Schedule M Standard for Pharma Sector

Prelims: *Current events of national and international importance*

Why in news?

The Union Health Ministry has asked states/UTs to ensure strict compliance with Revised Schedule M – updated Good Manufacturing Practices (GMP) by all drug manufacturers.

- **Schedule M –** Refers to the Good Manufacturing Practices (GMP) standards for pharmaceutical and biopharmaceutical products in India
- **Under the –** Drugs and Cosmetics Act, 1940
- **Purpose –**
  - **Quality Assurance –** To ensure that pharmaceutical products are of high quality and fit for their intended use, meeting licence requirements.
  - **Patient Safety –** To prevent patients from being exposed to risks due to inadequate drug safety, quality, or potency.
  - **Global Alignment –** To bring India's GMP standards in line with international guidelines, such as those of the World Health Organization (WHO).
- The revised one was introduced in 2023-2024, brings India’s GMP norms closer to international standards.
- It mandates enhanced quality systems, with a compliance deadline of December 31, 2025.
- **Key changes in the Revised Schedule M –**
  - Establishes a comprehensive ***Pharmaceutical quality system (PQS)*** for managing quality across all aspects of drug manufacturing.
  - Mandates the use of ***Quality Risk Management (QRM)*** principles to identify and mitigate potential quality issues.
  - Product quality review (PQR)
  - Qualification and validation
  - Implementation of a computerized storage system
  - Specific guidelines for new product category containing hazardous

substances, such as sex hormones, anabolic steroids, cytotoxic compounds, biological products, and radiopharmaceuticals.

Quick Fact

Drugs and Cosmetics Act, 1940
• Regulates the ***import, manufacture, distribution, and sale*** of drugs and cosmetics to ensure they are safe, effective, and meet quality standards. • **Implemented through** – *Drugs and Cosmetics Rules, 1945*, which classifies drugs into schedules and provides specific guidelines for their storage and sale.

References

1. The Hindu | Compliance with revised Schedule M norms
2. India Code | Drugs and Cosmetics Act, 1940