Pharma & Healthcare Update

December 31, 2021

REGULATORY YEARLY WRAP 2021: PHARMACEUTICALS IN INDIA

INTRODUCTION

Over the past year and a half, the COVID-19 pandemic has posed a multitude of challenges and opportunities for the pharma industry. As India accounts for 60 percent of global vaccine production and is one of the largest producers of generic drugs,[1] the pandemic has enlarged the demand for essential drugs including HCQ, Paracetamol, Vaccines, TB, Insulin and cardiac drugs. Simultaneously, the shortage of active pharmaceutical ingredients and lowered demand for non-essential medicines has handicapped the industry and disrupted supply chains.

The Government and the drug regulator have shown a growing inclination to lend a willing ear to the industry's grievances and issue clarifications/amendments in the law to ensure that the pharma industry in the country is aided in its operation while ensuring a baseline level of compliance. In 2021, there have been significant developments in the regulation of the pharmaceutical and healthcare sector in India. The regulator has also placed an increased focus on price control with the National List of Essential Medicines ("**NLEM**") up for revision this year.

In this update we have discussed the major developments in the pharma sector in India in 2021. For understanding the various developments across the pharmaceutical and healthcare industry, refer to our updates on medical devices, healthcare, and digital health.

CDSCO INTRODUCES A MECHANISM TO REPORT SERIOUS ADVERSE EVENTS ONLINE

The Central Drugs Standards Control Authority ("**CDSCO**") – India's apex drug regulator released a notice on February 25, 2021[2] announcing the launch of a software for online submission of serious adverse event ("**SAE**") reports through the SUGAM portal ("**SAE Notice**"). An SAE is defined as any untoward medical occurrence which results in death or permanent disability, or hospitalisation of the trial subject[3] under the CT Rules. The SUGAM portal was first developed by the CDSCO in 2015 as part of an e-governance initiative to permit manufacturers, importers, and sellers to make applications online for the registrations/licenses required under the Drugs and Cosmetics Act, 1940 ("**D&C Act**") – India's primary drug control legislation. By way of this SAE Notice, the initiative has been extended to SAE reporting.

The SAE Notice states that the CDSCO will cease accepting physical reports of SAEs that have taken place during clinical trials with effect from 14.03.2021 and will only accept them through the SUGAM portal. Under the CT Rules, the investigator and sponsor of a clinical trial are also required to submit reports to the CDSCO in the event a SAE takes place during a clinical trial. Upon the occurrence of any SAE, the sponsor is also obligated to provide medical management and care to the trial subject free of cost in addition to the compensation requirements prescribed under the Clinical Trial Rules, 2019. The SUGAM portal simplifies the process of submission of SAE reports for sponsors and investigators of clinical trials.

RELAXATION IN RESIDUAL SHELF LIFE FOR IMPORT OF DRUGS

The CDSCO has released several circulars permitting the import for drugs with residual shelf life less than 60%. The latest circular grants the extension up to April 30, 2022 ("**Import Circular**").[4] The Import Circular was first issued on April 17, 2020 with subsequent circulars extending the duration of the original circulars issued on July 10, 2020,[5] December 18, 2020[6] and April 13, 2021[7], and September 13, 2021[8].

India's drug regulatory framework i.e., D&C Act and Drugs and Cosmetics Rules, 1945 ("**D&C Rules**") requires that drugs imported into India have at least 60% of their residual shelf life remaining at the time of import.[9] The Import Circular temporarily relaxes this requirement in light of the COVID-19 pandemic. However, the Import Circular states that in exceptional cases, the CDSCO may allow the import of any drug with a lesser shelf life provided such drug has not crossed the date of expiry.

The Import Circular has been issued in a bid to ensure continued supply and availability of medicines in the country amidst COVID-19 pandemic. The Import Circular is part of a series of regulatory relaxations provided by the CDSCO. Other relaxations provided by the CDSCO during the pandemic include extending the validity of (i) registration certificates and import licenses, and (ii) Good Manufacturing Practice Certificates granted under the D&C Rules. The relaxations have proved a welcome measure to ensure the continuity of business in these tough times.

DRUG CEILING PRICES TO BE REVISED EVERY FIVE YEARS

The Department of Pharmaceuticals ("**DoP**") issued a Gazette Notification to bring the Drugs (Prices Control) Third

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Amendment Order, 2021 into effect. With the Amendment, the clause (i) in the Paragraph 18 in the Drug Price Control Order, 2013 ("**DPCO**") has been notified, requiring the ceiling prices for formulations specified under Schedule I of the DPCO to be revised every five years from the date of fixing of the ceiling price of the drug.[10]

A "scheduled formulation" is a formulation listed in the First Schedule of DPCO, while all other formulations are known as a "non-scheduled formations." Scheduled formulations cannot be priced above the prescribed ceiling price.

