

**GOVERNMENT OF INDIA
MINISTRY OF AYURVEDA, YOGA & NATUROPATHY,
UNANI, SIDDHA AND HOMOEOPATHY
(AYUSH)**

**LOK SABHA
UNSTARRED QUESTION NO. 154
TO BE ANSWERED ON 15TH DECEMBER, 2017**

SUPPLY OF SPURIOUS AYUSH MEDICINES

**154. SHRIMATI V. SATHYA BAMA:
SHRIMATI RITI PATHAK:
SHRI K.N. RAMACHANDRAN:
SHRI PR. SENTHIL NATHAN:
SHRI BHARATHI MOHAN R.K.:**

Will the Minister of **AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)** be pleased to state:

- (a) the details of AYUSH clinics and hospitals running at present in the country, State/UT-wise;
- (b) whether the Government has received information regarding the supply of spurious AYUSH medicines and if so, the details thereof;
- (c) whether the Government has taken any stringent measures to control and curb the sale of such medicines in the country;
- (d) if so the, details thereof and the list of cases booked against the sale and distribution of spurious medicines during each of the last three years, State/UT-wise; and
- (e) whether the Government has chalked out any plans to provide adequate supply of good quality AYUSH medicines and drugs in the country and if so, the details thereof?

**ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA,
YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY
(SHRI SHRIPAD YESSO NAIK)**

- (a): The States/UTs wise number of AYUSH hospitals/dispensaries is furnished at **Annexure-I.**
- (b): Information received from some States/UTs regarding the number of ASU&H medicines tested and declared spurious/ sub-standard/adulterated during the last three years is placed at **Annexure-II.**

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(c) & (d): The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 have provisions for the regulation and quality control of Ayurvedic and Unani medicines in the country, which are enforced by the State Governments. It is mandatory for the manufacturers to adhere to the prescribed requirements for licensing of manufacturing units & medicines including proof of safety & effectiveness and comply to Good Manufacturing Practices (GMP) and quality standards of drugs given in the pharmacopoeia. Spurious, Adulterated and Misbranded medicines and the penal provisions thereto are defined in the Act. Accordingly, the Licensing Authorities/Drugs Controllers appointed by the State Governments are empowered to take necessary action against the defaulters acting in contravention of the legal provisions.

Following steps have been taken by the Government for effective quality control of AYUSH medicines:

- 1) Rule 158-B in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Ayurvedic and Unani medicines in accordance with the proof of safety and effectiveness.
- 2) Display of shelf-life for expiry date on the label of medicines has been made mandatory under the provisions of Drugs and Cosmetic Rules, 1945.
- 3) Scheduled list of potentially hazardous substances of Ayurvedic and Unani systems is notified under the provisions of Drugs and Cosmetics Rules, 1945. It is mandatory for the manufacturer to label the container with the words "Caution: To be taken under medical supervision" both in English and Hindi languages for the formulations containing such ingredients.
- 4) 27 State Drug Testing Laboratories and 47 State Pharmacies have been supported for strengthening their infrastructural and functional capacity. As on date 55 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.
- 5) In order to promote safe use of AYUSH medicines, the Ministry of AYUSH has signed a MoU with the Advertising Standards Council of India (ASCI) to undertake monitoring of misleading advertisements appearing in the print and TV media and bring the defaulters to the notice of the Central Government and the State Regulators for taking necessary action.
- 6) The Medical Store In-charges of respective systems of medicine and Medicines Inspection Committee (MIC) randomly check the medicines supplied under Central Government Health Scheme. If the store receives any complaint in respect of any medicine, the supply of that medicine is stopped immediately and process of withdrawal of the issued medicine from dispensary or hospital is started. Samples of medicines are sent for testing to Central Laboratory or NABL accredited /Government approved laboratory.

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7) Powers are vested with the Central Government under Section 33P of the Drugs & Cosmetics Act, 1940 to give directions to the State Governments as and when required for enforcement of the legal provisions related to Ayurvedic, Siddha and Unani drugs.

8) Central Government issued orders to procurement agencies of ASU&H Drugs to obtain batch-wise testing reports of the medicines being procured and supplied to hospitals & dispensaries. States-wise information of testing of drugs and action taken for Spurious/adulterated Drugs is provided in **Annexure-II**.

(e): In order to provide Good Quality AYUSH medicines the Government is providing Grant-in-aid to the States and UTs under National AYUSH Mission (NAM) for augmenting quality control of these drugs, including strengthening of Pharmacies, Drug Testing Laboratories, enforcement framework and testing of drugs.

