**GOVERNMENT OF INDIA**
**MINISTRY OF CHEMICALS & FERTILIZERS**
**DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA

STARRED QUESTION NO. *57

TO BE ANSWERED ON 06th February, 2018

**Price Fixation by NPPA**

***57. SHRIMATI VASANTHI M.:**

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

(a) whether the National Pharmaceutical Pricing Authority (NPPA) is making inordinate delay in fixing the prices of new drugs;

(b) if so, the details thereof and the reasons therefor; and

(c) the details of the measures taken/being taken by the Government to expedite the pricing of new drugs to ensure adequate supply of drugs in the market?

**ANSWER**

**MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS AND PARLIAMENTARY AFFAIRS (SHRI ANANTH KUMAR)**

(a) to (c): A statement is laid on the Table of the House.

**Statement referred to in reply to Lok Sabha Starred Question No. *57 for answer on 06/02/2018 regarding Price Fixation by NPPA.**

(a) & (b): No Madam, there is no such inordinate delay in fixing the prices of new drugs. Out of 664 applications received till 31st December 2017, notifications for fixing the retail prices of 598 applications for new drugs have already been issued. Under the provisions of Drugs (Prices Control) Order, 2013 (DPCO, 2013), all drug manufacturers are under obligation to issue a price list to distributors, State Drug Controllers and the Government. The new drug applications of only those manufacturers/marketers were temporarily put on hold by National Pharmaceutical Pricing Authority (NPPA), who had either not submitted the complete information for Integrated Pharmaceutical Database Management System (IPDMS) or had prima facie launched new drugs without prior price approvals. Other cases have been pending because of non-submission of necessary data by the industry.

(c): The Government regularly monitors the number of manufacturers in the market for various formulations and that there is sufficient flow of medicines in the market. The Government also checks whether such manufacturers continue the production of concerned scheduled formulations. The Government has issued instructions to NPPA that new drug approvals need not be linked to IPDMS compliance or any such other conditionalities which are strictly not ordained according to the DPCO, 2013 and directed NPPA to revisit all pending applications of pharma companies including those for new drugs expeditiously. NPPA has also been directed to take a decision within 30 days from the receipt of the “New Drug” application and within 7 days if drug of similar composition has been approved earlier or the manufacturer is offering lower price than decided for similar drug earlier. Also, in cases where drug of higher strength if being offered at the ceiling price of drug of lower strength, then the approval may be given within 7 days. In case of negative decision, a reasoned order should be given.

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