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

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Dear Readers,

In the first quarter of 2025, India's healthcare sector witnessed continued momentum, influenced by evolving regulations, rising consumer expectations, and growing investor confidence. As the quarter drew to a close, global trade dynamics added a new layer of complexity. In early April, a tariff-related executive order from the US administration brought fresh implications for Indian exports. While pharmaceutical products were exempted due to their strategic relevance to global health systems, medical devices were not, raising concerns about competitiveness and supply chain costs. These shifts, alongside ongoing domestic reforms, have prompted Indian businesses to re-evaluate market strategies, strengthen manufacturing depth, and focus on building broader, more resilient global partnerships. In this edition of *Synapse*, we explore these emerging themes, along with key regulatory and sectoral developments that continue to shape the future of Indian healthcare.

Significant regulatory developments in India's healthcare sector, between January-March 2025, highlight the government's ongoing emphasis on ethics, quality, and public health. The AYUSH Ministry issued new guidelines for ASU nasal sprays and revised the list of poisonous substances in ASU medicines. It also expanded the First Schedule of the Drugs and Cosmetics Act, 1940, to include additional vernacular texts and recognised the French and European Homoeopathic Pharmacopoeias, aligning domestic standards with global norms. Meanwhile, the Health Ministry extended compliance timelines for small and medium drug manufacturers and banned Chloramphenicol and Nitrofurans in food-producing animals. The drugs regulator introduced online approvals for cosmetics and clinical trial site additions, issued updates on NSQ drugs and device classifications, and fixed retail prices for several formulations. Parallelly, the food safety authority tightened labelling norms, simplified approvals for RAFT kits, and introduced new licensing categories for Anganwadi centres. Together, these measures reflect a comprehensive approach to regulatory reform and public health protection.

Recent updates in India's healthcare sector highlight a policy focus on improving accessibility, affordability, and fostering innovation. The Union Budget 2025-26 reinforced this outlook with increased allocations and major announcements, including Ayushman Bharat coverage for gig workers, customs duty exemptions for life-saving and rare disease therapies, and a plan to establish 200 district-level cancer care centres. Parliamentary Standing Committees have recommended structural reforms such as a unified Ayush drug regulator, expansion of the National List of Essential Medicines, stronger enforcement against counterfeit drugs, and tighter price controls for cardiac stents. Concerns have also been raised over the modest allocation to the health budget, with a call for improved fund

utilisation, greater staffing, and enhanced digital integration. The government is moving ahead with a standardised hospital billing format to bring greater transparency in patient charges, while the ICMR is shaping responsible innovation through ethical AI guidelines and fresh vaccine development initiatives. This edition also covers significant industry movement with the India launch of Eli Lilly's Mounjaro, a breakthrough therapy for diabetes and obesity, priced more accessibly to meet domestic demand.

In the litigation space, courts continued to address regulatory gaps and reinforce patient rights and safety standards. The Supreme Court called upon states to appoint officers under the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, and establish grievance redressal platforms to curb misleading medical claims, making it clear that liability extends to advertisers, publishers, and designers. In a PIL concerning clinical trials on vulnerable populations, the Court demanded a comprehensive affidavit from the Centre, drawing attention to ethical and procedural lapses under the New Drugs and Clinical Trials Rules, 2019. In another significant order, the Court reiterated that doctors providing paid medical services are covered under the Consumer Protection Act, 1986, refusing to revisit its 1995 decision in *Indian Medical Association v. V.P. Shantha*, and affirmed that patients can seek legal redress for deficiencies in such services.

High Courts have also issued directions with far-reaching implications. The Madhya Pradesh High Court resolved a long-standing divergence between benches by issuing SOPs for medical termination of pregnancies in sexual assault cases. It clarified that termination up to 24 weeks requires no court approval, but cases exceeding this period must be placed before the High Court. The SOPs mandate prompt referral to medical boards and time-bound decisions, reinforcing urgency and sensitivity during such situations. Other High Courts also weighed in on healthcare infrastructure and public health enforcement, signalling a judiciary increasingly attuned to systemic accountability and patient dignity.

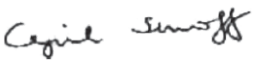
This quarter also saw several significant developments on the transactions and investments front, reflecting the evolving dynamics of the healthcare and life-sciences sector. We have captured some of the key updates in this edition of *Synapse*.

Cyril Amarchand Mangaldas, India's premier full-service law firm, has an industry-leading 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 ffor more articles on matters of interest in the Indian pharmaceuticals, 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. Meanwhile, please stay safe and healthy.

Regards,

CYRIL SHROFF



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Regulatory Updates

1. The Ministry of Health and Family Welfare extends compliance timeline for small and medium drug manufacturers[1]

The Ministry of Health and Family Welfare (**MoH&FW**), *vide* notification G.S.R. 127(E), dated February 11, 2025, has introduced the Drugs (Amendment) Rules, 2025, extending the compliance timeline for small and medium pharmaceutical manufacturers with an annual turnover of less than INR 250 (two hundred fifty) crore. These manufacturers can now apply to the Drugs Controller General of India (**DCGI**), using Form-A, within three months from the date of notification, along with an upgrade plan, to seek an extension for compliance with the revised Good Manufacturing Practices (**GMP**) under Schedule M of the Drugs Rules, 1945 (**Drugs Rules**). Upon approval, the compliance deadline may be extended up to December 31, 2025. The amendment seeks to provide regulatory relief to small and medium enterprises (**SMEs**), allowing them to align with quality norms while ensuring continued availability of essential medicines.

2. MoH&FW bans Chloramphenicol and Nitrofurans in Food-Producing Animals[2]

The MoH&FW, *vide* notification S.O. 1158(E), dated March 12, 2025, has banned the import, manufacture, sale, and distribution of antibiotics *chloramphenicol* and *nitrofuran*-class drugs for use in any food-producing animals with immediate effect, citing availability of safer alternatives. The decision follows recommendations from the Drugs Consultative Committee (**DCC**) and consultation with the Drugs Technical Advisory Board (**DTAB**), citing misuse in poultry and animal feed.

3. The Ministry of Ayush introduces new guidelines for ASU nasal sprays[3]

The Ministry of Ayush (**AYUSH Ministry**), *vide* notification G.S.R. 28(E), dated January 10, 2025, has introduced the Drugs (First Amendment) Rules, 2025, bringing new regulatory guidelines for nasal spray formulations in Ayurveda, Siddha, and Unani (**ASU**) medicine. The amendment introduces Rule 158B (VI), requiring licensing authorities to adhere to guidelines provided under Schedule TB while approving ASU nasal sprays. In ASU formulations, Nasya preparations are categorised into three types: *Churna* (finely powdered medicines), *Gritha* (ghee-based formulations), and *Thailam* (oil-based preparations). The new norms differentiate modern nasal sprays from traditional Nasya therapies by mandating the use of specific dispensing devices, making administration more precise and user-friendly. The amendment also permits aqueous-based nasal sprays, alongside conventional oil and powder-based formulations while ensuring compliance with the Drugs and Cosmetics Act, 1940 (**D&C Act**). The amendment mandates specific standards for nasal spray devices, including material and functional parameters, to ensure consistency in administration. It aims to standardise manufacturing, enhance quality control, and boost consumer confidence in ASU nasal sprays, facilitating their wider acceptance in domestic and international markets.

4. AYUSH Ministry issues draft rules to revise list of poisonous substances in ASU medicines[4]

The AYUSH Ministry, *vide* notification G.S.R. 115(E), dated January 28, 2025, has proposed draft rules to revise the list of poisonous substances used in ASU medicines. The amendment seeks to expand the classification of poisonous substances based on plant (botanical), animal, and mineral origins. The updated list includes 24 (twenty-four) plant-based substances for Ayurveda, 17 (seventeen) for Siddha, and 8 (eight) for Unani, while mineral-based substances total 20 (twenty), covering arsenic, lead, copper sulfate, and mercury compounds. Additionally, animal-derived substances such as snake venom and beetle poison are specified for Siddha and Unani. Certain plant-based substances used in Bhasma, Parpam, Kushta, and similar formulations are exempted. The draft also strengthens safety and efficacy requirements for proprietary medicines and mandates clear labeling in English and Hindi, with a warning that medicines containing Schedule E(I) substances are to be taken under medical supervision.

1 https://egazette.gov.in/WriteReadData/2025/260908.pdf
2 https://egazette.gov.in/WriteReadData/2025/261585.pdf
3 https://egazette.gov.in/WriteReadData/2025/260208.pdf
4 https://egazette.gov.in/WriteReadData/2025/260797.pdf

5. AYUSH Ministry issues draft amendment to expand books on ASU medicines[5]

The AYUSH Ministry, *vide* notification S.O. 643(E), dated February 7, 2025, has issued a draft amendment to the First Schedule of the D&C Act, expanding the list of authoritative books prescribing drug formulations under the ASU system. The revised list now includes more vernacular texts, specifying the author's name and language of publication. Ayurveda now comprises of 227 (two hundred and twenty-seven) books, including texts in Telugu, Malayalam, Hindi, and Marathi. The Siddha section has expanded to 88 (eighty-eight) books from 31 (thirty-one), while the Unani Tibb system now includes 112 (one hundred and twelve) books, including Urdu translations. In December 2024, a similar amendment had added 20 (twenty) books for Homoeopathy and 34 (thirty-four) for *Sowa-Rigpa*, and recognised French and European Homoeopathic Pharmacopoeias for regulating imports and manufacturing. The update aims to broaden the scientific foundation and regulatory clarity for ASU medicines.

6. Central Drugs Standards Control Organisation (CDSCO) Updates

a. *CDSCO declares Not of Standard Quality (**NSQ**) drugs list for January-February 2025*

i. *NSQ drugs list for January 2025*[6]

The CDSCO, *vide* its monthly review for January 2025, declared 52 (fifty-two) drugs as NSQ, based on testing conducted either at CDSCO or central laboratories. The NSQ list includes samples of Nimesulide and Paracetamol tablets (SOMOO) by Kshipra Drugs Pvt Ltd, Calcium and Vitamin D3 tablets by Life Max Cancer Laboratories, and Cefixime and Ofloxacin tablets by J.M. Laboratories, among others. Additionally, 93 (ninety-three) drugs were declared NSQ by State Laboratories during the same period, including compound sodium lactate injection and amoxycillin trihydrate capsules.

ii. *NSQ drugs list for February 2025*[7]

The CDSCO, *vide* its monthly review for February 2025, declared 47 (forty-seven) drugs as NSQ, based on testing conducted either at CDSCO or central laboratories. The NSQ list includes samples of Rabeprazole Tablets IP 20 mg by Martin & Brown BioSciences Pvt. Ltd., Azithromycin Oral Suspension I.P. by M/s. Overseas Healthcare Pvt Ltd, etc. Additionally, 56 (fifty-six) drugs were declared NSQ by State Laboratories[8] during the same period, including Calcium & Vitamin D3 Tablets IP, Para 500, etc.

b. *CDSCO announces spurious drugs list for February 2025*[9]

The CDSCO declared Telma H (Telmisartan 40mg & Hydrochlorothiazide 12.5mg) spurious. The drugs control organisation made the declaration following complaints from the original manufacturers that they had not produced the batches concerned of these drugs.

c. *CDSCO imposes immediate ban on Nimesulide for animal use in India*[10]

The CDSCO, *vide* notice DC-DT-13011(11)/2/2024-eOffice, dated February 20, 2025, has imposed an immediate ban on manufacturing, sale, distribution, and use of Nimesulide and its formulations for animal use across India. This decision follows the MoH&FW notification S.O. 5633(E), dated December 30, 2024, and arises from a public interest litigation in *Gaurav Kumar Bansal v. Union of India*, where the Delhi High Court questioned the continued availability of the drug. Regulatory authorities have been directed to enforce compliance strictly, prevent illegal distribution, and report violations to the Central Government. The prohibition seeks to safeguard animal welfare and mitigate harm to vulnerable species.

