

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:5193
ANSWERED ON:26.04.2013
QUALITY OF HERBAL MEDICINES
Venugopal Shri P.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether the Government has taken note of the recent findings of certain British scientists which suggest that herbal medicines are exposing millions of people in India to the risk of kidney failure and bladder cancer;
- (b) if so, the details thereof and the reaction of the Government thereto;
- (c) the steps being taken by the Government to verify the above claims; and
- (d) the measures taken/proposed by the Government to ensure the quality of herbal medicines in the country?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

(a): Yes. The Government has taken note of the news item regarding the findings of certain British Scientists about herbal drugs containing Aristolochic Acid and their risk to cause kidney failure and bladder cancer.

(b) & (c): The news item does not mention the form of medicine, whether the alleged herbs were found to be used as such or their extracted active principles, the amount of Aristolochic Acid present in the herbal drugs and duration of intake that leads to such ailments.

The Drugs & Cosmetics Act, 1940 does not have any category in the name of herbal drugs, as such, beyond the scope of statutory definition of Ayurveda, Siddha and Unani (ASU) drugs.

The news item has immediately been referred to the Drugs Controller General (India), Central Drug Standard Control Organisation for regulatory action in such cases of non-ASU herbal medicines and also to a Working Group consisting of prominent scientists and experts set up by the Department of AYUSH for examination and to submit a report.

(d): For such herbal medicines, which fit in to the definition of Ayurveda, Siddha and Unani medicines as contained in Section 3(a) and (h) of the Drugs & Cosmetics Act, 1940 and are in the regulated category of medicines, a number of measures including compliance to quality standards, compliance to Good Manufacturing Practices (GMP), notification of Schedule of poisonous substances, regulatory guidelines for licensing of ASU medicines, use of excipients, preservatives etc, permissible limits of heavy metals, aflatoxins, pesticide residue and microbial load, and mentioning of shelf life of medicines have been introduced. Also, Pharmacopoeial Standards for 600 single Ayurvedic drugs and 152 compound Ayurvedic formulations; 298 Single Unani drugs and 100 compound Unani formulations and 139 single Siddha drugs have been published by the Department of AYUSH.