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

Volume VIII | Issue I | October - December 2024

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Dear Readers,

With favourable regulatory momentum, evolving consumer expectations, and the accelerating adoption of advanced technologies, 2024 has been a transformative year for India's healthcare ecosystem. Efforts to expand access, strengthen compliance, and improve health outcomes have positioned the sector for sustained growth and resilience. As we step into 2025, the focus shifts toward driving innovation, refining policy frameworks, and addressing healthcare disparities. This edition provides a detailed review of key developments across the regulatory, news, litigation, and transaction landscapes from the past quarter, shedding light on their implications for the future of healthcare in India.

Significant regulatory developments in the Indian healthcare sector during October-December 2024 quarter underscore the government's continued focus on ethics, quality, and public health. In a landmark enforcement under the UCPMP 2024 - the guidelines that seek to regulate drug promotion - the Department of Pharmaceuticals took action against an industry player finding it guilty of sponsoring foreign trips for healthcare professionals, setting a precedent of sorts on the much-debated issue of alleged unethical marketing practices in the pharmaceutical industry. In parallel, the AYUSH Ministry amended the First Schedule of the Drugs and Cosmetics Act, 1940, to include books on the Homeopathy and Sowa-Rigpa (Tibetan) systems of medicine, expanding the scope of recognised traditional medicine literature. It also updated the Second Schedule to incorporate the French Homeopathic Pharmacopoeia and European Pharmacopoeia, aligning domestic standards for homeopathic medicine manufacturing and imports with global benchmarks. Further advancing public health, the Ministry of Health and Family Welfare issued the Cigarettes and Other Tobacco Products (Packaging and Labelling) Amendment Rules, 2024, mandating updated health warnings on tobacco packaging effective June 1, 2025. Meanwhile, the Food Safety and Standards Authority of India reclassified packaged drinking and mineral water under the "high-risk" food category, requiring annual third-party safety audits and inspections to enhance consumer safety. Collectively, these initiatives reflect a holistic approach to strengthening regulatory oversight and safeguarding public health.

In the disputes space, we saw several significant rulings that may impact healthcare and public welfare across India. The Hon'ble Supreme Court, calling for stronger measures against the sale of counterfeit drugs, issued a notice in response to and in acknowledgment of a petition filed by the Indian Pharmaceutical Alliance, which highlighted the urgent need for enhanced enforcement mechanisms to safeguard consumers from substandard products. In another important ruling, the Apex Court dismissed a petition seeking the mandatory disclosure of all drug-related risks by doctors, citing the impracticality of such a broad requirement and emphasising medical professionals' discretion

when assessing individual patient conditions. The Court also rejected a public interest litigation seeking regulations for food safety at religious places, asserting that the existing guidelines issued by FSSAI were sufficient to address food safety concerns. High Courts across India have played a critical role in shaping healthcare jurisprudence, addressing key issues that impact public health and welfare. Recognising the importance of improving health outcomes for young women, the Delhi High Court directed the government to enhance menstrual hygiene facilities in educational institutions. Similarly, the Bombay High Court reinforced patient rights by holding a hospital liable for medical negligence, setting an important precedent in medical malpractice cases. The High Court of Karnataka emphasised the need for equitable healthcare access, mandating the state government to provide free and timely treatment for children with rare genetic disorders. The Calcutta High Court took steps to safeguard public health by calling for stricter regulations on the sale of over-the-counter antibiotics, while the Madras High Court addressed healthcare disparities, directing the Tamil Nadu government to improve the quality and accessibility of healthcare facilities in rural areas. Collectively, these rulings reflect the judiciary's commitment to ensuring comprehensive and equitable healthcare across the country.

In this issue, we shed light on some key news updates, including the DTAB/DCC deliberations on the uniform implementation of the New Drugs and Clinical Trials Rules, 2019, and the establishment of sub-committees for their effective enforcement. We also cover the Parliamentary Committee's recommendations for reforms in medical devices sector and the Inter-Ministerial Committee's proposed amendments to the FSS Act concerning nutraceuticals and other food sector policy initiatives.

On the transactions front, this quarter witnessed significant activity, marked by marquee deals and series rounds, particularly in the hospital sector, with Aster DM-Quality Care merger emerging as a frontrunner. In addition, we have captured other noteworthy investment updates across the broader healthcare space, including expansions, strategic partnerships, and health-tech series rounds reflecting sustained investor confidence and interest in this ever-evolving sector.

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,

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Managing Partner

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Regulatory Updates

1. Pharma marketing and promotion. DoP action on alleged unethical marketing practices[1]

The Apex Committee for Pharma Marketing Practices (**ACPMP**) under the Department of Pharmaceuticals (**DoP**), in its order dated December 23, 2024, issued under the chairmanship of Dr. Arunish Chawla, Secretary of DoP, reprimanded M/s. AbbVie Healthcare India Pvt. Ltd., the Indian subsidiary of global biopharma major AbbVie Inc. for sponsoring foreign trips to Monaco and Paris for 30 healthcare professionals (**HCPs**) - a clear violation of the Uniform Code for Pharmaceutical Marketing Practices-2024 (**UCPMP 2024**). The order reflects the Government's intensified efforts to curb unethical practices in the pharmaceutical industry.

The ACPMP also directed the Central Board of Direct Taxes to assess under the Income Tax Act, 1961, the tax liabilities of AbbVie and the HCPs involved. It also requested the National Medical Commission (**NMC**) to take disciplinary action against the HCPs under the Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulations, 2002. An anonymous complaint triggered the case. The DoP's Special Audit Committee's findings, which confirmed the allegations, were in contrast to that of the Organisation of Pharmaceutical Producers of India, which had found no irregularities. This action under UCPMP 2024 sets a precedent in so far actions that the DoP can take against industry players for not following the UCPMP.

Readers are encouraged to refer to our Client Alert dated March 21, 2024 where we have addressed some concerns and questions with respect to the applicability of UCPMP 2024 on the industry.

2. AYUSH ministry introduces Drugs (Fifth Amendment) Rules, 2024[2]

The Ministry of Ayush (**AYUSH Ministry**), *vide* notification G.S.R. 669(E) dated October 28, 2024, issued the Drugs (Fifth Amendment) Rules, 2024, bringing significant changes to the licensing and manufacturing processes for Ayurveda, Siddha, Sowa-Rigpa (Tibetan), Unani, and Homeopathic medicines in India, as dealt under Drugs Rules, 1945 (**Drugs Rules**). The Amendment Rules define *"New Homeopathic Medicines"* and elucidate the import and approval process. It allows these medicines, approved evidence of safety and therapeutic efficacy, to retain the "new" designation for five years after initial approval. The amendment also mandates online applications for the sale, stocking, and distribution of homeopathic medicines through the e-AUSHADHI portal and introduces standardised fees for license applications.

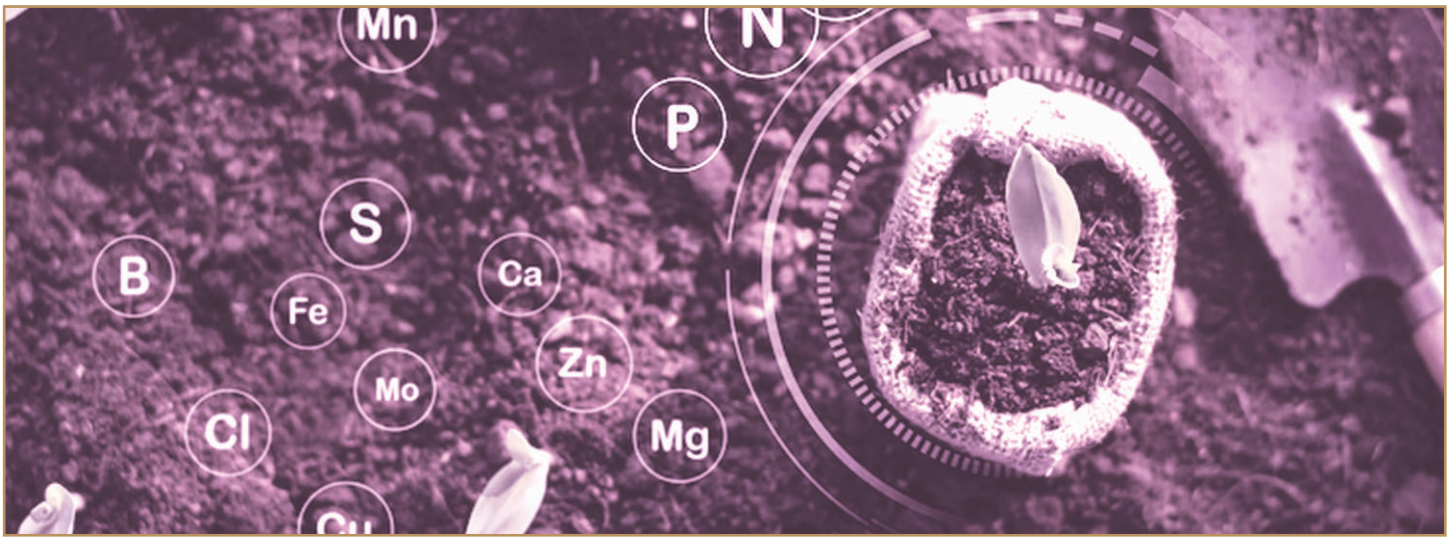
3. AYUSH ministry amends First and Second Schedules of the Drugs and Cosmetics Act, 1940[3]

The AYUSH Ministry, *vide* notification S.O. 5285(E) dated December 4, 2024, amended the First Schedule of the Drugs and Cosmetics Act, 1940 (**D&C Act**) to include books on Homeopathy and Sowa-Rigpa systems of medicine, broadening the scope of recognised literature of traditional systems of medicine in India. It also amended the Second Schedule of the D&C Act to include French Homeopathic Pharmacopoeia and the European Pharmacopoeia as recognised standards for importing and manufacturing homeopathic medicines in India. These amendments aim to enhance the quality and accessibility of traditional medicines in India while aligning global domestic standards with global pharmacopoeial benchmarks.

4. MoHFW updates health warnings on cigarette and other tobacco product packaging[4]

The Ministry of Health and Family Welfare (**MoHFW**), *vide* notification G.S.R. 742(E) dated December 2, 2024, issued the Cigarettes and other Tobacco Products (Packaging and Labelling) Amendment Rules, 2024. Effective June 1, 2025, cigarette and other tobacco product packaging must feature updated health warnings on their product packaging, including the message "TOBACCO CAUSES PAINFUL DEATH" on a bright red background with a quit line number (1800-11-2356) printed in white on a black background. Annually, new graphic images depicting health risks will be published on the MoHFW and National Tobacco Control programme websites. As per the Amendment, existing graphic warnings will remain for the next 12 (twelve) months or until the MoHFW uploads new graphic warnings. The changes aim to enhance public awareness of the severe health risks posed by tobacco consumption.

[1] In the matter of: M/s. Abbvie Healthcare India Private Ltd. under Uniform Code for Pharmaceutical Marketing Practices (UCPMP), Order dated December 23, 2024 in ACPMP No. 01/ 2024
[2] https://egazette.gov.in/WriteReadData/2024/258344.pdf
[3] https://egazette.gov.in/WriteReadData/2024/259267.pdf
[4] https://egazette.gov.in/WriteReadData/2024/259125.pdf



5. MoHFW bans Nimesulide for animal use[5]

The MoHFW, *vide* notification S.O. 5633(E) dated December 30, 2024, has banned the manufacture, sale, and distribution of *"Nimesulide* and its formulations for animal use". It imposed the ban in public interest, citing risks to animals and the existence of safer alternatives.

