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# Regulatory Scenario of Pharmaceuticals during COVID-19 Pandemic in India

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## Abstract

In India, CDSCO controls all the activities related to importing, exporting, manufacturing, warehousing, and selling drugs, biologics, and medical devices. The CDSCO's intention to expedite the evaluation and licensing of a COVID-19 vaccine was announced in the Vaccine Notice, which was released at the start of the pandemic. After getting authorization from the CDSCO, the hospitals/medical institutions may import or produce the unapproved medicine as long as the unapproved drug is undergoing Phase-III clinical trials in India or elsewhere. CDSCO issued a notice regarding the launch of the online platform for adverse event reporting of medicines through the SUGAM portal. Under extraordinary circumstances, the CDSCO may only modify the eligibility criteria for importing drugs with a shorter shelf life if they have not passed their expiration date. Manufacturers of medical devices are no longer required to seek a manufacturing or import license before manufacturing or importing the regulated devices under the medical devices compliance orders. India's leading drug regulatory authority CDSCO permitted Covaxin and Covishield vaccines developed by Bharat Biotech Ltd. and Serum Institute of India Ltd., respectively, for restricted use in an emergency. The Subject Expert Committee's recommendations grant authorization for restricted use in emergencies ("SEC"). Manufacturers of vaccines in India must supply at least 50 percent of vaccines to the Government of India to fulfil the demand. In this review, most of the regulatory guidelines related to the import, export, manufacture, warehouse, and sale of drugs, biologics, and medical devices, especially related to COVID-19, have been discussed.

**Keywords:** COVID-19 • Emergency use authorization • Medical devices • Expedited approval • Vaccines

## Introduction

The COVID-19 pandemic has explained the loopholes in the healthcare infrastructure and made us realise that we are not prepared for such challenging situations. This Pandemic has been a real stress test to show how much extra load our healthcare system can carry. In this pandemic era, the healthcare industry is the main focus that has never been seen before; the pharmaceutical sector has played a crucial role indeveloping the COVID-19 treatments and vaccines and fulfilled the demand for essential medicines apart from COVID-19 medicines. During this epidemic, the drug regulatory authorities have worked promptly and aggressively to ensure that pharmaceutical businesses have the support they require to maintain a consistent supply of medications. The COVID-19 epidemic has presented the pharmaceutical sector with numerous problems and opportunities over the past two years. The COVID-19 pandemic has increased demand for vital pharmaceuticals like HCQ, paracetamol, vaccines, TB, insulin, and cardiac treatments. India produces 60% of global vaccines and is one of the leading makers of generic drugs [1].

Simultaneously, the business has been hampered by a lack of APIs and decreasing consumption of non-essential drugs, which has disrupted supply chains. From an annual output of only 10 lakh liters, India's hand sanitiser manufacturing capacity increased 1,000-fold to 30 lakh liters per day, during the COVID-19 outbreak, with the support of the Central and State governments. The recent COVID-19 epidemic in the nation has resulted in a surge in demand for surgical masks among healthcare personnel and the general public. The panic-buying habit of the populace increased once the government made wearing masks mandatory in public settings. The surgical mask market in India was worth $71.73 million in 2019 and is predicted to grow at a CAGR of 10.3 percent from 2020 to 2027, reaching $157.13 million. The Govt. of India hence framed some regulations and amended the existing laws through public notices and office memorandums concerning the sale, manufacture, import, and export of drugs, biologics, and medical devices [2,3].

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## Literature Review

### Notice regarding expedited approval process for COVID-19 vaccines

On March 19, 2020, CDSCO – India's Apex regulatory body released a notice regarding COVID-19 vaccine development through the expedited approval process. It states that companies having vaccines under the development phase can approach the regulatory authorities for guidance on the regulatory approval process and expedited pathways for biologicals [4].

An import license can be issued in case of anemergency without a registration certificate (Form 41), provided the central government approves it [4].

The Vaccine Notice revealed the CDSCO's desire to accelerate the evaluation and licensing of a COVID-19 vaccine, released at the start of the COVID-19 pandemic. The office memorandum gives significantly more specific guidelines, including two methods for expediting the licensing of a COVID-19 vaccine. Initially, the office memorandum released by the CDSCO states that clinical trials conducted abroad may be considered for a clinical trial application submitted under Drugs and Cosmetic Rules, 1945.

