GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO. 328
TO BE ANSWERED ON 03rd February, 2026

"Evidence, adverse events and quality control of Ayush products"

328. Dr. Syed Naseer Hussain:

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

(a) the number of Ayush formulations approved or recommended for post-COVID management and other chronic conditions since 2021 and how many of these are backed by published, peer-reviewed clinical evidence;

(b) the number of Adverse Drug Reaction (ADR) reports involving Ayush medicines received in the last three years and the action taken, including product withdrawals or warnings;and

(c) whether, in light of past controversies over claims around products such as Patanjali's "Coronil", the Ministry has tightened its rules on advertising, clinical trials and evidence requirements and if so, the details thereof?

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

(a) Ministry of Ayush has not approved or recommended any Ayush formulations for post-COVID management and other chronic conditions since 2021.

However, Ministry of Ayush constituted an Interdisciplinary Technical Review Committee (ITRC) for COVID-19 for the examination of the applications/claims on patent & proprietary (P&P) Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) medicines/ classical ASU&H medicines with new indication or re-purposing of licensed

P&P, ASU&H medicines for COVID-19, forwarded by the State Licensing Authorities/Individuals and referred by the Drug Policy Section of Ministry of Ayush.

(b) Ministry of Ayush is implementing a Pharmacovigilance Program for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs under its Central Sector Scheme-Ayush Oushadhi Gunvatta evam Uttpadan Samvardhan Yojana (AOGUSY). The program operates through a dedicated three-tier network comprising 01 National Pharmacovigilance Co-ordination Centre (NPvCC), 05 Intermediary Pharmacovigilance Centres (IPvC) and 97 Peripheral Pharmacovigilance Centres (PPvC) across the country. The All India Institute of Ayurveda (AIIA), New Delhi under Ministry of Ayush serves as the NPvCC for the implementation of the program. All PPvCs/IPvCs routinely report Misleading Advertisements (MLAs)/Objectionable Advertisements (OAs) and suspected Adverse Drug Reactions (ADRs) to the respective State/ UT Licensing Authorities for necessary action.

These reports are only suspected instances and are not actual adverse reactions. They are Individual Case Safety Reports, and will serve the purpose as Signals. None of the reports were serious, and no mortality was reported as on date.

The suspected Adverse Drug Reactions (ADRs) received under the Pharmacovigilance Programme for ASU&H drugs during the last three years are attached at **Annexure-I.**

(c) 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, 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.

In addition, as per Rule 158(B) of the Drugs Rules, 1945, already the provisions for issue of license by the State Licensing Authorities to the medicine with respect to Ayurvedic, Siddha and Unani medicines, the conditions relating to safety study and the experience or evidence of effectiveness has been specified. Rule 85 (A to I) in the Drugs Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathy medicines.

****

Annexure-I

The suspected Adverse Drug Reactions (ADRs) received under the Pharmacovigilance Programme for ASU&H drugs during the last three years are as below:

S. No.	Year	Suspected Adverse Drug Reactions (ADR)
1.	2023	420
2.	2024	521
3.	2025	728
	Total	**1,669**

****