Pharma & Healthcare Update

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REGULATORY YEARLY WRAP 2022: PHARMACEUTICALS IN INDIA

INTRODUCTION

The second half of the year witnessed a relatively slow movement in terms of regulatory changes in the pharmaceutical sector. The most significant of these developments is the introduction of the draft of a proposed law to overhaul the existing pharmaceutical regulation and the induction of the new National List of Essential Medicines ("**NLEM**") into drug price regulation law.

Despite the introduction of the new law, there have been some changes to the existing law in line with the Government's object to ease the screening and approval process. In this update we have discussed the key developments in the second half of 2022 in the Pharmaceuticals sector. In case you missed, do read our 2022 mid-year regulatory update covering developments from January to June in the pharmaceutical sector here.

NEW LAW PROPOSED FOR DRUGS, MEDICAL DEVICES AND COSMETICS IN INDIA

The Ministry of Health and Family Welfare ("**Ministry**") released the draft of New Drugs, Medical Devices and Cosmetics Bill, 2022 ("**Draft Bill**") for public comment in July 2022. The Draft Bill is intended to be a comprehensive legislation with provisions to regulate drugs, medical devices, cosmetics, clinical trials and online pharmacies, among others. Once enacted, the Draft Bill will replace the Drugs and Cosmetics Act, 1940 ("**D&C Act**") - India's primary drug regulation at the present.

The Draft Bill has been drafted to keep pace with changing needs, times and technology. It proposes new definitions for clinical trials, over-the-counter drugs, manufacturers, medical devices, new drugs, bioavailability studies, investigational new drugs and imported spurious drugs etc. More specifically, the Draft Bill introduces the provisions for (i) creation of Medical Devices Technical Advisory Board; (ii) creation of a Scientific Research Board for Ayurveda, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs; (iii) compensation for injury and death in clinical trial; (iv) license requirement for online pharmacies among others.

A welcome change which the Draft Bill seeks to bring about is the regulation of medical devices distinct from 'drug.' Currently, all medical devices are covered as 'drug' and regulated as per D&C Act and Medical Devices Rules 2020. The Draft Bill now intends to repeal the current laws and proposes a new definition for medical devices placing them outside the purview of 'Drugs'. Further, the Draft Bill also contains enabling provisions for the regulation of e-pharmacies.

The Draft Bill is still in the draft form and not a law. In terms of next steps, basis the comments from the public, the Draft Bill may undergo further changes before it is introduced as a bill in the Parliament for deliberation. Subsequently, it may be passed as a new law, effectively repealing the D&C Act. Currently, there is no visibility on timelines for the same.

Our detailed analysis of the Draft Bill is accessible here.

MINISTRY ISSUES NOTIFICATION TO RELAX CONDITIONS FOR EXEMPTION OF SALE LICENSE FOR LIQUID ANTISEPTICS FOR HOUSEHOLD USE

The Ministry issued a notification dated June 30, 2022 ("**Liquid Antiseptics Notification**")[2] providing a relaxation in the compliance with the conditions for exemption for liquid antiseptics for household use under Schedule K of the Drugs and Cosmetics Rules, 1945 ("**D&C Rules**") till November 30, 2022.

The Liquid Antiseptics Notification has been issued in light of the notification dated January 20, 2022[3] which originally inserted liquid antiseptics under the list of exempted drugs in Schedule K of D&C Rules. Accordingly, the exemption from sale license for liquid antiseptics for household use under the Schedule K was subject to four conditions – (a) the drugs are manufactured by licensed manufacturers; (b) the drugs do not contain any substance specified in Schedule G, H, H1, or X; (c) the drugs are sold in the original unopened containers of the licensed manufacturer; and (d) the drugs are purchased from a licensed wholesaler or a licensed manufacturer. The Liquid Antiseptics Notification exempts the sellers from condition (d) above, by adding to it, "provided that the condition (d) shall not be applicable for the drugs manufactured on or before November 30, 2022."

At the present, liquid antiseptics are regulated as drugs in India and therefore trigger license requirements for sale and manufacture. Recognising the high demand for liquid antiseptics during the COVID-19 pandemic, the Ministry has provided an exemption from the provisions mandating sale licenses under the D&C and D&C Rules to make them more accessible to the consumer. Subsequently, the Liquid Antiseptics Notification has been issued to further relax compliance with conditions to avail this exemption until November 30, 2022.