d. *CDSCO sets final deadline for Fixed Dose Combinations (**FDCs**) manufacturers to submit compliance applications*[11]

The CDSCO, *vide* 04-01/2013-DC (Misc. 13-PSC)(Pt. II)(Sub Part-1), dated February 24, 2025, has issued a final notice to manufacturers of pre-1988 permitted FDCs, directing them to submit applications for Phase IV clinical trial protocols or active post-marketing surveillance within 3 (three) months, i.e, by May 24, 2025. This move follows CDSCO's earlier notice on January 11, 2024, requiring manufacturers with State Licensing Authority approvals before October 01, 2012, to apply for evaluation. However, with low compliance rates, CDSCO is now offering a final

[5] https://egazette.gov.in/WriteReadData/2025/260853.pdf
[6] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI1NTU=
[7] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI2MTM=
[8] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI2MTQ=
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[10] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI1MzU=
[11] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI1NDM=

opportunity to ensure these FDCs meet regulatory standards.

e. *CDSCO classifies gastro-resistant & delayed-release tablets as "New Drugs"*[12]

The CDSCO, *vide* circular ND-13020/2/2024-eOffice, dated February 24, 2025, has directed all State and UT Drug Controllers to classify gastro-resistant and delayed-release tablets/capsules, including enteric-coated formulations, as *"new drugs"* under Rule 2(1)(w) of the New Drugs and Clinical Trials Rules, 2019 (**NDCT Rules**). As per the rule, any modified-release form of an already approved drug shall be treated as a *"new drug"* and will require approval from the Central Licensing Authority (**CLA**). This classification, based on discussions in the 64th DCC meeting held in June 2024, ensures uniformity in regulatory oversight across jurisdictions.

f. *CDSCO moves clinical trial site addition and principal investigator change applications for biological products online*[13]

The CDSCO, *vide* notice F.No.10171/DCGI/10/2024-eoffice, dated February 27, 2025, has enabled online submissions for clinical trial site additions and changes in Principal Investigators (PIs) for biological products, including vaccines and recombinant DNA therapies. This builds upon CDSCO's earlier initiative (December 26, 2024), enabling similar submissions for global clinical trials and other drug categories via the SUGAM portal. For biological trials, site additions will be deemed approved if no objection is raised within 30 (thirty) days, but PI changes will require approval upon complete submission. This digital transition is part of CDSCO's ongoing efforts to enhance regulatory efficiency.

g. *CDSCO introduces new one-year export no objection certificate system to ease compliance for pharma companies*[14]

The CDSCO, *vide* notice IMP/70/2024eoffice, dated March 07, 2025, has introduced a one-year validity system for Export No Objection Certificates (**NOCs**), to reduce the regulatory burden on pharmaceutical exporters. The new system includes a one-time registration at zonal offices and updated guidelines and checklists on the SUGAM portal. The reform is expected to streamline export approvals and significantly reduce the volume of NOC applications, which currently stands at approximately 5,000 (five thousand) annually.

h. *CDSCO introduces online registration for clinical research organisations ahead of April 2025 mandate*[15]

The CDSCO, *vide* notice DCG(I)/Misc./2025-4, dated March 04, 2025, has introduced an online registration system for Clinical Research Organisations (**CROs**) through the SUGAM portal, in line with the mandatory registration requirement, effective April 1, 2025. CROs must submit

[12] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI1NDA=
[13] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI1NDI=
[14] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI1Nzg=
[15] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI1NzU=

applications, along with the prescribed checklist of documents for registration. As per the New Drugs and Clinical Trials (Amendment) Rules, 2024, no CRO shall conduct clinical trials or bioequivalence studies without obtaining CLA registration. The registration, valid for 5 (five) years, will be granted within 45 (forty-five) working days, subject to compliance with the specified requirements. The amended rules also empower the CDSCO to inspect, search, or seize records and materials from CROs to ensure regulatory compliance. In case of violations, the CLA may issue warnings, suspend or cancel registrations, or debar the CRO from conducting future studies.

i. *CDSCO seeks Industry feedback on updated medical device classification*[16]

The CDSCO, *vide* notice MED-16014(12)/1/2024-eoffice, dated January 6, 2025, has released an updated risk-based classification list for 4 (four) categories of medical devices —Interventional Radiology, Radiotherapy, Oncology, and Class A (non-sterile, non-measuring) devices. The revised list revisits existing classifications and includes new entries in line with the Medical Devices Rules, 2017 (**MD Rules**), and global standards. The drug regulator invited industry stakeholders to submit their comments within 30 (thirty) days, i.e. by February 05, 2025, via a google form provided in the notice. This classification aims to update and streamline licensing, regulatory compliance, and quality assurance to align Indian medical device regulations with international best practices.

7. The National Pharmaceutical Pricing Authority notifications/ orders/ circulars on pricing and other price-control related measures

a. *Office Memorandum mandating online pharmacies to comply with Drugs (Prices Control) Order, 2013, provisions of price list display*[17]

The National Pharmaceutical Pricing Authority (**NPPA**), *vide* Office Memorandum No. 21(02)/2024/Div-III/NPPA, dated February 4, 2025, has directed online pharmacies to comply with the Drugs (Prices Control) Order, 2013 (**DPCO**) provisions, by displaying the current price list on their digital platforms, akin to physical retail outlets. Issued amid continuing legal uncertainty surrounding e-pharmacies, the directive reiterates the requirement under Para 24(4) and Para 25 of the DPCO to display price lists in a conspicuous part of the premises, extending to virtual premises as well. This includes both scheduled and non-scheduled formulations. The NPPA underscored that price transparency must be uniformly maintained across all modes of sale to safeguard consumer interests.

b. *Order on fixation of retail prices of 42 (forty-two) formulations under DPCO*[18]

The NPPA, *vide* order S.O. 660(E) dated February 7, 2025, has fixed the retail price of 42 (forty-two) drug formulations, including combination of Telmisartan, Cilnidipine and Chlorthalidone Tablets from M/s Corona Remedies Ltd; Atorvastatin and Ezetimibe Tablets from M/s Cadila Pharmaceuticals Ltd.; Diclofenac Sodium, Paracetamol and Chlorzoxazone Tablets from M/s Macleods Pharmaceuticals Ltd.; Bictegravir, Emtricitabine and Tenofovir Alafenamide Tablets from M/s Cipla Ltd; etc., exclusive of applicable goods and service tax (**GST**). The order clarifies that the fixed retail price applies only to the individual manufacturers/ marketers mentioned in the order. The retail price for these specified formulations must match the specified price.

c. *Order on revision of ceiling prices of azithromycin 250 mg tablets and a combination of Amoxicillin(A) and Clavulanic acid (B) injection*[19]

The NPPA, *vide* order S.O. 659(E), dated February 7, 2025, revised the ceiling price of 2 (two) formulations: a 250 mg tablet of Azithromycin and a FDC of Amoxicillin and Clavulanic Acid, following a review order from the Department of Pharmaceuticals (**DoP**). The review orders were in favour of Cipla Ltd, and the price of Azithromycin 250 mg has been revised upwards from INR 11.65 (eleven point six five) per tablet to INR 11.67 (eleven point six seven) per tablet through the notification. The ceiling price of Amoxicillin (A) 1g and Clavulanic Acid (B) 200 mg injection has been revised from INR 140.66 (one hundred forty point six six) per vial to INR 141.65 (one hundred forty-one point six five) per vial.

[16] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIzNDI=
[17] https://www.nppaindia.nic.in/uploads/tender/c99b75820cf3e516cffeda63f239a121.pdf
[18] https://egazette.gov.in/WriteReadData/2025/260821.pdf
[19] https://egazette.gov.in/WriteReadData/2025/260822.pdf

d. *Order on revision of retail price for Cilnidipine and Telmisartan tablets*[20]

The NPPA, *vide* order S.O. 661(E), dated February 7, 2025, has revised the retail price of a combination of Cilnidipine 20 mg and Telmisartan 40 mg Tablet, used to treat high blood pressure, following a review order passed on October 4, 2024. As per the revision order, the new retail price for Cilnidipine and Telmisartan Tablets (film coated; 20mg/ 40mg) has been set at INR 14.15 (fourteen point one five) per tablet. This is applicable to the formulation manufactured by M/s Akums Drugs & Pharmaceuticals Ltd. and marketed by M/s Glenmark Pharmaceuticals Ltd.

e. *Corrigendum in relation to fixing separate ceiling price for Synchrobreathe Inhaler device*[21]

The NPPA, *vide* corrigendum S.O. 662(E), dated February 7, 2025, corrected a typographical error, which resulted in a huge price difference for M/s Cipla Ltd.'s Synchrobreathe Inhaler for budesonide inhalation (MDI) 200 mcg/dose for 200 (two hundred) doses in one inhaler, which was earlier approved at a separate price. While the correct price was INR 81.20 (eighty-one point two zero) per inhaler, it was notified *vide* order S.O. 5496(E), dated December 19, 2024, as INR 41.20 (forty-one point two zero) per inhaler. The formulation is used to treat asthma and moderate to severe chronic obstructive pulmonary disease (**COPD**).

f. *Order on fixation of retail prices of 53 (fifty-three) formulations under DPCO*[22]

The NPPA, *vide* order S.O. 1094(E), dated March 5, 2025, fixed the retail price of 53 (fifty-three) drug formulations, including Paracetamol & Caffeine Tablets from M/s Juggat Pharma; Ibuprofen & Paracetamol Suspension from M/s Shiva Biogenetic Pharmaceuticals Ltd.; Lactulose Enema from M/s Naxpar Pharma Pvt. Ltd; etc., exclusive of applicable GST. The order clarifies that the fixed retail price applies only to individual manufacturers/ marketers mentioned in the order.

g. *Order on revision of ceiling price for Coronary Stents of 2 (two) formulations*[23]

The NPPA, *vide* order S.O. 1473(E), dated March 27, 2025, has increased the ceiling prices for Bare Metal Stents to INR 10,692.69 (ten thousand six hundred ninety-two point six nine) per unit and Drug Eluting Stents (DES), including metallic DES and Bioresorbable Vascular Scaffold (BVS) or Biodegradable Stents, to INR 38,933.14 (thirty-eight thousand nine hundred thirty three point one four) per unit, with Wholesale Price Index (**WPI**) increase of 1.74% (one point seven four per cent).

h. *Order on revision of ceiling price of 4 (four) strengths of Ringer Lactate injection*[24]

The NPPA, *vide* order S.O. 1474(E), dated March 27, 2025, has revised the ceiling price of Ringer Lactate injection in various strengths, manufactured by 21 (twenty-one) companies under different brand names, in accordance with the change in WPI. According to the notification, the price of Ringer Lactate injection 100 ml would be INR 30.42 (thirty point four two) per pack, price of 250 ml injection would be INR. 51.88 (fifty-one point eight eight) per pack, price of 500 ml injection would be INR. 66.09 (sixty-six point zero nine) per pack, and price of 1000 ml injection would be INR. 116.20 (one hundred sixteen point two zero) per pack. The revised price would be applicable to specific brands manufactured by companies including Otsuka Pharmaceuticals India, Fresenius Kabi India, B.Braun Medical (India), Albert David Ltd, among others.

i. *Order on revision of ceiling price of Piperacillin and Tazobactam of 2 (two) formulations*[25]

The NPPA, *vide* order S.O. 1475(E), dated March 27, 2025, has revised the ceiling price of 2 (two) strengths of antibiotic formulation piperacillin and tazobactam power for injection (2g+250 mg and 4g+500mg), manufactured by Gufic Biosciences Ltd and branded as Tazofic injection (DCB) to INR 224.10 (two hundred twenty-four point one zero) and INR 467.30 (four hundred sixty-seven point three zero) per dual chamber bag with special feature, respectively.

j. *Order on revision of ceiling prices of 152 (one hundred fifty-two) formulations under National List of Essential Medicine, 2015*[26]

