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synapse

A quarterly update on the pharmaceutical, life sciences and healthcare industry

Volume VII | Issue III | April - June 2024

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Dear Readers,

In this edition, we explore India's healthcare sector under Modi 3.0, witnessing a renaissance in pharmaceutical, healthcare, and life sciences innovation driven by robust research and development and initiatives targeting rare diseases. Economic growth, bolstered by a business-friendly environment and a burgeoning middle class, is fuelling substantial private investment in healthcare. Increased spending, expanded manufacturing capabilities, and technological advancements are positioning India as a global hub for healthcare investments. The upcoming budget aims to enhance rural healthcare access, strengthen the Ayushman Bharat scheme, and boost local manufacturing under the "Make in India" initiative, while also incentivising foreign investments to further propel this transformative growth.

As in the previous few quarters, the sector witnessed important regulatory and news updates even in the April–June 2024 quarter, which we have covered in this edition of Synapse. Aiming to make Medical Termination of Pregnancy Rules, 2003, more inclusive and align with the Rights of Persons with Disabilities Act, 2016, the Central Government amended the Rules by substituting the phrase *"mental retardation"* with *"women with intellectual disability"* in Rule 3B and Form E. Rule 3B now allows certain categories of women, including *"women with intellectual disability"*, to terminate a pregnancy up to 24 (twenty-four) weeks of gestation. Additionally, the draft *"Guidelines for Withdrawal of Life Support in Terminally Ill Patients"* for healthcare providers were released for comments from stakeholders. These guidelines are based on the principles of foregoing life support and compassionate care. They also recognise respect for patients' autonomy and physician duties of beneficence, non-maleficence, and distributive justice. In the food space, the FSSAI instructed Food Business Operators (FBOs) to remove the claim of 100 per cent fruit juices from the label and advertisement of reconstituted fruit juices and use existing packaging by September 1, 2024. Additionally, e-commerce FBOs must reclassify "Proprietary Food" with the nearest category – Dairy-Based Beverage Mix or Cereal-Based Beverage Mix or Malt-Based Beverage from "health drinks/energy drinks" on their website and place such products in the appropriate category.

In the litigation space, the Supreme Court issued notice in a plea filed challenging government regulation mandating uniform rates for ophthalmological procedures. The petition was filed against the implementation of Rule 9 of the Clinical Establishment Rules, 2012. The Apex Court, while issuing notice, tagged it with a similar writ petition filed by the "Veterans Forum for Transparency in Public Life", which seeks the implementation of Rule 9. In another PIL case concerning the onus to communicate drug side effects filed before the Delhi High Court, the High

Court ruled that the legislature has wisely placed the responsibility on manufacturers and pharmacists, and not on doctors. The High Court noted that there is no legal vacuum on this issue, and any judicial interference would amount to judicial legislation. In another instance, the National Consumer Disputes Redressal Commission affirmed that the absence of essential medical supplies in a hospital constitutes medical negligence. The National Forum upheld a compensation order issued by the Delhi State Consumer Disputes Redressal Commission. Due to the non-availability of "Nirmin", the patient was administered "Albumin" instead. The said patient subsequently died, and the patient's family brought the case to the District Forum.

We have also witnessed some significant transactions and investments-related updates in the sector and have endeavoured to cover the same in this edition of Synapse.

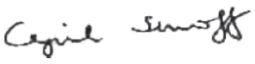
Cyril Amarchand Mangaldas, India's premier full-service law firm, has an industry leading and dedicated to pharmaceuticals, healthcare, and life sciences practice. Our class-leading practice specialists are always on top of the latest developments in the sector. In our endeavour to keep you abreast with the latest developments in this dynamic sector, we present to you the latest issue of Synapse. We hope you find this issue of interest. As always, your feedback makes us improve our efforts. Please feel free to send your comments, feedback, and suggestions to cam.publications@cyrilshroff.com.

We also encourage you to visit our blog at https://corporate.cyrilamarchandblogs.com for more articles on matters of interest in the Indian pharmaceutical, life sciences, and healthcare space.

We hope that you enjoy reading our newsletter as much as we have enjoyed preparing it. Your comments and feedback are most welcome. In the meanwhile, please stay safe and healthy.

Regards,

CYRIL SHROFF



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Regulatory Updates

1. Notification on amendment to the Medical Termination of Pregnancy Rules, 2003[1]

The Ministry of Health and Family Welfare (**MoHFW**), *vide* notification F. No. M-12015/27/2023-MCH dated June 10, 2024, issued an amendment to the Medical Termination of Pregnancy Rules, 2003 (**MTP Rules**), Through this amendment, the phrase *"mental retardation"* has been substituted with *"women with intellectual disability"* in Rule 3B and Form E of MTP Rules. Rule 3B of MTP Rules allows certain categories of women, now also including *"women with intellectual disability"*, to get a pregnancy terminated up 24 (twenty-four) weeks of gestation. This amended position is more inclusive and is in line with the provisions of the Rights of Persons with Disabilities Act, 2016.

2. Notification soliciting public comments on draft guidelines for withdrawal of life support for terminally ill patients[2]

The MoHFW, released the draft *"Guidelines for Withdrawal of Life Support in Terminally Ill Patients"* for healthcare providers. These guidelines are based on the principles of foregoing life support and compassionate care. It also recognises respect for patients' autonomy and physician duties of beneficence, non-maleficence, and distributive justice. According to the principles outlined in these guidelines, life-support may be withheld or withdrawn lawfully under certain conditions from persons with no decision-making capacity. The MoHFW had set a 30 (thirty)-day deadline for stakeholders submit their comments, suggestions, and objections to the draft guidelines.

3. Notification on issuance of "Guidelines for Ethical Use of Leftover/De-identified/Anonymous Samples for Commercial Purposes" [3]

The MoHFW, *vide* office memorandum No. Q-11022/ 59/2023-HR(ICMR) dated December 15, 2023, published the *"Guidelines for Ethical Use of Leftover/ De-identified/ Anonymous Samples for Commercial Purposes"* (**Leftover Guidelines**) on June 19, 2024. These guidelines aim to promote research and development of novel treatments and diagnostic tools. The Leftover Guidelines apply only to leftover samples that are anonymised irreversibly and do not apply to samples being used in original research. These guidelines are based on the principles of anonymity and data security; transparency and communication; and affordability and accessibility.

4. Notification on inclusion of Cochin and Thiruvananthapuram airports for drugs import[4]

The MoHFW, *vide* notification F. No. X.11035/131/2022-DR, dated May 28, 2024, notified the listing of Cochin and Thiruvananthapuram airports, in Kerala, for import of drugs by air under the Drugs Rules, 1945 (**Drugs Rules**). These 2 (two) airports are the 10th (tenth) and 11th (eleventh) airports through which the import of drugs is allowed in accordance with the Rule 43A of the Drugs Rules. As per this rule, no drug shall be imported into India except through one of the places listed under these rules, including Chennai, Kolkata, Mumbai, Delhi, Ahmedabad, Hyderabad, Goa, Bengaluru, and Visakhapatnam.

5. Notification on withdrawal of direction issued under Rule 170 of Drugs Rules[5]

The Ministry of AYUSH, *vide* letter No. T-13011/1/2022-DCC-Part (2) dated May 8, 2024, withdrew the earlier directions issued to all the State Licensing Authorities and Drugs Controller of AYUSH to refrain from taking any action under Rule 170 of Drugs Rules. Rule 170 of Drugs Rules prohibits advertisements of Ayurvedic, Siddha, or Unani drugs without the approval of the licensing authorities. Last year, all State Licensing Authorities and Drugs Controller of AYUSH were directed to not take any action under Rule 170 of Drugs Rules, following a recommendation from the Ayurvedic, Siddha, and Unani Drugs Technical Advisory Board (**ASUDTAB**).

