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CHECKING THE PULSE - HEALTHCARE NEWSLETTER

RECENT LEGAL DEVELOPMENTS IN INDIA

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INTRODUCTION

This newsletter highlights the key developments and measures as well as other major developments in the Indian healthcare and pharma sector for the months of June - July 2023.

RECENT LEGAL & REGULATORY DEVELOPMENTS

Delhi High Court directs the Government of India to submit details of deliberations in relation to draft rules to regulate e-pharmacies

The Delhi High Court in a recent order has directed the Government of India ("**GOI**") to submit the outcome of its consultation with stakeholders on the draft amendment[1] to the Drugs and Cosmetics Rules, 1945 which propose to regulate e-pharmacies. This order comes pursuant to the petitions filed by the South Chemists and Distributors Association ("**SCDA**") and others[2] seeking a ban on online sale of drugs by pharmacies.

Previously, in an order dated December 12, 2018 ("**Interim Order**"), the Delhi High Court had injuncted e-pharmacies from selling any medicines online if they did not possess licenses required to be obtained under the Drugs and Cosmetics Act, 1940 ("**Drugs Act**"). The court has remarked that the pendency of the above petitions will not affect the GOI's power to take action against companies who are violating the Interim Order.[3]

SCDA urges state drug regulators to take action against e-pharmacies

A letter has been issued by the SCDA urging drug regulators to take action against e-pharmacies who are in violation of the Interim Order.[4] Further, SCDA has also claimed that certain pharmacies are consistently violating the provisions of the notification dated March 26, 2020,[5] issued by the Ministry of Health and Family Welfare, during the outbreak of the Covid-19 pandemic.

The notification allowed pharmacies which were holding a valid license under the Drugs Act to undertake, in revenue districts where they held the license, door delivery of medicines specified in Schedule H of the Drugs Act such as Candesartan (medication to treat high blood pressure), Artemether (medication to treat malaria) etc. However, as per the SCDA, pharmacies have been: (a) selling medicines specified in Schedule H1 of the Drugs Act; (b) delivering medicines outside their respective revenue district; and/or (c) engaging logistics companies for delivery of medicines which do not hold the required licenses under the Drugs Act.

Gujarat Food and Drug Control Administration cancels 394 product licenses of 14 banned fixed dose combination

On June 2, 2023, the Ministry of Health and Family Welfare through a gazetted notification ("**FDCs Notification**") prohibited manufacturing, sale and distribution of 14 banned fixed dose combination drugs ("**Banned FDCs**") owing to their harmful effects on human lives.[6] In furtherance of the FDCs Notification, the Gujarat Food and Drug Control Administration ("**GFDCA**") has cancelled 394 product licenses issued to the companies engaged in manufacturing of the Banned FDCs in the state of Gujarat. The Banned FDCs include over the counter drugs such as ammonium chloride, bromhexine, dextromethorphan, chlorpheniramine, used for medication of cough, fever, and infections. Further, the GFDCA has also sent message alerts to manufacturers, distributors, and retailers requiring them to immediately stop the manufacturing and sale of the Banned FDCs.[7]

Delhi High Court directs GOI to file reply in relation to the petition filed against the FDCs Notification

In an order dated July 17, 2023,[8] the Delhi High Court has directed the GOI to submit its response in a writ petition filed by Seagull Laboratories (India) Private Limited.[9] The petition was filed to revoke the FDCs Notification which banned the manufacturing, sale, and use of the Banned FDCs. The petitioner has claimed that the FDCs Notification only states that the Banned FDCs may cause health risks to human beings without specifying the reasons, extent, or nature of such risks. In this regard, the Delhi High Court, in an earlier order dated July 3, 2023, had granted relief to the petitioner, and had passed directions that the Banned FDCs which were already in the distribution channel will not be withdrawn, and that no coercive steps will be taken against the petitioner.

