



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 **Pharmacopoeial 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 Guvatta Evam Utpadan 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)

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