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

Volume VII | Issue II | January - March 2024

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Dear Readers,

India is reaffirming its commitment to ensuring health and wellness for its citizens through groundbreaking investments and visionary policies. As the country sets its sights on achieving a monumental Rs. 5 trillion-dollar economy, the spotlight illuminates the transformative potential of the pharmaceutical, life sciences, and healthcare sectors as key drivers of national growth. India has reached significant milestones in healthcare, because of a concerted focus on developing infrastructure, enhancing access to quality care, and implementing transformative initiatives – all backed by substantial investments. The Government's Interim Budget 2024–25 further amplifies this dedication, with an impressive allocation of INR 90,171 crore for health, aimed at fortifying healthcare services and infrastructure across the nation. Join us as we journey through the latest regulatory updates, news highlights, litigation insights, and transaction developments shaping the future of healthcare delivery in India in our comprehensive newsletter.

As in the previous few quarters, the sector witnessed important regulatory and news updates even in the January–March 2024 quarter, which we have covered in this edition of Synapse. Most importantly, this quarter saw the introduction of an updated version of the Uniform Code of Pharmaceutical Marketing Practices (**UCPMP**) to mitigate unethical practices and ensure transparency, integrity, and accountability in the marketing of pharmaceutical and medical device products. With the aim of alleviating the challenges faced by married couples seeking parenthood while grappling with pre-existing medical conditions, the Central Government has revised the Surrogacy (Regulation) Rules, 2022, to permit such couples to utilize donor eggs or sperm. Additionally, the Government has provided clarification stipulating that single women, whether widowed or divorced, engaging in surrogacy, are mandated to use their own eggs in conjunction with donor sperm. In addition, this quarter also saw the notification of amendments in Jan Vishwas (Amendment of Provisions) Act, 2023, to provisions of Drugs and Cosmetics Act, 1940, which entail the removal of severe penalties, such as imprisonment. Some offences, such as the manufacturing of drugs in violation of the provisions outlined in Section 27, which are not adulterated or spurious, have been made compoundable.

In the litigation space, the Supreme Court directed the Central Government to present a concrete proposal for fixing rates for medical procedures and services. The Apex Court, while issuing this directive to the Central Government, reiterated that the State has a duty to provide medical assistance to its citizens. In another case concerning the recognition of offenses based on a complaint by a police officer under the Drugs and Cosmetics Act, the Apex Court clarified that within the

framework of such legislation, the authority to take cognizance rests with a drug inspector rather than a police officer. As a result, the Court quashed the proceedings initiated against the aggrieved party following such an unlawful action. In another instance, the High Court of Delhi granted the Central Government a four-month period to formulate its policy regulating the online sale of drugs in India. The High Court, in its order, reprimanded the Central Government by observing that more than five years had passed since the institution of the matter, and the Government had ample time to draft this policy.

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

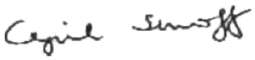
Cyril Amarchand Mangaldas, India's premier full-service law firm, has an industry leading and dedicated to pharmaceuticals, healthcare, and life sciences practice. Our class-leading practice specialists are always on top of the latest developments in the sector. In our endeavour to keep you abreast with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

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

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

Regards,

CYRIL SHROFF



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Regulatory Updates

1. Introduction of Uniform Code for Pharmaceutical Marketing Practices, 2024[1]

The Department of Pharmaceuticals under Ministry of Chemical and Fertilisers (**MoCF**), vide letter F. No. 31026/23/2022-Policy dated March 12, 2024, issued the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) 2024 (**UCPMP 2024**), an updated version of the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) 2014. The UCPMP 2024 will help mitigate unethical practices and ensure transparency, integrity, and accountability in the marketing of pharmaceutical and medical device products. Pharmaceutical associations, which has pharmaceuticals and medical devices companies as members, are expected to distribute the new code. These associations will oversee the implementation of the UCPMP through a committee, namely Ethics Committee for Pharmaceutical Marketing Practices (ECPMP).

We have addressed some concerns and questions with respect to the applicability of UCPMP 2024 on the industry in our *Client Alert dated March 21, 2024*.

