

**GOVERNMENT OF INDIA
MINISTRY OF AYUSH**

**LOK SABHA
UNSTARRED QUESTION NO. 1088
TO BE ANSWERED ON 08.12.2023**

“Productivity of Ayurveda Medicines”

1088. SHRI VIJAY KUMAR DUBEY:

Will the Minister of Ayush be pleased to state:

- (a) the roadmap prepared/proposed to be prepared by the Government to increase the productivity of Ayurveda and other Indian medicine products/herbs across the country, State/UT-wise;
- (b) the details of the productivity of such AYUSH medicines during the last three years and the current year in the country, State/UT-wise including Uttar Pradesh;
- (c) whether any Central Scheme implemented by the Government has strengthened the safety and vigilance/monitoring mechanism for ensuring the quality of AYUSH medicines/drugs;
- (d) if so, the details thereof along with the process of assessing/evaluating the quality and identification of adverse effects of such medicines/ drugs; and
- (e) the steps taken/proposed to be taken by the Government for qualitative production/distribution of AYUSH medicines along with widening and deepening the scope of their research?

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

(a) and (b) 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 and Unani 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. 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 of Drugs and Cosmetics Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

Details of the Ayurvedic medicines Turnover of IMPCL for last three years including U.P is as under:

Year	Value
2022-23	Rs. 174.53 Cr
2021-22	Rs. 230.15 Cr
2020-21	Rs. 139.65 Cr

As per the information received from various State/ UTs, the details of productivity of Ayush medicines and the steps taken to increase the productivity of Ayurveda and other Indian medicine products/herbs are at **Annexure-I**.

(c) and (d) Yes Sir. In the year 2021, Ministry of Ayush has implemented Central Sector Scheme AYUSH Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana (AOGUSY). 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. Detailed guidelines are available at <https://ayush.gov.in/images/Schemes/aoushdhi.pdf>.

Pharmacovigilance Program for Ayurveda, Siddha, Unani, and Homoeopathy (ASU & H) Drugs has been established under the Central Sector Scheme of Ministry of Ayush (AOGUSY Scheme). The program is working through a three-tier network of a National Pharmacovigilance Centre (NPvCC), Five Intermediary Pharmacovigilance Centres (IPvCs)

and 99 Peripheral Pharmacovigilance Centres (PPvCs) established across the country. Under the Pharmacovigilance Program for ASU & H Drugs major objectives are to keep vigilance over Ayush drugs and to report misleading advertisements. Through three tiers network of Pharmacovigilance (NPvC, IPvC, PPvC) regular reporting of suspected adverse drug reactions is being done. Since 2018 to till date, 1637 such individual case safety reports have been reported in a specified format for reporting such adverse reactions.

Also, there is regular reporting of objectionable advertisements appearing in print and electronic media. Since 2018 to till date, 32,527 such misleading advertisements have been reported. All misleading advertisements are being reported to the respective State Licensing Authorities by peripheral centers at regular intervals for the possibility of initiating action against the defaulters.

As on date, 35 Drug Testing Laboratories have been established under state governments and Union Territories. Further, 102 laboratories are approved or licensed under the provisions of Rule 160 A to J of the Drugs and Cosmetics Rules, 1945 for, quality testing of Ayurvedic, Siddha and Unani drugs and raw materials.

(e) The steps taken by the Ministry of Ayush for qualitative production/distribution of Ayush medicines along with widening and deepening the scope of their research are as follows –

(i) 05 Research Councils under Ministry of Ayush are engaged in activities like Medicinal Plant Research (Medico-Ethno Botanical Survey, Pharmacognosy and Tissue Culture), Drug Standardization, Pharmacological Research, Clinical Research, Literary Research & Documentation and Tribal Health Care Research Programme. Further, 12 National Institutes under Ministry of Ayush are also conducting various research studies on Ayush drugs.

