

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

UNSTARRED QUESTION NO:4439
ANSWERED ON:21.04.2015
PRODUCTION STOCK OF DRUGS
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Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether the Government has taken note that lifesaving drugs are being sold at high prices due to shortage/insufficient supply of such drugs in the country;
- (b) if so, the details thereof and the reasons therefor and the action taken in this regard by the Government;
- (c) whether there is any mechanism/ new policy for obtaining the information regarding stock/availability of life saving drugs from time to time;
- (d) if so, the details thereof along with the estimated stock/production of the said drugs in the country; and
- (e) the steps taken/proposed to be taken by the Government to ensure supply/ production of life saving drugs in adequate quantity to meet the demand in the country?

Answer

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a) & (b): All essential medicines specified in the National List of Essential Medicines, 20 M (NLEM) are included in the First Schedule of DPCO, 2013 and are under price control. However, Life saving drugs are not defined in the Drugs (Price Control) Order, 2013.

Based on the available pharmaceutical database in terms of moving annual turnover (MAT) of scheduled and non-scheduled drugs, both with respect to volume and value, there is no general evidence to believe that essential/ scheduled drugs or non-scheduled drugs are being sold at high price due to shortage/insufficient supply of the drugs in the country. In order to provide a consumer friendly mechanism to resolve such grievances, NPPA has started Pharma Jan . Samadhan (PJS), which is an online system for receiving and taking action related to non-availability and overcharging with respect to pharmaceuticals.

(c) & (d): There is a mechanism of monitoring the stock and availability of the essential drugs / scheduled drugs under para 21 (1) DPCO, 2013 that provides for submission of quarterly return in respect of production/ import and sales of scheduled medicines (NLEM medicines) and Active Pharmaceutical Ingredients contained in scheduled formulations as stated in Form- 111 of Schedule 11 of the said order by the manufacturer/ importer/ marketer. Further, any manufacturer / importer wanting to discontinue manufacture / import of a scheduled formulation has to apply to NPPA in Form-IV of Schedule U of DPCO, 2013 at least 6 months in advance, and NPPA can direct the applicant to continue production / import upto 1 year.

(e): NPPA monitors shortages & non-availability of drugs on the basis of 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 advice them to rush the stock in the affected area.

In the recent past, short supply of certain essential medicines namely albumin injection, anti-snake venom, rabies vaccine, rabies immunoglobulin and anti-malarial combination of sulfadoxine + pyrimethamine tablet was reported to NPPA. In order to maintain normal supply of these medicines in the domestic market and / or institutions, NPPA issued notification wherein the concerned manufactures / importers of the drugs were directed to ensure a smooth supply and to furnish a compliance report in this regard. In connection with specific shortages of Albumin injection reported in the country, NPPA has held a meeting with the major manufacturer / importer of Albumin injection. During the course of discussion meeting it was observed that the shortage of Human Plasma is one of the main constraint in expanding the production capacity of Human Albumin in the country. In this regard Chairman NPPA has written a D.O. letter on 02.04.2015 to the Additional Secretary, Department of Health regarding supply of Human Plasma to manufacturer of Human Albumin by NACO.