**GOVERNMENT OF INDIA**
**MINISTRY OF AYUSH**

**RAJYA SABHA**
**UNSTARRED QUESTION NO. 808**
**TO BE ANSWERED ON 30th JULY 2024**

**"AYUSH medicine"**

808 **Shri Sanjay Seth:**

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

(a) whether 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;
(d) the plan of 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?

**ANSWER**
**THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYUSH**
**(SHRI PRATAP RAO JADHAV)**

(a) and (b) Proposal to formulate any 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 as follows:

I. The Drugs & Cosmetics Act, 1940 and Rule made there under 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.

II. 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 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 and compliance to these quality standards are mandatory for the production of ASU&H drug 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 has been published. In addition to above, supporting documents in the form of Macro- Microscopic & TLC Atlas on 351 single drugs incorporated in API also published. Pharmacopoeias describe the minimum standards/specification to which a pharmaceutical product should comply with. This includes standards for raw materials for identity, purity, strength and quality to develop and standardize method of preparation, dosage forms, etc.

III. PCIM&H, also act as an appellate drug testing laboratory receives the samples from Govt. agencies as per Drugs & Cosmetics Act & Rules there under for ascertaining their quality. Further, PCIM&H on behalf of Ministry of Ayush is also impart training to the Drug Regulatory Authorities, State Drug Testing Laboratories (Drug Analysts), etc. on laboratory techniques and methods used to maintain the quality of ASU&H drugs.

IV. 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. 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-I.

(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 are as follows:

I. 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 In-vitro-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.

II. Further, the Ministry of Ayush is 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.

III. The ministry of Ayush is running/implementing central sector scheme namely Ayurswasthya. The Scheme has 02 components viz (i).Ayush & Public Health component. (ii). Up gradation of facilities to the Centre of Excellence. Under the Centre of Excellence component the financial assistance is provided to support creative and innovative proposal for prestigious organizations which have well-established buildings and infrastructure and wish to work for Ayush systems to the level of Centre of Excellence.

IV. The Ministry of Ayush has been signing Memorandum of Understanding (MoU) with Foreign Countries/ International Organizations for cooperation in the field of Ayush including to enhance research & development in AYUSH. The Ministry signed 24 Country to

Country MoU with Foreign Countries and 50 MoUs with International Institutes for undertaking Collaborative Research / Academic collaboration & 15 MoUs with Foreign Universities/Institutes for setting up AYUSH Academic Chairs in foreign nations. The Ministry also has collaboration with the World Health Organization (WHO), Geneva through signing of various agreements for the promotion of Ayush system globally. Bureau of Indian Standards (BIS) is working with International Organization for Standardization (ISO) for developing ISO standards in AYUSH system.

V. PCIM&H had signed a MOU with American herbal Pharmacopoeia (AHP), USA to with an aim to strengthen, promote and develop standards in the field of Ayurveda and other Indian Traditional systems of medicine in USA and to enhance the export potential of the ASU&H drugs. The major key points of this MOU are development of monographs on international standards to ensure the quality and safety of Ayurveda and other Indian Traditional Medicine products, encourage the adoption of Ayurveda standards developed out of this cooperation for the market authorization of Ayurveda products/drugs in USA and development of digital database on Ayurveda & other Indian Traditional Medicine products/drugs and herbal products.

(d) The plan of Government to promote quality AYUSH medicines and products for wider use by the consumers are as follows:

I. 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**

II. 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.

III. PCIM&H on behalf of Ministry of Ayush, works toward establishing Formulary specifications and Pharmacopoeial standards for Ayurveda, Siddha, Unani & Homoeopathic (ASU&H) medicines. The standards included in the Pharmacopoeias and Formularies of ASU&H medicines prescribing mandatory regulatory standards and are enforceable in India as part of Drugs and Cosmetics Act 1940 and Rules 1945 thereunder, further these standards have been identified as such to align with the recommendations of WHO/other major pharmacopoeias prevalent worldwide. Implementation of these pharmacopoeial standards ensures that the medicines reaching to masses conform to optimum quality standards in terms of identity, purity and strength.

(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-II.

