तहत फॉर्म–V में अधिसूचना की तारीख से आईपीडीएमएस के माध्यम से भरकर एनपीपीए को एक मूल्य सूची जारी करें तथा उसकी कॉपी राज्य औषधि नियंत्रकों और विनिर्माता वितरकों को जारी करें।

(ड़) औषध (मूल्य नियंत्रण) आदेश, 2013 के पैरा 24 (4) के उपबंधों के अनुसार प्रत्येक फुटकर विक्रेता और वितरक विनिर्माता द्वारा दिए गए रूप में ऐसे परिसर, जहां कारोबार को इस प्रकार किया जा रहा है कि उससे परामर्ष के इच्छुक किसी व्यक्ति के लिए पहुंच आसान हो, वहां उसके किसी सहजदृश्य भाग पर कीमत सूची और पूरक सूची, यदि कोई हो, को संप्रदर्शित करेगा।

(च) उपर्युक्त सारणी में यथा विनिर्दिष्ट खुदरा या प्रबलता या दोनों के साथ अनुसूचित विनिर्मिति का कोई मौजूदा विनिर्माता औषध मूल्य नियंत्रण आदेश, 2013 के पैरा 2(यू) के अनुसार कोई नई औषधि को लांच करता है तो ऐसे मौजूदा विनिर्माता की औषध (मूल्य नियंत्रण) आदेश 2013 की अनुसूची–II के अंतर्गत यथा विनिर्दिष्ट फार्म–I में एनपीपीए को ऐसी नई औषधि के पूर्व मूल्य अनुमोदन हेतु आवेदन करना होगा।

(छ) उपर्युक्त अनुसूचित विनिर्मितियों की उत्पादन/आयात और बिक्री के सम्बन्ध में निर्माताओं को औषध (मूल्य नियंत्रण) आदेश, 2013 के सूची II के फॉर्म III को आईपीडीएमएस के माध्यम से भरकर एनपीपीए को हर तिमाही की रिपोर्ट प्रस्तुत करेगा। उपर्युक्त अनुसूचित विनिर्मितियों के निर्माण को कोई निर्माता उत्पादन बन्द करने का इच्छुक हो तो इसकी सूचना एनपीपीए को अवगत करायेगा। इसके सम्बन्ध में अगर अनुसूचित विनिर्मितियों के उत्पादन और आयात को बन्द करने का इच्छुक है तो बन्द करने की तिथि से छः महीने पहले अनुसूची II के फॉर्म IV में भरकर एनपीपीए को प्रस्तुत करेगा।

(ज) विनिर्माता, उपरोक्त कथित सारणी में दर्शाये अधिकतम मूल्य और शर्तों का पालन नहीं करती हैं तो वे आवश्यक वस्तुएँ अधिनियम, 1955 के साथ पठित डीपीसीओ, 2013 के प्रावधानों के अधीन ब्याज सहित अधिप्रभारित राशि को जमा करने के लिए उत्तरदायी होंगे।

(झ) इस आदेश में उपरोक्त सारणी के स्तंभ (2) में की तत्स्थानी प्रविष्टि में विनिर्दिष्ट ऐसी विनिर्मितियों के पैकों की अधिकतम कीमत नियत होने के परिणामस्वरुप, अधिकतम या खुदरा मूल्य निर्धारित आदेश यदि कोई हो, जो कि इस आदेश से पूर्व जारी हुए है, स्वतः ही अधिक्रमण हो जायेंगे।

[कां.सं./221/89/2021/एफ फा.सं. 8(89)/2021/डीपी/एनपीपीए–डिवी-II]

प्रसेनजीत दास, उप निदेशक

ORDER

New Delhi, the 1st July, 2021

S.O. 2654(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 two years citing various reasons like increase in cost of production, exchange rates etc. resulting in unviability in sustainable production and marketing of the drugs.

4. And whereas NPPA 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.

5. And whereas SCAMHP in its 2nd meeting held on 07.11.2019 has recommended examination of formulations/ molecules experiencing manufacturing unviability due to low prices and consider price revision by allowing 50% increase from the ceiling price.

6. And whereas, the Inter-Ministerial Committee constituted for examination of cases under Para 19 of DPCO 2013 has examined the representations and observed that the formulations of the three drugs are essential medicines for public health management and pricing of these should not be reason for shortage and unavailability of these medicines, and accordingly recommended for upward revision of price under Para 19 of DPCO 2013.

7. And whereas, NPPA in its 89th meeting dated 28.06.2021 deliberated upon the case of upward price revision of the formulations of these drugs under para 19 of DPCO 2013 and noted that the 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. These drugs are used as first line of treatment and are important to the public health program of the country. 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.

8. 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 invokes extra ordinary powers in public interest under para 19 of DPCO 2013 for upward revision of the ceiling prices of the nine scheduled formulations of 3 drugs by giving one time increase of 50% from the present ceiling price.

9. 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.	Carbamazepine	Oral Liquid 100 mg/5ml	1 ml	0.29	1330(E) Sl. No. 139	25.03.2021
2.	Carbamazepine	CR Tablet 200 mg	1 tablet	2.34	1330(E) Sl. No. 140	25.03.2021
3.	Carbamazepine	CR Tablet 400 mg	1 tablet	4.61	1330(E) Sl. No. 141	25.03.2021

4.	Carbamazepine	Tablet 100 mg	1 tablet	1.02	1330(E) Sl. No. 142	25.03.2021
5.	Ranitidine	Oral Liquid 75 mg/5ml	1 ml	1.08	1330(E) Sl. No. 722	25.03.2021
6.	Ranitidine	Tablet 150 mg	1 tablet	1.10	1330(E) Sl. No. 723	25.03.2021
7.	Ranitidine	Injection 25mg/ml	1 ml	2.43	1330(E) Sl. No. 724	25.03.2021
8.	Ibuprofen	Tablet 200 mg	1 tablet	0.59	1330(E) Sl. No. 431	25.03.2021
9.	Ibuprofen	Tablet 400 mg	1 tablet	1.04	1330(E) Sl. No. 432	25.03.2021

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/221/89/2021/F F. No. 8(89)/2021/ DP/Div-II/NPPA]

PRASENJIT DAS, Dy. Director

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