

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

STARRED QUESTION NO:299
ANSWERED ON:23.07.2009
ESSENTIAL DRUGS UNDER PRICE CONTROL
Kodikunnil Shri Suresh

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

- (a) the details of essential drugs which are under the price control;
- (b) Whether the government proposes to bring more essential drugs under price control;
- (c) if so, the details of essential drugs that are being included under price control;
- (d) the steps taken by the Government in this regard;
- (e) whether the Government is formulating any regulation to take action against the pharmaceutical companies which are charging exorbitant prices on their drugs; and
- (f) if so, the details thereof?

Answer

MINISTER OF THE 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 IN REPLY TO PARTS (a) to (f) OF THE LOK SABHA STARRED QUESTION NO.299 FOR ANSWER ON 23.7.2009 REGARDING ESSENTIAL DRUGS UNDER PRICE CONTROL.

(a) There are 74 bulk drugs mentioned in the First Schedule of the Drugs (Prices Control) Order 1995 (DPCO, 1995) and formulations containing these drugs under price control. The list of 74 bulk drugs is enclosed at annexure-I.

(b)to(d) The Supreme Court in its interim order dated 10.3.2003 in SLP (C) No.3668/2003 directed the Government,inter alia, to 'consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control and further directed to review drugs which are essential and life saving in nature till 2nd May, 2003'. As per the directions of the Supreme Court, the Ministry of Health and Family Welfare reviewed the National Essential Drugs List 1996 and brought out the National List of Essential Medicines 2003 (NLEM 2003). Keeping in view the directions of the Supreme Court it has been proposed in the draft National Pharmaceutical Policy, 2006 that basket of drugs for price control would be the essential medicines as contained in the NLEM 2003 (subject to certain conditions and exemptions) in addition to the 74 drug (Price Control) Order 1995. The draft National Pharmaceutical Policy was submitted to the Cabinet for its approval. The Cabinet considered the Policy in its meeting held on 11.1.2007. It was decided that the matter may, in the first instance, be considered by a Group of Ministers (GOM). The GOM had held four meetings but did not finalise its recommendations to the Cabinet.

(e) & (f) Under the provisions of the Drugs (Price Control) Order,1995, the prices of 74 bulk drugs and the formulations containing any of these Scheduled drugs are controlled. 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. Whenever cases relating to companies charging prices more than the prices fixed by the NPPA are noticed, demand notices are sent by the NPPA to the concerned companies asking them to deposit with the Government the overcharged amount in terms of paragraph 13 of the DPCO, 1995. Since its inception demand notices for recovery of amounts totaling Rs. 2023.40 crore have been issued by the NPPA. Of this, Rs. 1901.69 crore is sub-judice in various Courts of law including the Supreme Court. Of the total demand, NPPA has recovered Rs. 172.62 crore till 30.06.09 and have referred cases involving recoveries totaling Rs. 137.03 crore to the Collectors for being recovered as arrears of land revenue. Of the total amount of Rs. 172.62 crore recovered till 30.06.09, Rs. 100.-12 crore was recovered before 2007-08, Rs. 4.51 crore in 2007-08, Rs. 51.41 crore in 2008-09 and Rs. 16.58 crore in 2009-10 (till 30.06,09).

In respect of drugs not covered under the Drugs (Prices Control) Order, 1995 i.e.non-Scheduled drugs,manufacturers are free to fix the prices by themselves without seeking 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. 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 the individual manufacturers are utilized for the purpose of monitoring prices of non-scheduled formulations. Wherever increase in

prices beyond 10% per annum (20% before 01.04.07) is noticed, the manufacturer is asked to bring down the price voluntarily failing which, if justified, action is initiated under paragraph 10(b) of the DPCO, 1995. This is an ongoing process.