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CHECKING THE PULSE – RECENT LEGAL DEVELOPMENTS IN THE INDIAN HEALTHCARE AND PHARMA SECTOR

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AUTHORS: SHANTANU JINDEL | SHWETA GUPTA | HARSHIT KUMAR | VATSAL AGARWAL | ABHINAV

INTRODUCTION

Over the past couple of months, regulatory authorities in the healthcare and pharmaceutical sectors have been highly active in the enforcement of good manufacturing practices amid drug quality concerns across India. In addition, the formulation of guidelines for regulating commercial usage of de-identified biological samples, the landmark injunction order issued by the Delhi High Court against Zydus' product 'Sigrima', and the lack of emphasis placed by the Union Budget on the healthcare industry dominated headlines in the space.

In this edition of *'Checking the Pulse'*, we delve into key updates from June 2024 to July 2024 in the healthcare and pharmaceutical sectors, while also tapping on notable deals that have gained interest from the industry.

RECENT LEGAL & REGULATORY DEVELOPMENTS

The Union Budget's lack of emphasis on the healthcare sector raises concerns among industry stakeholders

The Ministry of Health and Family Welfare ("**MoH&FW**") received INR 89.287 crore (eighty-nine thousand two hundred and eighty-seven crore rupees) as part of the budgetary allocation under the Union Budget for the year 2024-25 ("**Budget**").[1] While this is marginally higher than the allocation last year, the Budget has left industry stakeholders dissatisfied. The Budget failed to address significant issues, such as the rapidly rising out-of-pocket healthcare expenditures, the need to create an inclusive health insurance framework in view of the lack of penetration of health insurance among lower-income groups, as well as planned investment in the public healthcare infrastructure. Additionally, the modest increase in budgetary allocation for a sector where the gap between supply and demand is already substantial has led some experts to characterize this year's allocation to the sector as a "token budget for healthcare".

On a positive note, the Budget provided customs duty exemption on three targeted cancer drugs: (a) trastuzumab deruxtecan; (b) osimertinib; and (c) durvalumab, in a welcome move geared towards easing the financial burden on cancer patients. While trastuzumab deruxtecan is used to treat breast and stomach cancer, osimeritinib treats specific types of lung cancers. Durvalumabs treats multiple cancers of the biliary tract, endometrial, liver, non-small, and small cell lung cancers.

These drugs were previously subject to a customs duty of 10% (ten percent) but will now be exempt from import duty, resulting in a significant price reduction and higher affordability amongst the masses. The decision further consolidates the Government's aim of providing relief to patients, having exempted the drug pembrolizumab, used in the treatment of various cancers, from basic customs duty in 2023.

CDSCO plans to roll out key projects amid drug quality concerns

As the quality of drugs manufactured in the country continues to be a cause of concern, the Central Drugs Standard Control Organisation ("**CDSCO**") will initiate four key projects that will help the Indian pharmaceutical industry in maintaining and improving the quality of the drugs manufactured in India. These projects involve: (a) CDSCO coming up with its own digital platform, to be known as the Digital Drug Regulatory System, with the aim of bringing all stakeholders i.e., regulatory bodies, manufacturers and retailers aboard; (b) establishing a capable scientific cadre at CDSCO for review of its internal files; (c) assessment of the CDSCO's internal processes as well as the removal of redundancies in the Drugs and Cosmetics Act, 1940 ("**D&C Act**"); and (d) setting up Digital IP for the Indian Pharmacopoeia Commission for ensuring quality and safety of drugs.