The NPPA, *vide* order S.O. 1487(E), dated March 27, 2025, has revised the ceiling prices of 152 (one hundred fifty-two) scheduled formulations under National List of Essential Medicine (**NLEM**), 2015 due to an increase in the annual WPI by 1.74% (one point seven four percent), including Acetylsalicylic acid; Artesunate (A) +

[20] https://egazette.gov.in/WriteReadData/2025/260823.pdf
[21] https://egazette.gov.in/WriteReadData/2025/260824.pdf
[22] https://egazette.gov.in/WriteReadData/2025/261477.pdf
[23] https://egazette.gov.in/WriteReadData/2025/262012.pdf
[24] https://egazette.gov.in/WriteReadData/2025/262020.pdf
[25] https://egazette.gov.in/WriteReadData/2025/262021.pdf
[26] https://egazette.gov.in/WriteReadData/2025/262051.pdf

Sulphadoxine - Pyrimethamine (B); Betamethasone; Cefadroxil, etc. The revised ceiling prices are applicable effective April 1, 2025.

k. *Order on revision of ceiling prices of 748 (seven hundred forty-eight) formulations under NLEM, 2022*[27]

The NPPA, *vide* order S.O. 1489(E), dated March 27, 2025, has revised the ceiling prices of 748 (seven hundred forty-eight) scheduled formulations under NLEM 2022 due to increase in annual WPI by 1.74% (one point seven four percent), including Atorvastatin, Azithromycin, Caffeine, Diclofenac, Xylometazoline, etc. The revised ceiling prices are applicable effective April 1, 2025.

l. *Order on revision of ceiling prices of 6 (six) formulations under NLEM, 2011*[28]

The NPPA, *vide* order S.O. 1488(E), dated March 27, 2025, has revised the ceiling prices of 6 (six) scheduled formulations under NLEM 2011 due to increase in annual WPI by 1.74% (one point seven four percent), including Acetylsalicylic Acid, Calcium carbonate, Condoms, Dapsone, Medroxyprogesterone Acetate and Rifampicin. The revised ceiling prices are applicable effective April 1, 2025.

m. *Order on fixation of retail prices of 80 (eighty) formulations under DPCO*[29]

The NPPA, *vide* order S.O. 1490(E), dated March 27, 2025, has fixed the retail price of 80 (eighty) drug formulations, including Aspirin Gastro-resistant & Rosuvastatin Capsules from M/s Pure & Cure Healthcare Pvt. Ltd.; Telmisartan & Amlodipine Tablets from M/s Windlas Biotech Ltd; etc., exclusive of applicable GST. The order clarifies that the fixed retail price applies only to individual manufacturers/ marketers mentioned in the order.

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

a. *Government strengthens Plastic Waste Management Rules with stricter labelling and penalties*[30]

The Ministry of Environment, Forest and Climate Change (**MoEFCC**), *vide* notification GSR 73(E), dated January 23, 2025, has introduced the Plastic Waste Management (Amendment) Rules, 2025, revising the Plastic Waste Management Rules, 2016, to enhance transparency and accountability. Effective July 1, 2025, producers, importers, and brand owners must disclose packaging details under Rule 11 via barcodes, QR codes, brochures, or unique IDs and notify the Central Pollution Control Board (**CPCB**), which will maintain a public compliance list. Additionally, a new penalty provision, i.e., Rule 19, has been inserted, to ensure enforcement and hold violators accountable under Section 15 of the Environment Protection Act. These changes reinforce the government's commitment to reduce plastic waste and promote sustainability.

b. *MoEFCC introduces guidelines for grant, refusal, and cancellation of consent to control air pollution*[31] *and water pollution*[32]

The MoEFCC, *vide* notifications G.S.R. 84(E) and G.S.R. 85(E), dated January 29 and 30, 2025, has issued the Control of Air (Grant, Refusal or Cancellation of Consent) Guidelines, 2025, and Water Pollution (Grant, Refusal or Cancellation of Consent) Guidelines, 2025, respectively. The guidelines specify that applications must be submitted using prescribed forms with the requisite plant details and fees. A common application process is introduced for obtaining consent under both the Air and Water Acts, along with authorisation under the Hazardous and Other Wastes (Management and

[27] https://egazette.gov.in/WriteReadData/2025/262053.pdf
[28] https://egazette.gov.in/WriteReadData/2025/262059.pdf
[29] https://egazette.gov.in/WriteReadData/2025/262061.pdf
[30] https://egazette.gov.in/WriteReadData/2025/260415.pdf
[31] https://egazette.gov.in/WriteReadData/2025/260611.pdf
[32] https://egazette.gov.in/WriteReadData/2025/260660.pdf

Transboundary Movement) Rules, 2016. The guidelines aim to streamline the consent process while ensuring strict environmental safeguards for industrial operations.

c. *Battery Waste Management Amendment Rules, 2025*[33]

The MoEFCC, *vide* notification S.O. 958(E), dated February 24, 2025, has introduced amendments to the Battery Waste Management Rules, 2022, to simplify compliance for producers. The Battery Waste Management Amendment Rules, 2025, provide key relaxations, *inter alia* exemptions from labelling if packaging is covered under the Legal Metrology (Packaged Commodities) Rules, 2011, and permitting EPR registration disclosure via barcodes or QR codes. Mandatory marking of cadmium (Cd) and lead (Pb) is waived where concentrations are below 0.002% (zero point zero zero two percent) and 0.004% (zero point zero zero four percent), respectively. These amendments have been introduced to reduce the compliance burden, while upholding environmental responsibility.

9. Notifications/ Orders/ Circulars regarding food safety standards by Food Safety and Standards Authority of India

a. *Notification regarding draft amendment to Food Safety and Standards (Laboratory and Sample Analysis) Amendment Regulations, 2011*[34]

The Food Safety and Standards Authority of India (**FSSAI**), *vide* notification F. No. QA/11023/31/2022-QA-FSSAI (2), dated February 17, 2025, has proposed the draft Food Safety and Standards (Laboratory and Sample Analysis) Regulations, 2025. The draft seeks to strengthen the food testing framework by revising procedures relating to reporting timelines, sample quantities, methods of analysis, and issuance of test results. As per the proposed amendment, food analysts and referral laboratories are required to issue reports within 14 (fourteen) days for regulatory and appeal samples, respectively, while for imported food items, results must be furnished within 5 (five) days. The amendment also permits the use of validated methods from international bodies such as AGAC, ISO, BIS, and Codex Alimentarius, where specific procedures are not prescribed in official manuals. Additionally, Form-A (Certificate of Analysis) and Form-B (Food Analyst Report) are proposed to be omitted. Objections and suggestions from stakeholders were invited within 60 (sixty) days from the date of publication, i.e., by April 19, 2025.

b. *FSSAI proposes stricter labelling norms for food products*[35]

The FSSAI, *vide* notification F.No. SS-T017/1/2023-Standard-FSSAI, dated February 17, 2025, has proposed draft Food Safety and Standards (Labelling and Display) Regulations, 2025, aiming to enhance consumer awareness and ensuring transparency in food labelling. The key changes include mandatory display in bold letters of the percentage contribution of added sugar, saturated fat, and sodium to the Recommended Dietary Allowance (**RDA**) per serving, using a larger font size for better visibility. The draft also mandates a standardised logo for milk and milk-based products, with size variations based on packaging dimensions, ensuring clear identification. Additionally, coffee-chicory mixtures must now prominently display composition details on the front of the package in capital letters within a rectangular box. FSSAI has invited feedback from stakeholders and the public within 60 (sixty) days from the date of publication, before finalising the amendments.

c. *FSSAI directs referral laboratories to strictly adhere to NABL accreditation scope for food testing*[36]

The FSSAI, *vide* order QA-12013/6/2021-QA-FSSAI, dated February 25, 2025, has issued a directive mandating all referral laboratories to comply strictly with the National Accreditation Board for Testing and Calibration Laboratories' (**NABL**) scope of accreditation when testing referral food samples. As per clause 9.1(a) of the Food Safety and Standards (Recognition and Notification of Laboratories) Regulations, 2018, laboratories must conduct tests only within their approved premises and in accordance with the valid scope of recognition. The directive also requires that all FSSAI-notified referral laboratories under Section 43(2) of the Food Safety and Standards Act, 2006 (**FSS Act**), test only the parameters specified by Designated Officers (DOs)/ Authorised Officers (AOs) in Form VIA. This measure ensures regulatory compliance, enhances the credibility of food

[33] https://egazette.gov.in/WriteReadData/2025/261281.pdf
[34] https://egazette.gov.in/WriteReadData/2025/261172.pdf
[35] https://egazette.gov.in/WriteReadData/2025/2612156.pdf
[36] fssai.gov.in/upload/advisories/2025/02/67bdc964e9432Order%20dated%2025.02.2025.pdf

testing, and reinforces FSSAI's commitment to maintaining high standards in food safety.

d. *FSSAI introduces streamlined online approval process for RAFT kits and methods*[37]

The FSSAI, *vide* notice 11014 RAFT01/2023-QA, dated February 28, 2025, has issued a notice superseding previous guidelines and introducing a streamlined process for approval of Rapid Analytical Food Testing (**RAFT**) kits, equipment, and methods. The new process requires all applications to be submitted through the online RAFT Portal. Validation by an authorised third-party laboratory, including international organisations like AOAC (formerly Association of Official Analytical Chemists) and AFNOR (Association Française de Normalisation), is mandatory, requiring both single laboratory validation and a collaborative ring trial. The directive restricts applications to commercial manufacturers, excluding researchers, institutions, and innovators, while technology transfers must undergo re-validation. International manufacturers can apply directly, while Indian importers or distributors must provide authorisation letters. This initiative aims to enhance efficiency, transparency, and regulatory compliance for approval of food testing technologies.

e. *FSSAI proposes standardised export certification form for vegan food*[38]

The FSSAI, *vide* notification F. No. Expert committee on Vegan-1st meeting, dated February 28, 2025, has proposed the draft Food Safety and Standards (Vegan Foods) Amendment Regulations, 2025, introducing a standardised certification format, Form I for vegan food exports. The form outlines specific declarations by exporters, including the absence of animal-derived ingredients, no animal testing, contamination control, and adherence to hygienic manufacturing and storage practices. The amendment is open for public comments and suggestions until May 2, 2025.

f. *FSSAI waives registration fees and introduces new business category for Anganwadi centers*[39]

The FSSAI, *vide* order RCD-15001/3/2021-Regulatory-FSSAI (E-1142), dated March 12, 2025, has waived the registration fees for all Anganwadi (ICDS) Centers and introduced a dedicated "Kind of Business" (**KoB**) category under Food Services. This regulatory measure aims to facilitate ease of compliance for centers engaged in delivering supplementary nutrition to pregnant women, lactating mothers, and children, including those suffering from malnutrition. The waiver is applicable for both fresh registrations and renewals, and all newly registered Anganwadi centers will be issued a registration certificate valid for 5 (five) years, with no option for shorter validity.

g. *FSSAI notifies Food Safety and Standards (Packaging) First Amendment Regulations, 2025*[40]

The FSSAI, *vide* notification F. No. STD/SP-20/T (Recycled plastics-N), dated March 28, 2025, has notified the Food Safety and Standards (Packaging) First Amendment Regulations, 2025. The amendment permits the use of recycled polyethylene terephthalate (PET) for packaging, storing, carrying, or dispensing food products, subject to the condition that such packaging complies with prescribed national standards. These regulations will come into force on the date of their publication in the Official Gazette.