6. DoP unveils operational guidelines for "Strengthening of Medical Device Industry" scheme[6]

The DoP, Ministry of Chemicals and Fertilizers, on November 8, 2024, unveiled the operational guidelines for the Central Sector Scheme, "Strengthening of Medical Device Industry" (**SMDI**). With an allocation of INR 500 crore, the scheme aims to address over the next three years the unmet needs of the medical devices industry. The ministry expects the scheme to have a multiplier effect on the augmentation of Indian domestic manufacturing capacities and enhance the medical device value chains in India.

The SMDI integrates the previously existing schemes for the Development of Pharmaceutical Industries Assistance to Medical Device Clusters for Common Facilities and Human Resource Development in the Medical Device Sector. The DoP will constitute a Technical Committee to evaluate proposals under various components of the scheme and provide necessary technical guidance, expecting the initiative to act as a catalyst for the sector, driving growth and self-reliance in the medical device industry.

7. CDSCO releases updates on NSQ and spurious drugs, application procedures; calls meeting on cosmetics regulation

a. CDSCO declares NSQ drugs list for September-November 2024

i. NSQ drugs list for September[7]

The Central Drugs Standard Control Organization (**CDSCO**) declared as Not of Standard Quality (**NSQ**) 67 (sixty-seven) drugs tested either at central laboratories or by CDSCO in September 2024. The list of drugs that failed the quality test by the CDSCO and Central Laboratories includes samples of Pan 40 and Clavam 625 manufactured by Alkem Health Science, Ciprodac 500 from Cadila Pharmaceuticals, Zerodol-SP from Ipca Laboratories, and Paracetamol Pediatric Oral Suspension manufactured by Vismed Labs Limited, Metronidazole manufactured by Hindustan Antibiotics Limited, etc. Some other drugs declared as NSQ by the State Laboratories include cough syrups, pantoprazole injection, etc.

[5] https://egazette.gov.in/WriteReadData/2024/259761.pdf
[6] https://pharmaceuticals.gov.in/sites/default/files/Final%20guidelines%20for%20SMDI-8.11.2024.pdf
[7] https://thewire.in/health/67-drugs-substandard-in-september-6-manufactures-also-august

ii. *NSQ drugs list for October 2024*[8]

The CDSCO identified as NSQ 56 (fifty-six) drugs tested at laboratories including the Central Drugs Laboratory, Kolkata, RDTL Guwahati, CDTL Mumbai, and RDTL Chandigarh for October 2024. Products that failed the quality tests include Trypsin & Chymotrypsin Tablets (Ixsoflam Forte) manufactured by M/s Cachet Pharmaceuticals Private Limited; Diclofenac Sodium, Paracetamol, and Chlorzoxazone Tablets manufactured by M/s Modern Laboratories; and Liposomal Amphotericin B Injection 50 mg manufactured by M/s United Biotech (P) Limited.

iii. *NSQ drugs list for November*[9]

The CDSCO declared as NSQs 41 (forty-one) drugs tested at facilities such as the Central Drugs Laboratory, Kolkata, RDTL Guwahati, CDTL Mumbai, and RDTL Chandigarh for November 2024. Notable drugs in this list include Tofacitinib Tablets IP 5 mg manufactured by M/s Cipla Ltd, Paracetamol Tablets IP (Paracent 650 Tablets) manufactured by M/s Accent Pharmaceuticals & Diagnostics, and Folic Acid Tablets IP 5 mg (FOLITAS) manufactured by M/s Aagya Biotech Pvt. Ltd.

b. *CDSCO announces spurious drugs list for October and November 2024*

i. *Spurious drugs list for October 2024*[10]

The CDSCO declared as spurious Pantoprazole Gastro-Resistant and Domperidone Prolonged-Release Capsules IP (PAN-D), Cefixime Tablets IP (Taxim-O 200), and Rosuvastatin Tablets IP (Rosuvas 10). The control organisation made the declaration following complaints from the original manufacturers that they had not produced these batches concerned of these drugs.

ii. *Spurious drugs list for November 2024*[11]

The CDSCO declared as spurious Pantoprazole Gastro-Resistant Tablets I.P. (PAN-40) and Amoxycillin & Potassium Clavulanate Tablets IP (AUGMENTIN 625 DUO). It made the declaration following complaints from the original manufacturers that they had not produced the batches concerned of these drugs.

c. *CDSCO allows submission of applications on clinical trial site addition and Principal Investigator change through SUGAM portal*[12]

The CDSCO, *vide* notice bearing F. No. 10171/DCGI/10/2024 dated December 26, 2024, streamlined the regulatory application submission procedure for the addition of a clinical trial site and the change in Principal Investigator and allowed submitting these through the SUGAM online portal. Along with the online application, applicants must submit a checklist of documents and the Ethics Committee approvals. The proposed addition of the clinical site shall be deemed to be approved if the CDSCO does not object within 30 (thirty) days of the application. The proposed change in the Principal Investigator shall be approved from the date of the receipt of the application, provided the application is complete.

d. *Round table meeting with the Stakeholders on cosmetics regulation*[13]

The CDSCO, *vide* circular bearing F. No: COS-I 1 01 8/312024-eoffice, dated November 12, 2024, called a meeting with the manufacturers, importers, and industry associations to discuss regulatory provisions of Cosmetics at CDSCO (Head Office), New Delhi, on November 19, 2024. It requested the stakeholders to nominate subject - matter experts as their representatives at the meeting.

8. NPPA notifications / orders / circulars on pricing and other price-control related measures

a. *Order on fixation of retail prices of 20 (twenty) formulations under Drugs (Prices Control) Order, 2013*[14]

The National Pharmaceutical Pricing Authority (**NPPA**), *vide* order S.O. 4497(E) dated October 14, 2024, fixed the retail price of 20 (twenty) drug formulations, including Bisoprolol & Amlodipine Tablets manufactured by M/s Swiss Garnier Genexiaa Sciences Pvt. Ltd./M/s Abbott Healthcare Pvt. Ltd.; Gentamicin & Dexamethasone Eye Drops manufactured by M/s HAB Pharmaceuticals & Research Ltd/ M/s Mankind Prime Labs Pvt Ltd.; Ceftriaxone & Tazobactam manufactured by M/s GMH Organics/M/s Aurobindo Pharma Ltd., exclusive of applicable goods and service tax (**GST**). The order clarifies

[8] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIyMDQ=
[9] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIyOTI=
[10] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIyMDM=
[11] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIyOTE=
[12] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIyOTQ=
[13] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIxNDM=
[14] https://www.nppaindia.nic.in/uploads/tender/450d5e1ee4bba382527cea82cf3a0e0c.pdf

that the fixed retail price applies only to the individual manufacturers/marketers mentioned in the order.

b. *Order on revision of ceiling prices of 11 (eleven) Scheduled formulation of 8 drugs*[15]

The NPPA, pursuant to the Inter-Ministerial Committee's report dated April 4, 2024, *vide* order S.O. 4498(E) dated October 14, 2024, revised the ceiling price of 11 (eleven) Scheduled formulations of 8 (eight) drugs including Benzyl Penicillin, Atropine, Streptomycin, Salbutamol, Pilocarpine, reflecting a one-time increase of 50 (fifty) per cent from the current ceiling prices.

c. *Memorandum on MRP reduction of 3 (three) anti-cancer drugs over custom duty exemption and GST rate slash*[16]

The NPPA, *vide* its office memorandum bearing File No. 12(24)/2021/DP/NPPA/Div.II (Vol.II)-Part(1) dated October 28, 2024, directed all manufacturers and marketing companies of drugs/formulations to comply with the Department of Revenue, Ministry of Finance Notification 30/2024 dated July 23, 2024, which had reduced to NIL the custom duty on three anti-cancer drugs - Trastuzumab Deruxtecan, Osimertinib, and Durvalumab. Considering the applicable GST rates on these drugs were reduced from 12 (twelve) per cent) to 5 (five) per cent), the NPPA instructed manufacturers and marketing companies to revise the maximum retail price (**MRP**) of these drugs accordingly.

d. *Order on fixation of ceiling prices for 7 (seven) scheduled formulations under the Drugs (Prices Control) Order, 2013*[17]

The NPPA, *vide* order S.O. 5498(E) dated December 19, 2024, revised the ceiling prices, including WPI impact @0.00551 per cent exclusive of GST applicable for 7 (seven) scheduled formulations, including Thiamine, Clarithromycin, and Lignocaine. The order also specifies that manufacturers selling these scheduled formulations, both branded or generic, at prices higher than the ceiling price (plus GST applicable), revise the prices downward to comply with the ceiling price (plus GST as applicable).

e. *Order on fixation of ceiling prices of 13 (thirteen) scheduled drug formulations*[18]

The NPPA, *vide* order S.O. 5497(E) dated December 19, 2024, revised the ceiling prices of 13 (thirteen) scheduled formulations exclusive of GST applicable, if any, including anti-rabies immunoglobulin, Measles vaccine, BCG vaccine, water for injection, and Measles Rubella vaccine. The order also specifies that manufacturers selling these scheduled formulations, both branded or generic, at prices higher than the ceiling price (plus GST applicable), revise the prices downward to comply with the ceiling price (plus GST as applicable).

f. *Order on fixation of retail price for 65 (sixty-five) drug formulations*[19]

The NPPA, *vide* order S.O. 5493(E) dated December 19, 2024, fixed the retail price, exclusive of GST, of 65 drug formulations, including Acebrophylline & N-Acetylcysteine Tablets manufactured by M/s Win Medicare Pvt. Ltd./M/s Modi- Mundipharma Pvt. Ltd., Acyclovir Sustained-Release Tablets manufactured by M/s Rivpra Formulation Pvt. Ltd./M/s Mankind Pharma Ltd., and Atorvastatin & Ezetimibe Tablets manufactured by M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Sun Pharma Laboratories Limited. The order specifies that the retail prices apply only to the individual manufacturers / marketers mentioned in the order.

g. *Order on fixation of a separate ceiling price for Synchobreathe inhaler*[20]

The NPPA, *vide* order S.O. 5496(E) dated December 19, 2024, fixed a separate price for "Synchrobreathe Inhaler Device" for the formulations including Budesonide Inhalation (MDI) 100 mcg/dose for 200 (two hundred) doses in one inhaler, Budesonide Inhalation (MDI) 200 mcg/dose for 200 (two hundred) doses in one inhaler, and Budesonide 100mcg + Formoterol 6 mcg for 120 (one hundred and twenty) doses in one inhaler for M/s Cipla Ltd at 20 (twenty) per cent of the prevailing ceiling price of the formulation.

[15] https://www.nppaindia.nic.in/uploads/tender/2f1f1823dfb8405f43cd3b25dd581341.pdf
[16] https://www.nppaindia.nic.in/uploads/tender/52b2593ccf4a36153b1e4d44bd825336.pdf
[17] https://egazette.gov.in/WriteReadData/2024/259537.pdf
[18] https://egazette.gov.in/WriteReadData/2024/259537.pdf
[19] https://egazette.gov.in/WriteReadData/2024/259536.pdf
[20] https://egazette.gov.in/WriteReadData/2024/259534.pdf

h. Order extending separate ceiling price of IV Fluids in special packaging[21]

The NPPA, *vide* orders S.O. 5499(E), S.O. 5500(E), S.O. 5501(E), S.O. 5502(E), S.O. 5503(E), S.O. 5504(E), S.O. 5505(E), each dated December 19, 2024, has extended the separate ceiling price of IV Fluids in special packaging for product "JEDUX DOUBLE PORT WITH EURO HEAD, JPORT PLUS" manufactured by M/s Jedux Parenteral Private Limited.

