GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO. 2251
TO BE ANSWERED ON 21ST MARCH, 2023

QUALITY OF AYURVEDIC MEDICINES

2251 SHRI TIRUCHI SIVA:

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

(a) whether Government has taken any step to monitor the quality of Ayurvedic medicines in the country;

(b) if so, the details thereof;

(c) whether Government plans to keep a check on fake and adulterated Ayurvedic medicines;

(d) whether there is any mechanism to check the advertisements of such fake products; and

(e) if so, the details of the action taken by Government against the manufacturers of such fake medicines?

ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)

(a) and (b) Yes Sir. 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 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 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. As on date, there are 35 State Drug Testing Laboratories and 86 private Drug Testing Laboratories approved or licensed under Rule – 160 A to J of Drugs and

Cosmetics Rules, 1945, for quality testing of Ayurvedic, Siddha and Unani drugs and raw materials.

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

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.

Pharmacopoeia Commission of Indian Medicine & Homoeopathy (PCIM&H) under Ministry of Ayush, lays down the Formulary specifications and Pharmacopoeial Standards for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs, which serve as official compendia for ascertaining the Quality Control (identity, purity and strength) of the ASU&H drugs, included herein, as per Drugs & Cosmetics Act, 1940 and Rules 1945, thereunder. The summary of the ASU&H Formulary, Pharmacopoeial and related publications, till date are at **Annexure-I.**

Further, PCIM&H is also conducting the capacity building training programme on standardization and quality control of ASU&H drugs for State Drug Controlling/licensing authorities.

(c) to (e) Yes Sir. 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, which appear in the print and electronic media and Government has taken note thereof. State/UT Governments are empowered to enforce the provisions of Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 & Rules there under and Rule 170 of the Drugs & Cosmetics Rules, 1945 pertaining to control and prohibition of misleading advertisements and exaggerated claims of drugs.

Pharmacovigilance Centres for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) Drugs set up in different parts of the country under the Central Scheme of Ministry of Ayush are mandated to monitor and report the misleading advertisements to the respective State Regulatory Authorities. A three tier structure comprising of a National Pharmacovigilance Co-ordination Centre (NPvCC), Intermediary Pharmacovigilance Centres (IPvCs) and Peripheral Pharmacovigilance Centres (PPvCs) is established. All India Institute of Ayurveda (AIIA), New Delhi under Ministry of Ayush is the National Pharmacovigilance Co-ordination Centre (NPvCC) for the implementation of the National Pharmacovigilance program for Ayurveda, Siddha, Unani & Homoeopathy drugs. Objectionable advertisements are being reported to the respective State Licensing Authorities by PPvC at regular intervals.

As per the information received from various State/ UTs, actions taken against the manufacturers of fake Ayurvedic medicines are as follow –

S.no.	**Name of the State/UT**	**Actions taken by the State/UT government against the manufacturers of fake Ayurvedic medicines**
1.	Tamil Nadu	License of the following manufacturers had been suspended for one month for illegal advertisement with false claim - • License of Asthra Power Tonic Capsule & Cream of M/ s. Pee Gee Pharma, No. 2/143, Sivadapuram, S.O, Salem - 636307 • Boraxine Ointment of M/ s. Ancient Pharma, Door No. 4/150, Virathanur Road, Ayyanarpuram, Panaiyur Post, Madurai - 625009. • License of Segro Plus Capsule, Musli Segro Capsule & Kamana Capsule of M/ s. Shankaralaya Herbals Pvt Ltd, No. 9, 10th Cross Street, Mangalanagar, Chennai - 116 .
2.	Assam	Under the Drugs & Magic remedies Act, 1954, the State Dug Licensing Authority, AYUSH is monitoring fake and adulterated medicines manufacturers.
3.	Himachal Pradesh	Since 2014, 22 complaints have been received against misleading advertisements from various agencies. Action against the defaulters has been taken under Chapter IV A of Drugs & Cosmetics Act, 1940 and Rule 159 of Drugs & Cosmetics Rules, 1945.
4.	Andhra Pradesh	i. Mfg. License No. R-1909/Ayur. of M/s. Ojas Herbals, Kurnool, A.P., and Mfg. License No. A-1610/Ayur. of M/s. Susruta Ayurvedics of Ravulapalem, W.G. Dist., A.P. were cancelled and units were seized. ii. Sri. B. Anandaih's Covid Medicine (P, K, L, F & Eye drops), activity was stopped and the department has furnished all documents to Hon'ble High Court of Andhra Pradesh in connection with a case filed by others.

