GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1619
ANSWERED ON:15.07.2009
SALE OF BANNED DRUGS MEDICINES
Swamygowda Shri N Cheluvaraya Swamy

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

(a) whether a number of drugs/ medicines which are banned world-wide and in the country are being sold in the market;

(b) if so, the details thereof; and

(c) the steps taken/being taken by the Government in this regard?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) to (c): 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 ethnic groups in a given population, availability of safer substitutes and overall safety profile 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 Certain drugs or formulations withdrawn in one or some countries continued to be marketed in other countries including India. The rationality of such drugs had earlier been examined by various Expert Committees, set up for the purpose, from 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 WHO Newsletters or when a drug formulation is reported to have been withdrawn in some countries.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 context of present knowledge.