9. MoEFCC releases pharma and environmental regulatory updates; marks key developments for healthcare and life sciences

a. Biological Diversity Rules, 2024[22]

The Ministry of Environment, Forest and Climate Change of India (**MoEFCC**), *vide* notification G.S.R. 665(E) dated October 22, 2024, notified the Biological Diversity Rules, 2024 (**Biodiversity Rules 2024**) under the Biological Diversity Act, 2002, superseding the Biological Diversity Rules, 2004. Aiming to enhance the management and conservation of biological diversity in the country, the Biodiversity Rules 2024 provide for the procedures to follow when seeking approval from or registration with the National Biodiversity Authority the modifications to the forms and fees applicable for such approvals and registrations. The Biodiversity Rules 2024 also include provisions for the regularisation of violations prior to April 1, 2024, additional obligations as applicable to foreign entities, compliance requirements for the utilisation of foreign biological resources in the Indian territory, penalties ranging from INR 1 lakh to INR 50 lakh, etc.

b. Draft notification of Liquid Waste Management Rules, 2024[23]

The MoEFCC, *vide* notification S.O. 4341(E) dated October 7, 2024, issued the draft Liquid Waste Management Rules, 2024 (**Draft Liquid Waste Management Rules**) to address liquid waste management. These rules shall be applicable to urban and rural local bodies and public authorities involved in waste management. The Government has invited public comments on the Draft Liquid Waste Management Rules set to become effective from October 1, 2025. The Draft Liquid Waste Management Rules, *inter alia*, consist of provisions on the duties of wastewater generator, bulk water generators, duties of wastewater treatment facilities operators, duties of local bodies including public wastewater management authorities, extended user responsibility for treatment of wastewater, management of faecal sludge, duties of industries in relation to wastewater treatment and reuse, the establishment of a

[21] https://egazette.gov.in/WriteReadData/2024/259538.pdf
[22] http://nbaindia.org/uploaded/pdf/BD_Rules.pdf
[23] https://egazette.gov.in/WriteReadData/2024/257748.pdf

centralised online portal for registration and filing of returns by the entities concerned, environmental compensation based on polluter pays principle, and the creation of a committee for effective implementation of the rules.

c. *Air (Prevention and Control of Pollution) (Manner of Holding Inquiry and Imposition of Penalty) Rules, 2024,*[24] *Water (Prevention and Control of Pollution) (Manner of Holding Inquiry and Imposition of Penalty) Rules, 2024,*[25] *and Environment Protection (Manner of Holding Inquiry and Imposition of Penalty) Rules, 2024*[26]

The MoEFCC, *vide* notifications G.S.R. 701(E) dated November 13, 2024, G.S.R. 696(E) dated November 11, 2024, and S.O. 4790(E) dated November 4, 2024, issued the Air (Prevention and Control of Pollution) (Manner of Holding Inquiry and Imposition of Penalty) Rules, 2024 (**Air Rules 2024**) under the Air (Prevention and Control of Pollution) Act, 1981 (**Air Act**), the Water (Prevention and Control of Pollution) (Manner of Holding Inquiry and Imposition of Penalty) Rules, 2024 (**Water Rules 2024**) under the Water (Prevention and Control of Pollution) Act, 1974 (**Water Act**), and the Environment Protection (Manner of Holding Inquiry and Imposition of Penalty) Rules, 2024 (**EP Inquiry and Penalty Rules**) under the Environment (Protection) Act, 1986 (**EP Act**), respectively. These rules define the system for registration of complaints under the said Air Rules 2024, Water Rules 2024, and EP Inquiry and Penalty Rules. They also provide for the procedure of the consequent inquiry, the manner of transferring complaints, the extension of time, and the penalties that can be imposed once contravention has been established.

d. *Notifications on exemption of certain categories of industrial plants from the application of Section 25 of the Water Act and*[27] *and Section 21 of the Air Act*[28]

The MoEFCC, *vide* notifications G.S.R. 703(E) and G.S.R. 702(E) dated November 12, 2024, exempted all industrial plants with a pollution index score up to 20 (as listed in the Schedule to the notification) from the consent requirements under Section 25 of the Water Act and Section 21 of the Air Act. The exemption is subject to the condition that such plants shall inform the State Pollution Control Boards or the Pollution Control Committees in writing. Additionally, it exempted from such consent requirements all industrial plants that obtained prior environmental clearance.

e. *Decriminalisation of rules under the EP Act*[29,30]

The MoEFCC, *vide* various notifications dated November 12, 2024, has decriminalised contraventions under the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 (*vide* notifications G.S.R. 698(E)), and the E-Waste (Management) Rules, 2022 (*vide* notification G.S.R.699(E)), following the Jan Vishwas (Amendment of Provisions) Act, 2023. The amended rules now state that the contraventions shall be liable to penalties as provided under the Section 15 of the EP Act.

f. *Draft Environment Protection (EPR for Packaging made from Paper, Glass and Metal as Well as Sanitary Products) Rules, 2024*[31]

The MoEFCC, *vide* notification S.O. 5282(E) dated December 6, 2024, has issued the draft Environment Protection (EPR for Packaging made from Paper, Glass and Metal as Well as Sanitary Products) Rules, 2024 (**EP Packaging Rules**) to enhance the extended producer responsibility (**EPR**). The draft rules aim to ensure the environmentally sound management of specified packaging materials by entities. Furthermore, the draft EP Packaging Rules intend to mitigate environmental pollution by encouraging sustainable practices by promoting sustainable practices, encouraging a circular economy through reuse, recovery, and recycling, thereby creating new opportunities for economic activities and green jobs. The draft rules, once notified, shall be applicable to producers, importers, brand owners, and waste processors who introduce the specified packaging in the market. These entities shall be obligated to register on the centralised online portal of EPR.

g. *Draft Solid Waste Management Rules 2024*[32]

The MoEFCC, *vide* notification S.O. 5369(E) dated December 9, 2024, issued the draft Solid Waste

[24] https://egazette.gov.in/WriteReadData/2024/258629.pdf
[25] https://egazette.gov.in/WriteReadData/2024/258578.pdf
[26] https://egazette.gov.in/WriteReadData/2024/258458.pdf
[27] https://egazette.gov.in/WriteReadData/2024/258622.pdf
[28] https://egazette.gov.in/WriteReadData/2024/258619.pdf
[29] https://egazette.gov.in/WriteReadData/2024/258602.pdf
[30] https://egazette.gov.in/WriteReadData/2024/258591.pdf
[31] https://egazette.gov.in/WriteReadData/2024/259256.pdf
[32] https://egazette.gov.in/WriteReadData/2024/259407.pdf

Management Rules, 2024 (**Solid Waste Management Rules**) in an attempt to improve the quality of environment across the country. The draft Solid Waste Management Rules seek to address the adverse effects of unmanaged solid waste; implement principles of circular economy; and further strengthen monitoring, reporting, and enforcement of these rules covering both urban and rural areas. These draft rules, *inter alia*, provide for the duties of waste generators, bulk waste generators, operators of solid waste processing facilities, and industrial solid waste generators. These rules also include provisions on the Extended Generator Responsibility (**EGR**) Certificate for the treatment of waste, criteria for the operation of landfills and existing dumping sites, and the establishment of a centralised online portal for filing annual returns. The ministry also seeks to form a committee for effective implementation at central and state levels under these draft rules.

10. FSSAI updates on Food Safety Standards

a. *Treatment of "Packaged Drinking Water and Mineral Water" as high risk food category*[33]

The Food Safety and Standards Authority of India (**FSSAI**), *vide* order bearing file no. RCD-02001/9/2021 dated November 29, 2024, stated that "Packaged Drinking Water and Mineral Water", for which the Bureau of Indian Standards (**BIS**) certification was mandatory prior to the Gazette notification of Food Safety and Standards (Prohibition and restrictions on Sales) first Amendment Regulation dated October 17, 2024, shall be treated under "High Risk Food Categories". All centrally licensed manufacturers under High Risk Categories shall have to undergo annual business audit by FSSAI-accredited third-party food safety auditing agencies.

b. *Advisory for e-commerce food business operators on strengthening food safety compliances*[34]

The FSSAI, *vide* notification bearing file no. RCD-13/1/2024-Regulatory dated December 3, 2024, issued an advisory for e-commerce food business operators (**FBOs**) on strengthening food safety compliance, aiming to foster transparency and trust, ensuring that customers receive safe and accurately represented products. The key requirements highlighted in the advisory include training of the last-mile delivery personnel, aligning of product claims with the product label, compliance with FSS (Labelling and Display) Regulations, 2020, and display of FSSAI licenses / registration numbers of the sellers and the respective hygiene rating obtained by FBOs.

[33] https://fssai.gov.in/upload/advisories/2024/12/67519c13a6a94FSSAI%20Order%20dated%2029th%20Nov%202024%20on%20addition%20of%20Food%20Products%20under%20High%20Risk%20Categoies_omission%20of%20BIS%20Certification.pdf
[34] https://fssai.gov.in/upload/advisories/2024/12/674efa161d756Adobe%20Scan%203%20Dec%202024.pdf

News Updates

1. Committee directs CDSCO to ensure uniform implementation of NDCT Rules, 2019[35]

The Drugs Consultative Committee (**DCC**), while observing inconsistencies in the implementation of the New Drugs and Clinical Trials Rules, 2019 (**NDCT Rules**), has emphasised the need for uniformity across States and Union Territories (**UTs**) in the interpretation and application of these rules. It raised specific concerns regarding the issuance of manufacturing licenses and product approvals for gastro-resistant drugs. The DCC has recommended that the CDCSO issue a circular clarifying the classification of such drugs as "*new drugs*" under Rule 2(w) of the NDCT Rules.

As per the NDCT Rules, the CDSCO is responsible for granting approvals to new drugs, ensuring compliance with regulatory requirements. Gastro-resistant drugs are categorised as "*new drugs*," which necessitate specific approvals. Furthermore, the Drugs Rules, mandates that any imported drug falling within the ambit of a "new drug" secure new drug approval in addition to obtaining an import license and registration certificate. This recommendation seeks to streamline regulatory processes and ensure that all stakeholders adhere to consistent standards, thereby enhancing regulatory oversight and compliance within the pharmaceutical sector.

2. DTAB recommends setting up a subcommittee to amend NDCT Rules[36]

The Drugs Technical Advisory Board (**DTAB**) has proposed the formation of a subcommittee to amend the NDCT Rules, seeking to mandate that marketing companies submit periodic safety update reports (**PSURs**) annually throughout the marketing period of the drug. This replaces the current requirement of submissions only during the third and fourth years post-approval. Additionally, the DTAB has recommended the inclusion of Pharmacovigilance System Master File (**PSMF**) as an appendix to PSUR submissions. These measures aim to improve post-marketing surveillance and strengthen post-marketing surveillance of new drugs, enhancing safety and regulatory oversight. The PSMF will provide a comprehensive description of the pharmacovigilance system for marketed pharmaceutical products.

