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Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

New Delhi, 31st March, 2023

ORDER

S.O. 1579(E)- Whereas the National Pharmaceutical Pricing Authority (NPPA) was established vide Resolution No. 33/7/97-PI.I dated 29th August 1997 of the Government of India in the Ministry of Chemicals and Fertilizers to fix/revise, monitor prices of drugs/formulations and oversee the implementation of the Drugs (Prices Control) Order (DPCO); and whereas the Government of India by S.O. 1349(E) dated 30th May 2013 in exercise of the powers conferred by Section 3 and 5 of the Essential Commodities Act, 1955 (10 of 1955) has delegated the powers in respect of paragraphs 4,5,6,7,8,9,10,11,12,13,14,15, 16,18,19, 20,21,23,24, 25,26,27,28, 29,30 and 32 of the DPCO, 2013 to the NPPA to exercise the functions of the Central Government;

2. And whereas the aim of the DPCO, 2013 issued under section 3 of Essential Commodities Act, 1955, is to ensure that essential drugs are available to all at affordable prices.

3. Whereas, the Department of Pharmaceuticals (hereinafter referred as DOP) has amended Schedule I of the Drugs Price Control Order (hereinafter referred as DPCO) 2013 vide S.O. 5249(E) dated 11.11.2022 based on National List of Essential Medicine (hereinafter referred as NLEM 2022).

4. Whereas under the revised Schedule I, certain new formulations have been added where high Inter brand variation within the same company has been observed. This anomaly can largely be explained by the fact that in few cases, same formulation of one company is having multiple prices for various brands with price variation even upto 1000%. As these formulations were non –scheduled formulations under NLEM, 2015, ceiling price were not applicable and companies were at liberty to fix the prices of such non-scheduled formulation under NLEM, 2015.

5. Whereas, the newly added formulations are considered essential medicines and have been included in NLEM 2022 based on recommendation of Standing Committee on Medicines (SNCM). The **2022 Report of the SNCM** also notes that "*Out-of-pocket expenditure constitutes over 60% of total health expenditure, with a substantial 40% being incurred on medicines. With this background, it is of paramount importance that accessibility and affordability of medicines be enhanced in order to reduce the financial burden on the households."*

6. Whereas, Competition Commission of India in its Report titled "**Market Study on the Pharmaceutical Sector in India"** dated 18th November 2021 has also provided empirical evidence on large price variation amongst brands of the same formulation. It has been noted in the report that "*As evidenced by the data, despite the seemingly strong generic competition, gauged in terms of the number of players present in each therapeutic area and*

at the level of formulations/molecules, consumers in India ostensibly pay a premium for brands".

7. Whereas, the same formulation of one company having multiple prices for different brands and brands having inbuilt margins and high profits coupled with information asymmetry in the pharmaceutical sector, make many drugs beyond the reach of common man and also lead to financial burden / impoverishment. This is an extra-ordinary situation leading to market failure and working against public welfare. Therefore, it is essential to undertake an exercise to reduce the inter-brand price difference in the public interest in respect of schedule formulations since these formulations are considered to be essential medicines and have been included in the NLEM, 2022 for the first time and therefore, should not fall out of price control.

8. Whereas, as per Para 20 of DPCO, 2013, no manufacturer can increase the prices of non-scheduled formulation by more than 10% during preceding twelve months, where the increase in the prices of non-scheduled formulations is beyond 10% of MRP, the manufacturer shall reduce the same to the level of 10% of MRP for next twelve months. Thus, Para 20 does not recognise the brand, and monitoring under Para 20 is done at the formulation level. Also, Para 20 does not differentiate the price increase of the same formulation based on the situation under which such price increase has occurred. In all the situations, the manufacturer is bound to reduce the price to the level of 10%.

9. Whereas, such anomalies in variation in PTR of same formulations sold by same companies under different brand names is considered to be extra ordinary circumstance leading to the market failure and against public welfare. Thus, the Authority after due deliberation decided that it becomes essential to undertake such exercise to remove huge inter brand/pack size price variation by capping the PTR of various brands/ pack sizes of a formulation of a particular company at price of the lowest brand/ pack size plus 10%in the cases where non-scheduled formulations have come in the purview of NLEM, 2022 for the first time

10. Whereas, violation of the provisions of DPCO including Para 20 is not acceptable and should not form basis for fixation of ceiling prices under NLEM, 2022. Hence, in the cases where non-scheduled formulations have come in the purview of NLEM, 2022 for the first time, if the inter-brand variation in the price of same formulation is more than 10%, the manufacturer is bound to reduce the price to the level of 10% as per the provisions of DPCO, 2013.