1. The draft amendment was issued on August 28, 2018, and is yet to come into effect. It can be accessed at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTkzOQ==
2. Dr. Zaheer Ahmed v. Union of India (W.P.(C) 11711/2018 & CM APPL. 45307/2018).
3. https://retail.economictimes.indiatimes.com/news/health-and-beauty/pharmacy/centre-told-to-inform-outcome-of-consultations-of-draft-rules-to-regulate-e-pharmacies/100570578
4. http://www.pharmabiz.com/NewsDetails.aspx?aid=159505&sid=1
5. https://www.mohfw.gov.in/pdf/Doorstepdelivery26B.pdf
6. The notification can be accessed at: https://xln.gujarat.gov.in/DOCS/Prohibition_of_14_FDC.PDF
7. http://www.pharmabiz.com/NewsDetails.aspx?aid=159657&sid=1
8. Seagull Laboratories I Private Limited v. the Union of India (W.P.(C) 8460 of 2023).
9. The Delhi High Court through its earlier orders dated June 14, 2023, and July 3, 2023, had also directed the GOI to submit its responses to the above petition

Guidelines formulated to restrict changing of manufacturers by marketing companies

Recently, there have been growing instances of pharmaceutical marketing companies replacing their manufacturers without informing the National Pharmaceuticals Pricing Authority ("**NPPA**"). With an aim to decrease such instances, the NPPA has introduced guidelines to lay down a case specific assessment process in relation to filing and processing of applications from marketing companies seeking a change of their manufacturer for formulations whose retail prices have already been notified.

As per the guidelines, NPPA, going forward, will permit a marketing company to change its manufacturer only upon the occurrence of any of the following events: (a) cancellation or seizure of license of the manufacturing company; (b) natural calamity or civil riots leading to destruction of plant of the manufacturing company; (c) dissolution or winding up of the manufacturing company; (d) closure of the concerned business unit by the manufacturing company; or (e) any other circumstances proved to be beyond the control of the manufacturer or the marketing company. The responsibility of proving occurrence of any of the above events will be that of the applicant marketing company.[10]

Central Drugs Standard Control Organisation to undertake daily updation of cough syrup samples to enable time-bound testing

In order to facilitate time-bound testing and publications of reports, the Central Drugs Standard Control Organisation ("**CDSCO**"), through a circular dated June 13, 2023,[11] has notified that it will publish on its website, on a daily basis, the number of batches of cough syrup samples received and tested by central and state drug laboratories prior to their export. The new mechanism would ensure release of test reports in a time-bound manner. The CDSCO has adopted the new mechanism in light of the reports of the World Health Organisation alleging that the consumption of certain cough syrups imported from India has resulted in death and adverse reactions in people in Gambia and Uzbekistan.[12]

India to adopt Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme to strengthen the quality of its medical products

India is set to adopt the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme[13] with an aim to strengthen the quality and standard of medical products. This scheme allows its member nations to exchange knowledge, share best manufacturing practices, and jointly improve the safety and quality of medical products. Once this scheme is adopted by India, the Indian medical industries shall endeavour to adopt international standards relating to: (a) good manufacturing practices; and (b) quality control, in order to ensure consistency with other member nations such as Australia, Belgium, and Canada.[14]

United States Food and Drug Administration accepts application filed by Dr. Reddy's Laboratories for rituximab's biosimilar product

The United States Food and Drug Administration has accepted for substantive review the biologics license application filed by Dr. Reddy's Laboratories for its proposed rituximab's biosimilar product 'DRL_XI' ("**DRLXI**"). Rituximab is an antibody primarily used to treat autoimmune diseases and certain types of cancer (including non-Hodgkin's lymphoma and chronic lymphocytic leukaemia in adult patients). DRLXI has also been accepted for review by the European Medicines Agency and the (United Kingdom) Medicines and Healthcare Products Regulatory Agency. In India, DRLXI has been approved for marketing.[15]

