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

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INTRODUCTION

With 2024 coming to a close and 2025 starting to take shape, the healthcare and pharmaceutical sectors appear set to build on the positive momentum accumulated in the last year. The seismic developments that characterized 2024 have emboldened these sectors to embrace emerging technologies, tackle pressing global health challenges and further solidify the ever-evolving regulatory landscape in the new year. In this regard, continued efforts to bring uniformity in the regulation of medical devices, introduction of a novel framework for evaluating the validity and accuracy of rapid diagnostic tests and further streamlining of the application procedure for clinical trials serve as cases in point which highlight the upward trajectory that the healthcare and pharmaceutical sectors have been on lately.

In this edition of 'Checking the Pulse', we delve into key updates from December 2024 to January 2025 in the healthcare and pharmaceutical sectors, while also tapping on notable deals that have gained interest from the industry.

LEGAL & REGULATORY DEVELOPMENTS

The Ministry of Health and Family Welfare issues notification to amend the Cigarettes and other Tobacco Products (Packaging and Labelling) Rules, 2008

On December 2, 2024, the Ministry of Health and Family Welfare ("**MoH&FW**") issued the Cigarettes and other Tobacco Products (Packaging and Labelling) Amendment Rules, 2024 ("**Amendment Rules**") to amend the Cigarettes and other Tobacco Products (Packaging and Labelling) Rules, 2008.[1]

As per the Amendment Rules, with effect from June 1, 2025, cigarette and other tobacco product packaging must feature updated health warning, including the message "TOBACCO CAUSES PAINFUL DEATH" printed in white on a bright red background with a quit line number (1800-11-2356) printed in white on a black background. Additionally, the Amendment Rules prescribe the inclusion of 2 (two) new pictorial health warnings, to be displayed on tobacco product packaging in a phased manner. The first image shall be valid for a period of 12 (twelve) months starting from June 1, 2025, with the second image replacing it for the subsequent 12 (twelve) months.

To facilitate smooth implementation, MoH&FW shall make the digital versions of all specified health warnings available on its official platforms, ensuring that manufacturers and packagers have access to accurate and standardized materials.

The Amendment Rules aligns with the global best practices recommended by the World Health Organisation Framework Convention on Tobacco Control and reflects the Central Government's commitment towards safeguarding public health by raising awareness of the dangers of tobacco, encouraging cessation and deterring new users.

The Food Safety and Standards Authority of India issues advisory for e-commerce food business operators

On December 3, 2024, the Food Safety and Standards Authority of India ("**FSSAI**") issued an advisory for e-commerce food business operators ("**FBOs**") with the aim of strengthening the food safety compliance framework in India.[2] FSSAI cited the growing influence of e-commerce platforms in the food sector as the primary reason for issuing the advisory and highlighted the need for transparency and trust by customers as key to the overall strengthening of the food safety ecosystem in the country.

In pursuance of these objectives, the advisory requires FBOs to ensure that:

(a) their delivery staff are well trained in food safety and hygiene practices. The training should focus on safe handling and transportation of food to prevent contamination, as well as personal hygiene and proper sanitization procedures.

(b) food and non-food items are delivered separately in order to avoid the risk of cross-contamination.

(c) product claims made on e-commerce platforms are fully aligned with the information provided on the physical label of the product. In this regard, FBOs are required to have mechanisms in place to ensure that products listed on their platforms are in compliance with the Food Safety and Standards (Labelling and Display) Regulations, 2020.

(d) the food products being delivered to customers have sufficient remaining shelf life. In this regard, FSSAI has mandated that products must have a shelf life of 30% (thirty percent) or at least 45 (forty-five) days before expiry, at the time of delivery.

(e) they prominently display FSSAI license/ registration numbers of the sellers, and hygiene ratings obtained by them on the e-commerce platforms. FBOs shall be required to adhere to this requirement as a pre-requisite to listing the products of any seller on their platform.

These measures are intended to help mitigate risks associated with foodborne illnesses and fraudulent practices, safeguard consumer health and enhance consumer trust.