6. Advisory order on strict compliance with the labelling provisions by AYUSH drugs manufacturers[6]

The Ministry of AYUSH, *vide* an order dated April 18, 2024, issued an advisory to all the AYUSH drugs manufacturers to

[1] https://egazette.gov.in/WriteReadData/2024/254813.pdf
[2] https://main.mohfw.gov.in/sites/default/files/Guidelines%20for%20withdrawal%20of%20Life%20Support.pdf
[3] https://main.mohfw.gov.in/sites/default/files/Guidelines%20for%20Ethical%20use%20of%20Leftover%20De-identified%20%281%29.pdf
[4] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTEzMjU=
[5] https://drugscontrol.org/pdf/Rule170dtd29.8.2023_withdrawal.pdf
[6] https://ayushexcil.in/img/publication/Advisory-1.pdf

strictly adhere to the labelling and advertisements provisions of Ayurveda, Siddha, Unani and Homoeopathy (**ASU&H**) drugs. The advisory also warns of legal action if such manufacturers make any misleading claims or advertisements, including claims such as "Approved / Certified by Ministry of Ayush". The ministry has also asked all state drugs licensing authorities to inspect all ASU&H drugs.

7. Indian Council of Medical Research Updates:

a. Release of revised dietary guidelines[7]

The Indian Council of Medical Research (**ICMR**), released the revised *"Dietary Guidelines for India"* dated May 10, 2024, consisting of 17 (seventeen) different guidelines, that place special emphasis on the promotion of health and prevention of diseases for all age groups including infants, children, pregnant and lactating woman, elderly, and the adolescent. These guidelines intend to provide advice on the consumption of a variety of food for a balanced and diversified diet and facilitate optimal nutrition throughout the lifetime of an individual. Additional key recommendations in these guidelines include reading label information carefully, staying hydrated by drinking plenty of water, prioritising nutrient-rich foods in the diets of elderly individuals, consuming safe and clean food, and maintaining regular physical activity and exercise.

8. Food safety standards: Notifications / Orders / Circulars by Food Safety and Standards Authority of India (FSSAI)

a. Notification soliciting public comments on amendments to Food Safety and Standards Rules, 2011[8]

The MoHFW, *vide* notification F. No. P.15014/13/2019-FR dated May 29, 2024, released the draft Food Safety and Standards (First Amendment) Rules, 2024 (**FSS Amendment Rules 2024**). The FSS Amendment Rules 2024 enhance the scope of power of the adjudicating officer under sub-rule 3.1.1 of the Food Safety and Standards Rules, 2011. According to the FSS Draft Rules 2024, the adjudicating officer is now empowered to hold inquiries for offences punishable under Section 61 (penalty for false information) and Section 63 (penalty for carrying out business without license) of the Food Safety and Standards Act, 2006 (**FSS Act**). The intent behind publishing the draft amendment is to seek comments from the public.

b. Notifications soliciting public comments on amendments to Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011

The MoHFW, *vide* notifications No. STD/41-FA/Notification/2023[9] (**First Amendment Regulation**) dated June 5, 2024, and No. STD/42-FA/Notification/2023[10] (**Second Amendment Regulation**) dated June 5, 2024, released the draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2024, which seek to amend Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.

The First Amendment Regulation defines the term *"ultra pasteurization"* of milk. This method preserves quality while extending the shelf life at room temperature. Among other things, it suggests specifications for 4 (four) edible nut oils – coconut testa, pistachio, hazelnut, and walnut. This amendment also seeks to control the amount of water used in edible ice items, such as ice lollies. Along with defining new spice standards for juniper berries, a popular culinary spice, it also establishes new requirements for high fructose corn syrup. It also aims to establish guidelines for the amount of total and saturated fat used in chocolate spreads and imitation chocolate.

The Second Amendment Regulation introduces amendments to synthetic syrups for carbonated water. The more general word "sweeteners" is used in place of *"nutritive sweeteners"*. Furthermore, it eliminates the necessity for a minimum total soluble solid content. The acidity restrictions for retort and aseptically processed products no longer apply to culinary pastes, fruit, and vegetable sauces. Additionally, the draft specifies certain guidelines for whole maize (corn) flour and establishes the relevant limitations. It also suggests further specifications for the total ash content, alcoholic acidity, and calcium content for ragi flour. The amendment mandates specific quality requirements for flattened rice that include its physical appearance

[7] https://main.icmr.nic.in/sites/default/files/upload_documents/DGI_07th_May_2024_fin.pdf
[8] https://fssai.gov.in/upload/uploadfiles/files/rule.pdf
[9] Draft Food Safety and Standards_Food Products Standards and Food Additives_Amendment Regulations2024.pdf (fssai.gov.in)
[10] food product.pdf (fssai.gov.in)

(colour, stains, infestation), its lack of foreign objects (dirt, stones, etc.), and its flavour and taste (pleasant, no mustiness). It also proposes standards for edible rock and black salt.

c. *Notification soliciting public comments on amendments to Food Safety and Standards (Alcoholic Beverages) Amendment Regulations, 2024*[11]

The FSSAI, *vide* notification No. ADVT.-III/4/Exty./185/2024-25 dated June 13, 2024, released the draft Food Safety and Standards (Alcoholic Beverages) Amendment Regulations, 2024, which changes the requirements related to the characteristics of wines. This draft amendment increases the maximum content of "Esters expressed as ethyl acetate (g/l of absolute alcohol), Max" from 0.2 g/l of absolute alcohol to 3.0 g/l of absolute alcohol. However, this amendment is restricted to "fruit wine other than grape wine", and the amount of "Esters expressed as ethyl acetate" remains unaltered for all other wines. The FSSAI also set a 60 (sixty)-day deadline for stakeholders submit their comments, suggestions, and objections to the draft amendment.

d. *Advisory order on sale / marketing of reconstituted fruit juices as 100 per cent fruit juice*[12]

The FSSAI, *vide* order No. RCD-02004/1/2023-Regulatory-FSSAI dated (Part 5) dated June 3, 2024, directed all the Food Business Operators (**FBOs**) to remove the claim of 100 per cent fruit juices from the label and advertisement of reconstituted fruit juices and to exhaust all existing pre-printed packaging materials before September 1, 2024. FSSAI issued this order because several FBOs were selling reconstituted fruit juices by falsely labelling them as 100 per cent fruit juice. As per the Food Safety and Standards (Advertising and Claims) Regulations, 2018, a claim of 100 per cent fruit juice is not allowed and is considered misleading if the major ingredient of fruit juice is water and if it is reconstituted using water and pulp.

e. *Advisory order on unauthorised use of liquid nitrogen in food by the food serving establishments/restaurants, bars, etc.*[13]

The FSSAI, *vide* order No. RCD-15001/16/2023-Regulatory-FSSAI dated June 3, 2024, directed that any unauthorised use of liquid nitrogen in the food items shall result in initiation of statutory action against the food businesses in accordance with the FSS Act and the rules / regulations made thereunder. The order notes that usage of liquid nitrogen in restaurants, bars, food serving establishments / caterers in fair, marriages, etc., to make food items visually appealing has led to serious health issues for the consumers, prompting the FSSAI to issue this advisory order.

