GOVERNMENT OF INDIA
MINISTRY OF AYUSH

LOK SABHA
UNSTARRED QUESTION NO. 1098
TO BE ANSWERED ON 08th DECEMBER, 2023

"Ayurvedic Pharmaceutical Manufacturers"

1098. SHRI T.R.V.S. RAMESH:

DR. VISHNU PRASAD M.K.:

Will the Minister of AYUSH be pleased to state:

(a) whether the Government proposes to provide financial/technical assistance to any Ayurvedic pharmaceutical factories/manufacturers;

(b) if so, the details thereof and if not, the reasons therefor;

(c) whether the Government has taken/proposed to take any steps to encourage the entrepreneurs to establish such factories and if so, the details thereof;

(d) the details of the guidelines in place to ensure the quality of Ayurvedic medicines;

(e) whether the Government has identified any incidence of adulteration for profit;

(f) if so, the details thereof along with the action taken/proposed to be taken by the Government against the people involved in such illicit activities;

(g) whether there is any mechanism for certification of Ayurvedic medicines to ensure their quality of manufacturing; and

(h) if so, the details thereof and if not, the reasons therefor?

ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)

(a) to (c) 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.

Under "Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards" component of AOGUSY scheme, year-wise details of Grant in aid released to Ayush Pharmacies are as follows –

Year	**S.no.**	**Name of the Pharmacy**	**Amount released**
2022-23	1.	Inducare Pharma Pvt.Ltd., Pune	Rs.3,00,00,000 /-
	2.	Ayurchem Products, Maharashtra	Rs.2,69,00,000/-
	3.	Phytovedic India Pvt. Ltd., Maharashtra	Rs.2,14,61,000/-
	4.	Visesh Ayurved Pvt. Ltd Pharmacy, Kerala.	Rs.1,91,56,000/-
	5.	Amar Pharmaceuticals and labs (India) Pvt. Ltd., U.P	Rs.1,43,43,000 /-
	6.	Shree Baidyanath Ayurved Bhawan, Pvt. Ltd, Madhya Pradesh	Rs.2,08,92,000/-
	7.	Kollam District Ayurveda Oushada Nirmana Vyavasaya Co Operative Society, Kerela	Rs.64,29,000/-
2023-24	1.	Shree Baidyanath Ayurved Bhawan, Pvt. Ltd, Madhya Pradesh	Rs.91,08,000/-
		Total	**Rs. 14,82,89,000/-**

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

Further, the Central Sector Scheme of Ayush for Promotion of International Co-operation in AYUSH (IC Scheme) has provision to provide financial assistance to Ayush drug manufacturers, entrepreneurs, Ayush institutions and Hospitals etc. for international propagation of Ayush by participating in international exhibitions, trade fairs, road shows etc. The financial assistance is limited up to maximum of 75% of the expenditure limited to maximum of Rs. 03.00 lakh (whichever is less) per industry/ institution, for Asian and African Countries; and up to Rs. 05.00 lakh per industry or 75% of the total expenditure, whichever is less, for Countries of North and South America, Europe and Australia and per industry/ institution. Applications/ proposals having prior approval of the Ministry of Ayush are considered for reimbursement on submission of expenditure details with proof of participation within 2 month of completion of the event.

To encourage AYUSH Industry/Manufacturer to get market authorization for their product(s) for exports, the facility of reimbursement of expenditure is also extended, under the said IC scheme, for Preparation of product dossier (Excluding office expenses and administrative cost); Fee paid to the concerned regulatory agency for registration/ market authorization of Ayush product as Medicine in the foreign country etc. Reimbursement is limited to a sum of Rs.50 Lakhs or 75% of the actual total amount incurred on market authorization for one or more products; whichever is less.

(d) As prescribed in Drugs and Cosmetics Act 1940 and Rules made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Unani and Homoeopathy drugs, is vested with the State Drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government.

Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H) under Ministry of Ayush, lays down the Formulary specifications and Pharmacopoeial Standards for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs. The quality standards monographs published by PCIM&H are official as per the regulatory provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder for compliance by the Ayurvedic drug manufacturers.

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, 102 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) and (f) As per the information received from various States/UTs governments, the details of any incidence of adulteration for profit along with the action taken/proposed to be taken by the Government against the people involved in such illicit activities are at **Annexure-I**.

(g) and (h) As prescribed in Drugs and Cosmetics Act 1940 and Rules made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Unani and Homoeopathy 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.

In October 2009, Quality Control of India (QCI), at the behest of the then Department of AYUSH (Now Ministry of Ayush), launched a Voluntary Certification Scheme for Ayurvedic Products, which provides for testing for contaminants and compliance to standards prescribed in the regulation in order to enhance the consumer confidence and also facilitate exports. The Scheme has two levels - Standard Mark based on the compliance to the domestic regulatory requirements and the other being AYUSH Premium Mark based on the World Health Organisation-Good Manufacturing Practices (WHO-GMP) requirements and product requirements to certify against overseas regulations.

Central Drugs Standard Control Organization (CDSCO) issues the Certificate of Pharmaceutical Product (COPP) of Ayurvedic products for export purpose based on joint inspection by representatives from CDSCO, Ministry of Ayush and respective State Licensing Authority. Details are available at https://cdsco.gov.in/opencms/opencms/en/Aayush/ .

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Annexure-I

State/ UT-wise details of incidence of adulteration for profit along with the action taken/proposed to be taken by the Government against the people involved in such illicit activities are as follows -

<table>
<tr><th>S.no.</th><th>Name of the State/ UT</th><th>Details of productivity of Ayurveda products</th></tr>
<tr><td>1.</td><td>Assam</td><td>17 numbers of Ayurvedic medicines found to be of not of standard quality and Drug Inspector has initiated legal action against the manufacture.</td></tr>
<tr><td>2.</td><td>Maharashtra</td><td>Routine inspections are done and samples are drawn for testing. If it is found to be Not of Standard quality due to various reasons. The action is taken as per provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder. Details of Ayurvedic Samples drawn from Maharashtra state (information taken from fdamfg.maharashtra.in) -
<table>
<tr><td>Time 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 to 31.03.2023</td><td>833</td><td>526</td><td>17</td><td>12</td></tr>
<tr><td>01.04.2023 to 31.10.2023</td><td>360</td><td>282</td><td>01</td><td>NIL</td></tr>
</table></td></tr>
<tr><td>3.</td><td>Gujarat</td><td>In 2019, the court of law had given punishment till rising of the court and fine of Rs. 20,000/- for an Ayurveda product manufactured without license. In 2020, product permission of 02 Ayurveda products has been cancelled. In 2022, 02 Ayurveda products are under investigation and court case C.C. no. 2054/22 for 01 Ayurveda product has been launched.</td></tr>
<tr><td>4.</td><td>Arunachal Pradesh</td><td>NIL</td></tr>
<tr><td>5.</td><td>Goa</td><td>NIL</td></tr>
<tr><td>6.</td><td>Odisha</td><td>NIL</td></tr>
<tr><td>7.</td><td>West Bengal</td><td>NIL</td></tr>
<tr><td>8.</td><td>Puducherry</td><td>NIL</td></tr>
<tr><td>9.</td><td>Kerala</td><td>NIL</td></tr>
<tr><td>10.</td><td>Karnataka</td><td>NIL</td></tr>
<tr><td>11.</td><td>Haryana</td><td>NIL</td></tr>
<tr><td>12.</td><td>Uttarakhand</td><td>NIL</td></tr>
<tr><td>13.</td><td>Andaman & Nicobar</td><td>NIL</td></tr>
<tr><td>14.</td><td>Andhra Pradesh</td><td>NIL</td></tr>
<tr><td>15.</td><td>Delhi</td><td>NIL</td></tr>
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