

Pharma & Healthcare Update

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COVID-19 AND VACCINES REGULATORY UPDATE: THE STORY THUS FAR

The outbreak of the COVID-19 pandemic has created a significant impact on the healthcare and pharmaceutical industries. The past year in India has seen uncertainties with the second wave and shortage of vaccines. In the light of this, there has been increased regulatory focus on handling the crisis and providing relaxations to the industries.

In this update, we have provided a brief overview of the regulatory developments in 2021 advanced in the light of COVID-19 for the regulation of key Covid-19 management products and vaccines:

RESTRICTED USE AUTHORISATION OF VACCINES

The Drugs Controller General of India ("DCGI") who heads the Central Drugs Standards Control Authority ("CDSCO") – India's apex drug regulator approved two vaccines- Covishield and Covaxin developed by Serum Institute of India and Bharat Biotech for restricted use in emergency situations through a notification dated January 03, 2021¹. Subsequently, vaccines for use in under eighteen population have also been considered for restricted use authorization.²

The approvals for restricted use in emergency situations are based upon the recommendations of the Subject Expert Committee ("SEC"). The SEC consists of people with domain knowledge in fields such as pulmonology, immunology, microbiology, pharmacology, paediatrics, internal medicine, etc.

In India, there is no specific provision which lays down emergency use authorization. Instead, the New Drugs and Clinical Trials Rules, 2019 ("CT Rules") provide for the evaluation and process of accelerated approval under Second Schedule. Accordingly, relaxations and abbreviated procedures may be considered in instances of unmet medical need or disasters in India. If the remarkable efficacy is observed with a defined dose in the Phase II clinical trial of investigational new drug for the unmet medical needs of serious and life threatening diseases in the country, it may be considered for grant of marketing approval by the CDSCO based on Phase II clinical trial data. The type of information needed to demonstrate the potential of a drug to address an unmet medical need will depend on the stage of drug development.

If a restricted use authorisation is granted to a vaccine, then the approval is generally subject to certain regulatory requirements such submission of data demonstrate safety and efficacy and continuation of clinical trials in India.

GUIDANCE FOR EMERGENCY APPROVAL OF FOREIGN PRODUCED COVID-19 VACCINES

The CDSCO issued guidance on April 15, 2021³ laying down the conditions for grant of approval of foreign produced COVID-19 vaccines ("Guidance").

The Guidance has been issued based upon the recommendation of the National Expert Group of Vaccine Administration for COVID-19 ("NEGVAC"). The NEGVAC recommended the approval of vaccines which have been listed in the World Health Organisation Emergency Use Listing and/or approved in United States of America, United Kingdom, European Union and Japan in accordance with Second Schedule of the CT Rules.

The Guidance lays down that foreign manufactured vaccines with prior approval from the abovementioned jurisdictions may be granted authorisation for restricted use in emergency situations from the DCGI based on the condition that local safety and immunogenicity study is carried out. For this, observation of the first 100 beneficiaries for seven days to assess safety outcome must be undertaken. Further, post marketing clinical trials must be compulsorily carried out by the manufacturers within thirty days of such approval. An application for seeking approval may be made through the SUGAM Portal by a foreign manufacturer through its Indian Subsidiary in accordance with Drugs and Cosmetics Act, 1940 ("D&C Act") and Drugs and Cosmetics Rules, 1945 ("D&C Rules").

A foreign manufacturer proposing to import the vaccine into India may apply along with bridging trial protocol, import registration certificate, application for import license and the application for permission for restricted use in emergency situation to the CDSCO. Once an import license and registration is granted, a further approval from the Central Drugs Laboratory ("CDL") for every batch is required before usage as per the National Covid-19 Vaccination Program to generate safety data. On satisfying itself upon the safety data, the CDSCO will authorize the use of the vaccine.

Subsequently, on June 01, 2021⁴ in view of the object and increasing demand the CDSCO exempted the requirement of testing of every batch by the CDL if the vaccine has been certified and released by the national control laboratory of the country of origin.

The Guidance was issued with a view to encourage the import of foreign vaccines by extending the benefit of

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GUIDELINES RELEASED FOR IMPORT OF COVID-19 VACCINES BY PRIVATE ENTITIES

The CDSCO issued guidelines on May 04, 2021⁵ outlining the process for private entities to import COVID-19 vaccines into India ("**Guidelines**").

For vaccines that are not approved in India yet, the applicant wishing to import the vaccine is required to obtain approval for the vaccine prior to import. The CDSCO in April released guidance on providing expedited approval for COVID-19 vaccines approved in foreign jurisdictions. For vaccines that have been approved in India, the importer may import the vaccine in accordance with the D&C Act. The CDSCO (through previous notices) has committed to granting import licenses in just three days for import of COVID-19 vaccines that have been imported in specified foreign jurisdictions.

Under India's National COVID-19 Vaccination Strategy, vaccine manufacturers are required to supply at least 50% of vaccines manufactured in India to the Central Government. However, the imported vaccines may be utilized entirely in the private sector.

The Guidelines aim to enhance the role of private entities to supplement India's efforts to carry out the world's largest vaccination program. Presently, due to the requirement for domestic vaccine manufacturers to supply 50% of their output to the Central Government, private entities were struggling to procure vaccines. The Guidelines should help increase the overall supply of vaccines in India by (i) allowing the import of a wider range of vaccines which would otherwise not be manufactured in India, and (ii) allowing private entities to import vaccines from abroad.