[11] https://fssai.gov.in/upload/uploadfiles/files/Draft%20Notification_Alcoholic%20Bvg_13%20June%202024%20GAZETTED.pdf
[12] 665eb7e80327aAdvisory 100_percent Fruit juices.pdf (fssai.gov.in)
[13] https://www.fssai.gov.in/upload/advisories/2024/06/665eec4586728Advisory%20_liquid%20nitrogen.pdf

f. Advisory order on categorisation of health drinks / energy drinks on e-commerce website[14]

The FSSAI, *vide* order No. RCD-15001/12/2023-Regulatory-FSSAI-Part (1) dated April 4, 2024, directed all e-commerce FBOs to remove/delink food products licensed under "Proprietary Food" with the nearest category being dairy-based beverage mix, cereal-based beverage mix or malt-based beverage from the category of "health drinks/energy drinks" on their website and place such products in the appropriate category. This advisory has been issued to enhance clarity and transparency about the nature and functional properties of the said products so that consumers can make informed choices.

9. Central Drugs Standards Control Organisation Updates

a. Circular on extension to existing importer/manufacturer dealing in Class C and D medical devices[15]

The Central Drugs Standards Control Organisation (**CDSCO**), *vide* circular F. No. 29/Misc/03/2023-DC (344) dated May 16, 2024, granted a 3 (three) month extension to existing importers / manufacturer, who had applied for grant of importing / manufacturing licenses for Class C and D medical devices to the Central Licensing Authority on or before September 30, 2023. Importers / manufacturers already engaged in importing and manufacturing medical devices can continue these activities for up to 3 (three) months from the date of issue of the circular or until the Central Licensing Authority decides on their application.

b. Circular on mandatory compliance of medical devices with BIS standards[16]

The CDSCO, *vide* circular F. No. MED/48/2024-eoffice dated May 29, 2024, has mandated that the samples of medical devices must comply with Bureau of Indian standards (**BIS**) to ensure their quality and performance. Henceforth, testing of medical devices shall adhere to BIS standards requirements. In cases where no BIS standard is available, compliance with standards under Rule 7 of Medical Devices Rules, 2017 (**MDR 2017**), is required. This includes standards laid down by the International Organisation for Standardisation (**IOS**), International Electro Technical Commission (**IEC**), and validated manufacturers.

c. Draft guidance document on policy for vaccine approval[17]

The CDSCO released the draft guidance document on "*Policy for Vaccine Approval*" dated April 2, 2024, which provides broad guidelines and a framework for conducting clinical trials, obtaining marketing approvals, manufacturing, import, export, post marketing clinical assessment, and post marketing approvals of vaccines in India. The CDSCO had a 30 (thirty)-day deadline for stakeholders to submit their comments, suggestions, and objections to the draft guidance.

d. Draft guidelines on good distribution practices for pharmaceuticals products[18]

The CDSCO, *vide* document No. CDSCO/GDP.PP, released the draft guidelines on "Good Distribution Practices for Pharmaceutical Products" dated April 2, 2024. These guidelines align with the WHO Technical Report Series (**TRS**) on good storage and distribution practices for pharmaceutical products. They outline steps to fulfil the responsibilities / duties across various stages of the supply chain and prevent the introduction of not of standard quality and spurious products into the market. The CDSCO had a 30 (thirty) day deadline for stakeholders to submit their comments, suggestions, and objections to the draft guidelines.

e. Draft guidance document on stability studies of In-Vitro Diagnostic Medical Devices[19]

The CDSCO, *vide* document No. CDSCO / IVD / GD / Stability / 02/2022 dated April 5, 2024, released a draft guidance document on *"Stability Studies of In-Vitro Diagnostic Medical Device* (**IVDMD**). This document provides guidance for manufacturers engaged in preparing premarket review document for importing IVDMDs or applying for manufacturing licenses. It aids in integrating global regulatory practices within the licensing requirements of MDR 2017 for IVDMD license applications.

[14] https://www.fssai.gov.in/upload/advisories/2024/04/660d30f574b44Advisory_Health%20Drink_on%20e-commerce%20website.pdf
[15] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTEyMzE=
[16] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTEzMTg=
[17] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTEwNzA=
[18] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTEwNzE=
[19] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTEwODA=

f. *Guidance document for Industry for Biologicals Version 1.2*[20]

The CDSCO, *vide* documents No. CT/032024 Version – 1.2; MA/032024 Version – 1.2 and QI/032024 Version – 1.2, released the "Guidance for Industry Version 1.2" document dated May 15, 2024. This document supersedes the "Guidance for Industry (Biologicals) Version 1.1" released in year 2008 and has been developed in accordance with the New Drugs and Clinical Trials Rules, 2019, Good Clinical Practices Guidelines of India, and the SUGAM application process. It addresses the preparation of quality information required for new drug approval applications for biotechnological and biological products. Additionally, it outlines procedures for filing clinical trial applications to assess safety and efficacy requirements for obtaining new drug approval.

g. *Guidance document on "Post Approval Changes in Biological Products: Quality Safety and Efficacy Documents"*[21]

The CDSCO, *vide* document No. PAC/2024 Version – 1.2 dated May 16, 2024, released the guidance document on "Post Approval Changes in Biological Products", which provides guidance to market-authorisation holders on regulating modifications to the original marketing-authorisation dossier for approved biological products. The document also includes classification of changes to biological products and offers recommendations on the data needed for national regulatory authorities to assess the impact of these changes on product's quality, safety, and effectiveness.

h. *Circular on medical device related adverse events reporting by medical device licence holder under Materiovigilance Programme of India*[22]

The CDSCO, *vide* circular No. MED-12/30/2024-eoffice dated May 15, 2024, has instructed all stakeholders to promptly report adverse events related to medical devices to the Materiovigilance Programme of India (**MvPI**). This initiative aims to enhance procedures for identifying risk associated with medical device usage. MvPI, launched by MoHFW, improves patient safety by monitoring, recording, and analysing root causes of adverse events linked to medical device use by healthcare professionals.

i. *Draft guidance for industry on "Pharmacovigilance Requirements for Human Vaccines"*[23]

The CDSCO, *vide* F. No. PSUR-11011(14)/13/2024-eoffice dated May 29, 2024, released a draft guidance for industry on *"Pharmacovigilance Requirements for Human Vaccines 2.0"* aimed at manufacturers and importers of human vaccines concerning vaccine safety monitoring, audits and inspections, risk management plans, and periodic submission of risk benefit evaluation reports to the licensing authority. Its primary focus is on identifying risks, profiling vaccine risks, and designing appropriate pharmacovigilance plan to mitigate these risks. The CDSCO also had a 15 (fifteen) day deadline for stakeholders to provide comments, suggestions, and objections to the draft guidance.

10. Drugs pricing and price control: Notifications / orders / circulars by the National Pharmaceutical Pricing Authority and other price-control related measures

a. *Advisory order to fix retail prices of 54 (fifty-four) formulations, and 8 (eight) special feature product notifications approved in 124th (one hundred twenty fourth) Authority meeting*[24]

The National Pharmaceutical Pricing Authority (**NPPA**), *vide* orders S.O. 2284(E) to 2291(E) dated June 14, 2024, fixed the retail prices of 54 (fifty-four) formulations, including calcium and vitamins D3 tablets, ceftriaxone and sulbactam injections, and glimepiride and sitagliptin tablets. The pricing authority additionally approved 8 (eight) special-feature product notifications, including mannitol, ciprofloxacin, and dextrose.

b. *Advisory order to fix retail prices of 41(forty-one) formulations and ceiling prices of 6 (six) formulations approved in 123rd (one hundred twenty third) Authority meeting*[25]

The NPPA, *vide* orders S.O. 1990(E) to 1994(E) dated May 15, 2024, fixed the retail price of 41 (forty-one) formulations, such as vitamin D_3 oral solution, antacid anti-gas gel, and povidone-iodine and ornidazole ointments. Furthermore, it revised and fixed the ceiling prices of 6 (six) formulations, including isoniazid, oxaliplatin, and oral rehydration salts.

