

**GOVERNMENT OF INDIA
MINISTRY OF AYUSH**

**LOK SABHA
UNSTARRED QUESTION NO. 1503
TO BE ANSWERED ON 28TH JULY, 2023**

“EFFORTS FOR PRODUCTION OF AYURVEDA PRODUCTS”

**1503. SHRI KRUPAL BALAJI TUMANE:
SHRIMATI BHAVANA PUNDALIKRAOGAWALI:**

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

- (a) the framework prepared/proposed to be prepared by the Government for increasing the productivity of Ayurveda products of medicinal plants/herbs and other Indian medicinal products across the country;
- (b) the details of the high and low productivity of such products all over the country including Maharashtra, State/UT-wise;
- (c) whether the Government has taken/proposed to take any action against the misleading advertisements about AYUSH treatment and medicines during the last three years and the current year and if so, the details thereof;
- (d) the number of registered manufacturing units of AYUSH medicines, State/UT-wise and year-wise;
- (e) whether any subsidies/incentives have been provided to such manufacturers and if so, the details thereof; and
- (f) the efforts made/proposed to be made by the Government to ensure the quality and harmlessness of Ayurvedic, Unani and Homoeopathic medicines to win the trust of global community?

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

- (a) As prescribed in Drugs and Cosmetics Act 1940 and Rules 1945 made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Unani and Homoeopathic drugs, is vested with the State drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government.

Ministry of Ayush has implemented Central Sector Scheme AYUSH Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana (AOGUSY), was approved by Standing Finance Committee on 16.03.2021. The total financial allocation to this scheme is Rs. 122.00 crores for five years. The components of AOGUSY scheme are as follows -

A. Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards.

B. Pharmacovigilance of ASU&H drugs including surveillance of misleading advertisements.

C. Strengthening of Central and State regulatory frameworks including Technical Human Resource & Capacity Building programs for Ayush drugs.

D. Support for development of standards and accreditation/certification of Ayush products & materials in collaboration with Bureau of Indian Standards (BIS), Quality Control of India (QCI) and other relevant scientific institutions and industrial R&D centres.

(b) As per the information received from State/UTs, details of productivity of Ayurveda products are at **annexure-I**.

(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 & Rules thereunder.

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.

Under “Pharmacovigilance of ASU&H drugs including surveillance of misleading advertisements” component of AOGUSY Scheme; following misleading advertisements of Ayurveda, Siddha, Unani and Homoeopathy drugs have been reported to the state licensing authorities for possible action against the defaulters-

Year	No. of misleading advertisement
2020	5861
2021	8144
2022	7367

As per the information received from States/ UTs, action taken against the misleading advertisements about Ayush medicines during the last three years and the current year are at **Annexure-II**.

(d) As per the information received from States/ UTs, the number of registered manufacturing units of AYUSH medicines, State/UT-wise and year-wise are at **Annexure-III**.

(e) Yes sir. Under “Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards” component of AYUSH Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana (AOGUSY) scheme, details of Grant in aid released to Ayush Pharmacies in the year 2022-23, is as follows –

S.n o.	Name of the Pharmacy	Amount released (in rupees)
1.	Inducare Pharma Pvt. Ltd., Pune	Rs. 3,00,00,000/-
2.	Ayurchem Products, Maharashtra	Rs. 2,69,00,000/-
3.	Phytovedic India Pvt. Ltd., Maharashtra	Rs. 2,14,61,000/-
4.	Visesh Ayurved Pvt. Ltd Pharmacy, Kerala.	Rs. 1,91,56,000/-
5.	Amar Pharmaceuticals and labs (India) Pvt. Ltd., U.P	Rs. 1,43,43,000/-
6.	Shree Baidyanath Ayurved Bhawan, Pvt. Ltd, Madhya Pradesh	Rs. 2,08,92,000/-
7.	Kollam District Ayurveda Oushada Nirmana Vyavasaya Co Operative Society, Kerela	Rs. 64,29,000/-
Total		Rs. 13,91,81,000/-

(f) The efforts made by the Ministry of Ayush to ensure the quality and harmlessness of Ayurvedic, Unani and Homoeopathic medicines are as follows -

