Pharmacopoeia Commission for Indian Medicine

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The Government of India has established Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), as a subordinate office under Ministry of Ayush by merging Pharmacopoeia Commission of Indian Medicine & Homoeopathy (PCIM&H) and the two central laboratories namely Pharmacopoeia Laboratory for Indian Medicine (PLIM), Ghaziabad and Homoeopathic Pharmacopoeia Laboratory (HPL) vide gazette dated 6th July, 2020).

The Commission is engaged in development of Pharmacopoial Standards for Ayurvedic, Unani, Siddha & Homoeopathic drugs. Further, PCIM&H is also acting as Central Drug Testing cum Appellate Laboratory for Indian systems of Medicine & Homoeopathy.

After re-establishment, a total of 1483 samples of ASU&H drugs have been tested during 6th July, 2020 to till date and 03 Pharmacopoeial monographs along with their formulary specifications for AYUSH Kwath related formulation has been published. Apart from Pharmacopoeial Monographs, National Formulary for Unani Medicines, Part-IV (2nd Edition) comprising formulary specifications of 166 formulations have also be published.

50 monographs of single drugs of Ayurveda along with 51 monographs of formulation of Ayurvedic drugs, 1 monograph of formulation of Siddha drug and 101 monographs of formulation of Unani drugs have been published during the last five years .

However, since inception of PLIM & HPL (now PCIM&H *w.e.f.* 6th July 2020), a total number of 2199 quality standards on raw materials (Single Drugs of plant/animal/mineral/metal/ Chemical origin) used in ASU&H systems of medicines have been published in various Pharmacopoeias and also 405 quality standards of ASU formulations also been published in respective pharmacopoeias.

As prescribed in Drugs and Cosmetics Act 1940 and Rules 1945 made thereunder, 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/ State Licensing Authorities appointed by the concerned State/ Union Territory Government. Rule 158-B in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license 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) as per Schedule T of Drugs and Cosmetics Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

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Licensing Authorities regarding production/sale of sub-standard Ayurvedic medicines/formulations is as follows –

S. no.	Name of the State/UTs	Action taken
1.	Tamil Nadu	92 license suspended/ cancelled since 2017 to 2021
2.	Odisha	13 license of cancelled since 2017-18 to 2022-23
3.	Maharashtra	Since 2016-17 to 2022, 84 prosecution orders issued, 38 prosecutions filed and 46 are pending.

1. This Ministry has issued Gazette notification no. G.S.R 716 E for Amendment in the Drugs Rules, 1945 related to licensing process of ASU drugs on 01.10.2021. The amendments have been done with a view to reduce the compliance burden and facilitate ease of doing business. The process to grant license to manufacture Ayurveda, Siddha and Unani (ASU) drugs has been made swift, paperless and more transparent the license application system through online e-aushadhi.gov.in portal. The license of the ASU drugs have been made perpetual i.e. with one time registration fee the license of the product will be valid lifetime with no further retention or renewal fees thereafter. The maximum time in granting the license to manufacture ASU drugs has been reduced from three months to two months.

In addition to the above, 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.

(3.) Ministry of Ayush has implemented Central Sector Scheme AYUSH Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY). The objectives of the Scheme are as under;

i. To enhance India's manufacturing capabilities and exports of traditional medicines and health promotion products under the initiative of Atmanirbhar Bharat.

ii. 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.

iii. To strengthen regulatory frameworks at Central and State level for effective quality control, safety monitoring and surveillance of misleading advertisements of Ayush drugs.

iv. To encourage building up synergies, collaborations and convergent approaches for promoting standards and quality of Ayush drugs & materials.

The components of the AYUSH OushadhiGunvattaEvamUttpadanSamvardhanYojana (AOGUSY) Scheme are as under;

A. Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards.

B. Pharmaco vigilance of ASU&H drugs including surveillance of misleading advertisements.

C. Strengthening of Central and State regulatory frameworks including Technical Human Resource & Capacity Building programs for Ayush drugs.

D. Support for development of standards and accreditation/ certification of Ayush products & materials in collaboration with Bureau of Indian Standards (BIS), Quality Control of India (QCI) and other relevant scientific institutions and industrial R&D centres.

This information was given by Minister of Ayush Shri Sarbananda Sonowal in a written reply in Loksabha today.

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