These projects are the need of the hour following staggering revelations by the Drug Controller General of India that risk-based inspections conducted by CDSCO of over 400 (four hundred) pharmaceutical manufacturing units over the past year and a half resulted in the closure of 36% (thirty six percent) of these facilities owing to failure in meeting compliance requirements.[2]

DoE exempts over a hundred drugs from GFRs to facilitate Global Tender procurement

The Department of Expenditure ("**DoE**"), under the Union Ministry of Finance, has allowed government procurement of 120 (one hundred twenty) drugs through Global Tender Enquiry ("**GTE**") by exempting these drugs from the General Financial Rules, 2017 ("**GFRs**"), until March 31, 2027. The DoE issued an office memorandum dated June 7, 2024, confirming that "in view of the request of MoH&FW, a general exemption has been granted herewith under Rule 161(iv) of GFRs, from the instructions issued by DoE for issuance of GTE for procurement of 120 drugs listed at Annexure-A till March 31, 2027, or further orders."[3]

As per Rule 161(iv) of GFRs, a GTE is floated when a particular Ministry or Department feels that the goods of required quality, specifications, etc., may not be available in India and finds it necessary to look for suitable competitive offers from abroad. This procurement is facilitated by sending copies of tender notice to: (a) Indian Embassies abroad; and (b) Foreign Embassies in India. Pertinently, while the minimum limit for inviting tenders is INR 200 crore (two hundred crore rupees), a relaxation can be sought from the competent authority specified by DoE.

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1. https://www.indiabudget.gov.in/doc/bh1.pdf
2. https://www.livemint.com/industry/dcgi-inspection-brings-curtains-down-on-36-of-400-pharma-units-plans-for-new-digital-projects-11719489892389.html
3. The office memorandum can be accessed at: https://doe.gov.in/files/circulars_document/Relaxation_under_Rule_161_iv_of_General_Financial_Rules_2017_for_issuance_of_Global_Tender_Enquiry_GTE_for_procurement_of_Drugs_reg.pdf

The drugs which stand exempted following the release of the office memorandum include trulicity branded pre-filled pen for diabetes from Eli Lilly, risdiplam, sold under the brand name evrysdi by Roche, rheumatoid arthritis drug simponi from Johnson & Johnson, ryzodeg penfill branded by Novo Nordisk, among others.[4]

MoH&FW issues guidelines to regulate commercial usage of leftover and de-identified biological samples

On June 19, 2024, the MoH&FW issued the Indian Council of Medical Research's ("I**CMR**") 'Guidelines for Ethical Use of Leftover, De-Identified/Anonymous Samples for Commercial Purposes' ("**Guidelines**").[5]

As per the Guidelines, discarded specimens such as cells, tissues, saliva, nail clippings, among others, can serve as a resource for research and development activities, as well as identification of specific disease markers and determination of relevant health parameters. Owing to the huge potential, companies have been actively procuring and using these samples for the development of commercial kits or technologies for improving future patient outcomes, providing diagnostic accuracy or offering therapeutic advancements benefitting the society.

The Guidelines place an obligation on hospitals to ensure that samples are completely autonomous and de-identified irreversibly, to prevent any potential re-identification of patients. Robust data security measures are mandated to safeguard residual information associated with the samples.[6] These could be pooled samples or samples without any traceable identifiers that could potentially lead back to the patient.

Department of Pharmaceuticals sanctions initial funding to set up Centers of Excellence in NIPERs under the Scheme for Promotion of Research and Innovation in Pharma MedTech Sector

On June 21, 2024, the Department of Pharmaceuticals ("**DoP**") approved funding of INR 243 crore (two hundred forty-three crore rupees) for the establishment of Centers of Excellence ("**CoE**") in the National Institutes of Pharmaceutical Education and Research ("**NIPERs**") for 2024-25.[7] A steering committee, chaired by the DoP secretary, approved the CoE proposals for all NIPERs, with a total budget of INR 700 crore (seven hundred crore rupees) over 5 (five) years. This is part of the Scheme for Promotion of Research and Innovation in Pharma MedTech Sector ("**PRIP Scheme**") aimed at promoting research and development, and innovation in pharmaceuticals, medical devices, and animal health. The PRIP Scheme is geared towards: (a) establishing CoEs in the seven existing NIPERs at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata, Mohali and Raebareli; and (b) promoting research in: (i) new chemical and biological entities, and natural products; (ii) complex generics and biosimilars; (iii) precision medicines; (iv) medical devices; (v) orphan drugs; and (vi) drug development for antimicrobial resistance.[8]

The newly set-up CoEs will aid in building specific research capacities in these priority areas in a focused time-bound program, and accordingly contribute to strengthening the research infrastructure in Pharma-MedTech sectors in the country.