3. DTAB recommends amendment of Rule 64 to revise qualifications for wholesale drug licenses[37]

The DTAB has reiterated its recommendation to amend Rule 64 of the Drugs Rules to restrict the qualifications required for competent persons holding wholesale drug licenses

[35] https://www.pharmabiz.com/NewsDetails.aspx?aid=172775e
[36] https://www.pharmabiz.com/NewsDetails.aspx?aid=1730901
[37] https://www.pharmabiz.com/PrintArticle.aspx?aid=173163

under Forms 20B and 21B. Rule 64 currently allows registered pharmacists as well as individuals with diverse qualifications, including those with matriculation with four years' experience in drug sales or a university degree with one year of experience, to hold such licenses. By removing clauses allowing other qualifications, the proposed amendment seeks to limit this eligibility exclusively to individuals with a pharmacy background, such as those holding D. Pharmacy, B. Pharmacy, M. Pharmacy, or Pharm. D. degrees. Originally proposed in 2016, the draft amendment remains unfinalised. Following stakeholder consultations, the Central Government has requested the DTAB's input, which has emphasised finalising the amendment to strengthen the drug supply chain and ensure the quality, safety, and efficacy of medicines. The CDSCO has also formed a committee to revisit Rule 64 in light of the current scenario, with the DCC advising further deliberations to achieve nationwide uniformity in implementation.

4. DCC Recommends BIS Standards for Cosmetics Ingredient Labelling[38]

The DCC has advised that the cosmetics industry adopt the BIS for ingredient labelling instead of using the International Nomenclature of Cosmetic Ingredients (**INCI**) by citing space constraints on product labels. The Central Government had initially proposed mandating INCI names to ensure ingredient transparency, but the DCC believes that compliance with BIS standards is a more practical solution. The Cosmetics Rules, 2020, already stipulate detailed labelling requirements, including the necessity for imported cosmetics to display an import registration certificate number.

5. MoHFW urges states to implement Menstrual Hygiene Policy for School Girls[39]

The MoHFW has issued a notice to all State governments, urging them to implement the *"Menstrual Hygiene Policy for School Girls"* (**Menstrual Hygiene Policy**) to ensure access to affordable hygiene supplies and gender-responsive restrooms in public and government schools. This notice follows the Apex Court directive emphasising the need for comprehensive, state-specific action plans tailored to the unique circumstances of each region for effective implementation. The Menstrual Hygiene Policy seeks to integrate menstrual hygiene into the educational system, empowering schoolgirls with knowledge, positive attitudes, and improved behaviour. By addressing low awareness and stigma, the initiative aims to eliminate barriers that hinder girls' mobility, participation, and engagement in daily activities.

6. Parliamentary panel headed by Kirti Azad Jha calls for expedited efforts to establish medical device parks[40]

The reconstituted Department-Related Standing Committee on Chemicals and Fertilisers, under the chairpersonship of Lok Sabha member Kirti Azad Jha, has urged the DoP to accelerate the establishment of medical device parks under the Promotion of Medical Device Parks Scheme. It received proposals from 16 (sixteen) states but granted approvals to only Uttar Pradesh, Tamil Nadu, Madhya Pradesh, and Himachal Pradesh, with the latter withdrawing from the scheme. The panel's November 2024 report highlighted severe underutilisation of funds, with just INR 90 lakh spent in 2022-23 and 2023-24, despite budget allocations of INR 60 crore, INR 32.93 crore, INR 200 crore, and INR 150 crore for consecutive years. The scheme, running from 2020-21 to 2024-25 and a total outlay of INR 400 crore, provides financial assistance of up to INR 100 crore per park or 70-90 per cent of CIF costs. With India relying on imports for 70 per cent of its medical devices, and the market projected to grow from USD 11 billion in 2020 to USD 50 billion by 2030, the panel stressed the urgent need to boost domestic manufacturing and infrastructure.

7. Parliamentary panel to address medicine price rise and regulatory reforms in pharmaceuticals[41]

The Parliamentary panel, chaired by Kirti Azad Jha, has identified 6 (six) key topics for review within the DoP for its 2024-25 term. The agenda includes tackling the rising prices of medicines, assessing the functions of pharmaceutical regulatory authorities with a focus on stringent reforms, and curbing the proliferation of spurious and fake medicines. Additionally, the committee will examine efforts to achieve self-sufficiency in active pharmaceutical ingredient (**API**) production through initiatives such as the production-linked incentive (**PLI**) scheme, evaluate the performance of National Institutes of Pharmaceutical Education and

[38] https://www.pharmabiz.com/NewsDetails.aspx?aid=172866
[39] https://www.ptinews.com/story/national/states-asked-to-submit-action-plans-for-implementation-of-national-menstrual-hygiene-policy/2058695
[40] https://www.fortuneindia.com/macro/parliament-panel-pulls-up-govt-for-slow-development-of-medical-device-park/119817
[41] https://www.pharmabiz.com/NewsDetails.aspx?aid=173823&sid=1

Research (**NIPERs**), and promote inclusive growth in the pharmaceutical sector by enforcing quality and safety standards while fostering traditional and indigenous medicines. The committee, comprising 31 (thirty-one) members from the Lok Sabha and Rajya Sabha, will review policy documents, budgetary demands, and regulatory frameworks for the pharmaceutical, fertiliser, and chemicals sectors. Its prior reports have played a crucial role in shaping the pharmaceutical industry, addressing issues such as irrational fixed-dose combinations and challenges within the CDSCO.

8. Inter-ministerial committee recommends amendments to FSS Act on nutraceuticals[42]

The MoHFW-constituted inter-ministerial committee has recommended amendments to the Food Safety and Standards Act, 2006 (**FSS Act**), and its regulations pertaining to nutraceuticals and health supplements. The committee proposed transferring the regulation of certain nutraceutical products, including vitamins, minerals, and amino acids, to the CDSCO, while food products containing macronutrients would remain under the purview of the FSSAI. It also recommended that CDSCO regulate disease risk reduction (**DRR**) claims and good manufacturing practices (**GMP**) be implemented for health supplements. With the Ayush Ministry and FSSAI regulating certain categories, the committee has also called for the re-examination of existing regulations regarding probiotics, prebiotics, and botanical products. These proposed amendments aim to enhance regulatory clarity, ensure the safety and efficacy of nutraceutical products, and address emerging challenges within the sector.

9. India's First Indigenous Antibiotic Launched: Nafithromycin[43]

In a groundbreaking achievement for India's biotechnology sector, the Minister of State (Independent Charge) of the Ministry of Earth Sciences (**MoES**), Dr. Jitendra Singh officially launched "*Nafithromycin*," the country's first indigenous antibiotic aimed at treating resistant infections. Developed over 14 (fourteen) years of research and with an investment of INR 500 crore, Nafithromycin is more effective than current treatment options. This launch represents a significant step towards addressing the global crisis of Antimicrobial Resistance (**AMR**). Awaiting final approval, this innovation underscores India's growing capabilities in biotechnology and the potential for public-private collaboration. According to the PIB release, Nafithromycin is specifically designed to treat Community-Acquired Bacterial Pneumonia (**CABP**), a severe illness caused by drug-resistant bacteria, which disproportionately affects vulnerable populations, including children, the elderly, and immune-compromised individuals, such as patients with diabetes and cancer.

10. FSSAI reinforces Food Safety Standards and compliance for e-commerce food operators[44]

The FSSAI convened a meeting with e-commerce FBOs on November 12, 2024, under the chairpersonship of its CEO to reinforce food safety compliance within the sector. The discussion emphasised that the FBOs ensure a minimum shelf life of 30 per cent or 45 (forty-five) days before expiry at the time of delivery to consumers. The Food Authority also cautioned against making unsupported claims online, highlighting the need for accurate product information to protect consumer rights. The meeting also emphasised that e-commerce FBOs could not operate without a valid FSSAI license or registration and stressed the importance of implementing proper food safety training for delivery personnel and ensuring separate delivery of food and non-food items to prevent contamination. Attended by over 200 participants from across the country, the meeting reinforced FSSAI's commitment to enhancing food safety standards and transparency within the e-commerce food sector.

11. NCCE recommends draft standards for disposal of unused drugs[45]

The National Council for Clinical Establishments (**NCCE**), constituted under the Clinical Establishment Act, 2010 (**CE Act**), has recommended drafting minimum standards for the disposal of unused and expired medicines by clinical establishments, ensuring public accessibility to these guidelines. As part of the minimum requirements for allopathic clinical establishments, the NCCE also proposed the formation of a committee of emergency physicians to update the list of emergency drugs and supplies. The draft standards are among 13 (thirteen) minimum requirements currently under review for notification in the Gazette,

[42] https://www.pharmabiz.com/NewsDetails.aspx?aid=173518&sid=1
[43] https://pib.gov.in/Press ReleasePage.aspx?PRID=2075174
[44] https://pib.gov.in/PressReleasePage.aspx?PRID=2072832
[45] https://www.pharmabiz.com/NewsDetails.aspx?aid=172822&sid=1

covering various clinical setups such as clinics, polyclinics, hospitals, mobile clinics, dental vans, collection centers, and centers for dietetics and physical therapy. Additionally, the NCCE has reviewed standards for clinical establishments specialising in cosmetology, point-of-care testing, hair transplant services, and prosthetics and orthotics.

12. NCCE suggests setting up expert panel to review rates under Clinical Establishments Rules[46]

The NCCE has proposed the formation of an expert committee to determine rates for clinical establishments under the Clinical Establishments (Central Government) Rules, 2012 (**CE Rules**). This recommendation addresses ongoing litigations and disputes surrounding the pricing of medical services and procedures. Rule 9(ii) of CE Rules mandates that clinical establishments charge rates for medical services and procedures within a range set by the Central Government in consultation with state governments. However, implementation challenges have resulted in 24 (twenty-four) legal cases pending across various courts, including in the Apex Court.

The proposed expert committee will include representatives from key stakeholders, including healthcare providers, regulatory authorities, and patient advocacy groups, to ensure a transparent and comprehensive approach. This initiative seeks to balance the operational costs of clinical establishments with the need for affordable and equitable access to healthcare. By streamlining pricing mechanisms and fostering regulatory compliance, the NCCE aims to reduce disputes and ensure uniformity in the implementation of the CE Act.

13. Karnataka High Court provides relief to Pharma Units on Nutraceutical Manufacturing[47]

The Karnataka High Court has granted interim relief to pharmaceutical companies by directing the Government not to take action against firms manufacturing nutraceuticals in drug-licensed facilities until the next hearing. This is in response to the industry's challenge to the newly notified Schedule M of Drugs Rules,[48] which prohibits the production of non-drug items, including nutraceuticals, in drug-manufacturing premises. Industry bodies such as the Federation of Pharma Enterprises and Karnataka Drugs and Pharmaceutical Manufacturers Association argued that

setting up separate facilities for nutraceuticals would impose severe financial strain on medium and small-scale enterprises. They sought permission to manufacture nutraceuticals in areas designated for topical products like creams and lotions within drug facilities. The Court acknowledged these concerns and instructed the government to refrain from any action pending further deliberations.

14. CDSCO and NRA meet WHO international standards for vaccine regulations[49]

The World Health Organization (**WHO**) has validated the CDSCO and the National Regulatory Authority of India (**NRA**) and affiliated institutions for meeting global vaccine regulatory standards Following an extensive review, WHO experts recognised India's regulatory system as functional per the WHO Global Benchmarking Tool (**GBT**) Version VI, maintaining Maturity Level 3 with high scores. This recognition highlights India's significant role in global health as a leading vaccine producer, with over 36 (thirty-six) manufacturing facilities. This achievement affirms India's commitment to global health, underpinned by robust regulatory practices and a strong pharmaceutical sector.