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Annexure-I

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 as follows:

| S.no. | Name of the State/ UT | Details |
|---|---|---|
| 1. | Haryana | • All District Ayurvedic Officers of Haryana State are notified as Drug Inspectors in their jurisdiction. Samples are being taken from ASU drug manufacturers in regular intervals by the Drug Inspectors and being tested in Govt. Ayurvedic Drug Testing Laboratory Kurukshetra. |
| 2. | Karnataka | • Government of India has introduced a uniform system to approve ASU medicines through www.e-aushadi.gov.in Portal.<br>• Technical Expert committee has been constituted comprising experts in field of Dravyaguna & Rasashastra and Drug regulatory authorities.<br>• 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 161B & Rule 169 of Drugs and Cosmetics Rules 1945. |
| 3. | Tamil Nadu | • As per the Drugs and Cosmetics Act, 1940 and Rules 1945, the Drug Inspectors (IM) in the state are being monitoring the quality of drugs manufactured through Sample Collection and Sample Testing.<br>• As far as Tamil Nadu State is concerned, there are 23 Drugs Inspectors available. As per L.Dis. No. 582/SS/15, dated 20.02.2015 of the Commissionerate of Indian Medicine and Homoeopathy, all the Drug Inspectors (IM) are instructed to take minimum of 8 statutory samples per month with effect from 01.032015 and it send to the State Drug Testing Laboratory (IM) for testing. These 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. |
| 4. | Maharashtra | As per the provisions of The Drugs and Cosmetics Act 1940 and Rules 1945 the measures are taken to check quality of Drugs.<br>• 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 manufactures for non-compliance of the provisions of the Drugs & Cosmetics Act 1940 & Rules thereunder.<br>• 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 Drugs and Cosmetics Act 1940& Rules thereunder.<br>• Routine inspections are done and samples are drawn for testing. If it is found to be Not of Standard quality due to |