[37] fssai.gov.in/upload/advisories/2025/02/67c1900bbf818RAFT%20Notice%20signed.pdf
[38] https://egazette.gov.in/WriteReadData/2025/261443.pdf
[39] fssai.gov.in/upload/advisories/2025/03/67d2c9d55e228FSSAI%20Order%20dated%2012th%20March%202025-Waiving%20of%20registration%20fees%20for%20Anganwadi%20Centres.pdf
[40] https://egazette.gov.in/WriteReadData/2025/262130.pdf

News Updates

1. US Tariffs impact on Indian healthcare: Pharma spared, but devices to bear the brunt

On April 2, 2025, the US administration issued an executive order imposing a 26% (twenty-six percent) tariff on Indian imports, signaling a notable shift in bilateral trade policy, which will be effective from July, in the absence of an agreement to the contrary. However, Indian pharmaceutical products were exempted from the tariff, highlighting the sector's strategic value and India's critical role as the world's largest supplier of generic medicines, which make up for nearly half of all generics consumed in the US. The decision underscores the continued reliance on Indian pharma amid a tightening trade environment. In FY23-24, India exported pharmaceutical goods worth USD 27.9 (twenty-seven point nine) billion, with nearly USD 9 (nine) billion directed to the US[41].

The medical devices sector, in contrast, did not receive similar relief. In FY23-24, India exported medical devices worth USD 3.8 (three point eight) billion, while imports rose to USD 8.2 (eight point two) billion, marking a 13% (thirteen percent) year-on-year increase. Exports to the US totaled USD 714.38 (seven hundred and fourteen point three eight) million, while imports from the US exceeded USD 1.5 (one point five) billion. With Indian devices now falling under the 26% (twenty-six percent) tariff category, challenges around cost competitiveness and market access are expected to intensify. The move reflects a broader push by the US to recalibrate trade relationships in essential sectors and underscores the vulnerability of Indian exporters to policy shifts in key markets.[42]

For India, this development exemplifies the need to diversify both its manufacturing base and its trade relationships. Overdependence on the US market has heightened the exposure to external shocks, particularly in high-technology healthcare products. Strengthening domestic capacity, expanding into alternative global markets, and building more resilient value chains will be critical. As India aims to scale up its role in global healthcare, recalibrating its export strategy to withstand geopolitical and economic fluctuations/ shocks has become imperative.

2. Union Budget 2025: Healthcare sector highlights[43]

The Union Budget 2025-26 introduced targeted measures to strengthen India's pharmaceutical and healthcare ecosystem, with an enhanced allocation of INR 99,858.56

[41] https://indianexpress.com/article/health-wellness/us-trump-tariffs-medical-device-india-decoding-ripple-effect-9922718/
[42] Ibid.
[43] https://www.indiabudget.gov.in/doc/budget_speech.pdf

(ninety-nine thousand eight hundred and fifty-eight point five six) crore[44]. Reinforcing the Government's commitment to equitable access, innovation-driven care, and public health infrastructure, the Budget lays out a comprehensive roadmap with the following key highlights:

a. *Customs Duty Exemptions on Life-Saving Therapies*

To improve affordability and access, the government has added 36 (thirty-six) additional life-saving drugs to the list of medicines exempted from Basic Customs Duty (**BCD**). This includes 12 (twelve) next-generation cancer therapies, such as asciminib, pegylated liposomal irinotecan, daratumumab, and teclistamab, as well as drugs used in the treatment of rare diseases like Spinal Muscular Atrophy. These changes are expected to substantially ease the financial burden on patients requiring high-cost treatments.

b. *Expansion of Patient Assistance Programs (PAPs)*

The Budget further expands the scope of industry-led affordability initiatives by adding 37 (thirty-seven) new drugs and 13 (thirteen) additional Patient Assistance Programs to the BCD exemption list, provided these therapies are distributed free of cost. This is a significant step in bolstering access to essential treatments through public-private collaboration.

c. *District-Level Cancer Care Infrastructure*

The Government has committed to establishing 200 (two hundred) day-care cancer centres in district hospitals over the next 3 (three) years. This decentralised model of care aims to improve early access to treatment, particularly for patients in underserved and rural areas, while alleviating the burden on tertiary care centres.

d. *Ayushman Bharat Coverage extended to Gig Workers*

In a landmark move to expand social protection, healthcare benefits under the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (**AB-PMJAY**) will now be extended to gig workers, a rapidly growing segment of India's informal workforce. Workers registered through the e-Shram portal will receive identity cards and access to health coverage under the scheme. According to NITI Aayog, India's gig workforce is expected to grow from 7.7 (seven point seven) million in 2024 to 23.5 (twenty-three point five) million by 2029-30, underscoring the scale of this intervention.

3. Parliamentary Panel recommends Independent Ayush Drug Regulator and Unified Research Framework[45] [46]

In a slew of regulatory reforms, the Parliamentary Standing Committee on Health and Family Welfare, in its 165th report on the AYUSH Ministry's 2025-26 budget demands, has called for sweeping regulatory and research reforms in the Ayush sector. The Committee has recommended the establishment of a single independent drug controller to unify standard-setting and licensing processes for Ayurveda, Siddha, Unani, and Homoeopathy (ASU&H) medicines across states. It has also urged the creation of a dedicated pharmacovigilance body to monitor safety, curb misleading advertisements, and strengthen the scientific basis of traditional medicines through enhanced collaboration between Pharmacopoeia Commission for Indian Medicine and Homoeopathy (**PCIM&H**) and the Central Council for Research in Ayurvedic Sciences (**CCRAS**).

Further, the Committee has proposed the development of a robust Clinical Trial Management System (**CTMS**) to consolidate Ayush research activities across all councils and institutes. By automating trial workflows, standardising protocols, and incorporating Artificial Intelligence (AI)-based analytics, the CTMS aims to improve documentation, accelerate regulatory approvals, and enable multi-centre clinical studies, positioning India as a global leader in evidence-based integrative medicine.

4. Parliamentary Panel recommends expansion of NLEM, stricter enforcement against counterfeit drugs, and price regulation for cardiac stents[47]

The Parliamentary Standing Committee on Chemicals and Fertilizers has called for urgent policy intervention to improve access, affordability, and safety within India's pharmaceutical and medical device landscape. In its 8th report, the panel urged the DoP to expand the NLEM to include more widely used and life-saving drugs, citing the financial burden faced by patients due to the unchecked rise in prices of non-NLEM medicines. The Committee

[44] https://sansad.in/getFile/loksabhaquestions/annex/184/AU3529_YMONeo.pdf?source=pqals
[45] https://www.pharmabiz.com/NewsDetails.aspx?aid=176814&sid=1
[46] https://www.pharmabiz.com/NewsDetails.aspx?aid=176857&sid=1
[47] Eighth Report (18th Lok Sabha) on Demands for Grants (2025-26) pertaining to the Department of Pharmaceuticals, available at https://sansad.in/ls/committee/departmentally-related-standing-committees/45-Chemicals%20&%20Fertilizers-name

emphasised the need for a comprehensive and transparent review process and stronger coordination between the DoP, CDSCO, and NPPA to ensure affordability for lower-income households.

The Committee further recommended strengthening regulatory enforcement to curb the manufacturing and sale of substandard and counterfeit drugs. It called for making Good Distribution Practices (**GDP**) legally enforceable and emphasised uniform implementation of regulations across States and Union Territories. It also advocated for improved inspections, timely punitive action, and national awareness campaigns to educate stakeholders about the risks of counterfeit drugs.

On the medical devices front, the panel raised concerns over profiteering in the cardiac stent market and called for immediate action to ensure strict compliance with ceiling prices. It proposed transparent monitoring mechanisms, stronger accountability for hospitals and manufacturers, and a comprehensive review of pricing trends for critical devices. The Committee underscored the need for ethical medical practices and institutional accountability to prevent exploitation and ensure access to affordable life-saving interventions.

5. Parliamentary Panel raises concern on health budget allocation[48]

The Parliamentary Standing Committee on Health and Family Welfare, in its latest report on the 2025–26 budget, has flagged concerns over the stagnant allocation to the Department of Health and Family Welfare, which stands at just 1.89% (one point eight nine percent) of the total Union Budget and 0.27% (zero point two seven percent) of GDP, falling short of the National Health Policy's target of 2.5% (two point five percent) by 2025. While acknowledging a 10.83% (ten point eight three percent) increase over the previous year's revised estimate, the Committee emphasised that actual expenditure often fails to match allocations, undermining healthcare delivery. It also expressed concern over 428 (four hundred and twenty-eight) vacancies in the Ministry and urged steps to enhance fund utilisation, strengthen execution capacity, and leverage digital tools to improve scheme performance. Highlighting India's ongoing demographic and epidemiological transition, the Committee reiterated that improving access to affordable, quality healthcare is essential for supporting human productivity and economic growth.

6. The Indian Council of Medical Research issues EoI for joint development of Broad-Spectrum Typhoid-Paratyphoid Vaccine[49]

The Indian Council of Medical Research (**ICMR**) has issued an Expression of Interest (**EoI**) inviting private manufacturers and companies to collaborate on the joint development and commercialisation of a novel, broad-spectrum Typhoid-Paratyphoid vaccine developed by ICMR-NIRBI, Kolkata. The vaccine, based on Outer Membrane Vesicles (**OMVs**) from Salmonella Typhi and Paratyphi A, aims to fill a critical gap in India's enteric fever prevention strategy by offering dual protection not addressed by current Vi-based vaccines. The partnership will follow a two-phase roadmap, beginning with independent validation and followed by joint R&D, clinical trials, regulatory approvals, and large-scale manufacturing. With promising preclinical results and the potential to curb India's high disease burden, the vaccine is positioned at TRL 4/5 and, upon successful development, will grant the partner commercialisation rights in return for a 2% (two percent) royalty on net sales.

7. ICMR releases draft list of essential tests to be made available at government healthcare facilities[50]

The ICMR has released a draft National Essential Diagnostics List (**NEDL**), outlining a minimum set of diagnostic tests to be mandatorily available across all tiers of public healthcare facilities — from village-level centres and Ayushman Arogya Mandirs to primary, community, sub-district, and district hospitals. Anchored in a hub-and-spoke model, the draft proposes decentralised sample collection with centralised testing at better-equipped facilities to ensure both accessibility and quality. The list recommends that village-level centres offer diagnostics for nine key conditions, including diabetes, malaria, tuberculosis, HIV, and syphilis, with progressive additions such as Hepatitis B and Japanese encephalitis at higher levels. By standardising diagnostics access nationwide, the draft NEDL represents a foundational move toward equitable, evidence-based healthcare delivery.

[48] https://www.hindustantimes.com/india-news/parl-panel-raises-concern-on-health-budget-allocation-101741805487543.html
[49] https://health.medicaldialogues.in/vaccines/news/icmr-invites-proposals-for-joint-development-of-typhoid-paratyphoid-vaccine-143307
[50] https://www.thehindu.com/sci-tech/health/what-are-the-minimum-number-of-tests-that-should-be-available-at-government-healthcare-facilities-icmr-releases-draft-list/article69095289.ece#:~:text=According%20to%20the%20revised%20draft,in%20village%2Dlevel%20health%20facilities.

8. ICMR launches New Ethical Guidelines for AI in Healthcare[51]

The ICMR has released comprehensive ethical guidelines for AI in biomedical research and healthcare. These guidelines aim to ensure responsible AI development, focusing on patient safety, data privacy, and transparency in decision-making. The framework covers critical areas such as informed consent, bias mitigation, and regulatory compliance. By establishing these principles, ICMR seeks to foster innovation while maintaining ethical standards in India's rapidly evolving AI-driven healthcare landscape.

9. CDSCO & ICMR seek stakeholder comments on draft evaluation protocols for In Vitro Diagnostic licensing[52]

The CDSCO and the ICMR have jointly released draft Standard Performance Evaluation Protocols for issuing licences to In Vitro Diagnostic (**IVD**) devices under the MD Rules. The draft protocol covers evaluation protocols for fourteen diagnostic tests, including those for chikungunya, dengue, and zika virus. These protocols aim to streamline and standardise performance evaluation to ensure only quality-assured kits are licensed for use in India. The draft also clarifies that once a test kit is deemed not of standard quality, repeat testing will not be permitted unless valid proof of modifications in kit composition is furnished. The draft was released for stakeholder consultation, with feedback invited until March 15, 2025.