15. CDSCO becomes IMDRF member[50]

The CDSCO has become an affiliate member of the International Medical Device Regulators Forum (**IMDRF**), an

[46] https://www.pharmabiz.com/NewsDetails.aspx?aid=172924&sid=1
[47] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/karnataka-hc-stays-action-against-drug-units-making-nutraceuticals/articleshow/116639618.cms?from=mdr
[48] Substituted by Drugs (..... Amendment) Rules, 2023, vide Notification No. GSR922(E) dated December 28, 2023
[49] https://www.mohfw.gov.in/?q=pressrelease-106
[50] https://pib.gov.in/PressReleasePage.aspx?PRID=2061397

international group of medical devices regulators from across the globe committed to streamlining and harmonising regulations for medical devices. The regulatory bodies from the United States, the European Union, Canada, the United Kingdom, Brazil, etc., are members of the IMDRF. By encouraging collaboration and harmonising regulations, IMDRF promotes convergence of standards and reduces complexity for manufacturers of medical devices.

16. DCGI urges cosmetics industry to follow regulatory protocols and avoid misleading claims[51]

The Drugs Controller General of India (**DCGI**) has urged the cosmetics industry to adhere to regulatory protocols and refrain from making misleading claims, particularly those suggesting effects on younger-looking skin, which may overlap with pharmaceutical claims. Under the D&C Act, cosmetics in India are subject to strict regulations. During a recent meeting with stakeholders from the cosmetics industry, importers raised concerns regarding the challenges they face, particularly with regard to product approvals. They have reported significant financial losses following the rejection of imported cosmetics at ports for failing to meet the DCGI's regulatory standards. While importers sought a relaxation of these stringent protocols, the DCGI emphasised the need to maintain high standards of quality and safety for cosmetic products.

17. ICMR introduces pioneering initiative to address complex health challenges[52]

In November 2024, the Indian Council for Medical Research (**ICMR**) announced the "First in the World Challenge," an initiative aimed at fostering innovative solutions to complex health issues. Designed to encourage high-risk, high-reward research, the program seeks transformative advancements in health technologies, including vaccines, therapeutics, diagnostics, and interventions, while excluding incremental or process-based innovations. Reflecting ICMR's commitment to positioning India as a global leader in healthcare innovation, a distinguished committee of experts, policymakers, and innovators will evaluate the challenge, which is open to individual researchers and collaborative teams across institutions.

18. ICMR invites EOI for non-invasive hemoglobinometer[53]

The ICMR has invited expression of interest (**EOI**) from eligible organisations, companies, and start-ups to manufacture *"non-invasive/minimally invasive hemoglobinometer"* devices, as part of its efforts to address anemia through the Anaemia Mukt Bharat (**AMB**) program. A significant national health priority, the AMB program seeks to improve the detection and screening of anemia, particularly among vulnerable populations such as children and pregnant women, by promoting non-invasive diagnostic tools. ICMR intends to validate these devices through clinical trials and will provide support for protocol development, data analyses, and study planning. Applicants will be required to supply necessary equipment, infrastructure, technical data, and secure regulatory approvals, with the goal of advancing effective, scalable solutions for anemia screening in India.

19. ICMR invites EOI for monkeypox detection assay commercialisation

The ICMR has invited eligible organisations, companies, and manufacturers to submit expressions of interest for commercialising a colorimetric isothermal assay for rapid detection of the monkeypox virus. Developed by ICMR's National Institute of Virology, the assay offers swift and accurate diagnosis, crucial for managing outbreaks. ICMR aims to license this innovative technology to qualified companies for further development and deployment.

20. Call for ban on import of pre-owned medical devices[54]

Industry stakeholders and associations, including PHDCCI, AiMed, MITRA, and ADMI, have urged Prime Minister Narendra Modi to enforce an immediate ban on the import of refurbished and pre-owned medical devices, considering these also manufactured in India. This appeal follows a Central Government Office Memorandum issued in August and October, 2024, which revised a list of 38 (thirty-eight) high-end, high-value used or refurbished medical devices-

[51] https://www-livemint-com.cdn.ampproject.org/v/s/www.livemint.com/news/india/dcgi-cosmetics-regulation/amp-11732099325506.html
[52] https://www-thehindu-com.cdn.ampproject.org/v/s/www.thehindu.com/sci-tech/health/icmr-announces-first-in-the-world-challenge-to-encourage-scientists-to-find-innovative-ideas-to-tackle-health-issues/article68822688.ece/amp
[53] https://www.icmr.gov.in/icmrobject/uploads/Call/1729676112_eoiforparticipationofcompanieshavinghemoglobinometerdeviceforvalidationbyicmr_revised.pdf
[54] https://www.pharmabiz.com/ArticleDetails.aspx?aid=173310

excluding critical care equipment-permitted for import into India. These associations argued that the policy would significantly undermine the domestic manufacturing sector, contradicting the Government's "Make in India" and "Aatmanirbhar Bharat" initiatives. They also contend that the policy contradicted the objectives of the National Medical Device Policy 2023, which seeks to promote self-reliance in India's medical device industry. The call reflects concerns over potential setbacks in the growth of the sector and the long-term sustainability of India's medical device manufacturing capabilities.

21. NPPA extends Serum Institute of India's mandate to manufacture TT injections [55]

The NPPA has extended Serum Institute of India's (**SII**) mandate to manufacture two formulations for TT injections by another year, as per powers granted under Paragraph 3 of Drug Price Control Order, 2013 (**DPCO**). SII had earlier submitted its intent to discontinue the two formulations. However, under the provisions of DPCO, the government can direct manufacturers to continue production of essential formulations. NPPA has extended SII's mandate multiple times to ensure the availability of these critical formulations.

22. NABL launches new accreditation program for biobanking based on ISO 20387:2018 standard[56]

The National Accreditation Board for Testing and Calibration Laboratories (**NABL**) has introduced a new accreditation program for biobanking, aligned with the international ISO 20387:2018 standard. This initiative aims to ensure high quality, traceability, and consistency in biobanking processes, essential for preserving biological materials used in medical research and drug development. The accreditation will enhance the credibility of Indian biobanks, facilitating their recognition on the global stage and promoting high-impact research both nationally and internationally.

23. NABH releases guidebook on climate action and sustainability in healthcare[57]

The National Accreditation Board for Hospitals and Healthcare Providers (**NABH**) has introduced a guidebook to support NABH-accredited and certified healthcare organisations in addressing climate change, achieving resilience, and adopting sustainable practices. The guidebook includes a user-friendly checklist to help healthcare providers evaluate their current practices and identify areas for improvement. The checklist aims to streamline the process of meeting climate goals and fostering environmentally sustainable healthcare systems.

24. NABH introduces Care Home Accreditation Standards to enhance quality and safety[58]

NABH has launched the first edition of Care Home Accreditation Standards to improve the quality and safety of care homes serving the elderly, ill, and disabled. These standards cover both medical and non-medical care services. Care homes can begin the accreditation process using NABH's self-assessment toolkit, followed by an on-site evaluation. The standards are freely available on the NABH website and include key performance indicators to monitor and enhance compliance.

25. WHO declares that India has eliminated trachoma as a public health problem in 2024[59]

The WHO has declared that India has eliminated trachoma as a public health problem, making it the third country in the South-East Asia Region to achieve this milestone. India's National Trachoma Control Program, launched in 1963, significantly reduced trachoma-related blindness to less than 1 per cent by 2017. The National Trachomatous Trichiasis Survey and an ongoing surveillance confirmed the achievement.

26. Zydus Lifesciences Limited receives in principle WHO acceptability for its vaccine[60]

Zydus Lifesciences Limited's vaccine, ZyVac TCV, a registered vaccine for typhoid, has received in principle approval from WHO. This acceptability makes the typhoid vaccine eligible for purchase by United Nations procurement agencies. ZyVac TVC is manufactured indigenously and is for the age group 6 (six) months to 65 (sixty-five) years.

[55] https://www.pharmabiz.com/NewsDetails.aspx?aid=174345&sid=1s
[56] https://www.pharmabiz.com/NewsDetails.aspx?aid=173039&sid=1
[57] https://portal.nabh.co/Announcement/NABH%20Guidebook%20for%20Climate%20Action%20and%20Sustainability%20in%20Healthcare.pdf
[58] https://www.digitalhealthnews.com/nabh-introduces-care-home-accreditation-standards-to-enhance-quality-safety
[59] https://pib.gov.in/PressReleasePage.aspx?PRID=2063310
[60] https://www.thehindu.com/business/Industry/zydus-lifesciences-gets-who-prequalification-for-typhoid-vi-conjugate-vaccine/article68786578.ece

27. Accenture and HCG collaborate for cancer research[61]

TAccenture has partnered with Healthcare Global Enterprises (**HCG**) to revolutionise cancer research using AI technologies. The initiative, which focuses on analysing patient data through image analysis, informatics, and molecular profiling, aims to identify new drug targets, therapeutic approaches, and biomarkers, starting with head and neck cancers and lung adenocarcinomas. Reports suggest that the first-of-its-kind in project in South Asia will eventually expand to other cancer types.

28. KIMS signs MoU to launch robotic surgery programs[62]

Krishna Institute of Medical Sciences (**KIMS**), a leading healthcare group in India, has signed a Memorandum of Understanding (**MoU**) with Intuitive, a global leader in robotic-assisted surgeries. The agreement includes the establishment of 25 (twenty-five) robotic surgery programs featuring the "da Vinci surgical systems" across Karnataka, Maharashtra, Andhra Pradesh, and Telangana. This initiative is set to expand KIMS' presence into tier-1 and tier-2 cities, improving access to advanced surgical care.

29. Blinkit pilots 10-minute ambulance service in Gurgaon[63]

Blinkit has launched a 10-minute ambulance service, piloting in Gurgaon. The ambulances, equipped with emergency medical supplies, such as oxygen cylinders, automated external defibrillators, and suction machines, are staffed by a paramedic and an assistant. While Blinkit has excluded neonatal and ventilator care, it plans to expand the service to more cities over the next two years.

30. Swiggy and Flipkart prepare for 10-minute medicine delivery services[64,65]

Swiggy and Flipkart are reportedly gearing up to deliver medicines within 10 minutes through their "Instamart" and "Flipkart Minutes" platforms, respectively. Swiggy has partnered with PharmEasy to leverage its infrastructure and regulatory approvals, while Flipkart Minutes plans to collaborate with licensed chemists. These partnerships are required to comply with drug regulations, as foreign-backed e-commerce platforms are not permitted to hold inventory directly.

