

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

UNSTARRED QUESTION NO:2111
ANSWERED ON:12.08.2011
AMENDMENTS IN DRUGS IN COSMETICS ACT
Ahir Shri Hansraj Gangaram

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

- (a) whether the Government proposes to make certain amendments in the Drugs and Cosmetics Act, 1940 in order to make it relevant to present time;
- (b) if so, the details thereof;
- (c) whether the Government has sought suggestions from the State Governments for making amendment in the said Act; and
- (d) if so, the details of suggestions received from the State Governments in this regard alongwith the other steps taken/proposed to be taken to make this more relevant and effective?

Answer

THE MINISTER OF HEALTH & FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) to (d): In order to implement the recommendations of the Expert Committee headed by Dr. R. A. Mashelkar, the then Director General, Council of Scientific and Industrial Research (CSIR) a Bill, namely, the Drugs and Cosmetics (Amendment) Bill, 2007 was introduced in the Rajya Sabha on the 21st August, 2007 containing the following main provisions:

- (i) Creation of an autonomous Central Drugs Authority in place of the existing Central drugs regulatory body, namely, the Central Drugs Standard Control Organisation (CDSCO);
- (ii) Centralised Licensing of import and manufacture of Drugs, including Ayurvedic, Siddha and Unani (AYUSH) drugs;
- (iii) Regulatory provisions for Clinical Trials; and
- (iv) Regulatory provisions for export of drugs and cosmetics.

The Bill was referred to the Department Related Parliamentary Standing Committee on the 23rd August, 2007 for examination and report. On the basis of the recommendations of the Parliamentary Standing Committee as contained in its 30th Report on the said Bill, Government circulated the draft amendments to the said Bill to the State / Union Territory Governments for their comments. No final view has so far emerged on account of the general opposition to certain provisions of the said Bill by the State / Union Territory Governments.