Further, the Office Memorandum declares that "depending on scientific rationale and level of completeness of evidence in human trials, Clinical trial data gathered outside of India, in addition to acceptable pre-clinical evidence, may be used to establish a shortened pathway for COVID-19 vaccination.

### Expedited process for licensing of oxygen manufacturing units

All state/Union Territory (UT) drug authorities received a notification (no. DCGI/MISC/2020/96) from the CDSCO headquarters on April 7, 2020, to cater to the needs and supply of oxygen for medical use during the COVID-19 pandemic period, premises with the capability to manufacture industrial oxygen for medical use should be granted a manufacturing license to manufacture oxygen for medical use within 24 hours of receiving the application, fees, and other requirements [5].

### Rapid response regulatory framework for COVID-19 vaccine development

The Ministry of Science and Technology, Department of Biotechnology issued an office memorandum (no. B.T./ 03/27/2020-PID) on May 26, 2020, outlining the rapid response regulatory framework for COVID-19 vaccine development. DBT has expedited the regulatory process for COVID-19 vaccine development in India, allowing manufacturers of vaccines to submit preclinical and clinical data generated outside of India for vaccine authorisation in India. The DBT has also allowed applicants to submit a parallel application to the Central Drugs Standard Control Organization (CDSCO) for consideration while Performing Preclinical Toxicity (PCT) studies based on proof of concept during the conduct of Preclinical Toxicity (PCT) research [6].

### Conduct of clinical trials during COVID-19 pandemic

The CDSCO published a notification no. DCGI/MISC/2020 (104) on March 30, 2020, regarding the conduct of clinical trials during the COVID-19 outbreak. According to the letter, patient rights, safety, and well-being are all important concerns, and decisions should be made keeping trial subjects in mind. In addition, any communication between the sponsor/Ethics Committee (EC) and the investigator on implementing protocolamendments/deviations/modifications due to the current scenario may be forwarded to Indian H.A. by E-mail or any other electronic channel.

### Circular regarding the validity of BA/BE study centers

CDSCO issued a circular (no. 7-5/2020/Misc./070) on April 30, 2020, discussing extending the validity of BA/BE study centres in response to various stakeholder concerns. It was concluded that unless the CDSCO makes an order to the contrary, registrations for BA/BE study centres that have registered or will apply for renewal of registration 90 days prior to the expiration date with all relevant papers and fees will remain valid.

### Guidelines for ethics committee released by ICMR during COVID-19 pandemic in India

On May 6, 2020, India's main regulatory body for biomedical research, the Indian Council of Medical Research (ICMR), published the National Guidelines for Ethics Committees Reviewing Biomedical and Health Research under the supervision of the COVID-19 National Ethics Committee. The ICMR Bioethics section, NCDIR Bengaluru, has fabricated this paper to encourage ethical research practices during the COVID-19 pandemic in India. The ethics committee has played a key role in conducting ethical research in India during the COVID-19 pandemic. The guidelines address broad principles, general ethical concerns, ethical review procedures, informed consent, and vulnerability.

### Letter on the extension of the who good manufacturing practice/pharmaceutical product certificate

The CDSCO headquarters sent a notification (no. 7-5/2020/ Misc./070) to all state/U.T. drug controllers on May 1, 2020. The CDSCO issues a Certificate of Pharmaceutical Product ("COPP") with certifying Indian pharmaceutical goods in other countries as part of the WHO-GMP certification program, allowing Indian companies to export their pharmaceuticals. The COPP certification that has been issued is valid for three years. The validity of certifications like the WHO GMP/COPPs, which were set to expire between March to August 2020, has been extended by six months due to the COVID-19 epidemic, ensuring the continuation of critical pharmaceutical industry activities.

## Draft regulatory guidelines for vaccine development, focusing on the COVID-19 vaccine

The Central Drugs Standard Control Organization (CDSCO) office released draft recommendations for vaccine development on September 21, 2020, focusing on COVID-19 vaccines. This 40-page guideline document covers an introduction, background, chemistry manufacturing and controls, nonclinical development program, clinical development program, and references.