[61] https://health.economictimes.indiatimes.com/news/industry/hcg-and-accenture-collaborate-to-advance-cancer-research/115977944?utm_source=newslisting&utm_medium=latestNews
[62] https://health.economictimes.indiatimes.com/news/hospitals/kims-inks-mou-with-intuitive-to-launch-25-new-robotic-surgery-programs-in-india/113908835
[63] https://www.thehindu.com/sci-tech/technology/blinkit-launches-10-minute-ambulance-service-starting-with-gurugram/article69056311.ece
[64] https://timesofindia.indiatimes.com/technology/tech-news/swiggy-may-have-an-answer-for-medicine-delivery-platforms-tata-1mg-and-apollo-pharmacy/articleshow/114599792.cms
[65] https://pharma.economictimes.indiatimes.com/news/pharma-industry/flipkart-minutes-eyes-10-min-drug-delivery-to-outpace-its-rivals/115915376?utm_source=category_listing&utm_medium=sectionListing

Litigation Updates

1. Supreme Court issues notice in plea to frame Procedural Guidelines against counterfeit drugs[66]

The Supreme Court (**SC**), in W.P. (Civil) 746 of 2024, *vide* order dated on November 29, 2024, issued notice on a petition seeking directions to the Union to frame procedural guidelines to combat the manufacturing and sale of counterfeit drugs. Filed by the Indian Pharmaceutical Alliance (**IPA**), the petition cites health risks and non-action by authorities, including CDSCO and FDA, despite incidents where the custom department raid in Kolkata. The raid uncovered a premises being used for packing, storing and supply of spurious drugs (both branded and generic), including reputed branded drugs such as, Montek LC, Pantocid, Ursocol, Augmentin, and Sompraz.

The reliefs sought by the Petitioner IPA, *inter alia*, include directions to the CDSCO for proper investigations into complaints of counterfeit drug manufacturing, formulation of guidelines or registering FIRs, and arresting accused persons under the D&C Act, Bharatiya Nyaya Sanhita, 2023 (**BNS**)/Indian Penal Code, 1860 (**IPC**) and Trade Marks Act, 1999, and provision of necessary equipment and training for drug inspectors to ensure adequate enforcement. The plea emphasised the urgent need for procedural safeguards and regulatory action to address the growing threat of spurious drugs. The matter was posted for further proceedings on February 5, 2025.

2. SC dismisses plea seeking mandatory disclosure of medicine side effects by doctors[67]

The SC, in S.L.P. (C) Diary No. 48665 of 2024, *vide* order dated November 14, 2024, dismissed a plea seeking mandatory disclosure by doctors of all risks and adverse effects associated with prescribed medicines. The Petitioner had sought a directive requiring medical professionals to provide patients with a printed slip in the regional language detailing the side effects of medicines alongside prescriptions.

The case of the Petitioner revolves around the argument that *"informed consent"* includes the right to be informed about the contraindications and adverse effects. The argument also expressed that pharmacists are under obligation to include a note inside the medicine box informing patients about the adverse effects and contradictions. However, it was stated that patients rely only on the expert opinion of doctors, who rarely follow such practices. While dismissing the plea, the bench comprising Hon'ble Justice B. R. Gavai and Hon'ble Justice K. V. Viswanathan noted that deeming the proposal impractical would limit doctors to seeing only 10-15 patients daily and could overwhelm pharmacies with consumer complaints. Justice Viswanathan suggested that the only solution would be to display advisory boards in pharmacies in local languages, urging patients to read the medicine packaging.

[66] Indian Pharmaceutical Alliance v. Union of India & Ors, Order(s) dated November 29, 2024 and December 12, 2024 in W.P. (Civil) 746 of 2024
[67] Jacob Vadakkanchery v. Union of India and Anr., Order dated on November 14, 2024 in S.L.P.(C) 48665 of 2024

The bench also noted that the issue involves legislative policy, echoing a similar decision by the High Court of Delhi (**Delhi HC**), which had dismissed a petition seeking a direction to mandate all medical professionals practicing in the country to specify (in the form of an additional slip in the regional language) all possible risks and side effects associated with a prescribed drug or pharmaceutical product.

3. SC dismisses PIL seeking regulation of quality of prasad/food Items distributed at religious places[68]

The SC, in W.P. (Civil) 780 of 2024, *vide* order dated November 29, 2024, dismissed a public interest litigation (**PIL**) that sought the regulation of food quality, specifically focusing on the "*prasad*" distributed at religious places across India. The petition advocated for pan-India regulations to ensure the hygiene and purity of *prasad* and food offerings, emphasising the lack of an effective system to check food adulteration at temples, shrines, and religious places where the purity of *prasad* is critical for health and hygiene. It also cited instances of adulteration, including reports from the Baba Baidyanath Temple in Jharkhand and Tirumala Tirupati Devasthanam, and FSSAI's Annual Report (2020-21), which highlighted an increase in food adulteration cases.

The reliefs the Petitioner sought, *inter alia*,[69] included directions to ensure the purity of *prasad* or *bhog* offerings through regular testing before distribution, establishment of a strict regulatory regime for religious food offerings, and formulation of guidelines for food preparation and handling at temples, gurudwaras, shrines, community kitchens, and religious gatherings. Additionally, the plea urged the FSSAI to formulate and enforce stringent rules regarding random sampling and testing of food items used in *prasad* and other religious offerings to ensure their quality and safety.

The Apex Court noted that the FSS Act already provides an enforceable legal framework to address these concerns. The Court, while dismissing the PIL, suggested that the Petitioner directly approach the FSSAI for specific grievances reaffirming the sufficiency of existing guidelines to ensure foods safety at religious places.

4. SC seeks Menstrual Hygiene Policy for School-Going Girls[70]

The SC, in W.P. (Civil) 1000 of 2022, *vide* order dated November 12, 2024, sought an action plan from the Union, States, and UTs for the effective implementation of the "*Menstrual Hygiene Policy for School Girls*". Filed by Dr. Jaya Thakur, a social worker under Article 32 of the Constitution in public interest, the petition sought directions to the Respondents - the Union of India, the States, and UTs - for ensuring the provision of (i) free sanitary pads to every female student in Classes 6 to 12 and (ii) separate toilets for females in all government-aided and residential schools. In addition to these, the petition also sought certain other consequential reliefs. The petition raises crucial issues of public interest, highlighting the need for proper sanitation and menstrual hygiene for female students in schools.

The Court observed that while the Union Government has formulated a national policy, additional steps are necessary for its effective implementation, particularly in ensuring the distribution of free sanitary pads to girls in Classes 6-12 at all government, government-aided, and residential schools. It directed the Union to provide a detailed action plan and stressed the need for better coordination with States and UTs to ensure the policy's success. The case addresses menstrual hygiene management in schools and aims to resolve challenges such as the lack of sanitation facilities and menstrual products, which contribute to high dropout rates among schoolgirls. The Court also suggested the Union submit a two-page note to clarify the current status of implementation. It has reserved its judgment in this matter as per the last available order dated December 10, 2024.

5. Delhi HC issues comprehensive directions on free medical treatment for survivors of sexual assault[71]

The Delhi HC, in Crl. A. 728 of 2024, *vide* judgment dated December 10, 2024, addressed the lack of free medical treatment for survivors of sexual assault, particularly in cases requiring repeated intervention by the Delhi State Legal Services Authority (**DSLSA**). The case involved a father accused of repeatedly committing penetrative sexual

[68] Preeti Harihara Mahapatra v. Union of India and Ors., Order dated on November 29, 2024 in W.P. (Civil) 780 of 2024
[69] https://www.livelaw.in/top-stories/supreme-court-dismisses-pil-for-quality-regulation-of-prasad-food-items-distributed-in-religious-places-fssai-276800?fromIpLogin=35287.56680807856
[70] Dr. Jaya Thakur v. Government of India and Ors., Order dated November 12, 2024 in W.P. (Civil) No. 1000 of 2022
[71] S.V. v. State, Judgement dated December 10, 2024 in CRL.A. 728 of 2024

assault on his daughter. The Court noted delays in disbursing compensation and instances of denial of treatment of survivors despite legal provisions under Section 397 of the Bharatiya Nagarik Suraksha Sanhita (**BNSS**) and Rule 6(4) of the POCSO Rules, 2020. Justice Prathiba M. Singh and Justice Amit Sharma issued detailed directions to ensure compliance with these provisions and emphasised the need for sensitising hospitals and staff.

The Court's directives included immediate and free medical treatment for victims/survivors of sexual assault (as also rape, gang rape, acid attacks, etc.) at public or private medical facilities, including physical and mental counseling; no demand for ID proof in emergencies; proper handling of pregnancies and sexually transmitted diseases; mandatory posting of informational boards about free treatment availability; and penalties for non-compliance by medical staff. The Court also ordered ambulance assistance for transfers, police facilitation for medical aid, and the involvement of DSLSA/DLSA in providing legal and medical support. It mandated circulation of its order to all courts, police stations, hospitals, and clinics to ensure awareness and adherence to survivors' statutory rights.

6. Delhi HC dismisses PIL on adoption of integrated medicine system[72]

The Delhi HC, in W.P. (Civil) 6632 of 2022, *vide* order dated November 19, 2024, dismissed a PIL filed by Advocate Ashwini Upadhyay, which sought the adoption of an "Indian holistic integrated medicinal system" in the country. The Petitioner argued that instead of practicing Allopathy, Ayurveda, Yoga, Naturopathy, Unani, Siddha, and Homeopathy (AYUSH) as separate streams, the Government should introduce an integrated approach to medical education and treatment. He proposed the inclusion of all branches of medicine in a unified curriculum, at least during the first years of medical education, to ensure comprehensive knowledge and better patient care. Upadhyay also suggested the introduction of a dedicated integrated medicine MBBS course that combines modern and traditional medical systems.

The PIL emphasised the constitutional obligation to protect the Right to Health under Articles 21, 39(e), 41, 43, 47, 48(a), and 51A under Constitution of India. The Petitioner contended that practitioners of modern medicine are often restricted to their specialized domains and are unable to utilise the benefits of other therapeutic systems, thereby limiting the healthcare options available to patients. A division bench comprising Chief Justice Manmohan (then) and Justice Tushar Rao Gedela noted that such decisions are policy matters and fall within the purview of the Union Health Ministry. The Court also acknowledged the Union Government's affidavit, which stated that NITI Aayog's Health and Family Welfare Division has constituted a committee to study and recommend an integrated health policy. Since the committee had not yet submitted the report, the Delhi HC directed the PIL to be treated as a

[72] Aswhini Upadhyay v. Union of India, Order dated November 19, 2024 in W.P. (Civil) 6632 of 2022

representation for consideration by the said committee in accordance with the law[73].

7. Delhi HC directs MoU signing for PM-ABHIM implementation in Delhi[74]

In W.P. (Civil) 3903 of 2017, *vide* order dated December 24, 2024, the Delhi HC has directed the MoHFW and the Delhi Government to sign a MoU by January 5, 2025, to implement the PM-Ayushman Bharat Health Infrastructure Mission (**PM-ABHIM Scheme**) in the national capital. A division bench comprising Justice Prathiba M. Singh and Justice Manmeet Pritam Singh Arora emphasised that the PM-ABHIM Scheme be fully implemented to ensure residents receive the full benefits, including funds and facilities. The Court ruled that the MoU be signed irrespective of any Model Code of Conduct, stating that the scheme's delay was unjustified, especially since 33 (thirty-three) states and the UTs have already implemented it.

This case originated from a *suo motu* PIL initiated in 2017 concerning ICU beds and ventilator availability in government hospitals.[75] In February 2024, the Dr. S. K. Sarin Committee was set up to enhance medical infrastructure in the National Capital Territory of Delhi. The Delhi HC had previously directed the Delhi Government to establish Jan Aushadhi Kendras in all hospitals and scale up the PM-ABHIM scheme across the city. The Court also instructed the Delhi Government to disclose its health sector spending and present a report on infrastructure development. It continues to monitor the issue, with the next hearing scheduled in January 2025.

