



# OXIMETER: GASPING FOR REGULATORY OXYGEN PROFITEERING IN OXIMETER AND NEED FOR IMMEDIATE REGULATION

This article presents an analysis of 'systemic loops' in regulatory mechanisms during public health emergency, i.e. COVID-19 second wave. This 'once in a century crisis' has highlighted regulatory lapses and oversight in the functioning of the National Pharmaceutical Pricing Authority (NPPA). Taking specific case for oximeter, this article analyses that how the manufacturers and retailers used regulatory lapses for profiteering, rendering orders useless, toothless and ineffective, issued by National Pharmaceutical Pricing Authority (NPPA). Moreover, this underlines the problems in MRP regime and over reliance of regulator to depend on MRP as a key tool to regulate the prices. The later section of the article deals with the Drug Price Control Order, 2013 and powers provided by it to the NPPA- to take necessary measures to carry out its functions; ensuring quality, availability and affordability of the drugs. It also provides for viable alternatives to determine the prices using integration of data. The last part of article talks about possible impact of these regulatory lapses on income levels of lower-middle income groups and vulnerable sections of the society aggravating socio-economic inequity.

## Pandemic and Crumbling Health System

The coronavirus pandemic has wreaked havoc at an unimaginable scale leading to overburdening of already overburdened hospital system in India. The SOS was issued by many hospitals citing that they are left with only few hours of oxygen supply across the states. There are many incidents of death of COVID patients due to either no or low flow of oxygen.

There was overburdening of cases at the peak as more number of patients returned positive. The positivity rate in cities like Delhi touched as high as 35 %<sup>[1]</sup>. There was a cause for concern and alarm bells were ringing high in ivory tower. The shortage of medical equipment, therapeutics and hospitals beds highlighted systemic vulnerabilities of health infrastructure. Reports of black marketing and hoarding of essential lifesaving drugs such as remdesivir, fabiflu, oxygen and oxygen concentrator skyrocketed their prices adding more to the trouble.

There has been exorbitant increase in sales of pulse oximeter for its early diagnosis capability of oxygen saturation level. In the second wave, almost 54.5% of admissions<sup>[2]</sup> required supplemental oxygen during treatment. Many doctors advised the patients to monitor their oxygen level at home including our Union Health Minister (MoFHW, GoI). Several incidents have been reported where patients have seen sudden dip in their oxygen levels requiring immediate oxygen supplementation and hospitalisation. This led to sudden surge in demand of oximeter as it is a critical early warning medical equipment.

## Role of Oximeter in COVID-19 Pandemic

During the first wave of COVID-19, the demand for oximeter increased and so did its price. To address this issue, an order was passed by National Pharmaceutical Pricing Authority (NPPA) to regulate the price based on MRP. It is only until second wave that the demand for oximeter increased manifolds due to its key role in monitoring oxygen saturation level. The demand increase was a result of large number of COVID-19 positive cases and high influx of hypoxia as compared to the first COVID-19 wave.

The new guidelines by Ministry of Health and Family Welfare for rural, peri-urban and tribal areas lay special emphasis on oximeter and thermometer. The most interesting part of these guidelines is that it put forward a case for "resource pooling and sharing" as it mentions:



“A system of providing the pulse oximeters and thermometers on loan to families with a confirmed case of COVID should be developed through ASHA/ Anganwadi workers and village-level volunteers. The pulse oximeters and thermometers should be sanitized after each use with cotton/cloth soaked in alcohol-based sanitizer”.<sup>[3]</sup>

The Ministry of Health and Family Welfare has time and again recognized the key role of oximeter as an early warning system and included oximeter et al, in COVID care kit to tackle pandemic. A tweet by the former Health Minister Harsh Vardhan emphasising on monitoring the oxygen saturation level as an important aspect of COVID-19 care also highlights its importance.<sup>[4]</sup>

## Medical Equipment brought under the definition of Drugs

Recently in February 2020, the medical equipments were brought in accordance to definition of drugs under Cosmetics and Drugs Act, 1940 through Medical Devices Amendment Rules, 2020 broadening its scope of regulation.<sup>[5]</sup>

The definition of medical equipment in Indian laws is almost same as provided by WHO except it also includes animals. It includes all instruments, apparatus, implements, machines, appliances, implants, reagents for in vitro use, software, material or other similar or related articles, intended by the manufacturers to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:<sup>[6][7]</sup>

- ☐ diagnosis, prevention, monitoring, treatment or alleviation of disease,
- ☐ diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- ☐ investigation, replacement, modification, or support of the anatomy or of a physiological process,
- ☐ supporting or sustaining life,
- ☐ control of conception,
- ☐ disinfection of medical devices,
- ☐ providing information by means of in vitro examination of specimens derived from the human body.

