

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

**LOK SABHA  
UNSTARRED QUESTION NO. 2119  
TO BE ANSWERED ON 23<sup>RD</sup> SEPTEMBER, 2020  
MONITORING OF AYUSH MEDICINES**

**2119. SHRI NAYAB SINGH:  
SHRI RAVI KISHAN:  
SHRI GAJENDRA SINGH PATEL:  
SHRI RAVINDRA KUSHWAHA:  
SHRI JOHN BARLA:**

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

- (a) whether the Central Scheme started by the Government has strengthened the safety vigilance monitoring mechanism for AYUSH medicines;
- (b) if so, the details thereof;
- (c) whether the mechanism is ensuring the safety and quality of AYUSH drugs; and
- (d) if so, the manner in which it is assisting in assessing and evaluating these medicines including identification of the adverse effects of these medicines?

**ANSWER  
THE MINISTER OF HEALTH AND FAMILY WELFARE  
(DR. HARSH VARDHAN)**

(a) & (b): Ministry of AYUSH has implemented a Central Sector Scheme of Pharmacovigilance of Ayurvedic, Siddha, Unani and Homoeopathic (ASU&H) drugs since December, 2017. Through this scheme, a network of National Pharmacovigilance Centre, five Intermediary system-wise PharmacovigilanceCentres and sixty three Peripheral PharmacovigilanceCentres has been established and made functional since August 2018 to inculcate the culture of reporting Adverse Drug Events and misleading advertisements of ASU&H drugs for regulatory action. Eleven more Peripheral Centres have recently been added to the network. All India Institute of Ayurveda (AIIA), New Delhi is designated as the National Pharmacovigilance Coordination Centre (NPvCC) with five National AYUSH institutes as Intermediary Pharmacovigilance Centres (IPvCs) and seventy four Peripheral Pharmacovigilance Centres (PPvCs) distributed across the country. Project Appraisal Committee and Project Sanctioning Committee are set up under the scheme to consider the proposals related to pharmacovigilance activities and surveillance of misleading advertisements. Signal Detection Committee and Causality Assessment Committee are constituted under the pharmacovigilance scheme to analyze the adverse effects data of ASU&H medicines reported from different centres and make recommendations, if any regulatory action is required. The pharmacovigilance centres have reported ASU&H drugs related 8203 cases of misleading advertisements and 463 cases of suspected Adverse Drug Events (186 from Ayurveda drugs, 70 from Siddha drugs, 151 from Unani drugs and 56 from Homoeopathic drugs) up to August, 2020.

(c) & (d): Implementation of the pharmacovigilance scheme has facilitated safety and quality assessment of ASU&H medicines by the Expert Committees as well as it assisted in identifying and detecting misrepresentation and possible adverse effects of these medicines for needed regulatory action by the Central and State authorities.