GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:2218
ANSWERED ON:06.12.2012
COMPREHENSIVE DRUGS POLICY
Jagannath Dr. M.

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

(a) whether bringing drugs under price control is not likely to solve all the problems in the health sector;

(b) if so, whether licensing policies so far have allowed dozens of brands for single molecules, leading to aggressive marketing, wide variation in prices and unethical promotion before doctors;

(c) if so, the details thereof;

(d) whether the Government proposes to bring in a comprehensive drug policy which promotes essential and rational drugs with necessary emphasis on access and affordability; and

(e) if so, the details thereof?

Answer

MINISTER OF STATEfINDEPENDENT CHARGED OF THE MINISTRY OF STATISTICS AND PROGRAMME IMPLEMENTATION AND MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS fSHRI SRIKANT KUMAR JENA)

(a): The objective of, National Pharmaceuticals Pricing Policy-2012(NPPP-2012) which has been approved by the Cabinet in its meeting held on 22.11.2012, is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines - `essential medicines` -at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well being for all.

(b)&(c): The Regulatory Control over the manufacture and sale of drugs is exercised by the State Licensing Authorities (SLAs) appointed by the State Governments under the provisions of the Drugs and Cosmetics

(D&C) Act, 1940. Under the provisions of the Drugs & Cosmetics (D&C) Rules, 1945, applications in various forms for grant /renewal of a license to manufacture for sale or distribution of various categories of drugs as well as various forms for grant /renewal of such licenses require the name of the drug to be specified but do not require mentioning of any Trade Name/Brand Name. It has been observed that at the time of the grant of the license for manufacture of a drug formulation, the trade name as submitted by the manufacturer is also endorsed by the State Licensing Authorities alongwith proper name of the product thereby giving legitimacy to market the drug under the brand or the trade name. To check this practice, the Government has issued statutory direction to the State/UT Governments on 01.10.2012 under Section 33P of the Drugs& Cosmetics Act, 1940 to grant /renew licenses to manufacture for sale or for distribution of drugs in proper/generic names only.

(d): There is no such proposal at present before the Department. However, drug policy as amended from time to time also envisages making available quality medicines at a reasonable price to the masses.

(e): In view of reply to (d) above, does not arise.