रजिस्ट्री सं. डी.एल.- 33004/99 REGD. No. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

सी.जी.-डी.एल.-अ.-15102024-257880
CG-DL-E-15102024-257880

असाधारण
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (ii)
PART II—Section 3—Sub-section (ii)

प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 4135] नई दिल्ली, सोमवार, अक्तूबर 14, 2024/आश्विन 22, 1946
No. 4135] NEW DELHI, MONDAY, OCTOBER 14, 2024/ASVINA 22, 1946

MINISTRY OF CHEMICALS AND FERTILIZERS

(Department of Pharmaceuticals)

(NATIONAL PHARMACEUTICALS PRICING AUTHORITY)

ORDER

New Delhi, the 14th October, 2024

S.O. 4498(E).—Whereas the National Pharmaceutical Pricing Authority (NPPA) was established vide the Resolution of the Government of India in the Ministry of Chemicals and Fertilizers No. 33/7/97-PI.I dated 29th August, 1997, *inter-alia*, to fix prices and notify the changes therein, if any, of bulk drugs and formulations, monitor the prices of non-scheduled drugs and formulations and oversee the implementation of the provisions of the Drugs (Price Control) Order (DPCO).

2. And whereas, the Ministry of Chemicals and Fertilizers vide S.O.1394 (E) dated the 30th May, 2013, in exercise of the powers conferred by Section 3 and 5 of Essential Commodities Act, 1955 has delegated the powers in respect of specified paras of the DPCO, 2013, including para 19 of the said Order to be exercised by the NPPA on behalf of the Central Government.

3. And whereas, NPPA has been receiving applications for upward price revision under para 19 of DPCO, 2013 since last more than three years citing various reasons like increase in cost of Active Pharmaceutical Ingredients, increase in cost of production, exchange rates etc. resulting in unviability in sustainable production and marketing of the drugs. Companies have also applied for discontinuation of some of the formulations on account of their unviability.

4. And whereas, in 2019 NPPA referred the issue to the Committee on Affordable Medicines and Health Products (CAMHP, earlier known as SCAMHP), NITI Aayog, Government of India for guidance on the modalities/ methodology to be followed. CAMHP in its 2nd meeting held on 07.11.2019 recommended an increase of 50% in the ceiling prices and also authorized NPPA to examine additional formulations / molecules experiencing similar issues of manufacturing unviability due to low prices and apply upward price revision on principles determined by CAMHP. Accordingly, prices were increased for twenty-one (21) formulations of twelve (12) drugs in the 71st Authority meeting held on 09.12.2019 and for nine (09) formulations of three (03) drugs in the 89th Authority meeting held on 28.06.2021.

5. And whereas, NPPA has received applications for 76 formulations of 28 APIs. These have been examined by the Committee on Para 19 (Inter-Ministerial Committee) constituted by the Authority in its 65th meeting held on 27.03.2019 in its 6th & 7th meeting held on 14.03.2024 & 04.04.2024 respectively. The committee deliberated on the various applications based on the inputs/details/data available in the NPPA as well as data relating to API prices for the years 2020 to 2023 provided by the O/o DCGI. The Inter-Ministerial Committee in the meetings considered the applications on different parameters including 'essentiality' of these formulations; market share of the companies requesting for price revision; the period since when the formulation is under price control; concern regarding possible shortages; request, if any for discontinuation received from the companies; and trend of API prices during the last three years from 2020 to 2023 as reported by the O/o DCGI.

6. And whereas, the Inter-Ministerial Committee in its report dated 05.04.2024 recommended the price revision for fourteen (14) formulations, rejected forty-six (46) formulations and deferred sixteen (16) formulations for further examination.

7. And whereas, NPPA in its 127th meeting held on 08.10.2024 deliberated upon the report dated 05.04.2024 of the Inter-Ministerial Committee and requests received subsequent to the issue of report by the Inter-Ministerial Committee.