2. Notification on inclusion of texts on Homoeopathic System and Sowa-Rigpa System under the Drugs and Cosmetics Act, 1940[2]

The Ministry of Ayush, *vide* S.O. No. 155(E) dated January 11, 2024, released the draft amendment to further amend the Drugs and Cosmetics Act, 1940 (**Drugs Act**), specifically the First and Second Schedule of the Drugs Act. While the First Schedule will add books on Homoeopathic System and Sowa-Rigpa System, the Second Schedule, in item number 4A, under "Class of Drug", will include French Homoeopathic Pharmacopoeia and the European Pharmacopeia after German Homoeopathic Pharmacopoeia. The intent behind publishing the draft amendment is to seek comments from the public.

3. Notification on Surrogacy (Regulation) Amendment Rules, 2024[3]

The Ministry of Health and Family Welfare (**MoHFW**), *vide* notification G.S.R. 119(E) dated February 21, 2024, substituted paragraph 1 (d) in Form 2 of Surrogacy (Regulation) Rules, 2022. This amendment will allow donor gametes if the District Medical Board certifies that either of the intending couple suffers from a medical condition. However, it is necessary that for the embryo to have at least one gamete from the intending couple. No changes were made to the provision regarding surrogacy of single woman, i.e., she must use self-eggs and donor sperm to avail the surrogacy procedure.

4. Notification on amendments in Jan Vishwas (Amendment of Provisions) Act, 2023, to provisions of Drugs Act[4]

The MoHFW, *vide* S.O. 1577(E) dated March 28, 2024, notified that the amendments related to Jan Vishwas (Amendment of Provisions) Act, 2023, on the Drugs Act shall come into force from December 31, 2024. These amendments will remove severe penalties, such as imprisonment, from certain provisions of the Drugs Act. Some offences, such as the manufacturing of drugs in violation of the provisions outlined in Section 27, which are not adulterated or spurious, will now become compoundable. Additionally, the maximum penalty for the use of Government analysts' reports for advertisement purposes under Section 29 is now INR 1 lakh. Subsequent offenses under Section 29 will now incur a minimum penalty of INR 5 lakh.

5. Notification on Drugs (Second Amendment) Rules, 2024[5]

The MoHFW, vide notification G.S.R. 216(E), has amended the "Schedule P1" of Drugs Rules with regard to the pack-size requirements pertaining to the formulations of the chest pain drugs, glyceryl trinitrate and isosorbide dinitrate. This will help patients adhere to the recommended dose duration of therapy. The amendment also modifies Rule 105 of the Drugs Rules to alter the pack-size requirements of pharmaceuticals not listed in Schedule P1, so that the number of capsules is in multiples of five or seven in pack sizes exceeding ten tablets or capsules. Earlier, the number of capsules could only be in multiple of five.

1 https://pharmaceuticals.gov.in/sites/default/files/UCPMP%202024%20for%20website_0.pdf
2 https://egazette.gov.in/WriteReadData/2024/251311.pdf
3 https://egazette.gov.in/WriteReadData/2024/252270.pdf
4 https://egazette.gov.in/WriteReadData/2024/253435.pdf
5 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTEwMTE=

6. Notification of National Nursing and Midwifery Commission Rules, 2024[6]

TThe MoHFW, *vide* notification G.S.R. 187 (E) dated March 13, 2024, notified the National Nursing and Midwifery Commission Rules, 2024, outlining the qualifications and experience required for nursing and midwifery leaders. These include a postgraduate degree in any discipline of nursing and midwifery education from a recognised university, registration with the National Register or State Register, and at least 15 (fifteen) years' experience, including 4 (four) years in an administrative position in the field of nursing and midwifery at a recognised institution or university. These rules aim to regulate and advance nursing and midwifery education in the country.

7. Notification of National Dental Commission Rules, 2024[7]

The MoHFW, *vide* notification G.S.R. 189(E) dated March 13, 2024, notified the National Dental Commission Rules, 2024. A significant provision includes facilitating the nomination of members from states or union territories without Government Dental Colleges to the Dental Advisory Council. Individuals with post-graduate degrees in dental sciences, registration with the National or State Register, and at least 15 (fifteen) years' experience in the field will be eligible for appointment to the council. The rules aim to reform dental education and regulation as well as promote dental healthcare across the country.

