

Drugs with side effects

1313. SHRI A.W. RABI BERNARD: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether it is a fact that the country doesn't have a sound system to filter the drugs with serious side effects and such medicines are sold in the country even decades after being banned in developed countries for causing harmful side-effects; and

(b) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR) : (a) and (b) No Sir, Safety issues of drug formulations, as and when reported are assessed in consultation with the Expert Committees/Drugs Technical Advisory Board (DTAB). Based on the recommendations of the Expert Committees/DTAB, the Central Government regulates, restricts or prohibits manufacture, sale and distribution of such drugs in the country through Gazette Notification.

Every country has its own system for evaluation of continued marketing of drugs. The marketing of a drug in a country, which is banned in another country, is decided based on evaluation of disease pattern, reported side effects and overall safety and efficacy profile of the drug, availability of safer alternatives etc.

Certain drugs like Pioglitazone, Nimesulide, Analgin banned in certain countries, are allowed to be marketed in India with certain restrictions based on their evaluation in the country.

Action by USFDA and EU on Indian Pharmaceutical Companies

1314. SHRIMATI JAYA BACHCHAN: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether Government has taken note of the action taken by US Food and Drug Administration and European Union against some Indian Pharmaceutical Companies for substandard production and quality;

(b) if so, whether Government has undertaken any checking and auditing of these plants and products in the country; and

(c) if so, the details thereof and if not, the reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR): (a) Isolated action by foreign countries against Indian Pharmaceutical Companies involved in export in drugs have