[20] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTEyMzU=
[21] cdsco.gov.in/opencms/opencmvaccine s/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTEyMzY=
[22] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTEyMjk=
[23] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTEzMjg=
[24] https://www.nppaindia.nic.in/uploads/tender/aba40e1cc7fcb1f3bc6943f313d3aec4.pdf
[25] https://egazette.gov.in/WriteReadData/2024/254199.pdf

News Updates

1. Central Government expands the committee on pricing reforms of drugs and medical devices[26]

The Central Government has expanded the committee that was formed to look into and suggest pricing reforms of drugs and medical devices. The expanded committee has representation from industry bodies including US-India Strategic Partnership Forum (**USISPF**), Organisation of Pharmaceutical Producers of India (**OPPI**), and Medical Technology Association of India (**MTAI**). The terms of reference of the committee, among other things, include institutional reforms within NPPA, designing a price moderation framework for medical devices, and drafting a new Drugs and Medical Devices (Control) Order.

2. Union Health Minister weighs on the expansion of Pradhan Mantri Jan Arogya Yojana[27]

The Union Minister for Health and Family Welfare, J.P. Nadda, while chairing a high-level meeting called to discuss the plans which the Government wants to take on priority in the first 100 days, emphasised on the expansion of health insurance coverage under the Pradhan Mantri Jan Arogya Yojana (**PMJAY**). The ambit of the scheme has been proposed to extend to include all aged 70 (seventy) years and older. News reports suggested that, the launch of the National Health Claims Exchange to expedite processing of health insurance claims, a special drive against tobacco use among youth, non-communicable diseases, and the deployment of the U-Win portal to maintain an electronic registry of all immunisations were among the top agenda items discussed during the said meeting

3. MoHFW issues inter-departmental referral guidelines for hospitals[28]

The MoHFW has released the *"Guidelines for Inter-Departmental Referral (within hospitals)"* for inter-departmental referral in hospitals to enhance communication and cooperation among departments. These guidelines aim to address issues such as increased inconsistencies, lack of accountability, unclear procedures, inadequate training for healthcare professionals, and non-standardised referral formats. Reports suggest that these guidelines stress upon the timely initiation of referrals when patients require consultations, specialised care, or diagnostic evaluations beyond the scope of the admitting department.

[26] https://www.business-standard.com/industry/news/govt-expands-committee-for-drugs-medical-devices-pricing-reforms-124042401219_1.html
[27] https://www.rediff.com/news/report/expanding-ayushman-bharat-on-cards/20240615.htm
[28] https://www.thehindu.com/news/national/health-ministry-issues-inter-departmental-referral-guidelines-for-hospitals/article68296132.ece

4. MoHFW launches initiatives to improve the quality of healthcare in India[29]

The MoHFW, to enhance healthcare service quality and facilitate business operations in India, has introduced three new initiatives – (i) the assessment of National Quality Assurance Standards (**NQAS**) for Ayushman Arogya Mandirs (**AAM**); (ii) the implementation of a virtual dashboard to monitor compliance with Indian Public Health Standards (**IPHS**) at national, state, and district levels across health institutions and facilities; (iii) and a streamlined process for issuing spot food licenses and registrations to vendors through the Food Safety and Compliance System (**FSCBS**). The NQAS for Integrated Public Health Laboratories (**IPHL**) aims to enhance the quality and competence of management and testing systems in IPHLs.

5. Ministry of Finance allows global tenders for 120 patented drugs[30]

The Department of Expenditure (**DoE**) under the Union Ministry of Finance has issued an order enabling global procurement of 120 patented drugs through Global Tender Enquiry (**GTE**) by exempting these drugs from the relevant rule in the General Financial Rules, 2017 (**GFR**) till March 31, 2027. This would include drugs for diabetes, breast cancer, spinal muscular atrophy, Fabry disease, and obesity. The move, prompted following a request from the MoHFW, exempts procurement of these drugs from the GFR instructions. According to Rule 161 (iv) of GFR, no GTE shall be invited for tenders up to INR 200 crore.

6. Committee formed to review nutraceuticals manufacturing in drugs production facility[31]

The Government has constituted a 5 (five)-member committee, headed by A. Visala, Joint Drugs Controller (I) CDSCO, to investigate the feasibility of manufacturing of nutraceuticals products at existing drugs production units. This initiative aims to ensure that nutraceuticals manufacturing meets the same stringent standards as applicable to pharmaceuticals production facilities. The decision to form the committee arose in the wake of CDSCO's warning of taking action against companies producing drugs and nutraceuticals in the same production facility. Recently, after the recent amendment to Schedule M of Drugs Rules, the laws stipulates separate production facilities for nutraceuticals and drugs as mandatory. Reports suggest that the said committee is expected to submit its report within 3 (three) weeks.

7. CDSCO cracks down on unapproved antibiotic combinations[32]

The CDSCO has directed State Drugs Controllers to monitor the availability of unapproved antibiotics as part of its efforts to reduce their irrational use. These measures align with the recommendations from an expert sub-committee formed under the Drugs Technical Authority Board (**DTAB**) in further regulating the use of antibiotics. The CDSCO also directed State Drugs Controllers to promptly take necessary action and report to it on a priority basis. The sub-committee was established following a proposal to address antibiotic misuse during the 90th (ninetieth) DTAB meeting held on January 25, 2024.

8. CDSCO prohibits marketing of Olaparib tablets for advanced ovarian cancer[33]

The CDSCO, in a letter to all State Drug Controllers, directed manufacturers of Olaparib tablets in 100 (one hundred) mg and 150 (one hundred fifty) mg strengths to discontinue marketing them for the treatment of patients with advanced ovarian cancer and gBRCA mutation. However, the letter clarifies that the drug can be marketed for other approved indications. Olaparib was originally approved for various indications, including ovarian cancer, recurrent epithelial ovarian, fallopian tube, primary peritoneal cancer, gBRCA mutation, and breast cancer.

9. CDSCO announces risk-based audit for large pharmaceutical companies[34]

The CDSCO announced that it will begin risk-based auditing of large pharmaceutical companies with turnovers exceeding INR 250 (two hundred fifty) crore, starting from July 1, 2024. This initiative aims to ensure compliance with the Schedule M of Drugs Rules, which sets forth good manufacturing practices and requirements for premises,

[29] https://pib.gov.in/PressReleasePage.aspx?PRID=2029386
[30] https://www.pharmabiz.com/NewsDetails.aspx?aid=169728
[31] https://www.pharmabiz.com/NewsDetails.aspx?aid=169893&sid=1
[32] https://www.expresspharma.in/cdsco-cracks-down-on-export-licenses-antibiotic-approvals/
[33] https://www.business-standard.com/health/state-regulators-asked-to-withdraw-marketing-of-cancer-drug-olaparib-124052200491_1.html
[34] https://www.pharmabiz.com/PrintArticle.aspx?aid=170019&sid=1

plant, and equipment for pharmaceutical products. Since December 2022, the CDSCO has been conducting risk-based audits of manufacturing facilities and has now identified around 250 (two hundred fifty) large pharmaceutical companies for these audits.

