GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2385
ANSWERED ON:15.12.2004
APPROVAL OF NEW DRUGS
Paraste Shri Dalpat Singh

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

(a) whether for all the new drug approvals , the reporting of adverse reactions is one of the conditions ;

(b) if so, whether majority of the companies are not complying with this condition ;

(c) if so, the details thereof;

(d) the names of the companies who have submitted the ADR reports; and

(e) the action taken against the defaulting companies?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) to (e): All New Drug approvals under Drugs & Cosmetics Rule 122-A & 122-B carries following condition i.e. `Post Marketing Surveillance study shall be conducted during initial period of two years of marketing of the new drug formulation, after getting the protocol and the names of the investigators duly approved by the Licensing Authority`.

The Post Marketing Surveillance (PMS) are to be undertaken by the Pharmaceutical firm, for a period of two years from its approval. However, time for submission of PMS study report depends upon the time by which the product is actually launched and marketed in the country. For the products approved from Jan, 2002 the PMS study reports of those products which have completed two years of marketing have been furnished by most of the firms.