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

New Delhi, the 13th December, 2019

ORDER

S.O. - 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 two years citing various reasons like increase in API cost, increase in cost of production, exchange rates etc. resulting in unviability in sustainable production and marketing of the drugs.

4. And whereas NPPA in its 62nd meeting dated 21.01.2019, deliberated upon 49 such applications consisting of 72 formulations, received from manufacturers/marketers seeking upward revision of ceiling price under paragraph 19 of DPCO, 2013 and shortlisted 19 formulations for further examination.

5. And whereas NPPA in its 65th meeting held on 27th March, 2019 constituted a committee comprising Adviser (Cost), Adviser DGHS and Deputy Drug Controller, DCGI under the convenorship of Director (Pricing), NPPA for examination of cases under para 19 of DPCO 2013 based on parameters of essentiality, market share of the applicant company and available alternatives etc, which in its 2nd meeting dated 23.05.2019 recommended that these 19 formulations could be considered for a upward price revision under para 19 of DPCO, 2013 to ensure availability of these medicines.

6. And whereas NPPA in its 68th meeting held on 25.06.2019 examined the recommendations of the Committee constituted for examination of cases under para 19 of DPCO 2013 and after deliberating upon the matter at length took a view that the revision of ceiling prices under para 19 of DPCO 2013 should be undertaken only in exceptional circumstances as there is neither a precedent nor any formula prescribed for upward revision of ceiling prices under para 19 of DPCO, 2013. Accordingly, NPPA in its 68th meeting held on 25.06.2019 based on the analysis, further shortlisted 12 formulations and referred the issue to the Standing Committee on Affordable Medicines and Health Products (SCAMHP), Niti Aayog, Government of India for guidance on the modalities/ methodology to be followed for such cases.

7. And whereas SCAMHP in its 2nd meeting held on 07.11.2019 recommended that there was a need to revisit the prices of the 12 formulations presented to it for upward price revision under para 19 of DPCO 2013 by allowing one-time 50% increase from the present ceiling price. It was also recommended that NPPA may examine any other additional formulations/ molecules for upward price revision and present to the Authority.

8. And whereas, the Committee constituted for examination of cases under Para 19 in its 3rd meeting dated 26th November, 2019 examined the 9 formulations (including 7, earlier deferred by NPPA, and additional 2 formulations Clofazimine 50mg & 100mg capsules) for upward price revision under para 19 of DPCO 2013. The committee reiterated that the seven scheduled formulations recommended earlier are essential and pricing of these shouldn't be

reason for shortage or unavailability of these medicines. Further, regarding Clofazimine capsules the committee noted that these formulations are included in National Program as first line treatment of leprosy and are essential. Accordingly, the committee recommended that these 9 formulations can be considered for revision of ceiling price under para 19 of DPCO, 2013 in addition to the 12 formulation already being considered.

9. And whereas, NPPA in its 71st meeting dated 09.12.2019 deliberated upon the case of upward price revision of the twenty one formulations under para 19 of DPCO 2013 and noted that the twenty one scheduled formulations being considered for upward price revision under para 19 of DPCO 2013 are low priced drugs and have been under repeated price control. Most of these drugs are used as first line of treatment and are crucial to the public health program of the country. Many companies have applied for discontinuation of the product on account of unviability. Further, the mandate of NPPA is to ensure availability of drugs at affordable prices and it was noted that while ensuring affordability, access cannot be jeopardized and the life saving essential drugs must remain available to the general public at all times. Therefore, the NPPA is 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 is forced to switch to costly alternatives.

10. And whereas, NPPA is cognizant that as per the prevailing policy, cost based pricing is not feasible. To address the situation arising due to repeated price control, one time price increase of 50% from the present ceiling price is being considered in public interest as an exceptional measure as advised by SCAMHP. Accordingly, NPPA invoked extra ordinary powers in public interest under para 19 of DPCO 2013 for upward revision of the ceiling prices of the twenty one scheduled formulations of 12 drugs by giving one time increase of 50% from the present ceiling price.

