

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:2822

ANSWERED ON:26.11.2010

REGISTRATION OF PRODUCTS BY DRUG MANUFACTURERS

Muttemwar Shri Vilas Baburao

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

- (a) the norms laid down by the Government for the registration of various brands of medicines in the country;
- (b) whether it is mandatory for the drug manufacturers to register their products before their marketing in the country;
- (c) if so, the details thereof;
- (d) if not, the reasons therefor; and
- (e) the corrective measures proposed by the Government in this regard?

Answer

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE (SHRI DINESH TRIVEDI)

(a) to (e) No norms have been prescribed for the registration of brands of medicines in the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1955 made thereunder. The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1955 regulate the import, manufacture and sale of drugs in the country. No drug can be imported, manufactured or sold in the country without a valid license issued under the provisions of the said Act and Rules. Licenses for the purposes are issued keeping in view the aspects relating to the safety, efficacy and quality of the drugs.