GOVERNMENT OF INDIA HEALTH AND FAMILY WELFARE LOK SABHA

UNSTARRED QUESTION NO:3209 ANSWERED ON:04.02.2004 RETESTING OF DRUGS SAMPLES ADHIR RANJAN CHOWDHURY;BHASKAR RAO PATIL

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

(a) the details of the safeguards provided under the Drugs and Cosmetic Rules available in case the report of a Government Analyst is to be challenged;

(b) whether there is a provision for retesting of samples of Drugs in the presence of the manufacturers;

(c) if so, the details thereof;

(d) whether the drug inspectors are sending samples at the first instance to Central Drug Laboratory, Kolkata instead of other Government approved laboratories; and

(e) if so, the revised guidelines issued by the Drug Controller of India in this regard?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (DR. VALLABHBHAI KATHIRIA)

(a) Section 25 of Drugs and Cosmetics Act, 1940, lays down the following provisions in respect of retesting of drugs:-

(1) Any document purporting to be a report signed by a Government Analyst under this chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken or the person whose name, address and other particulars have been disclosed under section 18A has, within twenty eight days of the receipt of a copy of the report, notified in writing the Inspector or the court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in contravention of the report.

(2) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in contravention of a Government Analysts report, the court may, of its own motion or in its discretion, at the request either of the complainant or the accused, cause the sample of the drug or cosmetic produced before the magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said laboratory, which shall make the test or analysis and report in writing signed by, or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.`

(b) No, Sir.

(c) Question does not arise.

(d) & (e) The officers of Central Drugs Laboratory are appointed by some State Governments as Government Analysts, for testing specific categories of drugs, because of absence of or inadequate testing facilities available in the concerned State. Samples of such drugs only are sent to CDL for testing as Government Analyst at the first instance.Central Drugs Inspector's also send samples of drugs to any one of the Central Drugs Laboratories in the first instance.