GOVERNMENT OF INDIA
MINISTRY OF AYUSH
LOK SABHA
STARRED QUESTION NO. 01
TO BE ANSWERED ON 2nd February, 2024

"Quality of AYUSH Medicines"

01. DR. KRISHNA PAL SINGH YADAV:
SHRI UNMESH BHAIYYASAHEB PATIL:

Will the Minister of AYUSH be pleased to state:

(a) whether the Government proposes to formulate any mechanism to address the issue of standardization and quality control of AYUSH medicines and products in the country;
(b) if so, the details thereof, State/UT-wise along with the efforts to improve the quality of AYUSH medicines/products;
(c) the measures taken/proposed to be taken to enhance research and development in the field of AYUSH along with the efforts to collaborate with international organizations to promote AYUSH practices globally;
(d) the plan of the Government to promote quality AYUSH medicines and products for wider use by the consumers; and
(e) whether any shortfall has been noticed in the manufacturing of various AYUSH medicines and if so, the details thereof?

ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)

(a) to (e) A statement is laid on the Table of the House.

THE STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 01 FOR 2nd February, 2024.

(a) and (b) Yes sir. The Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945 have exclusive regulatory provisions for Ayurvedic, Siddha, Unani, and Homoeopathy drugs. Provisions relating to Ayurveda, Siddha and Unani Drugs are contained in Chapter IVA and Schedule- I of the Drugs and Cosmetics Act, 1940 and in Rules 151 to 169, Schedules E(I), T & TA of the Drugs and Cosmetics Rules, 1945. Further, second schedule (4A) of the Drugs and Cosmetics Act, 1940 provides standards for Homoeopathic drugs and Rules 2dd, 30AA, 67 (C-H), 85 (A to I), 106-A, Schedule K, Schedule M-I of the Drugs and Cosmetics Rules, 1945 pertain to Homoeopathic drugs. 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 & Schedule M-I of Drugs and Cosmetics Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

Ministry of Ayush, Government of India has established Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H) as its subordinate office. PCIM&H on behalf of Ministry of Ayush lays down the formulary specifications and pharmacopoeial standards for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs which serves as official compendia for ascertaining the quality (identity, purity and strength) of the ASU&H drugs. AS per the Drugs & Cosmetics Act, 1940 and rules thereunder, the compliance to this quality standards are mandatory for the production of ASU&H drugs being manufactured in India. So far, 2259 quality standards on raw materials (single drugs of plant/ animal/ mineral/ metal/ chemical origin) used in ASU&H drugs, 405 quality standards of ASU formulations and 2666 formulary specifications of ASU drugs has been published. In addition to above, supporting documents in the form of Macro-Microscopic &

TLC Atlas on 351 single drugs incorporated in Ayurvedic Pharmacopoeia of India (API) has also published. Details are available at **Annexure-I.**

PCIM&H also acts as the Central Drugs Laboratory for Indian Medicine and Homoeopathy for the purpose of testing or analysis of ASU&H Drugs. Further, it imparts Capacity Building Trainings at regular interval for standardization/quality control/ testing or analysis of ASU&H drugs to Drug Regulatory Authorities, State Drug Testing Laboratories (Drug Analyst) and other stakeholders on quality control of ASU&H drugs on laboratory techniques and methods used to maintain the quality of ASU&H drugs.

Rule 160 A to J of the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for approval of Drug Testing Laboratory for carrying out such tests of identity, purity, quality and strength of Ayurvedic, Siddha and Unani drugs as may be required under the provisions of these rules, on behalf of licensee for manufacture of Ayurvedic, Siddha and Unani drugs. As on date, 34 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. Further, 106 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. Details of the State Drug Testing Laboratories and Private Drug testing laboratories licensed under the provisions of Drugs and Cosmetics Rules, 1945 are available at https://ayush.gov.in/images/domains/quality_standards/StateDrugTestingLaboratoryASUHEng. and https://ayush.gov.in/images/domains/quality_standards/ListofAyurvedaSiddhaUnani.pdf.

As per the information received from states/UTs governments, the details of the mechanism to address the issue of standardization and quality control of Ayush medicines and products in the country along with the efforts to improve the quality of Ayush medicines/products are attached at **Annexure-II.**

(c) Government of India has established Central Council for Research in Ayurvedic Sciences, Central Council for Research in Unani Medicine, Central Council for Research in Homoeopathy, Central Council for Research in Siddha and Central Council for Research in Yoga & Naturopathy under the Ministry of Ayush as apex organizations for undertaking, coordinating, formulating, developing and promoting research in Ayush system on scientific lines. Core Research activities comprise of Medicinal Plant Research (Medico-Ethno Botanical Survey, Pharmacognosy and invitro-propagation technique), Drug Standardization, Pharmacological Research, Clinical Research, Literary Research & Documentation and Tribal Health Care Research Programme. Research activities are carried out through its peripheral Institutes/Units located across the country and also in collaboration with various Universities, Hospitals and Institutes.

