

**GOVERNMENT OF INDIA
MINISTRY OF AYUSH**

**LOK SABHA
UNSTARRED QUESTION NO. 4866
TO BE ANSWERED ON 1st April, 2022**

**SAFETY AND QUALITY OF AYURVEDA, UNANI AND HOMEOPATHY
MEDICINES**

**4866. SHRI B.B.PATIL:
SHRI JAYANT SINHA:**

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

- (a) the efforts being made by the Government to win the trust of the global community about the safety and quality of Ayurveda, Unani and Homeopathy medicines;
- (b) the roadmap prepared/being prepared by the Government to increase the productivity of Ayurveda and other Indian medicinal products and herbs across all States in the country;
- (c) the details of the productivity (high and low) of the said medicines, State/UT-wise including Telangana;
- (d) whether any action was taken in 2021-22 against misleading advertisements for treatment and drugs under AYUSH and if so, the details thereof;
- (e) the number of registered manufacturing units of AYUSH drugs, State-wise, and year-wise; and
- (f) whether any subsidies or incentives are being given for manufacturing AYUSH drugs and if so, the details thereof?

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

(a) To assure safety and quality of Ayurveda, Siddha, Unani and Homeopathy medicines, the manufacturing of these medicines has been brought under the scope of Drugs and Cosmetics Act, 1940 and rules made thereunder. As per the provisions of the Drugs rules, 1945, manufacturing license is granted by the concerned State Licensing Authority only after ensuring that the requirements specified under Schedule T for Ayurveda, Siddha, Unani medicines and Schedule M1 for Homoeopathy medicines.

The Ministry of Ayush has also implemented a Central Sector Scheme of Pharmacovigilance of Ayurveda, Siddha Unani & Homeopathy drugs since June 2018 for inculcating the culture of Adverse Drug Events (ADE) reporting, documentation and analysis for further regulatory action. The Scheme has an established three tier network. All India Institute of Ayurveda (AIIA), New Delhi has been designated as the National Pharmacovigilance Coordination Centre (NPvCC). At present, there are 5 Intermediary Pharmacovigilance Centres (IPvC's) and 74 Peripheral Pharmacovigilance Centres (PPvC's).

International standards for AYUSH products are governed by WHO-GMP, EU-GMP or any other standards that are laid down by the importing countries and to comply with other requirements of importing countries. The WHO certification scheme, which is a scheme of Certificate of Pharmaceutical Product (COPP) is issued by National Regulatory Authority (NRA) for the purpose of international commerce i.e. for registration of products in foreign countries. Central Drugs Standard Control Organisation (CDSCO) issues Certification of Pharmaceutical Product (COPP) to Ayurvedic, Siddha or Unani products after examination of such applications in consultation with the Ministry of Ayush.

In addition to the above, for facilitating export, the Ministry of Ayush encourages following certifications of AYUSH products as per details below:-

- (i) Certification of Pharmaceutical Products (CoPP) as per WHO Guidelines for herbal products.
- (ii) 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.

Further, on 25th March, 2022 a Host Country agreement has been signed between the Government of India and the World Health Organization (WHO) at Geneva for establishment of the WHO Global Centre for Traditional Medicine (WHO GCTM) in Jamnagar, Gujarat. This would be the first and only global outposted Centre (office) for traditional medicine across the globe. It shows the support offered by Government of India to this cause and its recognition globally.

(b) Ayush Ministry has taken various steps to increase the productivity of Ayurveda and other Indian medicinal products and herbs at different levels:

i. Ease out licensing process: This Ministry has issued Gazette notification no. GSR 716 E for Amendment in the Drugs Rules, 1945 related to licensing process of ASU drugs on 1.10.2021. 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 swift, paperless and more transparent the license application system has been made online through 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.

ii. Promotion of Ayush products for Covid-19:

- In the wake of COVID-19 outbreak, the Ministry of Ayush has issued direction to All State Government/UT's to give permission for issue of license to the Ayurvedic drug manufactures to manufacture and sell in Generic name as 'AyushKwath' in accordance with the provisions of Drugs and Cosmetics Rules 1945.
- The medicines which emerged out to be useful and mentioned in the National Guidelines issued by the Ministry of Ayush, are being manufactured by most of the Ayurvedic drugs manufacturers.
- Research and Transfer of technology: During the second wave of this pandemic, the scientists of reputed research institutions of the country have found that AYUSH 64, a poly herbal formulation developed by the Central Council for Research in Ayurvedic Sciences (CCRAS) is useful in the treatment of asymptomatic, mild and moderate COVID-19 infection as an adjunct to standard care. In order to provide maximum benefit of Ayush systems of medicine, a Nation-wide campaign for distribution of AYUSH-64 and KabasuraKudineer (Siddha Medicine) was taken up across the country. CCRAS has transferred AYUSH-64 manufacturing technology through National Research Development Corporation (NRDC) to 46 manufacturing units for manufacturing of AYUSH-64.
- During COVID-19/Omicron surge the Ministry promoted the use of Ayuraksha Kit, BalRaksha Kit and Ayur care Kit for the health promotion of the masses. In