Ministry of Ayush has also implemented AYURGYAN Scheme for promoting education and research in the field of Ayush and to support Research & Innovation in Ayush by extra mural research and education in Ayush by providing academic activities, training, Capacity Building etc. Further, under the Centre of Excellence component of AYURSWASTHYA Yojana, financial assistance is provided to eligible individual organizations/institutes for establishing and upgrading their functions & facilities and/or for research & development activities in Ayush.

(ii) 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, 35 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. Further, 102 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.

(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) As per the information received from States/UTs -

- State/UT has also 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.
- State Government of Odisha has made provisions for funds towards manufacture of Ayurvedic medicines in the Government pharmacies of the State at Bolangir, Bhubaneswar and Puri. The State Drugs Testing and Research Laboratory (ISM), Bhubaneswar is functioning as in-house laboratory of these pharmacies for quality testing of the drugs.
- State of Kerala has appointed a committee to study the standardization of Ayurveda drugs in the state, as per order number G.O.(P) 291/2023/AYUSH dated 01/08/2023. Research and development facilities need to be established in the state, and currently, no government agencies are engaged in the research and development of Ayush drugs/products.

Annexure-I

Details of steps taken to increase the productivity of Ayurveda and other Indian medicine products/herbs –

S.No.	Name of the State/UT	Information received from State/ UT government
1.	Haryana	The ASU Drug Manufacturing License is being issued to increased ASU Drug manufacturers under the provisions of Drug and Cosmetic Act, 1940 and Rules made thereunder. There are 994 ASU drug manufacturing units in the Haryana State.
2.	Himachal Pradesh	The provisions of Drugs & Cosmetic Act/Rules made thereunder & instruction/guidelines issued by the Ministry of Ayush, Govt. of India are being followed.
3.	Kerala	Kollam District Oushadha Nirmana Co-operative Society Limited has received an amount of Rs. 64.29 Lakh under AOGUSY scheme.
4.	Assam	Nil
5.	Maharashtra	Nil
6.	Puducherry	Nil
7.	Gujarat	Nil
8.	Madhya Pradesh	Nil
9.	Goa	Nil
10.	Odisha	At present 03 nos. of Government Ayurvedic Drug manufacturing units are functioning in the State at Bolangir, Bhubaneswar and Puri to increase the productivity of Ayurveda and other Indian medicine products. The details of the productivity of such Ayush medicines during

		the last three years and the current year for Odisha is as under	
		Financial Year	Allotment in the un Medicine
		2020-21	Rs. 2,72,60,000/-
		2021-22	Rs. 2,72,60,000/-
		2022-23	Rs. 2,72,60,000/-
		2023-24	Rs. 7,67,60,000/-
11.	Karnataka	Details of productivity of Ayurvedic medicines are as follows —	
		S.no	Category of medicine
		•	Quantity of production (in metric system)
		1.	Anjana/Pisti
		2.	Churna/ Nasya Manjan/ Lepa/ Kwath Churn
		3.	Pills/ Vatti/ Gutika/ Matirai and tablets
		4.	Kupi pakva/ Ksara/Parpati/ Lavana/ Bhasma/ Satva/ Sindhura/ Karpu/ Uppu/ Param
		5.	Kajal
		6.	Capsules
		7.	Ointment/ Marham/ Pasai
		8.	Pak/ Avleh/ Khand/ Modak/ Lakayam

		9.	Panak, Syrup/ Pravahi Kwath manapaku	1612978.79 gallon
		10.	Asava/ Aristha	3695962.5 gallon
		11.	Sura	17079.78 gallon
		12.	Ark/ Tinir	18646.58 gallon
		13.	Tail/ Ghrit/ Ney	1684979.96 gallon
		14.	Ashcyton/ Netra Malham panir/ Karn Bindu/ Nasabindu	261303.54 gallon
12.	Andhra Pradesh	Proposal are prepared by the Andhra Pradesh Medicinal and Aromatic Plants Board production of quality planting material (QPM) through 15 small nurseries are started for increasing the productivity of raw material good agriculture practices (GAP) will be imparted to the formers to various Information education and communication (IEC) programs Activities		