In addition, the CDSCO office issued a notification on September 21, 2020, with information on the aforementioned Draft regulatory requirements. In view of the current pandemic, it was proposed that thorough vaccine development guidelines be devised so that vaccine developers could be better understood. As stated in this notice, the nature of these guidelines is dynamic and recommendatory. According to this release, stakeholders were urged to submit any comments on the proposed rules by October 12, 2020.

## Bioavailability and bioequivalence (BA/BE) studies for export purposes

CDSCO, India's leading regulatory Authority, released a notification (No. 12-09/BA-BE/2020/MISC-18/DC) regarding challenges/difficulties experienced during the conduct of BA/BE research, especially adhering to authorised protocol, related procedures, and regulatory requirements in view of the pandemic scenario. The significance of protecting trial subjects' safety, rights, and well-being was re-emphasised in this notification. BA/BE centres and sponsors were urged to conduct assessments and make the right decisions in cooperation with investigators and the ethics committee, in line with local health authority instructions and circulars to safeguard the safety and well-being of trial participants.

## Draft for the use of unapproved drugs for compassionate use

The Ministry of Health has suggested changes to the C.T. rules to allow medical colleges and hospitals to import and manufacture some unapproved drugs for the treatment of "patients suffering from a life-threatening disease or disease-causing serious permanent disability or disease requiring therapy for unmet medical need" ("Draft CT Amendment"). After gaining clearance from the CDSCO, medical colleges and hospitals may import and produce unapproved drugs as long as the unapproved drug is undergoing Phase-III clinical trials in India or abroad. Specific restrictions would be anticipated of the hospitals and medical institutions importing the unapproved pharmaceuticals; manufacturers are obligated not to sell the drugs in the open market and retain all the import/manufacture records.

## Exemption of sale license for hand sanitizer sale

On July 27, 2020, the Health Ministry published a notification under Section 26B of the Drugs and Cosmetics Act, 1940, exempting anyone from having a sale license to sell hand sanitizers ("Hand sanitizer sale notification"). The Notification was issued in response to the COVID-19 pandemic to ensure the availability of hand sanitizers. The CDSCO sent a notification to state drug authorities on March 18, 2020, encouraging them to process applications for manufacturing hand sanitizers within three working days.

According to Drugs and Cosmetic Act 1940, Hand Sanitizers come under the pharmaceutical category. Therefore, a manufacturing and sale license is required to produce and sell hand sanitizers. Beforehand sanitizer sale notification, retailers of hand sanitizers are supposed to get a license from CDSCO to sell hand sanitizers and adhere to the terms of the sale license, such as keeping proper records. But after the implementation of the Hand Sanitizer Sale Notification, retailers are only obligated to assure that the hand sanitizers are not sold after the 'Date of Expiry of Potency' as specified on the label.

## Notification regarding stock and sale of drugs, biologics used during COVID-19 pandemic

Ministry of Health and Family Welfare released a notification (no. S. O. 1511 (E)) on May 18, 2020, which states that companies indulged in vaccine development can submit a manufacturing application seeking permission to manufacture the COVID-19 vaccine during Clinical trials only. On the other hand, applicants can only sell or distribute after obtaining approval from the Health Authority (HA). It will reduce the time it takes for a local COVID-19 vaccine manufacturer to reach the market.

## Import of medical devices based on self-attested documents

According to Medical Device Rules, 2017 ("MDR"), an import license is a must before bringing medical devices into India. The applicant must notarize and apostilled certain documents as a part of the draft for an import license. Applicants can submit these documents following self-attestation under the Import Relaxation. They guarantee to send notarized/apostilled documents within four months or as soon as the situation has been 'normalized,' whichever comes first. The CDSCO may provide a provisional import license based on the self-attested evidence if the application is in order.

## Extension of time for registration certificates of manufacturing units

Pharmaceutical companies were concerned that their registration certificates were going to expire. Therefore, the R.C. notification was issued by authorities in response. In the COVID-19 pandemic, the R.C. notification aims to prevent a negative impact on pharmaceutical supplies.

To take advantage of the R.C. notification's exemption, holders of registration certificates must apply for a new registration certificate before their current one expires. The existing registration certificate will be valid for six more months after the application has been filed or until a decision on the application for a new registration certificate is issued, whichever comes first. The CDSCO provides a certificate of registration to the drug's foreign manufacturer and a corresponding import license to the drug's Indian importer for sale or distribution. Importing pharmaceuticals into India requires a valid registration certificate and an import license.

