

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

RAJYA SABHA
UNSTARRED QUESTION No. 2266
TO BE ANSWERED ON THE 21st March, 2023

Production of APIs

2266 Shri Sushil Kumar Gupta:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

- (a) whether Government is aware that there is a steep price increase, of over 100 per cent, from pre-pandemic levels of certain raw materials for essential drugs and the Active Pharmaceutical Ingredients (APIs);
- (b) if so, the steps being taken in this regard to improve the situation; and
- (c) the measures proposed to have more production of APIs in the country?

ANSWER

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

(a) & (b): Under the National Pharmaceutical Pricing Policy (NPPP), 2012 and DPCO, 2013, the fixation of ceiling price of scheduled formulations and retail prices of formulations of new drugs is done based on market data and not on cost of inputs such as APIs. As per media news, fluctuations in the prices of some raw materials and Active Pharmaceuticals Ingredients (APIs) for drug formulations was observed during the pandemic.

The National Pharmaceutical Pricing Authority (NPPA) has been receiving applications for *upward price revision* of formulations under para 19 of the Drug Price Control Order (DPCO), 2013 since last three years citing various reasons like increase in cost of production, exchange rates etc. The NPPA revised the prices of 21 formulations in 2019 and 9 formulations in the year 2021 exercising extraordinary powers under of DPCO, 2013. The revision was done as NPPA was of the considered view that unviability of these formulations should not lead to a situation, where these drugs become unavailable in the market and the public interest adversely impacted.

(c): The Government of India has taken several measures to encourage domestic manufacturing of Pharmaceutical drugs including bulk drugs to reduce import dependence and to establish a dominant position in the global market. The Programmatic interventions to support Pharma Industries as on date are as follows;

- i. The *Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India*, with a financial outlay of Rs. 6,940 crores and the tenure from FY 2020-2021 to FY 2029-30, provides for the financial incentive for 41 identified products. A total of 51 applications have been selected under the scheme.

Out of these, 22 projects have already been commissioned with the installed capacity of 34,255 MT. As per the information submitted by the applicants on the sales for the period from April 2022 to December 2022, a total sale of 3972.55 MT of 12 Bulk Drugs covered under the scheme, with a value of Rs.389.89 Cr has been reported. The details of Critical KSMs / DIs / APIs Ingredients approved under the scheme, whose production is expected to increase, are given and sales details of 12 bulk drugs are given at **Annexure**.

- ii. *PLI Scheme for Pharmaceuticals*, with a financial outlay Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. This scheme also covers the APIs, other than those covered under the PLI scheme under Bulk Drugs as mentioned at Point (i).
- iii. Under the Scheme for Promotion of Bulk Drug Parks proposals of Andhra Pradesh, Gujarat and Himachal Pradesh have been approved for financial support to facilitate setting up of three (3) Bulk Drug Parks in the country. The total financial outlay of the scheme is Rs. 3000 crore and the tenure of the Scheme is from 2020-21 to 2024-25. The financial assistance by the centre is subject to a maximum limit of Rs.1000 Crore per park or 70% of the project cost of CIF (90% in case of North Eastern States and Hilly States), whichever is less.
- iv. Under the major non-schematic intervention, in order to attract investments in Pharma sector including for APIs, the Government has allowed 100% FDI in pharma sector for greenfield projects under automatic route. For the brownfield projects, upto 74%, FDI investments are allowed under automatic route and beyond 74% to 100%, FDI investments are allowed under government approval route.

Annexure

Details of Critical KSMs / DIs /APIs Ingredients approved under PLI scheme for Promotion of Domestic Manufacturing of Critical KSMs / DIs / APIs in India

Sl. No.	Target Segment or Category of KSMs / DIs / APIs	Products approved under the PLI scheme
1.	Key Fermentation Based KSMs /Drug Intermediates	Penicillin G, 7 – ACA and Clavulanic Acid
2.	Fermentation Based Niche KSMs / Drug Intermediates / APIs	Betamethasone, Dexamethasone, Prednisolone, Rifampicin and Clindamycin Base.
3.	Key Chemical Synthesis Based KSMs/Drug Intermediates	1,1 Cyclohexane Diacetic Acid (CDA), Para amino phenol and Dicyandiamide (DCDA)
4.	Other Chemical Synthesis Based KSMs/Drug Intermediates/APIs	Meropenem, Atorvastatin, Olmesartan, Aspirin, Ritonavir, Lopinavir, Acyclovir, Carbamazepine, Oxcarbazepine, Vitamin B6, Valsartan, Losartan, Levofloxacin, Ofloxacin, Diclofenac Sodium, Carbidopa, Levodopa, Sulfadiazine, Ciprofloxacin, Vitamin B1, Telmisartan, Levetiracetam, Norfloxacin and Artesunate

Details of the Sales reported by the PLI applicants under PLI scheme for Promotion of Domestic Manufacturing of Critical KSMs / DIs / APIs in India

S. No.	Product	Total Sales (Apr 22 – Dec 22) (₹ in crore)	Total Sales Quantity (Apr 22 - Dec 22) (MT)
1	1,1 Cyclohexane Diacetic Acid (CDA)	2.62	28.54
2	Para Amino Phenol	177.97	3,695.00
3	Para Amino Phenol	31.95	0.33
4	Sulfadiazine	26.79	115.63
5	Telmisartan	2.81	4.48
6	Atorvastatin	86.85	66.97
7	Carbamazepine	0.39	0.47
8	Oxcarbazepine	47.95	41.68
9	Norfloxacin	0.20	0.58
10	Ofloxacin	0.91	2.66
11	Carbidopa	0.15	0.03
12	Levofloxacin	11.31	16.20
Total		389.89	3,972.55
