

**Minutes of the 220<sup>th</sup> (overall) and 88<sup>th</sup> Meeting of the Authority under DPCO, 2013 held on 3<sup>rd</sup> June 2021 at 6:00PM**

The 220<sup>th</sup> Meeting of the Authority (overall), which is the 88<sup>th</sup> Meeting under the DPCO, 2013, was held on 3<sup>rd</sup> June 2021 at 6:00PM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following Authority members of the NPPA were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri Amardeep Singh Chowdhary, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

Shri A. K. Pradhan, Deputy Drug Controller, CDSCO, Ministry of Health & Family Welfare (through Video Conferencing) represented DCGI

Ms. A. Srija, Economic Advisor, Department of Economic Affairs was granted leave of absence.

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 (Pricing)
- (iii) Shri Ratan Khatwani, Joint Director (Medical Devices)
- (iv) Shri Prasenjit Das, Deputy Director (Pricing)
- (v) Shri Alok Ranjan, Asst. Director (Medical Devices)

**II. Agenda Item – Regulation of prices of Oxygen Concentrators**

1.2 The Authority noted that:

i. With the increase in demand for Medical Oxygen during the Covid 2.0 pandemic, there is a surge in demand for Oxygen Concentrators in the country. Due to global demand–supply mismatch and related issues, the prices of the Oxygen Concentrators have recently shown substantial volatility in domestic market. This has resulted in various petitions and Public Interest Litigations (PIL) filed in various Courts across the country for regulation of its price

so as to ensure its availability at affordable price at this critical time of public health emergency.

ii. The Hon'ble Delhi High Court is hearing in daily sittings, arguments under W.P. (C) No. 3031/2020 among other issues, regarding issue of fixation of price of concentrator and other such medical devices essential for COVID since 2<sup>nd</sup> May 2021. The Government initially submitted before the Hon'ble High Court that it is striving to encourage up scaling of supply of Oxygen Concentrator in the country in the larger public interest. Currently, there is mismatch in demand & supply of the Oxygen Concentrator and measures are being taken to ensure the supply of the Oxygen Concentrators in the country in this pandemic. Looking at the limited availability of Oxygen Concentrators, any price cap at this stage may disincentivize domestic manufacturing that may impact their availability. Further, in view of the global demand for Oxygen Concentrators due to COVID 19 pandemic, any price cap at this stage may prove to be a deterrent for the imports.

iii. Hon'ble Court of Delhi vide its Orders dated 17.05.2021 directed the Government to consider the aspect as stated by the petitioners that *"It should be possible for the Government to come out with a standard formula for fixation of the ceiling price or retail price of such like Medical Devices. The ceiling price or retail price may not be fixed in absolute terms i.e. Rupee or Paisa, however, if a formula were to be prescribed by adopting the said formula, the ceiling price or retail price could be worked out and save the customers from being fleeced"*.

iv. In pursuance of the above Court Orders, Ministry of Health and Family Welfare (MoH&FW), Government of India in its letter dated 18th May 2021 addressed to Department of Pharmaceuticals, Government of India requested that NPPA be advised to expeditiously facilitate in implementing the said Order in larger public interest referring to the observations of Hon'ble High Court of Delhi.

### **III. Preparatory Action Taken by NPPA**

v. NPPA held two separate Meetings on 19<sup>th</sup> May 2021 through Video Conferencing (VC) viz., Inter-ministerial Meeting and Stakeholders Consultation. During the VC, following issues were raised by manufacturers / importers of the Oxygen Concentrators with regard to availability and pricing:

- The manufacturers highlighted the non availability of imported raw material like Zeolite, pumps, metal/plastic sheets, and medical electronic components etc. The prices have also increased remarkably in last month.
- The increase in freight charges for importing raw materials (For example Before Covid: 1.8 USD/kg After Covid: 5-8 USD/kg) in current scenario, to avoid delay/reduce lead time and fulfilling the need, air shipments are done instead of

cost- effective sea/ship route due to which additional charges are borne by the companies that are 4-5 times higher than the earlier freight charges.