Further, the Ministry of Ayush is running/implementing the Central Sector Scheme namely AYURGYAN Scheme from FY 2021-22.The Scheme has 03 components viz. (i) Capacity Building & Continuing Medical Education (CME) in AYUSH (ii) Research & Innovation in AYUSH from the FY 2021-22 and iii) Ayurveda Biology Integrated Health Research is also added under the scheme from this FY 2023-24. Under the Research & Innovation in AYUSH and Ayurveda Biology Integrated Health Research component, financial assistance is provided to the Organizations/Institutions for research studies, for promotion of research in AYUSH system.

To promote Ayush practices globally, Ministry of Ayush signs Memorandum of Understandings (MoUs) with International Institutes/Universities/Organizations for research collaboration in the field of Traditional Medicines including Ayush. As of now, the Ministry signed 46 MoUs with International Institutions.

(d) Ministry of Ayush has implemented Central Sector Scheme Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY). The total financial allocation to this scheme is Rs. 122.00 crores for five years. The components of AOGUSY scheme are as follows -

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. Detailed guidelines of AOGUSY scheme are available at **https://ayush.gov.in/images/Schemes/aoushdhi.pdf**.

Further Ministry of Ayush encourages following certifications of AYUSH products as per details below:-

- The scheme for Certification of Pharmaceutical Product (CoPP) as per World Health Organization (WHO) guidelines is extended to Ayurvedic, Siddha and Unani (ASU) medicines. This scheme is administered by Central Drugs Standard Control Organization (CDSCO) and the certificate is granted on the basis of joint inspection of the applicant manufacturing unit by the representatives of CDSCO, Ministry of Ayush and the concerned State Licensing Authority.

- Quality Certifications Scheme implemented by the Quality Council of India (QCI) for grant of AYUSH 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.

(e) As per the information received from States/ UTs governments, details of shortfall noticed in the manufacturing of various AYUSH medicines are available at **Annexure-III.**

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Annexure-I

Details of quality standards on raw materials used in ASU&H drugs, quality standards of ASU formulations, formulary specifications of ASU drugs and Macro-Microscopic & TLC Atlas on single drugs incorporated in Ayurvedic Pharmacopoeia of India (API) are as follows-

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 Ayush Kvatha Curṇa (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,	80

		2011	

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 Ayush Kvatha Curṇa (Stand-alone) 2021	01
	Part IV, 2022 (Veterinary)	50
Total		**1036**

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 Ayush Kuṭinīr Cūraṇam (Stand-alone), 2021	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 Ayush Kutinir Curanam (Stand-alone), 2021	01
	Total	**400**

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 Ayush Safūf-i-Joshānda (Stand-alone), 2021	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 Ayush Safūf-i-Joshānda (Stand-alone), 2021	01
	Total	**1230**

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, 2013	101
	Total	**1,117**

Annexure-II

State/UT wise details of the mechanism to address the issue of standardization and quality control of AYUSH medicines and products with the efforts to improve the quality of AYUSH medicines/products are as follows:

S.no.	Name of the State/ UT	Details
1.	Rajasthan	Drug manufacturing firms are inspected by drug inspectors regularly. Samples are collected and government Testing is done from approved laboratories.
2.	Tamil Nadu	There are 23 Drug Inspectors available in Tamil Nadu state. All drug inspectors are instructed to take minimum of 08 statutory samples per month with effect from 01.03.2015 and it send to the State Drug Testing Laboratory (IM) for testing. These samples are tested as per concerned pharmacopoeia. The action has been taken against declared spurious/ misbranded/ adulterated drugs as per section 33-I and 33-J and Rule 159 of the Drugs and Cosmetics Act 1940 and Rules, 1945.
3.	Karnataka	Technical Expert Committee has been constituted comprising experts in field of Dravyaguna & Rasashastra and Drug regulatory authorities. Technical Expert committee is convened every 21 days and Patent & Proprietary Drug master formulas are approved after verifying the submission of documents relating to safety study, evidence of effectiveness and stability studies as per Rule 158B, Rule 161 B & Rule 169 of Drugs and Cosmetics Rules 1945.
4.	Kerala	The Government of Kerala has constituted an expert committee to study the various challenges and problems regarding Ayurveda drug standardization. The Secretary of Ayush Department, Government of Kerala is the chairman of the Committee in which the Deputy Drugs Controller (Ayurveda) serves as the convener. The State Government has also constituted a committee to study the problems related to cultivation, collection and storage of raw materials for manufacture of Ayurveda siddha and Unani drugs. The Deputy Drugs Controller (Ayurveda) is the Chairman of the committee
5.	Uttarakhand	State government nominated 14 Drug Inspectors in the State to check the quality and production of Ayurvedic & Unani medicines. There are 06 Drug testing laboratories are working in Uttrakhand in which 01 Government and 05 drug