<table>
<tr><td></td><td></td><td>various reasons, the action is taken as per provisions of the Drugs & Cosmetics Act 1940 & Rules thereunder.<br><br><table><tr><td>Period</td><td>Ayurvedic Samples Collected</td><td>Ayurvedic Samples Tested</td><td>No. of Samples declared NSQ</td><td>No. of Consent for prosecution issued</td></tr><tr><td>01/04/2022-31/03/2023</td><td>833</td><td>526</td><td>17</td><td>12</td></tr><tr><td>01/04/2023-31/03/2024</td><td>732</td><td>476</td><td>08</td><td>05</td></tr><tr><td>01/04/2024-30/06/2024</td><td>36</td><td>133</td><td>03</td><td>Nil</td></tr></table></td></tr>
<tr><td>5.</td><td>Goa</td><td>• Details of Ayurvedic sample drawn by Drugs Inspector of this Directorate and tested at Food and Drug Laboratory, Bambolim is place below:<br><br><table><tr><td>Period</td><td>Ayurvedic Samples Collected</td><td>Ayurvedic Samples Tested</td></tr><tr><td>01/04/2022 - 31/03/2023</td><td>191</td><td>229</td></tr><tr><td>01/04/2023 - 31/03/2024</td><td>177</td><td>201</td></tr></table></td></tr>
<tr><td>6.</td><td>Andhra Pradesh</td><td>• In Drug Testing Laboratory, Visakhapatnam, the Research programs and collection of Raw materials and Quality Control of AYUSH Drug Testing is done to improve quality of AYUSH medicine products.</td></tr>
<tr><td>7.</td><td>Manipur</td><td>• The Drug and Cosmetic Act 1940 and Rules 1945 describe all necessary information.<br>• One Drug Testing Laboratory is coming up in the State.<br>• Officials of the Drug Section conducted regular inspection of the AYUSH medicines selling in the local markets.</td></tr>
<tr><td>8.</td><td>Uttarakhand</td><td>• State government nominated 14 Drug Inspectors in the State to check the quality and production of Ayurvedic & Unani medicines.<br>• There are 07 Drug testing laboratories are working in Uttarakhand in which 01 Government and 06 testing laboratories are approved by Ministry of Ayush in Private sector are sanctioned under Drug & Cosmetic Act 1940 and Rules 1945 under rule 160A to 160J for checking the quality of Ayurvedic & Unani Medicines.<br>• Uttarakhand Ayurvedic University nominated as peripheral pharmacovigilance Centre for compiling and reporting of adverse drug reaction (ADR).<br>• And also, adverse (ADR) drug reaction can reported at Ayush hospitals.</td></tr>
<tr><td>9.</td><td>Himachal Pradesh</td><td>• The provisions of Drugs & Cosmetic Act/Rules made thereunder & instructions/guidelines issued by the Ministry of Ayush, Govt. of India are being followed.<br>• "Expert Committee" has been constituted by the Department as per instructions of Govt. of India to grant permission for manufacturing ASU medicines by the manufacturing units. On the recommendations of Expert Committee the permission for</td></tr>
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| | | manufacturing medicines are being issued with the condition that the unit should send their approved formulations for testing in Govt. approved Labs. before sending the product in open market.<br>• Apart from above vide Notification dated 25.8.2018 Govt. of H.P has appointed 18 Drug Inspectors for the purpose to inspect the drug manufacturing units in their jurisdiction.<br>• The Government Drug Testing Laboratory at Jogindernagar, Distt. Mandi has been established for standardization and quality control of AYUSH drugs/products. |
| 10. | Delhi | • The provisions of the Drugs and Cosmetics Act, 1940 and the rules made there under provide for the quality control of AVUSH medicines and products in the country.<br>• 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. | Gujarat | • This information is Pertaining to the Central Government for the issue of standardization and quality control of AYUSH medicines. |
| 13. | Mizoram | • The Scheme AYUSH OUSHADHI GUNVATTA EVAM UTTPADAN SAMVARDHAN YOJANA (AOGUSY) has been made for quality control of AYUSH medicines and products.<br>• Mizoram has State Drug Testing Laboratory for ASU & H drugs for quality checking and sample testing. |
| 14. | Odisha | • One State Drugs Testing and Research Laboratory (ISM), Bhubneswar is functioning in the State to address the issue of standardization and quality control of AYUSH medicines and products in the State.<br>• The Drugs Inspectors are in the State to supervise the manufacture of the Ayurvedic medicines to improve the quality of those medicines/products. |
| 15. | J&K | • One Ayush Drug Pharmacy and one Ayush Drug Testing Laboratory have been upgraded in the UT of J&K under "Ayush Oushadhi Gunvatta evam Uttapadan Samvardhan Yojna" which are envisaged to address the Issue of Standardization and Quality control of Ayush medicines and products in the UT of J&K. |
| 16. | Tripura | • Samples of Ayurvedic drugs are drawn for testing its quality. |
| 17. | Andaman & Nicobar | The following mechanism is in place under the UT administration to address the issue of standardization and quality control of Ayush medicines and products in the UT:<br>• The Drugs Controller, Licensing, Authority and Drug Inspectors have been designated under the UT Ayush Drug control Cell for implementation of provision of Drugs & Cosmetics Act 1940 and Rules 1945.<br>• Quality test reports of all the procured medicines are obtained by the Govt. department mandatorily from the supplier firms.<br>• Random samples of Ayush Drugs are sent regularly for quality |

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| | | tests to the Notified laboratories. |
| 18. | Uttar Pradesh | • The State Government is following strictly standardization and quality control norms as provided in Drugs &Cosmetics Act, 1940 & along with their Rules, 1945.<br>• The State Government constituted an Expert Committee to examine the License application & associated documents, proof of Concept and testing protocols of intended patent or proprietary ASU drugs as provided In section 3 (h) (1) of the Drugs & Cosmetics Act, 1940 & along with their Rules, 1945<br>• The state government has established own one Drugs Testing Laboratory & 04 others drugs testing Laboratories in Private sector which are covered under rule 160 A Drugs & Cosmetics Act, 1940 In which all type of Ayurvedic & Unani medicines quality is checked. |
| 19. | Kerala | • Yes, Standardization of Ayurveda drugs is an important subject to the state the Government of Kerala has constituted an expert committee to study the various challenges and problems regarding Ayurveda drug standardization. The Secretary Ayush Department Government of Kerala is the Chairman of the Committee in which the Deputy Drugs Controller (Ayurveda) serves as the Convenor. Initial meeting of the committee was conducted on 10/10/2023 and a discussion regarding formation of sub-committees is on-going.<br>• 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 in Kerala. The Deputy Drugs Controller (Ayurveda) is the Chairman of the committee. |
| 20. | Ladakh | • Pertains to Ministry of Ayush. |
| 21. | Madhya Pradesh | • Drug Testing Laboratory is established. |
| 22. | Puducherry | • As per the guidelines of Ministry of AYUSH. |
| 23. | Jharkhand | • Concerned with Ayush Ministry, Central Govt. |
| 24. | Rajasthan | NIL Information |
| 25. | Assam | NIL Information |
| 26. | Arunachal Pradesh | NIL Information |

