GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:782
ANSWERED ON:09.07.2009
BAN ON MEDICINES
Ramasubbu Shri S.

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

(a) the names of medicines which are banned for sale through pharmaceutical outlets in the country

(b) whether many of the medicines which are banned in various countries due to health hazards are freely available in the country;

(c) if so, the reasons therefor;and

(d) the action taken/proposed to be taken by the Government in this regard?

Answer

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS(SHRI SRIKANT KUMAR JENA)

a): Seventy eight categories of drug formulations, viz.,Amidopyrine, Penicillin skin Ointment, Nialamide, Practolol, Methaqualone, Methapyrilene, Chloral Hydrate, Dovers Powder 1.P., etc have been prohibited for manufacture, sale and distribution in the country by the Central Government which were considered irrational or harmful in the context of present knowledge.

(b) to (d): The decision to ban or withdraw a drug by the regulatory authorities, is normally based on the risk assessment process, which is influenced by a number of factors such as disease pattern in a country, indications and dosages of the drug permitted, varying reactions of certain ethic groups in a given population, of the drug. It is well-known fact that administration of any drug is not absolutely free from side effects or adverse reactions in a statistically insignificant monitory of the population.

Certain drugs or formulations withdrawatn one or some countries continued to be marketed in other countries including India. The rationally of such drugs had earlier been examined by various Expert Committee, set-up for the purpose, form time to time. Based on the current knowledge available about the drugs and the nature of use in the country, these drugs were permitted to be used in the country and wherever considered necessary, restrictions were imposed on their use for certain indications only.

There is an adequate mechanism in India to review the status of the drug formulation as and when any serious adverse event is reported in the International journals, WHO Newsletters or when a drug formulation is reported to have been withdrawn in some countries. The use of the drug, so reported, is assessed in consultation with the experts, based on available technical information, benefit-risk ratio, local needs etc. The matter is further considered by the Drugs Technical Advisory Board (DTAB), a statutory body under the Drugs and Cosmetics Act, 1940. Seventy eight categories of drug formulations have so far been prohibited in the country by the Central Government, which were considered irrational or harmful in the contest of present knowledge.