Schedule M of Drugs and Cosmetics Rules: Health Ministry Notifies Revised Pharma Manufacturing Rules

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What's in Today's Article?

Why in News?

- Aimed at ensuring robust quality control for pharma and biopharmaceutical products, the Union Health Ministry 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 rules ensures that GMP is followed.

What are the Good Manufacturing Practices (GMP) for Pharma Companies?

- GMP is a system for ensuring that products are consistently produced and controlled according to quality standards.
- It is designed to minimise the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.
- The World Health Organisation (WHO) has established detailed guidelines for GMP and many countries have formulated their own requirements for GMP based on WHO GMP.
- Others (such as the ASEAN, EU) have harmonised their requirements through the Pharmaceutical Inspection Convention.

GMP for Pharma Companies in India

- 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 2005.
- With the amendment, the words ‘GMP’ has been replaced with ‘Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products’.

Need for the Revised Rules of the Schedule M of Drugs

- 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 India’s GMP recommendations at par with global standards, especially to those of WHO, and ensure production of globally acceptable quality of drug.
- Earlier, the Ministry had set a 6-month deadline for small manufacturers and 12 months for large units to get their WHO-GMP certification.

The Changes Introduced in the Revised Schedule M Drug Rules

- It includes introduction of a –
    - Pharmaceutical quality system (PQS),
    - Quality risk management (QRM),
    - Product quality review (PQR),
    - Qualification and validation of equipment, and
    - Computerised storage system for all drug products.

- The notification 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.
- The revised Schedule M has 13 parts which provide GMP guidelines for the specific requirements for manufacturing pharmaceutical drugs.
- The revised rules have 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

Implementation of the Revised Schedule M Rules

- The revised rules are to be implemented on the basis of company turnovers where –
    - The medium and small manufacturers (with an annual turnover of less than ₹250 crore) 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.

Significance of the Revision of Schedule M by the Government

- It 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 Indian industry and improving patient outcomes.
- It 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.

Q1) What is Schedule M in Drugs and Cosmetics Act 1945?

Schedule M guides on Good Manufacturing Practices regarding company premises, quality control system, quality check laboratories, production, cleaning of equipment, housekeeping, cross-contamination, and other related

topics.

Q2) What are the Drugs and Cosmetics Rules 1945?

The Drugs and Cosmetics Rules 1945 are the rules established through the Drugs and Cosmetics Act 1940. These rules classify drugs under given schedules and present guidelines for the storage, sale, display and prescription of each schedule.

Source: Health Ministry notifies revised Pharma manufacturing rules under schedule M to ensure quality control | IE

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