

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

UNSTARRED QUESTION NO:4601

ANSWERED ON:17.12.2009

SALE OF ESSENTIAL MEDICINES AT HIGHER PRICES

Ponnam Shri Prabhakar

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

- (a) whether a proposal is pending with the Government to prevent manufacturers and distributors of non-essential medicines by adopting medicines as listed by World Health Organisation (WHO) under essential drugs;
- (b) if so, the details thereof;
- (c) whether a huge number of medicines does not fall under the list of National List of Essential Medicines (NLEM) and all these medicines are being sold at very high rates in different parts of the country;
- (d) if so, the details thereof;
- (e) the total number of medicines which do not fall under the list of NLEM;
- (f) the time frame, if any, fixed for discontinuing sale/distribution of non-essential drugs/ medicines and following NLEM/WHO list; and
- (g) the details of steps proposed for controlling over-pricing of medicines sold by different Pharma companies?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)

(a)&(b): As reported by the Drugs Controller General (India) (DCGI)/ Ministry of Health & Family Welfare, there is no such proposal pending with them to prevent manufacturers and distributors of non essential medicines by adopting medicines as listed by World Health Organization (WHO) under essential drugs.

(c) to (g): As informed by DCGI/ Ministry of Health & Family Welfare, various formulations of 354 medicines are included in the National List of Essential Medicines (NLEM), 2003 which are of various categories including anti-cancer, anti-diabetics, anti-pyretics, anti-allergies, anti-epileptics, cardiovascular drugs etc. Medicines are imported under import registration and licence granted by Central Drugs Standard Control Organization (CDSCO). However manufacture of medicines for sale in the country is undertaken under licence obtained from State Licencing Authorities appointed by State Governments. Currently there is no centralised data base of actual number of drugs formulations available in the country. Hence total numbers of medicines which do not fall under the list of NLEM are not available. Further, DCGI/Ministry of Health & Family Welfare have mentioned that there is no such proposal for discontinuing sale/distribution of non-essential drugs/medicines and following NLEM/WHO list by the office of DCGI.

So far as controlling prices of medicines is concerned, under the provisions of the Drugs (Price Control) Order, 1995 (DPCO, 1995) the prices of 74 bulk drugs and the formulation containing any of these Scheduled drugs are controlled. National Pharmaceuticals Pricing Authority (NPPA) / Government fixes or revises prices of Scheduled drugs / formulations as per the provisions of the DPCO, 1995. No one can sell any Scheduled drug / formulation at a price higher than the price fixed by NPPA / Government. NPPA has fixed / revised the prices of Scheduled bulk drugs in 470 cases and 10253 formulation packs since its inception in August, 1997. Of these, the prices of 18 Scheduled bulk drugs and derivatives and 1737 formulations were fixed / revised during the period from 01.4.2009 to 30.11.2009.

in respect of drugs - not covered under the DPCO, 1995 i.e. non-Scheduled drugs, manufacturers are at liberty to fix the prices by themselves without seeking the approval of Government / NPPA. Such prices are normally fixed depending on various factors like the cost of bulk drugs used in the formulation, cost of excipients, cost of R&D, cost of utilities / packing material, sales promotion costs, trade margins, quality assurance cost, landed cost of imports etc. However, as a part of price monitoring activity, NPPA regularly examines the movement in prices of non-Scheduled formulations. The monthly reports of ORG IMS and the information furnished by individual manufacturers are utilized for the purpose of monitoring prices of non-Scheduled formulations. Wherever a price increase beyond 10% per annum w.e.f. 1.4.2007 (this was 20% prior to 1.4.2007) 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 formulations, NPPA has fixed prices in case of 27 formulation packs under para 10(b) and companies have reduced price voluntarily in case of 64 formulation packs. Thus in all, prices of 91 packs of non-Scheduled drugs have got reduced as a result of the intervention of NPPA.