GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO.2088
TO BE ANSWERED ON08TH AUGUST, 2023

"AYUSH MARKS AND LABELLINGS"

2088 **SHRI AYODHYA RAMI REDDY ALLA:**

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

(a) the details about various certification marks and labellings used to indicate the qualityand authenticity of AYUSH products, such as Ayurvedic Pharmacopoeia of India (API),AYUSH premium mark, and AYUSH certification mark;
(b) whether Government is promoting research and validation of AYUSH products toestablish their efficacy and safety and if so, the details thereof; and
(c) the plans and strategies of Government to further enhance the quality and authenticityof AYUSH products in the country?

ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)

(a) In October 2009, Quality Control of India (QCI), at the behest of the then Department of AYUSH (Now Ministry of Ayush), launched a Voluntary Certification Scheme for Ayurvedic Products, which provides for testing for contaminants and compliance to standards prescribed in the regulation in order to enhance the consumer confidence and also facilitate exports.The Scheme has two levels - Standard Mark based on the compliance to the domestic regulatory requirements and the other being AYUSH Premium Mark based on the World Health Organisation-Good Manufacturing Practices (WHO-GMP) requirements and product requirements to certify against overseas regulations.

The scheme contains Governing Structure, Certification criteria documents like GMP, Permissible Levels of Contaminants for AYUSH Premium Mark, Permissible Levels of Contaminants for AYUSH Standard Mark, Internal Quality Assurance Protocol, Certification

Process and requirements for certification bodies. Till date 02 certification bodies are approved by QCI. A total of 83 companies are certified with approx. 6000 products under the AYUSH Mark Scheme.Details of the scheme are available at https://qcin.org/voluntary-certification-scheme- for-ayush-products/.

Central Drugs Standard Control Organization (CDSCO)issues the Certificate of Pharmaceutical Product (COPP) of Ayurvedic products for export purpose based on joint inspection by representatives from CDSCO, Ministry of Ayush and respective State Licensing Authority. Details are available at https://cdsco.gov.in/opencms/opencms/en/Aayush/ .

Further, labelling provisions for Ayurvedic, Siddha and Unani drugs are prescribed under Rule 161 of Drugs & Cosmetics Rules, 1945 and labelling provisions for of Homoeopathic medicines are prescribed under Rule 106A of Drugs & Cosmetics Rules, 1945.

Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H) under Ministry of Ayush, lays down the Formulary specifications and Pharmacopoeial Standards for Ayurveda, Siddha, Unani and Homoepathy (ASU&H) drugs and publishd under respective pharmacopoeia viz. Ayurvedic Pharmacopoeia of India (API), Siddha Pharmacopoeia of India (SPI), Unani Pharmacopoeia of India (UPI) and Homoeopathy Pharmacopoeia of India (HPI), 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 and compliance to these quality standards are mandatory for the ASU&H drug being manufactured in India.

(b) Yes Sir. 05 Research Councils under Ministry of Ayush are actively engaged in research activities like Medicinal Plant Research (Medico-Ethno Botanical Survey, Pharmacognosy and Tissue Culture), Drug Standardization, Pharmacological Research, Clinical Research, Literary Research & Documentation and Tribal Health Care Research Programme. Further, 12 National Institutes under Ministry of Ayush are also conducting various research studies to establish efficacy and safety of Ayush drugs.

Ministry of Ayush has also implemented AYURGYAN Scheme for promoting education and research in the field of Ayush and to support Research & Innovation in Ayush by extra mural research and education in Ayush by providing academic activities., training, Capacity Building

etc. Further, under the Centre of Excellence component of AYURSWASTHYA Yojana, financial assistance is provided to eligible individual organizations/institutes for establishing and upgrading their functions & facilities and/or for research & development activities in Ayush.

(c)The efforts madeby the Ministry of Ayushto further enhance the quality and authenticity of Ayush products in the countryare as follows -

(i) 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.
(ii) Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H) under Ministry of Ayush, lays down the Formulary specifications and Pharmacopoeial Standards for Ayurveda, Siddha, Unani and Homoepathy (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.

(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.

(iv) 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.

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