(i) As prescribed in Drugs and Cosmetics Act 1940 and Rules 1945 made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Unani and Homoeopathy drugs, is vested with the State Drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government. Rule 158-B in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Ayurvedic, Siddha, Unani medicines and Rule 85 (A to I) in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathy medicines. It is mandatory for the manufacturers to adhere to the prescribed requirements for licensing of manufacturing units & medicines including proof of safety & effectiveness, compliance with the Good Manufacturing Practices (GMP) as per Schedule T & Schedule M-I of Drugs and Cosmetics Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

(ii) Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H) under Ministry of Ayush, lays down the Formulary specifications and Pharmacopoeial Standards for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs, which serve as official compendia for ascertaining the Quality Control (identity, purity and strength) of the ASU&H drugs, included herein, as per Drugs & Cosmetics Act, 1940 and Rules 1945, thereunder. These standards and quality parameters included in the monographs of these Pharmacopoeias have been identified as such to align with the recommendations of World Health Organization (WHO) or other major pharmacopoeias prevalent worldwide.

PCIM&H has also signed a MOU with American Herbal Pharmacopoeia (AHP), USA to with an aim to strengthen, promote and develop standards in the field of Ayurveda and other Indian Traditional systems of medicine in USA and to enhance the export potential of the ASU&H drugs.

(iii) For facilitating exports of Ayush products, Ministry of Ayush encourages following certifications of AYUSH products as per details below:-

- Certification of Pharmaceutical Products (CoPP) as per WHO Guidelines for herbal products.
- Quality Certifications Scheme implemented by the Quality Council of India (QCI) for grant of AYUSH Premium 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.

iv. Rule 160 A to J of the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for approval of Drug Testing Laboratory for carrying out such tests of identity, purity, quality and strength of Ayurvedic, Siddha and Unani drugs as may be required under the provisions of these rules, on behalf of licensee for manufacture of Ayurvedic, Siddha and Unani drugs. As on date, 27 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. Further, 95 laboratories are approved or licensed under the provisions of Drugs and Cosmetics Rules, 1945 for quality testing of Ayurvedic, Siddha and Unani drugs and raw materials.

v. Ayush Export Promotion Council (AYUSHEXCIL), is a newly formed Export Promotion Council (set up by Ministry of Ayush and supported by Ministry of Commerce, Government of India), launched at Global Ayush Investment and Innovation Summit held in Gandhinagar, Gujarat on April 20, 2022). It is aimed to oversee exports of products of Ayurveda, Homoeopathy, Siddha, Sowa Rigpa and Unani systems and address trade issues pertaining to these sectors. It mandates to facilitate capacity building of its members on export procedures, organize Business to Business meetings, international events, road shows, seminars and workshops on the export of Ayush products, and to safeguard the scientific research in the field of Ayush healthcare. AYUSHEXCIL has conducted a workshop on “Attractive Packaging and Branding of various AYUSH/Traditional products to be Globally Competitive” on 7th July, 2023 at Juniper Hall, Indian Habitat Centre, New Delhi.

As per the information received from States/UTs, many State/UT has constituted technical expert committee regarding approval of patent & proprietary Ayush drugs after verifying the submission of documents relating to safety study, evidence of effectiveness and stability studies as per Rule 158B, Rule 161B and Rule 169 of Drugs & Cosmetics Rules, 1945.

Annexure-I

State/ UT-wise details of productivity of Ayurveda products are as follows –

S.no.	Name of the State/ UT	details of productivity of Ayurveda products	
1.	Andhra Pradesh	The high yielding products cultivated and developed by the farmers are Ashwagandha, Guduchi, Pippali, Shankha puspi, Bhumalaki, Karanja etc. The low yielding products are saffron, sandalwood due to local climatic condition.	
2.	Karnataka	High productivity – Asava and Aristas Low productivity – Kupa pakva rasayan and Bhasma	
3.	Odisha	State government has made provisions for funds towards manufacture of Ayurvedic medicines in the Government pharmacies of the State of Bolangir, Bhubaneshwar and Puri as detailed below for the last three years –	
		Financial year	Allotment in the unit of medicine
		2021-22	Rs. 2,72,60,000/-
		2022-23	Rs.2,72,60,00/-
		2023-24	Rs. 7,67,60,000/-
4.	Uttarakhand	In the year2022-23, approximately 2700 Ayurvedic patent products approved.	
5.	Tamil Nadu	In the past years, numbers of fresh license issued per year has been constantly raising i.e. 14 in the year 2021 and 19 in the year 2022	