Annexure-II

**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>Karnataka</td><td>• No shortfall has been reported in the manufacture of Ayurvedic, Siddha and Unani medicines in the State of Karnataka.</td></tr>
<tr><td>2.</td><td>Maharashtra</td><td>• Yes, in the State of Maharashtra shortfall have been noticed in the manufacturing of various Ayush medicines as follows:
<table>
<tr><td>Period</td><td>Ayurvedic Samples Collected</td><td>Ayurvedic Samples Tested</td><td>No. of Samples declared NSQ</td><td>No. Consent prosecutic issued</td></tr>
<tr><td>01/04/2022-31/03/2023</td><td>833</td><td>526</td><td>17</td><td>12</td></tr>
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<tr><td>01/04/2024-30/06/2024</td><td>36</td><td>133</td><td>03</td><td>Nil</td></tr>
</table></td></tr>
<tr><td>3.</td><td>Chennai</td><td>• No shortfall has been noticed in the manufacturing of AYUSH Medicines.</td></tr>
<tr><td>4.</td><td>Goa</td><td>• No such incidents are noticed by this Directorate.</td></tr>
<tr><td>5.</td><td>Andhra Pradesh</td><td>• Yes, some of the Ayurvedic Manufacturing Units are not following the Drug and Cosmetic Act rules and procedures and noticed the short falls, and the department may give advice to rectify the shortfalls to manufacturing the AYUSH medicines.</td></tr>
<tr><td>6.</td><td>Manipur</td><td>• At present there is no functionable manufacturing unit of AYUSH medicines in the State .</td></tr>
<tr><td>7.</td><td>J & K</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>8.</td><td>Tripura</td><td>• The shortfall has not been noticed in the manufacturing of various AYUSH medicines.</td></tr>
<tr><td>9.</td><td>Andaman & Nicobar</td><td>• Through no manufacturing unit of Ayush medicines exists in the UT, one of the Samples of the quality tested Homoeopathy medicine (ie. SYZIGIUM JAMBOLNUM Q), manufactured by M/s. Goa Antibiotics Ltd, had failed in the Quality test done through the approved Drug testing lab during the year 2021-22. The action has been taken on the same by the Drug Control cell of this UT as per the provision of D & C Act 1940 and rules there under.</td></tr>
<tr><td>10.</td><td>Rajasthan</td><td>• Medicines are also found sub-standard during testing.<br>• Action is taken against the manufacturer of sub-standard medicines as per rules.</td></tr>
<tr><td>11.</td><td>Mizoram</td><td>• There are no manufacturing units of AYUSH medicines in Mizoram.</td></tr>
<tr><td>12.</td><td>Delhi</td><td>• All the manufacturing units are in the state of Delhi are complying GMP norms as per the provisions of the Drugs and Cosmetics Act, 1940.</td></tr>
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| 13. | Assam | • No information available with this office. |
| 14. | Chhattisgarh | • Yes, In Year 2023-2024 03 samples failed. |
| 15. | Madhya Pradesh | • Yes action taken from time to time. |
| 16. | Gujarat | NIL Information |
| 17. | Arunachal Pradesh | NIL Information |
| 18. | Uttarakhand | NIL Information |
| 19. | Himachal Pradesh | NIL Information |
| 20. | Haryana | NIL Information |
| 21. | Ladakh | NIL Information |
| 22. | Puducherry | NIL Information |
| 23. | Odisha | NIL Information |
| 24. | Uttar Pradesh | NIL Information |
| 25. | Kerala | NIL Information |
| 26. | Jharkhand | Yes. |

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