

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

STARRED QUESTION NO:33
ANSWERED ON:03.12.2003
ANTI-DIABETIC DRUG PHENFORMIN
JAYABEN B. THAKKAR;NARESH KUMAR PUGLIA

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

- (a) whether the anti-diabetic drug `Phenformin` was banned in the United States in 1971 and subsequently it was withdrawn from 188 of the 191 WHO member countries because of its risk to human beings;
- (b) if so, the details thereof;
- (c) whether this drug is continued to be manufactured and sold in India;
- (d) if so, the reasons therefore;
- (e) whether the Government have now prohibited the manufacture, sale or distribution of this drug in India; and
- (f) if so, the details thereof?

Answer

MINISTER OF HEALTH AND FAMILY WELFARE AND PARLIAMENTARY AFFAIRS (SMT. SUSHMA SWARAJ)

(a)to(f): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 33 FOR 3.12.2003

The drug `Phenformin` was withdrawn in USA in 1977 because of occurrence of lactic acidosis with the use of the drug. The matter was then examined in consultation with experts in India and it was opined by the experts that lactic acidosis reported in the West is not common in Indian Population and the drug was effective as an oral anti-diabetic drug. The drug remained available in Spain, Italy, Mexico and some other parts of Europe and continued to be marketed in India also.

The drug Phenformin has, however, been now prohibited for manufacture and sale in the country with effect from 1st October, 2003 vide Gazette Notification GSR 780 (E) dated 01.10.2003 on the recommendations of Drug Technical Advisory Board (DTAB) which on reconsideration of the matter opined that as large number of oral drug for treatment of diabetes are now available in the country, the continued marketing of Phenformin may be stopped.