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

LOK SABHA
UNSTARRED QUESTION NO. 3677
TO BE ANSWERED ON 16TH MARCH, 2018

EFFECTIVENESS OF AYUSH DRUGS

3677. SHRI ANTO ANTONY:

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

(a) whether it is a fact that the Government has received a number of queries under the Right to Information (RTI) Act and complaints also regarding effectiveness of AYUSH drugs such as IME-9;

(b) if so, the details thereof, and the response of the Government thereto; and

(c) the steps being taken by the Government to ensure foolproof clinical trials of AYUSH medicines?

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

(a) & (b): Yes, the Government has received queries under the Right to Information (RTI) Act, public complaints and grievances regarding effectiveness claims of AYUSH drugs including IME-9. Such issues have been brought up to the notice of Ministry of AYUSH directly by the consumers including public representatives and after registered in the GAMA (Grievances against Misleading Advertisements) portal maintained by the Department of Consumer Affairs and monitored by the Advertising Standards Council of India. Since enforcement of the legal provisions of licensing, quality control and advertisements of Ayurvedic, Siddha, Unani and Homeopathic (ASU&H) medicines is vested with the State Governments, the Central Government in the Ministry of AYUSH has been providing relevant information/clarification to the applicants or complainants and forwarding the alleged matters to the concerned State Licensing Authorities for appropriate action under the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder and Drugs and Magic Remedies (Objectionable Advertisements), Act, 1954. In order to address quality issues of ASU&H medicines, it is mandatory for the manufacturers to comply with the Good Manufacturing Practices and quality standards prescribed in the respective pharmacopoeia including permissible limits of heavy metals, pesticide residue, afla-toxins and microbial load.

Contd…….

(c): The extant Rule 158-B of the Drugs & Cosmetics Rules, 1945 prescribes the regulatory requirement of submission of proof of safety and effectiveness inter alia based on pilot studies for licensing of various categories of ASU medicines. Enforcement of these provisions is under the purview of the Licensing Authorities appointed by the State Governments. Ministry of AYUSH has published "Good Clinical Practice Guidelines for conduct of clinical trials in Ayurveda, Siddha and Unani Medicine. These guidelines are for voluntary use and encompass the design, conduct, termination, audit, analysis, reporting and documentation of the systematic studies involving human subjects for determining the safety and efficacy of Ayurvedic, Siddha and Unani (ASU) medicines and to ensure that the studies are scientifically and ethically sound and the clinical properties of the ASU medicines under investigation are properly documented.

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