

**GOVERNMENT OF INDIA  
CHEMICALS AND FERTILIZERS  
LOK SABHA**

UNSTARRED QUESTION NO:6764  
ANSWERED ON:09.05.2000  
MANUFACTURING SELLING OF BANNED DRUGS  
SU THIRUNAVUKKARASAR

**Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:**

- (a) whether some drugs banned by the developed nations are still being manufactured and sold in the Indian market;
- (b) if so, the details thereof and the reasons therefore;
- (c) whether the Government have conducted any study in this regard;
- (d) if so, the details thereof; and
- (e) the steps taken/proposed to be taken by the Government to check the manufacturing and sale of banned drugs in the country?

**Answer**

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS

(SHRI RAMESH BAIS)

(a) to (e): There is a definite procedure for examination of drugs reported to be withdrawn or the use of which has been restricted in some countries abroad. Such information is generally received by the Govt. from WHO. Banning or restricting the use of certain drugs may be preferred by some countries, while the drug may continue to be marketed in many other countries. The banning is not necessarily due to adverse reactions but may also be due to availability of better substitutes, disease prevalence etc.

WHO has so far reported withdrawal of 46 drugs by some countries. Out of these, 26 drugs were not at all approved for marketing in India. On receipt of the information regarding banning of drugs or restricting the use in some countries abroad, Drugs Controller (I) invariably consult medical experts and expert bodies like ICMR seeking their opinion on the subject. Action has been taken to withdraw 13 drugs from the Indian market.

The remaining 7 drugs, namely

- (1) Nitrofurans compounds
- (2) Phenformin
- (3) Hydroxyquinoline (Enteroquinol)
- (4) Lynestrenol
- (5) Piperazine
- (6) Phenylbutazone/Oxyphenbutazone and
- (7) Analgin were withdrawn in some countries but continue to be marketed in a number of countries. Decision to permit the marketing of the single ingredient formulations of these drugs in the country has been taken in consultation with the medical experts subject to a cautionary statement and contra-indications being given on the label/package insert in some cases.

However, of these seven drugs, Liquid Oral anti diarrhoeals or any other dosage form for paediatric use containing halogenated hydroxy quinolines, fixed dose combinations of Hydroxyquinoline group of drugs with any other drug except for preparations meant for external use, fixed dose combination of oxyphenbutazone/Phenylbutazone with any other drug and fixed dose combination of Analgin with any other drug have been prohibited for manufacture and sale in the country.

As and when a drug is banned, strict instructions are issued to all State Drug Control Organisations to check any possible illegal sale. Wide publicity through trade journals and newspapers is also given about the banning of drugs.