8. MoCF's Introduction of Revised Guidelines for the Scheme for "Strengthening of Pharmaceuticals Industry"[8]

The Department of Pharmaceuticals under MoCF, *vide* letter No. G-30015/25/2021-Scheme dated March 14, 2024, issued the Revised Guidelines for the Scheme for Strengthening of Pharmaceuticals Industry (**SPI**). The aim is to consolidate three existing schemes – Assistance to Pharmaceutical Industry for Common Facilities (APICF), Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS), and Pharmaceutical Promotion and Development Scheme (PPDS) to enhance India's pharmaceutical sector by supporting infrastructure, upgrading production facilities, and promoting knowledge-sharing initiatives for global competitiveness and sustainable growth. These guidelines also lists the member composition and functions outline of the Scheme Steering Committee (SSC), which includes overseeing the implementation, evaluation, monitoring, decision-making regarding the scheme, and ensuring meetings at least once every three months.

9. Indian Council of Medical Research (ICMR) Updates:

a. *Guidelines on Ethical Requirements for Laboratory Validation Testing*[9]

The ICMR, *vide* the document "Guidance on Ethical Requirements for Laboratory Validation Testing", published comprehensive guidelines on the ethical requirements for laboratory validation testing to maintain standards of ethics in medical research. The guidelines emphasise the importance of ethical considerations when using biological samples such as DNA, blood, urine, tissue, cells, and saliva. These highlight requiring administrative approval before conducting the validation tests that are necessary to ensure the accuracy and reliability of test data and results. The guidelines also cover various aspects of laboratory validation testing, including reproducibility, sensitivity, specificity, accuracy, dependability, and quality control/assurance using different types of samples.

b. *Guidelines for National Health Research Priority Projects*[10]

The ICMR, *vide* OM No. 16/01/2024-Admn. / E.office No. 175200 dated January 11, 2024, issued the "Guidelines for National Health Research Priority Projects" to focus on different projects for various health issues – from communicable diseases to ailments related to reproductive health and nutrition. Depending on requirements, these projects would be open on an EoI basis for participation by ICMR and non-ICMR Indian scientists.

6 https://egazette.gov.in/WriteReadData/2024/252966.pdf
7 https://egazette.gov.in/WriteReadData/2024/252968.pdf
8 https://pharmaceuticals.gov.in/sites/default/files/Revised%20guidelines%20SPI%20dated%2014.03.2024_0.pdf
9 https://main.icmr.nic.in/sites/default/files/upload_documents/Guidance_on_Ethical_Requirements_for_Laboratory_Validation_Testing.pdf
10 https://main.icmr.nic.in/sites/default/files/upload_documents/Final_Rev_Guidelines_NHRP0301204.pdf

10. Central Drugs Standards Control Organisation (CDSCO) Updates:

a. *Circular to establish portal mandating online safety reporting for Medical devices /In-vitro Devices*[11]

The CDSCO, *vide* circular F. No. PSUR-13011(15)/1/2024-eoffice dated March 19, 2024, to enable online submission of Periodic Safety Update Reports (**PSURs**) for Medical Devices / In-vitro Devices' Marketing Authorisation (**MA**) via the Online System for Medical Devices portal accessible at https://www.cdscomdonline.gov.in/ to enhance the efficiency of the regulatory submission process. All individuals are now required to submit PSURs by using the Online System for Medical Devices and adhere to the checklist provided on the portal. As of April 1, 2024, the offline submission option – hard copy or any other format – is no longer available.

b. *Circular on Regulatory Guidelines for Sampling of Drugs, Cosmetics & Medical Devices by Drugs Inspectors of Central & State Drug Authorities*[12]

The CDSCO, *vide* circular e-F. No. Enforc-11021(11)/16/2024-eoffice dated February 9, 2024, released the Regulatory Guidelines for the sampling of Drugs, Cosmetics & Medical Devices by Drugs Inspectors of Central & State Drug Authorities to streamline the process of sampling of drugs, cosmetics, and medical devices and maintaining a centralised monthly database of "Not of Standard Quality" and "Spurious" drugs.

c. *Draft Guidance for Post Approval Changes in Biological Products: Quality Safety and Efficacy Documents for soliciting comments and suggestions*[13]