## The Game of MRP and Profiteering: Regulatory Lapses

In a notification published in Press Information Bureau in July 2020, the Ministry of Chemical and Fertilizers had issued directions to National Pharmaceutical Price Authority (NPPA) to specifically control prices for oxygen concentrators and pulse oximeter. NPPA had issued it to the manufacturers and had asked them to share the details of their MRP (Maximum Retail Price).

The MRP regime in India is non-transparent and is in dire need of reforms. In India, MRP has symbolic value as it does not reflect the actual market price. This has become more evident with the current COVID crisis where MRP was used as a shield for profiteering in medical equipments like oximeter.

The oximeter which was earlier available in market before second COVID- 19 wave at Rs. 900 is now being sold at Rs. 2000-3000. The catch here is that the MRP marked on the box is Rs.3500-4000.<sup>[8]</sup>

There is no set method in India to derive at the MRP. Ideally, it should be the cost of production plus profit but manufacturers are using MRP to escape the regulatory net of authorities like NPPA. The over reliance of our laws to regulate prices of packaged products and goods (non-scheduled) based on only MRP is a grave error. It makes the whole regulation process toothless and ineffective.

Last year, in June 2020, the NPPA issued a memorandum saying that the MRP cannot be increased by more than 10 % in a year. As oximeter comes under non-scheduled list, its MRP is not calculated by the method



provided in Drugs Price Control Order, 2013 (DPCO) leaving the scope of MRP manipulation at the will of manufacturers. In DPCO, 2013 the retail margin is capped at 16%.<sup>[9]</sup>

The whole regulation of non-scheduled list is based on MRP. It is shocking that there is no check as how this MRP is fixed by manufacturers. This means manufacturer can set MRP 150-250% high over and above the production cost and can keep earning super profits while escaping the regulatory radar of NPPA.

There are widely reported sub-standard 'white labelled' 'make in India' oximeter being sold in the market at quadrupled prices. The regulator has failed to establish regulatory control on the sales and availability of spurious or sub-standard oximeter; putting buyers at risk amid health crisis.

Many whole sellers sold oximeter in bulk at Rs.615-750 including 12% GST. The delivery timeline ranged between 5-10 days. The product came with one year manufacturer warranty.

## Immediate Action Required for “Once in a century crisis”

The NPPA should put a price ceiling on oximeter keeping in view public health emergency. There are two ways in which it can be done which are as follows:

- ❑ There is a need for bringing the oximeter under scheduled list of Drugs Price Control Order, 2013 (DPCO) read with Essential Commodities Act to bring down the price and curb excessive profiteering. The DPCO also provides for a method to determine ceiling price with a reasonable retail margin of 16%.<sup>[10]</sup>
- ❑ There is a need for immediate price ceiling on Pulse Oximeter under DPCO, 2013, paragraph 19, which says that “The Government can fix the ceiling price of any medicine even the non-scheduled one in case of certain extra ordinary situations or in public interest”. This provision should be timely invoked as it is indeed an ‘extra ordinary’ situation - “once in a century crisis”.<sup>[11]</sup>

It is an urgent call for the government to do the necessary and help people with whatever it can. NPPA should rise up to the task to give people a sigh of relief and ray of hope by doing what it is mandated to do.

The government must take speedy measures as it had taken for sanitizers and masks (N95 and surgical) during the onset of pandemic which significantly brought down their MRP. The regulators are mandated to check quality, availability and affordability but are missing in action. The people suffered not just because system strained under the burden of cases but also due to sheer inaction and oversight of regulatory agencies. It is a multi-facet system paralysis which requires thorough review and analysis of functioning and performance of regulatory agencies.<sup>[12][13]</sup>

The government must quickly swing into action as the number of cases may rise or there may be a possibility of third wave <sup>[14]</sup>. More new demands will pour in for oximeter, hence, its affordability and availability will be very crucial. It is imperative for people to monitor their oxygen levels and be aware of any looming dangers, if any, ensuring their overall well-being. In current situation when hospitals are flooded with patients. the early diagnosis can provide much needed respite and potentially save lives.