## CDSCO launched an online portal for reporting serious adverse events

On February 25, 2021, India's foremost authority, the Central Drugs Standards Control Authority ("CDSCO"), issued a notice regarding the launch of an online platform for adverse event reporting of drugs through the SUGAM portal. Under the C.T. Rules, an SAE is defined as any untoward medical event that results in death, permanent disability, or hospitalization of the trial subject. CDSCO fabricated the SUGAM portal in 2015 as a part of the e-governance module of the government of India. The primary utility of the SUGAM portal is to provide manufacturers, importers, and distributors to apply for mandatory registration licenses as per India's fundamental drug control legislation, the Drugs and Cosmetics Act, 1940 ("D and C Act"). SAE reporting is done *via* the SUGAM portal after the official notification is issued by the government.

With effect from 14.03.2021, the CDSCO is not accepting the serious adverse event reporting of drugs through physical mode. If a serious adverse event occurs during clinical trials of drugs, the investigator and sponsors of the event are bound to send details to the primary regulatory authority CDSCO. Apart from this, the sponsor is also compelled to provide free medical facilities to the trial subject in the case of SAE.

## Relaxation of residual shelf life for drugs importation

CDSCO has issued several circulars allowing pharmaceuticals with less than 60 percent residual shelf life to be imported. The most recent circular ("Import Circular") extends the deadline to April 30, 2022.

According to the Drugs and Cosmetics Act, 1940 and D and C rules, 1945, drugs imported into India must have at least 60% of their residual shelf life remaining at the time of import. The regulatory authorities provisionally modify the requirements during the pandemic. Under extraordinary circumstances only, the CDSCO may modify the eligibility criteria for importing drugs with a shorter shelf life if they have not passed their expiration date. Amid the COVID-19 epidemic, the import circular was established to assure the country's sustained supply and availability of medications. The CDSCO has issued a series of regulatory reliefs, including the Import Circular. The CDSCO also extended the validity of (1) Registration certificates and import permits, as well as (2) GMP certificates issued during the epidemic. Relaxations have proven to be a welcome step to continuing business in this difficult circumstance.

## Revision of drug ceiling prices

The Department of Pharmaceuticals amended the drug price control order through a gazette notification in 2021, para 18 clause I of DPCO reveals that the ceiling price of formulations specified in schedule I must be revised every five years after the drug ceiling price is determined.

Only those formulations mentioned in schedule I of DPCO are scheduled formulations, while those not mentioned come under non-scheduled formulations. Only scheduled formulations have a ceiling price of more than 10 percent increment in the MRP (Maximum Retail Price) of any formulation, whether scheduled or non-scheduled, which is not allowed. Para 18 of DPCO addresses adjusting ceiling prices of scheduled formulations according to moving annual turnover per year.

## Government is in the process of notifying the updated NLEM

NLEM, 2021, National List of Essential Medicines, was revised by the expert committee and recommended to MOHFW in September 2021.

The National List of Essential Medicines is revised every five years; NLEM was the last updated; it includes price regulation of essential medicines, which began in 2016 and finished in 2021. The MOHFW will now review and approve the NLEM 2021. Standing Committee was introduced in the year 2019 NLEM named SCAMHP, Standing Committee on Affordable Medicines and Health Products to modify and evaluate NLEM, which recommended including medical devices and other relevant general public health and hygiene products in NLEM.

The switch from the trade margin rationalization technique is depicted in NLEM 2021. Non-scheduled formulations are also included under the trade margin rationalization technique based on the Pharmaceuticals Report of the Committee on High Trade Margins in Drug Sales, 2016. There has been a recent consensus toward adopting TMR for non-scheduled pharmaceuticals. In the case of anti-cancer drugs, medical devices, and oxygen concentrators, the NPPA has used this clause to limit prices in the public interest under unusual circumstances. However, the proposed NLEM 2021 list includes drugs like Azacytidine, Fulvestrant, and Irinotecan HCl Trihydrate, which were already subject to trade margin rationalization.

