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

LOK SABHA
UNSTARRED QUESTION NO.678
TO BE ANSWERED ON 18TH NOVEMBER, 2016

EXPORT OF AYUSH MEDICINES

678. SHRI ASHWINI KUMAR CHOUBEY:

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

(a) whether India's share in the global herbal medicinal market is less than 1 per cent in comparison to the growing demand 210 for Herbal exports including medicines of AYUSH products;

(b) if so, the reasons therefor;

(c) the action taken/proposed to be taken by the Government to increase the share of export of the AYUSH medicines;

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

(e) 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) There is no specific data available. However, estimated global herbal market is around 70 USD bn. As per the available information India’s export of Ayush and value added products of medicinal plants during 2015-16 was 358.60 USD mn.

b) The reasons for lacking the India’s share in the global herbal market including medicines of AYUSH products are as under:

- Lack of awareness of International opportunities that Ayush products can be exported with improved standards in different categories like Dietary supplements, Health supplements, nutraceuticals depending upon the local regulatory requirements.
- Ayush system of medicine/practice is recognised in only few countries like Sri Lanka, Nepal, Bhutan, Malaysia, and Bangladesh.
- Need for scientific research and generation of data as required by overseas countries.
- Enforcement of Biodiversity act, where several medicinal plants are covered under the act restricting the access to resources and thereby exports are getting affected.
- Financial support to Herbal & AYUSH Industry.

c) For enhancing export of the AYUSH medicine, Ministry of AYUSH takes various steps, which include signing of Memoranda of Understanding for country to country 'Cooperation in the field of traditional medicine' to promote and propagate AYUSH systems of medicines across the world and by offering incentives, under the Ministry's Central Sector Scheme for International Cooperation. AYUSH Drug manufacturers participating in the Trade Fairs/Exhibitions and Road shows held in the foreign countries; and getting market authorizations/ registration for their AYUSH products with USFA/EMEA/UK-MHRA and other International Regulatory Agencies are reimbursed the expenditure incurred by them with certain ceilings.

d) Drugs & Cosmetics Rules, 1945 provide for compliance of the Good Manufacturing Practices (GMP) for licensed manufacturing of Ayurvedic, Siddha, Unani and Homoeopathic drugs. Certification in this aspect is done by the State Licensing Authorities. Voluntary certification of Pharmaceutical Products (COPP) under WHO Guidelines is extended to Ayurvedic, Siddha and Unani medicines. This scheme is administered by the Office of Drugs Controller General (India) and the certification is done on the basis of joint inspection of the applicant manufacturing unit by the representatives of Drugs Controller General, Ministry of AYUSH and the State Licensing Authority. Another voluntary quality certification scheme is implemented by the Quality Council of India (QCI) for grant of AYUSH Standard and AYUSH Premium marks to Ayurvedic, Siddha and Unani products on the basis of third party evaluation of quality in accordance with the status of compliance to domestic regulations and international norms respectively.

e) There is a provision in the Drugs and Cosmetics Rules, 1945 for conducting inspection of the manufacturing units as well as approving of Drug Testing Laboratories by the Inspectors appointed under the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder. The joint inspection is also done by the Central Officer and State Officer for verification of space, equipment, technical manpower, reference books and reference samples in the AYUSH laboratory. Thereafter, license to the laboratory is issued by the State Licensing Authority, only if the joint inspection report recommends grant of approval.