GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:344
ANSWERED ON:03.12.2003
VIOLATION OF TRADE MARK ACT
M. JAGANNATH

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

(a) whether the drug markets across the country are flooded with the drugs phonetically similar to the existing famous brands and packed exactly in the same packaging and colour combination in violation of the Trade Mark Act as reported by the `Indian Express`, dated August 18, 2003;

(b) if so, the reaction of the Government thereto;

(c) whether the Hon`ble Delhi High Court has directed the Government to constitute a Committee of experts to ensure that no new drug is allowed to be launched in the market without its approval and to monitor the quality of the drug;

(d) if so, the details thereof; and

(e) the concrete action taken by the Government in this regard?

Answer

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

(a)&(b): The issue of manufacture of look-alike products of well established brands in terms of design pattern, packaging and having phonetically similar names was examined by a Committee constituted in July, 2001 by Ministry of Health and Family Welfare under the Chairmanship of Director General of Health Services.The committee took note that State Drugs Controllers are empowered under Drugs and Cosmetics Act, 1940 and Rules thereunder for grant of product permission, therefore it was recommended that they should exercise adequate care not to allow or encourage look-alike product to the licensed companies. The findings of the report of the said Committee were also sent to all State Drugs Controllers for adaptation and implementation.

(c)&(d): Yes, Sir. The relevant portion of the order is reproduced below:

`54 ..... We recommend to Union of India that a suitable legislation be enacted so that severe punishment be given to people who are involved in the manufacture, distribution, trade and business of spurious drugs. The Ministry of Health and the Director General of Health Services and other concerned agencies without further loss of time must ensure that the drug manufacturers should not be permitted to market their drugs unless the quality of the drug is approved by a high level committee or body consisting of doctors and other experts of impeccable integrity and eminence.....`

(e): Every manufacturer is required to test every batch of a drug before its release in the market, and a check on quality is further kept by drug regulatory authorities by random testing of drugs from market. The GMP norms adopted by manufacturing firms is also checked through inspection of manufacturing facilities and process. In respect of new drugs, approved in other countries, apart from detailed evaluation of its safety and efficacy data, consultation with renowned subject experts is held. For a New Molecular Entity (NME), a multidisciplinary group of experts under DG, ICMR has been constituted to evaluate pre-clinical data as well as the data at different phases of clinical trial.