Pharma & Healthcare Update

June 24, 2022

MID-YEAR REGULATORY UPDATE 2022: PHARMACEUTICALS IN INDIA

INTRODUCTION

The first half of 2022 has witnessed a lot of regulatory activity in the pharmaceutical sector. The sector has witnessed numerous regulatory developments to streamline the regulation of the sector including the introduction of new Indian pharmacopeia, notification on over-the-counter drugs, display of unit sale price of packages, etc.

Some of the key developments that have taken place in the first half of 2022 are captured below:

NEW INDIAN PHARMACOPEIA PUBLISHED

The Indian Pharmacopoeia Commission has published the Indian Pharmacopoeia 2022 ("**IP 2022**") to supplement the current Indian Pharmacopoeia ("**IP**") – the book of standards under the Drugs and Cosmetics Act,1940 ("**D&C Act**").[1] IP 2022 is likely to be effective from December 1, 2022. IP 2022 contains 92 new monographs, 21 vitamins, minerals, amino acids, fatty acids, 27 active pharmaceutical ingredients, 2 herbal products, 3 biotechnology derived products, 4 vaccines and immunosera for human use, 33 dosage forms and 2 blood and blood related products.

The IP 2022 also incorporates 12 general chapters on – (a) microbiological examination of Burkholderia Cepacia complex in non-sterile products; (b) approach to alternative microbiological methods; (c) design and development of biological assay and its validation; (d) subvisible particulate matter in therapeutic protein injections; (e) assay of calcium pantothenate; (f) Raman spectrometry; (g) uniformity of dosage units; (h) test for absence of mycobacteria; (i) protocol for determination of the PRP content of Haemophilus type B conjugate vaccine by HPAECPAD (j) adjuvants for vaccines; (k) elemental impurities; (l) Nitrosamine impurities. The IP 2022 also introduces general requirements for (i) therapeutic monoclonal antibodies for human use and (ii) phytopharmaceuticals.

Drugs manufactured and marketed in India are required to adhere to the standards prescribed in the Indian Pharmacopoeia. Failure to adhere to the standards specified under IP may render the drug not of Standard Quality and may result in penalties under the D&C Act.

AMENDMENT TO THE LEGAL METROLOGY RULES REQUIRES DECLARATION OF UNIT SALES PRICE ON PACKAGES

The Ministry of Consumer Affairs ("**Ministry**") amended the Legal Metrology (Packaged Commodities) Rules 2011 ("**LM Rules**")by the Legal Metrology (Packaged Commodities) Amendment Rules, 2022 ("**Amendment Rules**") requiring declaration of unit sales price on packages of pre-packaged commodities.[2] Subsequently, the Ministry released official clarification in the form of Frequently Asked Questions on LM Rules ("**FAQs**") on such requirement introduced through the Amendment Rules.[3]

The LM Rules notified under the Legal Metrology Act, 2009, regulate the packaging and labelling of pre-packed commodities in India. It places an obligation on any person intending to pre-pack for sale, distribution or delivery, to ensure the package bears certain declarations including standard weight, maximum retail price, details of the manufacturer, quantity, etc. Such declarations are important for the medical device industry to ensure quality control and standardize production processes within the industry.

The Amendment Rules require the declaration of the unit sale price per unit (g/ml/cm) in rupees (rounded off to the nearest two decimal places) on every pre-packaged commodity in addition to the Maximum Retail Price ("**MRP**"). As per the clarifications provided by the Ministry the unit sale price shall be declared on the principal display panel of the pre-packaged commodity. If a free pack is provided along with the sale pack, then the unit sale price should appear only on the sale pack. The computation of unit sale price for the sale pack would exclude the net contents/quantity of the free pack.

The Amendment Rules read along with the clarifications issued by the Ministry exempt the declaration of the unit sale price on the packages (not being drugs, fast-food items and packaged commodities sold in packages up to 10g/10ml) where such price is equal to the MRP; on wholesale packages; or in advertisements and on e-commerce websites.

The Amendment Rules will come into effect on October 01, 2022.