Further, under the Centrally Sponsored Scheme of National AYUSH Mission (NAM) for providing adequate supply of good quality AYUSH medicines and drugs in the country, following provision has been made:

- a) Essential drugs and medicines required for implementation of the Mission will have to be procured from Essential Drugs List (EDL) for Ayurveda, Unani, Siddha and Homoeopathy published by Department of AYUSH, Government of India.
- b) At least 50% of the Grant-in aid provided for procurement of medicines should be used for procuring medicines from M/s Indian Medicine Pharmaceutical Corporation Limited (a Central Public Sector Undertaking) or from Public Sector undertakings, pharmacies under State Governments and Co-operatives manufactured in their own manufacturing units and having Good Manufacturing Practices (GMP) compliance, keeping in view the need for ensuring quality of AYUSH drugs and medicines.
- c) The remaining Grant-in aid provided under the Mission for purchase of medicines may be used for procuring medicines as per Essential Drugs List (EDL) of Ayurveda, Unani, Siddha and Homoeopathy published by Department of AYUSH, Government of India, from other Good Manufacturing Practices (GMP) compliant units having valid manufacturing licenses.
- d) Essential non drug items like dressing items for first aid etc. may be provided out of the amount sanctioned for medicine/ essential drugs under different components required for achieving the desired objectives subject to a ceiling of five percent of the total amount sanctioned for the purpose.

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Annexure-I

State/UT wise/System wise Number of AYUSH Hospitals as on 1-4-2016

S. No	State / UT	Ayurveda	Unani	Siddha	Yoga	Naturopathy	Homoeopathy	Sowa - Rigpa	Total
1	Andhra Pradesh	3	2	0	0	0	3	0	8
2	Arunachal Pradesh	10	0	0	0	0	2	0	12
3	Assam	1	0	0	0	0	3	0	4
4	Bihar	5	1	0	0	0	2	0	8
5	Chhattisgarh	9	1	0	1	0	3	0	14
6	Delhi	2	1	0	0	0	2	0	5
7	Goa	0	0	0	0	0	0	0	0
8	Gujarat	42	0	0	0	6	16	0	64
9	Haryana	9	1	0	0	0	1	0	11
10	Himachal Pradesh	31	0	0	0	1	0	0	32
11	Jammu & Kashmir	1	1	0	0	0	0	0	2
12	Jharkhand	1	0	0	0	0	4	0	5
13	Karnataka	170	18	0	3	6	16	0	213
14	Kerala	124	0	1	0	1	31	0	157
15	Madhya Pradesh	21	0	0	0	0	2	0	23
16	Maharashtra	63	6	0	0	0	46	0	115
17	Manipur	0	2	0	0	13	7	0	22
18	Meghalaya	3	0	0	0	0	7	0	10
19	Mizoram	0	0	0	0	0	8	0	8
20	Nagaland	0	0	0	0	0	2	0	2
21	Odisha	8	0	0	0	0	6	0	14
22	Punjab	5	0	0	0	0	4	0	9
23	Rajasthan	118	11	0	1	2	6	0	138
24	Sikkim	1	0	0	0	0	0	0	1
25	Tamil Nadu	2	1	271	1	0	1	0	276
26	Tripura	2	0	0	0	0	2	0	4
27	Uttar Pradesh	1771	204	0	0	0	8	0	1983
28	Uttarakhand	402	2	0	0	0	1	0	405
29	West Bengal	6	1	0	0	0	12	1	20
30	A&N Island	1	1	1	1	0	1	0	5
31	Chandigarh	1	0	0	0	0	1	0	2
32	D & N Haveli	0	0	0	0	0	0	0	0
33	Daman & Diu	1	0	0	0	0	1	0	2
34	Lakshadweep	0	0	0	0	0	0	0	0
35	Puducherry	0	0	0	0	0	0	0	0
36	Telangana	7	3	0	0	1	5	0	16
	TOTAL	2820	256	273	7	30	203	1	3590

Source: State Governments & concerned agencies.