NEW NATIONAL LIST OF ESSENTIAL MEDICINES NOTIFIED AND INDUCTED INTO DRUG PRICE REGULATION

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The Ministry released the National List of Essential Medicines ("**NLEM**") 2022 on September 13, 2022.[4] The NLEM 2022 contains a total of 384 medicines of which 34 are new medicines. These include anti-cancer drugs, patented drugs, fixed dose combinations, modified release dosage forms among others.

The NLEM is a dynamic list which is updated by the Government from time to time. The first NLEM was introduced in 1996 and has subsequently been revised in 2003, 2010 and 2015. The NLEM 2022 has been revised from the last issued version from 2015 considering aspects of cost, safety and efficacy in light of use and demand for medicines in the country. NLEM 2022 contains a total of 384 medicines of which 34 are new medicines. These include anti-cancer drugs, patented drugs, fixed dose combinations, modified release dosage forms among others.

The purpose of the NLEM is to twofold- (i) ensure the availability of the drugs specified in the NLEM to primary; secondary and tertiary healthcare centres and; (ii) the list of medicines in the NLEM is notified as Schedule-I to the DPCO to enable the fixation of ceiling prices by the NPPA to increase the affordability for such medicines.

Subsequently, the Department of Pharmaceuticals has issued the Drugs (Prices Control) Amendment Order, 2022 dated November 11, 2022 ("**Amendment Order**")[5]. The Amendment Order inserts the NLEM 2022 into Schedule I of the Drugs (Prices Control) Order 2013 ("DPCO") issued under Essential Commodities Act, 1955 to regulate the prices of drugs in India. Schedule I to the DPCO contains a list of drugs ("Scheduled Formulations") which are subject to price control in India. Specifically, (a) the National Pharmaceutical Pricing Authority is authorised to ceiling price caps for Scheduled Formulations and; (b) there are restrictions on companies from undertaking annual price increases in respect of Scheduled Formulations. By way of the Amendment Order, the list of drugs contained in the NLEM 2022 will now be regulated as Scheduled Formulation.

AMENDMENT INTRODUCED TO ALLOW PARALLEL SUBMISSION OF MANUFACTURING AND MARKETING APPROVALS IN INDIA

The Ministry notified the Drugs (Seventh Amendment) Rules, 2022 on August 24, 2022 ("**Amendment Rules**")[6] for enabling the parallel submission of applications for marketing approvals and manufacturing licenses for new drugs in India.

The Amendment Rules have incorporated Section 75(3A) into the D&C Rules which provides that for grant of permission to manufacture 'new drug' for sale or distribution under the New Drugs and Clinical Trials Rules, 2019 - the clinical trials framework or the D&C Rules, an application for license to manufacture the new drug may be made under the D&C Rules parallelly. The license to manufacture for sale or distribution of the new drugs shall be granted after approval of the drug as new drug.

The above-mentioned procedure introduced through the Amendment Rules comes as part of simplifying the process of application of new drugs and reducing the timeline for approval for these applications.

The Amendment Rules have been issued after taking into consideration the various representations from the industry submitting that the entire process of obtaining new drug permission and manufacturing licence is sequential and has led to serious delays in introducing the product in the market.

UPDATES IN PRODUCTION LINKED INCENTIVE SCHEMES

The Scheme for Strengthening of Pharmaceuticals Industry, 2022 ("**SPI Scheme**")[7] was launched in July 2022. The object of the SPI Scheme is to address demands of support required to existing Pharma clusters and Micro, Small and Medium Enterprises ("**MSMEs**"), to improve their productivity, quality and sustainability. The SPI Scheme has a financial outlay of INR 500 crores and a tenure from FY 2021-2022 to FY 2025-26. It comprises of the following three components, to provide infrastructure support for pharma MSMEs in clusters and to address the issues of technology upgradation of individual pharma MSMEs:

- *Assistance to Pharmaceutical Industry for Common Facilities*

It will strengthen the existing pharmaceutical clusters' capacity for sustained growth. It pprovides for an assistance of up to 70 % of the approved project cost or INR 2 crores (whichever is lesser).

