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

LOK SABHA
STARRED QUESTION NO.256
TO BE ANSWERED ON 12TH MARCH, 2021
QUALITY OF AYURVEDIC MEDICINES

†*256. SHRI AJAY BHATT:

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

(a) whether the Government proposes to formulate guidelines on Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) for compliance by units manufacturing Ayurvedic medicines, on the lines of Allopathy;

(b) if so, the details thereof;

(c) the steps taken by the Government to check the use of heavy metals and other harmful ingredients in Ayurvedic medicines; and

(d) the other steps taken including the mechanism set up to improve the efficacy/quality of Ayurvedic medicines?

ANSWER
THE MINISTER OF STATE(IC) OF THE MINISTRY OF YOUTH AFFAIRS AND SPORTS AND ADDITIONAL CHARGE OF MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY

(SHRI KIREN RIJIJU)

(a) to (d): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 256 * FOR 12TH MARCH, 2021

(a) & (b) As per the provisions of Rule 157(1) of Drugs and Cosmetics Rules, 1945, the manufacture of Ayurvedic (Including Siddha) or Unani drugs are to be carried out in such premises and such hygienic conditions as are specified in Schedule-T (Good Manufacturing Practices). It is mandatory for the manufacturers to comply with GMP for obtaining license of Ayurveda, Siddha and Unani (ASU) drug manufacturing.

There are no separate guidelines of Good Laboratory Practice (GLP) for Ayurvedic Medicines. However under Rule 160 A to J of Drug & Cosmetics Rules 1945, there are provisions for approval of laboratories for carrying out tests on Ayurvedic drugs and raw materials.

(c) As per Drugs & Cosmetics Act 1940 and Rules made thereunder, it is mandatory for all Ayurvedic medicines to comply with the standards prescribed under Ayurvedic Pharmacopeia of India (API), published by Ministry of AYUSH, Government of India from time to time, which includes pharmacopoeial standards for heavy metals content, microbiological limits, aflatoxins etc. and products are tested against the set standards. However, heavy metals are in built ingredients of certain ASU drugs and mentioned under Schedule E-1 of the Drugs & Cosmetics Rules, 1945. For such substances, 'Caution: to be taken under medical supervision' is to be conspicuously labeled on the container.

An advisory has been issued on 14th October, 2005 by this Ministry which prescribes limit and testing of heavy metals mandatory for export purposes in respect of every batch of purely herbal ASU drugs by every licensee.

(d) Ministry of AYUSH has a Central Sector Scheme of Pharmacovigilance of Ayurveda, Siddha Unani & Homeopathy Drugs already functional since June 2018 for inculcating the culture of Adverse Drug Events (ADE) reporting, documentation and analysis for further regulatory action. The Scheme has an established three tier network. All India Institute of Ayurveda (AIIA), New Delhi, has been designated as the National Pharmacovigilance Coordination Centre (NPvCC), 5 Intermediary Pharmacovigilance Centres (IPvC's) and 74 Peripheral Pharmacovigilance Centres (PPvC's).

Rule 158B in the Drugs & Cosmetics Act Rules, 1945, has mandatory provision relating to safety study and the experience or evidence of effectiveness for issuing license to ASU drugs.

The Government has established Pharmacopoeia Commission for Indian Medicine and Homoeopathy under the Ministry of AYUSH. The prime mandate of the Commission is to publish and revise Ayurvedic Pharmacopoeia of India (API), Siddha Pharmacopoeia of India (SPI), Unani Pharmacopoeia of India (UPI) and Homoeopathic Pharmacopoeia of India (HPI). The Pharmacopoeial standards are basic need to ensure quality, safety and efficacy of Ayurvedic, Siddha, Unani and Homoeopathic medicines.

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