The CDSCO, vide notice F. No. VAC-16011(11)/9/2024-eoffice dated February 28, 2024, released the draft guidance "Post Approval Changes in Biological Products: Quality Safety and Efficacy Documents" to align the standards with the international guidelines of World Health Organisation (**WHO**) and the current international practices of various regulatory agencies. The guidance aims to provide information on the quality, safety, and efficacy changes to biological products. It emphasises quality, safety, and efficacy assessments of biological products using a science- and risk-based approach. CDSCO also had a 45-day deadline for stakeholders to make their comments, suggestions, and objections to the draft guidance.

d. *Online application for Neutral Code for manufacturing of Medical Devices for export purpose*[14]

The CDSCO, *vide* notice F. No. MED-13011(15)/3/2024-eoffice dated February 11, 2024, mandating the

[11] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTEwMTI=
[12] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTA5MzU=
[13] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTA5NTM=
[14] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTA5Mjk=

submission of applications for the Neutral Code for manufacturing medical devices for export only through the Online System of Medical Devices portal (https://cdscomdonline.gov.in/) in an effort to streamline the regulatory submission procedure. The Central Licensing Authority under Medical Devices Rules, 2017 ("**MDR**") will issue the Neutral Code.

11. Drugs pricing and price control: Notifications/ orders/ circulars by the National Pharmaceutical Pricing Authority ("NPPA") and other price-control-related measures

a. *Advisory order to fix retail prices of 65 formulations and ceiling prices of 923 formulations approved in 122nd Authority meeting*[15]

The NPPA, *vide* orders S.O. 1547(E) to 1559 (E) dated March 26, 2024, fixed the retail price of 65 (sixty-five) formulations (includes mefenamic acid and paracetamol tablets, and pantoprazole and domperidone tablets) and revised and fixed the ceiling prices of 923 (nine-hundred twenty five) formulations (includes amoxicillin, diclofenac, caffeine, and hepatitis B vaccine).

b. *Advisory order on fixing retail prices of 69 formulations and ceiling prices of 31 formulations approved in 121st Authority meeting*[16][17][18]

The NPPA, *vide* orders S.O. 937(E), S.O. 938(E), and S.O. 939(E) dated February 28, 2024, fixed the retail price of 69 (sixty-nine) formulations (includes tranexamic tablets, and calcium & vitamins tablets); the ceiling prices of 25 (twenty-five) formulations (includes zidovudine, and folic acid); and the ceiling prices of 6 (six) formulations (includes darunavir (a) +ritonavir (b) and nicotine).

c. *Advisory order on fixing retail price of 39 formulations and 4 special feature products approved in 120th Authority meeting*[19]

The NPPA, *vide* order S.O. 423(E) dated February 2, 2024, fixed the retail price of 39 (thirty-nine) formulations and 4 (four) special feature products including paracetamol and dicyclomine hydrochloride tablets, albendazole & ivermectin suspension, and amoxycillin and potassium clavulanate tablets IP.

d. *Advisory order on fixing of ceiling prices of 19 formulations and certain other formulations*[20]

The NPPA, *vide* order S.O. 15(E) dated January 1, 2024, fixed the ceiling price of 19 (nineteen) formulations, including bisoprolol fumarate & amlodipine tablets, povidone iodine gargle, bilastine and montelukast tablets, and 16 (sixteen) other formulations.

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

a. *Advisory order on time-bound processing of applications for licenses marked for inspections*[21]

The FSSAI, vide order No. RCD-11004/1/2020-Regulatory-FSSAI dated February 21, 2024, directed that all designated officers avoid unnecessarily delaying the processing of applications and consequently delaying the grant of licences. The advisory ordered that all Licensing Authorities strictly adhere to the timelines as prescribed under Clause 2.1.4 of FSS (Licensing and Registration of Food Business) Regulations, 2011, and orders issued by the FSSAI.

b. *Advisory order on appropriate endorsement of Kind of Businesses (KoBs) by flight kitchens and in-flight catering services, and labelling requirements for prepared food being served in flights/trains and other moving vehicles – reg.*[22]

The FSSAI, vide order No. RCD-15001/11/2023-Regulatory-FSSAI dated March 7, 2024, acknowledging concerns regarding discrepancies in the endorsement of KOBs by Flight Kitchens Operators and In-Flight Catering Services, directed that they fix such discrepant endorsements in their FSSAI licenses. The advisory also directed them to comply with the regulatory requirements of the FSS Act, 2006, and follow labelling norms for prepared foods as specified under FSS (Labelling & Display Regulations), 2020.

