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

# LOK SABHA UNSTARRED QUESTION NO. 2759 TO BE ANSWERED ON 4<sup>th</sup> August, 2023

#### **Production of Medicines under Price Control**

#### 2759. DR. BEESETTI VENKATA SATYAVATHI:

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

- (a) whether it is true that pharmaceutical companies have stopped manufacturing medicines which are placed under price control in the country;
- (b) if so, the details thereof;
- (c) the extent to which such action affects the availability of many life-saving essential medicines in the country; and
- (d) the steps taken/proposed to be taken by the Government to prevent companies from stopping their manufacturing of essential drugs placed under price control in the country?

## **ANSWER**

# MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI BHAGWANTH KHUBA)

(a) to (d): To ensure the availability of scheduled drugs, Paragraph 21(2) of the Drugs Price Control Order (DPCO) 2013 provides that any manufacturer intending to discontinue any scheduled formulation from market shall intimate the Government in Form IV of Schedule-II of DPCO, 2013 in this regard, at least six months prior to the intended date of discontinuation. NPPA received 226 intimations under Form IV during FY 2020-21 to FY 23-24 (till 31st July 2023) and approved 157 Form IV cases over the same period and invoked Para 3 for invoking continued production of the drug. The Form IV intimation are approved only in cases where the market share is not significant and there are sufficient number of other players in the market.

Further, in case, it is considered necessary in public interest to extend the period of continued production beyond one year from the intended date of such discontinuation, the government may do so under Para 3 of DPCO, 2013 and direct the manufacturer to increase/maintain the production level of the medicine. In the last three financial years, Para 3 have been invoked for ensuring continued production of the drugs in four (4) cases wherein Form IV was filed.

Further, no complaints of non-availability of scheduled drugs due to discontinuation have been received in the last two financial years.

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