GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. **2118**
TO BE ANSWERED ON THE **31st JULY, 2026**

Pharmaceutical Pricing Policy Reforms

2118. Smt. Sanjna Jatav:

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

(a) whether the Government is considering to introduce long pending changes sought by the pharma industry regarding the liability of drugs manufacturers in overcharging cases and other issues, if so, the details thereof;
(b) whether a new company manufacturing a drug being produced by another company and whose price has already been fixed need not apply to the department for the pricing of the drugs as it had been approved by the department for some other company, if so, the reason therefor; and
(c) whether the concept of Ease of Doing Business helped in the pharmaceutical industry, if so, the details thereof along with the benefits thereof to the public?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a) to (c): Department of Pharmaceuticals, *vide* S.O. 3516(E) dated 30.06.2026 has notified amendments to some of the existing provisions of the Drugs (Prices Control) Order, 2013 which *inter alia* addresses the issues regarding liability of drugs manufacturer in overcharging cases, need for prior approval of retail price for a new drug that an existing manufacturer intends to launch etc. The amendments made vide the aforesaid notification will promote ease of doing business and incentivising innovations in the sector. The said notification is available at the web link: https://pharma-dept.gov.in/sites/default/files/13th%20Amendment%20%20S.O.%203516%20%28E%29%20dated%2030%20June%202026.pdf.

The amendment restricts the manufacturer's overcharging liability to the quantity of stock actually overcharged by the concerned distributor, retailer, or stockist subject to compliance with the provisions made in this regard in DPCO, 2013. Further, the DPCO provision that all existing manufacturers of scheduled drugs shall individually take prior price approval for launching a formulation that it manufactured by combining an essential drug with another drug or by changing the strength or dosages or both of the essential drug has been

amended. As per the amended provision, once NPPA has fixed the retail price of a new drug for a manufacturer, other existing manufacturers of the same formulation may adopt the same or lower price over the next 12 months, without obtaining prior price approval. In addition, DPCO 2013 did not provide for any specified time limit for maintenance of records by manufacturer in respect of sales of individual active pharmaceutical ingredients or bulk drugs manufactured or imported and marketed by him, the sales of formulations units and packs etc. This provision has been amended to restrict the requirement for maintaining records to a period of seven financial years immediately preceding the current financial year. Furthermore, to incentivize innovation in the sector, Government has provided for fixing separate ceiling or retail prices for the same drug where such separate pricing is justified based on therapeutic rationale so as to encourage innovations that improve health outcomes

These amendments eliminates the need for prior approval for subsequent applications, reduces the compliance burden and allows for speedier launch of such drugs in the market facilitating availability of more effective, efficacious and/or convenient to use drugs to the users of such drugs and improves patient access, benefiting both the consumer and the manufacturer.

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