10. CDSCO constitutes sub-committee to examine over the counter classification[35]

The CDSCO has established an eight member sub-committee to amend Schedule K of Drugs Rules, and incorporate appropriate provisions for certain drugs to be declared as "over the counter", following a recommendation from DTAB. This proposal was presented during the DTAB meeting held on January 25, 2024. Dr Anupam Prakash, Director and Professor of Medicine, Lady Hardinge Medical College, Delhi, will head the newly formed sub-committee. The sub-committee is expected to submit its report within three months of its constitution.

11. CDSCO to release guidelines on disposal of expired drugs[36]

The CDSCO announced that is in the final stages of drafting the guidelines for the proper disposal of expired drugs. These proposed guidelines will outline methods for safe disposal and procedures for the collection, storage, and transportation of expired or unused drugs. Improper disposal of expired drugs can harm the environment, animals and public health. Schedule M of the Drugs Rules also provides for proper and safe storage of waste pending disposal by manufacturers.

12. CDSCO allows continuation of Phase-II clinical trial of Serum's dengue vaccine[37]

The Subject Expert Committee - Vaccine (**SEC**), constituted under the CDSCO, has allowed the continuation of Phase II clinical trial of the dengue tetravalent vaccine developed by the Serum Institute Private Limited (**SIPL**). Following the SEC's recommendation dated July 18, 2023, SIPL presented the Phase I clinical trial report of the dengue tetravalent vaccine. After deliberation, SEC noted the results of Phase I and recommended the vaccine for continuation of Phase II clinical trial. The SEC meeting was convened to review proposals and assist the Drugs Controller General of India in relation to biologicals and Post Approval Changes (**PAC**) proposals.

13. Ministry of Agriculture allows drones for spreading pesticide formulations for another year[38]

The Ministry of Agriculture and Famers Welfare (**MOFW**) has extended the interim approval for use of pesticide

[35] https://www.pharmabiz.com/NewsDetails.aspx?aid=169150&sid=1
[36] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/norms-soon-on-disposing-of-expired-medicines/articleshow/111295169.cms
[37] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/cdsco-panel-gives-nod-for-continuation-of-phase-ii-clinical-trial-of-siis-dengue-accine/articleshow/110772972.cms
[38] https://www.thehindubusinessline.com/economy/agri-business/govt-extends-use-of-pesticide-formulations-through-drone-by-an-year/article68110571.ece

formulations through drones till April 18, 2025. Previously, in April 2022, the MOFW had released a memorandum, allowing spraying of approved pesticides formulations through drones until April 30, 2024. This decision regarding the extension of approval comes following a request from the Central Insecticides Board and Registration Committee (**CIBRC**). This extension means that registered pesticide formulations, already approved for manual spraying, can now be applied through drones until April 18, 2025.

14. FSSAI alerts FBOs to cease the usage of calcium carbide for artificial ripening of fruits[39]

The FSSAI has alerted FBOs operating ripening chambers to ensure strict compliance with the prohibition on calcium carbide for artificial ripening of fruits. Calcium carbide, commonly used for ripening fruits, can cause serious health issues such as skin ulcers, difficulty in swallowing, weakness, etc. On account of these dangers, the usage of calcium carbide has been expressly prohibited under Regulation 2.3.5 of the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011. The FSSAI has allowed the usage of ethylene gas as a safer alternative for fruit ripening, another alternative; the CIBRC too has also approved Ethephon 39% SL. These measures aim to protect consumer health while maintaining effective ripening practices.

15. State Licensing Authorities' power to issue NOC for manufacture of unapproved, banned, or new drugs for export purpose revoked[40]

The State Licensing Authorities' power to issue NOCs for drugs exports has been withdrawn and delegated to the zonal offices of CDSCO from May 15, 2024. All the manufacturers are required to obtain NOCs for the manufacture of unapproved/banned/new drugs for export from the zonal offices of CDSCO. This step was taken after various incidents of contamination in drugs and cough syrups manufactured in India caused health concerns in several countries.

16. Pharma companies to submit affidavits on ethical practices[41]

The government has asked all pharmaceutical companies to submit an undertaking stating their compliance with the Uniform Code for Pharmaceutical Marketing Practices, 2024 (**UCPMP**). The UCPMP prohibits pharmaceutical companies from giving any gifts of personal benefits to healthcare professionals. It also prohibits organising workshops for healthcare professionals or inviting them for expensive cuisine or hotel stays. All pharmaceutical companies must file this self-declaration signed by their executive heads, affirming adherence to the UCPMP.

17. DTAB considers banning use of chloramphenicol and nitrofurans in food producing[42]

The DTAB is soon going to evaluate imposing ban on the production, distribution, and import of chloramphenicol and nitrofurans for use in any food-producing system. This comes after reports of misuse of these drugs in poultry and animal feed supplements. These drugs are commonly used for treating bacterial and urinary infections in humans. The Drugs Consultative Committee (**DCC**) also discussed the ban, with members agreeing that these drugs were being misused in the feed supplements for poultry and other animals.

18. World Health Organization collaborates with National Institute of Indian Medical Heritage, Hyderabad, for traditional medicine research[43]

The World Health Organization (**WHO**) announced its collaboration with National Institute of Indian Medical Heritage (**NIIMH**) Hyderabad, a unit under Central Council for Research in Ayurvedic Sciences, Ministry of Ayush, for research in traditional medicine. This collaboration will be in place for a period of 4 (four) years. NIIMH is a known institution in the field of Ayurveda, Yoga Naturopathy, Unani, Siddha, Sowa-Rigpa, Homoeopathy, Biomedicine, and other related healthcare disciplines in India. Along with NIIMH, the WHO has also recognised Institute for Teaching and Research in Ayurveda, Jamnagar, and Morarji Desai National

[39] https://pib.gov.in/PressReleasePage.aspx?PRID=2021025
[40] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTExNDQ=
[41] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/pharma-bosses-told-to-submit-affidavits-on-ethical-practices/articleshow/110543321.cms
[42] https://drugscontrol.org/news-detail.php?newsid=39661
[43] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2025296

Institute of Yoga, New Delhi, as collaborating centres for research in traditional medicine.

19. Maharashtra Government to introduce advance diagnostic services with private firms[44]

Government hospitals in Maharashtra have started collaborating with private firms to deploy advanced diagnostic and treatment facilities on their premises. These facilities include CT scans, MRI, cardiac catheterisation lab, and dialysis. The Public Health Department has entered into multiple agreements with private players to install 22 (twenty-two) MRIs and 31 (thirty-one) CT scan facilities in government hospitals. This move aims to provide better healthcare facilities in remote areas of Maharashtra.

20. Sanofi introduces diabetes drug, Soliqua, in India[45]

Sanofi India has introduced its diabetes drug, Soliqua, in India after receiving necessary CDSCO approval last year. Soliqua, prescribed for adults diagnosed with type 2 (two) diabetes mellitus and obesity, is a once-daily injection that delivers sustained blood sugar control throughout the day. It is suggested that the approved drug be used in addition to exercise and dietary routines for enhanced glycaemic control.