## Complaints about manufacturer's refusal to sell drugs based on commercial interests are not within the NPPA'S jurisdiction

An office memorandum is released by NPPA on November 22, 2021, declaring that a drug manufacturer's: a) Denial to designate a person as a dealer and b) NPPA has no power over those who refuse to sell pharmaceuticals directly and insist on getting them *via* a licensed dealer. NPPA is not liable for commercial disputes between the dealer and the pharmaceutical company. Suppose the company's reluctance to supply the drugs has a negative impact on the public interest in that case, The NPPA has the power to make directives that

either: a) Assure adequate drug supply or b) Penalize the drug's manufacturer. Manufacturers and distributors are prohibited under DPCO paragraph 28 from delaying or refusing to distribute the medicine to any dealer lacking valid reason. If this provision is violated, the NPPA may impose orders to ensure that the medication is available to the public in sufficient quantities.

## Relaxation in licensing requirements of medical devices

Three orders dated December 28, 2020, April 18, 2021, and November 03, 2021,"Medical Devices Compliance Orders," were issued by the Central Drugs and Standard Control Organization (CDSCO), India's main drug regulatory Authority. The CDSCO first eased the manufacture and import licensing procedures for nebulizers, blood pressure monitoring devices, digital thermometers, and glucometers through the Medical Device Compliance Order. After that, makers and traders of implanted devices, C.T. scan equipment, and MRI equipment were given a similar "Notified Devices" reprieve. As per the medical device compliance order, the existing medical device manufacturer can produce and import medical devices until June 2022. Manufacturers of medical devices are no longer required to seek a manufacturing or import license prior to manufacturing or importing the regulated devices under the medical devices compliance orders. Multiple processes are involved in acquiring a manufacture and import license, including inspection of manufacturing facilities and document scrutiny. CDSCO received many applications from manufacturers of medical devices to review. Therefore, medical compliance orders are issued by the authority. Importers/manufacturers must have a license. It must be imprinted on the label of a medical device manufactured in India from July 31, 2022. All the applications lacking the required documents submitted before April 2022 must be completed.

## Price capping of medical devices

The trade margin of medical devices, including pulse oximeters, nebulizers, Glucometer, and blood pressure monitoring machines, is fixed at 70 percent by the regulatory authority which controls the price of pharmaceuticals and medical devices, the National Pharmaceutical Pricing Authority (NPPA), on July 13, 2021. The Maximum Retail Price (MRP) of these medical devices is fixed by adding a 70 percent trade margin to the price at which the distributor purchases them from the manufacturer. The trade margin is touching the peaks before the issuing of this order. Around 70 percent of trade, margins were observed prior to this order. The manufacturers of these five medical products selling at a greater price than the new MRP structure must lower their pricing; otherwise, they must face serious consequences. "Under the provisions of the drugs (Prices control) Order, 2013, manufacturers who do not comply with the MRP so computed shall be liable to deposit the overcharged amount along with 15% interest per annum from the date of price increase in addition to a penalty of up to 100% of the overcharged amount." During emergencies, paragraph 19 of DPCO empowers NPPA to limit the cost of pharmaceuticals not present in NLEM.

## Voluntary registration period for medical devices and relaxation in ISO compliance

"CDSCO issued voluntary registration notice" on September 28, 2021, which reveals that the voluntary registration period of medical devices, would end on September 30, 2021. But "Draft amendment rules" issued by MOHFW on October 12, 2021, proposed for the extension of submission of ISO 13485 for medical device registration. Once enacted, the draft rules will ease the requirements for medical device registration by providing an extra period to fulfil the ISO 13485 standard, which is a necessity for the registration of medical devices. According to the draft rules, the MDR should be amended to allow an applicant to obtain provisional registration for a medical device by submitting an undertaking by November 30, 2021, announcing that by May 31, 2022, an ISO 13485 compliance certificate will be obtained by the applicants. The provisional registration will be regarded as cancelled if the application does not receive an ISO 13485 compliance certificate within this time limit.

## Emergency use authorization of vaccines in India during COVID-19 pandemic

India's leading drug regulatory authority CDSCO permitted Covaxin and Covishield vaccines developed by Bharat Biotech Ltd and Serum Institute of India Ltd, respectively, for restricted use in an emergency through a notification dated January 3, 2021.

