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

LOK SABHA
UNSTARRED QUESTION NO. 2375
TO BE ANSWERED ON 11TH MARCH, 2016

CERTIFICATION OF AYURVEDIC MEDICINES

2375. SHRI DILIP PATEL:

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

(a) whether the Government has introduced/proposes to develop institutional mechanism for evaluation of the efficiency and safety of ayurvedic medicines and certify such medicines;

(b) if so, the details thereof, if not, the reasons therefor; and

(c) whether ayurvedic medicines are allowed to be taken without proper doctoral advice along with the manner in which ayurvedic medicines are classified from other medicines?

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

(a) & (b): Rule 158-B of the Drugs & Cosmetics Rules, 1945 seeks proof of safety and effectiveness for the purpose of licensing of various categories of Ayurvedic, Siddha and Unani drugs. In this regard ASU drugs not having textual rationale or evidence in the scientific literature need to undergo safety and efficacy evaluation studies for consideration of grant of manufacturing license by the State Licensing Authority. The Government has published Good Clinical Practice guidelines for conduct of clinical trials on Ayurvedic, Siddha and Unani drugs and a directive issued to have such clinical trials registered with the Clinical Trials Registry, India (CTRI). A committee of experts is also in place in the Ministry of AYUSH to examine the proposals of clinical trials seeking permission of the Government. Central Research Councils also undertake safety & efficacy studies of Ayurvedic, Siddha and Unani formulations and support is provided through Extramural Research Scheme to such projects. Certification of compliance to Good Manufacturing Practices as prescribed in Schedule-T of the Drugs & Cosmetics Rules, 1945 is mandatory for the manufacturers and two voluntary schemes are implemented by Quality Council of India and Drugs Controller General(India) for certification of quality of ASU drugs in granting AYUSH Standard & Premium Marks and WHO-CoPP respectively.

Contd…….

(c): Ayurvedic medicines are classified in two categories i.e. classical and Patent or Proprietary medicines as defined under section 3 (a) & (h) of the Drugs & Cosmetics Act, 1940. Registration of the Ayurveda practitioner in the Central or State Register of the practitioners is essential for doing clinical practice and prescribe Ayurvedic medicines to the patients. Rule 161 (2) of the Drugs & Cosmetics Rules, 1945 has a specific provision of caution for use of certain Ayurvedic medicines containing potentially toxic ingredients under medical supervision.

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