

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

**LOK SABHA
UNSTARRED QUESTION NO. 4810
TO BE ANSWERED ON 23RD MARCH, 2018**

QUALITY OF MEDICINES

**4810. SHRI TAMRADHWAJ SAHU:
SHRI K.C. VENUGOPAL:**

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

- (a) the details of the activities being carried out by the Government for promotion and development of Ayurveda, Yoga, Naturopathy, Unani, Siddha and Homoeopathy systems of medicines in the country;
- (b) the details of the funds earmarked and allocated for the said purpose during each of the last three years and the current year, State/UT-wise;
- (c) whether the Government proposes to set up a Central Drug Controller's Office for AYUSH to strengthen regulatory measures to ensure safety and quality of AYUSH medicines and if so, the details thereof;
- (d) whether 36 samples out of 330 samples which were tested during the last three years have been failed and if so, the details thereof and the action taken by the Government against such defaulter companies; and
- (e) the other measures being taken by the Government for safety, quality and standardisation of AYUSH medicines in the country?

ANSWER

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

(a): To promote and develop AYUSH systems of medicines in the country, the activities undertaken by the Government are detailed as under:

- (i) Implementation of National AYUSH Mission (NAM) which envisages better access to AYUSH services, strengthening of AYUSH educational institutions, facilitate the enforcement of quality control of Ayurveda, Siddha and Unani & Homoeopathy (ASU &H) drugs and sustainable availability of ASU & H raw-materials by promotion of medicinal plants cultivation in the States/UTs;

(ii) Promotion of quality standards of ASU&H drugs to promote safe use of AYUSH medicines;

(iii) Organization of Arogya fairs / melas, conference, exhibitions, seminars, workshops, symposium and also publicity through electronic multimedia, print media campaigning for awareness amongst the citizens all over the country;

(iv) Providing of financial assistance to the various research organizations for conducting the research in AYUSH system of Medicine;

(v) Celebration of each stream of AYUSH on a specified date, viz. Ayurveda day, Yoga day, Unani day, Siddha day and Homoeopathy day;

(vi) Establishment of National level Institutes under different systems of AYUSH in different parts of the country.

(b): The funds allocated for the different activities for promotion and development of AYUSH system are done through both Central Sector and Central sponsored schemes. The total allocation to Ministry of AYUSH for the purpose during last three years are detailed as under:

(Rs. In Crore)

2014-15	2015-16	2016-17	2017-18 (only revenue/ capital section)
691	1125	1307.86	1557.80

Further, the details of the fund allocated to different States under the Centrally Sponsored Scheme of National AYUSH Mission are at **Annexure-I**.

(c): Yes, the Government has set up a Central Drug Controller's Office for AYUSH under Central Drugs Standard Control Organization (CDSCO) to strengthen regulatory measures to ensure safety and quality of AYUSH medicines. Ministry of Finance has approved the proposal for creation of posts of two posts of Deputy Drugs Controllers, three posts of Assistant Drugs Controllers and seven posts of Inspectors.

Ministry of Health & Family Welfare has approved the proposal for creation of vertical structure of AYUSH in CDSCO. Accordingly, CDSCO has issued an order dated 05.02.2018 for creating AYUSH vertical in CDSCO with 12 posts operationalized by giving additional charge to the existing Officers of this Ministry. Recruitment Rules for these posts have been drafted.

(d): The details of test report and action taken by the State Government against defaulter companies during the last three years are enclosed at **Annexure-II**.

(e): The Government have taken measures for safety, quality and standardisation of AYUSH medicines in the country as detailed below:-

(i) Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM& H) and Pharmacopoeia Committees have been set up to develop and revise the quality standards and the Standard Operating Procedures for the manufacturing of medicines.

(ii) Quality standards of 847 Ayurvedic drugs and 448 Unani drugs have been developed and published in the respective pharmacopoeias. Permissible limits of heavy metals, pesticide residue, aflatoxins and microbial load in the medicines are also prescribed.

(iii) 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.

(iv) Two Central Laboratories- Pharmacopoeial Laboratory of Indian Medicine and the Homoeopathic Pharmacopoeial Laboratory have been established and notified as appellate laboratories under the provisions of the Drugs and Cosmetics Rules, 1945.

(v) Guidelines of Good Manufacturing Practices (GMP) for Ayurvedic, Siddha, Unani and Homoeopathic medicines have been incorporated in the Drugs & Cosmetics Rules, 1945.

(vi) System of WHO-GMP Certification and quality certification of ASU medicines by Quality Council of India on voluntary basis is in place for the industrial units which are interested to export these medicines.