The Ministry of AYUSH inks MoU to ensure safety in the production of ayurvedic medicines

On July 3, 2024, the Ministry of AYUSH signed a Memorandum of Understanding ("**MoU**") with the Commissionerate of Indian Medicine and Homoeopathy ("**CIM&H**"), Arumbakkam, Chennai, Tamil Nadu.[9] The MoU marks a significant step towards strengthening collaborative efforts between the Ministry of Ayush and CIM&H and aims to enhance the quality and safety of ayurvedic and homeopathic medicines.

The MoU outlines a framework for: (a) providing National Accreditation Board for Testing and Calibration Laboratories' approved training guidance to the laboratory of CIM&H; and (b) conducting a joint research project for standardization and evaluation of the toxicity study for the preparation of selected higher order medicines.

The partnership intends to promote ongoing knowledge exchange and capacity building in order to foster a collaborative environment that facilitates harmonization of modern Indian medicine and homeopathy and encourages innovation in this field.

4. https://www.pharmabiz.com/NewsDetails.aspx?aid=169728&sid=1#:~:text=The%20Department%20of%20Expenditure%20(DoE,2017%20till%20March%2031%2C%202027.
5. https://mohfw.gov.in/?q=diseasealerts-7
6. https://www.deccanherald.com/india/health-ministry-issues-guidelines-for-ethical-use-of-leftover-de-identified-and-anonymous-samples-for-commercial-use-3081118
7. https://www.livemint.com/politics/policy/govt-sanctions-700-crore-for-setting-up-pharma-and-med-tech-centres-11719480603861.html
8. https://www.pharmabiz.com/NewsDetails.aspx?aid=170037&sid=1
9. https://pib.gov.in/PressReleaseIframePage.aspx?PRID=2029682

Delhi High Court issues injunction order against Zydus' biosimilar Sigrima

On July 9, 2024, the Delhi High Court issued an interim injunction order, restraining Zydus Lifesciences from selling its breast cancer drug 'sigrima', a biosimilar version of Roche's Perjeta, in a patent infringement case filed by the latter. The Swiss pharmaceutical giant Roche had sought an injunction, claiming that two products, namely: (a) sigrima by Zydus; and (b) womab, a petruzumab biosimilar co-marketed by Zydus and Dr. Reddy's in India, violated its patents.[10]

The injunction order was issued in view of false submissions made by Zydus concerning the timeline of obtaining the requisite drug approvals from CDSCO, and their decision to launch the product despite pending lawsuits.

PCI frames new regulations in line with the amendments under the Jan Vishwas Act, 2023

On July 9, 2024, the Pharmacy Council of India ("**PCI**") invited comments on the proposed inclusion of a new chapter, i.e., "Part XII – Manner of Holding Enquiry, Imposing Penalty and Preferring Appeal", in the Regulations of the Pharmacy Council of India, 1999 ("**PCI Regulations**"). The proposed chapter aims to regulate the manner of enquiry, imposition of penalty, and appeal procedure in dealing with cases of individuals falsely claiming registration as pharmacists under the Pharmacy Act, 1948 ("**Pharmacy Act**").[11]

This move comes in pursuance of the recent directive from the MoH&FW to revisit and frame laws in compliance with the amendment brought about by the Jan Vishwas (Amendment of Provisions) Act, 2023 ("**Jan Vishwas Act**").