There is no ceiling price imposed on non-scheduled formulations. However, the maximum retail price ("**MRP**") of all the drugs, including the non-scheduled formulations cannot be increased to more than ten percent during the preceding twelve months and is monitored by the Central Government.

Paragraph 18 of the DPCO 2013 deals with revision of ceiling price of scheduled formulations on the basis of Moving Annual Turnover ("**MAT**"), where it stipulates three instances in which the revision of ceiling prices should be carried out. Prior to amendment, one of the instances which mandated a price revision was when the NLEM is revised by the MoHFW or five years from the date of fixing the ceiling price under DPCO whichever was earlier.

Following the amendment, the revision of prices has been delinked from the revision of the NLEM. As a result, ceiling prices of scheduled formulations will mandatorily be revised every five years under the DPCO. The DoP has granted a one-time exemption from revision of ceiling prices under Paragraph 18 (i) of the DPCO, 2013, and to keep in abeyance the revision of ceiling prices after completion of five years term till NLEM 2021 is released by the MoHFW.[11]

GOVERNMENT IS IN THE PROCESS OF NOTIFYING THE UPDATED NLEM

The National List of Essential Medicines, 2021 ("**NLEM 2021**") has been updated by the Expert Core Committee which has been submitted to the MoHFW as of September 4, 2021.[12] It is part of the 5-year revision of the National List of Essential Medicines last updated in 2015 ("**NLEM 2015**"), which had been implemented in 2016 and ended in March 2021, regarding price regulation of the essential medicines.[13] The NLEM 2021 is to be now vetted and approved by the MoHFW. Once the MoHFW notifies the same, it will be vetted by the Standing Committee on Affordable Medicines and Health Products ("**SCAMHP**") under NITI Aayog. Based on the recommendations of SCAMHP, the National Pharmaceutical Pricing Authority ("**NPPA**")- the apex authority for drug price control in India will fix the prices of the drugs in NLEM 2021.[14]

The renewal of the NLEM happens every five years. As NLEM 2015 was due to expire, the SCAMHP was constituted in 2019[15] to revise and review the NLEM and suggest the inclusion of Medical Devices, Medical Disposables, Medical Consumables and such other products which are important for the health and hygiene of the General Public in the NLEM.

NLEM 2021 depicts shift from the trade margin rationalization approach ("**TMR**"). In the recent past, based on the Pharmaceuticals' Report of the Committee on High Trade Margins in Sale of Drugs, 2016, there has been a consensus towards adopting TMR for non-scheduled drugs. The NPPA has invoked this provision to regulate prices of anti-cancer drugs[16], medical devices[17] and oxygen concentrators[18] in the view of public interest during extraordinary circumstances. However, proposed NLEM 2021 list incorporates drugs such as azacytidine, fulvestrant, Irinotecan HCl Trihydrate etc. which were already subject to trade margin rationalization.[19]

NLEM 2021 also includes various drugs in their modified release forms in addition to drugs included within NLEM 2015, which indicates that the incremental innovations such as controlled release/sustained release, extended release, etc. have all been aggregated as 'modified releases.' However, in the absence of any specific forms being specified in the list against the drugs all modified release forms will be deemed to be included within the ambit of price control under the schedule for the notified drugs.

It remains to be seen whether NLEM 2021 will see the light of the day and be adopted into the Drug Price Control Order 2013. Unlike its predecessors, NLEM 2021 will have to withstand the review procedure of the SCAMHP and therefore likely to be subject to further revisions before it is finalised. The role played by NPPA in drug pricing may be moulded in light of the new provisions under NLEM 2021.

NPPA CLARIFIES THAT COMPLAINTS REGARDING MANUFACTURER'S REFUSAL TO SELL DRUGS ON GROUNDS OF COMMERCIAL INTERESTS IS NOT WITHIN ITS PURVIEW

NPPA has issued an Office Memorandum dated November 22, 2021 ("**Office Memorandum**")[20] clarifying that a drug manufacturer's a) refusal to appoint a person/firm as a dealer and b) refusal to sell drugs directly and demand to procure the drug from an authorized dealer shall not fall within the purview of NPPA.

The Office Memorandum states that commercial issues/terms and disputes between the dealer and the concerned pharmaceutical manufacturing company is not within the purview of NPPA. However, if the refusal to sell the drug by the manufacturer adversely impacts the public interest, then the NPPA is authorized to issue orders a) to ensure adequate availability of the drug and/or b) for prosecution of the manufacturer of the drug.

