GOVERNMENT OF INDIA
MINISTRY OF AYUSH

LOK SABHA
STARRED QUESTION NO. 491
TO BE ANSWERED ON 27TH March, 2026

Regulatory Mapping of AYUSH Products

491. Shri Praveen Khandelwal:

Will the Minister of AYUSH be pleased to state:

(a) whether a country-wise regulatory mapping of AYUSH products and therapies has been conducted to identify export barriers and if so, the details thereof;
(b) whether harmonisation of quality standards with major global markets is underway in the country and if so, the details thereof;
(c) whether internationally accredited testing and certification infrastructure has been expanded in the country and if so, the details thereof;
(d) whether AYUSH pharmaceutical supply chains meet global pharmacovigilance standards and if so, the details thereof; and
(e) the steps taken by the Government to position AYUSH as a regulated global wellness export rather than a domestic only healthcare stream?

ANSWER
THE MINISTER OF STATE (IC) OF MINISTRY OF AYUSH

(SHRI PRATAPRAO JADHAV)

(a) to (e) A statement is laid on the Table of the House.

THE STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 491 FOR 27TH MARCH, 2026

(a) The Forum on Indian Traditional Medicine (FITM), established within the Research and Information System for Developing Countries (RIS) in collaboration with the Ministry of Ayush, had conducted a regulatory review and trade-barrier analysis of three major Ayush export markets – United States of America (USA), European Union (EU) and United Arab Emirates (UAE) in relation to exports of medicinal plants/ herbs, extracts, pharmaceuticals and health/ dietary supplements. This included a mapping of pathways that were adopted by exporters for quick access to market and distribution channels, and additionally highlighted tariff and non-tariff barriers to exports. The report titled "Ayush Exports: Regulatory Opportunities and Challenges in Key Markets" was brought out in 2023.

Ayush Export Promotion Council (AYUSHEXCIL) notified by Directorate General of Foreign Trade (DGFT), Ministry of Commerce and supported by Ministry of Ayush, had published in 2024 "IndieExport: Compliance Roadmap for Traditional & Complementary Medicine (T&CM) Exports" for region-wise regulatory compliances. The existing compliance roadmap for T&CM of the concerned region is based on 13 parameters, including recognition of T&CM, administrative/technical structure, infrastructure, Research & Development, clinical trials, registration, raw material procurement, manufacturing, sale, licenses, import, export, and panel action.

(b) The Government has taken various steps to harmonise quality standards with major global markets as under:

i. Ministry of Ayush has established Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), as its subordinate office. PCIM&H on behalf of Ministry of Ayush lays down the Formulary specifications and Pharmacopoeial Standards 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 therein, as per Drugs & Cosmetics Act, 1940 and Rules 1945, thereunder and compliance to these quality standards are mandatory for the production of ASU&H drugs being manufactured, sold and stocked in India. The quality parameters included in the Pharmacopoeias and Formularies of ASU&H drugs prescribing mandatory regulatory standards have been identified to align the parameters prescribed by World Health Organization (WHO)/other major pharmacopoeias prevalent worldwide.

ii. Rule 158-B in the Drugs Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Ayurveda, Siddha, Sowa Rigpa, Unani medicines and Rule 85 (A to I) in the Drugs 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 Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia. As on date, there are 34 State Drug Testing Laboratories and 108 Drug Testing Laboratories approved or licensed under Rule 160 A to J of the Drugs Rules, 1945, for quality testing of ASU drugs and raw materials. Provisions related to labelling of Ayurveda, Siddha and Unani drugs are prescribed under Rule 161 of the Drugs Rules, 1945.

iii. Ministry of Ayush has implemented Central Sector Scheme-Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) with financial outlay of Rs.122.00 crores for five years since 2021-2022. 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 Ayurveda, Siddha, Unani and Homoeopathy (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.

iv. Ministry of Ayush, in collaboration with the WHO, has developed a classification of diseases used in Ayurveda, Siddha and Unani under Traditional Medicine Module-2 of the International Classification of Diseases 11th Revision (ICD-11). This standardized system enables uniform documentation, reporting and exchange of health data globally, improves comparability of clinical evidence and regulatory evaluation, and supports integration with international health information systems. The alignment with ICD-11 helps harmonize health standards with global markets and enhances the international acceptance of Ayush practices and products.

v. An agreement was signed between the Ministry of Ayush and the WHO on May 24, 2025 towards developing Traditional Medicine intervention categories and index for the International Classification of Health Interventions (ICHI), with a holistic approach and focus on Traditional Medicine systems of Ayurveda, Siddha and Unani. The agreement marks the beginning of work on a dedicated Traditional Medicine module under the ICHI. This development aligns with India’s vision of bringing its rich heritage of traditional wisdom into the global healthcare mainstream, backed by scientific classification and international standards.