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1. The Amendment Rules can be accessed here: https://www.legalitysimplified.com/wp-content/uploads/2024/12/Cigarettes-and-other-Tobacco-Products-Packaging-and-Labelling-Amendment-Rules-2024.pdf
2. The advisory can be accessed here:https://www.fssai.gov.in/upload/advisories/2024/12/674efa161d756Adobe%20Scan%203%20Dec%202024.pdf

The Ministry of AYUSH notifies amendments to the Drugs and Cosmetics Act, 1940

On December 4, 2024, the Ministry of AYUSH ("**AYUSH**") issued a notification amending the First and Second Schedules of the Drugs and Cosmetics Act, 1940 ("**D&C Act**").[3] Pursuant to the notification, the following changes have been brought to the D&C Act:

(a) in the First Schedule, a list of 20 (twenty) authoritative books on the Homeopathy system of medicine and 34 (thirty-four) authoritative books on the Sowa-Rigpa system of medicine has been included. As a result of this inclusion, the definition of "Ayurvedic, Siddha and Unani drugs" under Section 3(a) of the D&C Act has significantly broadened. The D&C Act only recognizes Ayurvedic, Siddha and Unani drugs that have been manufactured in accordance with the formulae prescribed in the books that have been specified in the First Schedule.

(b) in the Second Schedule, the French Homeopathic Pharmacopoeia and the European Pharmacopoeia have been added as recognised standards based on which the import and manufacture of Homoeopathic medicines will be allowed in India. Accordingly, the forms of Homoeopathic medicines that can be imported or manufactured in India has increased as, prior to the amendment, only the drugs included in the Homoeopathic Pharmacopoeia of India, the United States of America ("**USA**"), United Kingdom and Germany could be manufactured or imported in the country.

Through this move, AYUSH aims to enhance the quality and accessibility of traditional medicines in India while aligning domestic standards with globally recognized benchmarks.

The Central Drugs Standard Control Organisation streamlines application procedure for clinical trials through SUGAM portal

The Central Drugs Standard Control Organisation ("**CDSCO**") has announced a streamlined procedure for submitting applications related to clinical trials by introducing an online system through the SUGAM portal. In this regard, CDSCO issued a notice on December 26, 2024, mandating applications for: (a) addition of clinical trial sites; and (b) changing principal investigators, to be made through the online portal.[4] This requirement is applicable to various forms of clinical trials, including global clinical trials, trials for new drugs, subsequent new drugs, investigational new drugs, fixed-dose combinations, as well as bioavailability and bioequivalence studies.

As per the notice, each application must be accompanied by a checklist of required documents along with proof of approval from the ethics committee supervising the trial. The notice also sets out the timelines for approval of these applications by CDSCO:

(a) in relation to the proposed addition of clinical trial sites, the application shall be deemed to be approved if no objection is received from CDSCO within 30 (thirty) days of receipt of application; and

(b) in relation to the proposed change of principal investigator, the application shall be deemed to be approved from the date of receipt of application itself, subject to the condition that the application is complete as per the checklist.

The initiative to streamline the application procedure is in line with continued efforts by CDSCO to instil efficiency and transparency in clinical trial management, while minimizing administrative delays.

MoH&FW prohibits manufacture, sale and distribution of veterinary drug Nimesulide

On December 30, 2024, MoH&FW issued a notification to prohibit the manufacture, sale and distribution of all formulations of the drug Nimesulide for animal use, with immediate effect.[5] The ministry cited the risk posed by the drug to animals and the availability of safer alternatives as primary reasons for issuing the ban in public interest, pursuant to its powers under Section 26A of the D&C Act.

3. The notification can be accessed here: https://egazette.gov.in/WriteReadData/2024/259267.pdf
4. The notice can be accessed here:https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/10171.pdf
5. The notification can be accessed here: https://www.legalitysimplified.com/central-government-prohibits-nimesulide-formulations-for-animal-use/

The decision to prohibit the drug was taken based on the recommendation given by the Drugs Technical Advisory Board early last year, which was backed by a study conducted jointly by the Bombay Natural History Society and the Indian Veterinary Research Institute. The study found that vultures treated with Nimesulide died within 2 (two) days of treatment due to elevated uric acid levels and highlighted that the veterinary use of the drug to treat cattle posed a major risk to vulture populations in India.

Notably, in 2023, MoH&FW had issued a similar ban on all formulations of the drugs Ketoprofen and Aceclofenac, in an effort to protect the vulture population from going extinct in the country.

Draft evaluation protocols issued for establishing uniformity in performance evaluation of in-vitro diagnostic kits

On December 31, 2024, CDSCO and the Indian Council of Medical Research jointly released the draft standard evaluation protocols ("**Protocol**") in order to streamline the procedure for issuance of license for in-vitro diagnostics under the Medical Devices Rules, 2017 ("**MDR**").[6]

The move intends to ensure the availability of high-quality, standardized diagnostic kits in India by bridging critical gaps in the evaluation of diagnostic kits prior to their licensure. In this regard, the Protocol establishes clear guidelines for sensitivity and specificity, alongside defining standardized procedures for reproducibility and field evaluations. Furthermore, the Protocol places emphasis on ethical and transparent testing processes to maintain integrity in the evaluation framework.