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10. Guidelines were adopted at the 113th meeting of the NPPA. The minutes of the meeting containing the guidelines can be accessed at: https://www.nppaindia.nic.in/wp-content/uploads/2023/06/113th-Authority-Meeting.pdf.
11. https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTAyNDU=
12. http://www.pharmabiz.com/NewsDetails.aspx?aid=159733&sid=1
13. https://picscheme.org/docview/2147
14. https://www.livemint.com/economy/india-to-join-global-scheme-to-improve-quality-of-drugs-11685896539717.html
15. https://www.thehindu.com/business/dr-reddys-application-for-rituximabs-biosimilar-candidate-accepted-by-us-fda-for-review/article67073154.ece

The Drugs, Medical Devices and Cosmetics Bill, 2023 to be introduced in the monsoon session of Lok Sabha

The GOI will introduce the Drugs, Medical Devices and Cosmetics Bill, 2023 ("**New Bill**") for its consideration and passing in the monsoon session of the Lok Sabha.[16] The New Bill, if notified by the GOI, will replace, and repeal the Drugs Act. The New Bill is intended to be a comprehensive legislation which will contain provisions to regulate drugs, cosmetics, medical devices, clinical trials, clinical investigations, and online pharmacies.

Ministry of Communications, GOI launches portal for simplifying export of pharmaceuticals products by micro, small, and medium enterprises and other small traders

With an aim to simplify the export of pharmaceutical products by micro, small, and medium enterprises and other small exporters, the Ministry of Communications, GOI has launched the 'Dak Ghar Niryat Kendra Portal' ("**Portal**"), to enable the exporters to seamlessly export pharmaceutical products. Through the Portal, the exporters would be permitted to avail various benefits such as digital customs clearance, system generated invoices and postal export bill, online barcode generation, paperless documentation, volume discount, and pickup facility. The Portal would provide a cost-effective mechanism by reducing various export related expenses (such as custom house agent expenses and expenses usually incurred on third party software used for generating invoices) and aid in ease of doing business.[17]

Department of Pharmaceuticals, GOI releases strategy document in relation to the National Medical Devices Policy, 2023

To ensure the effective implementation of the National Medical Devices Policy, 2023 released on May 2, 2023,[18] the Department of Pharmaceuticals, GOI ("DoP") has released a strategy document.[19] The strategy document provides recommendations to address issues such as: (a) adoption of a national nomenclature for medical devices; (b) implementation of suitable mechanisms for data security to ensure patient data safety; (c) development of processes to manage e-waste of obsolete medical devices; and (d) establishment of a single window system for obtaining licenses under the Drugs Act.[20]

Certain medicines and food for special medical purpose exempted from the levy of integrated goods and services tax

The Goods and Services Tax Council, in its meeting held on July 11, 2023, has exempted the levy of integrated goods and services tax on the following products: (a) anti-cancer medicine dinutuximab (quarziba) imported for personal use; and (b) medicines and food for special medical purposes used in the treatment of rare diseases enlisted under the National Policy for Rare Diseases, 2021 (such as phenylketonuria, osteopetrosis, galactosemia) if imported: (i) for personal use; (ii) by the Centres of Excellence for Rare Diseases established by the GOI; or (iii) by any person or institution on the recommendation of such centres. Without this exemption, patients would have to pay a goods and services tax of 12%. This exemption will play a significant role in providing greater access to crucial medicines used in the treatment of rare diseases by reducing the cost of treatment.[21]

Final cabinet note on National Policy on Research and Innovation in Pharma MedTech Sector submitted to the cabinet

The DoP has submitted the final cabinet note on the National Policy on Research and Innovation in Pharma MedTech Sector for the cabinet's approval and is in the process of submitting the Scheme of Promotion of Research and Innovation in Pharma MedTech Sector for the approval. The economic finance committee had earlier approved the scheme on March 15, 2023, with an overall outlay of INR 5,000 crores for a period of 5 years (i.e., from 2023-24 to 2027-28). Following this, the DoP had sent the policy and the scheme to the empowered technology group for approval. Based on the suggestions provided by the empowered technology group, the DoP revised the cabinet note, and the final cabinet note was sent for approval on June 21, 2023, to the cabinet secretariat/Prime Minister's office.

