Revised Good Manufacturing Practices Standards

For Prelims: Good Manufacturing Practices, Pharmaceutical quality system, Pharmaceutical Companies, Drugs Manufacturing Standards, **Deaths of Children in the Gambia.**

For Mains: Revised Good Manufacturing Practices Standards.

Source: IE

Why in News?

Recently, the government of India has directed all pharmaceutical companies to implement the **Revised Good Manufacturing Practices (GMP),** bringing their processes at par with Global Standards.

- Larger companies with a turnover of over Rs 250 crore have been asked **to implement the changes within six months,** while medium and small-scale enterprises with turnover of less than Rs 250 crore have been asked to do so within a year.

What are Good Manufacturing Practices (GMP)?

- **About:**
  - GMP is a system for ensuring that **products are consistently produced and controlled according to quality standards.**
  - It is designed to **minimize the risks involved** in any pharmaceutical production that cannot be **eliminated through testing the final product.**
- **The Main Risks:**
  - Unexpected contamination of products
  - Causing damage to health or even death
  - Incorrect labels on containers, which could mean that patients receive the wrong medicine
  - Insufficient or too much active ingredient, resulting in ineffective treatment or adverse effects.
- **WHO (World Health Organization)** has established detailed guidelines for GMP. Many countries have formulated their own requirements for GMP based on WHO GMP.
- Others have harmonized their requirements, for example in the Association of South-East Asian Nations (ASEAN), in the European Union and through the Pharmaceutical Inspection Convention.
- The GMP system was first incorporated in India in 1988 in **Schedule M of the Drugs and Cosmetics Rules, 1945**, and the last amendment was done in June 2005. WHO-GMP standards are now part of the revised Schedule M.

What are the Major Changes in Revised GMP Guidelines?

- **Pharmaceutical Quality System and Risk Management:**

    - The new guidelines introduce a **pharmaceutical quality system**, which emphasizes the establishment of a comprehensive **quality management system throughout** the manufacturing process.
    - Companies are now required to **implement quality risk management practices** to identify potential risks to the quality of their products and take appropriate preventive measures, also **regular quality reviews** of all products are **mandated to ensure consistency** in quality and processes.
- **Stability Studies:**
    - Companies are now required to **conduct stability studies based** on climate conditions. This involves maintaining **drugs in stability chambers** at specified temperatures and humidity levels to assess their stability over time. Additionally, accelerated **stability tests may be conducted** to assess the product's stability under accelerated conditions.
- **GMP-Related Computerized Systems:**
    - The new guidelines emphasize the use of computerized systems to **manage GMP-related processes.**
    - These systems are designed to prevent data tampering, unauthorized access, and omission of data. They also automatically record all steps and checks to ensure adherence to processes without any tampering.
- **Investigational Products for Clinical Trials:**
    - The new **schedule M also lists out the requirements** for additional types of products, including biological products, **agents with radioactive ingredients,** or plant-derived products.
    - The new guidelines lay out requirements for **investigational products being manufactured** for clinical trials. This ensures that the products used in clinical trials meet the **necessary quality and safety standards.**

What is the Need for Revised GMP Guidelines?

- **Alignment with Global Standards**:
    - Implementation of the new norms will bring the Indian industry **on par with global standards.**
- **Incidents of Contamination:**
    - There have been a **string of incidents where other countries have reported alleged contamination** in India-manufactured syrups, eye-drops, and eye ointments.
    - The **deaths of 70 children in the Gambia**, 18 children in Uzbekistan, three persons in the United States, and six deaths in **Cameroon have been linked to these products.**
- **Deficiencies in Current Practices:**
    - Risk-based inspection found numerous deficiencies in 162 manufacturing units in India.
        - Deficiencies include inadequate testing of raw materials, lack of product quality review, infrastructure issues, and missing qualified professionals.
    - There are only 2,000 of the 10,500 drug manufacturing units in India at **present that meet global standards**, being WHO-GMP certified.
    - The improved standards will **ensure that pharmaceutical companies follow standard processes,** quality control measures, and do not cut corners, improving the quality of medicines available in India as well as sold in the global market.
- **Confidence to Regulators from Other Countries:**
    - Instituting the same quality across the industry will give confidence to regulators from other countries.
    - In addition, it will improve the **quality of drugs in the domestic markets.** Most of the 8,500 manufacturing units that are not WHO-GMP certified supply medicine within India.

Way Forward

- India's move to implement revised GMP guidelines signifies a significant step toward achieving global quality standards in the pharmaceutical industry.
- The revised standards **aim to enhance quality control measures,** proper documentation, and IT support, thus ensuring the production of high-quality medicines in India and for the global market.