10. CDSCO introduces online approval process for additional variants of approved cosmetics[53]

The CDSCO has rolled out an online approval process for additional variants of already approved cosmetic products, marking another stride in the Centre's e-governance and regulatory streamlining efforts. This digital module, hosted on the SUGAM portal, is aimed at enhancing efficiency and transparency in the cosmetics product approval ecosystem. As per the official circular, stakeholders are encouraged to utilise this newly introduced functionality for seamless application submissions, further aligning with the regulator's broader push toward simplified, tech-enabled compliance pathways

11. The Materiovigilance Programme of India seeks stakeholder feedback on draft IVD adverse event reporting form[54]

The Materiovigilance Programme of India (**MvPI**), under the Indian Pharmacopoeia Commission (**IPC**), has released a draft IVD Adverse Event Reporting Form, inviting stakeholder

[51] https://www.icmr.gov.in/icmrobject/uploads/Guidelines/1724842648_ethical_guidelines_application_artificial_intelligence_biomed_rsrch_2023.pdf
[52] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI0NTY=
[53] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI1MjA=
[54] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI1Mjk=

feedback. Developed in collaboration with the CDSCO and IVD manufacturers' associations and incorporating industry suggestions, the form is a step toward streamlining post-market surveillance and strengthening the safety net around diagnostics devices. The reporting tool is intended for domestic manufacturers, importers, distributors, pathology laboratories, and blood donation centres, enabling systematic documentation of adverse events. Anchored in scientific vigilance, the initiative aims to support timely identification of risks, reinforce regulatory decision-making, and safeguard public health through enhanced diagnostics oversight.

12. Consideration of proposal for issuing guidelines under Section 33P of the D&C Act[55]

In compliance with the Hon'ble Supreme Court's order dated August 28, 2020, in Criminal Appeal No. 200 of 2020, the DCC considered issuing guidelines for uniform implementation of Section 33P of the D&C Act. After reviewing the expert committee's report, the DCC recommended that the committee revisit the matter, co-opt relevant domain experts, and propose stepwise modalities, with a report due in 3 (three) months. In a related development, aimed at strengthening regulatory oversight, the DCC also considered a proposal to introduce a State Drug Regulatory Index to benchmark and enhance regulatory standards across states. The DCC endorsed the proposal and suggested the inclusion of additional enforcement metrics, such as the number of raids and inspections to ensure a robust and transparent evaluation framework.

13. Centre to implement standardised hospital billing format for transparency[56]

The Central Government is poised to introduce a uniform hospital billing format across clinical establishments, including hospitals, nursing homes, and diagnostic centres, to enhance transparency and ensure greater clarity in healthcare costs. Spearheaded by the Bureau of Indian Standards (**BIS**), in collaboration with the MoH&FW, healthcare industry, and patient advocacy groups, the initiative mandates a comprehensive and itemised breakdown of all charges incurred by patients, covering services, consumables, and facilities. This measure follows the directive used by the Apex Court last year, which underscored the need for price regulation in private healthcare institutions. Once finalised, the standardised billing system is expected to empower patients with financial clarity, promote consumer-centric reforms, and streamline billing practices nationwide.

14. The Indian Pharmaceutical Association submits suggestions to ICMR for an action plan to ensure rational use of antibiotics[57]

The Indian Pharmaceutical Association (**IPA**) has submitted a comprehensive set of recommendations to the ICMR to formulate an actionable roadmap to combat antimicrobial resistance (**AMR**) through the rational use of antibiotics. The proposals range from monitoring antibiotic production and distribution, enforcement of prescription-only sales, introduction of Standard Treatment Guidelines (**STGs**), and mandating warning labels. Further, the IPA has called for restrictions on promotional practices, introduction of Point-of-Care testing at pharmacies, and cautious use of new antibiotics. Recognising the multi-sectoral nature of AMR, the submission also calls for a robust surveillance framework, spanning healthcare, food, and environment. This initiative underscores the IPA's intent to work closely with the ICMR to promote antibiotic stewardship and awareness at a national scale.

15. Gujarat IMA opposes '*mixopathy*' proposal[58]

The Gujarat chapter of the Indian Medical Association (**IMA**) has expressed concerns over *"mixopathy,"* which involves combining different medical systems such as allopathy, homeopathy, and Ayurveda for patient treatment. The IMA warned that mixopathy poses severe risks to public health and requested lawmakers to consider the long-term implications. This comes after the state health department called a meeting to discuss allowing Ayurvedic doctors to practice allopathy. The IMA opposed the idea, emphasising that mixopathy undermines the integrity and expertise of each medical system, potentially leading to compromised patient care, misdiagnosis, and adverse events. The IMA also highlighted the need to prioritise safe and evidence-based medical practices to avoid hazardous outcomes. They stressed that such an approach could lead to serious public

[55] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MjQ5OA==
[56] https://www.newindianexpress.com/nation/2025/Mar/24/centre-to-introduce-standardised-hospital-billing-format-to-ensure-transparency
[57] https://www.pharmabiz.com/PrintArticle.aspx?aid=175607&sid=1
[58] https://health.economictimes.indiatimes.com/news/industry/gujarat-ima-opposes-mixopathy-proposal-says-it-poses-severe-risks-to-peoples-health/116833503

health crisis and urged the government to uphold the sanctity of different medical systems.

16. NABL rolls out QR code and unique laboratory report-based authentication system to strengthen lab report integrity[59]

To elevate transparency, traceability, and data integrity within the accredited Conformity Assessment Bodies (**CABs**), the NABL has launched a dedicated software platform, enabling integration of QR codes and Unique Laboratory Report (**ULR**) numbers into test reports and calibration certificates. The NABL ULR and QR Code Generation System empowers accredited testing, calibration, and Reference Material Producer (**RMP**) labs to issue uniquely identifiable, tamper-resistant documentation aligned with their accreditation scope. Designed to support even those CABs with limited IT infrastructure, the system streamlines report authentication through blockchain-backed traceability, ULR-based verification without revealing report content, and QR code-enabled validation, fortifying the credibility of lab-issued certificates and reinforcing NABL's commitment to digital transformation in quality assurance.

17. Launch of Indian Genomic Data Set & the Indian Biological Data Centre Portals to empower global research[60]

India marked a major milestone in scientific self-reliance with the launch of the Indian Genomic Data Set at the Genome India Data Conclave in New Delhi, alongside the introduction of the Framework for Exchange of Data Protocols (**FeED**) and the Indian Biological Data Centre (**IBDC**) Portals. With 10,000 (ten thousand) whole genome sequences now made accessible to researchers globally, these initiatives aim to catalyse innovation in precision medicine, genetic diagnostics, and mRNA-based therapeutics. Spearheaded by the Department of Biotechnology, under the GenomeIndia project, the broader vision is to sequence 10 (ten) million Indian genomes, building a comprehensive map of the country's genetic diversity to support advanced research and development in genomics, rare disease treatment, and personalised healthcare.

18. Central Government announces structured timeline for compliance with amendments in labelling Provisions under the Legal Metrology (Packaged Commodities) Rules, 2011[61]

The Central Government has formalised a structured compliance timeline for implementation of amendments to labelling provisions under the Legal Metrology (Packaged Commodities) Rules, 2011. To facilitate smoother industry adaptation, any such amendments will henceforth come into force either on January 1 or July 1, with a minimum transition period of 180 (one hundred and eighty) days. In exceptional circumstances, implementation timelines may be decided on a case-by-case basis to ensure practical and timely solutions. The Legal Metrology framework plays a pivotal role in promoting transparency and consumer protection in trade by mandating standardised declarations on packaged goods. These include essential disclosures such as net quantity, maximum retail price, date of manufacture, country of origin, and manufacturer information. The revised approach seeks to balance the regulatory objectives of safeguarding consumer interests while reducing compliance friction for businesses and ensuring clarity across the supply chain.

19. Karnataka to come out with first-ever NSQ Recall Policy to ensure speedy withdrawal of substandard medicines[62]

In a significant regulatory stride, the Karnataka government is preparing to roll out India's first dedicated NSQ Recall Policy to expedite the removal of substandard and spurious medicines from circulation. This initiative is aligned with the DCC's emphasis on stringent measures to curb the presence of NSQ drug samples. Health and Family Welfare Minister Dinesh Gundu Rao highlighted the policy's focus on enhancing transparency and accountability within the pharmaceutical distribution chain. A key feature of the initiative is the development of a software capable of tracking NSQ stock across retailers, wholesalers, manufacturers, and their authorised agents, thereby enabling real-time identification and recall. Presently, while state regulators conduct raids and mandate recalls, there is no structured mechanism for private healthcare

[59] https://www.pharmabiz.com/NewsDetails.aspx?aid=176926&sid=1
[60] https://pib.gov.in/PressReleasePage.aspx?PRID=2091577#:~:text=Singh%20proudly%20stated%2C%20%E2%80%9CIndia%20has,only%20within%20India%20but%20globally.
[61] https://pib.gov.in/PressReleasePage.aspx?PRID=2097258
[62] https://www.pharmabiz.com/ArticleDetails.aspx?aid=175609.

establishments to comply with such directives. The proposed policy will introduce enforceable penalties, including monetary fines and imprisonment, for entities found complicit in the manufacture or distribution of substandard medicines, marking a pivotal step in reinforcing public health safeguards.

20. Wipro GE Healthcare launches 'AI Enabled - Made in India' ultrasound system[63]

Wipro GE Healthcare has unveiled the Versana Premier R3, an advanced AI-powered ultrasound system, aimed at enhancing clinical precision and operational efficiency. Developed and manufactured at the company's Bengaluru facility under the 'Make in India' initiative, the Versana Premier R3 integrates artificial intelligence to enable dynamic tissue imaging, streamline volume calculations, and optimise diagnostic workflows. The system's Vision Boost architecture, coupled with an eight million-channel digital processing engine, delivers high-resolution imaging across a wide range of applications. Compatible with 23 (twenty-three) different probes, it allows comprehensive organ scanning. A self-learning onboarding module further supports clinicians in adapting to new workflows, reinforcing diagnostic confidence. This launch reflects Wipro GE Healthcare's ongoing commitment to fostering AI-driven healthcare innovation and addressing India's increasing diagnostic needs amidst the growing burden of non-communicable diseases.

21. Eli Lilly launches 'Mounjaro' in India for management of Obesity and Type 2 Diabetes[64]

Eli Lilly and Company has launched its innovative diabetes and obesity management drug *Mounjaro* (tirzepatide) in India, following marketing authorisation from the CDSCO. *Mounjaro*, a first-in-class dual GIP and GLP-1 receptor agonist, is indicated for adults with Type 2 diabetes, obesity, or overweight conditions as an adjunct to a reduced-calorie

diet and increased physical activity. Clinical trials have shown that patients on the highest dose (15 mg) experienced an average weight loss of 21.8 kg, while those on the lowest dose (5 mg) lost 15.4 kg over a 72 (seventy-two) -week period. The drug is priced at INR 3,500 (three thousand and five hundred) for a 2.5 mg vial and INR 4,375 for a 5 mg vial, translating to a monthly cost of INR 4,000 (four thousand) to INR 17,500 (seventeen thousand and five hundred) depending on the dosage, significantly lower than its US price range of USD 1,000-1,200. The India launch aims to expand access to advanced metabolic therapies, amid the growing burden of lifestyle-related diseases.

22. AstraZeneca secures CDSCO nod for Durvalumab in lung cancer treatment [65]

AstraZeneca has received approval from the CDSCO for its drug, Durvalumab, which helps to treat limited-stage small cell lung cancer (**LS-SCLC**). The approval marks a significant advancement in cancer care, providing a new immunotherapy option for patients. Durvalumab, already approved for extensive-stage SCLC, has shown promise in improving survival rates and treatment outcomes.

