

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

**LOK SABHA  
UNSTARRED QUESTION NO. 1047  
TO BE ANSWERED ON 18<sup>th</sup> SEPTEMBER, 2020**

**TRADITIONAL SYSTEM OF MEDICINE**

**1047. SHRI RAVINDRA KUSHWAHA:**

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

- (a) the action plan formulated by the Government to bring the knowledge of traditional medicines into mainstream by including them in modern health care;
- (b) whether the Government has developed any strategy for ensuring State of the art safety protocols and effective standards of traditional system of medicine, if so, the details thereof;
- (c) whether the Government is aware of the dangers emerging to bio-diversity due to excessive cutting of medicinal plants or due to increasing use of body parts of endangered animals in traditional medicines; if so, the details thereof; and
- (d) the remedial measures being taken by the Government in this regard?

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

(a) & (b): A new category of drugs called 'Phytopharmaceutical drugs' made from purified and standardized fraction with minimum four bio-active or phytochemical compounds of medicinal plants used in traditional medicine or ethnomedicine has been included under the provisions of Drugs & Cosmetics Rules, 1945 since November, 2015 and these drugs are under the regulatory control of Central Drug Standards Control Organization. Provisions for proof of safety and effectiveness and quality standards for manufacturing of Ayurveda, Siddha and Unani medicines are prescribed under Rules 158-B and 168 of the Drugs & Cosmetics Rules, 1945 and respective pharmacopoeias. These provisions are framed by the Central Government and enforced by the State Governments through the Licensing Authorities/Drug Controllers. Central Government has established Pharmacopoeia Commission of Indian Medicine & Homoeopathy to develop, revise and lay down the standards of Ayurvedic, Siddha, Unani and Homoeopathy drugs and formulations and publish respective Pharmacopoeias and Formularies. New indications, new dosage forms and new formulations of traditional medicine need to follow the procedure of quality assessment and safety & effectiveness evaluation in accordance with the provisions of Drugs & Cosmetics Rules, 1945. Ministry of AYUSH has published Good Clinical Practices (GCP) guidelines based on scientific parameters for conduct of clinical trials in Ayurvedic, Siddha and Unani medicine.

(c) & (d): Yes, Government is aware of the dangers related to biodiversity protection and use of threatened species of animals. Accordingly, in order to conserve biological resources including medicinal plants, the National Biodiversity Authority and the State Biodiversity Boards are facilitating and regulating the use of biological resources and associated knowledge for research and commercial use in accordance with the provisions of the Biological Diversity Act, 2002. The Biological Diversity Act, 2002 has provisions to impose penalties for violations involving accessing of biological resources including medicinal plants for commercial purpose without obtaining approval from the National Biodiversity Authority or the State Biodiversity Boards. Biodiversity registers maintained by the Biodiversity Management Committees record the details of available natural resources and traditional knowledge including traditional medicines.

Government has established National Medicinal Plants Board under the aegis of Ministry of AYUSH to support, undertake and promote cultivation, conservation and sustainable development of medicinal plants and augment the supply of bio-resources and various raw materials for the Ayush drugs industry from cultivated sources. Ministry of Finance has recently announced on 15.5.2020 a special package of Rs. 4000 crore for National Medicinal Plants Board under Atmanirbhar Bharat Campaign to augment cultivation and development of medicinal plants over 10 lakh hectares of land. Ministry of Environment, Forest and Climate Change set up a Working Group on 19.8.2020 to look for required amendment in the Biological Diversity Act, 2002, Rules-2004 and Access Benefit Sharing (ABS) Regulations