Pharma & Healthcare Update

October 04, 2023

REGULATORY UPDATE 2023: PHARMACEUTICAL AND MEDICAL DEVICES SECTOR IN INDIA

INTRODUCTION

The developments in the pharmaceutical and medical devices sector have experienced a steady growth in the first half of 2023 with trends indicating an increased focus on research and development and innovation in the sectors.

The most important and notable development in the first half of the year are the amendments to the income tax regime. In an effort to tighten the noose around the tax deduction at source ("**TDS**") regime, the Government of India ("**Government**") has introduced new penalty provisions. Given the current legal regime for drug marketing in India, these amendments have direct impact on pharmaceutical and medical devices companies engaging consultant healthcare professionals. In addition to this, other significant developments include the new price regime for off-patent drugs, deliberations by the Delhi and Madras High Courts on e-pharmacies, coming into force of new labelling requirement for certain drug formulations, guidelines for deployment of artificial intelligence ("**AI**") in biomedical research and healthcare, the notification of the national policy on research and development in the Pharma-Med Tech sector and the national medical devices policy to encourage innovation and research.

The Draft Drugs, Medical Devices and Cosmetics Bill, 2022 continues to be in draft form even after a year since its publication while the Government contemplates on the industry feedback. Additionally, the draft of the Medical Devices (Amendment) Rules, 2023[1] were notified by the Ministry of Health and Family Welfare ("**Ministry**") in June 2023 to establish State Medical Devices Testing Laboratories, Central Medical Devices Testing Laboratory for carrying out the testing and evaluation of medical devices in India. Although, the regulations remain in the draft form until they are notified in the official gazette.

In this update we have discussed the key developments in the first half of 2023 in the Pharmaceutical and Medical Devices Sector.

NEW PENALTY PROVISIONS FOR FAILURE TO DEPOSIT TDS HAS IMPLICATIONS ON PHARMACEUTICAL COMPANIES

The Finance Act, 2023 ("**Finance Act**")[2] – the annual fiscal legislation containing multiple provisions relating to taxes, duties, exemptions and reliefs and fiscal tax rates for the fiscal year of 2023-24 is effective since April 1, 2023. Among other things, the Finance Act has included a penalty under the Income Tax Act, 1961 ("**ITA**") for failure to deduct or deposit tax which has been deducted from any benefit or perquisite provided to a tax resident of India.

Accordingly, the penalty is a sum equal to the amount of tax which such person failed to deduct or pay.[3] Separately, if the person without reasonable cause or excuse, fails to deduct or after deducting fails to pay the tax, a penalty of rigorous imprisonment for a term which may extend to six months and a minimum fine of fifteen percent per annum on the amount of tax due calculated from the date on which such tax was deductible to the date on which such tax is actually paid shall be levied.[4] In April 2023, the Supreme Court of India held that the penalty is triggered only for the failure to deduct or pay the taxable amount and not for belated remittance of the tax deducted at source after the same is deducted by the assessee.[5]

These penalties under the Finance Act have been brought in light of the tax reforms introduced in 2022. Last year, the Government of India ("**Government**") amended the ITA and mandated companies to deduct tax at the value of ten percent on benefits or perquisites (whose total value exceed INR 20,000 (approximately USD 241)) arising from the exercise of business or profession.[6] The Central Board of Direct Taxes ("**CBDT**") issued a Circular dated June 16, 2022[7] which clarified that healthcare professionals receiving perquisites and benefits for consultancy services are subject to tax deductions under this provision. The Finance Act inserts penalty provisions into the ITA for non-compliance with the above-mentioned tax deduction provisions.

With the passage of the Finance Act, marketing activities of pharmaceutical and medical device companies will be impacted. Specifically, given that since 2022, freebies and samples, consultancy fees and other benefits are now taxable income in the hands of healthcare professionals, the Government has now introduced provisions to ensure accountability of companies providing such benefits to healthcare professionals to deduct and deposit tax.

NEW FORMULA TO DETERMINE PRICING OF MEDICINES THAT ARE LOSING PATENT PROTECTION

The Department of Pharmaceuticals, Ministry of Chemical and Fertilizers, by way of notification dated May 11, 2023 ("**DPCO Amendment**"),[8] has amended the Drugs (Price Control) Order 2013 ("**DPCO**") - the price regulation

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framework for drugs and medical devices in India - to introduce a formula to calculate the retail price of new drugs that are no longer protected by a patent under Indian law.