[15] https://www.nppaindia.nic.in/wp-content/uploads/2024/03/253444.pdf
[16] https://www.nppaindia.nic.in/wp-content/uploads/2024/02/Retail-69.pdf
[17] https://www.nppaindia.nic.in/wp-content/uploads/2024/02/CP-Revised-25.pdf
[18] https://www.nppaindia.nic.in/wp-content/uploads/2024/02/CP-New-6.pdf
[19] https://www.nppaindia.nic.in/wp-content/uploads/2024/02/Retail-Engl-Hindi.pdf
[20] https://egazette.gov.in/(S(jjdxhanhzrabjhbuemgtfpip))/ViewPDF.aspx
[21] https://fssai.gov.in/upload/advisories/2024/02/65d88929a6c29Advisory_isnpection_dated%2023%20feb%202024.pdf
[22] https://fssai.gov.in/upload/advisories/2024/03/65ea9e52c6399Advisory-%20Airlines%20&%20Caterers.pdf

News Updates

1. 2024 Interim Budget: Highlights for the Pharmaceuticals Sector[23]

The 2024–25 Interim Budget presented significant updates in the pharmaceuticals sector, including using current hospital infrastructure to establish additional medical colleges. It extended coverage for healthcare under the Ayushman Bharat insurance scheme to all ASHA and Anganwadi workers and helpers. The Government will encourage vaccinations against cervical cancer for girls aged between 9 and 14 years. Swift nationwide implementation is planned for the U-WIN platform, which was established recently to oversee vaccination programs and promote Mission Indradhanush initiatives. Child and maternal care programs will be merged into a holistic scheme to ensure coordinated execution. Improvements under Poshan 2.0 and Saksham Anganwadi will enhance nutrition delivery, early childhood care, and development. A bio-manufacturing and bio-foundry plan will also be introduced to provide eco-friendly alternatives (e.g., bio-degradable polymers, bio-plastics, bio-pharmaceuticals, and bio-agri inputs).

2. 2024 Interim Budget: Highlights for the Food Industry[24]

The 2024-25 Interim Budget updates for the food industry include the establishment of INR 1 lakh crore fund and a 50 (fifty) year interest-free loan, to help catalyse private-sector research and innovation in emerging sectors. The threshold for presumptive taxation applicable to retail businesses will also be elevated. A new initiative introduced for bio-manufacturing and bio-foundry is expected to promote environmentally sustainable growth. A comprehensive strategy to support dairy farmers has also been planned. The Pradhan Mantri Matsya Sampada Yojana (**PMMSY**) also plans to construct five integrated aquaparks to intensify the implementation efforts to bolster aquaculture production, triple exports, and generate employment opportunities.

3. Launch of National Single Window System (NSWS) for CDSCO[25]

The Government launched the NSWS to establish a unified platform for CDSCO to serve as a comprehensive and one-stop solution for obtaining approvals, licenses, registrations, and clearances. The portal offers an innovative approach to business approvals and is aimed at fostering economic growth, simplifying procedures, and enhancing transparency. While the user-friendly digital interface will streamline the approval process for investors and entrepreneurs, the increased efficiency, reduced administrative burdens, and improved revenue collection

[23] https://www.healthcareradius.in/government-policy/budget-2024-25-at-a-glance-for-indias-healthcare-sector#:~:text=Total%20Healthcare%20Expenditure%3A%20Total%20expenditure,4%2C108%20crore%20in%202024%2D25.
[24] https://www.investindia.gov.in/team-india-blogs/agro-food-cluster-interim-budget-highlights-2024-25
[25] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTA4MTE=

will benefit the Government. The NSWS portal is independent of the SUGAM portal.

4. Drugs Technical Advisory Board (DTAB) recommends drug labels for hypersensitivity-causing excipients[26]

The DTAB directed the CDSCO to compile a comprehensive list of hypersensitivity-triggering excipients to ensure prominent display on medication labels, thereby enhancing transparency in pharmaceutical products. The medication labels, however, do not need to include excipients other than those that cause hypersensitivity. Manufacturers are currently not legally obligated to provide information about excipients on medication labels.

