

**GOVERNMENT OF INDIA  
MINISTRY OF AYUSH**

**RAJYA SABHA  
UNSTARRED QUESTION NO.650  
TO BE ANSWERED ON 13<sup>TH</sup> DECEMBER, 2022**

**STEPS TAKEN TO ASSURE QUALITY CONTROL OF AYUSH DRUGS**

**650. SHRI K.C. VENUGOPAL:**

Will the Minister of **AYUSH** be pleased to state:

- (a) the actions that have been taken by Government for the assured quality control of AYUSH drugs in the country;
- (b) the details thereof;
- (c) whether it is a fact that nine major posts in Central Drug Controller for AYUSH are functioning with temporary staffs; and
- (d) if so, whether Government will expedite the recruitment process to fill up nine posts in Central Drugs Standard Control Organisation (CDSCO) on regular basis and the details thereof?

**ANSWER  
THE MINISTER OF AYUSH  
(SHRI SARBANANDA SONOWAL)**

(a) & (b): 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 and Homoeopathic drugs, 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 and Rule 85 (A to I) in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathic 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 & Schedule M-I of Drugs and Cosmetics Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

Ministry of Ayush has taken various steps for assured quality control of AYUSH drugs in the country:

- i. Schemes to support Ayurvedic medicines production: Under National Ayush Mission (NAM) from 2014-2021, apart from other services Grant-in-aid were also provided for Strengthening of

State Government ASU&H Pharmacies. At present, Central Sector Scheme for Ayush Oushadhi Gunavatta evam Utpadan Samvardhan Yojana (AOGUSY) has been implemented for the year 2021-2026. The components of the AYUSH Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana (AOGUSY) Scheme are as under;

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

B. Pharmacovigilance 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.

ii. Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), a subordinate office under Ministry of Ayush lays down Pharmacopeial Standards and Formulary specifications for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs within the ambit of Drugs & Cosmetics Act, 1940, which serve as official compendia for ascertaining the quality of the drugs included therein. Further, PCIM&H as an appellate drug testing laboratory receives the samples from Government agencies as per Drugs & Cosmetics Act & Rules there under for ascertaining their quality. In 2021, Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), Ghaziabad a sub-ordinate office of Ministry of Ayush has signed a MoU with American Herbal Pharmacopeia, United States of America (USA) for developing standards of Ayurveda and other Indian systems of medicine on international standards. Further, PCIM&H and Indian Pharmacopoeia Commission (IPC) have signed a MoU for developing “ONE HERB ONE STANDARD”.

iii. 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.

iv. 27 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. As on date 81 laboratories are approved or licensed under the provisions of Drugs and Cosmetics Rules, 1945 for quality testing of Ayurvedic, Siddha and Unani drugs and raw materials.

v. Pharmacovigilance Centres for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) Drugs set up in different parts of the country under the Central Scheme of Ministry of Ayush are mandated to monitor and report the misleading advertisements to the respective State Regulatory Authorities. A three tier structure comprising of a National Pharmacovigilance Co-ordination Centre (NPvCC), Intermediary Pharmacovigilance Centres (IPvCs) and Peripheral Pharmacovigilance Centres (PPvCs) is established. All India Institute of Ayurveda (AIIA), New

Delhi under Ministry of Ayush is the National Pharmacovigilance Co-ordination Centre (NPvCC) for the implementation of the National Pharmacovigilance program for Ayurveda, Siddha, Unani & Homoeopathy drugs. Objectionable advertisements are being reported to the respective State Licensing Authorities by PPvC at regular intervals.

(c) & (d): Yes Sir. Total 09 posts i.e. 04 posts of Drug Inspectors (01 in each stream- Ayurveda, Siddha, Unani and Homoeopathy); 04 posts of Assistant Drug Controller (01 each for Ayurveda, Siddha, Unani and Homoeopathy) and 01 post of Deputy Drug Controller (ASU&H) has been created for setting up of the Office of the Central AYUSH Drugs Controller in the Ministry of Ayush. Ministry of Ayush has appointed its 09 officers for the additional charge of above mentioned 09 posts in addition to their normal duties in the Ministry of Ayush, without any additional remuneration vide gazette notification S.O. 4562(E) dated 27.09.2022. Ministry of Ayush is in process of filling the 09 posts created for setting up the office of Central Ayush Drugs Controller on regular basis in consultation with Union Public Service Commission (UPSC).

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