		testing laboratories are approved by Ministry of Ayush in Private sector are sanctioned under Drug & Cosmetic Act 1940, Ruls1945 under rule 160A to 160J, for checking the quality of Ayurvedic & Unani medicines.
6.	Odisha	One state drug testing and Research laboratory (ISM), Bhubaneshwar is functioning in the state for quality testing of the drugs and address the issue of standardization. The drug inspectors are in the state to supervise the manufacture of the Ayurvedic medicines to improve the quality of those medicines/products.
7.	Maharashtra	As per the provisions of the Drugs and Cosmetics Act 1940 and Rules 1945, the measures are taken to check Quality of Drugs are as follows: 1. Periodic inspections are carried out of the Ayurvedic manufacturers to ensure compliance of the provisions of the Drugs & Cosmetics Act 1940 & Rules thereunder.The GMP compliance as per Schedule T is checked. Action against the manufacturers for non-compliance of the provisions of the Drugs & Cosmetics Act 1940 & Rules thereunder. 2. Samples of Ayurvedic medicines are drawn from manufacturers and distributors to ensure the quality of Ayurvedic medicines. Administrative / Legal action is taken against the concerned for non-compliance of the provisions of the Drugs & Cosmetics Act 1940 & Rules thereunder.
8.	Himachal Pradesh	The provisions of Drugs & Cosmetic Act/Rules made there under strictly followed.
9.	Mizoram	Government of Mizoram has state drug testing laboratory for checking sample and quality testing of ASU & H drugs.
10.	Delhi	Routine inspections and testing of samples is done to improve the quality of Ayush medicines/products.
11.	Chhattisgarh	Standardization and quality control of Ayush medicines/ products are done as per the Ayurvedic Pharmacopoeia of India.
12.	Puducherry	As per the guidelines of Ministry of Ayush.
13.	Arunachal Pradesh	Ayush DTL is set up for quality control of Ayush Drugs.
14.	Jammu and Kashmir	One Ayush Drug Pharmacy and one Ayush Drug testing Laboratory are envisaged to address the issue of Standardization and quality control of Ayush medicines and products in the UT of J&K.
15.	Goa	NIL
16.	Assam	NIL

Annexure-III

State/ UT-wise details of shortfall noticed in the manufacturing of various AYUSH medicines are as follows -

<table>
<tr><th>S.no.</th><th>Name of the State/ UT</th><th>Details of shortfall noticed</th></tr>
<tr><td>1</td><td>Maharashtra</td><td>Details of Ayurvedic samples drawn from Maharashtra State:
<table>
<tr><td>Period</td><td>01.04.2022 to 31.03.2023</td><td>01.04.2023 to 31.12.2023</td></tr>
<tr><td>Collected</td><td>833</td><td>370</td></tr>
<tr><td>Tested</td><td>526</td><td>352</td></tr>
<tr><td>Declared Not of standard quality</td><td>17</td><td>02</td></tr>
<tr><td>Prosecution issued</td><td>12</td><td>NIL</td></tr>
</table></td></tr>
<tr><td>2</td><td>Rajasthan</td><td>Samples of Ayush medicines were tested and if a deficiency was found in the manufacturing of these medicines. Action is taken against them as per rules.</td></tr>
<tr><td>3</td><td>Tamil Nadu</td><td>NIL</td></tr>
<tr><td>4</td><td>Jammu and Kashmir</td><td>In the UT of J&K there is no separate Ayush Drug Controlling Authority which can monitor any shortfalls in manufacturing of various Ayush medicines.</td></tr>
<tr><td>5</td><td>Chhattisgarh</td><td>NIL</td></tr>
<tr><td>6</td><td>Puducherry</td><td>NIL</td></tr>
<tr><td>7</td><td>Uttarakhand</td><td>NIL</td></tr>
<tr><td>8</td><td>Goa</td><td>NIL</td></tr>
<tr><td>9</td><td>Assam</td><td>NIL</td></tr>
<tr><td>10</td><td>Mizoram</td><td>NIL</td></tr>
<tr><td>11</td><td>Kerala</td><td>NIL</td></tr>
<tr><td>12</td><td>Karnataka</td><td>NIL</td></tr>
<tr><td>13</td><td>Ladakh</td><td>NIL</td></tr>
<tr><td>14</td><td>Delhi</td><td>NIL</td></tr>
<tr><td>15</td><td>Himachal Pradesh</td><td>NIL</td></tr>
<tr><td>16</td><td>Odisha</td><td>NIL</td></tr>
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