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

LOK SABHA
UNSTARRED QUESTION NO. 94
TO BE ANSWERED ON 15TH DECEMBER, 2017

STANDARDISATION OF AYURVEDIC DRUGS

94. SHRI MANSHANKAR NINAMA:

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

(a) whether any steps are being taken by the Government for Global Standardisation of Ayurvedic drugs in view of the growing demand;

(b) if so, the details thereof;

(c) the steps being taken to ensure availability of required medicinal materials for manufacturing of Ayurvedic drugs; and

(d) the steps taken by the Government for standardisation quality control of Ayurvedic medicines in the market and ensure manufacture of every drug as per the international standards?

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

(a): Yes.

(b): The Pharmacopoeia Commission for Indian Medicine and Homeopathy (PCIM&H) has signed a MoU with United States Pharmacopoeial Convention (USP) for cooperation in the field of traditional medicine. First meeting with USP was conducted on 7th November, 2017.

(c): To ensure the availability of required raw material of medicinal plants for manufacturing of Ayurvedic drugs, the NMPB under its "Central Sector Scheme on Conservation, Development and Sustainable Management of Medicinal Plants" provides project based support for resource augmentation of medicinal plants and to encourage cultivation of Medicinal Plants in the farmers' field. The Ministry of AYUSH under its National AYUSH Mission (NAM) scheme provides financial assistance as subsidy @ 30%, 50%, 75% of cost of cultivation.

Contd…….

(d): Government of Indian established Pharmacopeia Commission for Indian Medicine and Homeopathy (PCIM&H) under Ministry of AYUSH with the prime mandate to develop standards and quality specifications for identity, purity and strength of raw materials and compound formulations and to develop SOPs for the process of manufacture included or to be included in the Ayurvedic, Siddha, Unani and Homeopathic Pharmacopoeia/ formulary. Till date the PCIM&H has developed 645 monographs of single drug and 202 monographs of compound formulations used in Ayurveda.

- As per the provisions of Drugs & Cosmetics Rules, 1945 it is mandatory for the manufacturers to follow the quality standards given in the Pharmacopeia and adhere to the Good Manufacturing Practices.
- Display of shelf life/expiry date of different kinds of Ayurvedic medicines on the label has been made mandatory under provisions of Drugs & Cosmetics Rules, 1945.
- Rule 158(B) of the Drugs & Cosmetics Rules, 1945 provides the regulatory requirements for issue of license for the manufacturing of different types of Ayurvedic medicines including the proof of safety and effectiveness.
- Quality certification system as per the WHO-GMP guidelines has been made applicable for Ayurvedic medicines under the administrative control of Drug Controller General (India). Similarly, a volunteer mechanism for quality certification of Ayurvedic products as AYUSH Premium Mark as per international standards has been implemented by the Quality Council of India.

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