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<tr><td>5.</td><td>Odisha</td><td>No such complaints have come to notice.</td></tr>
<tr><td>6.</td><td>Karnataka</td><td>Manufactures of fake medicines have not been reported.</td></tr>
<tr><td>7.</td><td>Tripura</td><td>NIL</td></tr>
<tr><td>8.</td><td>Goa</td><td>No violations detected till date.</td></tr>
<tr><td>9.</td><td>Kerala</td><td>Legal action to 05 manufacturers has been taken.</td></tr>
<tr><td>10.</td><td>Maharashtra</td><td><table>
<tr><td>Period</td><td>No. of Ayurvedic Samples tested</td><td>No. of Ayurvedic Samples declared Not of Standard Quality (NSQ)</td></tr>
<tr><td>01.04.2021 to 31.03.2022</td><td>458</td><td>16</td></tr>
<tr><td>01.04.2022 to 31.01.2023</td><td>423</td><td>17</td></tr>
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<tr><td>11.</td><td>Punjab</td><td>Actions are taken according to the Drugs and Cosmetics Act, 1940 and Rules thereunder.</td></tr>
<tr><td>12.</td><td>Uttarakhand</td><td>There are 14 Drug inspectors nominated by government under Drugs and Magic Remedies (Objectionable advertisements) Act, 1954 to monitor misleading advertisements of Ayush products. Uptill now, no any these types of complaints received.</td></tr>
<tr><td>13.</td><td>Haryana</td><td>Action has been taken as per Drugs and Cosmetics Act, 1940 and Rules thereunder.</td></tr>
<tr><td>14.</td><td>Delhi</td><td>A total of 119 show cause notices under violation of Drugs and Magic remedies (OA) Act, 1954 including warnings to such violators has been served till date.</td></tr>
<tr><td>15.</td><td>Chandigarh</td><td>No complaint regarding fake medicines reported.</td></tr>
<tr><td>16.</td><td>Manipur</td><td>At present there is no Ayurvedic manufacturer in the state. However, the State Government served notice against illegal advertisements to following two companies-
i. Allen Ayur Herbals
ii. Ban Labs. (P). Ltd.</td></tr>
<tr><td>17.</td><td>Mizoram</td><td>Peripheral Pharmacovigilance Centre has been set up in AYUSH OPD, Civil Hospital, Aizawl, Mizoram to monitor false advertisements/ claims</td></tr>
<tr><td>18.</td><td>Lakshadweep</td><td>Not applicable as UT of Lakshadweep does not have any manufacturing units and Drugs Testing Laboratories.</td></tr>
<tr><td>19.</td><td>Andaman & Nicobar</td><td>Not applicable as there is no manufacturing unit of Ayurvedic medicine.</td></tr>
<tr><td>20.</td><td>Puducherry</td><td>Nodal officer has been appointed for the Drugs and Magic Remedies (Objectionable advertisements) Act, 1954</td></tr>
<tr><td>21.</td><td>Ladakh</td><td>NIL</td></tr>
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Annexure-I