21. Aurobindo Pharma and Kinvan to produce "Penicillin G" after Production-Linked Incentive scheme boost[46]

The Government has allowed Aurobindo Pharma and Kinvan to commence production of "Penicillin G" and clavulanic acid through its production-linked incentive (**PLI**) scheme to reduce dependence on China for the import of these crucial drugs. Manufacturers use penicillin in several antibiotics and clavulanic acid in Amoxyclav. This is a significant step for India to establish itself as a key player in the antibiotics global supply chain while meeting domestic demand.

22. United States Food and Drug Administration investigates Indian spice manufacturers[47]

The United States Food and Drug Administration (**USFDA**) initiated an investigation into products from MDH and Everest, Indian spices manufacturers. This action follows sale suspensions by Hong Kong and Singapore after contaminants were found in their products. These contaminants are deemed unfit for human consumption and become potentially carcinogenic with prolonged exposure. The FSSAI has also commenced quality checks on MDH and Everest products and has requested export-related data related from authorities in Hong Kong and Singapore.

[44] https://timesofindia.indiatimes.com/city/mumbai/maharashtra-govt-hospitals-set-to-outsource-critical-services/articleshow/110061609.cms
[45] https://www.business-standard.com/companies/news/sanofi-india-introduces-diabetes-drug-soliqua-at-rs-1-850-per-pen-124043000892_1.html
[46] https://www.pharmabiz.com/NewsDetails.aspx?aid=168329&sid=1
[47] https://www.business-standard.com/industry/news/usfda-gathering-information-on-indian-spices-after-alleged-contamination-124042700237_1.html

Litigation Updates

1. Supreme Court issues notice in petition challenging government regulation mandating uniform rates for ophthalmological procedures[48]

The Supreme Court (**SC**), in W.P.(C) 214 of 2024, *vide* order dated April 29, 2024, issued a notice in a plea the All India Ophthalmological Society had filed challenging government regulation on uniform rates for ophthalmological procedures in India. The Petitioner initiated a writ petition against the implementation of Rule 9 of the Clinical Establishment Rules, 2012 (**CE Rules**). The CE Rules have been promulgated and notified under the aegis of the Clinical Establishments 47 (Registration and Regulation) Act, 2010 (**CE Act**).[49] Rule 9 of the CE Rules stipulates that every clinical establishment display the rates charged for each type of service provided and facilities available. It also states that the clinical establishments charge the rates for each type of procedure and service within the range of rates determined and issued by the Central Government from time to time, in consultation with the State Governments.

The SC issued notice in the writ petition and tagged it with a similar writ petition filed by the "Veterans Forum for Transparency in Public Life". The latter seeks the implementation of Rule 9 of the CE Rules[50] and requests issuance of the *writ of mandamus* and a consequent direction be issued to Union of India (Respondent) to determine the rate of fee chargeable from the patients in terms of Rule 9 of the CE Rules. The Veterens Forum argued that the State Governments had, in its letter and spirit, not effectively implemented the CE Rules notified in 2012. They sought a *writ of mandamus* against the Central Government for effective enforcement of Rule 9 of the CE Rules.

The SC summarily heard all matters, including those involving a few intervenors, and directed that both these petitions (matters) be listed together. It issued the notice and directed all parties to complete their pleadings.

2. SC issues notice on petition against enhanced superannuation for ayurvedic doctors[51]

The SC, in Special Leave Petition (Civil) 9563 of 2024, *vide* order dated May 3, 2024, issued notice in Rajasthan Government's petition against the Rajasthan High Court's order granting an enhanced age of superannuation for ayurvedic doctors at parity with the allopathic doctors. The SC noted that ayurvedic doctors contribute as much to society as allopathic doctors. The counsel for the Petitioner

[48] All India Ophthalmological Society vs. Union of India, Order dated April 29, 2024 in W.P. (C) 214 of 2024.
[49] The CE Act governs the registration and regulation of clinical establishments in the country. The CE Act was enacted to prescribe minimum standards of facilities and services for improvement in public health
[50] Veterans Forum for Transparency in Public Life vs. Union of India, in W.P. (C) 648 of 2020.
[51] State of Rajasthan vs. Anisur Rahman, Order dated May 3, 2024 in SLP(c) 9563 of 2024.

highlighted the practical difficulty in reinstating retired ayurvedic practitioners. The SC, while issuing notice, observed that the question of reinstatement is a policy issue.

3. Delhi High Court rules onus to communicate drug side effects of drugs lie with manufacturers and pharmacists, not doctors[52]

The Delhi High Court (**Delhi HC**), in W.P. (C) 5120 of 2024, *vide* order dated May 15, 2024, dismissed a Public Interest Litigation (**PIL**) seeking to mandate that all medical professionals practicing in the country provide their patients with information in an additional slip in the regional language on all possible risks and side effects associated with the drugs in their prescriptions. The Petitioner argued that prescribing drugs without specifying the possible side effects does not constitute valid patient consent. They contended that patients have the right to be aware of potential side effects to make an informed choice.

Under the current regime, the obligation to communicate the potential risks and side effects falls on manufacturers under Clause 6.2 of Schedule D(II) of the Drugs and Cosmetics Act, 1940 (**Drugs Act**), and on pharmacists under Regulation 9.11 of Chapter 4 of the Pharmacy Practice Regulations, 2015. The Petitioner suggested shifting this onus to doctors as they prescribe the medication.

On the other hand, Union of India, the Respondent, argued that the existing legal framework ensures patients are informed of potential side effects and that doctors, who are often overworked and serve across the country, cannot be expected to communicate risks in regional languages. The Delhi HC, while dismissing the PIL, concluded that the legislature has wisely placed the responsibility on manufacturers and pharmacists, noting that there is no legal vacuum on this issue and any judicial interference would amount to judicial legislation.

4. Delhi HC directs police action against oxytocin usage in dairy colonies[53]

The Delhi HC, in W.P.(C) 13236 of 2022, *vide* order dated May 1, 2024, directed police to take action against the usage of oxytocin hormone in dairy colonies. The Petitioner, Sunayna Sibal, had approached the Delhi HC highlighting the plight of Delhi's dairy colony animals that were forcefully administered oxytocin to increase milk production.

The Court noted that administering oxytocin amounted to animal cruelty and was a cognisable offence under Section 12 of the Prevention of Cruelty to Animals Act, 1960 (**Prevention of Cruelty to Animals Act**). Consequently, the Delhi HC directed the Department of Drugs Control, Government of National Capital Territory of Delhi, to conduct weekly inspections and ensure that all cases of spurious oxytocin usage or possession are registered under Section 12 of the Prevention of Cruelty to Animals Act and Section 18(a) of the Drugs Act. The Delhi HC ordered that the jurisdictional police stations investigate these offences. It also directed the Intelligence Department of Delhi Police to identify the sources of spurious oxytocin production, packaging, and distribution and to take action in accordance with the law.

5. Delhi HC directs implementation of Committee recommendations for streamlining free medical treatment in NCR[54]

The Delhi HC, in W.P.(C) 5188 of 2014, *vide* order dated May 10, 2024, directed the Chief Secretary of the Delhi Government to implement the recommendations of a Court-appointed committee to improve the process of availing free medical treatment in the National Capital Region (**NCR**). The Petitioner approached the Delhi HC to seeking a free hip and knee replacement surgery from the All India Institute of Medical Sciences, the Respondent in the matter.