8. Madras High Court rules magic mushrooms not narcotic drugs unless psilocybin content is detected[76]

The High Court of Madras (**Madras HC**), in Criminal O.P. (**MD**) No.19504 of 2024, *vide* judgment dated on November 27, 2024, ruled that magic mushrooms are not classified as narcotic drugs or psychotropic substances *per se* under Section 2 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (**NDPS Act**) and that their classification depends on the presence and quantification of "*psilocybin*." The case pertained to a bail plea filed by Mohan, who was arrested for offences under Section 8(C) read with Section 22(C) of the NDPS Act. The prosecution alleged that Mohan was found in possession of 60 gm of magic mushrooms. The Petitioner contended that magic mushrooms, being natural fungi, are not explicitly categorised as narcotic drugs or psychotropic substances, unlike psilocybin. He argued that the Forensic Science Laboratory report did not quantify psilocybin, rendering the assumption that the mushroom's weight equaled that of psilocybin unsustainable.

The Madras HC concurred with the Petitioner, noting procedural lapses under Section 52A of the NDPS Act, as the Magistrate had not certified the samples. However, it refrained from delving into the merits of the case at the bail stage. Justice Anand Venkatesh disagreed with a prior observation by Justice Bharatha Chakravarthy, clarifying that the entire mushroom weight does not determine commercial quantity. Instead, magic mushrooms are contraband only upon the detection of psilocybin. The Court granted him bail after considering Mohan's lack of prior offences, his incarceration since August 2024, and the anticipated delay in trial.

9. Gujarat High Court emphasises comprehensive guidelines for pregnancy termination[77]

The High Court of Gujarat (**Gujarat HC**), in R/Special Criminal Application No. 14775 of 2024, *vide* order dated November 8, 2024, highlighted the importance of registered medical practitioners (**RMPs**) and medical boards adhering to detailed guidelines while forming opinions on termination of pregnancy. The case involved a minor rape survivor from Jamnagar who sought termination of a 24-week and 5-day pregnancy. Justice Sanjeev Thaker, while allowing the termination, underscored the necessity for medical opinions to address not only statutory criteria under Section 3(2)(b) of the Medical Termination of Pregnancy Act, 1971 (**MTP Act**) but also the physical and emotional well-being of the pregnant person.

Referring to the SC guidelines in *Mother of X v. State of Maharashtra and Ors.*, the Gujarat HC emphasised the following:

a. *Comprehensive Evaluation*: RMPs/medical boards must consider the physical and emotional well-being of the pregnant person, alongside the statutory criteria under Section 3(2)(b) of the MTP Act.

[73] https://www.livelaw.in/high-court/delhi-high-court/delhi-high-court-pil-indian-holistic-integrated-medicinal-system-275664#:~:text=The%20Delhi%20High%20Court%20on,Siddha%20and%20Homeopathy%20in%20order
[74] Court On Its Own Motion v. Union of India & Ors, Order dated December 24, 2024 in W.P. (Civil) 3903 of 2017
[75] https://www.livelaw.in/high-court/delhi-high-court/non-implementation-of-pm-abhim-scheme-in-delhi-unjustified-high-court-orders-signing-of-mou-by-january-05-279457
[76] S. Mohan v. State, Judgement dated November 27, 2024 in Criminal O.P. (MD) 19504 of 2024
[77] XYZ through her father v. State of Gujrat and Anr., Order dated November 8, 2024 in R/Special Criminal Application. No. 14775 of 2024

b. *Impact Assessment*: The medical report must state whether carrying the pregnancy to full term would affect the physical or mental health of the individual.

c. *Safety of Termination*: Medical boards should evaluate whether the pregnancy can be safely terminated without causing harm to the pregnant person.

d. *Additional Criteria*: Medical boards are free to consider and include additional relevant factors based on the facts and circumstances of each case.

This recent judgment by the Gujarat HC reinforces the need for medical boards to take a holistic and empathetic approach when addressing requests for termination of pregnancy, ensuring the dignity and well-being of the individual are safeguarded.

10. Kerala High Court upholds sensitivity in cases of Attempt to Suicide under the Mental Healthcare Act, 2017[78]

The High Court of Kerala (**Kerala HC**) in Criminal M.C. 8305 of 2019, *vide* order dated September 12, 2024, reiterated the humane approach mandated under Section 115 of the Mental Healthcare Act, 2017, which presumes attempts to suicide as acts committed under severe stress, shielding individuals from prosecution unless proven otherwise. Justice Bechu Kurian Thomas observed that the Act significantly decriminalises such attempts and focuses on care and rehabilitation. The case concerned an accused who, while in police custody, repeatedly banged his head against the lockup wall due to mental distress. Despite clear indications of his psychological condition, the police registered an FIR against him under Section 309 of the IPC Code.

The Court expressed strong disapproval of the police's actions, emphasising that they should have prioritised psychological support over prosecution. It noted the State's duty under the Act to provide care, treatment, and rehabilitation to individuals experiencing severe distress. Clarifying that not every act of headbanging constitutes an attempt to suicide, the Court stressed the need for a sensitivity-driven, evidence-based approach in handling such situations. Accordingly, the Kerala HC allowed the petition and quashed the proceedings against the accused, reaffirming the importance of compassionate responses to mental health crises.

11. Rajasthan High Court recognises right to health amid healthcare lapses in the State[79]

The High Court of Rajasthan (**Rajasthan HC**), in *Re: Right to Health and Well Being of Everyone*, arising out of D. B. Civil Writ Petition (PIL) No. 17308 of 2024, *vide* order dated November 11, 2024, took *suo motu* cognisance of two newspaper articles exposing severe lapses in the State's healthcare system. The reports, published in *Rajasthan Patrika* on November 8 and 10, 2024, highlighted issues such as improper dialysis procedures and a lack of resources in hospital emergencies. Justice Anoop Kumar Dhand issued notices to the Union of India and the State of Rajasthan, emphasising the need to strengthen the healthcare system to uphold citizens' constitutional rights. The Court considered whether the right to health, as a component of human dignity and well-being, is an intrinsic part of the right to life under Article 21 of the Constitution.

Citing constitutional provisions and international principles, the Rajasthan HC declared that healthcare is essential for individual well-being and national progress. It noted that although the Constitution does not explicitly recognise the right to health, it is implicit under Article 21 and supported by the Directive Principles of State Policy in Articles 38, 39(e), 41, and 47. The Court also referred to ancient texts like the *Yajur Veda* and Article 25 of the Universal Declaration of Human Rights to emphasise the universal importance of healthcare. Highlighting negligence in managing hospital facilities, the Court directed the Union and State governments to submit reports within four weeks on measures taken to address the deficiencies. Additionally, it appointed senior legal counsels to oversee the case and scheduled the matter for further review.

[78] Naveed Raza v. State of Kerala and Another, Order dated September 12, 2024 in Crl.) M. C. 8305 of 2019
[79] In RE:Right to Health and Well Being of Everyone arising out of D. B. Civil Writ Petition (PIL) No. 17308 of 2024, Order dated November 11, 2024

Transaction Updates

1. Aster DM completes merger with Quality Care India[80]

Aster DM Healthcare (**Aster**), a leading healthcare service provider in India, has announced its merger with Quality Care India Limited (**QCIL**), backed by private equity firms Blackstone and TPG. The merger, which remains subject to shareholder and regulatory approvals, will create one of India's top three hospital chains by revenue and bed capacity, operating under the name Aster DM Quality Care Limited (**Merged Entity**). As part of the agreement, Aster will retain a 57.3 per cent ownership stake in the Merged Entity, while QCIL will hold 42.7 per cent. The control of the Merged Entity will be shared between Aster's promoters, with a 24 per cent stake, and Blackstone, holding 30.7 per cent. According to its statement release, Aster expects the merger to result in significant strengths including scale, diversification, enhanced financial metrics, synergies, increased growth potential, and backing of marquee PE investors. Following the merger, Dr. Azad Moopen will continue in his role as the Executive Chairman and will oversee the Merged Entity, while Mr. Varun Khanna, Group MD of QCIL, will be the MD and Group CEO of the Merged Entity.

2. GIC becomes majority stakeholder in Asia Healthcare Holdings[81]

Singapore's sovereign wealth fund, GIC, has committed an additional investment of USD 150 million in Asia Healthcare Holdings (**AHH**), positioning itself as the largest shareholder ahead of a potential initial public offering (**IPO**). This investment follows GIC's initial funding of USD 170 million in February 2022 and is expected to value AHH at USD 800–900 million. According to AHH's statement, the latest transaction will see global private equity firm TPG reduce its stake to a minority position, with GIC assuming a majority stake. AHH operates several single-specialty hospital chains, including Motherhood Hospitals, the Asian Institute of Nephrology and Urology, and Nova IVF, and was previously majority-owned by TPG.

3. Intas Pharmaceuticals to acquire Coherus' Udenyca assets[82]

Intas Pharmaceuticals (**Intas**), a leading Indian pharmaecutical company, has entered into an agreement to acquire the Udenyca franchise from Coherus BioSciences for a total consideration of up to USD 558.4 million. Reports suggest that the transaction includes an upfront payment of USD 483.4 million and up to USD 75 million in milestone payments contingent upon achieving specified net sales targets. *Udenyca* (pegfilgrastim-cbqv), a biosimilar to *Neulasta* (pegfilgrastim), is approved in the United States to reduce the risk of febrile neutropenia. As part of the agreement, Intas will acquire identified assets related to the Udenyca franchise, including pre-filled syringe, autoinjector,

[80] https://www.asterdmhealthcare.in/newsroom/detail/aster-and-blackstone-backed-quality-care-to-merge-and-create-one-of-the-top-3-hospital-chains-in-india-with-10150-beds
[81] https://www.livemint.com/companies/news/gic-investment-asia-healthcare-holdings-ipo-hospital-chain-healthcare-platform-tpg-11734504787616.html
[82] https://www.worldpharmaceuticals.net/news/intas-to-acquire-coherus-udenyca-assets/?cf-view

and on-body injector products, along with associated liabilities. The acquisition, which aims to strengthen Intas' biosimilar portfolio, is anticipated to close by the end of the first quarter of 2025, subject to customary regulatory and closing conditions.

4. Manipal HealthMap completes acquisition of iGenetic Diagnostics[83]

Manipal HealthMap, a Manipal Group and Morgan Stanley-backed entity, has successfully acquired a 100 per cent stake in Mumbai-based iGenetic Diagnostics, following approval from the National Company Law Tribunal (**NCLT**). This strategic acquisition strengthens Manipal HealthMap's capabilities in molecular diagnostics and critical care services, particularly in specialised testing areas such as oncology, infections, and fertility. Following the merger, Manipal HealthMap aims to expand its presence to over 200 centers by 2027, utilising greenfield and brownfield growth strategies across Metro, Tier 1, Tier 2, and Tier 3 cities through various business models, including PPP, B2B, B2C, and institutional partnerships.

5. Laurus Bio receives investment from Eight Roads Ventures and F Prime Capital[84]

Laurus Bio, a subsidiary of Laurus Labs, has received an investment of INR 120 (one hundred and twenty) crore from Eight Roads Ventures and F Prime Capital. Laurus Labs will also infuse an additional INR 40 (forty) crore at the same valuation. The transaction includes the issuance of share warrants to Laurus Bio's promoters, exercisable within 2 (two) years at the same valuation. Post-transaction, Laurus Labs, Laurus Bio's promoters, and Eight Roads Ventures will hold fully diluted stakes of 75 per cent, 14 per cent, and 9 per cent, respectively. The funding will support the company's plans to expand its fermentation-based manufacturing capabilities.

