

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

UNSTARRED QUESTION NO:5146

ANSWERED ON:27.08.2010

REFORMS IN DRUG INDUSTRY

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

- (a) whether the Government proposes various reforms in drug industry including the implementation and establishment of good laboratory practices by pharma units in the country;
- (b) if so, the details thereof;
- (c) the progress made for implementation of the new National Drug Policy;
- (d) whether the permission for drugs under various trade marks of a single active pharmaceutical ingredients is leading to exploitation of the public by pharma companies; and
- (e) if so, the remedial measures taken/ proposed in this regard?

**Answer**

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

(a) & (b): Government has made it mandatory for the drug industry and Pharma Units to implement Good Laboratory Practices contained in Schedule LI of the Drugs & Cosmetics Rules 1945 which was notified vide G.S.R. 780(E) dated 10th November 2008. It will come into force on the 1st day of November, 2010.

(c): The National Pharmaceuticals Policy is formulated by the Department of Pharmaceuticals in the Ministry of Chemicals and Fertilizers. As informed by that Department, the draft National Pharmaceutical Policy, 2006 was prepared by that Department after extensive discussions with various stakeholders and in line with the declared objective of the Government in the National Common Minimum Programme. In that connection, that Department has further constituted a Group of Ministers.

(d) & (e): The license to manufacture / import of drugs is given as per the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 made thereunder. The Trade-marks do not fall under the preview of the Drugs and Cosmetics Act and the Rules made thereunder.