

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

STARRED QUESTION NO:306
ANSWERED ON:22.12.2004
SALE OF BANNED MEDICINES
Saroj Shri Tufani;Tripathi Shri Chandramani

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

- (a) whether the Government is aware that a large number of multi-national companies having patent rights are selling those medicines in our country on a large scale which are banned in European Countries;
- (b) if so, the details of the companies involved in this trade;
- (c) the names of the medicines being sold in the country whereas they are banned in European Countries; and
- (d) the reasons for giving permission by the Government to sell such medicines 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. 306 FOR 22ND DECEMBER, 2004

There are no specific reports regarding marketing in India by multi-national companies of such patented drugs which are banned in European countries.

There is no system of global banning of drugs. Drugs withdrawn in some countries may continue to be used by other countries and the decision to ban a drug in a country rests on various factors such as the disease pattern in a country, the varying reaction of certain ethnic groups in a given population to the drug, the availability of safer substitutes as well as the cost factor involved in the treatment of the disease.

There is an adequate mechanism to review the status of drugs in India as and when any serious adverse event is reported in international journals or WHO news letters etc. The drug or formulations reported to have been discontinued in some developed countries are assessed in consultation with leading experts in the given specializations. Based on their advice, technical information and factors like benefit-risk ratio, local needs etc., the matter is considered by the Drug Technical Advisory Board (DTAB), a statutory body under the Drugs & Cosmetics Act, 1940, which comprises of representatives from the medical profession, the state drug enforcement authorities and other experts, institutions and agencies and which advises the Government on technical issues related to the implementations of the Drugs and Cosmetics Act, 1940 and Rules, 1945.

In addition, a National Pharmacovigilance Programme has been launched in 2004 to capture data on adverse reaction to drug use in the country.