

**GOVERNMENT OF INDIA  
MINISTRY OF AYUSH**

**RAJYA SABHA  
UNSTARRED QUESTION NO.163  
TO BE ANSWERED ON 19<sup>th</sup> JULY, 2022**

**COMPLAINTS ABOUT MISLEADING CLAIMS MADE IN ADVERTISEMENTS  
REGARDING AYUSH  
MEDICINES**

**163 SHRI IRANNA KADADI:**

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

- a) the number of complaints received against misleading claims made about any herbal medicine in advertisements given in electronic or print media during the last three years;
- b) whether complaints have been received against the sale of these herbal medicines/products in the market without any authentic clinical trial and the subsequent death of persons by consumption of these medicines; and
- c) if so, the extent to which Government has succeeded in checking these misleading advertisements and the details thereof ?

**ANSWER  
THE MINISTER OF AYUSH  
(SHRI SARBANANDA SONOWAL)**

(a) 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. Central Government has notified insertion of Rule 170 in the Drugs & Cosmetics Rules, 1945 on 24<sup>th</sup> December, 2018 specifically for controlling inappropriate advertisements of Ayurvedic, Siddha and Unani medicines.

State/UT Governments are empowered to enforce the provisions of Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules there under and Rule 170 of the Drugs & Cosmetics Rules, 1945 pertaining to control and prohibition of misleading advertisements and exaggerated claims of drugs. Accordingly, directives have been issued to the States/UTs for appointing Officers 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. The state-wise information regarding the number of complaints received against misleading claims for Ayush medicines during the last three years is at **Annexure I.**

The Advertising Standards Council of India (ASCI) received complaints against misleading advertisements including those of herbal medicines / products in various media. During the period of April 2019 to March 2022, ASCI received 948 advertisement specific to herbal medicines/products.

(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 Ayurveda, 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. No death has been reported by consumption of ASU medicines.

(c) 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), Intermediary Pharmacovigilance Centres (IPvCs) and Peripheral Pharmacovigilance Centres (PPvCs) is established. 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. Objectionable advertisements are being reported to the respective State Licensing Authorities by PPvC at regular intervals. Total misleading advertisements at NPvCC received during last three years is as follows which are being reported to the respective State Licensing Authorities by PPvCs:

From March, 2019-February, 2020	4885
From March, 2020-February, 2021	6804
From March, 2021-June, 2022	10035

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**Annexure-I**

The state-wise information received regarding the number of complaints against misleading claims for Ayush medicines during the last three years:

S.no.	Name of the State/UT	Year –wise number of complaints received			
		2019	2020	2021	2022
1.	Arunachal Pradesh	0	0	0	-
2.	Goa	0	0	0	-
3.	Himachal Pradesh	04	05	06	-
4.	Uttarakhand	11	27	17	06
5.	Tripura	0	0	0	-
6.	Manipur	0	0	4	-
7.	West Bengal	-	18	16	09
8.	Gujrat	32	30	9	-
9.	Delhi	0			
10.	Rajasthan	0			
11.	Uttar Pradesh	06			
12.	Karnataka	11			
13.	Kerala	53			