GOVERNMENT OF INDIA

MINISTRY OF AYUSH

RAJYA SABHA

UNSTARRED QUESTION NO. 977

TO BE ANSWERED ON 29.07.2025

"Global recognition of Ayush formulations"

977. Shri Raghav Chadha:

Will the Minister of ***Ayush*** be please to state:

a) whether there have been any challenges in gaining global recognition for Ayush formulations due to inadequate regulatory and research standards and if so, the details thereof;

b) whether Government is working with the World Health Organization (WHO) or other international agencies for the standardization and global acceptance of Ayush products;

c) the number of Ayush products that have received approval or registration in international markets during the last five years; and

d) the steps being taken by Government to strengthen documentation, quality control, and pharmacovigilance mechanisms in Ayush systems to meet global regulatory standards?

ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYUSH
(SHRI PRATAPRAO JADHAV)

(a) International regulatory frameworks vary from country to country. However, Ministry of Ayush addresses the international regulatory frameworks through negotiations, collaboration and signing of Memorandum of Understandings (MoUs).

(b) With the support of Government of India, WHO has published Benchmark document for training and practice of Ayurveda & Unani and also published WHO terminology in Ayurveda, Unani and Siddha. Further, Ministry has signed project collaboration agreement with WHO to support the development of International Herbal Pharmacopeia with focus on South-East Asia region's traditional medicine. Additionally, Ministry of Ayush encourages Certification of Pharmaceutical Product (CoPP) as per World Health Organization (WHO) guidelines is extended to Ayurvedic, Siddha and Unani (ASU)

medicines. These initiatives aim to enhance the credibility, standardization, and international acceptance of Ayush systems.

(c) Ayush products are registered independently by different Ayush industries in various countries. No data regarding approval or registration international markets is maintained. However, under International Cooperation (IC) Scheme, assistance is provided to the Ayush industries for registration of Ayurveda, Siddha, Unani, Sowa Rigpa and Homoeopathy products (Classical/ Proprietary/ Patented medicines) in foreign country in the form of medicines for the purpose of export as per the requirement of the foreign country.

To encourage Ayush Industry to get market authorization for their product(s) for exports, the facility of reimbursement of expenditure is extended for the following activities:

i. Preparation of product dossier (Excluding office expenses and administrative cost)

ii. Fee paid to the concerned regulatory agency for registration/ market authorization of product.

iii. 50% of fee paid to reputed international consultant (if any).

(d) The steps being taken by the government to strengthen quality control and Pharmacovigilance mechanism in Ayush systems to meet global regulatory standards are as follows:-

1. The scheme for Certification of Pharmaceutical Product (CoPP) as per World Health Organization (WHO) guidelines is extended to Ayurvedic, Siddha and Unani (ASU) medicines.
2. Quality Certifications Scheme implemented by the Quality Council of India (QCI) for grant of AYUSH 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. The Pharmacovigilance programme for Ayurvedic, Siddha, Unani and Homoeopathy (ASU & H) drugs has been implemented under Central Sector Scheme Ayush Oushadhi Gunavatta Evam Uttpadan Samvardhan Yojana (AOGUSY), which work through a three-tier network of a National Pharmacovigilance Centre (NPvCC), Five Intermediary Pharmacovigilance Centers (IPvCs) and 97 Peripheral Pharmacovigilance Centers (PPvCs) established across the country. These centres are mandated to monitor and report misleading advertisements to the respective State Regulatory Authorities for suitable action against the defaulter.

4. Further, Ministry of Ayush has developed and launched an IT enabled online portal “Ayush Suraksha” for Ayush Health care professionals and general public to track the reported misleading advertisements (MLAs)/Objectionable Advertisements (OAs) and Adverse Drug Reactions (ADRs) on 30th May 2025.

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