मिसिल स.- 8(90)/2021/डी.पी/एनपीपीए-डीवी-II
F. No. 8(90)/2021/DP/NPPA-Div. II

कार्यवाही स. : 222/90/2021/F
Proceeding No: 222/90/2021/F

**Minutes of the 222nd (overall) and 90th Meeting of the Authority under DPCO, 2013 held on 12th July 2021 at 4:00PM**

The 222nd Meeting of the Authority (overall), which is the 90th Meeting under the DPCO, 2013, was held on 12th July, 2021 at 4:00PM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following Authority members of the NPPA were present during the meeting:

(i) Ms. A. Srija, Economic Advisor, Department of Economic Affairs (through Video Conferencing)
(ii) Shri Amardeep Singh Chowdhary, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
(iii) Dr. V. G. Somani, Drug Controller General of India (through Video Conferencing)
(iv) Dr. Vinod Kotwal, Member Secretary, NPPA

Shri A. K. Pradhan, Deputy Drug Controller, CDSCO, Ministry of Health & Family Welfare was also present through Video Conferencing.

1.1 The following officers of NPPA attended the meeting and assisted the Authority in its deliberations:

(i) Shri N. I. Chowdhury, Advisor
(ii) Shri S. S. Ojha, Joint Director (Medical Devices)
(iii) Ms Rashmi Tahiliani, Joint Director (Pricing)
(iv) Shri Prasenjit Das, Deputy Director (Pricing)
(v) Shri Rajesh Kumar T, Deputy Director (Medical Devices)

**II. Agenda items**

**1. Agenda Item – Regulation of prices of medical devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer**

1.1 The Authority noted that the Drug Prices Control Order, 2013, is applicable to all drugs and NPPA monitors the prices of all the drugs including non-scheduled drugs under Para 20. NPPA also fixes the prices of scheduled formulations and monitors price increase of non scheduled formulations so as to ensure that the prices of these drugs do not increase beyond 10 percent in a year. The Authority further noted that 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.

1.2 The Authority also noted that:

i. Ministry of Health and Family Welfare vide SO. 648(E) dated 11.02.2020 notified that the medical devices intended for use in human beings or animals is to be treated as Drugs under the Drugs and Cosmetics Act 1940 w.e.f 01.04.2020. Accordingly, NPPA has vide SO. 1232(E) dated 31.03.2020 notified that all medical devices, including medical devices, namely, (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.

ii. All the above medical devices are essential devices for diagnostic purposes, in general and specially for COVID management. These devices are widely used in hospitals for early detection of COVID symptoms as well as for self diagnostics at home by the patients. With the cases continuing under COVID 2.0 pandemic in the country, demand for these medical devices has gone up considerably. Further, Governments at Central and State level are undertaking various measures including introduction of health care packages to deal with the pandemic effectively and efficiently.

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

iv. 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.

v. NPPA had directed manufacturers/ importers to provide price related information of (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii)Nebulizer, (iv) Digital Thermometer, and (v) Glucometer vide Office Memorandums dated 29.06.2020, 16.02.2021, 12.03.2021 and 15.05.2021. In response, so far, 89 Companies (66 Importers and 23 Domestic Manufacturers) manufacturing/importing these products have submitted the requisite data in the prescribed format. The scrutiny of the data shows no violation under Para 20 of the DPCO 2013 in respect of these devices. Several companies are dealing in more than one of these products. The data analysis shows margins ranging up to 709% from Price to Distributor to MRP level across the medical devices.

vi. Authority also noted that 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 consumers and rationalization in the price of these drugs and medical devices.

1.3 The Authority deliberated upon the matter in detail. In view of the extraordinary circumstances arising due to COVID pandemic and with the aim of making these medical devices affordable during the evolving pandemic, it is felt necessary to regulate the trade margin on these medical devices.

1.4 Accordingly, in view of extra ordinary circumstances mentioned herein above, the Authority decided to invoke Paragraph 19 of the DPCO, 2013 to regulate the price of (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii)Nebulizer, (iv) Digital Thermometer, and (v) Glucometer under "Trade Margin Rationalisation" Approach, as detailed below:

**Methodology for fixation of Maximum Retail Price (MRP) -**

**Table-A**

| **Maximum Retail Price = Price to Distributor (PTD) + (PTD x TM) + Applicable GST**<br>**Where TM = Trade Margin not exceeding 70%.** |
|---|

1.5 The Authority also noted the following:

**a) Price to Distributor (PTD) =**

$$\frac{\text{Sum of Net sales realization of product by the manufacturer as the case may be for the sales during the year from 01.4.2020 to 31.03.2021}}{\text{Total Quantity of such product sold during the year from 01.4.2020 to 31.03.2021}}$$

b) Authority noted that the companies had submitted price related data for the financial year 2020-21 and same data has been considered for the calculation of PTD. The Authority also noted that PTD based on full financial year average is more representative than only one month average.

c) Net sales are to be worked out considering all sales, namely, Distributors / Stockist / Institutional / Hospital / Government / E-commerce / E-Pharmacy / Free Samples (incl. under Patient Aid Programme).

d) Authority noted the representations received from industry associations such as CII, MTaI, AiMED and AMCHAM etc., on Notification issued on 03.06.2021 pertaining to Oxygen Concentrator. It was agreed that any supply in connection with sales should be included for the purpose of calculation of PTD. Accordingly, the free quantities supplied under schemes like Patient Assistant/Aid Programme (PAP) (viz., like PAP Program for cancer patients, patient is eligible for two free strips (1*10 Tabs) on purchase of one strip (1*10 tabs) or patient is edible for free drugs till disease progression on purchase of 4 Months of therapy, etc.,), quantity discounts, are connected with the sales and these quantities are to be considered for calculation of PTD. However, quantities of medical devices distributed under Corporate Social Responsibility (CSR), submitted to regulators for regulatory

approvals, and given to provide hands on training to health care professionals and given as samples while quoting tenders, free of cost, not to be included for calculation of PTD.

e) In case, the medical device has been launched after 31.03.21, MRP will be fixed as per the formula in Table-A based on current PTD.

f) The revised prices shall come into effect from 20th July, 2021.

g) 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 above formula.

h) 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.

i) 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(s) and Dealers by 20th July 2021.

j) 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.

k) 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.

l) No manufacturer, distributer, 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.

m) The price so fixed shall remain in force up to 31st January 2022 or until further orders, whichever is earlier.

n) State Drug Controller(s) shall ensure compliance of this Order. The manufacturers / Dealers / Hospitals / Medical Institutions shall assist the State Drug Controller(s) in verifying the compliance to this Order. Any violation of this Order is required to be brought to the notice of NPPA.

o) 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 sales quantities for Financial Year 2020-21 and every quarter thereafter of products manufactured / imported, sold and exported, if any, in the prescribed format for monitoring purpose.

1.6 The Authority noted that as on date, Pulse oximeter is currently under voluntarily licensing framework under D&C Act, 1940 and its standards and specification have not been issued by the Government. However, Medical Devices (Amendment) Rules, 2020 prescribes standards like BIS, ISO and other internationally recognized standards. Hence, in order to have effective regulation of pricing enforcement, Authority requested Ministry of Health and Family Welfare (MoH&FW), Government of India to issue necessary direction so as to enable compulsory registration of the manufactures / importers of Pulse oximeter during the period of voluntary licensing regime and issue guidelines regarding product standardization for Pulse Oximeter for better synergies in operations in the larger public interest.

The Meeting ended with a vote of thanks to the Chair and all the participants in the meeting.

Kotwal

**(Dr. Vinod Kotwal)**
Member Secretary