GOVERNMENT OF INDIA
MINISTRY OF AYUSH

LOK SABHA
UNSTARRED QUESTION NO. 3883
TO BE ANSWERED ON 11TH AUGUST, 2023

"PRODUCTIVITY OF AYUSH MEDICINES"

3883. SHRI C.N. ANNADURAI:
SHRI KULDEEP RAI SHARMA:
SHRIMATI MANJULATA MANDAL:
DR. SUBHASH RAMRAO BHAMRE:
SHRI SELVAM G.:
SHRIMATI SUPRIYA SULE:
DR. AMOL RAMSING KOLHE:
SHRI DHANUSH M. KUMAR:
DR. DNV SENTHILKUMAR S.:

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

(a) the roadmap prepared/proposed to be prepared by the Government to increase the productivity of Ayurveda and other Indian medicine products/herbs across the country, State/UT-wise;
(b) the details of the productivity of such AYUSH medicines during the last three years and the current year in the country, State/UT-wise including Tamil Nadu and Odisha;
(c) whether any Central Scheme implemented by the Government has strengthened the safety and vigilance/monitoring mechanism for ensuring quality of AYUSH medicines/drugs;
(d) if so, the details thereof along with the process of assessing/evaluating of quality and identification of adverse effects of such medicines/ drugs; and
(e) the steps taken/proposed to be taken by the Government for qualitative production/distribution of AYUSH medicines along with widening and deepening the scope of their research?

ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)

(a) and (b) 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, Siddha and Unani 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, Siddha, Unani 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.

The year-wise of turnover of Indian Medicines Pharmaceutical Corporation Limited (IMPCL), the public sector manufacturing unit of the Ministry of Ayush are as follows –

Year	Turnover of IMPCL (In Lacs)
2018-19	Rs.8683.20/-
2019-20	Rs.9704.06/-
2020-21	Rs.16401.89/-
2021-22	Rs.26084.31/-

As per the information received from various State/ UTs, the details of productivity of Ayush medicines and the steps taken to increase the productivity of Ayurveda and other Indian medicine products/herbs are at **Annexure-I.**

(c) and (d) Yes Sir. In the year 2021, 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 are available at https://cdn.ayush.gov.in/wp-content/uploads/2023/05/Revised-AOGUSY-Scheme-Guidelines.pdf

Pharmacovigilance Program for Ayurveda, Siddha, Unani, and Homoeopathy (ASU & H) Drugs has been established under the Central Sector Scheme of Ministry of Ayush (AOGUSY Scheme). The program is working through a three-tier network of a National Pharmacovigilance Centre (NPvCC), Five Intermediary Pharmacovigilance Centres (IPvCs) and 99 Peripheral Pharmacovigilance Centres (PPvCs) established across the country. Under the

Pharmacovigilance Program for ASU & H Drugs major objectives are to keep vigilance over Ayush drugs and to report misleading advertisements. Through three tiers network of Pharmacovigilance (NPvC, IPvC, PPvC) regular reporting of suspected adverse drug reactions is being done. Since 2018 to till date, 1473 such individual case safety reports have been reported in a specified format for reporting such adverse reactions.

Also, there is regular reporting of objectionable advertisements appearing in print and electronic media. Since 2018 to till date, 30039 such misleading advertisements have been reported. All misleading advertisements are being reported to the respective State Licensing Authorities by peripheral centers at regular intervals for the possibility of initiating action against the defaulters.

As on date, 35 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. Further, 95 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.

(e) The steps taken by the Ministry of Ayush for qualitative production/distribution of Ayush medicines along with widening and deepening the scope of their research are as follows –

(i) 05 Research Councils under Ministry of Ayush are engaged in activities like Medicinal Plant Research (Medico-Ethno Botanical Survey, Pharmacognosy and Tissue Culture), Drug Standardization, Pharmacological Research, Clinical Research, Literary Research & Documentation and Tribal Health Care Research Programme. Further, 12 National Institutes under Ministry of Ayush are also conducting various research studies on Ayush drugs.

Ministry of Ayush has also implemented AYURGYAN Scheme for promoting education and research in the field of Ayush and to support Research & Innovation in Ayush by extra mural research and education in Ayush by providing academic activities., training, Capacity Building etc. Further, under the Centre of Excellence component of AYURSWASTHYA Yojana, financial assistance is provided to eligible individual organizations/institutes for establishing and upgrading their functions & facilities and/or for research & development activities in Ayush.

(ii) Pharmacopoeia Commission of Indian Medicine & Homoeopathy (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, hereunder and compliance to these quality standards are mandatory for the ASU&H drug being manufactured in India. Implementation of these pharmacopoeial standards ensures that the production of ASU&H drugs conform to optimum quality standards in terms of identity, purity and strength.

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.

(iii) 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, 35 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. Further, 95 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.