11. Therefore, now in exercise of the powers conferred by paragraphs 19 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes the ceiling prices exclusive of goods and services tax applicable, if any, as specified in column (5)and increased by Whole sale Price Index (WPI) of 12.1218% under para 16 (1) of DPCO 2013 , with effect from 1.04.2023as specified in column (6) of the table 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 and strength	Unit	Ceiling Price fixed under NLEM, 2022 (Rs.)	Ceiling price (wef 1.4.2023 with WPI @ 12.1218%)
(1)	(2)	(3)	(4)	(5)	(6)
1	Amikacin	Injection 250mg/mL	1 ML	48.31	54.16
2	Amoxicillin	Oral liquid 125 mg/5 mL (p)	1 ML	0.91	1.02
3	Cefuroxime	Injection 1500 mg	1 Vial	302.12	338.74
4	Clindamycin	Injection150mg/mL	1 ML	54.05	60.60
5	Doxycycline	Power for Injection 100 mg	1 Vial	448.27	502.60
6	Glycerin/glycerol (as mentioned in IP)	Topical - Lotion	1 ML	1.1	1.23
7	Glycerin/glycerol (as mentioned in IP)	Topical - Cream	1 GM	2.11	2.36
8	Human chorionic gonado tropin	Injection10000IU	1 Vial	827.89	928.24
9	Human chorionic gonado tropin	Injection2000 IU	1 Vial	306.49	343.64
10	Insulin Glargine	Injection 100 IU/ml	1 ML	181.45	203.44
11	Iohexol	Injection 350mg iodine/mL	1 ML	12.7	14.23
12	Irinotecan HCltrihydrate	Solution for injection 20mg/mL	1 ML	860.53	964.84
13	Itraconazole	Capsule 100mg	1 Capsule	14.87	16.67
14	Itraconazole	Capsule 200mg	1 Capsule	19.73	22.12
15	Labetalol	Tablet 100 mg	1 Tablet	13.52	15.15
16	Meropenem	Powder for Injection 500 mg (as trihydrate)	1 Vial	644.82	722.98
17	Meropenem	Powder for Injection1000mg (as trihydrate)	1 Vial	849.69	952.68
18	Mupirocin	Ointment 2%	1 GM	18.1	20.29
19	Nicotine (for nicotine replacement therapy)	Lozenge 2mg	1 Lozenges	7.06	7.91
20	Nicotine (for nicotine replacement therapy)	Gum 2 mg	1 Gum	7.66	8.58
21	Nicotine (for nicotine replacement therapy)	Gum 4 mg	1 Gum	9.49	10.64
22	Nicotine (for nicotine replacement therapy)	Lozenge 4mg	1 Lozenges	8.7	9.75
23	Ormeloxifene	Tablet 30mg	1	7.53	8.44

	(Centchroman)		Tablet		
24	Rota virus vaccine	As licensed	1 Vial	762.14	854.52
25	Salicylicacid	Ointment 3%	1 GM	1.84	2.06
26	Teneligliptin	Tablet 20mg	1 Tablet	9.89	11.08
27	Terbinafine	Cream 1%	1 GM	4.69	5.25

Notes:

(a) The above mentioned ceiling prices as fixed under NLEM 2022 shall be effective from 1st April, 2023 after application of Wholesale Price Index (WPI) and as specified in column (6) above.

(b) 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 and then they may further make corresponding increase in MRP (excluding GST) upto the level of WPI @12.1218% with effect from 1st April, 2023 not exceeding ceiling prices as specified in column (6) in the above table.

(c) All the existing manufacturers of above-mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table plus GST as applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013 and they may further make corresponding increase in MRP upto the level of WPI @12.1218% with effect from 1st April, 2023.

(d) 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 (6) of the above said table.

(e) Information about the revision, if carried out, shall be forwarded to the Government in either electronic or physical form in Form-II within a period of fifteen days of such revision and non-submission of information under this sub-paragraph shall be construed as non revision of maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the pre-revised maximum retail price (MRP), alongwith interest thereon from the date of overcharging.

(f) 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 (6) 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.

(g) 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.

(h) 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.

(i) 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.

(j) 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.

(k) 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/243/111/2023/F F. No. 8(111)/2023/D.P./NPPA-Div.-II

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