

**GOVERNMENT OF INDIA
MINISTRY OF AYUSH**

**LOK SABHA
UNSTARRED QUESTION NO. 3247
TO BE ANSWERED ON 05TH AUGUST, 2022**

“PHARMACOPOEIA COMMISSION FOR INDIAN MEDICINE”

**3247. SHRI RAJA AMARESHWARA NAIK:
DR. SUKANTA MAJUMDAR:
SHRI BHOLA SINGH:
SHRI RANVEER SINGH (RAJU BHAIYA):
SHRI VINOD KUMAR SONKAR:
SHRIMATI SANGEETA KUMARI SINGH DEO:**

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

- a) Whether the Government has established Pharmacopoeia Commission for Indian Medicine and Homoeopathy to publish and revise Pharmacopoeia standards which are basic need to ensure quality, safety and efficacy of Ayush medicines in the country, if so, the progress made thereon so far;
- b) the Number of monographs of single drugs and compound formulations published during the last five years, year-wise;
- c) the Number of Ayurvedic companies functional and established across the country during the last five years; year-wise and state wise;
- d) Whether there is any mechanism to control and monitor the quality of Ayurvedic medicines and formulations in the country, if so, the details thereof;
- e) Whether several complaints have been received regarding production/sale of sub-standard Ayurvedic medicines/formulations in the country, if so, the action taken thereon; and
- f) The proposed corrective steps to be implemented for the betterment of the Ayurvedic medicine industry?

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

(a): Yes, Sir. The Government of India has established Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), as a subordinate office under Ministry of Ayush by merging Pharmacopoeia Commission of Indian Medicine & Homoeopathy (PCIM&H) and the two central laboratories namely Pharmacopoeia Laboratory for Indian Medicine (PLIM), Ghaziabad and Homoeopathic Pharmacopoeia Laboratory (HPL) vide gazette dated 6th July, 2020).

The Commission is engaged in development of Pharmacopoeial Standards for Ayurvedic, Unani, Siddha & Homoeopathic drugs. Further, PCIM&H is also acting as Central Drug Testing cum Appellate Laboratory for Indian systems of Medicine & Homoeopathy.

After re-establishment, a total of 1483 samples of ASU&H drugs have been tested during 6th July, 2020 to till date and 03 Pharmacopoeial monographs along with their formulary specifications for AYUSH Kwath related formulation has been published. Apart from Pharmacopoeial Monographs, National Formulary for Unani Medicines, Part-IV (2nd Edition) comprising formulary specifications of 166 formulations have also be published.

(b): 50 monographs of single drugs of Ayurveda along with 51 monographs of formulation of Ayurvedic drugs, 1 monograph of formulation of Siddha drug and 101 monographs of formulation of Unani drugs have been published during the last five years . The details may be seen at **Annexure-I**.

However, since inception of PLIM & HPL (now PCIM&H *w.e.f.* 6th July 2020), a total number of 2199 quality standards on raw materials (Single Drugs of plant/animal/mineral/metal/ Chemical origin) used in ASU&H systems of medicines have been published in various Pharmacopoeias and also 405 quality standards of ASU formulations also been published in respective pharmacopoeias.

(c): The number of Ayurvedic companies functional and established across the country during the last five years, year-wise and State wise may be seen at **Annexure-II**.

(d): 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, 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.

(e) : As prescribed in Drugs and Cosmetics Act 1940 and Rules 1945 made there under, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Unani, is vested with the State drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government. As per the information received from States/ UTs, action taken by State drug Controllers/ State Licensing Authorities regarding production/sale of sub-standard Ayurvedic medicines/formulations is as follows –

S. no.	Name of the State/UTs	Action taken
1.	Tamil Nadu	92 license suspended/ cancelled since 2017 to 2021
2.	Odisha	13 license of cancelled since 2017-18 to 2022-23
3.	Maharashtra	Since 2016-17 to 2022, 84 prosecution orders issued, 38 prosecutions filed and 46 are pending.

(f): 1. This Ministry has issued Gazette notification no. G.S.R 716 E for Amendment in the Drugs Rules, 1945 related to licensing process of ASU drugs on 01.10.2021. The amendments have been done with a view to reduce the compliance burden and facilitate ease of doing business. The

process to grant license to manufacture Ayurveda, Siddha and Unani (ASU) drugs has been made swift, paperless and more transparent the license application system through online e-aushadhi.gov.in portal. The license of the ASU drugs have been made perpetual i.e. with one time registration fee the license of the product will be valid lifetime with no further retention or renewal fees thereafter. The maximum time in granting the license to manufacture ASU drugs has been reduced from three months to two months.

