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

LOK SABHA
UNSTARRED QUESTION NO. 3305
TO BE ANSWERED ON 13TH MARCH, 2020

GLOBAL HERBAL MEDICINAL MARKET

3305. MS. RAMYA HARIDAS:
SHRIMATI POONAM MAHAJAN:

Will the Minister of **AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)** be pleased to state:

(a) whether it is fact that the share in the global herbal medicinal market is less than one per cent in comparison to the growing demand for herbal exports including medicines of AYUSH in the country;

(b) if so, the details thereof and reasons therefor along with the action taken/proposed to be taken by the Government to increase the share of export of AYUSH medicines;

(c) whether drug companies follow India's Good Manufacturing Practice (GMP) regulation and regulatory guidelines for herbal drugs, if so, the details thereof; and

(d) whether regular inspections have been followed for the same and if so, the details thereof and if not, the reasons therefor?

ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA,
YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY
(SHRI SHRIPAD YESSO NAIK)

(a): The export value of herbals (value added extracts of medicinal plants) pertaining to Pharmexcil basket during the year 2017-18 has been USD 311.50 million and of Ayush products to the tune of USD 144.36 million. The global herbal medicinal market has been estimated at USD 70 billion approximately during the year 2017-18.

(b): AYUSH systems are not recognized in many of the countries, which is the main reason for comparatively low share of Indian herbal/Ayush products in the international trade. Ministry of AYUSH has implemented a central scheme of international cooperation and signed MoUs with WHO and various countries for promotion of AYUSH. Ministry is providing incentive to AYUSH drug manufacturers, entrepreneurs, AYUSH institutions etc. for participation in international exhibitions, conferences, workshops, seminars, road shows, trade fairs, etc. for generating awareness about the AYUSH systems and to facilitate export by registration of AYUSH products for market authorization in foreign countries. Quality

certification system under WHO-GMP guidelines is implemented under the administrative purview of Drugs Controller General for promoting export of Ayurvedic, Siddha and Unani herbal medicines. National Medicinal Plants Board (NMPB) under the Ministry of AYUSH is supporting large scale cultivation of medicinal plants to make available quality raw materials to the AYUSH drug industry.

(c): Exclusive regulatory guidelines, quality control provisions and Good Manufacturing Practices for Ayurvedic, Siddha, Unani and Homoeopathic drugs manufacturing units are prescribed in the Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945, which are framed and amended by the Central Government and enforced by the State Governments. GMP guidelines are prescribed in Drugs & Cosmetics Rules, 1945 under Schedule 'T' for ASU drugs and under Schedule 'M1'for homoeopathic drugs, which are mandatory for compliance by the licensed manufacturing units. Quality certification system of ASU herbal products in accordance with WHO-GMP guidelines for herbal medicines is in place under the administrative control of Central Drugs Standard Control Organization.

(d): Provisions for appointing Central and State Drug Inspectors are prescribed in the Drugs & Cosmetics Act, 1940 and Rules thereunder. Licenses to the manufacturing units are granted and renewed by the State Licensing Authorities on the basis of inspection carried out by the appointed Drug Inspectors. Ministry of AYUSH has also notified central inspectors, who are deputed to carry out joint inspection of the drug testing laboratories and manufacturing units, for consideration of granting approval under Drugs & Cosmetics Rules, 1945 and WHO-GMP certification system respectively.

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