Summary of pharmacopoeial and related publications

I. Ayurveda pharmacopoeial publication

Publication	Part	Volume & Year	Number of Monographs
Ayurvedic Pharmacopoeia of India	Part I (Single Drugs)	Vol. I, 1986	80
		Vol. II, 1999	78
		Vol. III, 2001	100
		Vol. IV, 2004	68
		Vol. V, 2006	92
		Vol. VI, 2008	101
		Vol. VII, 2008 (Minerals & Metals)	21
		Vol. VIII, 2011 (Hydro-alcoholic & Water extracts)	60
		Vol. IX, 2016 (Hydro-alcoholic & Water extracts)	45
		Vol. X, 2022 (Minerals & Metals	20
	Total		**665**
	Part II (Formulations)	Vol. I, 2007 Vol. I, 2011 (Hindi Ed.)	50
		Vol. II, 2008 Vol. II, 2011 (Hindi Ed.)	51
		Vol. III, 2010	51
		Vol. IV, 2017	50
		Pharmacopoeial Monograph of AyushKvāthaCūrṇa(Stand-alone) 2021	01
		Total	**203**
Supporting Pharmacopoeial Publications	Thin Layer Chromatography (TLC) Atlas	API Drugs Pt. I, Vol. I, 2009	80
		API Drugs Pt. I, Vol. III, 2016	99
	Macroscopy and Microscopy Atlas	API Drugs Pt.-I Vol. V, 2009	92
		API Drugs Pt.-I Vol. I, 2011	80

Publication	Part & Year	Number of Formulations
Ayurvedic Formulary of India	Part I, 2003 (2nd Edition)	444
	Part II, 2000	191
	Part III, 2011 (Bilingual)	350
	Formulary specification of AyushKvāthaCūrṇa (Stand-alone) 2021	01
	Part IV, 2022 (Veterinary)	50
Total		**1036**

II. Siddha pharmacopoeial publications

Publication	Part	Volume & Year	Number of Monographs
Siddha Pharmacopoeia of India	Part I (Single Drugs)	Vol. I, 2008	73
		Vol. II, 2011	66
		Total	**139**
	Part II (Formulations)	Pharmacopoeial Monograph of AyushKuṭinīrCūraṇam(Stand-alone)	01

Publication	Part & Year	Number of Formulations
Siddha Formulary of India	Part I (Tamil), 1984 Part I (English), 1992	248
	Part II (Tamil), 2011	151
	Formulary specification of AyushKuṭinīrCūraṇam (Stand-alone)	01
	Total	**400**

III. Unani pharmacopoeial publication

Publication	Part	Volume & Year	Number of Monographs
The Unani Pharmacopoeia of India	Part-I (Single Drug)	Vol. I, 2007	45
		Vol. II, 2007	50
		Vol. III, 2007	53
		Vol. IV, 2007	50
		Vol. V, 2008	52
		Vol. VI, 2009	48
		Vol. VII, 2022	40
	Total		**338**

Publication	Part	Volume & Year	Number of Monographs
The Unani Pharmacopoeia of India	Part II (Formulations)	Vol. I, 2009	50
		Vol. II, 2010	50
		Vol. III, 2016	50
		Vol. IV, 2019	50
		Pharmacopoeial Monograph of AyushSafūf-i-Joshānda(Stand-alone)	01
Total			**201**

Publication	Part & Year	Number of Formulations
National Formulary of Unani Medicine	Part I, 1984	441
	Part II, 1994	202
	Part III, 2001	103
	Part IV, 2006	166
	Part V, 2008	178
	Part VI, 2011	139
	Formulary specification of AyushSafūf-i-Joshānda (Stand-alone)	01
	Total	**1230**

IV. Homoeopathy pharmacopoeial publication

Publication	Volume & Year	Number of Monographs
Homoeopathic Pharmacopoeia of India	Vol. I, 1971	180
	Vol. II, 1974	100
	Vol. III, 1978	105
	Vol. IV, 1984	107
	Vol. V, 1987	114
	Vol. VI, 1990	104
	Vol. VII, 1999	105
	Vol. VIII,2000	101
	Vol. IX,2006	100
	Vol. X, 2016	101
	Total	**1,117**