Revamped Pharmaceuticals Technology Upgradation Assistance Scheme and UCPMP 2024

For Prelims: PTUAS Scheme, PMPDS**,** PLI scheme for Pharmaceuticals, Schedule M and WHO-GMP Standards

For Mains: Indian pharmaceutical industry, health, Government policies and interventions

Source: PIB

Why in News?

The **Department of Pharmaceuticals (DoP),** Ministry of Chemicals and Fertilizers, announces the **Revamped Pharmaceuticals Technology Upgradation Assistance Scheme (RPTUAS).**

- It aims to upgrade the technological capabilities of the pharmaceutical industry in alignment with global standards.
- Additionally, the DoP released the **Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024.** The code aims to ensure responsible marketing practices and curb misleading promotional activities.

What are the Key Highlights of the RPTUAS?

- **Objective:**
  - The Department of Pharmaceuticals through RPTUAS aims to contribute to the growth of the pharmaceutical industry and ensure compliance with global manufacturing standards.
- **Key Features:**
  - **Broadened Eligibility Criteria:**
    - Expanded eligibility **beyond** Micro, Small, and Medium Enterprises (MSMEs) to include any pharmaceutical manufacturing unit with a turnover of less than Rs 500 crores.
      - Preference remains for MSMEs, supporting smaller players in achieving high-quality manufacturing standards.
  - **Flexible Financing Options:**
    - Introduces subsidies on a reimbursement basis, offering more flexibility than the traditional credit-linked approach.
  - **Comprehensive Support for Compliance:**
    - Supports a wide range of technological upgrades in line with revised **Schedule-M** and World Health Organization (WHO)**- Good Manufacturing Practices (GMP)** standards, including HVAC systems, testing laboratories, clean room facilities, etc.
  - **Dynamic Incentive Structure:**
    - Offers incentives based on turnover, ranging from 20%, 15%, and 10% of investment under eligible activities for turnovers less than Rs. 50.00 crore, Rs. 50.00 to less than Rs. 250.00 crore, and Rs. 250.00 to less than Rs. 500.00 crore,

respectively.
    - **State Government Scheme Integration:**
        - Allows integration with state government schemes to provide additional top-up assistance.
    - **Enhanced Verification Mechanism:**
        - Implements a robust verification mechanism through a Project Management Agency to ensure transparency and accountability.

Pharmaceuticals Technology Upgradation Assistance (PTUAS) Scheme

- PTUAS helps drug companies upgrade their facilities to produce medicines that meet global standards. It was launched in July 2022.
- **Incentives under the Scheme:**
    - **Interest Subvention:**
        - Up to a maximum of 5% per annum (6% for units owned and managed by Scheduled Castes **and** Scheduled Tribes) of interest subvention for the loan component eligible under the scheme, capped at Rs. 10 crore.
        - This subsidy is applicable for a maximum period of 3 years on the reduced balance for loans sanctioned by **scheduled commercial banks /financial institutions**, both in the public and private sectors.

What are the Revised Schedule M and WHO-GMP Standards?

- The Union Health Ministry's notification in January 2024 introduced revisions to **Schedule M of the Drugs and Cosmetics Rules, 1945,** focusing on robust quality control measures for pharmaceutical and biopharmaceutical products.
    - **Schedule M** prescribes **Good Manufacturing Practices (GMP)** for pharmaceutical products.
        - 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.
            - With the amendment, the words 'Good Manufacturing Practices' (GMP) have been replaced with 'Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products'.
- The revised Schedule M emphasizes adherence to GMP and incorporates requirements for premises, plant, and equipment. This ensures alignment with the **World Health Organization (WHO) GMP Standards.**
    - GMP is the mandatory standard that builds and brings quality into a product by way of control on materials, methods, machines, processes, personnel, facility/environment, etc.
- The updated Schedule M introduces 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.

Recent Cases of Quality Issues in the Indian Medicines

- In December 2023 the data from the **Central Drugs Standard Control Organisation (CDSCO),** shows that at least **6% of cough syrup samples from 54 Indian manufacturers failed a mandatory quality test for export.**
    - Gambia, Uzbekistan, Cameroon, and the World Health Organization (WHO) expressed concerns following the deaths of children who had taken these medications.
- **In April 2023, the US Centers for Disease Control and Prevention (CDC)** and the Food and Drug Administration (USFDA) raised concerns over a **drug-resistant bacteria strain allegedly linked to eye drops imported from India.**

What are the Key Provisions of UCPMP 2024?

- **Restrictions on Inducements:**
  - Medical representatives are **prohibited from using inducements** to gain access to healthcare professionals.
- **Prohibition of Payments and Gifts:**
  - Companies are barred from offering cash, monetary grants, or pecuniary benefits to healthcare professionals or their family members.
  - Pharmaceutical companies are forbidden from giving gifts or any pecuniary advantages to individuals qualified to prescribe or supply drugs.
- **Evidence-Based Claims:**
  - Claims about a **drug's usefulness must be supported by up-to-date evidence**, and terms like "safe" and "new" must be used appropriately.
- **Transparent CME Programs Only:**
  - Pharmaceutical companies can only engage with healthcare professionals (HCPs) for Continuing Medical Education (CME) through well-defined, transparent, and verifiable guidelines.
- **Strict Compliance:**
  - The UCPMP will be circulated for strict compliance by all pharmaceutical companies and associations.
  - All associations must constitute an **Ethics Committee for Pharmaceutical Marketing Practices.**

Pharmaceutical Industry in India

- **Industry Scenario:**
  - The **Economic Survey 2022-23** mentions that India is ranked **3rd worldwide in the production of pharma products by volume and 14th by value.**
  - The Pharma Industry is expected to reach USD 130 Bn by 2030. India is a major exporter of Pharmaceuticals, with over 200+ countries served by Indian pharma exports.
  - The nation is the largest provider of **generic medicines globally,** occupying a 20% share in global supply by volume, and is the **leading vaccine manufacturer globally.**
    - India supplies over 50% of Africa's requirement for generics, 40% of generic demand in the US and 25% of all medicine in the UK.
  - India also accounts for approximately **60% of global vaccine demand.** 70% of WHO's vaccines are sourced from India.
- **Schemes Related to the Pharma Sector:**
  - **Promotion of Bulk Drug Parks Scheme.**
  - **Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS).**
  - **Production-linked incentive (PLI) scheme for pharmaceuticals.**
  - **National Medical Device Policy 2023.**

UPSC Civil Services Examination, Previous Year Question (PYQ):

Mains:

Q. How is the Government of India protecting traditional knowledge of medicine from patenting by pharmaceutical companies? **(2019)**