The Protocol includes performance and field evaluation guidelines for diagnostic tests targeting critical arboviral infections, including Chikungunya, Dengue, and Zika virus. Pertinently, if any kit is found to be Not of Standard Quality (NSQ), no repeat testing of the same kit shall be entertained, until valid proof of change in the kit composition is submitted by the manufacturer.

MoH&FW extends deadline for compliance with revised Schedule M norms for small and medium manufacturers

On January 4, 2025, MoH&FW issued a draft notification, proposing extension of the deadline for implementation of the revised Schedule M manufacturing norms by micro, small and medium manufacturers having turnover of INR 250 crores (Indian Rupees Two Hundred and Fifty Crores) or less ("**MSMEs**"), subject to public consultation and feedback.[7] Pertinently, on February 11, 2025, MoH&FW confirmed the decision to extend the deadline for compliance with Schedule M by issuing the Drugs Amendment Rules, 2025 ("**DA Rules**").[8]

Schedule M of the Drugs and Cosmetics Rules, 1945 outlines Good Manufacturing Practices (GMP) for pharmaceutical manufacturing premises in India. It provides guidelines for the layout, design and construction of manufacturing facilities, as well as standards for equipment, utilities and quality control systems. In December 2023, MoH&FW notified the revised Schedule M, with major changes in the manufacturing standards for drugs manufactured in India, in conformity with established global standards.

To facilitate smooth transition for manufacturers from the erstwhile paradigm to the revised one, large manufacturers i.e., manufacturers having turnover exceeding INR 250 crores (Indian Rupees Two Hundred and Fifty Crores) were given a period of 6 (six) months (i.e., till June 28, 2024) to implement changes while MSMEs were accorded a period of 12 (twelve) months (i.e., till December 28, 2024). However, MSMEs have repeatedly requested for an extension of this deadline due to not being in a position to comply with the requirements of the revised norms within a short timeframe.

In view of this, the DA Rules now enables MSMEs to apply to the Central Licensing Approving Authority in Form A for seeking an extension of the deadline, within a period of 3 (three) months from the date of publication of the DA Rules, along with a plan of upgradation. Pertinently, for such applicants, the timeline for implementation of revised Schedule M norms shall stand extended till December 31, 2025.

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6. The Protocol can be accessed here:https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIzNDA=
7. The draft notification can be accessed here:https://mohfw.gov.in/sites/default/files/Notification%20GSR%2010%28E%29_0001_0.pdf
8. The DA Rules can be accessed here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI1MTk=

Central Government plans to reclassify medical devices in a bid to enhance regulatory uniformity

In an attempt to bring uniformity and clarity in the regulation of medical devices in India, the Central Government is planning to reclassify medical devices based on their risk levels, in line with the provisions of MDR. As part of these efforts, CDSCO issued a notice dated January 6, 2025, whereby it released a draft list of the intended classification for feedback from stakeholders.[9]

The draft list classifies 1,178 (one thousand one hundred and seventy-eight) medical devices into 4 (four) main categories based on their intended use and risk levels. These categories include: (a) Interventional Radiology, consisting of 186 (one hundred and eighty-six) devices used for minimally invasive procedures like angiographic systems and catheters; (b) Radiotherapy, consisting of 114 (one hundred and fourteen) devices, including linear accelerators and brachytherapy systems used in cancer treatment; (c) Oncology, consisting of 75 (seventy-five) devices, including biopsy instruments and tumour markers, specifically designed for cancer detection and treatment; and (d) Class A Non-Sterile and Non-Measuring Devices, consisting of 803 (eight hundred and three) low-risk devices, including surgical instruments and diagnostic tools.

The revised classification incorporates new devices based on their risk levels under MDR and is in alignment with internationally recognized standards. The classification based on risk levels will provide greater clarity to manufacturers applying to procure license for manufacturing medical devices. This is because under the current framework, separate authorities are responsible for issuing licenses for distinct categories of medical devices – while manufacturing licenses for low-risk devices are issued by State Licensing Authorities, the Central Licensing Authority is responsible for issuing licenses in relation to high-risk devices.[10] The classification is intended to be dynamic, with periodic updates expected based on new products and innovations being manufactured/ imported into India.