this regard all the State licensing authorities were informed that requirement of separate Licence for making kits with the specified components of Ayuraksha Kit, BalRaksha Kit and Ayur care Kit for the manufacturers having valid license of the individual component of the kit is not required.

iii. Schemes to support Ayurvedic medicines production: Under National Ayush Mission (NAM) from 2014-2021, apart from other services Grant-in-aid were also provided for Strengthening of State Government ASU&H Pharmacies. Also, under medicinal plants component of NAM, financial assistance has been provided in the form of subsidy to encourage the farmers for cultivation of medicinal plants throughout the country. At present, Central Sector Scheme for AyushOushadhiGunavattaevamUttipadanSamvardhanYojana (AOGUSY) has been implemented for the year 2021-2026. One of the components of the scheme is Strengthening and up-gradation of Ayush Pharmacies to achieve higher standards.

iv. In order to provide a platform for trade of Medicinal Plants & to provide easy market access, National Medicinal Plants Board (NMPB), Ministry of Ayush has launched “e-CHARAK” mobile application as well as web portal for the promotion and marketing of medicinal plants/herbs. “e-CHARAK” is a platform to enable information exchange between various stakeholders mainly farmers involved in the medicinal plants sector across the country. The “e-CHARAK” application supports different local languages and it also provides fortnightly market price of 100 Medicinal Plants from 25 herbal markets across India.

(c) State-wise details of the productivity (high and low) of the said medicines is not maintained by the Ministry of Ayush.

(d) The 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. The State/UT Governments are empowered to enforce the legal provisions under this Act.

339 such misleading advertisements of Ayush products and services registered on the Grievance Against Misleading Advertisement (GAMA) portal of Department of Consumer Affairs in the F.Y. 2021-22 and 8144 misleading advertisements of Ayush products and

services reported by the Pharmacovigilance centres in 2021 (Jan-Dec) were forwarded to the respective State Licensing Authorities for taking appropriate action as per extant rules.

(e) The number of registered manufacturing units of AYUSH drugs, State-wise, and year-wise is at Annexure.

(f) In order to support the pharmacies, the Ministry of Ayush is implementing a Central Sector Scheme for Ayush Oushadhi Gunavattaevam Utpadan Samvardhan Yojana (AOGUSY) for the year 2021-2026. One of the components of the scheme is Strengthening and up-gradation of Ayush Pharmacies to achieve higher standards, wherein financial support is provided to both private and public sector manufacturing units.

Annexure

Number of registered manufacturing units of AYUSH drugs, State-wise, and year-wise

Sl. No.	State/UT	2019	2020	2021
1	A&N Island	0	0	0
2	Andhra Pradesh	304	261	261
3	Arunachal Pradesh	1	1	1
4	Assam	40	40	44
5	Bihar	252	155	286
6	Chandigarh	1	1	2
7	Chhattisgarh	32	30	30
8	D&N Haveli & Daman and Diu	17	23	23
9	Delhi	103	120	125
10	Goa	6	9	11
11	Gujarat	587	751	797
12	Haryana	518	613	447
13	Himachal Pradesh	138	144	161
14	Jammu & Kashmir	15	21	22
15	Jharkhand	27	28	34
16	Karnataka	222	358	226
17	Kerala	905	814	753
18	Ladakh	0	0	0
19	Lakshadweep	0	0	0
20	Madhya Pradesh	584	679	699
21	Maharashtra	725	882	834
22	Manipur	0	0	0
23	Meghalaya	0	0	0
24	Mizoram	0	0	0
25	Nagaland	0	0	0
26	Odisha	90	92	91
27	Puducherry	40	60	55
28	Punjab	232	293	352
29	Rajasthan	350	355	317
30	Sikkim	3	5	5
31	Tamil Nadu	305	343	313
32	Telangana	634	774	1162
33	Tripura	0	0	0
34	Uttar Pradesh	1755	1784	1835
35	Uttarakhand	196	270	324
36	West Bengal	325	373	218
	TOTAL	8407	9279	9428