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

New Delhi, 13th July 2021

ORDER

S.O. _____ 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 regulate and 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. 1394(E) dated 30th May 2013 and S.O. 1249(E) dated 6th April 2020 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 various paragraphs including paragraph 19 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 the Essential Commodities Act, 1955, is to ensure that Essential Drugs are available to all, at affordable prices.

3. And whereas, Ministry of Health and Family Welfare vide S.O. 648(E) dated 11.02.2020 notified all the medical devices intended for use in human beings or animals as “Drugs” under the Drugs and Cosmetics Act 1940 w.e.f. 01.04.2020. And whereas, NPPA has accordingly, vide S.O. 1232(E) dated 31.03.2020 notified that all medical devices including (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer, shall be governed under the provisions of DPCO, 2013 w.e.f. 01.04.2020.

4. And whereas, NPPA is entrusted with the mandate to ensure the availability of essential drugs at affordable prices, and keeping in view the evolving Covid 2.0 pandemic, it is necessary to regulate the prices of these medical devices.

5. And whereas, the Authorities, viz., Drug Controller General Of India (DCGI), Director General of Health Service (DGHS) and National Pharmaceutical Pricing Authority (NPPA) are in consensus that these medical devices are essential for COVID Management.

6. And whereas, Governments at Central and State level are undertaking various measures including health care packages to deal with the pandemic effectively and efficiently.

7. And whereas, in pursuance to the above, NPPA collected data regarding the Trade Margins for these five medical devices from the manufacturers/marketers/importers and noted that margins ranging up to 709% from Price to Distributor to MRP level have been reported.

8. And whereas, NPPA has earlier vide its Notification S.O. 1041(E) dated 27.02.2019, capped the price of select Anti-cancer drugs, and vide its Notification S.O. 2161 (E) dated 3rd June 2021, capped the price of Oxygen Concentrators through 'Trade Margin Rationalisation Approach', which has resulted in significant savings to the consumer and rationalization in the price of these drugs and medical devices.

9. And whereas, these five medical devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, (v) Glucometer are Non-Scheduled Medical Devices/Drugs. The Pulse Oximeter is under the voluntarily licensing framework of the Central Drugs Standard Control Organization (CDSCO). Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer, Glucometer are under compulsory licensing framework under CDSCO w.e.f. 01.01.2021. With the aim of making these medical devices affordable during the evolving situation of Covid pandemic, it is felt necessary to regulate the trade margin on these medical devices.

10. Now, therefore, in the exercise of the powers vested by the Government of India in the Ministry of Chemicals and Fertilizers, having been satisfied that in view of the extraordinary circumstances in public interest, as explained above, the Government, hereby, invokes the provisions of Paragraph 19 of the DPCO, 2013 to regulate the price of these five medical devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, (v) Glucometer under "Trade Margin Rationalisation Approach".

11. And whereas, by invoking Paragraph 19 of DPCO, 2013, the Government hereby puts a cap on trade margin of (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, (v) Glucometer at first point of sale of product (hereinafter referred as Price to Distributor) and directs manufacturers to fix the Maximum Retail Price as formulated in Table-A below:

Table-A

Maximum Retail Price = Price to Distributor (PTD) + (PTD x TM) + Applicable GST
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Where TM = Trade Margin not exceeding 70%.

12. Further, in the exercise of the powers vested by the Government of India in the Ministry of Chemicals and Fertilizers under Paragraph 9(2) of the DPCO, 2013, *hereby directs manufacturers to submit the information in Annexure-I containing details of PTD, Retail Price, existing and revised MRP, by using the formula prescribed in Table-A, and other details for (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, (v) Glucometer to NPPA by 20th July 2021.*

Notes:

- a) Price to Distributor (PTD) =
Sum of Net sales realization of product by the manufacturer as the case may be for the sales during the year from 01.4.2020 to 31.03.2021
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Total Quantity of such product sold during the year from 01.4.2020 to 31.03.2021