The Subject Expert Committee's recommendations grant authorization for restricted use in emergencies ("SEC"). The SEC comprises experts in immunology, pharmacology, microbiology, etc.

In India, there is no specific statute governing emergency use authorization. However, the second schedule of C.T. rules, 2019 have provision for expedited approval and review of pharmaceuticals. As a result, relaxations and shortened procedures may be considered in cases of unmet medical needs or calamities in India. If significant efficacy with a specified dose is achieved in Phase II clinical trials, CDSCO may consider granting marketing approval based on Phase II clinical trial results. Depending on the stage of drug development, different types of data will be required to demonstrate a drug's ability to fulfil an unmet medical need. If a vaccine is granted limited use authorization, it must meet specific regulatory requirements, such as submitting data confirming safety and effectiveness and continuing clinical studies in India.

### Emergency use authorization of foreign-manufactured vaccines in India

The CDSCO made recommendations on April 15, 2021, defining the criteria for authorizing foreign-produced COVID-19 vaccines ("Guidance") in India. NEGVAC proposed the approval of vaccines already approved in the USA, U.K., and European Union and listed in the WHO emergency use list, considering the C.T. rules. According to the guidance, if a local safety and immunogenicity review is completed, foreign-produced vaccines that have gained approvals from the above listed may be approved by the DCGI for limited use in emergencies. The first 100 recipients must be observed for one week to assess the safety results. Furthermore, manufacturers are obligated to post-marketing surveillance within 30 days from the approval. Through its Indian subsidiary, a foreign producer may submit an application for clearance through the SUGAM portal.

The CDSCO must receive an application from global firms requesting to import the vaccine into India. Import license, registration certificate, and application for approval are necessary statutes required by a foreign company to import vaccines in India. After receiving an import license and registration, The National COVID-19 Vaccination Program requires permission from the Central Drugs Laboratory ("CDL") for every batch before it can be used to generate safety data. The CDSCO can approve the vaccine's usage once the safety data has been verified. To fulfil India's high demand, the Guidance was released to promote the import of foreign vaccines by extending the advantage of restricted emergency use formerly offered to indigenous vaccines.

## Discussion

### Guidelines for import of COVID-19 vaccines

On May 4, 2021, the CDSCO announced rules defining the process for commercial firms wishing to import COVID-19 vaccines into India. Applicants intending to import vaccines that have not yet been licensed in India must get approval for the vaccination before importing it. In April 2020, the CDSCO issued recommendations on giving accelerated clearance for COVID-19 vaccines approved in other countries [7]. The importer may import vaccines that have been approved in India in compliance with the "D and C Act, 1940". CDSCO promised to grant import licenses for vaccines within three days already approved by USFDA, EMA, and MHRA, Manufacturers of vaccines in India must supply at least 50 percent of vaccines to the Government of India to fulfil the demand.

Private entities are currently having difficulty obtaining vaccines due to the requirement that domestic vaccine makers provide the Central Government with 50% of their output. The Guidelines should help enhance the import of a larger range of vaccines that would otherwise be unavailable in India and allow commercial enterprises to import vaccines from outside, increasing India's overall vaccine supply.

### Case studies during COVID-19 pandemic in India

**The rise in demand for ventilators during the COVID-19 Pandemic:** The COVID-19 outbreak highlighted significant flaws in the whole world healthcare system. The COVID-19 epidemic in India and abroad necessitated the use of ventilators. Before the COVID-19 pandemic, India had only eight ventilator manufacturers, having a capacity of around 3360 ventilators per year. Nine new firms entered the market during the COVID-19 crisis, bringing India's annual manufacturing capacity to 396,260. In Gujarat, Max Ventilator increased manufacturing and updated its in-house R and D center.

**Falsified ventilators entered the market:** At least 237 out of the 320 ventilators obtained under the PM CARES Fund at the three government medical schools are faulty and non-functional as COVID-19 cases continue to rise in Punjab, putting the province's medical infrastructure to the test.

Jyoti CNC Automation's ventilator systems were also discovered to be inoperable; the company's representatives are obligated to come to the premises where ventilators are installed and found that the ventilators are missing oxygen connectors; this was the main reason behind not working ventilators.

