GOVERNMENT OF INDIA MINISTRY OF AYUSH

RAJYA SABHA UNSTARRED QUESTION NO. 975 TO BE ANSWERED ON 9th December, 2025

"Regulation of ayurveda-based immunity boosters during post-pandemic period"

975. Smt. Geeta alias Chandraprabha:

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

- (a) whether clinical data are being collated regarding claims made by Ayurveda-based immunity booster products post-2024 to assess their efficacy and safety;
- (b) whether any adverse event reports or disease flare-ups have been recorded among consumers;
- (c) whether the Ministry has issued advisories or initiated regulatory audits against misleading product labels or advertising; and
- (d) whether collaboration with Central Drugs Standard Control Organization (CDSCO) and FSSAI is being intensified to standardise immunomodulatory Ayush formulations in the State of Uttar Pradesh?

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

- (a) As per Rule 158(B) of the Drugs Rules, 1945, provisions for issue of license by the State Licensing Authorities to the medicine with respect to Ayurvedic, Siddha and Unani, the conditions relating to safety study and the experience or evidence of effectiveness has been specified. However, there is no such clinical data is maintained by the Central Government regarding claims made by Ayurveda-based immunity booster products post-2024 to assess their efficacy and safety.
- (b) Ministry of Ayush has implemented Central Sector Scheme, namely Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) since 2021-22. Reporting of Suspected Adverse Drug reactions is one of the components of Pharmacovigilance Program for Ayurveda, Siddha, Unani, and Homoeopathy (ASU&H) drugs under the AOGUSY Scheme with a three tier structure

comprising of 01 National Pharmacovigilance Co-ordination Centre (NPvCC), 05 Intermediary Pharmacovigilance Centres (IPvCs) and 97 Peripheral Pharmacovigilance Centres (PPvCs) across the country.

However, no adverse event or disease has been reported for Ayurveda-based immunity booster products post-2024 under this program till date.

(c) Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules thereunder encompass the provisions for prohibition of misleading advertisements and exaggerated claims of drugs and medicinal substances including Ayush medicines, which appear in the print and electronic media and Government has taken note thereof.

The three tier structure of Pharmacovigilance for ASU&H drugs set up in different parts of the country under AOGUSY Scheme of Ministry of Ayush are mandated to capture and report the misleading advertisements to the respective State Authorities.

Ministry of Ayush has issued advisory on dated 18th April, 2024 regarding "Compliance to the labelling provisions for ASU&H drugs/medicines".

Gazette notification dated 21.11.2025 has been issued by the Ministry of Ayush nominating Coordinator, The National Pharmacovigilance Coordination Centre (NPvCC), established at All India Institute of Ayurveda, New Delhi under section 79 (3) b of IT Act, 2000 and IT Rules, 2021 for taking action against misleading advertisements/ objectionable advertisements.

Further, Ministry of Ayush has developed an IT enabled online portal "Ayush Suraksha" and launched the portal on 30th May, 2025 to enhance regulatory transparency and accountability in the Ayush sector. The portal features a centralized dashboard for real-time tracking of suspected Adverse Drug Reactions and capturing of Misleading Advertisements/Objectionable Advertisements for prompt regulatory action and in-depth data analysis. The portal allows consumers and Ayush healthcare professionals to report and regulatory authorities to monitor misleading advertisements and adverse drug reactions.

(d) As per the information received from the State of Uttar Pradesh, there is no such collaboration with Central Drugs Standard Control Organization (CDSCO) and FSSAI to standardize immunomodulatory Ayush formulations in the State of Uttar Pradesh.