5. DTAB recommends bar codes on all vaccine products[27]

The DTAB recommended affixing barcodes or quick response (**QR**) codes on vaccines with an aim to meet the maturity levels specified by the WHO Global Benchmarking Tool (**GBT**). It also suggested the gradual extension of the tracking mechanism to all antimicrobials and narcotic and psychotropic substances. This recommendation aligns with India's preparations for the WHO benchmarking process involving the assessment of the National Regulatory Authority (**NRA**) by a WHO team using GBT. This evaluation encompasses various regulatory functions at relevant institutions in India, with the CDSCO acting as the NRA.

6. DTAB urges Drugs Consultative Committee (DCC) to establish a single licensing and approval authority[28]

The DTAB suggested that the DCC gather States' inputs in upcoming meetings and work towards establishing a single, nationwide licensing and approval authority. In a recent hybrid meeting, the DTAB discussed various regulatory enhancements for medication safety and patient rights, including uniform brand names, self-medication, and e-pharmacy regulation. This proposal followed past discussions on centralised drug regulation, which were prompted by incidents of Indian-made medicines causing adverse effects abroad.

7. Good Distribution Practices soon for pharmaceutical products[29]

The DCC recommended enforcing swiftly the draft of revised Good Distribution Practices rules for pharmaceutical products as mandatory after it noted a legal loophole in drug-storage requirements, which were affecting the quality of pharmaceuticals. While owners of drug-related facilities (e.g., warehouses) have been obligated to uphold appropriate storage conditions for their products, drug transporters are under no such obligation.

8. Parliamentary Panel identifies key issues inhibiting medical devices industry growth[30]

The Standing Committee on Chemicals and Fertilisers, chaired by Dr. Shashi Tharoor, released its report "Promotion of Medical Device Industry" on February 8, 2024, highlighting several key observations and recommendations on the growth constraints of the medical devices industry. India currently focuses only on manufacturing low to moderate-end medical devices domestically but imports high-end devices, which comprise 70 per cent of the market. Some factors hindering growth in the sector include inadequate investment in research & development, limited tax concessions, an inverted duty structure disadvantaging domestic manufacturers, insufficient capital investment, a shortage of skilled personnel, limited price & quality regulation, and a scarcity of trained healthcare professionals. No tangible outcomes despite several Department of Pharmaceuticals (**DoP**) initiatives since 2015 have made it imperative to address these challenges and take further action to promote the growth of this industry.

9. Parliamentary Panel flags concerns on regulation of second-hand medical devices[31]

In a recent report, the Department-related Parliamentary Standing Committee on Chemicals and Fertilisers underscored that second-hand medical equipment goes beyond the MDR's scope of regulation. Pointing out CDSCO's failure to assess the potential adverse effects of such used devices on public health or to enforce requisite safety standards, the Committee advised establishing regulatory

[26] https://pharmabiz.com/NewsDetails.aspx?aid=168193&sid=1
[27] https://www.pharmabiz.com/ArticleDetails.aspx?aid=166877&sid=1
[28] https://www.pharmabiz.com/ArticleDetails.aspx?aid=166900&sid=1
[29] https://pharmabiz.com/NewsDetails.aspx?aid=168133&sid=1
[30] https://prsindia.org/policy/report-summaries/promotion-of-medical-device-industry
[31] https://prsindia.org/files/policy/policy_committee_reports/Promotion_of_Medical_Device_Industry.pdf

frameworks to ensure the efficacy, safety, and quality of imported second-hand medical devices. Furthermore, it also recommended imposing limitations on specific imports to safeguard the interests of domestic manufacturers.

10. Parliamentary panel recommends inclusion of more medical devices into NLEM[32]

The Parliamentary Panel, currently investigating the growth of the medical devices industry in the country, has advised the DoP to include medium and high-end medical devices used for critical care in the National List of Essential Medicines (**NLEM**). This recommendation is in the public interest and aims to enhance access to essential medical devices. Currently, the NLEM only includes 4 (four) medical devices – cardiac stents, drug-eluting stents, condoms, and intrauterine devices.