8. And whereas, the Authority noted that the formulations recommended by the Inter-Ministerial Committee for upward price revision are mostly low-priced scheduled formulations and have been under repeated price control, but are generally used as first line of treatment and are important to address the public health needs of the country.

9. And whereas, the mandate of NPPA is to ensure availability of drugs at affordable prices. While ensuring affordability, access cannot be jeopardized and the life-saving essential drugs must remain available to the general public at all times. Therefore, unviability of these formulations should not lead to a situation, where these drugs become unavailable in the market and the public is forced to switch to expensive alternatives.

10. And whereas, the Authority after deliberating on the report dated 05.04.2024 of the Inter-Ministerial Committee and requests received subsequent to the issue of report invoked extraordinary powers in public interest under para 19 of DPCO, 2013 for upward price revision of the ceiling process of eleven (11) formulations of 8 drugs by giving one time increase of 50%, as per the guidance of CAMHP, from the present applicable ceiling prices.

11. Therefore, in exercise of extra ordinary powers in public interest, conferred by paragraph 19 of the Drugs (Prices Control) Order, 2013, read with S.O. No. 1394(E) dated the 30th May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in supersession of the Order(s) of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) S.O. Number and date specified in column no. 6(a) & 6(b) mentioned in the table below, the National Pharmaceutical Pricing Authority, hereby fixes the prices as specified in column (5) of the Table below as ceiling prices exclusive of Goods and Services Tax applicable, if any in respect of the Scheduled formulations specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

TABLE

Sl. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Approved revised Ceiling Price (Rs.)	Existing S.O. No. & Date	
(1)	(2)	(3)	(4)	(5)	6(a)	6(b)
1.	Benzyl Penicillin	Powder for	Each Pack	14.57	1548(E)	26.03.2024

Sl. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Approved revised Ceiling Price (Rs.)	Existing S.O. No. & Date	
(1)	(2)	(3)	(4)	(5)	6(a)	6(b)
		Injection 10 Lac Units			Sl. No. 24	
2.	Atropine	Injection 0.6mg/ml	1 ML	6.86	1547(E) Sl. No. 64	26.03.2024
3.	Streptomycin	Powder for Injection 750 mg	1 Vial	15.15	1547(E) Sl. No. 617	26.03.2024
4.	Streptomycin	Powder for Injection 1000 mg	1 Vial	16.29	1547(E) Sl. No. 618	26.03.2024
5.	Salbutamol	Tablet 2 mg	1 Tablet	0.27	1547(E) Sl. No. 596	26.03.2024
6.	Salbutamol	Tablet 4 mg	1 Tablet	0.32	1547(E) Sl. No. 595	26.03.2024
7.	Salbutamol	Respirator Solution (Solution for Nebulizer 5mg/mL)	1 ml	1.02	1547(E) Sl. No. 599	26.03.2024
8.	Pilocarpine	Drops 2%	1 ml	16.25	1547(E) Sl. No. 535	26.03.2024
9.	Cefadroxil	Tablet 500 mg	1 Tablet	6.71	1547(E) Sl. No. 114	26.03.2024
10.	Desferrioxamine	Powder for injection 500mg	1 Vial	282.98	1547(E) Sl. No. 705	26.03.2024
11.	Lithium	Tablet 300mg	1 Tablet	2.45	1547(E) Sl. No. 411	26.03.2024

Note:

(a) All manufacturers of scheduled formulation, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus Goods and Services Tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus Goods and Services Tax as applicable, if any.

(b) The provisions of para 13(2) of DPCO 2013 would not be applicable on the ceiling price specified in column (5) in respect of the formulations with dosage & strength mentioned in column (2) and (3) respectively.

(c) The manufacturers may add Goods and Services Tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.

(d) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(e) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(f) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2(1) (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.

(g) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(h) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

(i) Consequent to the issue of ceiling price of such formulation as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

[PN/259/127/2024/F/F. No. 8(127)/2024/ DP/ NPPA/Div-II]

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Uploaded by Dte. of Printing at Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054.