

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

STARRED QUESTION NO:234
ANSWERED ON:21.07.2004
CHANGES IN DRUGS AND COSMETICS ACT
Rajendran Shri P.

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

- (a) whether the Government is aware of the reports that one out of every four medicinal drugs produced in the country is spurious or fake or substandard;
- (b) if so, whether the Government has taken note of various studies including the WHO Survey which pegs the Indian fake Pharma Market at 4000 crores;
- (c) if so, whether the Government has any plans to inject changes in the Drugs and Cosmetics Act in view of the above; and
- (d) if so, the details thereof?

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. 234 FOR 21ST JULY, 2004

The term 'Spurious Drug' has been defined under Section 17-B of the Drugs and Cosmetics Act, 1940, as amended by the Drugs and Cosmetics (Amendment) Act, 1982. In brief, a drug shall be deemed to be spurious if it is manufactured under a name which belongs to another drug, if it is an imitation of another drug or if it has been substituted wholly or partly by another drug or if it wrongly claims to be the product of another manufacturer.

There is no definition for 'sub-standard' or 'fake' drugs under the Drugs and Cosmetics Act, 1940. A drug is popularly termed as 'fake' or 'counterfeit' by the media when it is materially copied from a leader brand.

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% of the 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. However, the Government had taken a serious note of such reports and constituted an expert committee under the Chairmanship of Dr.R.A. Mashelkar in January, 2003, to undertake a comprehensive examination of drug regulatory issues including spurious drugs in the country.

The Committee in its report, submitted in November, 2003, examined the figures quoted in the media reports as well as the alleged WHO figures. The Mashelkar Committee has noted that according to the data available from the drugs samples tested annually in the country, the extent of spurious drugs varied from 0.24 to 0.47% and that of adulterated/misbranded drugs varied from 8.19% to 10.64%. The Committee observed that the media has continued to take an alarmist view by giving unsubstantiated figures about the alleged circulation of spurious drugs in the country.

Based on the recommendations of Dr.R.A. Mashelkar Committee, a legislation to amend the penal provisions of Drugs & Cosmetics Act, 1940, and to provide for stricter penalties to the offenders manufacturing and/or selling spurious or adulterated drugs, and including a maximum penalty of capital punishment, was introduced in the Parliament in December, 2003.

The salient amendments proposed under the Bill are:-

1. Enhance 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 relating to manufacture or sale of spurious or adulterated drugs.
5. To confer powers upon police officers not below the rank of sub-inspector or other designated officer powers to institute prosecutions under the said Act.
6. Provision for compounding of minor offences under the Act.

The proposed amendments will make the law deterrent to the offenders involved in the manufacture or sale of spurious or adulterated 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.

Since the Bill has now lapsed with the dissolution of previous Lok Sabha, necessary action to introduce a bill to enhance penalties for manufacture and/or sale of spurious and/or adulterated drugs under the Drugs & Cosmetics Act, 1940, will be initiated by the Ministry of Health and Family Welfare.