Pharmacopoeia Commission for Indian Medicine

For Prelims: Ministry of AYUSH, AYUSH Drugs, Drug Regulations

For Mains: Significance of PCIM&H, Government's Intervention

Why in News?

The Government of India has established the **Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H)** as a subordinate office under the **Ministry of Ayush.**

- Government has merged the **Pharmacopoeia Commission of Indian Medicine & Homoeopathy (PCIM&H)** and the two central laboratories namely:
  - **Pharmacopoeia Laboratory for Indian Medicine (PLIM)** and
  - **Homoeopathic Pharmacopoeia Laboratory (HPL).**

What do we need to know about the Commission?

- **About:**
  - PCIM&H is an **autonomous body** under the aegis of **Ministry of Ayush, established since 2010.**
  - Pharmacopoeia is an **officially recognized book of standards** as per the **Drugs and Cosmetics Act, 1940 and Rules 1945** thereunder.
    - As per the **Second Schedule** of the Drugs and Cosmetics Act, it is designated as the **official book of standards for drugs imported** and/or **manufactured** for sale, stock or exhibition for sale or distribution in India.
    - It specifies the **standards of drugs manufactured and marketed in India** in terms of their identity, purity and strength.
- **Functions:**
  - The Commission is engaged in development of **Pharmacopoial Standards** for Ayurvedic, Unani, Siddha & Homeopathic drugs**.**
  - PCIM&H is also acting as **Central Drug Testing** cum **Appellate Laboratory** for **Indian systems of Medicine & Homoeopathy.**
- **Benefits of Merger with PLIM & HPL:**
  - **Optimum use** of infrastructural facilities, technical manpower and financial resources of the three organizations for **enhancing their standardised outcomes.**
  - Focused and cohesive **development of standards of AYUSH drugs** and **publication** of pharmacopoeias and formularies.
  - The merger intends to **accord legal status to the merged structure of PCIM&H** and its laboratory by making the necessary amendments and enabling provisions in the **Drugs and Cosmetics Rules, 1945.**
    - Consultations have been done with the Director General Health Services, **Drugs Controller General** and the **Ayurveda, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB).**

What is Ayurveda, Siddha and Unani Drugs Technical Advisory Board?

- ASUDTAB is a **statutory body** under the provisions of **Drugs and Cosmetics Act, 1940.**
- It advises the **central and state governments in regulatory matters of Accelerated Shelf Life Testing (ASLT) drugs.**
    - **ASLT** is an **indirect method of measuring and estimating** the stability of a product by storing the product under controlled conditions that **increase the rate of degradation** occurring in the product under normal storage conditions.

How is the Government Supporting AYUSH Products/Drugs?

- **Drugs and Cosmetics Act 1940:**
    - Enforcement of the legal provisions pertaining to **Quality Control and issuance** of drug license of Ayurveda, Siddha, Unani, is vested with the **State drug Controllers appointed by the concerned State.**
    - It provides the **regulatory guidelines** for issuing licenses to manufacture Ayurvedic, Siddha, Unani medicines.
    - It is **mandatory for the manufacturers** to adhere to the prescribed requirements for **licensing of manufacturing units & medicines** including proof of safety & effectiveness, compliance with the **Good Manufacturing Practices (GMP)**.
- **Certifications of AYUSH products:**
    - For facilitating exports, **Ministry of Ayush** encourages following **certifications of AYUSH products** as per details below:
        - **Certification of Pharmaceutical Products** (CoPP) as per WHO **Guidelines** for herbal products.
        - Quality Certifications Scheme implemented by the **Quality Council of India (QCI)** for grant of **AYUSH Premium mark** to Ayurvedic, Siddha and Unani products on the basis of **third-party evaluation of quality** in accordance with the status of compliance to international standards.
- **AYUSH Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY):**
    - The Ministry of Ayush has implemented the **Central Sector Scheme of AOGUSY.**
    - **Objectives:**
        - To **enhance India's manufacturing capabilities** and **exports** of **traditional medicines** and **health promotion products** under the initiative of **Atmanirbhar Bharat.**
        - To facilitate adequate **infrastructural & technological upgradation** and **institutional activities** in public and private sector for standardization, **quality manufacturing** and **analytical testing** of Ayush drugs & materials.
        - To strengthen regulatory frameworks at **Central and State level** for effective quality control, safety monitoring and surveillance of misleading advertisements of Ayush drugs.
        - To encourage building up **synergies, collaborations and convergent approaches** for promoting standards and quality of Ayush drugs & materials.

UPSC Civil Services Examination, Previous Year Questions (PYQs)

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

Source: PIB