As per the proposal, upon receipt of a complaint against any person falsely claiming to be a registered pharmacist, the President of the respective State Council ("**Adjudicating Officer**") will have the power to form an inquiry committee. The committee will conduct an inquiry and submit a detailed report, with relevant documents, to the registrar or secretary of the State Council within 14 (fourteen) days. In case the registrar or secretary of the respective State Council finds sufficient grounds for supporting the complaint, they are required to prepare a detailed report with evidentiary proofs and submit the same to the Adjudicating Officer within 7 (seven) days. The Adjudicating Officer will review the findings and determine the guilt of the accused. Any person contravening the provisions of the Pharmacy Act will be subject to monetary penalties, to the effect of up to INR 1 lakh (one lakh rupees) for the first conviction and up to INR 2 lakhs (two lakh rupees) for each subsequent conviction.[12]

MoH&FW issues draft rules to provide clarity on the compounding of offences under D&C Rules

On July 10, 2024, the MoH&FW, in consultation with the Drugs Technical Advisory Board ("**DTAB**"), released the draft Drugs and Cosmetics (Compounding of Offences) Rules, 2023 ("**Draft Rules**") to regulate the compounding of minor offences under the D&C Act.[13] While the provision related to compounding of offences, i.e., Section 32-B, was introduced in the D&C Act in 2008, it is only now that the Draft Rules have been formulated in order to regulate the procedure for such compounding.

The Draft Rules require applications for compounding be made under the aforesaid provision, which states that the following offences can be compounded if they are not punishable with imprisonment solely, or with imprisonment and a fine: (a) importing any drug or cosmetic prohibited under Section 10 of the D&C Act; (b) manufacturing any drug or cosmetic for sale or distribution in contravention of the Drugs and Cosmetics Rules, 1945 ("**D&C Rules**"); and (c) failure to maintain records and registers as required under the D&C Act upon obtaining license to manufacture drugs or cosmetics for sale or distribution.

Pertinently, the Draft Rules state that the applicant cannot claim compounding of their offence as a matter of right and lay down an extensive framework for such determination. As per these rules, upon receipt of an application for compounding, the compounding authority, appointed either by the Central Government or the relevant State Government, will require the reporting authority under whose jurisdiction the offence has been

10. https://www.cnbctv18.com/market/delhi-high-court-temporarily-bars-zydus-lifesciences-from-selling-breast-cancer-drug-19441700.htm
11. The proposed chapter can be accessed at: https://pcionline.co.in/wp-content/uploads/2024/07/Annexure-1.pdf
12. https://www.pharmabiz.com/NewsDetails.aspx?aid=170232&sid=1
13. The draft rules can be accessed at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE0NTE=

committed to furnish a report concerning the particulars mentioned in the application within one month from the date of such communication. Taking cognizance of the contents of the application, the compounding authority will either allow the application and grant the applicant immunity from prosecution subject to the payment of a compounding amount or reject the application.

MoH&FW releases draft notification for prohibiting advertisements of drugs specified in Schedule G of the Drugs and Cosmetics Rules

The MoH&FW released a draft notification ("**Notification**") on July 10, 2024, to prohibit advertisements of drugs specified in Schedule G of D&C Rules, without the prior approval of the Central Government.[14] This move comes in pursuance of the recent recommendation of the DTAB, accepting a proposal from the Director of Food and Drugs Administration, Goa.

The Notification highlights that while Rule 74 and 78 of D&C Rules state that no advertisement of the drugs specified in Schedule H, Schedule H1 & Schedule X shall be made except with previous sanction of the Central Government, there is no such provision for prohibition of advertisements for drugs specified in Schedule G, which may result in self-medication.[15]

Some of the drugs that are listed in Schedule G include blood sugar controlling drugs, including metformin and its salts; all types of insulin, glibenclamide; chemotherapy and oncology drugs such as aminopterin, L-asparaginase, busulfan and its salts, chlorambucil and its salts, cyclophosphamide and its salts, daunorubicin, hydroxyurea; antibiotic bleomycin; anti-epileptic drug methsuximide; anticonvulsant drugs ethosuximide, hydantoin, among others.