- Currently, the 5 litre Oxygen Concentrator is available at an average rate of 500-550 USD. Earlier the same product was available @250 -300 USD. Similarly, 10 litre model now costs between 500 -750 USD.
- Quality Standards and Service capabilities in respect of components used in spurious product challenge the devices that are manufactured / imported legitimately and to curb such spurious and sub-standard products in Indian market there should be quality audit requirements for imports.
- It was also highlighted & emphasized by the Associations that registration should be mandatory under CDSCO for importing/manufacturing of product.
- The formula for fixation of price should be flexible and dynamic so that it covers the price variation in the market in respect of raw materials as well as finished goods, else the price intervention may result in curtailed imports and impede efforts to enhance availability during the pandemic.
- Considering the current price movement globally, compliance of 10% price increase on MRP should be revisited in case of import.
- AiMed asked for price regulation formula at Landed Cost with three times margin, to promote Make in India

vi. NPPA had asked for price related information from manufacturers/ importers of (i) Pulse Oximeters and (ii) Oxygen Concentrators vide Office Memorandum dated 29.06.2020. In response, 13 companies had submitted the requisite data in the prescribed format for Pulse Oximeters and 10 companies for Oxygen Concentrators. Further, in order to monitor prices movement of Oxygen Concentrators in the preceding twelve months in the second wave of the COVID surge, NPPA vide OM dated 15.05.2021 had directed manufacturers / importers of Oxygen Concentrators and Pulse Oximeters to submit price related information in the prescribed format within seven days. In response, a total no. of 89 manufacturers / importers (including previous one) submitted the price related information to NPPA in respect of 179 products. The Authority was informed as follows:

- a) As on date, Oxygen Concentrator is a Non Scheduled Drug under voluntary licensing regime under D&C Act, 1940 and its standards and specification have not been issued by the Government. The SUGAM portal of CDSCO has no categories defined and no data of manufacturers.
- b) As per data collected by NPPA, the Oxygen Concentrators have been categorized as under:
  - ❖ Portable (5, 7, 8 , 9 and 10 litres)
  - ❖ Stationary (5, 7 and 10 litres)

- c) The range of Trade Margin reported for PTD-MRP is 7%-198%.

#### **IV. Examination by and Recommendations of SCAMHP**

vii) With regard to observations of the Hon'ble High Court of Delhi for fixing a formula to work out Retail Price for Oxygen Concentrators, NPPA noted that there is no policy framework to guide regulation of Trade Margin for Medical Devices. In the given scenario, Department of Pharmaceuticals/NPPA approached Standing Committee on Affordable Medicines and Health Products (SCAMHP), NITI Aayog, Government of India for guidance in the matter to finalise the formula under Trade Margin Rationalization and broader ecosystem for price regulation of Oxygen Concentrators and such like Medical Devices.

viii) SCAMHP held two Meetings on 25.05.2021 and 30.05.2021 in light of the observations of the Hon'ble High Court of Delhi to discuss and decide formula for fixation of price of Oxygen Concentrators and such like Medical Devices.

ix) SCAMHP in the aforesaid Meetings has noted the following:

- a) Taking note of the current need to maintain steady supply of sufficient volume of oxygen concentrator of good quality, to meet the abnormal demand in the pandemic, there is a need to proceed in a calibrated manner with price controls without creating obstacles to availability and supply of Oxygen concentrators. The relatively high dependence on imported products, the emergence of domestic manufacturers, the voluntary nature of licensing and the wide variation in quality and performance were highlighted. However, looking to the need to provide transparency and stability in the prices of Oxygen concentrators within these constraints, a TMR approach at PTD offers an acceptable option in the present pandemic scenario to regulate prices of Oxygen Concentrators.
- b) The Trade Margin Rationalisation (TMR) approach has been under the consideration of the Government since the 2015.
- c) The Department of Pharmaceuticals Committee recommended in 2015 to roll out of TMR for non-scheduled Drugs at PTD plus 30% Margin.
- d) For non-scheduled anti-cancer drugs, a pilot was conducted in 2019 and the formula extended by SCAMHP was :

$$\text{MRP} = \text{PTD} + 43\% \text{ Margin}^1 + \text{GST}$$

e) NITI Aayog has examined the formula for TMR for Medical Device in August 2018 at a high level meeting wherein it was agreed that TMR on Medical Device should be