The Delhi HC noted that a division bench had previously appointed a 7 (seven) member committee to enhance healthcare services in Delhi. The committee proposed several recommendations:

a. Upgradation of all government hospital websites to dynamic platforms for real-time updates on available medicines, implants, and devices, with the assistance of National Informatics Centre or selected vendors.

b. Installation of electronic display systems with updated information on drugs and devices to be made accessible to visitors.

c. Appointment of nodal officer in all public hospitals to oversee financial assistance schemes.

[52] Jacob Vadakkanchery vs. Union of India, Order dated May 15, 2024 in W.P. (C) 5120 of 2024.
[53] Sunayna Sibal vs. Government of NCT Delhi, Order dated May 1, 2024 in W.P.(C) 13236 of 2022.
[54] Sarvesh vs. All India Institute of Medical Sciences, Order dated May 10, 2024 in W.P.(C) 5188 of 2014.

d. Implementation of a single-window mechanism for patient convenience, and development of software to streamline the Delhi Arogya Kosh and RAN IT platforms, reducing the need for repeated patient visits.

e. Usage of E-office for efficient, transparent processing until software development is complete.

f. Preparation of rate card for medical equipment and treatments within three months, and continue local procurement of non-listed items, ensuring no patient involvement in procurement processes.

The Delhi HC accepted these recommendations of the committee and directed the Chief Secretary of the Delhi Government to ensure effective compliance of the same.

6. Madras High Court rules that COVID duty performed by post graduate doctors will be treated as bond service[55]

The High Court of Madras (**Madras HC**), in W.P. (MD) 9966 of 2024, *vide* order dated April 25, 2024, held that the service rendered by post-graduate doctors during COVID-19 will be considered as bond service. The Petitioner, a post-graduate doctor, approached the Madras HC seeking a directive for Thanjavur Medical College to return his original certificates and to consider his compulsory bond service as complete.

The Court HC noted that the issue was no longer *res integra*, as there existed a precedent wherein the Court had treated COVID duty as bond service. The Court further held that educational certificates cannot be retained for any reason, as no lien can be claimed on them. It ruled that educational certificates are not marketable commodities within the meaning of Section 171 of the Indian Contract Act, 1872. Consequently, it directed the Thanjavur Medical College to return the Petitioner's certificates.

7. Allahabad High Court prohibits electro-homeopathy practitioners from using "doctor" prefix [56]

The High Court of Allahabad (**Allahabad HC**), in W.P. (C) 6856 of 2009, *vide* order dated May 16, 2024, held that practitioners of electro-homeopathy are not eligible to use the prefix "doctor". The Petitioner had challenged the order of the Central Government dated November 25, 2003, which did not recommend electro-homeopathy as an alternate system of medicines and directed the States and the Union Territories to publicise this stance widely.

The Allahabad HC clarified that electro-homeopathy could be practiced provided it was not prohibited. The Court noted that the Central Government's order dated November 25, 2003 did not bar the practice of electro-homeopathy, but emphasised that recognised Indian medical institutions refrain from conferring any degree / diploma for the course. However, it was permissible to issue certificates for the study of electro-homeopathy. The Court concluded that, in the absence of any rules framed by a competent authority, there is no restriction on the practice of electro-homeopathy. Nevertheless, practitioners of electro-homeopathy are not entitled to use the prefix "doctor".

8. National Consumer Disputes Redressal Commission rules absence of essential medical supplies as medical negligence[57]

The National Consumer Disputes Redressal Commission (**NCDRC**), in FAO 2365 of 2019, *vide* order dated April 12, 2024, upheld a compensation order issued by the Delhi State Consumer Disputes Redressal Commission (**DCDRC**) against Safdarjung Hospital in New Delhi. The DCDRC had held the hospital liable for medical negligence due to the absence of essential medical supplies.

The deceased patient was suffering from chronic obstructive pulmonary disease, lower respiratory tract infection, cardiomyopathy with a very poor heart function, and leaking heart valves at the time of admission. The patient was initially supposed to receive a dose of "Nirmin" injection, as was recommended for the treatment course. However, due to non-availability of "Nirmin", the patient was administered "Albumin" instead. The patient subsequently died, and the patient's family brought the case to the DCDRC. Upholding the DCDRC's decision, the NCDRC affirmed that absence of essential medical supplies in a hospital constitutes as medical negligence.

[55] Dr. Wanbor Sungoh vs. The State, Order dated April 25, 2024 in W.P. (MD) 9966 of 2024.
[56] Rajesh Kumar vs. Union of India, Order dated May 16, 2024 in W.P. (C) 6856 of 2009.
[57] Safdarjung Hospital vs. Asha Goyal, Order dated April 12, 2024 in FAO 2365 of 2019.

Transaction Updates

1. Apollo HealthCo enters into agreement with Advent International to raise INR 2475 crore[58]

Apollo HealthCo Limited, a subsidiary of Apollo Hospitals Enterprise Limited, announced execution of a binding agreement to raise equity capital of INR 2475 crore from Advent International, a leading private equity investor. In addition, as per a statement released by Apollo HealthCo, the company has entered into a framework agreement to integrate Keimed Private Limited, a leading wholesale pharmaceutical distributor, in a phased manner over the course of next 24 (twenty four) to 30 (thirty) months. The merged entity will be positioned as a retail health company with a leading business model in the market with a pan-India footprint.

2. Omega Hospitals raises INR 500 crore from Morgan Stanley Private Equity Asia[59]

Omega Hospitals, a renowned Hyderabad-based healthcare organisation, raised INR 500 crore from Morgan Stanley Private Equity Asia. With the aid of the capital infused, Omega Hospitals plans to expand across the twin states of Telangana and Andhra Pradesh, as well as nearby states like Karnataka, Maharashtra, Tamil Nadu, Madhya Pradesh, and West Bengal. Omega Hospitals is the second biggest network of cancer-focused hospitals in India, with over 10 (ten) hospitals and more than 1400 (fourteen hundred) beds.

3. Matrix Pharma acquires Viatris' API business[60]

Matrix Pharma Private Ltd, funded by Kotak Strategic Situations Fund II (KSSF II), announced that it has acquired Viatris' active pharmaceutical ingredients (API) business. Reports suggest that this acquisition will make Matrix the second largest Indian API player with a global presence in antiretroviral APIs. As part of the transaction, Matrix will gain access to research capabilities, over 185 scientists, and 600-odd DMFs (Drug Master Files), besides leveraging existing relationships with global pharma companies. The cost of acquisition was reportedly INR 1445 crore.

4. Serum Institute of India set to acquire 20 per cent stake in IntegriMedical[61]

Serum Institute of India announced its acquisition of 20 per cent stake in IntegriMedical, a US-based company, to further the development of needle-free injection system technology. IntegriMedical is a pioneer in the Needle-Free Injection System (**N-FIS**), having patents granted in the

[58] https://www.businesstoday.in/industry/pharma/story/apollo-247-secures-rs-2475-cr-investment-and-121-advent-stake-in-mega-merger-with-keimed-427179-2024-04-27
[59] https://www.thehindubusinessline.com/companies/morgan-stanley-pe-asia-invests-500-crore-in-omega-hospitals-to-enhance-cancer-care-across-india/article68308139.ece
[60] https://www.thehindubusinessline.com/companies/matrix-pharma-buys-viatris-api-business-for-1445-crore-funded-by-kssf-ii/article68277558.ece
[61] https://www.financialexpress.com/business/healthcare-serum-institute-of-india-to-acquire-20-percent-stake-in-integrimedical-3491938/

United States (**US**), and uses mechanical power to create high-velocity jet streams for the administration of medications and biologics. This partnership, which will soon make N-FIS available in the Indian market, aims to combine their strengths in vaccine production, cutting-edge medication delivery technologies, and strong research capabilities.

