Health Ministry notifies revised Pharma manufacturing rules under schedule M to ensure quality control

The revised Schedule M prescribes the Good Manufacturing Practices (GMP) and requirements of premises, plant, and equipment for pharmaceutical products; official says this will ensure Indian guidelines are at par with global standards

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Aimed at ensuring robust quality control for pharma and biopharmaceutical products, the Union Health Ministry on January 6 notified revised rules under Schedule M of the Drugs and Cosmetics Rules, 1945.

Schedule M prescribes the Good Manufacturing Practices (GMP) for pharmaceutical products and the revised Schedule M has been notified as rules to ensure GMP is adhered to, and requirements of premises, plant, and equipment for pharmaceutical products.

GMP is mandatory standards which builds and brings quality into a product by way of control on materials, methods, machines, processes, personnel, and facility/environment, etc. GMP was first incorporated in Schedule M of the Drugs and Cosmetics Rules, 1945 in the year 1988 and the last amendment was done in June, 2005.

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With the amendment, the words 'Good Manufacturing Practices' (GMP) has been replaced with 'Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products'.

'On par with global benchmark'

"To keep pace with fast-changing manufacturing and quality domain, there was a necessity to revisit and revise the principles and concept of GMP mentioned in current Schedule M. This would bring our GMP recommendations at par with global standards, especially to those of World Health Organization (WHO), and ensure production of globally acceptable quality of drug," said a senior Health Ministry official about the recent move.

The changes introduced in the revised Schedule M include introduction of a pharmaceutical quality system (PQS), quality risk management (QRM), product quality review (PQR), qualification and validation of equipment, and a computerised storage system for all drug products.

The notification, dated December 28, 2023 states that manufacturers must assume responsibility for the quality of the pharmaceutical products to ensure that they are fit for their intended use, comply with the requirements of the licence, and do not place patients at risk due to inadequate safety, quality, or efficacy.

It adds that companies must market a finished product only after getting "satisfactory results" on tests of the ingredients and retain a sufficient quantity of the samples of intermediate and final products to allow repeated testing or verification of a batch.

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Speaking about the revision, Sudarshan Jain, secretary general, Indian Pharmaceutical Alliance (IPA) said, "The revision of Schedule M by the government is a positive step and an important milestone for the Indian pharmaceutical sector. This will elevate and update the quality standards of medicines, reinforcing the reputation of our industry and

improving patient outcomes. We welcome this initiative helping India's journey to become a global benchmark in quality."

"The revised regulations of Schedule M will help ensure compliance with international quality standards and will benefit both patients and the industry by promoting the manufacturing of safe, effective, and high-quality drugs. The focus on risk management, qualification and validation of equipment, and self-inspection will be vital contributions."

Earlier in August, the Ministry had set a six-month deadline for small manufacturers and 12 months for large units to get their World Health Organization-Good Manufacturing Practices (WHO-GMP) certification.

The revised rules is to be implemented on the basis of company turnovers where the medium and small manufacturers include those with an annual turnover of less than ₹250 crore who will have to implement the revised rules within 12 months from its date of publication, whereas large manufacturers with an annual turnover of over ₹250 crore will be given six months to do so.

The revised Schedule M has 13 parts which provide GMP guidelines for the specific requirements for manufacturing pharmaceutical drugs. The revised rules has five new categories of drugs including pharmaceutical products containing hazardous substances such as sex hormones, steroids (anabolic and androgenic), cytotoxic substances, biological products and radiopharmaceuticals.

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