

**GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA**

UNSTARRED QUESTION NO:3411
ANSWERED ON:13.12.2012
RECOMMENDATIONS OF Dr. Mashelkar Committee
Ahir Shri Hansraj Gangaram

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether Dr. Raghunath Mashelkar Committee on drugs has submitted its report to the Government;
- (b) if so, the details of the recommendations made by the Committee;
- (c) whether the Government has taken any action in the light of the recommendations of the said Committee to regulate the pharmaceutical industry;
- (d) if so, the details thereof; and
- (e) if not, the reasons therefor?

Answer

MINISTER OF STATE (INDEPENDENT CHARGE) OF THE MINISTRY OF STATISTICS AND PROGRAMME IMPLEMENTATION AND MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)

(a) & (b): An Expert Committee was constituted under the chairmanship of Dr. R.A. Mashelkar to examine the aspects regarding the regulatory infrastructure and the extent and problem of spurious / substandard drugs in the country. The Committee noted that the problems in the drug regulatory system in the country are primarily due to inadequate or weak drug control infrastructure at the State and Central level. Therefore, the Committee recommended that a strong, well equipped, empowered, independent and professionally managed Central Drugs Standard Control Organization (CDSCO) should be given the status of Central Drug Administration (CDA) reporting directly to the Ministry of Health & Family Welfare.

(c) & (d): As per the recommendations of the Mashelkar Committee, the Drugs & Cosmetics Act, 1940 was amended by the Drugs & Cosmetics (Amendment) Act, 2008 for enhancing the penalties in the Drugs & Cosmetics Act, 1940 so as to help tackle the problem of spurious and adulterated drugs. The salient features of the amended provisions of the Drugs & Cosmetics Act, 1940 are as follows:

- a) Maximum penalty life imprisonment and fine of Rs. 10 lakhs or 3 times the value of the confiscated goods, whichever is more.
- b) Some of the offences cognizable and non-bailable;
- c) Besides officers from the Drug Controller's Office, other gazetted officers also authorised to launch prosecution under the Act;
- d) Specially designated courts for trial of offences covered under the Act;
- e) Provision for compounding of minor offences.
- (e): In view of reply (c) & (d) above, does not arise.