The DPCO Amendment has amended Paragraph 5 of the DPCO to include that the retail price of a new drug or a new drug[9] that contains molecules or components or ingredients that have become off-patent or are about to become off-patent shall be fixed in accordance with the new formula. The new formula provided under the newly inserted Paragraph 5(3) of DPCO and Paragraph 18A is as follows:

- Determination of Retail Price[10]

  New Drug Available in the Domestic Market: On expiry of the patent, the retail price of the new drug shall be revised to 50% of the current ceiling price calculated in accordance with Paragraph 4(1) of the DPCO.

  New Drug Not Available in India: On expiry of the patent, the retail price of the new drug should be fixed by the Government on the principles of Pharmacoeconomics of the new drug, on the recommendation of a Standing Committee of Experts. The retail price of such new drug shall be fixed by adding sixteen percent margin to retailer on the price to retailer.

- Price Revision[11]

  After one year, the ceiling price of scheduled formulation will be revised again based on market data. The timeline for one year is calculated basis the (i) date on which the retail price was fixed as per item or (ii) the date on which "price to retailer" of at least one company fixed per item and captured in the pharmaceutical market database whichever is later.

The DPCO Amendment comes in light of the Government's view that if the price of patented new drugs are determined by the current mechanism for fixing the price of new drugs available in the market (i.e. on the basis of six-months' prior market data), the benefit of price reduction would not be passed on to the consumers.

Our detailed analysis of the DPCO Amendment can be accessed here.

DRUGS AND COSMETICS RULES, 1945 AMENDED TO INCLUDE LABELLING OF DRUGS WITH QR CODE

The Ministry of Health and Family Welfare ("**Ministry**") notified the Drugs (Eight Amendment) Rules, 2022 ("**Amendment Rules**") on November 17, 2022[12] which amends the Drugs and Cosmetics Rules, 1945 ("**D&C Rules**") to insert a new labelling requirement for drug formulation products specified under Schedule H2 of the D&C Rules. The Amendment Rules came into force on August 01, 2023.

The Amendment Rules require manufacturers of drug formulation products specified under Schedule H2 to bear a Bar Code or a Quick Response code ("**QR Code**") on its label at primary packaging level and in some instances on its secondary packaging label. Schedule H2 contains a list of 300 drugs which are required to be in compliance with the Amendment Rules. The requirement is introduced to enable storage of data or information regarding the product, 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 proper and generic name of the drugs, unique product identification code, brand name, batch number, date of manufacturing, date of expiry, name and address of the manufacturer, 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 and distribution of the drug and to identify any instances of counterfeit drugs being circulated in the market. It will also enable greater access to information for the consumers and will increase awareness regarding the drug formulations being circulated in the market.

NEW ETHICAL GUIDELINES FOR USE OF ARTIFICIAL INTELLIGENCE IN BIOMEDICAL RESEARCH AND HEALTHCARE

The Indian Council for Medical Research ("**ICMR**") - the apex body for biomedical research in India - has introduced the Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare, 2023 ("**AI Guidelines**")[13]. The AI Guidelines lay down the ethical framework for development, deployment and adoption of AI based tools and is relevant to innovators, developers, technologists, researchers, healthcare professionals, Ethics Committees ("**EC**"), sponsors and funding agencies involved in research related to AI in biomedical research and healthcare.

The AI Guidelines recognize that the deployment of AI in healthcare research involves additional concerns such as potential biases, data leakage, interpretation risk, autonomy and professional competence. In consideration of the same, it lays down the ethical principles to minimize the risk of the potential issues of AI in biomedical research- (i) validity; (ii) non-discrimination and fairness; (iii) optimization and data quality; (iv) accessibility and equity; (v) risk minimization and safety; (vi) collaboration; (vii) autonomy; (viii) data privacy; (ix) accountability and liability and(x) trustworthiness. In addition to the general ethical principles, the AI Guidelines also specify guiding principles for each of these stages - developmental phase, validation phase and deployment phase. The EC is responsible for ensuring that the research proposals and implementation of AI tools follow the said principles and guidance. Further, the AI Guidelines also require specific consent to be obtained from the study participants for the deployment of AI - based technologies.

Over the recent years, there has been increasing momentum to regulate biomedical research and clinical trials in India in an efficient manner. The AI Guidelines are an addition to the existing biomedical research and clinical trials framework - ICMR Guidelines for Biomedical and Health Research Involving Human Participants, 2017 and New Drugs and Clinical Trial Rules, 2019. Similar to the other regulations overlooking this sphere, the AI Guidelines are patient-centric and seek to protect individuals from potential threats of AI-based research and applications.