vi. A separate sub-committee on Ayurveda and Yoga (ISO/TC 249/ SC 2) has been established under ISO/TC 249 (Traditional Medicine). The secretariat of the newly created subcommittee on Ayurveda and Yoga has been assigned to Bureau of Indian Standards (BIS), India.

vii. The launch of the Ayush Quality Mark at the Second Global Traditional Medicine Summit in December 2025 is an important step towards harmonization of quality standards with global markets. This is intended to ensure internationally accepted standards of quality, safety and efficacy with respect to specific categories of Ayush products and services.

viii. An existing scheme for Certification of Pharmaceutical Product (COPP) as per World Health Organization (WHO) guidelines has been further extended to Ayurveda, Siddha and Unani (ASU) medicines to strengthen regulatory measures ensuring safety and quality of Ayush drugs. This scheme is being administered by Central Drugs Standard Control Organization (CDSCO). Based on a joint inspection of the applicant manufacturing unit by the representatives of CDSCO, Ministry of Ayush and the concerned State Licensing Authority, a certificate is granted.

(c) The Government has taken following steps to expand internationally accredited testing and certification infrastructure for Ayush products in the country:

i. Ministry of Ayush is implementing Central Sector Scheme Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) which includes, inter-alia, a component which supports 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 Research & Development centres.

ii. India has expanded internationally recognized testing and certification capacity for Ayush products, primarily through certification bodies accredited by the National Accreditation Board for Certification Bodies (NABCB) and specialized Ayush testing laboratories. The AYUSH Premium Mark programme is implemented through NABCB-accredited certification agencies, which audit manufacturers against World Health Organization–Good Manufacturing Practices (WHO-GMP) aligned and internationally recognized quality management standards. Several private laboratories compliant with Good Laboratory Practices (GLP) and International Organization for Standardization (ISO) standards provide testing services for composition, contamination, and microbiological parameters of herbal and Ayush products.

iii. An Ayush vertical has been created in Central Drugs Standard Control Organization (CDSCO) to strengthen regulatory measures ensuring safety and quality of Ayush drugs. CDSCO issues the Certificate of Pharmaceutical Product (CoPP) to Ayurvedic products for export purpose based on joint inspection by representatives from CDSCO, Ministry of Ayush and respective State Licensing Authority.

iv. 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 of 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 WHO-GMP requirements and product requirements to certify against overseas regulations.

v. Ministry of Ayush has launched Ayush Quality Mark on 19.12.2025 during the 2nd WHO Global Summit for products and services of global standards. The Mark will cover Ayush Products/ Medicinal Plants/ Herbs, Ayush Hospitals/ Day Care Centres/ Clinics, Medical Value Travel Facilitators (MVTF), Ayush Wellness Centres and Laboratory Services for Testing Products.

(d) Under Central Sector Scheme-Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) of Ministry of Ayush, Pharmacovigilance Program for Ayurveda, Siddha, Unani, and Homoeopathy (ASU&H) drugs is functional since 2018, with 01 National Pharmacovigilance Co-ordination Centre (NPvCC), 05 Intermediary Pharmacovigilance Centres (IPvC) and 97 Peripheral Pharmacovigilance Centres (PPvC) across the country.

The program is functioning with objectives to collect, collate and analyse data related to suspected Adverse Drug Reactions (ADRs) and undertake surveillance of advertisements related to ASU&H drugs, thus to establish evidence on clinical safety of these drugs.

Further, the programme is being implemented in collaboration with the Indian Pharmacopoeia Commission (IPC), a WHO Collaborating Centre for Pharmacovigilance and the Central Drugs Standard Control Organization (CDSCO) to ensure systematic monitoring and evaluation of adverse drug reactions.

(e) The Government has taken following steps to position Ayush as a regulated global wellness export rather than a domestic only healthcare stream:

i. Ministry of Ayush, in collaboration with the Health Sector Skill Council (HSSC), established the Sub-Council of Ayush in 2018 to enhance skill development, capacity building, and employability in the Ayush sector. Currently, 19 Ayush courses are ongoing, covering diverse areas like Panchakarma, Yoga, Ayurveda, Cupping Therapy, and Naturopathy. These courses aim to train professionals in traditional medicine and holistic healthcare.

ii. The Ayurveda Training Accreditation Board (ATAB) was established by the Ministry of Ayush under the administrative framework of Rashtriya Ayurveda Vidyapeeth (RAV), through a Gazette Notification issued in December 2019. ATAB was created to accredit Ayurveda training courses in India and abroad that are not regulated under existing statutory bodies. Till date, ATAB has accredited 151 Ayurveda training courses, comprising 137 courses from 34 Indian institutions and 14 international

courses from 02 countries, thereby significantly contributing to the standardization and credibility of Ayurveda education on a global scale.

iii. Ministry of Ayush has established the Yoga Certification Board (YCB) which is functioning for certifying Yoga professionals and accrediting Yoga institutions.

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