PROPOSED AMENDMENT TO SCHEDULE K OF THE DRUGS AND COSMETICS RULES, 1945

The MoHFW[4] has proposed an amendment to Schedule K of the Drugs and Cosmetics Rules, 1945 ("**D&C Rules**") which grants exemption to certain classes of drugs from the applicability of the provision on obtaining sale license

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under the Drugs and Cosmetics Act, 1940 ("**D&C Act**"). The proposed amendment seeks to introduce a new class of drugs to be sold 'over-the-counter' ("**OTC Drugs**") by retail under a valid license without the requirement of prescription of an RMP. The list of proposed drugs includes Antifungal, Analgesics, Decongestants, Laxatives, etc.

The exemption to sell the OTC Drugs without the prescription of RMP applies only when the pack size of the drugs being sold does not exceed the recommended doses for five days. Thus, sale of such drugs in larger pack sizes may require the prescription of a RMP.

D&C RULES AMENDED TO INCLUDE QR CODE IN API LABELLING

The MoHFW has notified the Drugs (Amendment) Rules, 2022 ("**Amendment Rules**") which amends the D&C Rules to insert a new labelling requirement for active pharmaceutical ingredients ("**API**") or bulk drugs manufactured or imported in India. The Amendment Rules will come into force on January 01, 2023.[5]

The Amendment Rules require API manufactured or imported into India to bear a Quick Response code ("**QR Code**") on its label at packaging level to store data or information readable with software application to facilitate tracking and tracing of the product. The stored data associated with the QR code to include certain minimum particulars prescribed, which include name of the API, unique product identification code, brand name, batch number, batch size, date of manufacturing, date of expiry, etc.

The QR Code labelling requirement is expected to improve tracking and tracing of drugs and would collect all drug related information in one place for easy access to individuals. It is expected to help the supply chain in maintaining security and integrity in proper storage of the API and will assist drug manufacturers to undertake quality checks during the manufacturing process.

CDSCO PERMITS IMPORT OF DRUGS WITH RESIDUAL SHELF LIFE LESS THAN 60%

The CDSCO issued a circular on May 06, 2022[6] extending the applicability of circulars previously issued, under which import of drugs with residual shelf life less than 60% were permitted. The extension is granted up to October 31, 2022 or till further orders of the CDSCO, whichever is earlier.

The circular has been issued considering the representations received by the industry and to ensure continued supply and availability of medicines in the country amid the COVID-19 pandemic. Rule 31 of the D&C Rules prohibits the import of a drug with a residual shelf life of less than 60% as on the date of import. However, in exceptional cases, the CDSCO may allow the import of any drug with a lesser shelf life before its expiry.

MOHFW RELAXES NORMS FOR STOCKPILING OF NEW DRUGS UNDER PHASE III CLINICAL TRIALS IN LIGHT OF COVID-19

TheMoHFW has issued a notification dated February 9, 2022 ("**Notification**") which relaxes the norms related to the manufacturing and stocking, sale or distribution of new drugs under phase III clinical trials, for the treatment of Covid-19 and related diseases in public interest, after obtaining permission as per the New Drugs and Clinical Trials Rules, 2019 ("**CT Rules**").[7]

The Notification has been issued in the light of COVID-19 pandemic which has resulted in infections and diseases such as Mucormycosis, etc., due to which there is an emergency to make new drugs available for the treatment/management of COVID-19 and related diseases. The Notification provides that in order to manufacture and stock a new drug for COVID-19, which is currently under clinical trial for receiving marketing authorisation, permissions from the Central Licensing Authority shall be obtained under CT Rules (i) Form CT-06 to conduct a clinical trial and; (ii) Form CT-23 for marketing authorisation. An application for license to manufacture the drug for sale or distribution may be directly made to the State Licensing Authorities under the Drugs and Cosmetics Rules, 1945 along with the permission obtained under Form CT-06 under CT Rules. The State Licensing Authorities may grant a license for sale and distribution of the new drug on the condition that the licensee shall sell or distribute the new drug after obtaining a permission under Form CT-23 under the CT Rules. In case of any inconsistency between the Notification and any rule made under the Drugs and Cosmetics Act, 1940, the Notification shall prevail in the interest of public to meet the requirements of COVID-19 emergency.