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<sup>1</sup> Margin will imply mark-up from the cost price of a drug or device as per DPCO 2013

based on PTD and not on Landed Cost. During multiple discussions in 2018 and 2019, the formula under consideration of Niti Aayog for medical devices has been:

$$\text{MRP} = \text{PTD} + 100\% \text{ Margin} + \text{GST}$$

- f) Accordingly, it was agreed that TMR for Oxygen Concentrators may be based on PTD and not on Landed Cost.
- g) It was noted that at 70% Margin on PTD, total 59 out of 179 products reported by manufacturers will be impacted. Also, the present exercise being based on high prices due to the pandemic, 70% margin should suffice instead of 100% in normal times. Therefore, a consensus evolved that 70% Margin on PTD should be the way forward.
- h) It was also noted that, as in earlier TMR rollout on 42 anti-cancer drugs, the PTD would be arrived by considering average of all sales namely Distributors / Stockist / Institutional / Hospital / Government / E-commerce / E-Pharmacy / Free Samples (incl. under Patient Aid Programme).
- i) It was also noted that the revised MRP may vary from brand to brand. This will allow availability of range of a range of products with varying features and standard of quality.

1.3 SCAMHP vide Minutes dated 03.06.2021 has recommended the following:

- a) TMR would be considered on Price-to-Distributor. The formula prescribed by the Committee for Oxygen Concentrators is **MRP= PTD + 70% Margin + GST**.
- b) It was recommended that the formula prescribed above for Oxygen Concentrators may remain in force for six months or until further orders, whichever is earlier.
- c) For the price formula decided for Oxygen Concentrators based on PTD, may be based on current / May 2021 data.
- d) The formula for Oxygen Concentrators has been prescribed in extra ordinary circumstances and it should not be taken as a precedent for future price regulation for Medical Devices.
- e) NPPA may invoke suitable provisions under DPCO, 2013 and EC Act for rigorous implementation and enforcement of revised prices as per the extant provisions of DPCO, 2013 read with Essential Commodities Act, 1955.

## **V. Deliberations by Authority**

1.4 The Authority deliberated upon the matter in detail and was of the view that the extraordinary circumstances arising due to COVID pandemic has resulted in significant volatility in Maximum Retail Prices of Oxygen Concentrators available through imports and indigenous production and hence it is necessary to regulate the price of Oxygen Concentrators.

1.5 The recommendations of SCAMHP were deliberated and considered by the Authority.

1.6 The Authority also noted the Report of the Committee “High Trade Margins in the Sale of Drugs” (2015) constituted by Department of Pharmaceuticals had recommended regulation of Trade Margin of Medical Devices at Price to Distributor level. Further, NITI Aayog has examined the formula for TMR in Medical Devices in 2018 and 2019 in high level meeting wherein it was agreed that TMR on Medical Devices should be based on PTD and not on Landed Cost. Further, manufacturers / importers of Oxygen Concentrators have raised the issue of increased cost on account of increase in raw material cost, freight charges etc. At PTD level, all increased cost of manufacturer / importers would be subsumed and any pricing decision based on PTD would not impact imports of the Oxygen Concentrators in the given scenario. Further, NPPA in the year 2019, NPPA ran a pilot for Trade Margin Regulation on Anti-cancer Drug based on PTD which has resulted in significant savings to the consumer and rationalization in the price of those drugs.

1.7 The Authority further noted that the data submitted by 89 manufacturers / importers of Oxygen Concentrators for 179 products shows that for the imported goods, Trade Margin range for PTD-MRP is 7%-198% and in case of domestic manufacturers, the range is 12%-90%. Simulation analysis shows that at 100% Margin on PTD, 16 out of 179 products will be impacted. At 70% Margin on PTD, total 59 out of 179 products reported by manufacturers will be impacted. At this level, manufacturers / importers concern and consumers interest would have optimum balance and this will boost ‘Make in India’ initiative also. Thus, the Authority accepted the recommendation of SCAMHP for 70% Margin on PTD.