11. Period between April to December 2023 witnesses 90% FDI inflow growth into hospitals and diagnostic centres[33]

The hospitals and diagnostic centres sector in India witnessed a growth of approximately 90% (ninety per cent) in terms of the Foreign Direct Investment (**FDI**) equity inflow during the first 9 (nine) months of the current fiscal year. It is interesting to note that hospitals and diagnostic centres have attracted a foreign equity fund infusion of USD 1.08 billion during the period between April and December, 2023 when compared to the foreign equity fund infusion of USD 570.5 million during the same period of the previous year. Further, the medical and surgical appliances sector grew approximately 30 per cent during the period between April and December, 2023, to USD 462.4 million as compared to USD 35.63 million during the same period of last fiscal year.

12. DoP overhauls the Pharmaceutical Technology Upgradation Assistance Scheme[34]

The DoP revamped the Pharmaceutical Technology Upgradation Assistance Scheme (**PTUAS**) sub-scheme to introduce reimbursement subsidies ranging from 10 to 20 per cent for Micro, Small, and Medium Enterprises (**MSME**) manufacturers. The PTUAS was launched to provide financial support of up to INR 1 crore to pharma MSMEs aiming to upgrade their manufacturing facilities to meet WHO-GMP standards or Schedule M standards. These new subsidies are expected to facilitate quality enhancement, compliance with the revised Schedule M, and attainment of WHO's Good Manufacturing Practice (GMP) certifications. The approval aligns with the updated Schedule-M of the Drugs Rules. The revision eliminates the previous guidelines' penalty clause and requirement of the presence of a bank guarantee.

[32] https://sansad.in/getFile/lsscommittee/Chemicals%20&%20Fertilizers/17_Chemicals_And_Fertilizers_50.pdf?source=loksabhadocs
[33] https://www.pharmabiz.com/NewsDetails.aspx?aid=168557&sid=1
[34] https://www.expresspharma.in/dop-amends-ptuas-expands-eligibility-criteria-to-include-msmes/

13. AYUSH-ICMR Advanced Centre for Integrative Health Research to develop integrated traditional-modern medicine healthcare system[35]

The Centre announced the establishment of AYUSH-ICMR Advanced Centre for Integrative Health Research (**AI-ACIHR**) to pioneer integrative health research by merging AYUSH practices and conventional bio-medicine and modern technology. This initiative seeks to deliver integrative healthcare solutions and enhance patient outcomes through innovative approaches in diagnostics, preventive measures, health promotion, and treatment methods. It also mandated the deployment of AI-ACIHR at select All India Institutes of Medical Sciences (**AIIMS**); namely AIIMS Delhi, Nagpur, Jodhpur, and Rishikesh. AIIMS Jodhpur and Rishikesh will specialise in Geriatric Health under AI-ACIHR, while AIIMS Nagpur will focus on Cancer Care. AIIMS Delhi will work on Gastrointestinal Disorders and Women & Child Health.

14. FSSAI directs airline caterers to comply with food safety regulations[36]

On January 16, 2024, the FSSAI convened a meeting with leading flight caterers and airlines to enhance food safety protocols. The discussion focused on urging compliance with the stipulations outlined in sub-regulations 5(10)(f) and 8(4) of the FSS (Labelling and Display) Regulations, 2020. The CEO of FSSAI underscored the need for comprehensive labelling practices to furnish passengers with detailed information regarding in-flight meals. The initiative aims to address concerns regarding the absence of readily accessible information for passengers and ensure the delivery of safe and high-quality in-flight food services.

15. FSSAI certifies 500 Hospitals as "Eat Right Campuses"[37]

As an integral part of the "Eat Right India" campaign, FSSAI endorsed more than 500 hospitals across the nation as "Eat Right Campuses" to prioritise the establishment of secure, nourishing, and sustainable food environments across a variety of workplaces and institutions, notably hospitals. This marks a significant paradigm shift within the healthcare sector and highlights the significance of medical care and the crucial role that healthy eating choices play in enhancing the well-being of both staff and visitors.