## Challenges in Price Determination and Possible Recourse

The DPCO Act, 1995 factored in cost based pricing mechanism while the DPCO Act, 2013 uses market based price mechanism. The challenge in front of the NPPA will be how to come at a price where a common pricing mechanism can be devised. As most of these devices or their parts are being imported, the data from Directorate General of Foreign Trade (DGFT) or Directorate General of Commercial Intelligence and Statistics (DGCIS) could help in determining their purchase value or cost to the importer. The same data of 'imported

parts' to manufacture oximeter can be used to ascertain their prices after factoring in labour cost, risk factor, etc. This can then further be used to put a price ceiling on oximeter with reasonable profits after having discussions with concerned stakeholders.



## Dwindling Incomes and rising medical cost: Challenges

The second wave of pandemic has hit hard the already ailing economy and the brunt is borne by lower income groups and the poor, the most. The shrinking middle class also poses a challenge for future socio-economic prospects of the country. As per the US based Pew Research data, 75 million Indians have slipped into abject poverty, which is 60% of the global increase with most of them belonging to middle and lower income group pre-COVID.<sup>[15]</sup>

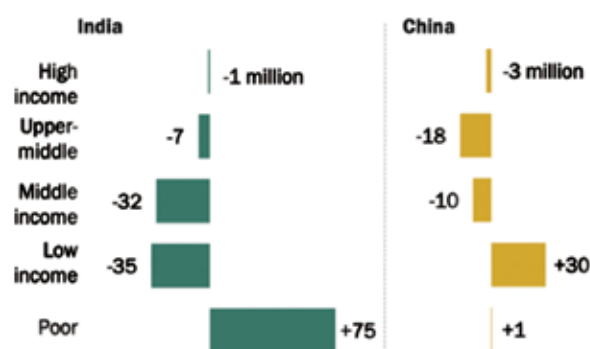
Recently CMIE data has revealed that India's urban unemployment rate has jumped to 10.7%.<sup>[16]</sup> With rising unemployment and falling income levels it is more important now than ever that regulators uphold their mandate. The NPPA was missing in action to perform its mandated functions<sup>[17]</sup>:

- ☐ To implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it.
- ☐ To deal with all legal matters arising out of the decisions of the Authority.
- ☐ To monitor the availability of drugs, identify shortages, if any, and to take remedial steps.
- ☐ To collect/ maintain data on production, exports and imports, market share of individual companies, profitability of companies, etc., for bulk drugs and formulations.
- ☐ To undertake and/ or sponsor relevant studies in respect of pricing of drugs/ pharmaceuticals.
- ☐ To recruit/ appoint the officers and other staff members of the Authority, as per rules and procedures laid down by the Government.
- ☐ To render advice to the Central Government on changes/ revisions in the drug policy.
- ☐ To render assistance to the Central Government in the parliamentary matters relating to the drug pricing.

The regulators have fallen short of upholding their mandate while 'oximeter gasped for regulatory oxygen' amid once in a century crisis. The socio- economically vulnerable sections of society are at the receiving end. The onus is on the government and its agencies like NPPA to protect people from the exploitation of profiteering. ■

### India is estimated to have seen a greater decrease in the middle class and a much sharper rise in poverty than China in the COVID-19 downturn

*Estimated change in the number of people in each income tier due to the global recession in 2020, in millions*



Notes: The poor live on \$2 or less daily, low income on \$2.01-\$10, middle income on \$10.01-\$20, upper-middle income on \$20.01-\$50, and high income on more than \$50; figures expressed in 2011 purchasing power parities in 2011 prices. The estimates show the difference in the number of people in an income tier based on pre-pandemic projections and post-pandemic estimates. The term "post-pandemic" refers to the period since the onset of the pandemic in January 2020. It is assumed there is no change in the income distribution from the benchmark year for the projection to 2020.

Source: Pew Research Center analysis of the World Bank's PovcalNet database.

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### AUTHOR



**Tilkesh Bhadala**

**(The author is a Social Activist)**