CDSCO issues guidance document to establish comprehensive framework for rapid diagnostic tests

On January 16, 2025, CDSCO issued a guidance document ("**Guidance Document**") for providing assistance to the innovators and testing laboratories in validating diagnostics meant for pathogen identification and antimicrobial ("**AMR**") susceptibility testing.[11] The Guidance Document establishes a comprehensive framework to systematically evaluate and confirm the diagnostic performance of a given test, in order to ensure its accuracy, reliability and utility for clinical decision-making.

The move comes amidst concerns that the lack of a standardized framework for validation processes in India has impeded its health care system in keeping pace with recent advances in molecular techniques that have enabled the development of new and improved diagnostic tests capable of identifying micro-organisms and detecting AMR genes. Furthermore, the significant consumption of antibiotics in India, owing to its dense population, a significant burden of infectious diseases and diverse healthcare practices has further compounded the problem.

To address these concerns, the Guidance Document elaborates on the requisites, steps and process-flow for undertaking the validation of diagnostic tests for AMR, and provides guidelines on selecting appropriate reference methods, designing validation studies, and defining acceptance criteria to ensure consistency with regulatory and clinical standards. Notably, the Guidance Document stresses the importance of considering diverse clinical scenarios and pathogen profiles during validation to maximise real-world applicability.

Union Budget presents positive outlook for the pharmaceutical and healthcare sector

The Union Budget ("**Budget**") released by the Ministry of Finance on February 1, 2025, has increased the budgetary allocation for the Union Health Ministry – from INR 89,974.12 crores (Indian Rupees Eighty Nine Thousand

9. The notice can be accessed here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIzNDI=
10. https://medicaldialogues.in/news/industry/medical-devices/cdsco-releases-draft-1178-medical-devices-to-be-reclassified-into-4-categories-aimed-welcomes-move-141384#:~:text=New%20Delhi%3A%20The%20Centre%20is,Rules%20(MDR)%2C%202017
11. The Guidance Document can be accessed here: https://www.teamleaseregtech.com/updates/article/38671/cdsco-issued-a-guidance-document-validation-of-rapid-diagnostics-for-p/

Nine Hundred and Seventy Four point One Two Crores) in the Union Budget for the year 2024-2025 to INR 99,858.56 crores (Indian Rupees Ninety Nine Thousand Eight Hundred and Fifty Eight point Five Six Crores).

The Budget has introduced several exemptions under the Basic Customs Duty ("**BCD**") framework to rationalise tariff structures, boost domestic manufacturing and provide relief to patients suffering from cancer, rare diseases and chronic ailments. In this regard, a total of 36 (thirty-six) life-saving drugs have been exempted from BCD, while 6 (six) new medicines have been added to the list of drugs and medicines attracting a concessional 5% (five percent) customs duty. This move will make vital drugs cheaper and more accessible to patients in need. In similar vein, the Budget has proposed that drugs under Patient Assistance Programmes operated by pharmaceutical companies will be fully exempted from BCD, provided they are supplied free of charge to the patients.

Other major highlights of the Budget in the healthcare and pharmaceutical sector include focus on: (a) establishment of 200 (two hundred) daycare cancer centres across all district hospitals in the India by 2026; (b) growth of medical education in the country through addition of medical seats in recognized educational institutions in the next 5 (five) years; (c) making the country a global hub for medical tourism by providing high-quality, affordable treatments to international patients; (d) developing a tech-enabled healthcare ecosystem by enhancing digital health and AI-driven diagnostics; (e) improving healthcare for senior citizens through establishment of cancer care centres and expanding healthcare insurance coverage for the elderly; and (f) boosting private-sector driven research and development and innovation.

MAJOR DEALS IN INDIA IN THE PHARMA AND HEALTHCARE INDUSTRY

The following are the key deals announced during the months of December 2024 and January 2025, in the pharma and healthcare industry:[12]

Tirupati group completes acquisition of Surya Herbal Limited[13]

Tirupati group, through one of its subsidiaries completed the acquisition of Surya Herbal Limited, a prominent manufacturer of herbal drugs and products and ayurvedic medicines. The acquisition will allow Tirupati group to enhance its manufacturing capabilities and expand its offerings to cater to a broader customer base.

Piramal Alternatives completes investment in 3Gen Consulting Services Private Limited[14]

Piramal Alternatives, the fund management vertical of the Piramal Group, completed its primary investment of USD 218 crores (US Dollars Two Hundred and Eighteen Crores) in 3Gen Consulting Services Private Limited ("**3Gen**"), a fast-growing healthcare consulting and revenue cycle management provider with presence in India and USA. The investment will allow 3Gen to expanding its operations, enhance its technological capabilities, and enter new markets.