1.8 The Authority further noted that in DPCO,2013 the word ‘margin’ was used to determine Retail Price from Price to Retailer. Thus, Authority accepted the term ‘margin’ to calculate MRP on PTD.

1.9 Accordingly, in view of the above, the Authority decided to regulate the prices of Oxygen Concentrators and rationalize the Trade Margins as recommended by SCAMHP. 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 Oxygen Concentrators under “Trade Margin Rationalisation Approach”, as detailed below:

**Methodology for fixation of Maximum Retail Price (MRP) of Oxygen Concentrator** - The Authority accepted the recommendation of SCAMHP and fixed the MRP of Oxygen Concentrator as follows:

**Maximum Retail Price = Price to Distributors (PTD) + (PTD x TM) + Applicable GST**

**Where TM = Trade Margin not exceeding 70%**

1.10 The Authority also decided the following:

i) Price to Distributors (PTD) =

Sum of Net sales realization of product by the manufacturer as the case may be for the sales in the **Current Month / May 2021**

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Total Quantity of such product sold in the **Current Month / May 2021**

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

iii) In case there is no sale during the month of May 2021 for an existing manufacturer, the month to be considered for PTD calculation may be immediate prior month to May 2021 in which sales were recorded.

iv) In case a manufacturer is intending to launch Oxygen Concentrator after issuance of this notification, MRP will be fixed as per the formula at Table-A based on current PTD.

v) The revised prices shall come into effect from 9<sup>th</sup> June, 2021.

vi) The price so fixed shall remain in force up to 30<sup>th</sup> November 2021 or until further orders, whichever is earlier.

vii) The manufacturers of Oxygen Concentrator selling at price higher than the Maximum Retail Price as per the formula given above, shall revise the prices of such Oxygen Concentrator downward not exceeding the Maximum Retail Price computed by above formula.

viii) All the existing manufacturers of Oxygen Concentrator having MRP lower than the Maximum Retail Price so computed as per the formula given above, subject to the provisions of Para 20 of the DPCO, 2013, shall maintain the existing MRP and not increase any price.

ix) The Authority noted and concurred with the recommendation of SCAMHP regarding rigorous implementation and enforcement of revised prices. The Authority also noted

that under the provisions of Para 15 of the DPCO, 2013, NPPA levies a penalty up to 100% for overcharging cases. Considering this, the Authority approved penalty up to 100% on overcharged amount for Oxygen Concentrators under Para 20(2) of DPCO, 2013.

- x) State Drugs Controllers shall monitor the compliance of this Order. The manufacturer/ dealers/ Hospitals/Medical Institutions shall assist the State Drug Controllers in verifying the compliance to this Order. Any violation of this Order would require to be brought to the notice of NPPA.

1.11 The Authority also noted the recommendation of SCAMHP for rigorous implementation and enforcement of revised prices of Oxygen Concentrators. In this regard, the Authority noted that as on date, Oxygen Concentrator is under voluntarily licensing regime 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, Ministry of Health and Family Welfare (MoH&FW), Government of India be requested to consider directions for compulsory registration of the manufacturers / importers of Oxygen Concentrator during the period of voluntary licensing regime and expedite finalization of guidelines for Standards for Oxygen Concentrators for better synergies in operations in the larger public interest.

1.12 The Authority noted that Oxygen Concentrators is presently under voluntary licensing regime and therefore, MAT for the same is not presently available. Hence, at this point of time, net saving to the consumers due to regulation on Trade Margin for Oxygen Concentrators may not be quantified. However, the Authority noted that the manufacturers of Oxygen Concentrators shall submit monthly stock details to NPPA to establish the net saving to the consumers from TMR in Oxygen Concentrators during the period of price intervention.

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

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