In 2020, the City of Punjab received 809 ventilators, 532 of which were installed and 277 of which were left unattended. Uttar Pradesh received 1,900 ventilators, Karnataka received more than 200 ventilators, and Gujarat received 3,400 ventilators. PM CARES Fund raised a total of Rs. 2,000 crores for the supply of ventilators at government-run hospitals across the country. Provided ventilators are considered to be poor in several states. The ventilators provided in the Gadag area were of low quality, and the oxygen connectors and sensors were missing, preventing them from being utilised. As a result of inadequate ventilators, several individuals have died. The ventilators provided by several manufacturers appeared to be operating. Still, they were kept neglected and unused by hospital management, who blamed the government for supplying fake ventilators for no purpose. Even though some ventilators were not working, not all of them were fabricated.

Companies juggled ventilator software: Two industry workers reported that the manufacturer tampered with the ventilators' software to conceal their poor performance. The device had been tampered with to show a larger pumping oxygen concentration than what was actually present. This was discovered when physicians at J.J. Hospital in Mumbai noticed inconsistencies between real performance and what was displayed on the gadget. The hospital received around 39 AgVa ventilators as a result of generous gifts. St. George Hospital acquired 42 AgVa ventilators. According to a statement made by a prominent doctor at J.J. Hospital, the highest level of percentage of inspired oxygen ($FiO_2$) didn't imply genuine delivered $FiO_2$ to the patient's lungs because the patient's saturation level was not maintained.

Ram Manohar Lohia Hospital, situated in Delhi, was also the victim of such an incident. Ventilators supplied by AgVa were susceptible to malfunction and failed to satisfy crucial parameters; they could not produce a required level of $FiO_2$% and failed to meet the demand of severely ill patients admitted to ICUs. At J.J. Hospital, one of the ventilators set up for testing failed after only 5 minutes. Seating, restlessness, and tachypnea were noted in the ventilator-connected patients. Several hospitals rejected AgVa ventilators because they couldn't replace high-end, ICU-grade ventilators. Two of AgVa Healthcare's workers claimed that software was manipulated to disguise device failures, but the company denied it. The AgVa ventilators supplied, according to the J.J. Hospital, were different, and older models of the ventilators were delivered. AgVa Healthcare offered the most recent equipment model following multiple ventilator complaints and dispatched engineers to hospitals to ensure correct ventilator installation.

**Falsified oximeters captured the market:** Various defective blood oxygen meters were introduced into the market during COVID-19, causing public outrage. The incorrect readings of oximeters have caused alarm among the public, prompting many to hurry to hospitals, where their oxygen saturation was confirmed to be normal. The sale of fingertip pulse oximeters was inspected by inspectors from the Drug Control Department in Thiruvananthapuram. The oximeters were discovered violating the Medical Devices Rules of 2017.

It was revealed that a company in the Anayara district was selling oximeters for Rs 2,499 that did not comply with medical equipment rules. Inspectors from the Kerala Drug Control Department blocked the sale of oximeters worth Rs 20 lakh and Rs 23 lakh, respectively, in Kozhikode and Malappuram. It was determined that these oximeters lacked basic information, including the address, manufacturing date, manufacturer's name, and batch number [8]. According to authorities, a rise in demand for oximeters has been noted as a result of the increase in COVID-19 instances; As a result, there has been a rise in the selling of substandard products in the market.

**Medical equipment procurement from different countries due to a shortage during the COVID-19 pandemic in India:** China has provided India with various APIs, medications, and equipment for COVID-19 treatment. To accommodate the rising demand during the epidemic, China has bought over 60,000 oxygen concentrators. Until late April 2021, China provided over 21.48 million masks, 5,000 ventilators, 21,569 oxygen concentrators, and 3,800 tons of medications. On May 2, 2021, China's Fosun Pharma and Gland Pharma sent medical protective equipment to several Indian states, including 100,000 masks, 150 ventilators, and 20,000 oxygen concentrators. UNICEF has also stepped up to assist India by delivering life-saving supplies. To help India fight against COVID-19, they sent medical kits, diagnostic test kits, oxygen concentrators, personal protection kits, nasal cannulas, COVID-19 testing kits, and other supplies. They also helped acquire and install 25 oxygen stations and 70 thermal scanners.