State/UT wise/System wise Number of AYUSH Dispensaries as on 1-4-2016

S. No	State /UT	Ayurveda	Unani	Siddha	Yoga	Naturopathy	Homoeopathy	Sowa Rigpa	Total
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
1	Andhra Pradesh	333	75	0	0	0	193	0	601
2	Arunachal Pradesh	17	1	0	0	0	95	0	113
3	Assam	380	1	0	0	0	75	0	456
4	Bihar	1082	449	0	0	0	644	0	2175
5	Chhattisgarh	956	26	0	0	0	112	0	1094
6	Delhi	37	19	0	0	0	101	0	157
7	Goa	11	0	0	0	0	15	0	26
8	Gujarat	555	0	0	16	14	216	0	801
9	Haryana	483	19	0	0	0	22	0	524
10	Himachal Pradesh	1112	3	0	0	0	14	4	1133
11	Jammu & Kashmir	240	177	0	0	0	0	25	442
12	Jharkhand	220	54	0	0	0	92	0	366
13	Karnataka	592	50	0	0	5	43	0	690
14	Kerala	807	2	6	0	1	661	0	1477
15	Madhya Pradesh	1496	64	0	0	0	213	0	1773
16	Maharashtra	466	25	0	0	0	1	0	492
17	Manipur	36	15	0	17	13	201	0	282
18	Meghalaya	6	0	0	0	0	6	0	12
19	Mizoram	2	0	0	0	0	22	0	24
20	Nagaland	109	0	0	0	1	93	0	203
21	Odisha	624	9	0	35	30	638	0	1336
22	Punjab	489	35	0	1	0	111	0	636
23	Rajasthan	3577	120	0	0	3	252	0	3952
24	Sikkim	2	0	0	0	0	9	1	12
25	Tamil Nadu	96	63	773	104	0	105	0	1141
26	Tripura	36	0	0	0	0	73	0	109
27	Uttar Pradesh	340	49	0	0	0	1575	0	1964
28	Uttarakhand	142	3	0	0	0	60	3	208
29	West Bengal	502	3	0	0	0	2020	0	2525
30	A&N Island	11	0	0	2	0	19	0	32
31	Chandigarh	10	1	0	0	0	10	0	21
32	D&N Haveli	8	0	0	0	0	6	0	14
33	Daman&Diu	6	0	0	0	0	6	0	12
34	Lakshadweep	8	0	0	0	0	7	0	15
35	Puducherry	27	0	24	4	0	17	0	72
36	Telangana	426	188	1	0	28	199	0	842
	TOTAL	15244	1451	804	179	95	7926	33	25732

Source: State Governments & concerned agencies.

Annexure-II

State/UT wise Number of ASU&H medicines tested and declared spurious/sub standard/adulterated during the last three years

S. No	Name of State/UTs	No. of medicines tested			Declared spurious/sub-standard/adulterated drugs (year wise)		steps taken to check the quality of medicines
		2015-16	2016-17	2017-18			
1.	Gujarat	322 Ay, 05 H	296 Ay	76 Ay	2015-16	10	Show cause notices issued to 8 cases and 21 Licenses suspended.
					2016-17	18	
					2017-18	01	
2.	Tripura	15 H	87 Ay, 01 H	83 Ay	Nil		Inspectors are regularly drawing samples of medicines to check the quality.
3.	Orissa	Nil			Nil		The suppliers of Ayurvedic medicines are insisted upon to submit the testing reports of the supplied batch from laboratory approved under Rule 160 A-J of the Drugs and Cosmetics Rules 1945. Further, random inspection and testing of the supplied drugs are also being carried out by the officials authorized for the purpose by the State Government.
4.	Tamil Nadu	-----			In the year 2015-16, 01 Ayurvedic proprietary medicine was found to be a spurious drug.		There are 23 Drug Inspectors available. The target has been fixed for Drug Inspectors for taking statutory samples every month for testing.
5.	Kerala	-----			-----		The enforcement officers of the Drugs Control Wing conduct frequent raids and inspection in the market as well as in the manufacturing units to check the supply of spurious and adulterated drugs. Samples are also drawn from the market and from the manufacturing firms for analysis in order to ensure the quality of drugs. Supply of 28 cases purported to be spurious drugs were reported in the State during the last few years.
6.	Delhi	3000 Ay, 1000 U	2048 Ay, 1000 U	600 Ay, 200 U	2015-16	13 Ay , 07 U	Drug Control Department, Directorate of AYUSH regularly do routine inspection and market survey and lift samples of Ayurvedic an Unani medicines for test/ analysis as a part of Quality Control activity to keep check on spurious/ sub-standard Ayurvedic and Unani medicines.
					2016-17	11 Ay , 11 U	
					2017-18	04 Ay , 01 U	

Abbreviation: Ay (Ayurveda), S (Siddha), U (Unani), H (Homoeopathy)

