

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

STARRED QUESTION NO:354
ANSWERED ON:13.12.2000
TESTING THE IMPORTED DRUGS
RAMDAS ATHAWALE

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

- (a) whether there is no mechanism in the country to test the purity of imported drugs as has been reported in the Hindustan, New Delhi, dated August 31, 2000;
- (b) if so, the details thereof;
- (c) if not, the reasons therefor; and
- (d) the steps being taken or proposed to be taken by the Government to ensure a mechanism to test the quality of imported drugs in the country?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 354 FOR 13.12.2000

There is a specific mechanism under the Drugs and Cosmetics Act 1940 and Rules made thereunder to check the quality of drugs imported into the country for compliance with specified standards, either at the Drug testing laboratories designated for this purpose or at Government approved private testing laboratories. There are provisions under the Drugs and Cosmetics Rules for regulating imports and for notifying ports of entry for drugs.

Officials of Central Drugs Standard Control Organisation (CDSCO) Government of India, are posted at these ports to monitor the import of drugs which include sampling from the imported consignments and testing them at Central Drugs Laboratories or Government approved private testing laboratories. Every batch of imported blood products is being tested for infectious diseases like HIV and Hepatitis at National Institute of Communicable Diseases, Delhi, National Institute of Biologrcals, Pune, All India Institute of Medical Science, Delhi, etc. Imported vaccines are tested at Central Research Institute, Kasauli. Indian Veterinary Research Institute, Izatnagar, tests veterinary vaccines.

The details of drugs imported into the country, samples tested and results thereof during the last 5 years are Annexed.

On 24.10.2000, the Government have notified proposed amendments to the Drugs and Cosmetics Rules calling for public comments and objections, on a proposal to further streamline the regulatory system for import of Drugs, by stipulating registration of overseas manufacturers and the products to be imported, in line with similar systems existing in other countries.

ANNEXURE

CONTROL OVER THE QUALITY OF IMPORTED DRUGS

S. No.	1995-96	1996-97	1997-98	1998-99	1999-2000
1. Total nos. of consignments of imported drugs examined	22050	24170	26550	27290	31540
2. Total c.i.f. value of drugs imported	1867	2358	2711	3050	3820

(Rs.in crores)

3. Total No. of	5660	5890	6090	6110	6295
samples tested	780	950	1040	1170	1205
- at CDL	4870	4940	5050	4940	5090
Laboratories					
- Govt. approved					
labs					

4. Total No. of	116	127	128	135	153
samples found not					
of standard quality					

5. Total No. of Import
Licences issued

(a) Form 10	765	836	875	850	810
(b) Test Licences	860	950	980	850	1050
(c) Personal Licences	90	115	95	130	125