

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

UNSTARRED QUESTION NO:1599

ANSWERED ON:15.07.2009

REVIEW OF DRUG REGULATORY SYSTEM

Ahir Shri Hansraj Gangaram;Chavan Shri Harischandra Deoram

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

- (a) whether the Pharmaceutical Industry has suffered heavy losses due to increasing volume of spurious drugs in the country during the last three years and the current year;
- (b) if so, the details thereof;
- (c) whether the Government had constituted a Committee of Experts to undertake a comprehensive review of the Drug Regulatory System in the country including extent of evaluation of the spurious and sub-standard Drugs;
- (d) if so, the details thereof;
- (e) whether the Committee has since submitted its Report;
- (f) if so, the main findings thereof; and
- (g) the action taken by the Government on the recommendations of the said Committee?

Answer

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

(a) & (b): No.

(c) to (f): Yes. An Expert Committee under the Chairmanship of Dr. R.A. Mashelkar, the then Director General and Secretary, Council of Scientific and Industrial Research (CSIR), was constituted in 2003 to examine drug regulatory issues including the problem of spurious drugs. The detailed report of the Committee is available on the Central Drugs Standard Control Organisation (CDSCO) website www.cdscn.nic.in. The salient items of recommendations of the Committee are as follows:-

- i. A new structure for the Drug Regulatory System in the country including the setting up of a National Drug Authority. A strong, well equipped, empowered, independent and professionally managed Central Drugs Standard Control Organisation(CDSCO), which could be given the status of Central Drug Administration (CDA) reporting directly to Ministry of Health.
- ii. Measures to strengthen the drug regulatory infrastructure in Centre and States.
- iii. The Central Government should provide assistance to undertake scientific and statistically significant study in order to have a clear picture about the exact extent of spurious drugs in the country.
- iv. Stricter penalty for spurious drug manufacturers.

(g): The following actions have been taken on recommendations:-

(i) The Drugs & Cosmetics (Amendment) Bill 2007 was introduced in the Rajya Sabha on the 21st August, 2007 containing provision inter alia for formation of Central Drugs Auhority and Centralized Licensing of Drugs.

(ii) Efforts have been undertaken continuously and consistently to strengthen the CDSCO with adequate infrastructure and manpower. All vacant posts are being filled up. 62 new post of Drugs Inspector and 10 new posts of Technical Officers have been created and are being filled up. The Department of Expenditure has been requested for sanction of more posts of Drugs Inspectors. Contractual staff (Technical data Associates and Data Entry Operator) have also been recruited to assist the regular staff. Under the Capacity Building Project through World Bank, assistance has been provided to upgrade testing facilities and to establish new drug testing laboratories so as to enhance the capacity of the laboratories to test large number of samples. Under this project 23 States and 6 Central Drug laboratories have been strengthened through renovations, extensions and equipments.

(iii) In order to assess the extent of spurious drugs in the country, a country wide Survey has been undertaken by the Ministry of Health, through CDSCO, on the basis of statistical principles provided by Indian Statistical Institute (ISI), Hyderabad. Under this survey around 24,300 samples of 61 brands of drugs belonging to 9 therapeutic categories of 29 manufacturers from over 100 different Pharmacy

outlets in different regions of the country and located in each stratum viz. Metros, big cities, district, towns and villages have been collected. This would help in identifying geographical areas where spurious drugs are available so that a focused monitoring is done by the concerned authorities in these areas for eliminating the menace of spurious drugs.

(iv) The Drugs & Cosmetics Amendment Bill Act, 2008 now provides for stringent penalties to manufacturers of spurious drugs.