GOVERNMENT OF INDIA
MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)

LOK SABHA
STARRED QUESTION NO. 336
TO BE ANSWERED ON THE 11TH AUGUST, 2023

AYURVEDIC PHARMACEUTICAL COMPANIES

***336. SHRI ARUN SAO:**
SHRI MOHAN MANDAVI:

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 any steps to encourage 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 incidents 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 AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY(AYUSH)

(SHRI SARBANANDA SONOWAL)

(a) to (h) A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 336* FOR 11TH AUGUST, 2022

(a) to (c) Yes sir. In 2021 Ministry of Ayush has implemented a 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 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 BIS, QCI and other relevant scientific institutions and industrial R&D centres.

The first component of the AOGUSY Scheme "Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards" has been formulated to provide financial/technical assistance to any Ayurvedic pharmaceutical factories/manufacturers. As per scheme guidelines, financial/technical assistance to State Government/U.T.'s/State Government Cooperatives's Ayush Pharmacies is provided upto Rs. 6.00 crore for strengthening infrastructure and technology up-gradation and meeting associated recurring costs in the ratio of 70:30%. Further, financial assistance to Private manufacturing units is provided for 50% of the project cost limited to Rs. 3.00 Crore for equipment, machinery and scientific instruments to achieve higher standards of GMP (like WHO-GMP, cGMP, EU-GMP).

The Grant-in-aid released to the pharmacies during the F.Y 2022-23 for strengthening and up-gradation of Ayush Pharmacies is as follows

SI No.	**Name of the Pharmacy**	**Funds Released (in Rs.)**
1	InducarePharmaPvt.Ltd. Pune	Rs. 3,00,00,000/-
2	Ayurchem Private Ltd. Maharashtra	Rs. 2,69,00,000/-
3	Phytovedic India Pvt. Ltd. Maharashtra	Rs. 2,14,61,000/-
4	VisheshAyurvedic Pvt. Ltd Pharmacy Kerala	Rs. 1,91,56,000/-
5	Amar Pharmaceuticals and labs (I) Pvt. Ltd. U.P	Rs. 1,43,43,000/-

6	Shree BaidyanathAyurvedBhawan Pvt. Ltd, Madhya Pradesh	Rs. 2,08,92,000/-
7	Kollam District Ayurveda OushdhaNirmanaVyavasaya Co-operative Society Ltd, Kerala	Rs. 64,29,000/-

(d) 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.

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.

In 2020, Ministry of Ayush has set up Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H) as a subordinate office by merging its two central laboratories i.e. Pharmacopoiea Laboratory for Indian Medicine (PLIM) and Homoeopathy Pharmacopoeia Laboratory (HPL) and an autonomous body i.e. Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H). Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H) is mandated to lays down the Pharmacopoeial Standards and Formulary specifications 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.

(e) and (f) Provisions related to adulteration of Ayurveda, Siddha and Unani drugs are prescribed under Section 33 EE and penalty for Ayurvedic, Siddha or Unani drug deemed to be adulterated under section 33EE drugs are prescribed under section 33-L clause (1) (a)(ii) of Drugs and Cosmetics Act, 1940. However State / UT Governments are empowered to enforce the provisions of Drugs and Cosmetics Act, 1940 and Rules, 1945 made thereunder.

As per the information received from State/UT Licensing Authorities, the reported incidents of adulteration for profit in Ayush drugs/ medicines are at Annexure -1.

(g) & (h)Yes sir. 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/.

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.

The scheme contains Governing Structure, Certification criteria documents like GMP, Permissible Levels of Contaminants for AYUSH Premium Mark, Permissible Levels of Contaminants for AYUSH Standard Mark, Internal Quality Assurance Protocol, Certification Process and requirements for certification bodies. Till date 02 certification bodies are approved by QCI. A total of 83 companies are certified with 5977 products (https://qcin.org/list-of-certified-clients-and-products-ayush/#'Himalaya,%20Zeon'!A1) under the AYUSH Mark Scheme. Details of the scheme are available at https://qcin.org/voluntary-certification-scheme- for-ayush-products/.

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Annexure- I

DETAILS OF REPORTED INCIDENTS OF ADULTERATION FOR PROFIT IN AYUSH DRUGS/ MEDICINES

Sr. No.	States/UTs	Incidents of Adulteration			
1.	Gujarat	Sl No.	Date of case filed	Name of company	Name of product
		1	09.12.2022 (Case No. 2054/2022)	Vajibhai Anubhai Bambhva	Tulshi Santra Ashav Herbal tonic
		2	29.07.2022 Case No. 21356/2022)	Pareshbhai H Chovatiya&Minalben P Chovatiya	Prashovan Tab, Pracury Capsules& Protigent Tablet
		3	05.05.2023 Case No. 11692/2023	Nitinbhai Ajithbhai Kotvani and Others	Ashvashav Ashav Herbal Tonic
2.	Maharashtra	NIL			
3.	West Bengal	NIL			
4.	Goa	NIL			
5.	Karnataka	NIL			
6.	Manipur	NIL			
7.	Odisha	NIL			
8.	Puducherry	NIL			
9.	Kerala	NIL			
10	Tamilnadu	NIL			
11	Himachal Pradesh	NIL			
12	Sikkim	NIL			
13	Madhya Pradesh	NIL			
14	Arunachal Pradesh	NIL			
15	Delhi	NIL			
16	Chandigarh	NIL			