GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO. 1610
TO BE ANSWERED ON 06th AUGUST, 2024

"Randomised clinical trials for Ayush medicines"

1610 **Dr. Fauzia Khan:**

Will the Minister of ***Ayush*** be pleased to state:

(a) whether Government has implemented provisions for conducting random clinical trials for Ayush medicines to evaluate their safety and efficacy through scientific research;

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

(c) whether Government has developed a dashboard to display the side effects and efficacy of Ayurvedic medicines, providing transparent information to consumers about the potential risks and benefits associated with their usage; and

(d) if so, the details thereof and if not, the reasons therefor?

ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYUSH
(SHRI PRATAPRAO JADHAV)

(a) and (b) As prescribed in Drugs and Cosmetics Act 1940 and Rules 1945 made thereunder, enforcement of the legal provisions pertaining to quality control and issuance of drug license of Ayurveda, Siddha, Unani and Homoeopathic drugs, is vested with the State drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government.

In the year 2013, the then Department of AYUSH (Now Ministry of Ayush) has published Good Clinical Practice for Clinical trials in Ayurveda, Siddha, and Unani Medicine (GCP-ASU) guidelines to ensure the ethical and scientific quality of clinical trials conducted in the field of Ayurveda, Siddha and Unani medicine. These guidelines provide a framework for designing, conducting, recording, and reporting trials that involve the participation of human subjects.

05 Research Councils and 12 National Institutes under the aegis of Ministry of Ayush are engaged in conducting research for Ayush medicine/ interventions including randomized clinical trials and the details regarding the same are available on Ayush Research Portal (https://ayushportal.nic.in.).

(c) and (d) No Madam. However, in 2021, Ministry of Ayush has implemented Central Sector Scheme AYUSH Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) and the total financial allocation to this scheme is Rs. 122.00 crores for five years. One of the components of AOGUSY scheme is "Pharmacovigilance of ASU&H drugs including surveillance of misleading advertisements". Under this pharmacovigilance program, the major objectives are to keep vigilance over possible adverse drug reactions with the use of Ayurveda, Siddha, Unani & Homoeopathy (ASU&H) drugs. The program is working through a three-tier network of a National Pharmacovigilance Centre (NPvCC), Five Intermediary Pharmacovigilance Centres (IPvCs) and 99 Peripheral Pharmacovigilance Centres (PPvCs) established across the country.

Each Centre (NPvCC, IPvCs & PPvCs) has been provided with format for reporting suspected adverse drug reactions where consumers can report any adverse drug reaction. Also, under the Pharmacovigilance Program for ASU&H drugs consumers can lodge complaints either directly or through online portal: https://www.ayushsuraksha.com.

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