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** | **Ceiling Price (Rs.)** | **Existing S.O. No. & Date** | |
|---|---|---|---|---|---|---|
| **(1)** | **(2)** | **(3)** | **(4)** | **(5)** | **6(a)** | **6(b)** |
| 1. | BCG vaccine | | Each Dose | 8.75 | 1485(E) Sl. No. 95 | 29.03.2019 |
| 2. | Benzathine benzylpenicillin | Powder for Injection 12 lac units | Each Pack | 17.84 | 1485(E) Sl. No. 96 | 29.03.2019 |
| 3. | Benzathine benzylpenicillin | Powder for Injection 6 lac units | Each Pack | 11.81 | 1485(E) Sl. No. 97 | 29.03.2019 |
| 4. | Benzyl penicillin | Powder for Injection 10 Lac Units | Each Pack | 7.64 | 1485(E) Sl. No. 100 | 29.03.2019 |
| 5. | Chloroquine | Tablet 150mg | 1 Tablet | 1.16 | 1485(E) Sl. No. 176 | 29.03.2019 |
| 6. | Dapsone | Tablet 100 mg | 1 Tablet | 0.35 | 1485(E) Sl. No. 243 | 29.03.2019 |
| 7. | Furosemide | Tablet 40 mg | 1 Tablet | 0.74 | 1485(E) Sl. | 29.03.2019 |

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|---|---|---|---|---|---|---|
| | | | | | No. 344 | |
| 8. | Furosemide | Injection 10mg/ml | 1 ml | 2.43 | 1485(E) Sl. No. 345 | 29.03.2019 |
| 9. | Metronidazole | Oral Liquid 200 mg/5ml | 1 ml | 0.44 | 1485(E) Sl. No. 555 | 29.03.2019 |
| 10. | Metronidazole | Tablet 200 mg | 1 Tablet | 0.68 | 1485(E) Sl. No. 556 | 29.03.2019 |
| 11. | Metronidazole | Tablet 400 mg | 1 Tablet | 1.25 | 1485(E) Sl. No. 557 | 29.03.2019 |
| 12. | Metronidazole | Injection 500mg/100ml | 1 ml | 0.20 | 1485(E) Sl. No. 554 | 29.03.2019 |
| 13. | Ascorbic Acid (Vitamin C) | Tablet 500 mg | 1 Tablet | 1.34 | 1485(E) Sl. No. 74 | 29.03.2019 |
| 14. | Co-trimoxazole (Sulphamethoxazole (A)+Trimethoprim (B)] | Tablet 400 mg(A)+80 mg(B) | 1 Tablet | 0.77 | 1485(E) Sl. No. 227 | 29.03.2019 |
| 15. | Co-trimoxazole (Sulphamethoxazole (A)+Trimethoprim (B)] | Tablet 800 mg(A)+160 mg(B) | 1 Tablet | 1.98 | 1485(E) Sl. No. 228 | 29.03.2019 |
| 16. | Co-trimoxazole (Sulphamethoxazole (A)+Trimethoprim (B)] | Oral Liquid 200mg(A)+40mg(B)/5 ml | 1 ml | 0.32 | 1485(E) Sl. No. 226 | 29.03.2019 |
| 17. | Pheniramine | Injection 22.75 mg/ml(10ml pack) | 1 ml | 1.67 | 1485(E) Sl. No. 639 | 29.03.2019 |
| 18. | Pheniramine | Injection 22.75 mg/ml (2ml pack) | 1 ml | 2.24 | 1485(E) Sl. No. 638 | 29.03.2019 |
| 19. | Prednisolone | Drops 1% | 1 ml | 4.92 | 1485(E) Sl. No. 672 | 29.03.2019 |
| 20. | Clofazimine | Capsule 50 mg | 1 Capsule | 2.13 | 1485(E) Sl. No. 199 | 29.03.2019 |
| 21. | Clofazimine | Capsule 100 mg | 1 Capsule | 3.63 | 1485(E) Sl. No. 198 | 29.03.2019 |

**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 (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/203/71/2019/F F. No. 8(71)/2019/ DP/Div-II/NPPA

**Sd/-**
(Prasenjit Das)
Asst. Director