- b) Net sales are to be worked out considering all sales, namely, Distributors / Stockiest / Institutional / Hospital / Government / E-commerce / E-Pharmacy / Free Samples (incl. under Patient Aid Programme). The quantity to be considered in Note (a) above, shall exclude the quantities, which are not connected with the sales such as products given under Corporate Social Responsibility activity, for regulatory approvals, and to provide hands on training to health care professionals.
- c) In case, the medical device has been launched after 31.03.21, MRP will be fixed as per the formula at Table-A based on current PTD.
- d) The revised prices shall come into effect from 20th July, 2021.
- e) The manufacturers of these five medical devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, (v) Glucometer selling at price higher than the Maximum Retail Price so computed as per Table-A, shall revise the prices downward, not exceeding the Maximum Retail Price computed by using above formula.
- f) All the existing manufacturers of (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, (v) Glucometer having MRP lower than the Maximum Retail Price so computed as per Table-A, shall maintain the existing MRP, subject to the provisions of Para 20 of the DPCO, 2013 and not increase the price on the basis of formula as per Table-A.
- g) The manufacturer shall submit a price list in **Form-V** as per Paragraph 25 of the DPCO, 2013 to NPPA and submit a copy to State Drug Controller and Dealers by 20th July 2021.
- h) As per Para 25(3) of DPCO 2013, every retailer, dealer, hospital and institution shall display price list and the supplementary price list, as furnished by the manufacturer, on a conspicuous part of the business premises in a manner so as to be easily accessible to any person wishing to consult the same.
- i) The manufacturers not complying with the Maximum Retail Price so computed as per Table-A and notes specified hereinabove shall be liable to deposit the overcharged amount along with 15% interest p.a. from the date of increase in price in addition to penalty upto 100% of the overcharged amount under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.
- j) No manufacturer, distributor, retailer shall sell these five medical devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, (v) Glucometer to any consumer at a price exceeding the revised price, as submitted in Form-V, or price indicated on the label of the container or pack thereof, whichever is less.
- k) The price so fixed shall remain in force up to 31st January 2022 or until further orders, whichever is earlier.
- l) State Drug Controllers shall ensure compliance of this Order. The manufacturers / Dealers / Hospitals / Medical Institutions shall assist the State Drug Controllers in verifying the

compliance to this Order. Any violation of this Order is required to be brought to the notice of NPPA.

m) The manufacturers of these five medical devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, (v) Glucometer shall submit quarterly details of products manufactured / imported, sold and exported, if any, in the prescribed format.

PN/222/90/2021/F

F. No. 8(90)/2021/D.P./NPPA-Div.-II

(Rajesh Kumar T)
Deputy Director

Annexure-I

Format for submission of Revised MRP by the Manufacturers / Importers.

1. Name and address of the Manufacturer/Importer/Distributor:
2. Name and address of the marketing company, if any:
3. Mobile Number:
4. E-mail id:

S. No.	Product Name	Brand Name	Type of Device	Minimal Unit of Sale/Retail Pack size	Quantity Sold in Quarter ending 30 th June 2021	Quantity Sold in Financial Year ending 31 st March 2021	Price to Distributor (Excluding GST) (Rs.) (According to this notification)	Retail Price (Excluding GST) (Rs.) (According to this notification)	Applicable Rate of GST %	Maximum Retail Price (MRP) arrived by applying the formula* (Including GST) (Rs.)	MRP before date of the Notification (Rs.)
1	2	3	4	5	6	7	8	9	10	11	12

*Formula to arrive MRP = [Price to Distributor + (Price to Distributor x TM)] + Applicable GST.

Where TM = Trade Margin not exceeding 70%

The information furnished above is correct and true to the best of my knowledge and belief.

Place:.....
Date:.....

(Signature and stamp)
Name of authorized person
Designation
Name of the organization