CDSCO decides to accept credible pre-clinical data for review of new drugs, subsequent new drugs and fixed-dose combinations

On July 29, 2024, the CDSCO released a circular to communicate its decision of accepting pre-clinical toxicity data already generated and accepted by regulatory authorities of other countries for review of new drugs, subsequent new drugs and fixed dose combinations. The CDSCO confirmed that "it has been decided to accept already generated pre-clinical toxicity data for review in the case of drug substance and drug product, based on the quality of data and the credentials of the laboratory where such data has been generated."[16]

In reaching this decision, the CDSCO relied on provisions of the New Drugs and Clinical Trials Rules, 2019, which makes a repeated dose toxicity study in India non-mandatory in certain cases including when data on animal toxicity has been submitted and the same has been considered by the regulatory authority of the country which had earlier approved the drug.

14. The notification can be accessed at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE0NTU=
15. https://www.pharmabiz.com/NewsDetails.aspx?aid=171261&sid=1
16. The circular can be accessed at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE0OTA=

MAJOR DEALS IN INDIA IN THE PHARMA AND HEALTHCARE INDUSTRY

The following are the key deals announced during the months of June 2024 and July 2024, in the pharma and healthcare industry:[17]

RV Group seeks to gain a foothold in India following its merger with KCH

RV Group, a multinational pharmaceutical powerhouse with a significant presence in the ASEAN and CIS regions, announced its merger with KCH, and the acquisition of legacy brands Celin and Septran.[18] This move is expected to allow RV Group to penetrate the Indian pharmaceutical landscape, a market they have been looking to grow in since acquiring a local manufacturing unit in Aurangabad. RV Group is dedicated to improving patients' lives with high-quality, affordable curative and preventive products, and is specifically planning on introducing nutraceutical products in India, where the market is being driven by an ageing population seeking healthy ageing solutions.

Dr. Reddy's to acquire Nicotinell and related portfolio to build a global consumer healthcare business

Dr. Reddy's Laboratories SA, a subsidiary of Dr. Reddy's Laboratories, has signed an agreement with Haleon PLC to acquire its global portfolio of nicotine replacement therapy (NRT) consumer healthcare brands outside the United States. Dr. Reddy's will purchase Northstar Switzerland SARL for GBP 500 million (five hundred million pounds sterling), with an upfront cash payment of GBP 458 million (four hundred and fifty-eight million pounds sterling) and contingent payments up to GBP 42 million (forty-two million pounds sterling), payable in the next 2 (two) years.

The acquisition includes brands like Nicotinell, Nicabate, Thrive, and Habitrol, spanning over 30 countries. Nicotinell, a leader in the NRT category, holds top positions in 14 of the top 17 global markets and generated GBP 217 million (two hundred and seventeen million pounds sterling) in revenue in 2023. The acquisition covers all formats, including lozenge, patch, and gum.[19]

Healthcare Global Enterprises Ltd. acquires Mahatma Gandhi Cancer Hospital & Research Institute to address demand-supply disparity

Cancer Care HealthCare Global Enterprises Limited ("**HCG**") has announced the acquisition of Mahatma Gandhi Cancer Hospital & Research Institute ("**MGCHRI**") in Vizag, Andhra Pradesh, at an enterprise value of INR 414 crore (four hundred and fourteen crore rupees). As per HCG's statement, it will initially hold a 51% (fifty-one percent) stake in MGCHRI, with plans to acquire an additional 34% (thirty-four percent) stake over the next 18 (eighteen) months.

