GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:487
ANSWERED ON:23.07.2003
NIMESULIDE DRUG
KAMBALAPADU E. KRISHNAMURTHY;M. JAGANNATH;VILAS BABURAO MUTTEMWAR

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

(a) whether the Government are aware that various formulations of Nimesulide are being marketed for paediatrics use without the prior mandatory approval of the Drugs Controller General of India (DCGI);

(b) if so, the details thereof;

(c) whether the government have decided not to ban the Nimesulide drug as has been done by many other countries on account of its side effects;

(d) whether the Government have asked the manufacturers of non-steroid anti-inflammatory drug to withdraw the paediatric drops from the market ;

(e) if so ,whether any laboratory tests have been conducted by the Government to ascertain the side effects of Nimesulide ;and

(f) if so, the details thereof?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE(SHRI A.RAJA)

(a) to (d): The use of non-steroidal anti-inflammatory Nimesulide, including in children (as 50 mg/5ml suspension) had been duly approved in the country, based on evaluation of its safety, efficacy and use in other countries etc. However, following some reports about its possible adverse effects, the matter of safety of Nimesulide was extensively reviewed by the Drugs Technical Advisory Board (DTAB) through its Expert Committee which held wide consultations with medical experts, Indian Academy of Pediatrics and Indian Medical Associationetc. According to the experts` opinion Nimesulide has been observed to be safe and useful including its use in children. It has, therefore, been decided not to ban Nimesulide.

However, the DTAB observed that some State Licensing Authorities have also permitted marketing of Nimesulide pediatric drops as 25mg/ml formulation. Since the safety and rationality of this formulation is not yet established, the concerned Licensing Authorities/manufacturers have been directed to withdraw the pediatric drops.

(e) to (f): Side effects of any drug cannot be determined by laboratory tests. Side effects/adverse drug reaction if any, of any drug can be known only after wide prescription and post marketing surveillance reports.