16. https://pib.gov.in/PressReleasePage.aspx?PRID=1940856
17. http://www.pharmabiz.com/NewsDetails.aspx?aid=160185&sid=1
18. https://pharmaceuticals.gov.in/sites/default/files/Gazette%20Notification%20%20National%20Medical%20Devices%20Policy%202023.pdf
19. https://pharmaceuticals.gov.in/sites/default/files/Strategy%20Document%20on%20NMDP%202023_0.pdf
20. http://www.pharmabiz.com/NewsDetails.aspx?aid=160035&sid=1#:~:text=In%20an%20effort%20to%20fine,of%20national%20nomenclature%20for%20medical.
21. https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1938812

Fixing of retail and ceiling prices of various formulations by NPPA

The NPPA has issued an order on June 8, 2023[22] notifying the retail pricing (exclusive of goods and services tax) of various formulations, including Telmisartan and Bisoprolol Fumarate tablets (medication to lower blood pressure), Gliclazide and Metformin Hydrochloride tablets (medication to treat diabetes), and Paracetamol and Caffeine Tablets IP (medication to treat migraine and influenza). The NPPA has also revised the ceiling price of scheduled formulations, including the medications to treat migraines and leprosy. The order specifies the prices basis the unit, dosage form, and strength of the formulations, along with specifying the name of manufacturer and the marketing company.

Bar codes and quick response codes to be mandatorily affixed on certain products

The CDSCO has issued a set of frequently asked questions on July 25, 2022,[23] ("**FAQs**") to ensure the effective implementation of the notification dated November 17, 2022,[24] issued by the Ministry of Health and Public Welfare, which mandates the printing of bar codes or quick response codes on Schedule H2 drug formulations products on and from August 1, 2023. The codes so printed on the products will be required to include the following particulars: (i) unique product identification code; (ii) proper and generic name of the drug brand name; (iii) name and address of the manufacturer; (iv) batch number; (v) date of manufacturing; (vi) date of expiry; and (vii) manufacturing licence number. The CDSCO through the FAQs has further clarified that the above notification will be applicable for all the manufacturers (domestic as well as foreign) who will be manufacturing the relevant drug formulations products for marketing in India.

22. https://egazette.gov.in/WriteReadData/2023/246403.pdf
23. https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTAzNzc=
24. https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTIwMg==

MAJOR DEALS IN INDIA IN THE PHARMA AND HEALTHCARE INDUSTRY

The following are the key deals announced during the months of June - July 2023, in the pharma and healthcare industry:[25]

Corona Remedies Private Limited, a ChrysCapital backed Ahmedabad based pharmaceutical company has acquired Myoril, the popular muscle relaxant brand of Sanofi Healthcare India for a consideration of INR 234 crore (approximately USD 28 million). Through this acquisition, Corona Remedies aims to strengthen its existing portfolio of more than 80 brands and become a key player in the muscle relaxant segment.[26]

Zydus Lifesciences Limited, a Hyderabad based drug manufacturer, has executed definitive agreements to acquire a 6.5% stake in biotech firm Mylab Discovery Solutions, an entity engaged in the business of developing, manufacturing, marketing, and selling in-vitro diagnostics kits, reagents, equipment, and related therapeutic products. Zydus acquired the stake from Rising Sun Holdings Private Limited for a consideration of INR 106 crore (approximately USD 12 million) through its wholly owned subsidiary Zydus Animal Health and Investments Limited. The deal is likely to be closed by the end of August 2023. The proposed investment will help Mylab to participate in the developing diagnostics space and allow Zydus to make its debut in the diagnostics segment.[27]