The partnership is intended to address the significant demand-supply gap in radiation therapy equipment, with HCG aiming to expand its multi-modality programmes and enhance customer engagement through the acquisition. By leveraging operational synergies and scale advantages, the integration will use established technology platforms for digital marketing.[20]

Sun Pharma announces successful merger with Taros

Sun Pharmaceutical Industries Ltd. ("**Sun Pharma**") announced the successful completion of the merger of Taro Pharmaceutical Industries Ltd. ("**Taro**") with its subsidiary.[21] Sun Pharma has been the majority shareholder of Taro since 2010. As part of the merger, Sun Pharma acquired all outstanding ordinary shares of Taro. Following the merger, Taro is now a private company which is wholly owned by Sun Pharma.

17. 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.
18. https://health.economictimes.indiatimes.com/news/pharma/mergers-acquisitions/asean-leading-pharma-company-rv-group-enters-indian-market-with-acquisition-of-gsks-celin-septran/110665006
19. https://www.business-standard.com/markets/capital-market-news/dr-reddy-s-lab-jumps-after-arm-inks-pact-to-acquire-nicotinell-brand-124062700332_1.html
20. https://www.business-standard.com/health/healthcare-global-enterprises-acquires-andhra-based-mgchri-for-rs-414-cr-124062801044_1.html
21. https://sunpharma.com/wp-content/uploads/2024/06/Press-Release-Sun-Pharma-Completes-Taro-Merger.pdf

Jagsonpal Pharmaceuticals diversifies its expertise by acquiring Yash Pharma

Jagsonpal Pharmaceuticals announced the acquisition of the India and Bhutan businesses of Yash Pharma.[22] The transaction is expected to not only expand the therapeutic reach of Jagsonpal but will also have a positive effect on improving its standing in the market. The acquirer has a storied legacy with its strong presence in gynaecology and orthopaedics. This will be further bolstered as Yash Pharma's well-established portfolio of several dermatology and paediatrics brands become part of their offerings.

Maiden issuance of listed, rated, redeemable non-convertible debentures by ERIS Lifesciences Limited[23]

ERIS Lifesciences Limited has completed its maiden issuance of listed, rated, redeemable non-convertible debentures, amounting to INR 1,250 crore. The issuance was structured in two STRPPs, each aggregating up to USD 75 million.

22. https://health.economictimes.indiatimes.com/news/pharma/mergers-acquisitions/jagsonpal-pharmaceuticals-acquires-yash-pharmas-india-bhutan-business/111055342
23. INDUSLAW advised Citigroup Global Markets India Private Limited

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www.induslaw.com

OUR OFFICES

BENGALURU
101, 1st Floor, "Embassy Classic"# 11
Vittal Mallya Road
Bengaluru 560 001
T: +91 80 4072 6600
F: +91 80 4072 6666
E: bangalore@induslaw.com

HYDERABAD
204, Ashoka Capitol, Road No. 2
Banjarahills
Hyderabad 500 034
T: +91 40 4026 4624
F: +91 40 4004 0979
E: hyderabad@induslaw.com

CHENNAI
#11, Venkatraman Street, T Nagar,
Chennai - 600017 India
T: +91 44 4354 6600
F: +91 44 4354 6600
E: chennai@induslaw.com

DELHI & NCR
2nd Floor, Block D
The MIRA, Mathura Road, Ishwar Nagar
New Delhi 110 065
T: +91 11 4782 1000
F: +91 11 4782 1097
E: delhi@induslaw.com

9th Floor, Block-B
DLF Cyber Park
Udyog Vihar Phase - 3
Sector - 20
Gurugram 122 008
T: +91 12 4673 1000
E: gurugram@induslaw.com

MUMBAI
1502B, 15th Floor
Tower – 1C, One Indiabulls Centre
Senapati Bapat Marg, Lower Parel
Mumbai – 400013
T: +91 22 4920 7200
F: +91 22 4920 7299
E: mumbai@induslaw.com

#81-83, 8th Floor
A Wing, Mittal Court
Jamnalal Bajaj Marg
Nariman Point
Mumbai – 400021
T: +91 22 4007 4400
E: mumbai@induslaw.com