[63] https://www.expresshealthcare.in/news/wipro-ge-healthcare-launches-ai-enabled-versana-premier-r3-ultrasound-system/448268/
[64] https://www.thehindu.com/sci-tech/health/obesity-and-diabetes-management-drug-launched-in-india-by-american-pharma-company-eli-lilly/article69353411.ece
[65] https://pharma.economictimes.indiatimes.com/news/drug-approvals-and-launches/astrazeneca-receives-cdsco-approval-for-durvalumab-in-treating-limited-stage-small-cell-lung-cancer/118796855

Litigation Updates

1. Supreme Court mandates stricter implementation of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954[66]

The Supreme Court (**SC**), in W.P. (C) No. 645 of 2022, *vide* order dated March 26, 2025, issued a series of directions to State Governments for effective implementation of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (**DMR Act**), which prohibits misleading advertisements relating to medical cures. The Court mandated the appointment of gazetted officers under Section 8 of the DMR Act within 1 (one) month and directed the establishment of grievance redressal mechanisms to enable the public to lodge complaints against such advertisements within 2 (two) months. It further held that publishers and designers of misleading advertisements would be equally liable under the DMR Act. Highlighting the substantial risks these advertisements pose to public health, the Court advocated for their stringent regulation. Additionally, the Union Government was directed to develop a digital dashboard within 3 (three) months to track enforcement actions.

These directions were issued in a Public Interest Litigation (**PIL**) filed by IMA, originally seeking regulation of misleading medical advertisements. The matter later expanded to include contempt proceedings against Patanjali Ayurved Ltd., Acharya Balkrishna, and Baba Ramdev for alleged violations of earlier court orders. These proceedings were subsequently closed, following public apologies. Reaffirming that the constitutional right to health includes protection from deceptive advertising, which is strictly prohibited under Sections 3, 4, and 5 of the DMR Act, the Court directed all States and the Union of India to submit compliance reports by June 2025. This order signals a significant step towards ensuring greater accountability and consumer protection in medical advertising.

2. SC examines ethical concerns in clinical trials conducted in poorer countries; highlights gaps in NDCT Rules[67]

The SC, in W.P (C) No. 33 of 2012, *vide* order dated March 21, 2025, has called for a comprehensive response from the Union Government in a long-standing public interest litigation that raises concerns over multinational pharmaceutical companies allegedly exploiting the economically weaker sections of the Indian society for clinical drug trials. The Centre informed the Court that the NDCT Rules, framed under the D&C Act, adequately addresses the issues raised and renders the petition infructuous. It was also submitted that public comments

[66] Indian Medical Association v. Union of India, Order dated March 26, 2025 in W.P. (Civil) No. 645 of 2022.
[67] Swasthya Adhikar Manch, Indore and Anr. v. Union of India and Ors., Order dated March 21, 2025 in W.P.(Civil) No. 33 of 2012.

were invited during the drafting process, and an amendment to the NDCT Rules was introduced in 2024. However, the Petitioners argued that systemic issues persist, including inadequate compensation for trial-related injuries and deaths, lack of regulatory oversight, and unethical subject selection practices.

The Court was also apprised of serious concerns regarding past clinical trials involving the survivors of the Bhopal Gas Tragedy and the HPV vaccine trials in Andhra Pradesh, which allegedly led to fatalities without adequate investigation. The original PIL, filed in 2012 by the Swasthya Adhikar Manch, had prompted earlier directions from the Court, mandating audio-visual consent for trial participants and greater regulatory scrutiny. While the NDCT Rules have introduced structural safeguards such as Ethics Committees and compensation mechanisms, the Petitioners submitted that implementation continues to remain weak. The Court emphasised that clinical trials disproportionately occur in developing countries and directed the Government to file a detailed affidavit addressing all outstanding concerns. The matter is scheduled to be heard again after 4 (four) weeks.

3. SC affirms that doctors rendering paid services fall under the Consumer Protection Act, 1986[68]

The SC, in Review Petition (C) Diary No(s). 57132/2024 in C.A. No. 2646 of 2009, *vide* order dated February 12, 2025, upheld the applicability of the Consumer Protection Act, 1986 (**CP Act**), to doctors and medical professionals rendering paid services. The Court dismissed a review petition challenging its earlier order, which had declined to reconsider the landmark 1995 judgment of the Hon'ble Apex Court in *Indian Medical Association v. V.P. Shantha*. That judgment had firmly established that medical professionals are subject to the provisions of the CP Act when their services are availed for consideration.

The Court specifically relied on Section 2(1)(o) of the CP Act, which defines *"service"* to include a wide range of offerings, such as those related to banking, housing, and medical treatment, provided they are not rendered free of charge or under a personal service contract. In this context, the Court reaffirmed that medical services provided for a fee falls squarely within the Act's ambit, thereby allowing patients to seek redress for any deficiency. The Medico-Legal Society of India had sought a review of this settled position, pointing to observations by a two-judge bench suggesting the 1995 judgment required reconsideration, particularly on the question of whether medical services are akin to trade or business. However, the SC maintained its stance that paid medical services remain within the purview of the CP Act and dismissed the review petition.

4. SC holds that possession of contraband under the Narcotic Drugs and Psychotropic Substances Act, 1985 must be both physical and conscious to sustain conviction[69]

The SC, in Criminal Appeal No. 1953 of 2014, *vide* order dated January 16, 2025, reiterated that for a conviction under the Narcotic Drugs and Psychotropic Substances Act, 1985 (**NDPS Act**), possession must be both physical and conscious. This means that the accused must not only have physical control over the contraband, but must also be aware of its presence and nature. The case concerned an individual found carrying 50 kg of poppy husk while travelling by train. The Trial Court had sentenced the accused to 10 (ten) years of rigorous imprisonment, along with a fine. The accused challenged the conviction before the Apex Court, contending that he was unaware of the contents of the cartons in his possession.

The Court referred to Sections 35 and 54 of the NDPS Act, which presume the existence of a culpable mental state and shift the burden onto the accused to prove the absence of knowledge or intent. Rejecting the appellant's defence of ignorance, the Court held that once possession is established, statutory presumption under Section 54 is triggered, warranting conviction unless rebutted. Finding no merit in the defence, the Court dismissed the appeal and directed the appellant to surrender within 8 (eight) weeks.

5. SC dismisses PIL related to quality of Anti-Rabies Vaccine, directs Petitioner to appeal to the Health Ministry[70]

The SC, in W.P.(C) No. 882 of 2022, *vide* order dated January 20, 2025, disposed a PIL challenging the safety and efficacy of anti-rabies vaccines administered to both humans and animals in India. While dismissing the plea, the Court permitted the Petitioner, Kerala Pravasi Association, to

[68] Medico Legal Society of India v. Bar of Indian Lawyers & Ors., Order dated February 12, 2025 in Review Petition (C) Diary No(s). 57132 of 2024 in C.A. No. 2646 of 2009.
[69] Rakesh Kumar Raghuvanshi v. The State of Madhya Pradesh, Order dated January 16, 2025 in Criminal Appeal No. 1953 of 2014.
[70] Kerala Pravasi Association & Anr. v. Union of India & Ors., Order dated January 20, 2025 in W.P. (Civil) No. 882 of 2022.

submit a representation to the MoH&FW, which has been directed to consider the concerns and take appropriate action. The PIL had sought the constitution of an independent expert committee to evaluate the quality of Intra-Dermal Rabies Vaccines (**IDRV**) administered to humans, and rabies veterinary vaccines used for dogs.

The Petition highlighted instances of individuals contracting and succumbing to rabies despite receiving post-exposure prophylaxis, thereby raising doubts about the efficacy of existing treatment protocols and vaccine quality. It further pointed to anomalies in the vaccine distribution timeline, with vaccines reportedly reaching states within 14 (fourteen) days of manufacture, contrary to the National Centre for Disease Control (**NCDC**) guidelines, which recommend a standard testing and release period of three to four months. The PIL also expressed concerns about the rising number of rabies-infected stray dogs and called for investigations into vaccine quality. It alleged violations of Articles 14, 19, and 21 of the Constitution of India and provisions under the D&C Act, while also urging periodic updates to the National Guidelines for Rabies Prophylaxis, 2019, in alignment with the World Health Organization (**WHO**) recommendations.

6. Madhya Pradesh High Court seeks NABL accreditation of pathological labs and clarification on regulatory standards for diagnostic materials[71]

The High Court of Madhya Pradesh (**MP HC**), in W.P. No. 12 of 2015, *vide* order dated February 21, 2025, directed the Central and State authorities to submit a comprehensive list of NABL-accredited pathological laboratories in the state. The Court also called for a roadmap to ensure NABL accreditation of all pathological labs operating within Madhya Pradesh. In addition, the Union of India and the IPC were directed to clarify whether any monographs or formularies exist for chemicals, reagents, salts, and diagnostic kits used in pathological testing and, if absent, whether such regulatory standards can feasibly be developed to ensure quality parameters such as identity, purity, and strength.

The PIL raised serious concerns about the use of unregulated chemicals and reagents in diagnostic labs, contending that such materials should be brought under the purview of the D&C Act, as *"drugs"* under Section 3(1). While government-run medicine testing laboratories are NABL-accredited, the petition noted that most private labs lack such accreditation, potentially compromising diagnostic reliability. The respondents stated that only certain notified diagnostic kits (e.g., HBsAg, HCV, HIV) are currently regulated under Section 3(b)(iv) of the D&C Act, while other non-notified kits fall under Section 3(b)(i). However, reagents, salts, and chemicals used in diagnostics remain unregulated, exposing a significant regulatory gap. The matter is listed for further hearing in April 2025.

7. MP HC issues SOPs for medical termination of pregnancy in sexual offence cases, resolves judicial divergence[72]

The MP HC, in W.P. No. 5184 of 2025, *vide* order dated February 20, 2025, issued standard operating procedures (**SOPs**) to streamline the process for terminating pregnancies arising from sexual assault, rape, or incest. The Court clarified that pregnancies up to 24 (twenty-four) weeks may be terminated without court intervention, whereas pregnancies beyond this threshold would require High Court approval. The SOPs aim to resolve conflicting judicial interpretations by the Indore and Jabalpur Benches on the application of the Medical Termination of Pregnancy Act, 1971 (**MTP Act**).

The *suo motu* petition arose in the context of procedural delays in the termination of pregnancies in sexual assault cases, notably in Crime No. 532/2024 at Police Station Mahidpur, District Ujjain. While the Indore Bench had previously insisted on judicial oversight in all cases, the Jabalpur Bench clarified that such oversight is only needed when the gestation period exceeds 24 (twenty-four) weeks. The SOPs now mandate that the police refer survivors to medical boards for prompt evaluation, and if found eligible under Sections 3(2)(a) and 3(2)(b) of the MTP Act, the termination be carried out within three days. In cases beyond 24 (twenty-four) weeks, the High Court will decide based on medical findings. The Court also invoked the POCSO Rules, 2020, which require medical care to be provided without awaiting legal requisitions, and directed authorities to ensure preservation of forensic evidence, confidentiality of the survivor, and compliance under pain of contempt.

[71] Amitabh Gupta v. Union of India And Ors., Order dated February 21, 2025 in W.P. No. 12 of 2015.
[72] In Reference (*Suo Motu*) v. The State of Madhya Pradesh and Ors, Order dated February 20, 2025 in W.P. No. 5184 of 2025.

8. Karnataka High Court affirms Healthcare as a Fundamental Right, orders urgent reforms[73]

The High Court of Karnataka (**Karnataka HC**), in W.P. No. 797 of 2024, *vide* judgment dated January 23, 2025, took *suo motu* cognizance of a news report titled *"Karnataka Short of 16,500 Medical Personnel"*, published in The New Indian Express on October 16, 2023. The report highlighted severe staffing shortages, including vacancies of 723 (seven hundred and twenty-three) doctors, 7,492 (seven thousand four hundred and ninety-two) nurses, 1,517 (one thousand five hundred and seventeen) lab technicians, 1,512 (one thousand five hundred and twelve) pharmacists, 1,752 (one thousand seven hundred and fifty-two) assistants, and 3,253 (three thousand two hundred and fifty-three) Group D employees, significantly impacting healthcare delivery, particularly in rural areas. In response, the Court directed the State Department of Health and Family Welfare to constitute a three-member oversight committee to address gaps in medical infrastructure and human resources across the state.

