

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

STARRED QUESTION NO:435

ANSWERED ON:25.08.2004

AMENDMENT IN DRUGS AND COSMETICS ACT

Adsul Shri Anandrao Vithoba;Singh Shri Uday

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

- (a) whether the Government is considering amending the Drugs and Cosmetics Act on the basis of recommendations of Mashalkar Committee;
- (b) if so, the details thereof;
- (c) whether the World Health Organisation estimates 35% fake drugs produced in the World comes from India only;
- (d) if so, whether the experts took a serious note of spurious drug mafia;
- (e) whether manufacture and sale of spurious drugs are continuing in the country in the absence of any clear cut concrete action;
- (f) if so, the facts thereof; and
- (g) the time by when the Mashalkar Committee's recommendations are likely to be implemented to check manufacture and sale of spurious drugs?

Answer

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

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO.435 FOR 25TH AUGUST, 2004

Bill No.93 of 2003 [called the Drugs and Cosmetics (Amendment) Bill, 2003] to further amend the Drugs and Cosmetics Act, 1940, was introduced on December 22, 2003, in the Lok Sabha. With the constitution of the 14th Lok Sabha, the Bill stands lapsed and is being re-processed for introduction in the Parliament with the approval of the Cabinet.

The salient amendments proposed under the Bill are given below:-

- (1) It has been proposed in the Bill to enhance the punishments relating to spurious drugs 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 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 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 investigations to book the culprits and in controlling anti-social elements involved in such activities.

There have been media reports quoting varying figures about the alleged extent of circulation of spurious drugs in the country including a reference to an alleged WHO study that 35% world's spurious drugs are produced in India.

The WHO, however, has denied having conducted any survey on spurious drugs in India as alleged by the media and having issued any such report that 35% of world's spurious drugs are produced in India.

Action against any possible manufacture or sale of spurious drugs is being taken by State Governments through their respective Drug Control Organizations. The Government of India has been taking various initiatives to ensure uniform and strict action to tackle the problem of spurious drugs. Some of such specific initiatives are as follows:-

(i) Issues concerning alleged sale of spurious drugs taken up by Union Health Minister with State Health Ministers in the conference of Central Council of Health & Family Welfare.

(ii) Meeting of State Drug Controllers together with representatives of Pharma industry and trade organizations, arranged.

(iii) Financial assistance provided to States for augmentation of drug testing facilities.

(iv) Matter concerning sale of spurious drugs and initiatives to be taken up by State Governments were taken up by Union Health Minister with all Chief Ministers in October, 2002.

(v) A World Bank assisted Capacity Building Project on Food Safety and Quality Control of Drugs has been launched with effect from October, 2003. This project aims at strengthening, inter-alia, the drug regulatory infrastructure in the country by augmenting the drug testing facilities by providing for equipments, civil works, staff and consumables and extensive training of drug regulatory/quality control officials and industry personnel. Annual drug testing capacity to be raised to 1,00,000 samples as against 36,000 to 38,000 samples.

(vi) Special training programme for improving investigations and legal skills organized for state officials.