

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

STARRED QUESTION NO:23
ANSWERED ON:02.03.2005
LEGISLATION ON SPURIOUS DRUGS
Chowdhury Shri Adhir Ranjan;Nikhil Kumar Shri

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

- (a) whether the Mashalkar Committee's report on spurious drugs has recommended a legislation for the amendment of the penal provisions of the Drugs and Cosmetics Act, 1940;
- (b) if so, whether the Government proposes to bring a legislation in this regard;
- (c) if so, the facts and details thereof; and
- (d) the steps taken/proposed to be taken by the Government to ensure that manufacture and sale of spurious drugs do not spread in the country?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a)to(d): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 23 FOR 2ND MARCH, 2005

Government of India had constituted a committee of experts on 27th January, 2003, under the Chairmanship of Dr. R. A. Mashelkar, D.G., CSIR to undertake a comprehensive review of the drug regulatory system in the country including evaluation of the extent of the problem of spurious and sub-standard drugs and to recommend remedial measures to deal with this problem effectively.

The expert committee submitted its final report to the Government in November 2003. Based on the recommendations given by the committee in its report, Central Government had initiated steps to bring legislation for amending the Drugs and Cosmetics Act, 1940, on the line suggested by the committee. A bill was introduced in the Lok Sabha in December, 2003, to amend the said Act. The salient amendments proposed under the Bill are given below: -

1. Enhancement of the punishments relating to spurious or adulterated drugs leading to death or grievous hurt within the meaning of Section 320 IPC upto punishment of death or imprisonment for a term which shall not be less than 10 years but which may extend to imprisonment for life and shall also be liable to fine of one lakh rupees or upto three times the value of the goods seized, whichever is higher.
2. Penalties for subsequent offences to be enhanced upto 10 years and with fine which shall not be less than one lakh rupees.
3. Offences relating to spurious or adulterated drugs to be made non-bailable and cognizable.
4. Provision for setting up of special courts to try offences of spurious or adulterated drugs.
5. To confer powers upon police officers not below the rank of sub-inspector or other designated officer to institute prosecutions under the said Act.
6. Provision for compounding of offences for minor offences under the Act.

The Bill has since lapsed with the dissolution of previous Lok Sabha, and necessary action to re-introduce the Bill has been initiated by the Ministry of Health & Family Welfare.

The present Cabinet accorded approval for the introduction of Drugs and Cosmetics (Amendment) Bill, 2005, in the Parliament subject to certain modifications. The Bill is likely to be introduced during the current session of the Parliament along with necessary modifications.

The proposed amendments will make the law deterrent to the offenders involved in the manufacture or sale of spurious drugs. The involvement of enforcing agencies like Police will help in speedy investigation to book the culprits and in controlling anti-social elements in such activities.

A permanent mechanism is already in place to regulate manufacture and sale of drugs in the country including monitoring of drugs suspected to be spurious/fake in nature under the ambit of Drugs & Cosmetics Act which clearly defines sub-standard and spurious drugs and provides specific penalties for offenders involved in manufacture or sale of spurious drugs.

The enforcement mechanism involves Central Drugs Control Organisation (CDSCO) in the Ministry of Health and Family Welfare, which provides policy and technical guidance. The actual enforcement is the responsibility of State Government who have established separate Drug Control machineries in each State/UT.

Manufacture of spurious/counterfeit/fake drugs is primarily a clandestine activity and trading in counterfeit products, including drugs, is reported world over. However, keeping in view the serious implications of spurious drugs on public health as well as the loss to genuine industry, the Government has taken the following measures to combat this menace:-

(i) Detailed guidelines have been issued to the State Governments to undertake focused surveillance over possible movement of spurious drugs.

(ii) A meeting of Health Ministers of all major States was especially convened in November 2002 to ensure action to check the menace of spurious drugs. The views that emerged in the meeting have been communicated to all State Governments in January 2003 for implementation.

(iii) A Capacity Building Project with World Bank assistance has been taken up to provide substantial assistance to State Government to upgrade drug testing facilities or to establish new drug testing laboratories. It is expected to increase the number of samples tested in the country from about 36,000 samples to 1,00,000 samples per year and to reduce the reporting time to less than a month as against the present period from 3 to 6 months. In addition, the project envisages extensive training of the Central and State/UT drug regulatory staff and the concerned personnel from the Pharmaceutical Industry and a campaign for Information, Education and Communication (IEC) for the consumers.

(iv) Specific training programmes for regulatory officials of State Government on logistics of intelligence work, prosecutions etc. has been conducted with the assistance of FDA, Maharashtra. This would be a continuing activity.

(v) In order to ensure efficient information exchange between drug regulatory officers in the country, in respect of licensing, sampling, prosecution, etc., a countrywide com

(vi) puter networking project has been undertaken by the Central Government. This will enable the Central Government to regularly monitor the enforcement activities and recommend corrective measures.

(vii) Pharma industry and traders have been motivated to fight the menace of spurious drugs as a shared responsibility. A number of cases could be successfully detected through the initiative, taken by Pharma industry involving hiring of retired intelligence/police officers.