Affirming the Right to Health as an enforceable fundamental right under the Constitution, the Karnataka HC held that its realisation requires not only robust medical infrastructure, but also an adequate number of qualified healthcare professionals and continuous availability of essential medicines. While the State cited various recruitment drives and the implementation of schemes such as AB-PMJAY and state-specific health programmes, the Court expressed concerns over systemic delays and inefficiencies. In its judgement, the Court issued comprehensive directions, including the establishment of district-level monitoring committees, structured recruitment timelines, and enhanced inter-agency coordination, including directions to the State Government to submit a detailed status report within 10 (ten) weeks.

9. MP HC calls for strict action against online sale of Prohibited Drugs[74]

The MP HC, Jabalpur Bench, in W.P. No. 27719 of 2024, *vide* interim order dated January 21, 2025, directed the Drug Controller, Narcotics Control Bureau (**NCB**), and law enforcement agencies to take immediate action against manufacturers and wholesalers involved in the online sale of banned FDCs, including *Chlorpheniramine Maleate + Codeine + Menthol syrup* and other prohibited substances.

The matter arose from a PIL flagging the widespread availability of such drugs online, particularly through platforms such as IndiaMART, despite prohibitions under Section 26A of the D&C Act.

The Petitioner submitted that the unchecked online availability of banned drugs not only undermines public health, but also contributes to illegal production and trafficking, luring unemployed youth into drug peddling networks. The Court observed that while small-scale offenders are routinely prosecuted, large-scale manufacturers and distributors often operate with impunity. Emphasising the urgency of the matter, the Bench called for stringent enforcement measures and directed the authorities to submit an action-taken report before the next hearing.

10. Bombay High Court dismisses allegation against Nestle India Ltd. for selling 'Sub-Standard' Maggi Noodles[75]

The High Court of Bombay (**Bombay HC**), in Criminal Application (Apl) No. 503 of 2024, *vide* judgment dated January 7, 2025, quashed a criminal case against Nestlé India and others, concerning the alleged non-compliance of "Maggi Instant Noodles with Tastemaker" under the FSS Act. The matter arose from a complaint dated April 4, 2016, filed by a Food Safety Officer, citing violations of the FSS Act, the Food Safety and Standards (Food Product Standards and Additives) Regulations, 2011, and the Food Safety and

[73] The Registrar General, High Court of Karnataka v. Union of India & Ors, Judgement dated January 23, 2025 in W.P. No. 797 of 2024 (GM-RES-PIL).
[74] Amitabha Gupta v. Union of India Health and Family Welfare Department & Ors., Order dated January 21, 2025 in W.P. No. 27719 of 2024.
[75] Shyamkumar Tulsilal Warnawal v. State of Maharashtra, Judgment dated January 07, 2025 in Criminal Application No. 503 of 2024.

Standards (Contaminants, Toxins and Residues) Regulations, 2011 (collectively referred to as "**FSS Regulations**"), which are punishable under Sections 59 and 66 of the FSS Act. The case stemmed from an inspection at Nestlé India's logistic hub, where samples of "Maggi Instant Noodles with Tastemaker" and "Baby and Me" Nutritional Supplements were drawn, leading to the filing of a criminal complaint before the Additional Chief Judicial Magistrate, Nagpur.

While the Food Analyst had initially reported that the Maggi Noodles samples conformed to the standards of "Macaroni Products" under the applicable FSS Regulations, the Designated Officer had sent another sample to the referral food laboratory in Ghaziabad. The Bombay HC held that the referral food laboratory was not NABL accredited at the relevant time. Since Section 43 of the FSS Act mandates food testing to be conducted only in accredited laboratories, recognised by the Food Authority, the Court ruled that the prosecution could not rely on the unaccredited lab's findings. Accordingly, the Court held that the Food Analyst's report dated December 31, 2015, lost its evidentiary value and could not form the basis of criminal prosecution. Consequently, the criminal proceedings against Nestlé India and other applicants were quashed.

11. Gauhati High Court seeks Assam Government's response on implementation of SOP for Transgender Healthcare[76]

The High Court of Gauhati (**Gauhati HC**), in PIL No. 74 of 2018, *vide* order dated January 7, 2025, directed the Assam Government to clarify whether it has implemented the SOP issued by the MoH&FW on September 3, 2024, for ensuring equitable medical treatment and healthcare access to transgender persons. The petitioner highlighted the state's failure to act upon this SOP, contending that this inaction amounts to denial of essential health services to the transgender community. It was also submitted that such failure violates the State's obligations under the Transgender Persons (Protection of Rights) Act, 2019 (**TPPR Act**), which mandates the implementation of welfare measures, including access to adequate healthcare, for transgender individuals.

The Division Bench, after considering an additional affidavit filed on January 6, 2025, directed the State to submit a detailed response, confirming whether the SOP had been implemented and what steps were being taken under the TPPR Act. The Court underscored the State's duty to uphold fundamental healthcare rights of transgender persons and stressed the need for timely and comprehensive response. It also allowed the petitioner to submit a further affidavit, if necessary, to address any remaining gaps in implementation at either the state or central level.

12. Delhi High Court to examine customs' jurisdiction over seizure of 'De-Addiction' devices under E-Cigarettes Act[77]

The High Court of Delhi (**Delhi HC**), in W.P. (C) 3200 of 2025, *vide* order dated March 12, 2025, issued notice to the customs authorities in a matter concerning the seizure of imported "empty atomizer devices" under the Prohibition of Electronic Cigarettes Act, 2019 (**E-Cigarettes Act**). The petitioner, a private company, contended that the seized goods were de-addiction devices intended to be filled with herbal formulations and do not qualify as e-cigarettes under the Act. It was further argued that these products are licensed medical devices and may require regulatory clearance under the D&C Act, not a ban under the E-Cigarettes Act.

The petitioner also challenged the jurisdiction of customs officials to carry out the seizure, arguing that only an officer authorised under the E-Cigarettes Act is empowered to take enforcement actions. The Court directed the Customs Department to file a counter-affidavit within 4 (four) weeks addressing these contentions, including the classification of the product and their authority to seize it. A rejoinder, if any, is to be filed within 2 (two) weeks thereafter. The matter is listed for further hearing on April 30, 2025.

13. Bombay HC directs 'Anti-Inflammatory', 'Anti-Bacterial', 'Analgesic' claims from toothpaste labels by June 2025 after FDA order[78]

The Bombay HC, in W.P. No. 2131 of 2025, *vide* order dated March 26, 2025, disposed of a writ petition filed by Dabur India Ltd., concerning regulatory objections to the use of terms such as "anti-inflammatory," "anti-bacterial," and "analgesic" on certain toothpaste product labels. The matter originated from directions issued by the Commissioner of the Food and Drug Administration (**FDA**), Government of Maharashtra, stating that such claims on non-medicinal

[76] Swati Bidhan Baruah v. The State of Assam & 2 Ors, Order dated January 7, 2025 in PIL/74/2018.
[77] Mea Ame Pvt. Ltd. v. Deputy Commissioner, Customs (Preventive), New Delhi, Order dated March 12, 2025 in W.P. (C) 3200 of 2025.
[78] Dabur India Ltd v. State of Maharashtra & Ors., Order dated March 26, 2025 in W.P. No. 2131 of 2025.

products violate the provisions of the D&C Act. Although the FDA clarified that the labels were not hazardous to health, it maintained that the language was legally impermissible and potentially misleading to consumers.

The Petitioner, Dabur, submitted an affidavit undertaking to discontinue the use of these terms on its 'Dabur Meswak Toothpaste' and 'Dabur Herb Anti-Bacterial Toothpaste Tulsi' products. The division bench of the Court recorded this assurance and ruled that the company shall not manufacture or sell toothpaste with the impugned claims from June 2025 onwards. However, the Court permitted Dabur to utilise the existing stock, valued at approximately INR 1 (one) crore, until May 31, 2025, after which such products would no longer be allowed for sale. The judgment reflects the Court's attempt to ensure regulatory compliance, while providing the manufacturer a reasonable transition window.

14. Kerala High Court permits married woman to undergo In-Vitro Fertilisation despite husband exceeding the Assisted Reproductive Technology (Regulation) Act, 2021 age limit[79]

The High Court of Kerala (**Kerala HC**), in in W.P. (C) No. 31161 of 2024, *vide* order dated February 24, 2025, permitted a 46 (forty-six)-year-old married woman to access Assisted Reproductive Technology (ART) services, even though her 57 (fifty-seven)-year-old husband exceeded the age limit prescribed under Section 21(g) of the ART (Regulation) Act, 2021 (**ART Act**). The provision sets the maximum age for availing ART services at 50 (fifty) years for women and 55 (fifty-five) years for men. The Petitioner had impugned the hospital's refusal to provide further treatment, arguing that her husband's age should not be a barrier as she alone would undergo the procedure using donor male gametes.

The Court held that eligibility for ART is to be assessed individually and not jointly for a couple. It emphasised that the ART Act adopts an individual-centric framework, and since the woman was within the permissible age, she should not be denied treatment merely because her husband did not meet the male age criteria. This ruling clarifies the scope of ART access for married women and affirms gender-specific rights under the law, ensuring that women are not unfairly denied reproductive healthcare on account of their partner's age.

[79] Sajitha Abdul Nazar v. Union of India, Order dated February 24, 2025 in W.P.(C) No. 31161 of 2024.

Transaction Updates

1. Kotak Alternate Assets invests INR 940 (nine hundred and forty) crore in Neuberg Diagnostics ahead of planned initial public offering[80]

Kotak Strategic Situations India Fund II, managed by Kotak Alternate Asset Managers Ltd., has invested INR 940 (nine hundred forty) crore in Neuberg Diagnostics Pvt. Ltd., India's fourth-largest diagnostics player. Founded by Dr. GSK Velu, Neuberg operates over 250 (two hundred fifty) labs across 250 (two hundred fifty) cities, with more than 10,000 (ten thousand) touchpoints, holding market leadership in Gujarat and Karnataka. The capital infusion will support Neuberg's inorganic expansion strategy and augment capabilities in personalised medicine and integrated diagnostics, as the company gears up for its upcoming initial public offering (**IPO**). Neuberg reported consolidated revenue exceeding INR 1,000 (one thousand) crore in FY24, up from INR 551 (five hundred fifty-one) crore in FY23.

2. Tatas to inject INR 500 (five hundred) crore in Mumbai's Breach Candy hospital[81]

Tata Group, India's largest conglomerate, is set to expand its presence in healthcare, with INR 500 (five hundred) crore contribution to Breach Candy Hospital. This move will make Tata Group the hospital's largest financial backer and will entitle them to nominate 3 (three) members to the 14 (fourteen) member board of trustees. The funding will support infrastructure and technological improvements at the 275 (two hundred seventy-five) bed multi-speciality hospital, which is favored by the rich and famous. This marks the Tata Group's third healthcare project in Mumbai, following the Tata Memorial Centre for cancer research and treatment and an animal hospital set up in Mahalaxmi.

3. Sun Pharma to acquire Checkpoint Therapeutics for USD 355 (three hundred and fifty-five) million[82]

Sun Pharmaceutical Industries Ltd. has announced the acquisition of US-based immunotherapy and oncology firm Checkpoint Therapeutics Inc. for approximately USD 355 (three hundred fifty-five) million. The deal includes an upfront cash payment of USD 4.10 per share, representing a 66% (sixty-six percent) premium to the company's recent trading price. Shareholders may receive an additional USD 0.70 per share if cosibelimab, Checkpoint's immunotherapy drug, receives marketing approval in the European Union (**EU**) within specified timelines. Upon completion, the deal will add UNLOQCYT™ (cosibelimab), an FDA-approved treatment for advanced skin cancer, to Sun Pharma's global oncology portfolio. The transaction is expected to close in Q2 2025, subject to regulatory approvals.

