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

LOK SABHA
UNSTARRED QUESTION NO. 127
TO BE ANSWERED ON 15TH DECEMBER, 2017

QUALITY CONTROL OF AYUSH DRUGS

127. SHRIMATI HEMA MALINI:
SHRI VINCENT H. PALA:
SHRI HARISH CHANDRA ALIAS HARISH DWIVEDI:

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

(a) the number of companies registered in Indian and foreign categories for production of AYUSH medicines along with the quantum of medicines produced during each of the last three years and the current year;

(b) whether the Government has taken note that a number of unregistered companies are manufacturing AYUSH drugs in the country, if so, the details thereof and the action taken by the Government against such companies;

(c) whether the Government has any system in place to monitor the production and marketing of medicines by these companies, if so, the details thereof;

(d)whether the Government is going to make clinical tests of ayurvedic medicines compulsory and if so, the details thereof; and

(e) the steps being taken by the Government for ensuring sufficient availability of desired medicinal components for manufacturing of medicines along with standardisation and quality control of AYUSH drugs/products?

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

(a): 8667 manufacturing companies of Ayurvedic, Siddha, Unani and Homoeopathic drugs are licensed in the country and about 250 companies of herbal & Ayurvedic products are registered with Pharmaceuticals Export Promotion Council (PHARMEXCIL) for the purpose of exporting their products to foreign markets. Direct annual production data of ASU&H drug industry has not been assessed. However, it is estimated on the basis of demand & supply assessment survey of medicinal plants in the country that about 1,95,000 metric tons of plant material was consumed by the domestic industry for the production of herbal and AYUSH medicines in the

year 2014-15. Export of AYUSH products & value added extracts of medicinal plant products during 2014-15, 2015-16 and 2016-17 amounted to the tune of US Dollars 354.87 million, 358.60 million and 403.90 million respectively.

(b): As per the provisions of Drugs & Cosmetics Rules, 1945 it is mandatory for every AYUSH drug manufacturer to take license from the concerned State Drug Licensing Authority and the State Governments are empowered to take action against such persons who do drug manufacturing for sale in contravention of the legal provisions.

(c): Compliance to the prescribed Good Manufacturing Practices and quality standards as provided in the respective pharmacopoeias is mandatory for the manufacturing of Ayurvedic, Siddha, Unani and Homoeopathic medicines under the supervision of qualified persons as specified in the Drugs & Cosmetics Rules. Regulatory Authorities/Drug Control Officers in the states are responsible to enforce the provisions of quality control of medicines being manufactured and marketed. Drugs & Magic Remedies (Objectionable Advertisement) Act, 1954 and Rules thereunder have provisions to prohibit misleading advertisements and Ministry of AYUSH has entered into an MoU with Advertising Standards Council of India to monitor the misleading or improper advertisements of AYUSH products appearing in print and TV media and report the cases of default to the regulatory authorities for taking action in accordance with the legal provisions.

(d): Drugs & Cosmetics Act, 1940 and Rules thereunder as on date do not have explicit provisions for the clinical trials of Ayurvedic medicines. Rule 158-B of the Drugs & Cosmetics Rules, 1945 does provide the requirement of pilot study to generate proof of safety & effectiveness of certain categories of Ayurvedic medicines. Ministry of AYUSH has published Good Clinical Practice Guidelines for conduct of clinical trials on Ayurvedic, Siddha and Unani medicines on voluntary basis.

(e): Government has set up National Medicinal Plants Board (NMPB) to coordinate and support cultivation, conservation and sustainable development of medicinal plants for supply of quality raw material to the AYUSH industry and Pharmacopoeia Commission of Indian Medicine & Pharmacopoeia Committees are in place to lay down the standards of AYUSH drugs. Quality standards of 847 Ayurvedic drugs, 448 Unani drugs, 139 Siddha drugs and 1117 Homoeopathic drugs are published in the respective pharmacopoeias. Quality control provisions for AYUSH drugs including their shelf life or expiry date are prescribed in the Drugs & Cosmetics Rules, 1945 enforced by the state authorities.

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