labs found several deficiencies, including absence of testing of raw materials before use,

manufacturing and testing areas, said officials.

According to officials, this will lead to at least 11 specific changes in the manufacturing process on the ground, including introduction of a pharmac quality system, quality risk management, product quality review, and valida equipment.

EXPLAINED

Quality control

ONLY 2,000 of the 10,500 manufacturing units in the country have been found to be compliant with the global WHO-GMP standards. Now, all will have to implement the revised GMP, ensuring quality medicines for the domestic market and abroad.

Experts said that while some of these processes were followed, they weren't documented properly, as required by global regulators. The companies will also have to introduce a GMP-related computerised system. "These computer programmes will be designed to automatically record all the steps followed and checks done, which will ensure all the processes are followed," said an expert.

The companies will also have to carry out stability studies as per the climate conditions. "At present, most companies store their samples under recommended conditions and test for various parameters from time to time. Now, they will have to keep the drugs in a stability chamber, set the proper temperature and humidity, and carry out an accelerated stability test as well," said the expert.

Currently, while companies exporting medicines to other countries already have to be WHO-GMP certified, those manufacturing medicines for the domestic market can be granted permission if they meet the requirements listed in Schedule M of rules under the Drugs and Cosmetics Act. Among other things, this lists the specifications of the manufacturing units, processes that need to be followed, and equipment needed.

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"This is a very welcome step as it will ensure that all the manufacturing units are at par with global standards, reducing the need for repeated inspections by different regulators. It will also make India a quality pharmaceutical hub, and ensure that our citizens receive export-quality medicines too," said Narender Ahooja, former drug controller of Haryana.

First published on: 03-08-2023 at 04:04 IST

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