(2.) In addition to the above, for facilitating exports, 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.

(3.) Ministry of Ayush has implemented Central Sector Scheme AYUSH Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana (AOGUSY). The objectives of the Scheme are as under;

- i. To enhance India's manufacturing capabilities and exports of traditional medicines and health promotion products under the initiative of Atmanirbhar Bharat.
- ii. To facilitate adequate infrastructural & technological upgradation and institutional activities in public and private sector for standardization, quality manufacturing and analytical testing of Ayush drugs & materials.
- iii. To strengthen regulatory frameworks at Central and State level for effective quality control, safety monitoring and surveillance of misleading advertisements of Ayush drugs.
- iv. To encourage building up synergies, collaborations and convergent approaches for promoting standards and quality of Ayush drugs & materials.

The components of the AYUSH Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana (AOGUSY) Scheme are as under;

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

Annexure - I

The number of monographs of single drugs and compound formulations published during the last five years, year-wise (2017 to 2022)

Sl.No.	System of Medicine	Single drugs and compound formulations published	Year of Publication	Number of Monographs
1.	Ayurveda			
	Single Drugs	Ayurvedic Pharmacopoeia of India Part I (Single Drugs), Vol. IX (Hydro-alcoholic & Water extracts)	2017	50
	Formulation	Ayurvedic Pharmacopoeia of India, Part II (Formulations), Vol. IV	2017	50
		Pharmacopoeial Monograph of AyushKvātha Cūrṇa(Stand-alone)	2021	01
2.	Siddha			
	Single Drugs	Nil		
	Formulation	Pharmacopoeial Monograph of AyushKuṭinīrCūraṇam (Stand-alone)	2021	01
3.	Unani*			
	Single Drugs	Nil		
	Formulation	Unani Pharmacopoeia of India, Part II (Formulations), Vol. III,	2017	50
		Unani Pharmacopoeia of India, Part II (Formulations), Vol. IV	2019	50
		Pharmacopoeial Monograph of AyushSafūf-i-Joshānda (Stand-alone)	2021	01
4.	Homoeopathy			
	Single Drugs	Nil		
	Formulation	Nil		

*Apart from Pharmacopoeial Monographs, National Formulary for Unani Medicine, Part-IV (2nd Edition) comprising formulary specifications of 166 formulations recently published in 2022.

ANNEXURE-II

Number of Ayurvedic companies functional and established across the country during the last five years; state wise

S.no.	Name of the State/UT		Year wise (for last five years)					
			2017	2018	2019	2020	2021	2022
1.	Karnataka		-	16	15	23	13	11
2.	Punjab		-	20	18	26	34	48
3.	Manipur		-	-	-	-	-	-
4.	Tripura		-	-	-	-	-	-
5.	Mizoram		-	-	-	-	-	-
6.	Lakshadweep		-	-	-	-	-	-
7.	Tamil Nadu		07	11	07	08	14	-
8.	Delhi		83	82	90	85	83	-
9.	Odisha	No. of existing units as on 01 st April of the year	79	84	85	87	90	96
		No. of new added	06	05	06	04	07	05
		No. of unit license cancelled	01	04	04	01	01	02
10.	Goa	No. of own Ayurvedic companies established	NIL	01	02	NIL	NIL	NIL
		No. of loan Ayurvedic companies established	NIL	02	01	01	NIL	NIL
		No. of own Ayurvedic companies functional in Goa is 09 and loan Ayurvedic companies functional in Goa is 05						
11.	West Bengal	No. of newly established firms	-	-	13	18	18	09
12.	Chhattisgarh	No. of newly established firms	03	01	03	00	05	-
13.	Uttarakhand	Companies established	-	07	09	29	12	02
		At present total 320 (223 units and 97 lone licensee) companies are registered for manufacturing of Ayurvedic & Unani medicine						
14.	Himachal Pradesh	License issued	10	12	03	12	11	-
		Total number of Ayurvedic companies functional - 159						
15.	Kerala	Functional firm	715	718	692	698	641	-
		Fresh license issued	38	48	65	52	54	-
16.	Maharashtra	Functional	440	460	458	477	495	482 (as on 31 st July, 2022)
		New established	28	31	14	31	33	13
17.	Puducherry	Total 42 Ayurvedic companies as of year 2022						
18.	Chandigarh	One pharmaceutical company Wahe Products was functional last year. Now, pharmaceutical company is closed						