GOVERNMENT OF INDIA

MINISTRY OF AYUSH

LOK SABHA

UNSTARRED QUESTION NO. 4336

TO BE ANSWERED ON 20th December 2024

"Complaints against AYUSH products"

4336. Dr. Kirsan Namdeo:

Will the Minister of Ayush be pleased to state:

(a) the total number of complaints received against misleading claims made about any herbal and AYUSH products through advertisements given in any electronic/print media during the last three years, year wise;
(b) whether any complaints have been received against sale of these herbal and AYUSH products in the market without any authentic clinical trial and if so, the details thereof;
(c) whether the Government has issued any directives to the States for appointing Gazetted Officers to monitor advertisements of such medicines, in order to check the veracity of AYUSHg products and if so, the details thereof; and
(d) the extent to which the Government has succeeded in checking these advertisements and misleading claims in the country?

ANSWER

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

(SHRI PRATAP RAO JADHAV)

(a) and (d) 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), Five Intermediary Pharmacovigilance Centres (IPvCs) and Ninety-nine Peripheral Pharmacovigilance Centres (PPvCs) is established across the country. 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.

Under the pharmacovigilance program, objectionable advertisements are regularly reported to the respective State Licensing Authorities for initiating action against the defaulters. Till date approximately 378 brands of Ayush system have been issued the notice for exploiting various regulations.

Under the Pharmacovigilance program till date a total of 42951 misleading advertisements related to Ayush drugs has been reported, details of last three years are as below:

Year	**Misleading Advertisements**
2022	7367 + 4 (COVID)
2023	7771
2024(Till Nov 2024)	9032
Total	**24174**

(b) Ministry of Ayush has issued a clarification on the request of State regulators and drug manufacturers about the provisions of Rule 158-B of the Drugs & Cosmetics Rules, 1945 in respect of pilot studies that are required as proof of safety and effectiveness for grant of license to manufacture for sale certain types of Ayureveda, Siddha & Unani (ASU) drugs. The term "clinical trial" as such is not mentioned in the context of ASU drugs-related regulatory provisions under Drugs & Cosmetics Rules, 1945. However, in accordance with the extant legal provisions, proof of effectiveness in the form of pilot study may be required for issuing license to an intended ASU drug, if the textual rationale, published literature and textual (authoritative book-based) indications are not furnished to support the claim of use or indication of that drug.

(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. State/UT Governments are empowered to enforce the provisions of Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules there under and Gazetted officers have been notified under section (8) of Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 to enter, search any premises or examine or seize any record related to the alleged misleading or improper advertisements and initiate action against the cases of default.

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