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

LOK SABHA UNSTARRED QUESTION NO.1888 TO BE ANSWERED ON 12TH February, 2021

EFFECT OF HERBAL MEDICINE

1888. SHRI RAJMOHAN UNNITHAN:

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

- (a) whether the Government has commissioned any study to evaluate the effectiveness and adverse effects of herbal medicines; and
- (b) if so, the details thereof?

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): Herbal Medicines as such is not defined under the Drugs and Cosmetics Act, 1940 and Rules 1945. Exclusive regulatory guidelines, quality control provisions and Good Manufacturing Practices for Ayurvedic, Siddha, Unani and Homoeopathic drugs manufacturing units are prescribed in the Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945. The Central Council of Ayurvedic Sciences (CCRAS) under Ministry of AYUSH is conducting trials for validation of Classical Ayurvedic formulations to generate tangible evidences on their clinical safety and efficacy.
- (b): Ministry of AYUSH has implemented the Central Sector Scheme of Pharmacovigilance Program of Ayurveda, Siddha, Unani & Homoeopathy drug since December 2017. Through this scheme a three tier network consisting of National Pharmacovigilance Co-ordination Centre (NPvCC), five Intermediary Pharmacovigilance Centres (IPvCs) and seventy four Peripheral Pharmacovigilance Centres (PPvCs) has been established for safety monitoring of Ayush drugs, reporting of adverse drug events and surveillance & reporting of misleading advertisements. Functionality of the pharmacovigilance centres is reviewed periodically. As a result of effective implementation of the scheme, pharmacovigilance centres have reported 608 suspected adverse drug reactions (ADRs) from January 2019 to December, 2020. System wise reported ADR's is as under:-

S.No.	System	Number of suspected ADR's (From January 2019 to December 2020)
01	Ayurveda	236
02.	Siddha	120
03.	Homoeopathy	76
04	Unani	176
	Total	608