The need for diverse medical equipment has arisen due to the epidemic, resulting in a nationwide scarcity. As a result, numerous deceptive vendors have joined the market, offering substandard/fake items under various company names to make money at the expense of people's lives. Doctors encouraged patients to utilize nebulizers and humidifiers while also alerting them about fraudulent items in the market. BPL Medical Technologies is an established oxygen concentrator producer in India. Scammers have been caught selling fake oxygen concentrators that claimed to be manufactured by BPL. They have also been detected selling oxygen concentrators for more than the real cost of the equipment when paid in advance online. After identifying the fraud occurrences, the company issued the pricing list of oxygen concentrators. It stated, "Please note that only the authorized sales channels of BPL do not exceed the price levels are allowed for sales." Furthermore, the corporation was committed to pursuing legal action against those selling counterfeit oxygen concentrators. Many people have also been arrested for selling canisters, oxygen concentrators, and oxygen cylinders at prices higher than the manufacturer's recommended retail price.

It was also discovered that several of the critical pharmaceuticals required for COVID-19 treatments, such as Remdesivir, Fabi-Flu, and others, are black-marketed in various regions of the nation. Thanks to various unlicensed and unregulated websites, people can obtain medications without prescriptions. Various con artists used these sites to peddle their bogus items, including drugs and endangering people's lives. Different nations, including Australia, China, Germany, the United Arab Emirates, the United Kingdom, and others, have stepped up to assist India in alleviating the oxygen crisis in hospitals. According to the Directorate General of Foreign Trade (DGFT) statement, the Indian government permitted the importation of oxygen concentrators for personal use from April 30, 2021. Due to increased COVID-19 instances in various parts of the country, people are scrambling to get medicine, masks, oxygen cylinders, oxygen concentrators, PPE kits, and other life-saving items. Unfortunately, this has enhanced the sale of counterfeit drugs and other critical COVID-19 infection preventive and therapeutic supplies.

People from numerous states have been detained for selling counterfeit Remdesivir vials, in the name of Remdesivir [9]. People were selling medications refilled with saline or vials filled with liquid paracetamol.

India is one of the world's leading producers of counterfeit drugs, according to OECD and E.U. Intellectual Property Office assessments. India, renowned as "Pharmacy to the World," is also a major player in developing numerous drugs and vaccines to treat COVID-19. The World Health Organization (WHO) created a global surveillance system and monitoring system in 2013 to encourage the reporting of SSFFC medicinal goods (substandard, spurious, fraudulently labelled, falsified, and counterfeit medical items).

The pharmaceutical security institute observed a 69 percent increase in counterfeiting incidents in the previous five years. The absence of anti-tampering, traceability and anti-counterfeiting measures is one of the key reasons for such actions, as is the prevalence of bogus medical items in the market. Other legal and administrative limitations include ineffective administrative actions, an insufficient legislative framework, a lack of brand and consumer awareness, the government's unwillingness to address the issue, a fragmented distribution channel, and systemic loopholes.

## Conclusion

The COVID-19 pandemic has dominated regulatory changes in the pharmaceutical industry. A lot of regulatory revisions were made through public notices and office memorandums rather than announcements in the Official Gazette, which is another trend that emerged. In addition, several of the notifications were issued under Section 26B of the D and C Act, which gives CDSCO the authority to control, regulate, or prohibit the manufacturing of medicine in the public interest. These options are faster than modifying the legislation for a limited time and indicate the regulator's response to stakeholder concerns. The COVID-19 pandemic era witnessed a rapid increase in the demand for medical devices. As a result, bogus and unauthentic medical devices were sold in the market with an unreasonable price hike. The government was also helpless to control the situation because there was a large gap between the demand and supply of medical devices. On the one hand, the COVID-19 Pandemic Era has deviated the general public's mindset toward using medical devices in day-to-day life. On the other hand, it has also drawn the attention of regulatory authorities to make more stringent regulations for the manufacture, sale, import, and export of medical devices. As a result, the medical Devices Rules framed in 2017 and enacted from 1 Jan, 2018 were also highlighted. Hence there is a demand to reconsider the regulations and amend the penalties for offences concerned with medical devices.

## Conflict of Interest

The authors do not have any conflict of interest.

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