GOVERNMENT OF INDIA
MINISTRY OF AYUSH

LOK SABHA
UNSTARRED QUESTION NO. 1538
TO BE ANSWERED ON 28TH JULY, 2023

"EXPORT OF AYURVEDIC MEDICINES"

1538 SHRI KANAKMAL KATARA:

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

(a) whether the Government Propose to implement any Scheme in Banswara-Dungarpur (Rajasthan) for promotion of export of Ayurvedic Medicines/Products;

(b) if so, the details thereof;

(c) the steps taken/proposed to be taken by the Government to check quality and impurity of the Ayurvedic medicines/Products as per International Standards;

(d) The name of International institutes/laboratory identified for carrying out such testing; and

(e) The names of the international institutes situated in other countries wherein AYUSH academic chairs are to be set up by India?

ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)

(a) and (b) No Sir, However Ministry of Ayush has implemented "*Central Sector Scheme for Promotion of International Co-operation in AYUSH"* for promoting exports, under the various component, which are as follows:

- Incentive 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. and registration of AYUSH products (Market Authorisation) with regulatory bodies of different countries such as USFDA (United States Food and Drug Administration)/ EMEA (Europe, Middle East, and Africa) / UK-MHRA (United Kingdome-Medicines and Healthcare products Regulatory Agency) / NHPD-Canada (Natural Health Products Directorate) / TGA (Therapeutic Goods Administration) etc. for export of products.

- Support for international AYUSH market development and AYUSH promotion-related activities.
- Ayush Export Promotion Council (AYUSHEXCIL), is a newly formed Export Promotion Council (set up by Ministry of Ayush and supported by Ministry of Commerce, Government of India), launched at Global Ayush Investment and Innovation Summit held in Gandhinagar, Gujarat on April 20, 2022). It is aimed to oversee exports of products of Ayurveda, Homoeopathy, Siddha, Sowa Rigpa and Unani systems and address trade issues pertaining to these sectors. It mandates to facilitate capacity building of its members on export procedures, organize Business to Business meetings, international events, road shows, seminars and workshops on the export of Ayush products, and to safeguard the scientific research in the field of Ayush healthcare. AYUSHEXCIL has conducted a workshop on "Attractive Packaging and Branding of various AYUSH/Traditional products to be Globally Competitive" on 7th July, 2023 at Juniper Hall, Indian Habitat Centre, New Delhi.

The rest of the details on IC-Scheme are available in the public domain at https://ayush.gov.in/images/Schemes/ic.pdf However, these promotional activities are not specific to any particular State or Region (Banswara-Dungarpur, Rajasthan), rather based on the proposals received through proper format.

Further 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.

(c) The steps taken/proposed to be taken by the Government to check quality and impurity of the Ayurvedic medicines/Products are as follows:

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 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 and Rule 85 (A to I) in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathy 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.

Consequent upon decision of Central Government (dated 3rd June, 2020), the Government of India has re-established Pharmacopoeia Commission for Indian Medicines and Homoeopathy (PCIM&H), as a subordinate office under Ministry of Ayush by merging into it, the two central laboratories namely PLIM and HPL (notified vide gazette dated 6th July, 2020). PCIM&H lays down Pharmacopoeial Standards and Formulary specifications for Ayurveda, Siddha, Unani & Homoeopathy (ASU&H) drugs, which serve as official compendia for ascertaining the identity, purity and strength of the drugs included therein. Pharmacopoeia Commission for Indian Medicine & Homoeopathy under Ministry of Ayush is committed to ensure safe and effective health care delivery through Indian Systems of Medicine and Homoeopathy. Towards furtherance of this commitment, PCIM&H works toward establishing quality standards for single drugs and formulations for Ayurvedic medicines. The standards and quality parameters included in the Pharmacopoeias and Formularies of Ayurvedic medicines prescribing mandatory regulatory standards have been identified as such to align with the recommendations of WHO/other major pharmacopoeias prevalent worldwide. The standards so published are enforceable as part of Drugs and Cosmetics act and rules there under. Implementation of these pharmacopoeial standards ensures that the medicines reaching to masses inland as well as globally conform to optimum quality standards in terms of identity, purity and strength.

(d) The Ministry of Ayush has set up Pharmacopoeia Commission for Indian Medicines and Homoeopathy (PCIM&H), as a subordinate office under Ministry of Ayush by merging into it, the two erstwhile central laboratories namely PLIM and HPL and has been given the status for appellate laboratory for testing of ASU&H drugs. Further 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, 27 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. (The rest of the details are available in the public domain at https://main.ayush.gov.in/ayush-drugs/drug-testing-facilities/)

(e) The Ministry of Ayush, Government of India has established Ayush academic chairs at various countries like Mauritius (University of Mauritius), Latvia (University of Latvia) and Bangladesh (Hamdard University Bangladesh).

*****