

**GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA**

UNSTARRED QUESTION NO:3892

ANSWERED ON:22.08.2005

BRAND NAME OF DRUGS

Singh Baba Shri K.C.

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether the Government has any mechanism to regulate the composition or formulation of drugs manufactured and sold by pharmaceutical companies under brand names;
- (b) if so, the details thereof;
- (c) whether the Government is aware that certain pharmaceutical companies are reported to have changed the composition of their fast selling drugs without changing the brand names;
- (d) if so, the list of such companies and brand names of the drugs whose composition has been changed; and
- (e) the steps taken by the Government to ensure that composition of the drugs being sold under brand names is not altered without sufficient notice?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS & MINISTER OF STEEL (SHRI RAM VILAS PASWAN)

- (a) & (b): It is not mandatory to require pharmaceutical manufacturers to register the brand names of their formulations. However, approval of drug formulations along with their brand name is granted by the concerned State Licensing Authorities. While granting the licence under the Drugs and Cosmetics Act 1940.
- (c): Manufacturers may sometime modify the composition of their formulation to improve it or to substitute an obsolete active ingredient while retaining the same brand name and indications.
- (d): As such changes are permitted by the State Licensing Authorities, routinely, in each State, no list of change of composition of formulations is maintained by the Central Government.
- (e): Prior approval from the State Licensing Authorities is obtained by the manufacturers before changing the composition of the drug formulations.