

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

STARRED QUESTION NO:40

ANSWERED ON:25.11.2014

LIFE SAVING DRUGS

Datta Shri Sankar Prasad;Mani Shri Jose K.

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

- (a) the details of indigenous companies in public and private sectors producing life saving drugs in the country;
- (b) the percentage of increase in the prices of life saving drugs during each of the last three years and the current year along with the details of demand and supply of such drugs in the country;
- (c) whether there has been a shortage of life saving drugs including medicines for HIV patients in the country;
- (d) if so, the details thereof and the reasons therefor along with the mechanism put in place to monitor the shortage of these drugs including medicines for HIV patients; and
- (e) the steps taken by the Government to ensure supply and production of these drugs/ medicines in adequate quantity to meet the demand in the country?

**Answer**

MINISTER OF CHEMICALS AND FERTILIZERS (SHRIANANTH KUMAR)

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

STATEMENT REFERRED TO IN REPLY TO PARTS (a) to (e) OF THE LOK SABHA STARRED QUESTION NO. 40 TO BE ANSWERED ON 25.11.2014 REGARDING LIFE SAVING DRUGS

(a): Under the Drugs and Cosmetic Act, 1940 and Rules, 1945, there is no definition of Life-saving drugs. However, all the essential medicines as specified in the 'National List of Essential Medicines, 2011 (NLEM)' are included in the First Schedule of Drugs (Price Control) Order, 2013 (DPCO, 2013) and are under price control. A list of 50 major indigenous companies manufacturing / marketing NLEM drugs are given in the Annexure- I to this statement (Source: PharmaTrac).

(b): The Government has notified DPCO, 2013 on 15.05.2013. National Pharmaceutical Pricing Authority (NPPA) has already fixed ceiling prices in respect of 489 essential drugs under provision of the said order. Significant reduction in prices have been effected on the medicines notified under DPCO, 2013 as compared to the highest price prevailing prior to the notification of DPCO, 2013. The details of price reduction are as follows:

% reduction with respect to Highest No. of drugs  
prevailing Price to the Retailer

0<= 5%	46
5<=10%	44
10<=15%	53
15<=20%	43
20<=25%	62
25<=30%	55
30<=35%	30
35<=40%	34
Above 40%	112
Total	489

Under DPCO, 2013 all the existing manufacturers producing essential medicines / scheduled formulations at a price lower than the ceiling prices so fixed and notified by the NPPA are required to maintain their existing 'maximum retail price' and annual increase in 'maximum retail price' is permissible as per the increase in the wholesale price index with respect to previous year. Further, no person is authorized to sell any scheduled formulations to any consumer at a price exceeding the price specified in current price list or maximum retail price indicated on the label of the container or pack thereof, whichever is less. NPPA does not have data on demand and supply of the drug formulations in the country. NPPA monitors production and availability of scheduled drugs, including active pharmaceutical ingredients used for producing those drugs.

(c)& (d): Reports on short supply of certain essential medicines namely Anti-snake venom, Rabies Vaccine, Rabies Immunoglobulin, Albumin Injection and Anti-malarial combination of Sulfadoxine + Pyrimethamine Tablets were received by the NPPA. In this regard, all the manufacturers / importers / marketing companies of these drugs were directed to submit production /availability data and also a compliance report of resolving the shortage of these drugs in the country immediately by issuing a gazette notification S.O. No. 2292 (E) dated 09.09.2014 (Annexure- II to this statement). NPPA regularly monitors shortages & availability of drugs on the basis of monthly reports received from State Drugs Control Administration and also complaints, if any, received from individuals etc. On receipt of such reports, NPPA immediately takes up the matter with the concerned manufacturer and advise them to rush the stock in the affected area. NPPA has not received complaints on shortage of medicines for HIV patients in the country.

(e): Paragraph 3 of DCPO, 2013 provides that the Government can direct manufacturers of Active Pharmaceutical Ingredients or bulk drugs or formulations with a view to achieve adequate availability and to regulate the distribution of drugs, in case of emergency or in circumstances of urgency or in case of non-commercial use in public interest, to increase the production and to sell such Active Pharmaceutical Ingredient or bulk drug to such other manufacturer(s) of formulations and to direct formulators to sell the formulations to institutions, hospitals or any agency as the case may be. Further, paragraph 21 (i) of DPCO, 2013 provides for monitoring the production and availability of scheduled formulations. The manufacturers of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulation are required to furnish the information quarterly, as stated in Form-III of schedule-II of DPCO, 2013.