PRICE CAP ON OXYGEN CONCENTRATORS AND OTHER COVID-19 MANAGEMENT DEVICES

The National Pharmaceutical Pricing Authority ("**NPPA**") – the regulator responsible for controlling the prices of drugs and medical devices – issued orders on June 04, 2021,⁶ and July 14, 2021⁷ capping the trade margins of oxygen concentrators, pulse oximeter, blood pressure monitoring machines, nebulizer, digital thermometer and glucometer at 70% ("**Trade Margins Order(s)**"). The trade margins for oxygen concentrators will be capped till May 31, 2022.⁸ While for other devices, the trade margins will be capped till January 30, 2022.

The Trade Margins Orders have been issued under Paragraph 19 of Drug Price Control Order ("**DPCO**") which empowers the NPPA to cap prices of drugs and medical devices in public interest. The maximum retail price ("**MRP**") of the above-mentioned devices is now required to be calculated by adding a 70% trade margin to the price at which the distributors procure the devices from the manufacturers. The 'price to distributor' i.e. the price at which the distributor procures the medical device from the manufacturer is calculated by dividing the sum of net sales realized in respect of the medical devices from all channels by the total quantity of the product sold during the preceding period as specified in the applicable Trade Margins Order.

The NPPA has stated that the trade margin capping has been issued since the above-mentioned medical devices are critical for COVID-19 management and must be made available to the public at reasonable prices. The NPPA has noted a high margin to the manufacturers and importers of these medical devices, therefore necessitating price-capping in the interest of public.

RETAIL PRICE HIKE OF PRICE REGULATED MEDICAL DEVICES PERMITTED AFTER EXPIRY OF TAX CONCESSION PERIOD

NPPA has issued an Office Memorandum dated September 30, 2021 ("**Office Memorandum**")⁹ granting permission to the manufacturers of oxygen concentrators, pulse oximeter, infrared thermometer and digital thermometer to raise the Maximum Retail Price ("**MRP**") post the expiry of the Goods and Services Tax ("**GST**") concession period for COVID-19 pandemic-related medical devices.

The Office Memorandum is only applicable to medical devices which are price regulated under Paragraph 19 of DPCO through the Trade Margins Orders. The revised MRP of Price-Regulated Medical Devices should commensurate with the increase in the GST Rate, subject to the actual payment of the GST.

Manufacturers and marketers of Price-Regulated Medical Devices are required to submit the revised price list to their distributors and retailers in addition to the NPPA. The Price-Regulated Medical Devices shall continue to be monitored under Paragraph 20 of DPCO which permits revision of MRP annually on the condition that the increase in price is not above ten percent of the MRP.

The MRP shall be revised in conformity with the general guidelines on price fixing issued by the NPPA on April 13, 2016 ("**Guidelines**").¹⁰ The Guidelines require manufacturers of medical devices to revise MRP of all available stock for which price has been fixed or revised by the NPPA. Submission of revised price lists to the retailer is also sufficient to prove compliance under these Guidelines.

CONCLUSION

The past year has seen multiple milestones in the COVID-19 immunization campaign. The accelerated approval process has enabled the approval of six vaccines. This has directly contributed to contain rampant spread of the virus. While, the CT Rules and the D&C Act and Rules provide for regulatory procedures, the notices and the guidance have substantially facilitated the smooth implementation of these provisions.

Further, as we proceed towards recovery from the pandemic, the regulators are shedding the relaxations previously provided for ensuring continuity of supply of drugs and medical devices and to cater to emerging needs. For 2022, we forecast a positive pull around for the pharma and medical device industry however, the regulators will sprint to tighten the noose around them.

¹ Press Statement dated January 03, 2021, available at:

https://www.icmr.gov.in/pdf/press_release_files/HFW_DCGI_emergency_use_authorisation_03012021_2.pdf

² Press Statement dated December 01 2021, available at: <https://pib.gov.in/PressReleasePage.aspx?PRID=1778842>

³ Guidance for Approval of COVID-19 Vaccines, available at: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/notice15april21.pdf

⁴ Guidance for Approval of COVID-19 Vaccines, available at:

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzI4Mg==

⁵ Guidance on Import of Vaccine by Private Sector on Any Person, available at:

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzE3Nw==

⁶ Order Issued by National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers dated June 04 2021, available at: <https://www.nppaindia.nic.in/wp-content/uploads/2021/06/227375.pdf>

⁷ Order Issued by National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers dated July 14 2021, available at: <https://www.nppaindia.nic.in/wp-content/uploads/2021/07/Doc0122113158.pdf>

⁸ Order Issued by National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers dated November 30 2021, available at: <https://www.nppaindia.nic.in/wp-content/uploads/2021/12/Gazette-Notification-signed-for-Oxygen-Concentrators-30.11.2021.pdf>

⁹ National Pharmaceutical Pricing Authority Office Memorandum permitting price hike dated September 30 2021, available at:

https://medicaldialogues.in/pdf_upload/om-dated-30092021gst-impact-1-161443.pdf

¹⁰ National Pharmaceutical Pricing Authority Guidelines for implementation of prices fixed and notified under DPCO dated April 13, 2016, available at: <https://www.nppaindia.nic.in/wp-content/uploads/2019/01/fixedprice13042016.pdf>

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