(vii) Grants-in- aid is provided to the States and UTs

under National AYUSH Mission (NAM) for augmenting quality control activities for ASU& H drugs, including strengthening of Pharmacies, Drug Testing Laboratories, enforcement framework and testing of drugs.

(viii) 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.

Annexure-I

**Details of funds earmarked/allocated to States/UTs during the years 2014-15,
2015-16, 2016-17 & 2017-18 under Centrally Sponsored Scheme of National
AYUSH Mission (NAM)**

(Rs. In Lakh)

S.No	Name of States/UTs	2014-15	2015-16	2016-17	2017-18	Grand Total
1	Andaman & Nicobar	0.00	151.77	394.82	302.33	848.92
2	Andhra Pradesh	309.92	1400.38	1125.53	1176.01	4011.85
3	Arunachal Pradesh	101.13	527.55	465.45	545.70	1639.84
4	Assam	668.97	1410.50	1631.64	2390.69	6101.82
5	Bihar	0.00	313.97	1752.91	0.00	2066.88
6	Chandigarh	0.00	0.00	509.32	490.52	999.84
7	Chhattisgarh	281.41	858.25	1624.73	1226.75	3991.16
8	Dadra & Nagar Haveli	0.00	0.00	91.79	143.40	235.20
9	Daman & Diu	0.00	0.00	113.18	0.00	113.18
10	Delhi	132.70	593.59	0.00	0.00	726.30
11	Goa	0.00	118.72	622.59	262.46	1003.79
12	Gujarat	332.39	792.69	1533.04	1274.39	3932.52
13	Haryana	213.58	579.79	1034.39	848.44	2676.21
14	Himachal Pradesh	0.00	421.48	614.21	718.92	1754.61
15	Jammu & Kashmir	226.26	792.15	769.20	992.58	2780.21
16	Jharkhand	0.00	624.72	48.01	0.00	672.73
17	Karnataka	359.11	1560.25	1241.45	2059.86	5220.69
18	Kerala	254.66	1273.77	891.20	2096.23	4515.88
19	Lakshadweep	0.00	189.22	509.72	63.74	762.69
20	Madhya Pradesh	644.94	3253.34	2645.33	3059.68	9603.29
21	Maharashtra	534.67	1282.73	529.18	1784.28	4130.87
22	Manipur	226.81	828.80	1229.98	1339.32	3624.92
23	Mizoram	134.64	405.69	603.75	693.47	1837.57
24	Meghalaya	116.27	375.11	802.74	738.25	2032.38
25	Nagaland	115.61	873.09	521.28	1516.91	3026.90
26	Odisha	471.72	1865.28	1221.30	1561.02	5119.32
27	Puducherry	60.00	144.17	170.00	200.00	574.17
28	Punjab	316.00	299.50	1317.81	1348.66	3281.98
29	Rajasthan	638.06	2819.60	2225.20	6893.25	12576.13
30	Sikkim	66.42	608.15	874.07	180.08	1728.73
31	Tamilnadu	0.00	87.70	1980.54	2789.07	4857.31
32	Telangana	330.00	1091.46	1330.69	1055.11	3807.27
33	Tripura	238.11	472.35	334.06	1195.54	2240.07
34	Uttar Pradesh	0.00	4539.27	8466.62	6280.23	19286.12
35	Uttarakhand	284.00	621.23	1187.92	1986.09	4079.26
36	West Bengal	471.23	1924.85	1298.05	1654.64	5348.78
	TOTAL	7528.70	33101.24	41711.84	48867.74	131209.55

Action Taken by the States/UTs during last three years against defaulters companies

S No.	Name of the State/UTs	No of tested conducted during the last three years and current year	Declared spurious/sub-standard/adulterated drugs	Cases booked against the sale and distribution of Spurious AYUSH medicines	Action Taken
1.	Chhattisgarh	309	19	Nil	Action was taken against failed sample as per recommendation of Screening Committee formed as per Govt. of India
2.	Gujarat	913	9	10	
3.	Karnataka	3433	76	-	1. Failed batch of medicine are withdrawn from the Market. 2. Sale of failed batch of medicine was banned in Karnataka.
4.	Chandigarh	2128	218	-	1. Licenses of 10 pharmacies were cancelled. Show cause notices were issued to 20 pharmacies. 2. Licenses of 08 pharmacies were suspended.
5.	Tamil Nadu	5574	171	-	
6.	Odisha	224		-	
7.	Delhi	13573	83	-	
8.	Tripura	307		-	
9.	Uttarakhand	513	46	-	
10.	West Bengal	31	10	4	Action has been taken against the firm as per parameter.
11.	Himachal Pradesh	2696	144	-	
12.	Kerala	1749	23	7	06 such products license were cancelled.

Note:- Remaining states have reported Nil information.