Annexure-II

Action taken by State/ UT government against the misleading advertisements about Ayush medicines during the last three years and the current year –

S.no.	Name of the State/ UT	Action taken against the misleading advertisements								
1.	Delhi	About 30 show cause notices or memorandum issued for violating the norms of Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 during the last three years								
2.	Uttarakhand	Complains of 27 misleading advertisement in 2020-21, 17 misleading advertisement in 2021-22 and 07 misleading advertisement in 2022-23 has been received and action has been taken in accordance with the provisions of Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954.								
3.	Manipur	Action has been taken against 08 misleading advertisement								
4.	Odisha	No cases of misleading advertisement of Ayurvedic medicines								
5.	Maharashtra	Action has been taken against approximately 101 misleading advertisement.								
6.	Tamil Nadu	License of following products has been suspended for one month for illegal advertisement with false claim – <ul style="list-style-type: none"> • Asthra Powder Tonic Capsule & Cream, • Boraxine ointment • Segra Plus Capsule, Musli Segra capsule and Kamana Capsule 								
7.	Gujarat	Year-wise action taken against misleading advertisement are as follows – <table border="1" style="margin-left: 20px;"> <thead> <tr> <th>2020</th> <th>2021</th> <th>2022</th> <th>2023</th> </tr> </thead> <tbody> <tr> <td>30</td> <td>09</td> <td>16</td> <td>06</td> </tr> </tbody> </table>	2020	2021	2022	2023	30	09	16	06
2020	2021	2022	2023							
30	09	16	06							
8.	Kerala	05 court case filed regarding violating the norms of Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954								
9.	Madhya Pradesh	Issued show cause notice for stopping the misleading advertisement.								

Annexure-III

Number of registered manufacturing units of AYUSH medicines, State/UT-wise and year-wise are as follows -

S.no.	Name of the State/UT	Number of registered manufacturing units of AYUSH medicines			
1.	Andhra Pradesh	285 Ayurvedic manufacturing, 07 Homoeopathic drug manufacturing unit and 05 Homoeopathic drug manufacturing units (Total = 297)			
2.	Chhattisgarh	33 Ayurveda drug manufacturing units			
3.	Delhi	114 manufacturing units of Ayurveda and Unani			
4.	Himachal Pradesh	146 Ayurvedic manufacturing unite in the year 2022-23 and 08 Homoeopathic drug manufacturing unit			
5.	Haryana	950 Ayurveda, Sidhha and Unani drug manufacturing units			
6.	Goa	2018	2019	2020	2021
		02	03	02	01
7.	Gujarat	2020-21	2021-22	2022-23	
		472	530	588	
8.	Maharashtra	874 manufacturing units of Ayurveda and Unani and 30 manufacturing units of Homoeopathy			
9.	Madhya Pradesh	825 manufacturing units			
10.	Karnataka	2019-20	2020-21	2021-22	2022-23
		13	21	15	19
11.	Kerala	709 manufacturing units			
12.	Puducherry	2014-15	01		
		2015-16	02		
		2016-17	10		
		2017-18	05		
		2018-19	03		
		2019-20	03		
		2020-21	05		
		2021-22	06		
		2022-23	06		
13.	Tamilnadu	Total 507 Ayurvedic, Siddha and Unani manufacturing units. year-wise license granted are as follows –			

		2014-15	12	
		2015-16	11	
		2016-17	19	
		2017-18	41	
		2018-19	31	
		2019-20	22	
		2020-21	36	
		2021-22	42	
		2022-23	50	
14.	Uttarakhand	Total 236 manufacturing units are registered for manufacturing Ayurveda and Unani medicines.		
15.	Odisha	103 manufacturing units		
16.	Arunachal Pradesh	01 manufacturing unit		
17.	Manipur	Nil		
18.	Mizoram	Nil		
19.	Ladakh	Nil		
20.	Jammu & Kashmir	Nil		
21.	Lakshadweep	Nil		
22.	Chandigarh	Nil		