(iv) For facilitating exports of Ayush products, Ministry of Ayush encourages following certifications of AYUSH products as per details below:-

- Certification of Pharmaceutical Products (CoPP) as per WHO Guidelines for herbal products.
- Quality Certifications Scheme implemented by the Quality Council of India (QCI) for grant of AYUSH Premium 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.

(v) As per the information received from States/UTs -

- State/UT has also constituted technical expert committee regarding approval of patent & proprietary Ayush drugs after verifying the submission of documents relating to safety study, evidence of effectiveness and stability studies as per Rule 158B, Rule 161B and Rule 169 of Drugs & Cosmetics Rules, 1945.
- State Government of Kerala has appointed a committee to study the standardization of Ayurveda drugs.
- State Government of Odisha has made provisions for funds towards manufacture of Ayurvedic medicines in the Government pharmacies of the State at Bolangir, Bhubaneswar and Puri. The State Drugs Testing and Research Laboratory (ISM), Bhubaneswar is functioning as in-house laboratory of these pharmacies for quality testing of the drugs.

****

Annexure-I

Details of steps taken to increase the productivity of Ayurveda and other Indian medicine products/herbs –

<table>
<tr><th>S.no.</th><th>Name of the State/UT</th><th>Information received from State/ UT government</th></tr>
<tr><td>1.</td><td>Arunachal Pradesh</td><td>Government Ayurvedic Pharmacy is functional and manufactured 63 Ayurvedic medicines in the year 2019-20, 68 Ayurvedic medicines in the year 2020-21 and 65 Ayurvedic medicines in the year 2022-23.</td></tr>
<tr><td>2.</td><td>Mizoram</td><td>No production of Ayush medicines as there is no manufacturing unit in the state of Mizoram.</td></tr>
<tr><td>3.</td><td>Tripura</td><td>No manufacturing unit in the state of Tripura.</td></tr>
<tr><td>4.</td><td>Manipur</td><td>There is no functional manufacturing unit of Ayush medicine in the state</td></tr>
<tr><td>5.</td><td>Kerala</td><td>Kollam district Oushadha Nirmana Co-operative Society Limited has received Rs. 64.29 Lakhs under AOGUSY Scheme.</td></tr>
<tr><td>6.</td><td>Karnataka</td><td>
<table>
<tr><th>Year</th><th>No. of ASU application received</th><th>No. of ASU applications approved</th><th>No. of ASU Pending Applications</th><th>No. of ASU Rejected Applications</th></tr>
<tr><td>2020</td><td>45</td><td>40</td><td>2</td><td>3</td></tr>
<tr><td>2021</td><td>37</td><td>32</td><td>5</td><td>-</td></tr>
<tr><td>2022</td><td>64</td><td>61</td><td>2</td><td>1</td></tr>
<tr><td>2023(Up to 31.07.2023)</td><td>31</td><td>23</td><td>8</td><td>-</td></tr>
</table>
</td></tr>
<tr><td>7.</td><td>Odisha</td><td>At present 03 nos. of Government Ayurvedic Drug manufacturing units are functioning in the State at Bolangir, Bhubaneswar and Puri . Financial Year Allotment in the unit of Medicine –
<table>
<tr><td>2020-21</td><td>Rs.2,72,60,000/-</td></tr>
<tr><td>2021-22</td><td>Rs.2,72,60,000/-</td></tr>
<tr><td>2022-23</td><td>Rs. 2,72,60,000/-</td></tr>
<tr><td>2023-24</td><td>Rs.7,67,60,000/-</td></tr>
</table>
</td></tr>
<tr><td>8.</td><td>Karnataka</td><td>Details of productivity of Ayurvedic medicines are as follows –
<table>
<tr><th>S.no.</th><th>Category of medicine</th><th>Quantity of production (in metric system)</th></tr>
<tr><td>1.</td><td>Anjana/Pisti</td><td>0</td></tr>
<tr><td>2.</td><td>Churna/ nasya manjan/ Lepa/ Kwath Churn</td><td>18883.06 tons</td></tr>
<tr><td>3.</td><td>Pills/ Vatti/ gutika/ matirai and tablets</td><td>2374.89 tons</td></tr>
<tr><td>4.</td><td>Kupi pakva/ Ksara/Parpati/ Lavana/ Bhasma/ Satva/ Sindhura/ Karpu/ Uppu/ Param</td><td>274.17 tons</td></tr>
</table>
</td></tr>
</table>

			5.	Kajal	1520000.00 tons
			6.	Capsules	3575.00 tons
			7.	Ointment/ Marham/ Pasai	8814.95 tons
			8.	Pak/ Avleh/ Khand/ Modak/ Lakayam	10867.86 tons
			9.	Panak, Syrup/ Pravahi Kwath manapaku	1612978.79 gallon
			10.	Asava/ Aristha	3695962.5 gallon
			11.	Sura	17079.78 gallon
			12.	Ark/ Tinir	18646.58 gallon
			13.	Tail/ Ghrit/ Ney	1684979.96 gallon
			14.	Ashcyton/ Netra Malham panir/ Karn Bindu/ Nasabindu	261303.54 gallon