5. Suven Pharmaceuticals to acquire majority equity stake in Sapala Organic[62]

Suven, backed by Advent International, announced that it would acquire a majority stake in Hyderabad-based Sapala Organic, a contract research development organisation. News reports suggested that Suven would initially acquire an initial 67.5 per cent controlling stake, operate the business together with the selling shareholders for the next few years, and eventually acquire 100 per cent of the shareholding in Sapala. Sapala Organic focuses on oligo drugs and nucleic acid building blocks including specialised/modified amidites and nucleosides, drug-delivery compounds (including GalNAc), pseudouridine, among others.

6. Manipal Hospitals acquires majority stake with Medica Synergie[63]

Manipal Hospitals has acquired an 87 per cent stake in Medica Synergie, a Kolkata-based subsidiary of Temasek Holdings, a Singaporean company. News reports suggested that the transaction is a part of Manipal Hospitals' strategic plan to increase its market share in Eastern India. Through the utilisation of Medica Synergie's clinical experience, infrastructure, and combined operations of its vast network, Manipal Hospitals will be in a strong position to address the growing need for superior tertiary and quaternary healthcare services in Eastern India.

7. Kotak Alternate Asset Managers Limited set to invest INR 400 crore Biorad Medisys[64]

Kotak Strategic Situations India Fund II, managed by Kotak Alt, is set to invest INR 400 crore in medical device manufacturer, Biorad Medisys. New reports suggested that the company will use the investment proceeds towards the establishment of a new manufacturing facility,debt payments, and to meet their working capital needs. Founded in 1999, Biorad Medisys produces orthopaedic implants for the knee and hip as well as surgical instruments and consumables for urology, gastroenterology, and neurovascular surgery. It has manufacturing facilities in Pune and Bengaluru.

8. Quadria Capital acquires minority stake in NephroPlus[65]

NephroPlus, biggest dialysis chain in India, has raised INR 860 crore in a "Series F" fundraising round headed by Quadria Capital. Quadria Capital, which values NephroPlus at more than INR 2000 crore, will join as a minority shareholder. This funding, which consists of both new money and proceeds from a secondary sale, will support the company's goals for domestic and international expansion. NephroPlus, founded in 2009 currently operates 440 (four hundred and forty) dialysis centres in 20 (twenty) states in India as well as Philippines, Nepal, Uzbekistan, and Saudi Arabia.

9. Morgan Stanley PE and India Life Sciences Fund-IV invests in Maiva Pharma[66]

Morgan Stanley PE and India Life Sciences Fund-IV have invested INR 1000 crore in Maiva Pharma (**Maiva**) to acquire a controlling position from current investors and put primary capital for the business. With the investment, Maiva intends to build a new manufacturing facility close to Hosur, Karnataka, which will produce sterile dosage forms such as bags, oncology, hormonal injectables, and pre-filled syringes. Maiva, based in Benguluru, is a pure-play injectables contract development and manufacturing organisation that caters to the US market.

10. Healthcare Global set to acquire majority stake in Vizag Hospital[67]

Healthcare Global Enterprises Ltd. has executed a share purchase agreement for an upfront acquisition of 51 per cent stake valued INR 207.8 crore in Vizag Hospital, according to

[62] https://www.expresspharma.in/suven-to-acquire-controlling-stake-in-sapala-organics-a-cdmo-player/
[63] https://www.reuters.com/markets/deals/indias-manipal-hospitals-acquires-majority-stake-medica-synergie-2024-04-29/
[64] https://timesofindia.indiatimes.com/business/india-business/kotak-alt-to-invest-in-medical-device-firm/articleshow/110117401.cms
[65] https://www.business-standard.com/companies/news/quadria-capital-acquires-minority-stake-in-nephroplus-for-102-million-124050600655_1.html
[66] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/maiva-pharma-raises-rs-1000-crore-from-morgan-stanley-private-equity-invascent/articleshow/109781316.cms?from=mdr
[67] https://www.moneycontrol.com/news/business/companies/healthcare-global-to-acquire-majority-stake-in-vizag-hospital-stock-rises-12758166.html

the company statement. New reports suggested that Healthcare Global would acquire a further 34 percent stake in Vizag Hospital within 18 months of the first closing date for a consideration of INR 155 crore. Dr. Murali Krishna Voonna, a renowned onco-surgeon, leads Vizag Hospital, which owns and operates a comprehensive cancer care hospital with 196 operational beds in Vishakhapatnam, Andhra Pradesh.

11. Cipla Health to acquire personal care and cosmetics business of Ivia Beaute Private Limited[68]

Cipla Health Ltd, the consumer healthcare arm of Cipla Limited, has signed a Business Transfer Agreement for the purchase of the distribution and marketing business undertaking of the cosmetics and personal care business of Ivia Beaute Pvt. Ltd. The deal is valued at INR 130 crore and aligns with Cipla's objective to expand its established presence in Tier 2-6 cities and enhance its consumer healthcare and wellness offerings.

12. Piramal Group invests INR 110 crore in Biodeal Pharmaceuticals[69]

Biodeal Pharmaceuticals (**Biodeal**), a contract development and manufacturing company, has received an INR 110 crore investment from Piramal Alternatives, the fund management arm of the Piramal Group. Biodeal is one of the top producers of nasal sprays in India, serving well-known national and worldwide pharmaceutical businesses. The investment will go towards enhancing capabilities and infrastructure, modernisation of technology, and establishing a facility for production of nutraceuticals.

13. Jashwik Capital invests USD 25 million in Futura Surgicare[70]

Jashvik Capital, a domestic private equity firm, has announced its investment of USD 25 (twenty-five) million in Futura Surgicare, a company based in Bangalore. This investment aims to foster the development of innovative devices and consumables across various specialties, support

both organic and inorganic growth, and ensure the provision of high-quality medical products at affordable prices in India and abroad. Futura Surgicare, founded in 1994 by A.D. Setty, is known for its production of surgical consumables and devices related to wound closure.

14. Dr. Reddy's Laboratories Limited set to acquire Haleon's Nicotine Replacement Therapy brand for INR 5290 crore[71]

Dr. Reddy's Laboratories Limited (**Dr. Reddy's**) has entered into a definitive agreement with Haleon's Northstar Switzerland SARL acquiring "Nicotinell", a leader in the nicotine replacement therapy (**NRT**) brand category. The deal is valued at INR 5290 crore, comprising an initial cash payment of INR 4089 crore and additional contingent payments up to INR 374 crore based on performance, due in 2025 and 2026. The acquisition is anticipated to be finalised in the early part of the 4th (fourth) quarter of this calendar year. The acquisition process will be gradually integrated into Dr. Reddy's operations and includes the NRT brand "Nicotinell" along with its regional variants such as "Nicabate", "Habitrol", and "Thrive", available in markets outside the United States.

[68] https://www.business-standard.com/companies/news/cipla-to-acquire-ivia-beaute-s-cosmetics-personal-care-biz-for-rs-130-cr-124041600197_1.html
[69] https://health.economictimes.indiatimes.com/news/pharma/pharma-industry/piramal-group-arm-invests-rs-110-cr-in-biodeal-pharma/109125363
[70] Jashvik Capital invests $25 million in Bengaluru-based medtech firm Futura Surgicare | Company Business News (livemint.com)
[71] https://www.ndtvprofit.com/business/dr-reddys-to-acquire-haleons-nicotinell-brand

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