6. Metropolis Healthcare to acquire Core Diagnostics[85]

Metropolis Healthcare Limited (**Metropolis Healthcare**), India's second-largest pathology chain, has announced the acquisition of oncology-focused diagnostic services provider Core Diagnostics Private Limited for INR 246.83 (two hundred forty-six point eight three) crore. The transaction includes a cash consideration of INR 135.76 (one hundred thirty-five point seven six) crore and a share swap for the remainder. Upon completion of the acquisition, Core Diagnostics will become a wholly owned subsidiary of Metropolis Healthcare. This acquisition will enhance Metropolis Healthcare's portfolio in advanced cancer testing and expand its footprint in northern and eastern India.

7. Even Healthcare secures USD 30 million in Series A funding round[86]

Bengaluru-based Even Healthcare has raised USD 30 million in its Series A funding round, led by Khosla Ventures, with participation from Founders Fund, 8VC, Lachy, Groom, and others. The company plans to utilise the funds to launch hospital operations and scale patient care and resource management. Founded in 2020 by Mayank Banerjee, Matilde Giglio, and Alessandro Lalongo, Even Healthcare provides its members with unlimited consultations, diagnostic tests, and medical services through a network of owned and partner clinics and insurance providers. Operating on a fee-based model, members can access consultations for an annual fee of INR 4,800, which includes episodic and chronic care, along with the option for additional health insurance coverage. The company is also incorporating artificial intelligence through its new initiative, "*Even Steven*," an AI-powered health assistant offering medically verified information to enhance patient care.

8. Quadria Capital acquires minority stake in Aragen Life Sciences[87]

Quadria Capital, the Singapore-based healthcare-focused private equity firm, is set to acquire a 10 percent minority stake in Hyderabad-based contract research, development, and manufacturing organisation (**CDMO**), Aragen Life Sciences, for INR 850 crore (approximately USD 100 million). The investment will involve two-thirds of the funding as primary capital, with the remainder coming from a secondary sale by the company's promoters. Aragen's promoters, Gunupati Aparna Reddy and Davinder Singh Brar (former CEO of Ranbaxy), each hold a 33.7 per cent stake, while Goldman Sachs holds about 31.3 per cent. With the

[83] https://www.financialexpress.com/business/healthcare-manipal-healthmap-acquires-igenetic-diagnostics-targets-200-centers-by-2027-3646654/
[84] https://pharma.economictimes.indiatimes.com/news/pharma-industry/laurus-labs-biotech-unit-raises-rs-120-crore-from-eight-roads-ventures/116120082?utm_source=top_news&utm_medium=sectionListing
[85] https://www.moneycontrol.com/news/business/metropolis-healthcare-to-acquire-core-diagnostics-for-rs-247-cr-12887853.html
[86] https://yourstory.com/2024/10/even-healthcare-secures-30-million-series-funding
[87] https://pharma.economictimes.indiatimes.com/news/mergers-and-acquisitions/quadria-capital-to-pick-up-minority-stake-in-drug-company-aragen/116427324?utm_source=top_news&utm_medium=sectionListing

primary investment, Aragen will expand its manufacturing capabilities, including establishing a biologics manufacturing facility in Bengaluru, further strengthening its position in the life sciences sector.

9. OmniActive Health acquires ENovate Biolife[88]

OmniActive Health Technologies (**OmniActive**), a global provider of scientifically validated health ingredients, has acquired ENovate Biolife (**ENovate**), a developer of proprietary botanical ingredients known for clinically researched solutions such as Muvz, RedNite, and Oxxjun, for an undisclosed amount. Funded through internal accruals, the acquisition strengthens OmniActive's portfolio and expands its geographic reach. ENovate's focus on innovative health ingredients aligns with OmniActive's mission to deliver high-quality solutions globally. This marks OmniActive's second major acquisition, following its purchase of Indfrag in 2017.

10. Carlyle Group sells stake in Indegene[89] [90]

Carlyle Group, through its US affiliate CA Dawn Investments, has divested its 4.3 per cent (four point three per cent) stake amounting to INR 636 (six hundred and thirty-six) crore, in Indegene, a healthcare tech firm. The divestment was a bulk deal and happened through an open market transaction. Post the divestment, the stake of Carlyle Group has reduced to its current 10.22 per cent from its previous 14.52 per cent. Founded in 1998, Indegene offers solutions that help enable biopharmaceutical and emerging biotech and medical devices companies to develop products, launch them in the market, and drive sales throughout their life cycle.

11. Suven Pharmaceuticals acquires NJ Bio Inc[91]

Suven Pharmaceuticals Limited (**Suven**), a listed pharmaceutical giant in India, has acquired 56 per cent stake in NJ Bio Inc (**NJ Bio**), a US-based company engaged in providing innovative solutions for the entire value chain of antibody drug conjugates. The deal, reportedly at USD 64.4 million, includes USD 15 million as primary equity infusion, along with the purchase of shares from current shareholders and subscription to new ones. In addition, the definitive documents signed by both parties, grant Suven a call option

to acquire the remaining shares of NJ Bio, while providing NJ Bios' shareholders with a put option to sell their shares to Suven, both of which can be exercised after 5 (five) years. On the trigging of either option, Suven could acquire full ownership of NJ Bio, enhancing its footprint in the biopharmaceuticals sector.

12. Lupin Limited acquires Eli Lily's insulin in India[92]

Lupin Ltd, a prominent pharmaceutical company committed to providing high-quality, affordable healthcare, has further reinforced its dedication to tackling the growing global diabetes challenge by acquiring the anti-diabetic medicine "*Huminsulin*" in India from Eli Lilly and Company for an undisclosed amount. This acquisition aligns with Lupin's strategy to expand and strengthen its diabetes portfolio. The company has already been marketing the Huminsulin range through existing distribution and promotion agreements with Eli Lilly in India. The Huminsulin range, used for the treatment of Type 1 and Type 2 diabetes mellitus, helps improve blood sugar control in adults and children.

13. Beta Drugs secures funding from investors led by Healthquad Fund Ii[93]

Beta Drugs Limited (**Beta Drugs**), a listed pharmaceutical company that provides oncology focused products, received INR 117 (one hundred and seventeen) crore funds from investors led by Healthquad Fund II, a Singapore-based

[88] https://www.thehindu.com/business/omniactive-health-acquires-enovate-biolife/article68837790.ece
[89] https://www.business-standard.com/markets/news/carlyle-group-sells-4-3-stake-in-indegene-for-rs-636-crore-via-bulk-deal-124120301237_1.html
[90] https://www.cnbctv18.com/market/stocks/ca-dawn-investments-likely-to-divest-2-9-stake-in-indegene-share-price-via-block-deal-at-rs-615-per-share-19518304.htm
[91] https://www.moneycontrol.com/news/business/markets/suven-pharma-acquires-majority-stake-in-us-based-nj-bio-12885182.html
[92] https://www.lupin.com/lupin-acquires-huminsulin-from-lilly-to-enhance-diabetes-portfolio/
[93] https://www.vccircle.com/healthquadleads-maiden-vc-funding-for-oncology-drug-maker-beta-drugs

investment fund and a private wealth management firm, in exchange for a minority stake in the company. The company will use the funds for expansion and to accelerate production and research capacity in relation to novel drugs. News reports suggest that Beta Drugs claims to be one of the fastest-growing oncology formulation companies in India, with products such as chemotherapy, targeted, hormonal and supportive therapies for cancer patients, which are sold in 46 (forty-six) countries.

14. DCDC Health Services receives funding from British International Investment[94]

DCDC Health Services (**DCDC**), a company operating hemodialysis clinics, received an investment amounting to INR 82 crore, from British International Investment, a UK-based finance institution. News reports suggest that the company will use the investment to finance capital expenditure and instal dialysis equipment for both public-private partnership and standalone centres approved by public insurance programs, which will enable DCDC to expand its network of dialysis facilities, thereby facilitating provision of life-saving treatment to low-income residents of isolated towns at affordable and reduced costs.

15. Senior Living start-up Primus secures funding[95]

Primus Senior Living (**Primus**), a platform offering healthcare, wellness, lifestyle, and social engagement services to the elderly, has raised USD 20 million (approximately INR 168 crore) in seed funding, marking one of the largest early-stage investments by an Indian start-up this year. US-based General Catalyst led the round, with participation from Zerodha co-founder Nikhil Kamath and Grubas, the investment firm he co-founded. A General Catalyst statement suggested the fully bootstrapped Primus community currently operates 163 homes for 330 elders with a median age of 70 years. The company aims to transform eldercare in India over the next 5-7 (five to seven) years by offering a "one-stop-shop" for aging services.

16. Senior Living start-up Primus secures funding[96]

PSpry Therapeutics Private Limited (**Spry**), a software-as-a-service start-up specialising in digital solutions for physical healthcare centres, has raised INR 120 crore in funding from F-Prime Capital, Together Fund, Fidelity's Eight Roads, and Flourish Ventures. Spry's platform enables clinic owners and physical therapists for efficient management of administrative tasks such as scheduling, patient intake, patient assessments, and home exercise regimens. Spry will use the funding to accelerate its expansion into the United States, strengthening its presence in the healthcare sector and broadening its reach.

17. Tamil Nadu-based A4 Hospitals raise funding[97]

Tamil Nadu-based hospital chain, A4 Hospitals, has secured a strategic investment from 360 ONE Asset, an asset management firm backed by Bain Capital, through its healthcare and life sciences fund. The funding will enable A4 Hospitals to expand its operations across southern India in the coming years. While the investment amount is undisclosed, the capital will support the growth of A4 Hospitals, which currently offers fertility treatments, maternity, and perinatal care through its eight operational centres. Aruna Ashok, co-founder and clinical director of A4 Hospitals, highlighted that this collaboration with 360 ONE Asset will bolster the hospital chain's clinical capabilities and extend the reach of their services in the fertility and maternity care sector.

18. Krsnaa, Medikabazar, and United Imaging collaborate to offer advanced diagnostic services[98]

Krsnaa Diagnostics Limited (**Krsnaa**), a company specialising in operating diagnostic centres, has entered into a collaboration with Medikabazar, India's largest B2B healthcare procurement and supply-chain solutions provider, and United Imaging, a global leader in advanced imaging technologies. The collaboration involves an investment of INR 300 crore for setting up over 30 (thirty) modern imaging centres across tier-II and -III cities. Reports suggest that this partnership will combine medical expertise with the latest technological advancements, improving patient care and accessibility to advanced diagnostic services in small towns and semi urban areas. Medikabazar's imaging technologies will be integrated throughout Krsnaa's extensive diagnostic network.

[94] https://www.bii.co.uk/en/our-impact/investment/dcdc-health-services-private-limited-investment-01/
[95] https://www.thehindubusinessline.com/companies/elder-care-start-up-primus-secures-20-m-seed-funding-from-general-catalyst-nikhil-kamath-and-gruhas/article68759832.ece
[96] https://economictimes.indiatimes.com/tech/funding/software-as-a-service-startup-spry-therapeutics-secures-15-million/articleshow/114074162.cms?from=mdr
[97] https://www.vccircle.com/baincapital-backed-360-one-asset-invests-in-a4-hospitals
[98] https://www.thehindubusinessline.com/companies/krsnaa-diagnostics-medikabazaar-united-imaging-join-hands-to-invest-300-cr-in-30-imaging-centres/article68701514.ece

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