Nova IVF Fertility, a fertility chain owned by Asia Healthcare Holdings, has acquired Wings IVF, an Ahmedabad based in-vitro fertilisation chain, for an undisclosed consideration. Pursuant to this acquisition and owing to Wings IVF's existing presence in states such as Gujarat, Rajasthan, Delhi, and Bihar, Nova will expand its operations in 44 cities through 68 centres and will further strengthen its position in-vitro fertilisation services market in the northern and western parts of India.[28]

Syngene International Limited, a drug research company backed by Singapore's sovereign wealth fund GIC, has executed definitive agreements with Stelis Biopharma Limited to acquire its manufacturing unit located in Bengaluru for a consideration of INR 702 crore (approximately USD 85 million). The deal is likely to be closed by the end of September 2023. The acquisition will strengthen Syngene's growing position as a leading biologics contract development and manufacturing services provider and will also provide Syngene with an additional capability of 2000 litres for producing biological medicinal substances.[29]

Fortis Healthcare Limited, a chain of hospitals controlled by the Malaysian hospital chain IHH Healthcare, has executed definitive agreements with Sri Kauvery Medical Care (India) Limited for sale of its hospital business operations situated at Vadapalani, Chennai for a consideration of INR 152 crores (approximately USD 18 million). The deal is likely to be closed by the end of July 2023. The Vadapalani facility currently has a capacity of 100 beds with a potential to scale up to nearly 200 beds. This acquisition comes just days after Fortis executed definitive agreements with VPS Group to acquire Medeor Hospital in Manesar, Haryana. The sale has been undertaken as part of Fortis's ongoing portfolio simplification strategy wherein it seeks to focus on strengthening its presence in selected geographic areas where it has considerable presence.[30]

Fortis Healthcare Limited has collaborated with Red.Health, an emergency response network, to provide comprehensive emergency services in minimal response time to patients across the National Capital Region. Pursuant to the collaboration, a fleet of 10 dedicated global positioning system enabled advance life support ambulances and an independent fleet of more than 30 vehicles will be deployed by Red.Health in the National Capital Region. As per Fortis, the collaboration will be implemented across its 7 hospitals and will play an essential role in reducing trauma and fatalities during medical crises as it will ensure that ambulances reach patients within an approximate time-period of 10 to 30 minutes.[32]

BPEA Private Equity Fund VIII, a subsidiary of Sweden headquartered investment firm EQT, has entered into definitive agreements to acquire a controlling stake in **Indira IVF,** a Mumbai based in-vitro fertilization chain. BPEA will acquire stakes from the founders and TA Associates. As per BPEA, the acquisition would allow BPEA to expand Indira IVF's presence across various parts of India and will allow it to also enter into the neighbouring markets. Through the acquisition, BPEA also plans to invest in the research and development capabilities of Indira IVF and make fertility services more accessible to the general public. [33]

22. https://egazette.gov.in/WriteReadData/2023/246403.pdf
23. https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTAzNzc=
24. https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTIwMg==
25. To the extent any transactions involve clients of INDUSLAW, the information herein is based on statements in the media and not our professional knowledge of the relevant transaction.
26. https://www.vccircle.com/chryscapbacked-corona-remedies-buys-sanofi-s-muscle-relaxant-brand
27. https://www.vccircle.com/zyduslife-picks-up-stake-in-mylab-for-13-mn
28. https://www.vccircle.com/tpgowned-nova-ivf-fertility-takes-over-wings-ivf
29. https://www.vccircle.com/gicbacked-syngene-inks-88-mn-deal-to-buy-stelis-biopharma-s-unit
30. https://www.livemint.com/companies/fortis-healthcare-to-divest-vadapalani-hospital-business-for-rs-152-crore-11687490925668.html
31. https://health.economictimes.indiatimes.com/news/industry/fortis-partners-with-red-health-to-strengthen-emergency-response-services-in-delhi-ncr/101302430
32. https://www.vccircle.com/bpeaeqt-to-acquire-controlling-stake-in-indira-ivf-ta-associates-to-exit

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