Reliance Industries acquires oncology platform Karkinos Healthcare

On December 28, 2024, Reliance Industries ("**Reliance**") announced the 100% (one hundred percent) acquisition of Karkinos Healthcare Private Limited ("**Karkinos**"), a technology-driven oncology-focused startup, through its wholly-owned subsidiary Reliance Strategic Business Ventures ("**RSBV**").[15] Karkinos specializes in early cancer detection, diagnosis, and management, and has partnered with around 60 (sixty) hospitals since its incorporation in 2020.

As part of the deal, RSBV subscribed to 1 crore (one crore) equity shares, along with 36.5 crore (thirty-six point five crore) optionally convertible shares of Karkinos, for a combined value of INR 375 crores (Indian Rupees Three Hundred and Seventy Five Crores). The deal came to fruition owing to Karnikos entering the corporate insolvency resolution process in accordance with the Insolvency and Bankruptcy Code, 2016, and RSBV submitting a resolution plan which was ultimately approved by the National Company Law Tribunal.

The acquisition aligns with the broader strategy of Reliance to enhance its presence in the healthcare sector and provide end-to-end solutions for cancer care at affordable rates in India.

Laurus Bio Private Limited secures equity investments from Eight Roads Ventures and F-Prime Capital

Laurus Bio Private Limited ("**Laurus Bio**") has signed definitive agreement for an equity investment of INR 120 crore (Indian Rupees One Hundred and Twenty Crores) from global investors Eight Roads Ventures and F-Prime Capital, with Laurus Labs Limited ("**Laurus Labs**") undertaking to co-invest an additional INR 40 crore (Indian Rupees Forty Crores) at the same valuation.[16]

Laurus Bio, a subsidiary of Laurus Labs, is an integrated research-driven biomanufacturing organization with specialization in microbial precision fermentation and recombinant technology. It intends to use the raised funds for expanding its fermentation-based manufacturing capabilities and catering to the growing demand for its products.

Orange Health Labs secures funding led by Amazon Smbhav Venture Fund

Bengaluru-based diagnostics startup Orange Health Labs ("**Orange Health**") secured INR 101.5 crore (Indian Rupees One Hundred and One point Five Crores) in

12. 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.
13. INDUSLAW advised Tirupati group.
14. INDUSLAW advised Piramal Alternatives and 3Gen Consulting Services Private Limited and its promoters.
15. https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/ril-buys-karkinos-health-for-rs-375-crore/articleshow/116749594.cms?from=mdr
16. https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/laurus-labs-biotech-unit-raises-rs-120-crore-from-eight-roads-ventures/articleshow/116047235.cms?from=mdr

a funding round led by the Amazon Smbhav Venture Fund, with participation from existing investors Accel, General Catalyst, Bertelsmann India Investments, and Y Combinator.[17]

Founded in 2020, Orange Health is an on-demand diagnostics service provider geared towards providing diagnostics services directly to customer's doorsteps, with booking available through its website and mobile application. It intends to utilize the funds raised to expand its product offerings, grow its workforce, and invest in new diagnostic innovations.

Lupin Limited strengthens diabetes portfolio by acquiring trademarks from Boehringer Ingelheim International GmbH

Lupin Limited ("**Lupin**") announced the acquisition of anti-diabetes trademarks GIBTULIO, GIBTULIO MET and AJADUO from Boehringer Ingelheim International GmbH ("**Boehringer**"), to strengthen its diabetes portfolio in India.[18] Lupin has been marketing GIBTULIO and GIBTULIO MET since 2016, and AJADUO since 2018 in the Indian market through existing co-marketing agreements with Boehringer. As per the terms of the agreement, the trademark rights for these brands will be transferred to Lupin by March this year.

GIBTULIO (empagliflozin), GIBTULIO MET (empagliflozin + metformin) and AJADUO (empagliflozin + linagliptin) belong to a novel class of oral anti-diabetic drug, sodium glucose co-transporter-2 (SGLT-2) inhibitor. The use of these drugs has shown to improve glycemic control in adults with type 2 diabetes mellitus as an adjunct to diet and exercise. Empagliflozin is also indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes, and the risk of cardiovascular death and hospitalization for heart failure in adults with chronic kidney disease.

17. https://www.orangehealth.in/blog/amazon-fuels-orange-healths-growth-with-latest-investment?post=70&utm_term=amazon-fuels-orange-healths-growth-with-latest-investment&utm_source=seo_search&utm_campaign=seo&utm_medium=google
18. https://www.lupin.com/lupin-acquires-3-trademarks-from-boehringer-ingelheim-to-strengthen-diabetes-portfolio/

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