

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

STARRED QUESTION NO:54
ANSWERED ON:24.11.2011
SALE OF LOW COST MEDICINES
Gandhi Shri Feroze Varun

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

- (a) whether the National Pharmaceutical Pricing Authority keeps track of the movement of non-scheduled drug, formulations;
- (b) if so, the details thereof;
- (c) whether the Government proposes to amend the Indian Patent Act, 1970 so as to ensure sale of low cost medicines by the local drug makers;
- (d) if so, the details thereof;
- (e) if not, the reasons therefor; and
- (f) the steps taken to ensure the availability of low cost essential drugs in the country?

Answer

MINISTER OF STATE (INDEPENDENT CHARGE) IN THE MINISTRY OF STATISTICS AND PROGRAMME IMPLEMENTATION AND MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)

(a)to(f): A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO PARTS (a) TO (f) OF THE LOK SABHA STARRED Q.NO.54 (14 POSITION) FOR ANSWER ON 24.11.2011 REGARDING SALE OF LOW COST MEDICINES.

(a)&(b): Yes, Sir. In respect of drugs which are not covered under the Drugs (Prices Control) Order, 1995 (DPCO, 95) i.e. non-scheduled drugs, manufacturers fix the prices by themselves without seeking the approval of Government / National Pharmaceutical Pricing Authority (NPPA). However, as a part of price monitoring activity, NPPA regularly examines the movement in prices of non-scheduled formulations. Wherever a price increase beyond 10% per annum is noticed, the manufacturer is asked to bring down the price voluntarily failing which, subject to prescribed conditions, action is initiated under paragraph 10(b) of the DPCO, 1995 for fixing the price of the formulation in public interest. This is an ongoing process. Based on monitoring of prices of non-scheduled formulation, NPPA has fixed prices in case of 30 formulation packs under para 10 (b) and companies have reduced price voluntarily in case of 65 formulation packs. Thus in all, prices of 95 packs of non-scheduled drugs have got reduced as a result of the intervention of NPPA.

(c): No, Sir.

(d): Does not arise.

(e): The Indian Patents Act, 1970 (as amended in 2005) effectively balances and calibrates Intellectual Property protection with public health concerns while meeting India's international obligations under the Agreement on Trade Related Intellectual Property Rights (TRIPS). The Patent Law utilizes the flexibilities available within the TRIPS Agreement to address concerns relating to public health and prevent misuse of rights by patent holders.

(f): The Department of Pharmaceuticals has launched `Jan Aushadhi Campaign` with the objective of making available medicines at affordable prices for all. Under this campaign less priced quality unbranded generic medicines are made available through Jan Aushadhi Stores. Till date 113 Jan Aushadhi Stores have been opened in different States/UTs in the country.

Further, the Department of Pharmaceuticals has prepared a draft National Pharmaceutical Pricing Policy 2011(NPPP-2011) based on the criteria of essentiality and requirements as stipulated by the Ministry of Health & Family Welfare. The draft NPPP-2011 has been circulated among the concerned Ministries/Stakeholders. The draft Policy envisages bringing the National List of Essential Medicines (NLEM) -2011 and associated medicines under price control.