GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO.642
TO BE ANSWERED ON 13TH DECEMBER, 2022

FDI IN AYURVEDA DRUG INDUSTRY

642. SMT. JEBI MATHER HISHAM:

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

(a) the number of herbal drug companies that have obtained the mandatory Good Manufacturing Practices (GMP) certification as laid down by WHO, State-wise and company-wise;
(b) the details of steps taken to ensure high quality and to maintain international standards of Ayurveda medicines amid concerns that majority of Ayurvedic drug makers in the country have quality issues;
(c) whether Government will establish Government-owned state-of-the-art testing facilities for Ayurveda drugs in every State to ensure the prescribed quality standards; and
(d) whether Government has planned to attract FDI in the Ayurveda drug industry, taking into account the massive potential for exponential growth, if so, the details thereof?

ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)

(a) Sir. 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, Unani and Homoeopathic 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 and Rule 85 (A to I) in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathic 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 & Schedule M-I of Drugs and Cosmetics Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

The list of Ayurvedic, Unani and Siddha (ASU) drug manufacturers to whom WHO-GMP Certificate has been issued are as follows:

S. No.	**Name of the State**	**Number of Companies**
1.	Himachal Pradesh	07
2.	Jammu & Kashmir	01
3.	Uttarakhand	04
4.	Haryana	01
5	Uttar Pradesh	02
6.	Rajasthan	01
7.	Gujarat	02
8.	Madhya Pradesh	01
9.	Maharashtra	03
10.	Karnataka	06
11.	Telangana	02
12.	U.T.of Daman & Diu	02
	TOTAL	**32**

(b) The steps taken by Ministry of Ayush and State/UTs government to ensure high quality and to maintain international standards of Ayurveda medicines are as follows –

- Ministry of Ayush has implemented Central Sector Scheme AYUSH Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) with financial allocation of 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 Bureau of Indian Standards (BIS), Quality Control of India (QCI) and other relevant scientific institutions and industrial R&D centres.

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

  i. Certification of Pharmaceutical Products (CoPP) as per WHO Guidelines for herbal products.
  ii. 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.

- Ministry of Ayush has setup Pharmacopoiea Commission of Indian Medicines & Homoeopathy (PCIM&H), Ghaziabad to lay down Pharamcopoeial Standards and Formulary specifications for Ayurveda, Siddha, Unani and Homoeopathy drugs, which serves as official compendia for ascertaining the identity, purity and strength of the drugs included therein. In 2021, Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), Ghaziabad a sub-ordinate office of Ministry of Ayush

has signed a MoU with American Herbal Pharmacopeia, USA for developing standards of Ayurveda and other Indian systems of medicine on international standards. Further, PCIM&H has taken up the task to harmonize all the monographs published/ being published through Ayurvedic Pharmacopoeia of India (API), Siddha Pharmacopoeia of India (SPI), Unani Pharmacopoeia of India (UPI), Homoeopathic Pharmacopoeia of India (HPI) and Indian Pharmacopeoia (IP). PCIM&H and Indian Pharmacopoeia Commission (IPC) have signed a MoU for developing "ONE HERB ONE STANDARD".

- Pharmacovigilance Centres for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) Drugs set up in different parts of the country under the Central Scheme of Ministry of Ayush are mandated to monitor and report the misleading advertisements to the respective State Regulatory Authorities. A three tier structure comprising of a National Pharmacovigilance Co-ordination Centre (NPvCC), Intermediary Pharmacovigilance Centres (IPvCs) and Peripheral Pharmacovigilance Centres (PPvCs) is established. All India Institute of Ayurveda (AIIA), New Delhi under Ministry of Ayush is the National Pharmacovigilance Co-ordination Centre (NPvCC) for the implementation of the National Pharmacovigilance program for Ayurveda, Siddha, Unani & Homoeopathy drugs. Objectionable advertisements are being reported to the respective State Licensing Authorities by PPvC at regular intervals.

(c) Sir. 27 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. As on date, 81 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. Central Council for Research in Ayurvedic Sciences (CCRAS) under Ministry of Ayush has 01 Drug Testing Laboratory at Captain Srinivasa Murthy Central Ayurveda Research Institute (CSMCARI), Chennai.

(d) Yes Sir. Ministry of Ayush has organized a three day Global Ayush Investment and Innovation Summit (GAIIS) from 20 -22 April, 2022 at Mahatma Mandir, Gandhinagar, Gujarat. The Global Ayush investment and Innovation Summit, 2022 was a distinctive

effort by the Government of India to attract the world's attention to India's ancient wisdom and traditional knowledge, and capitalize on it to pave the way for a sustainable future. The Summit was organized in line with Sustainable Development Goal Number 3 of promoting "Good Health and Well-being."A total of five plenary sessions, eight roundtables, six workshops, and two symposiums were organized and 90 eminent speakers and 100 exhibitors participated during GAIIS.

Ministry of Ayush, Government of India in consultation with Department of Commerce has supported to establish Ayush Export Promotion Council (Ayushexcil) to promote the export of Ayurveda products/ medicines as well as Ayurveda services. This was launched by the Hon'ble Prime Minister on 20th April 2022 at Global Ayush Innovation and Investment Summit in Gandhinagar (Gujarat).

As informed by Union Territory of Puducherry, Government of Puducherry informed that Department of Drugs Control, Govt. of Puducherry has organized an investor's meet on 07.03.2022 jointly with the Puducherry Drug manufacturers Association in the presence of Hon'ble Chief Minister, Secretary (Health), other officials and associations.

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