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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. 1580(E) - Whereas the Ministry of Chemicals and Fertilizers vide S.O.1394 (E) dated 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 National Pharmaceutical Pricing Authority (NPPA) on behalf of the Central Government.

2. 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 revised National List of Essential Medicine (hereinafter referred as NLEM) 2022. And whereas, Oxygen – As licensed for medicinal purpose and Nitrous Oxide As licensed for medicinal purpose are scheduled formulation under amended Schedule I of DPCO 2013.

3. Whereas Oxygen is mentioned as “Oxygen-As licensed for medicinal purpose” under NLEM, 2022, Empowered Group (EG) 3, now EG2, of the Government of India mandated to ensure availability of Medical Oxygen in its meeting held on 21.09.2020 EG2 requested NPPA to look into the ceiling price of medical oxygen, both LMO and cylinders. The Authority in its meeting on 25.09.2020 examined the issue at length including the recommendations of EG2 and inter-ministerial committee, and decided to cap the price of LMO & Oxygen Inhalation (Medicinal gas) in cylinder.

4. Whereas, market based data for the concerned formulations was not available and it is obligatory on the part of the NPPA to revise the ceiling prices of all the drugs notified under the Schedule I of DPCO, 2013 so as to ensure the benefit of fair and reasonable ceiling prices to the consumers of such essential medicines to protect public interest, there is a necessity to adopt alternative methods of price fixation; In this regard, NPPA uploaded Office Memorandum (i.e. OM) 12(90)/2022/DP- Division/NPPA/II dated 28.12.2022 to provide the data regarding MAT and PTR of July 2022 of the concerned formulation.

5. Whereas, it is necessary to fix ceiling prices of scheduled formulations and as no response was received, NPPA sought information from the various Central Government agency, State Government Hospitals and Private Sector Hospital in line with OM dated 05.02.2019 which clearly states that “When no market date is available, the ceiling price may be calculated on the basis of institutional data.

6. 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, and in supersession of the Order of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) No.S.O 5634(E) dated 02.11.2018, S.O3322 (E) dated 25.09.2020, and as extended time to time and last extended upto 31.03.2023 vide S. O. 6175(E) dated 30.12.2022 with respect to Oxygen and S.O 5634(E) dated 02.11.2018 and 1499(E) dated 30.03.2022 with respect to Nitrous Oxide, 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 Wholesale Price Index (WPI) of 12.1218% under para 16 (1) of DPCO 2013 , with effect from 1.04.2023 as 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

S. No.	Name of the Scheduled Formulation	Dosage form and Strength	Unit	Ceiling Price fixed under NLEM 2022 (Rs.)	Ceiling price (wef 01.04.2023 with WPI @ 12.1218%)	Existing S.O. No. & Date	
						7(a)	7(b)
(1)	(2)	(3)	(4)	(5)	(6)		
1	Oxygen – Liquid Medical Oxygen	As licensed for medical purpose	Cubic Meter	15.18	17.02	6175(E)	30.12.2022
2	Oxygen (in cylinder)	As licensed for medical purpose	Cubic Meter	25.71	28.83	6175(E)	30.12.2022
3	Nitrous oxide	As licensed for medical purpose	Cubic Meter	255.04	285.95	1499(E)	30.03.2022

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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