The Notification has been issued basis the recommendations of the Drug Technical Advisory Board ("**DTAB**") in its meeting held on November 8, 2021.[8] The DTAB has recommended that emergency and lifesaving drugs for COVID-19 and for conditions of similar public health importance should be marketed, sold and distributed only after approval of the clinical trials results.

DRUG PRICE REGULATOR EXTENDS THE PERIOD FOR PRICE CAP ON LIQUID MEDICAL OXYGEN AND OXYGEN INHALATION

The National Pharmaceutical Pricing Authority ("**NPPA**") – the regulator responsible for controlling, monitoring and ensuring availability and affordability of the prices of drugs - has issued a notice dated December 28, 2021 ("**Notice**") recommending that the price cap on liquid medical oxygen and oxygen inhalation may further be extended to another three months beyond December 31 or until further order, whichever is earlier, after which the issue may be reviewed again.[9]

Oxygen is a price-controlled drug since 2016. In the light of its increased demand during the COVID-19 pandemic, the notification dated September 25, 2020 notified a new lower ceiling price ("**revised price cap**").[10] Subsequently, the revised price cap has been extended by the NPPA through notices dated March 25, 2021[11] and September 23, 2021.[12] The present Notice further extends the duration of the revised price cap in the interest of public.

Paragraph 19 of the Drugs (Prices Control) Order, 2013 ("**DPCO**") – India's primary drug price control regulation enables the Government to fix ceiling prices of drug in view of extraordinary circumstances in the interest of public for a period as it may deem fit notwithstanding the wholesale price index. The revised price cap has been implemented under this provision.

CONCLUSION

Scope of judicial interference and inquiry in an application for appointment of arbitrator under the (Indian) Arbitration and Conciliation Act, 1996
September 22, 2024

The pharmaceutical sector has experienced numerous regulatory developments in the first-half of 2022 with additional requirements of labelling introduced for packages and display of QR code in API labelling, relaxation on import of drugs and others. The pharmaceutical sector is continuously evolving with active regulation of the pharmaceutical industry being underway, we are yet to see the implementation of the developments.

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

You can direct your queries or comments to the authors

[1] Accessible at: https://www.ipc.gov.in/images/Salient_Features_of_IP_2022.pdf (Last accessed on June 06, 2022)

[2] Accessible at: https://consumeraffairs.nic.in/sites/default/files/uploads/legal-metrology-acts-rules/GSR226.pdf (Last accessed on June 06, 2022)

[3] Accessible at: https://consumeraffairs.nic.in/sites/default/files/file-uploads/latestnews/LM_FAQs.pdf (Last accessed on June 06, 2022)

[4] Notification issued by MoHFW dated May 25, 2022. Accessible at: https://egazette.nic.in/WriteReadData/2022/236010.pdf (Last accessed on June 06, 2022)

[5] Accessible at:

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

num_id=ODEyMg== (Last accessed on June 09, 2022)

[6] Circular issued by Health Ministry, available at:

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

num_id=ODM2NA== (Last accessed on June 06, 2022).

[7] Accessible at: https://egazette.nic.in/WriteReadData/2022/233278.pdf (Last accessed on June 08, 2022)

[8] Accessible at:

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?

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[9] Accessible at: https://www.nppaindia.nic.in/wp-content/uploads/2021/12/Oxygen_English.pdf (Last accessed on June 09, 2022)

[10] Accessible at: https://www.nppaindia.nic.in/wp-content/uploads/2020/09/222006-1.pdf

[11] Accessible at: https://www.nppaindia.nic.in/wp-content/uploads/2021/03/8_Engl_Oxygen.pdf

[12] Accessible at: https://www.nppaindia.nic.in/wp-content/uploads/2021/09/English_Oxygen.pdf