- *Pharmaceutical & Medical Devices Promotion and Development Scheme*

It is aimed at creating a database of pharma and medical device sectors and facilitate growth and development of Pharmaceutical and Medical Devices Sectors through study/survey reports, awareness programs, creation of database, and promotion of industry.

- *Pharmaceutical Technology Upgradation Assistance Scheme*

It will facilitate pharmaceutical MSMEs with proven track records to upgrade their technology. Specifically, a ccapital subsidy of 10 % on loans up to a maximum limit of Rs 10 crore with a minimum repayment period of three years may be provided. There are also aadditional subsidies and relaxations provided to SC/ST owned units which may be availed.

NDA ANALYSIS AND CONCLUSION

Once again, the changes introduced this year have been in line with the objectives of the Government to promote India as a reliable pharmaceutical hub. Notably, the Draft Bill has been momentous in terms of the willingness of the Government to recognise the gap in the regulation and on-ground operations. We look forward to witness its final coming into force and the impact on the industry. Specifically, the Draft Bill provides a mechanism towards regulating online sale or distribution of medical devices, which will be a welcome move for the industry given that sale of drugs online has been a contentious issue since 2018 when the Ministry attempted to introduce an online pharmacy licensing regime.[8]

The permissibility of parallel applications for marketing approvals and manufacturing license also simplifies the drug approval process. This amendment comes in light of representations from the industry to accelerate the regulatory approval process and enable them to bring the drugs into the market immediately after a marketing approval thereby reducing the duration of processing by 3-6 months.

The NLEM 2022 is a departure from the previous versions in terms of inclusion of medical devices and patented drugs. The NLEM has been curated in consultation with stakeholders and the list includes drugs and devices which are

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considered essential for priority healthcare needs of the majority of the population. However, the 34 new medicines have been added in the list will have negative impact on the availability of these drugs in the country since importers, manufacturers and distributors are likely to be disincentivised from supplying the listed drugs and may also lead to reduced quality. Further, NLEM 2022 appears to be detrimental to the recent approach of the government to adopt a trade margin rationalization approach as opposed to imposition of stringent price caps.

The PLI schemes are also a welcome move and encourages the domestic industry to keep upgrading in order to cater to evolving requirements across global markets. It also signifies the shift of emphasis from volume to value-based innovation and production in the pharmaceutical industry. These are likely to boost investment, encourage research and innovation and also enable the industry to develop futuristic products and ideas.

All in all, 2022 has largely been a favourable year for the industry with only minor hiccups.

– Varsha Rajesh, Eshika Phadke, Darren Punnen & Dr. Milind Antani

You can direct your queries or comments to the authors

[1]New Drugs, Medical Devices and Cosmetics Bill, 2022, accessible here: https://main.mohfw.gov.in/newshighlights-97 (last accessed on January 20, 2023).

[2]Ministry of Health and Family Welfare Notification dated June 30, 2022, accessible here: https://egazette.nic.in/WriteReadData/2022/236975.pdf (last accessed on January 20, 2023

[3]Ministry of Health and Family Welfare Notification dated January 20, 2022, accessible here: https://egazette.nic.in/WriteReadData/2022/232790.pdf (last accessed on January 20, 2023).

[4]National List of Essential Medicines 2022, accessible here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTAxMw== (last accessed on January 20, 2023).

[5]Ministry of Chemicals and Fertilizers Notification dated November 11, 2022, accessible here: https://pharmaceuticals.gov.in/sites/default/files/Drugs%20Prices%20Control%20Amendment%20Order%202022.pdf (last accessed on January 20, 2023).

[6]Ministry of Health and Family Welfare Notification dated August 24, 2022, accessible here: https://egazette.nic.in/WriteReadData/2022/238359.pdf (last accessed on January 20, 2023).

[7]The SPI Scheme Guidelines and updates can be tracked here https://pharmaceuticals.gov.in/schemes (last accessed on January 20, 2023).

[8]Drugs and Cosmetics Draft Amendment Rules, 2018; accessible at: https://egazette.nic.in/WriteReadData/2018/189043.pdf (last accessed on January 20, 2023).

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