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synapse

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.

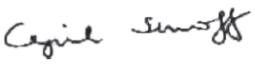
This quarter also saw several significant developments on the transactions and investments front, reflecting the evolving dynamics of the healthcare and life-sciences sector. We have captured some of the key updates in this edition of *Synapse*.

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=
[9] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI2MTI=
[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=

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