The Office Memorandum has been issued in the light of numerous complaints received by the NPPA from persons/firms seeking to become a dealer of a manufacturer and have been refused or where the person/firm has been re-directed by the manufacturer to procure drugs from an authorized dealer.

Paragraph 28 of DPCO prohibits manufacturers and distributors from withholding from sale and refusal to sell the drug to any dealer without good and sufficient reasons. In the event of violation of this provision, the NPPA may issue orders for ensuring adequate availability of the drug to the public.

CONCLUSION

The changes introduced this year have been in line with the objectives of the Government to promote India as a reliable pharmaceutical hub even during the toughest times. The import relaxation is a reassurance to for hassle-free passage of medicines into the Country in the wake of shortage of essential medicines worldwide.

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However, the changes expected to be brought through the NLEM 2021 has held the Pharma industry on a constant lookout for the revised notification in order to take active steps to be in compliance with the laws. The changes introduced to drug pricing such as price control of patented drugs, modified release forms and the shift from TMR comes in the wake of the drastic shifts anticipated in the drug pricing regulation in India. While a number of developments have been introduced in the regulation of pharmaceuticals in India, it remains to be seen how each of them will be impactful in the long-run.

– Varsha Rajesh, Tanya Kukade, Darren Punnen & Dr. Milind Antani

You can direct your queries or comments to the authors

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[1] Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Annual Report 2020-21, available at: https://pharmaceuticals.gov.in/sites/default/files/english%20Annual%20Report%202020-21.pdf

[2] Notice issued by Central Drugs Standard Control Organization dated February 25, 2021, available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Njk5NA==

[3] Rule 2(ff), CT Rules, 2019.

[4] Circular issued by the Central Drugs Standard Control Organization dated April 13, 2021, available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY1OA==

[5] Circular issued by the Central Drugs Standard Control Organization dated July 10, 2020, available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjEzMw==

[6] Circular issued by the Central Drugs Standard Control Organization dated December 18, 2020, available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Njc3Nw==

[7] Circular issued by the Central Drugs Standard Control Organization dated April 13, 2021, available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzE0NA==

[8] Circular issued by the Central Drugs Standard Control Organization dated September 13, 2021, available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY1OA==

[9] Rule 31, Drugs and Cosmetics Rules 1945.

[10] Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Notification dated August 12 2021, available at: https://pharmaceuticals.gov.in/sites/default/files/para%2018%20gazette%20notification_0.pdf (Last accessed on September 28, 2021).

[11] Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Notification dated July 19 2021,available at: https://pharmaceuticals.gov.in/sites/default/files/Para%2018%20notification%20Gazzette.pdf

[12] Shusmi Dey, 39 medicines added to list of essentials, prices to come down, Times of India (Sept. 4, 2021) https://timesofindia.indiatimes.com/india/39-medicines-added-to-list-of-essentials-prices-to-come-down/articleshow/85914265.cms

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[14] Sushmi Dey, 39 medicines added to list of essentials, prices to come down available at: https://timesofindia.indiatimes.com/india/39-medicines-added-to-list-of-essentials-prices-to-come-down/articleshow/85914265.cms

[15] Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Order dated January 21 2019, available at: https://pharmaceuticals.gov.in/sites/default/files/Constitution%20of%20Standing%20Committee%20on%20Affordable%20Medicines.pdf

[16] Notification No. S.O. 1041(E)., February 27, 2019, National Pharmaceuticals Pricing Authority, Ministry of Chemicals and Fertilizers, accessible here: https://egazette.nic.in/WriteReadData/2019/198807.pdf

[17] Order No. S.O. 2808(E)., July 13 , 2021, National Pharmaceuticals Pricing Authority, Ministry of Chemicals and Fertilizers, accessible here: https://egazette.nic.in/WriteReadData/2021/228283.pdf

[18] Order No. S.O. 2161(E).,June 03, 2021, National Pharmaceuticals Pricing Authority, Ministry of Chemicals and Fertilizers, accessible here: https://egazette.nic.in/WriteReadData/2021/227375.pdf

[19] Notification No. S.O. 1041(E).,27th February, 2019, National Pharmaceuticals Pricing Authority, Ministry of Chemicals and Fertilizers, accessible here: https://egazette.nic.in/WriteReadData/2019/198807.pdf

[20] NPPA Office Memorandum dated November 22, 2021 Regarding The Refusal To Sell Drugs By Pharmaceutical Manufacturers, accessible here:

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