[80] https://www.business-standard.com/markets/ipo/kotak-fund-invests-rs-940-cr-in-ipo-bound-diagnostics-chain-neuberg-125011000482_1.html
[81] https://www.cnbctv18.com/business/companies/tata-group-to-invest-rs500-crore-in-mumbais-breach-candy-hospital-to-boost-infrastructure-19561288.htm
[82] https://www.reuters.com/business/healthcare-pharmaceuticals/indias-sun-pharma-acquire-checkpoint-therapeutics-2025-03-10/

4. Fortis Healthcare to acquire Jalandhar-based multi-speciality Shrimann Superspeciality Hospital for USD 53 (fifty-three) million[83]

Fortis Healthcare Limited, a leading integrated healthcare service provider, has announced the acquisition of Shrimann Superspeciality Hospital, a Jalandhar-based multi-speciality hospital for a total consideration of INR 462 (four hundred sixty-two) crore in an all-cash deal. The transaction includes the purchase of the hospital and the 3-acre land on which it has been constructed, along with an additional 2.4-acre parcel, earmarked for future expansion. According to sources, the acquisition will expand Fortis's presence in Punjab, including key cities such as Mohali, Amritsar and Ludhiana. At present, Fortis manages 27 (twenty-seven) healthcare facilities, including JVs, and operations and management facilities, across India, comprising 4,700 (four thousand and seven hundred) operational beds and 405 (four hundred and five) diagnostic labs.

5. Motilal Oswal Alternates acquires majority stake in Megafine Pharma[84]

Motilal Oswal Alternates (**MO Alts**), the private equity division of Motilal Oswal Financial Services Ltd., has invested INR 460 (four hundred sixty) crore to acquire a majority stake in Megafine Pharma Pvt Ltd., an active pharmaceutical ingredient (**API**) manufacturer. Established in 1995, Megafine operates two US FDA-approved manufacturing facilities in Nashik and Vapi, producing a diverse range of high-value, low-volume niche APIs for chronic therapies. In fiscal year 2023-24, the company reported net sales of INR 322 (three hundred twenty-two) crore. This transaction marks MO Alts' first sole control investment, with plans to enhance Megafine's research and development, manufacturing capabilities, and explore further inorganic growth opportunities.

6. Zydus Lifesciences acquires Amplitude Surgical for €256.8 (two hundred and fifty-six point eight) million[85]

Zydus Lifesciences has acquired an 85.6% (eighty-five point six percent) stake in French orthopedics firm, Amplitude Surgical, for €256.8 (two hundred fifty-six point eight) million, marking its foray into the medtech segment. According to sources, the acquisition also includes a subsequent tender offer, which could raise the total deal value to €300 (three hundred) million. Amplitude Surgical specialises in knee and hip prostheses and generated €106 (one hundred six) million in revenue in FY24. The acquisition aligns with Zydus's strategy to diversify beyond generics into medical technology.

7. Alkem Labs to acquire two firms to foray into orthopedic medical devices, grow dermatology biz[86]

Homegrown drugmaker Alkem Laboratories has engaged in separate deals to acquire two smaller peers for a cumulative INR 287 (two hundred eighty-seven) crore in cash, to expand its product portfolio and gain market share in the country. The company will acquire Adroit Biomed Ltd., a derma-cosmetology company, for INR 140 (one hundred forty) crore, payable in two tranches. Its wholly owned subsidiary, Alkem Medtech, will be acquiring Bombay Ortho Industries, a manufacturer of knee and hip implants, for INR 147 (one hundred forty-seven) crore, payable in four tranches. These acquisitions will enable Alkem to enhance its manufacturing capabilities in the growing orthopedic segment, and also diversify its offerings in the dermato-cosmetology space. The deals follow Alkem Labs' recent announcement of 5.2% (five point two percent) year-on-year increase in its net profit.

8. Metropolis Healthcare to acquire Agra-based scientific pathology chain[87]

Metropolis Healthcare Ltd, India's second-largest pathology chain, through its wholly-owned subsidiary, Metropolis Clinical Pathology Private Limited, has entered into a Business Transfer Agreement (BTA) to acquire Agra-based Scientific Pathology, founded by Dr Ashok Kumar Sharma, through a slump sale transaction. The transaction, valued between INR 55 (fifty-five) crore and INR 83 (eighty-three) crore, involves the acquisition of all laboratories and collection centers owned by Scientific's laboratories in Agra and surrounding regions. According to a statement issued by Metropolis[88], this strategic move is poised to strengthen its

[83] https://www.vccircle.com/fortishealthcare-to-acquire-north-india-hospital-for-53-mn
[84] https://www.business-standard.com/industry/news/mo-alts-acquires-majority-stake-in-megafine-pharma-for-rs-460-crore-125022501188_1.html
[85] https://www.thehindu.com/business/zydus-lifesciences-to-acquire-amplitude-surgical-for-257-mn/article69318509.ece
[86] https://www.vccircle.com/alkemlabs-buying-two-firms-to-foray-into-medical-devices-grow-dermatology-biz
[87] https://www.business-standard.com/companies/news/metropolis-strengthens-up-presence-with-acquisition-of-scientific-pathology-125030300534_1.html
[88] https://www.metropolisindia.com/newdata/investors/adminpanel/corporate_announcements/metropolis_healthcare_to_acquire_agras_leading_diagnostic_chain_scientific_pathology.pdf

presence in Western Uttar Pradesh, and accelerate Business to Consumer (**B2C**) expansion, and unlock growth opportunities across the state and beyond. The deal is expected to close within 45 (forty-five) days, pending regulatory approvals. This acquisition follows Metropolis' recent acquisition of Core Diagnostics, in line with its ongoing strategy to expand in northern and eastern India.

9. MOC Cancer Care secures USD 18 (eighteen) million series B funding[89]

MOC Cancer Care & Research Centre (**MOC**), a network of oncology and hematology healthcare centers, has secured USD 18 (eighteen) million in a Series B funding round, led by venture capital firm Elevation Capital. This investment will be used to strengthen MOC's infrastructure, expand its network to bring cancer care closer to patients, and facilitate large-scale clinical trials and exploration of new therapies. Founded in 2018, MOC has treated over 4,50,000 (four lakh fifty thousand) cancer patients across 24 (twenty-four) centers in cities including Ahmedabad, Indore, Mumbai, and Pune. According to sources, MOC plans to utilise the funds to further expand its operations, develop a molecular oncology lab, and broaden its preventive oncology services.

10. DCDC Kidney Care secures INR 150 (one hundred and fifty) crore investment from ABC Impact[90]

DCDC Health Services Pvt Ltd, operating under the DCDC Kidney Care brand, has raised INR 150 (one hundred fifty) crore from Singapore-based ABC Impact, an Asia-focused impact investor backed by Temasek. The infusion will enable DCDC to establish over 150 (one hundred fifty) new dialysis clinics across India, with a sharp focus on improving access to quality kidney care, particularly in underserved areas. Established in 2009, DCDC currently operates over 200 (two hundred) clinics through a mix of public-private partnerships, standalone centers, and collaborations with private hospitals. Existing investors include the Danish government's IFU and the Asian Development Bank. The investment aligns with ABC Impact's broader healthcare mandate to drive equitable outcomes in Asia.

11. Quadria Capital invests USD 100 (one hundred) million in Aragen Life Sciences ahead of IPO[91]

Healthcare focused private equity firm Quadria Capital is investing USD 100 (one hundred) million (approximately INR 860 (eight hundred sixty) crore) in Hyderabad-based Aragen Life Sciences Ltd, a contract drug development and

[89] https://economictimes.indiatimes.com/tech/funding/moc-cancer-care-raises-18-million-from-elevation-capital/articleshow/118563528.cms?from=mdr
[90] https://www.business-standard.com/companies/news/dcdc-kidney-care-gets-rs-150-cr-investment-from-temasek-backed-investor-125032300401_1.html
[91] https://www.aragen.com/news/aragen-100m-pe-boost-to-bolster-cdmo-ambition-in-india-and-beyond

manufacturing company. The investment values Aragen at USD 1.4 (one point four) billion and includes both a fresh capital infusion and a minor stake purchase from existing shareholders. The funds will be used to expand Aragen's capabilities and infrastructure to meet the growing demand for outsourcing services from innovators in the US and Europe. Established in 2000, Aragen provides drug discovery and development services to pharmaceutical, agrochemical, and biotech companies, and operates five facilities in India and one in the US.

12. Geri Care raises INR 110 (one hundred and ten) crore from InvAscent for a minority stake[92]

Geri Care Health Services has secured an investment of INR 110 (one hundred ten) crore from InvAscent, a healthcare and life sciences-focused private equity investor, through its India Life Sciences Fund IV (**ILSF IV**). Marking its first institutional fundraise, this investment will bolster Geri Care's efforts to scale its services. The company offers a comprehensive care model for senior citizens, including multi-speciality hospitals, assisted living centres, home care, and clinics. The funds will be used to expand its footprint across key cities in Southern India.

13. Tata Capital Healthcare Fund partners with Blue Earth Capital to support Apex Kidney Care[93]

Tata Capital Healthcare Fund (**TCHF**) has secured a USD 9 (nine) million co-investment from Blue Earth Capital AG, one of its limited partners, to bolster Apex Kidney Care (**AKC**), a leading dialysis service provider in India. This investment follows TCHF's previous funding of USD 10 (ten) million into AKC, aiming to expand its dialysis services nationwide. According to TCHF's press statement, the collaboration aims to expand AKC's dialysis services nationwide and reflects a shared commitment to strengthening healthcare infrastructure and access to quality renal care across the country.

14. The National Company Law Tribunal sanctions the Cohance Lifesciences - Suven Pharmaceuticals merger[94]

Suven Pharmaceuticals has announced that the National Company Law Tribunal (**NCLT**) has sanctioned the Scheme of Amalgamation between Cohance Lifesciences and Suven Pharmaceuticals. As per the Scheme, the merger will become effective following the fulfillment of all specified conditions, including approvals from the DoP, where applicable. The effective date will be intimated to the Stock Exchanges, in line with regulatory requirements. The amalgamation seeks to establish a future-ready, diversified CDMO platform with strengths across Antibody Drug Conjugates (**ADCs**), Oligonucleotides, and Small Molecules. The combined entity will serve as an integrated, end-to-end partner to global innovator pharmaceutical companies, with enhanced capabilities in the Specialty CDMO and API+ business segments.

15. Syngene concludes acquisition of Emergent BioSolutions' biologics manufacturing facility[95]

Syngene International, an integrated research, development, and manufacturing (**RD&M**) services company and a subsidiary of Biocon, has acquired its first biologics manufacturing facility in the United States from Emergent Manufacturing Operations Baltimore, a unit of Emergent BioSolutions, for USD 36.5 (thirty-six point five) million. Strategically located near key biotech hubs in the US Northeast, the Baltimore-Bayview facility is equipped with multiple monoclonal antibody (mAb) production lines and is expected to become operational for client projects in the second half of 2025. With this acquisition, Syngene expands its total single-use bioreactor capacity to 50,000 (fifty thousand) liters, significantly enhancing its capabilities in large molecule discovery, development, and manufacturing. As part of the agreement, Emergent retains the rights to access manufacturing services and capacity at the facility, marking a collaborative transition as it pivots away from contract manufacturing.

[92] https://www.business-standard.com/content/press-releases-ani/invascent-invests-rs110-crore-in-geri-care-india-s-pioneer-in-integrated-geriatric-care-125012901465_1.html
[93] https://www.tatacapital.com/content/dam/tata-capital/pdf/media-center/press-release/2025/press-release-akc-tchf.pdf
[94] https://www.expresspharma.in/cohance-lifesciences-suven-pharmaceuticals-merger-sanctioned-by-the-nclt/
[95] https://www.reuters.com/business/healthcare-pharmaceuticals/indias-syngene-international-acquires-first-us-biologics-facility-50-mln-2025-03-10/

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