GOVERNMENT OF INDIA
MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)

RAJYA SABHA
STARRED QUESTION NO. 202
TO BE ANSWERED ON 8 TH AUGUST, 2023

IMPROVING THE QUALITY OF AYUSH PRODUCTS

202 DR. SONAL MANSINGH:

Will the Minister of Ayush be pleased to state:

(a) whether Government is making efforts to improve the quality of AYUSH products;

(b) if so, the plan of Government to promote such products for wider use by the consumers; and

(c) whether any shortfall has been found in the manufacturing of various AYUSH medicines, if so, the details thereof?

ANSWER
THE MINISTER OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY(AYUSH)

(SHRI SARBANANDA SONOWAL)

(a) to (c) A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA STARRED QUESTION NO. 202 FOR 8TH AUGUST, 2023

(a) to (c) Yes. 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 Homoeopathy 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 Homoeopathy 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.

The efforts made by the Ministry of Ayush to improve the quality of Ayush products are as follows -

(i) Ministry of Ayush has implemented Central Sector Scheme AYUSH Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY), was approved by Standing Finance Committee on 16.03.2021. The total financial allocation to this scheme is Rs. 122.00 crores for five years. The components of AOGUSY scheme are as follows -

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) In 2020, Ministry of Ayush has re-established Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H) as a subordinate office by merging its two central laboratories i.e. Pharmacopoiea Laboratory for Indian Medicine (PLIM) and Homoeopathy Pharmacopoeia Laboratory (HPL) and an autonomous body i.e. Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H).

Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H) is mandated to lays down the Pharmacopoeial Standards and Formulary specifications for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs, which serve as official compendia for ascertaining the Quality Control (identity, purity and strength) of the ASU&H drugs, included herein, as per Drugs & Cosmetics Act, 1940 and Rules 1945, thereunder. These standards and quality parameters included in the monographs of these Pharmacopoeias have been identified as such to align with the recommendations of World Health Organization (WHO) or other major pharmacopoeias prevalent worldwide.

(a) Following 2259 quality standards on raw materials (Single Drugs of plant/animal/Mineral/metal/ Chemical origin) used in ASU&H has been published -

Name of Pharmacopoeia	**Published quality standards of single drugs**
Ayurvedic Pharmacopoeia on India (Part I, Vol. I to X)	665
Siddha Pharmacopoeia on India(Part I Vol. I to II)	139
Unani Pharmacopoeia on India (Part I Vol. I to VII)	338
Homoeopathic Pharmacopoeia on India (Vol. I to IX)	1117

(b) Following 405 quality standards of ASU formulations also been published in respective Pharmacopoeias -

Name of Pharmacopoeia	**Published quality standards of formulations**
Ayurvedic Pharmacopoeia on India (Part II, Vol. I to IV)	202 and 01 standalone quality standard
Siddha Pharmacopoeia on India(Part II)	01 standalone quality standard
Unani Pharmacopoeia on India (Part II Vol. I to IV)	200 and 01 standalone quality standard

(c) Following 2666 formulary specifications of ASU drugs also published in Formularies of respective system. The details as follows -

Formulary	**Specifications**
Ayurvedic Formulary of India(Part I to III)	1035 and 01 standalone formulary specification
Siddha Formulary of India(Part I to II)	399 and 01 standalone formulary specification
National Formulary of Unani Medicine (Part I to VI)	1229 and 01 standalone formulary specification

In addition to above, supporting documents in the form of Macro-Microscopic & TLC Atlas on 351 single drugs incorporated in API also published.

(iii) 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. This program sensitizes various stakeholders across the country towards the quality of medicines, posologies and other drug-related issues. This scheme has components focused on

reporting objectionable advertisements and Suspected Adverse Drug Reactions (ADRs) with ASU&H Drugs. Till date, 776 awareness programs for 63594 beneficiaries has been conducted and 30039 misleading advertisements and 1473 suspected ADR's has been reported.

(iv) For facilitating exports of Ayush products, 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.

(v) Rule 160 A to J of the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for approval of Drug Testing Laboratory for carrying out such tests of identity, purity, quality and strength of Ayurvedic, Siddha and Unani drugs as may be required under the provisions of these rules, on behalf of licensee for manufacture of Ayurvedic, Siddha and Unani drugs. As on date, 35 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. Further, 95 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.

(vi) Ayush Export Promotion Council (AYUSHEXCIL), is a newly formed Export Promotion Council (set up by Ministry of Ayush and supported by Ministry of Commerce, Government of India), launched at Global Ayush Investment and Innovation Summit held in Gandhinagar, Gujarat on April 20,2022). It is aimed to oversee exports of products of Ayurveda, Homoeopathy, Siddha, Sowa Rigpa and Unani systems and address trade issues pertaining to these sectors. It mandates to facilitate capacity building of its members on export procedures, organize Business to Business meetings, international events, road shows, seminars and workshops on the export of Ayush products, and to safeguard the scientific research in the field of Ayush healthcare.

AYUSHEXCIL has conducted a workshop on “Attractive Packaging and Branding of various AYUSH/Traditional products to be Globally Competitive”. Directorate General of Foreign Trade, Department of Commerce, and Ministry of Commerce & Industry has notified AYUSHEXCIL on 31.07.2023.

(vii) As per the information received from States/UTs, State/UT has also constituted technical expert committee regarding approval of patent & proprietary Ayush drugs after verifying the submission of documents relating to safety study, evidence of effectiveness and stability studies as per Rule 158B, Rule 161B and Rule 169 of Drugs & Cosmetics Rules, 1945.

No shortfall in the manufacturing of various Ayush medicines has been reported by State/ UT governments.

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