

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

UNSTARRED QUESTION NO:5969
ANSWERED ON:11.05.2012
STANDARDIZATION OF DRUGS
Rawat Shri Ashok Kumar;Singh Shri Bhupendra

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

- (a) whether the Government has provided the information of poisonous and non-poisonous impurities to drug manufacturers to maintain purity and standardization of drugs;
- (b) if so, the details thereof and if not, the reasons therefor;
- (c) whether the Government has taken/proposed any steps to make available full details of impurity profile to the small pharmaceutical companies from the National Institute of Pharmaceutical Education and Research;
- (d) if so, the details thereof;
- (e) whether any observation has been made by the Supreme Court in regard to making amendments in the Drugs and Cosmetics act; and
- (f) if so, the details thereof alongwith the reaction of the Government thereto?

Answer

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

(a) & (b):- The Drugs permitted to be marketed in the country are required to comply with the standards as per Second Schedule of Drugs and Cosmetics Act, 1940. As per the Second Schedule, the drugs should comply with the standards of identity, purity and strength specified in the concerned edition of the Indian Pharmacopoeia and such other standards as may be prescribed. The Indian Pharmacopoeia, the official book for standards of drugs published by the Indian Pharmacopoeia Commission, updated from time-to-time on continuous basis, contains monographs for drugs. It also addresses issues of impurities.

(c) & (d) Do not arise.

(e) & (f) The Government is not aware of any observation made by the Supreme Court for amendments in the Drugs & Cosmetics Act, 1940.