DELHI HIGH COURT DIRECTS THE CDSCO TO CLARIFY THE LEGAL POSITION ON E-PHARMACIES

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Sale of drugs online has been a contentious legal conundrum over the last decade. For background, Draft E-Pharmacy Rules to the D&C Rules were proposed in August 2018, to add a chapter to the D&C Rules to specifically regulate e-pharmacies ("**Draft E-Pharmacy Rules**").[14] Petitions were filed before the Delhi High Court and Madras High Court challenging the legal status of e-pharmacies. While initially both the Madras[15] and Delhi[16] High Courts had passed orders banning online sale of medicines, subsequently both High Courts have passed orders requiring that drugs are not sold without a license. The Madras High Court also directed the Central Government to notify the Draft E-Pharmacy Rules. The petitions continue to remain pending.

In its most recent order, the Delhi High Court directed the Central Drugs Standards Control Organisation ("**CDSCO**") to report the outcome of the stakeholder consultations held for the Draft E-Pharmacy Rules in 2018. The CDSCO submitted a status report in which it stated that majority of the representations from various stakeholders had opposed the Draft E-Pharmacy Rules and that the Draft E-Pharmacy Rules continues to be pending for further consultations and deliberations. The Delhi High Court further directed CDSCO to report the final decision on the regulation of e-pharmacies, the hearing for the said matter has been scheduled for November 2023. Separately, the Delhi High Court also clarified that the pendency of the matter will not come in the way of the Government taking action against the persons who are violating the interim order issued in 2018 prohibiting the sale of drugs online without a valid license.

In addition to the above, in a notable development since 2018, the Draft Drugs, Medical Devices and Cosmetics Bill, 2022 has been released. This proposed law which will overhaul the Drugs and Cosmetics Act, 1940 upon enactment, also contains enabling provisions for the regulation of e-pharmacies. However, there are no specific requirements proposed under the current draft of this proposed law (as in the Draft E-Pharmacy Rules). At present, it is also unclear how the two parallel proposed laws would interplay in terms of implementation.

GOOD MANUFACTURING PRACTICES TO BE REVISED TO REFLECT UNIFORMITY WITH GLOBAL STANDARDS

The Good Manufacturing Practices ("**GMP**") provided under Schedule M of the D&C Rules proposed to be revised in line with the draft amendment notification published by the Ministry on October 5, 2018.[17] The draft of the Drugs and Cosmetics amendment rules, 2018 ("**Draft Amendment Rules**") were issued to bring Schedule M in tandem with international GMP standards introduced by the World Health Organization ("**WHO-GMP**"). While numerous sources hint at a notification regarding bringing into effect of the Draft Amendment Rules and the timeline provided for compliance by small and large manufacturers, there is no circular or notification to this regard yet. As per news reports, the revised GMP is likely to be made mandatory from October 2023.[18]

The GMP was brought under scrutiny amidst various risk-based inspections carried out by the regulatory authorities and the concerns raised over the existing quality management mechanisms being followed at various drug manufacturing plants in the country.

The GMP comprise of mandatory requirements and standards to ensure quality of products, maintenance of facilities, personnel, storage and transport of material, etc. The Draft Amendment Rules introduces a quality risk management system, self-inspection requirement, pharmaceutical quality system, quality audit team, specific requirements for manufacture of hazardous products, etc. The small and large manufacturers are required to comply with the revised GMP and obtain the WHO-GMP certifications within the timelines that may be prescribed. Further clarity on the date of coming into effect of the Draft Amendment Rules and the applicable timelines would assist the industry in streamlining their compliances under the D&C Rules.

NATIONAL POLICY ON RESEARCH & DEVELOPMENT AND INNOVATION IN THE PHARMA-MED TECH SECTOR NOTIFIED

The Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers notified the National Policy on Research & Development and Innovation in the Pharma-Med Tech Sector in India, 2023 ("**Research Promotion Policy**") on August 16, 2023, to promote local research and development of pharmaceutical preparations and medical devices (including health software) in India.[19]

The Research Promotion Policy aims to achieve the following objectives:

a) Rapid drug discovery and development and innovation in medical devices by streamlining of regulatory processes;

b) Incentivize private sector investment in research;

c) Encourage collaboration between academia and the industry;

d) Enable coordination among the existing policies and programs of various departments/ agencies/ institutes for research; and

e) Facilitate the rapid development and availability of innovative drugs and medical devices in India.

At present, the Research Promotion Policy lays down a skeletal framework and the objectives meant to be achieved through a proper implementation of the same. A High-level Task Force is proposed to be set-up under the Department of Pharmaceuticals for the implementation of the Research Promotion Policy. Further, ten-year strategy and action plans will be released under the Research Promotion Policy to provide details on the plan for implementation of the policy.

NATIONAL MEDICAL DEVICES POLICY NOTIFIED

The Department of Pharmaceuticals ("**DoP**") notified the National Medical Devices Policy, 2023 ("**Medical Devices Policy**") on May 2, 2023.[20] The Medical Devices Policy seeks to provide a holistic policy framework to accelerate growth of domestic production of medical devices and reduce dependency on imports. This builds upon the recent initiatives of Government in introducing production linked incentive ("**PLI**") schemes to encourage domestic manufacturing and the establishment of medical device manufacturing parks in the country.

The Medical Devices Policy identifies certain key strategies to realize the objective of domestic manufacturing of medical devices which include:

a) regulatory streamlining to enhance ease of doing research and business in India;

b) enabling infrastructure for the establishment and strengthening of large medical device parks and industry clusters;

c) facilitating research and development and innovation in the sector;

d) attracting investment in the sector;

e) development of domestic human resources such as scientists, regulators, health experts, managers, technicians to aid the medical device sector; and

f) creation of a dedicated Export Promotion Council to boost exports of India-manufactured medical devices globally.

The implementation of the Medical Devices Policy is expected to attract foreign investments, public-private partnerships as well as a jumping board for the Government to introduce sector specific laws in the country to place India as a manufacturing hub of medical devices.

CONCLUSION

The first half of this year has witnessed a mixed bag of regulatory developments in the pharmaceutical and medical devices sectors. The compliance requirements introduced for manufacturers for labelling of certain drug formulations with unique identification markers such as bar codes and QR Code is a step in the right direction to encourage consumer awareness and access to information. The pharmaceutical and medical devices sectors have also experienced a push for research and development which is evident from the policies and schemes being introduced to support innovation in the sector.

The regulatory steps towards introducing new regimes in the pharmaceutical sector are unique and project tremendous potential for the growth of the sector. The adoption of unique policies and schemes in each sector remains to be seen int eh second half of 2023.

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You can direct your queries or comments to the authors.

[1]Accessible at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTAzMjg=

[2]Finance Bill, 2023 effective as Finance Act, 2023 from April 1, 2023: https://www.indiabudget.gov.in/doc/Finance_Bill.pdf

[3]Section 271C, ITA.

[4]Section 276B, ITA.

[5]MS US Technologies International Private Limited v Commissioner of Tax, Civil Appeal Nos. 1258□1260 of 2019, accessible at: https://main.sci.gov.in/supremecourt/2010/13647/13647_2010_4_1502_43314_Judgement_10-Apr-2023.pdf

[6]Section 194R, ITA.

[7]CBDT Circular dated June 16, 2022, accessible at: https://incometaxindia.gov.in/communications/circular/circular-no-12-2022.pdf

[8]DPCO Amendment 2023, accessible at: https://egazette.gov.in/WriteReadData/2023/245818.pdf

[9]Under the DPCO "new drug" means a formulation launched by an existing manufacturer of a drug of specified dosages and strengths listed in the National List of Essential Medicines ("**NLEM**") by combining the drug with another drug (either listed or not listed in the NLEM) or a formulation launched by changing the strength or dosages or both of the such drug.

[10]Paragraph 5 (3)(i), DPCO.

[11]Paragraph 18A, DPCO.

[12]Drugs (Eight Amendment) Rules, 2022, accessible at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTIwMg==

[13]Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare, 2023, accessible at: https://main.icmr.nic.in/sites/default/files/upload_documents/Ethical_Guidelines_AI_Healthcare_2023.pdf

[14]Accessible here: https://egazette.nic.in/WriteReadData/2018/189043.pdf

[15]Accessible here: https://www.mhc.tn.gov.in/judis/index.php/casestatus/viewpdf/430512

[16]Accessible here: https://dhcappl.nic.in/dhcorderportal/GetOrder.do?ID=rjm/2018/253471_2018.pdf

[17]Accessible at: https://egazette.gov.in/(S(fwz3uluv433dnlct3lxfdnku))/SearchMinistry.aspx?id=882142

[18]Teena Thacker, Pharma companies must adopt revised quality norms: Government, ET Pharma, (September 21, 2023), accessible at:https://health.economictimes.indiatimes.com/news/pharma/pharma-companies-must-adopt-revised-quality-norms-government/103821906?utm_source=Mailer&utm_medium=newsletter&utm_campaign=ethealth_news_2023-09-21&dt=2023-09-21

[19]Accessible at: https://egazette.gov.in/WriteReadData/2023/248177.pdf

[20]Accessible at: https://pharmaceuticals.gov.in/sites/default/files/ Gazette%20Notification%20%20 National%20Medical%20Devices%20Policy%202023_0.pdf

based on the specific facts and circumstances. This Hotline does not substitute the need to refer to the original pronouncements.

list.