16. FSSAI does away with BIS and AGMARK certification for food products[38]

In a move to streamline the certification process, rationalise bureaucratic procedures, and facilitate compliance within the food industry, the FSSAI, in its 43rd meeting, nullified the need for Food Business Operators (**FBOs**) to secure separate certifications from the Bureau of Indian Standards (**BIS**) or the Agricultural and Processed Food Products Export Development Authority (**AGMARK**) alongside their FSSAI license. Going forward, FBOs, irrespective of their scale, will only need the FSSAI certification. Centralising certification under FSSAI will enhance clarity and standardisation in food safety regulations.

17. IPC releases draft Pharmacovigilance Guidance Document for Pharmaceutical Products[39]

The Indian Pharmacopoeia Commission (**IPC**), in its efforts to enhance pharmacovigilance standards and ensure robust drug safety and regulation in the pharmaceutical sector, released the Draft Pharmacovigilance Guidance Document 2.0 in alignment with the Drugs Act and Drugs Rules objectives and included the New Drugs and Clinical Trials Rules, 2019 (**NDCT Rules**). The guidance document aims to streamline the submission of the safety profiles of drugs by Marketing Authorisation Holders (**MAHs**) who manufacture, sell, import, and distribute pharmaceutical products in India. The guidance document is presently open for comments and suggestions from MAHs.

18. Essential medicines prices marginally increased from April 1, 2024[40]

The prices of essential medicines (e.g., painkillers, antibiotics, and anti-infectives) will rise marginally from April 1, 2024. NPPA declared an annual increase of 0.0055 per cent for drugs listed under the NLEM, aligning with the annual change in the Wholesale Price Index (**WPI**). In the previous year - 2022, the WPI change had exceeded 10 per cent, but as this year - 2023's movement is considerably lower, resulting in only a marginal increase in scheduled formulation prices.

[35] https://www.medicalbuyer.co.in/centre-launches-ai-acihr-in-aiims/
[36] https://business.outlookindia.com/news/fssai-directs-airline-caterers-to-comply-with-food-safety-rules
[37] https://health.economictimes.indiatimes.com/news/industry/fssai-certifies-500-hospitals-across-the-nation-as-eat-right-campus/107756970
[38] https://www.business-standard.com/india-news/only-fssai-certification-would-be-mandatory-for-food-products-124020501517_1.html
[39] https://www.indiapharmaoutlook.com/news/ipc-s-new-draft-advancing-pharmacovigila nce-in-pharmaceuticals-nwid-2032.html
[40] https://www.hindustantimes.com/business/from-antibiotics-to-painkillers-these-medicines-will-get-expensive-from-today-check-complete-list-here-101711957062290.html

19. CDSCO nod to AstraZeneca India for Trastuzumab deruxtecan import and distribution[41]

AstraZeneca Pharma India, a leading pharmaceutical company, received CDSCO's approval to import and distribute trastuzumab deruxtecan lyophilised powder for concentrate for solution for infusion (100mg). The approval was for two new indications: HER2-low metastatic breast cancer and locally advanced or metastatic gastric cancer. Trastuzumab deruxtecan is indicated for adult patients with unresectable or metastatic HER2-low breast cancer who have had undergone prior chemotherapy in the metastatic setting or experienced disease recurrence within 6 (six) months of completing adjuvant chemotherapy.

20. Cipla partners with CSIR-CDRI to develop formulation for fungal keratitis[42]

Cipla has partnered with the CSIR-Central Drug Research Institute (**CSIR-CDRI**) to develop a novel ophthalmic formulation for fungal keratitis. This collaboration was driven by the shared goal of joining forces to create a safe and effective drug for treating fungal keratitis. Agricultural workers, frequently exposed to fungal pathogens from organic materials, are particularly vulnerable to this condition, especially in the aftermath of ocular trauma.

21. AI lab for precision medicine opened by IISc Bangalore and Siemens Healthineers[43]

Siemens Healthineers and the Indian Institute of Science, Bangalore (**IISc**) have jointly unveiled the Siemens Healthineers-Computational Data Sciences Collaborative Laboratory for Artificial Intelligence (**AI**) in Precision Medicine at IISc to revolutionise neurology research through the development of open-source AI-based tools. These tools will automate the meticulous segmentation of pathological findings in neuroimaging data and emphasise on precise diagnosis of neurological diseases and the comprehensive, population-level analysis of their clinical implications.

22. Dr Reddy's–Pharmazz licensing pact to market novel therapy Centhaquine in India[44]

US-based biopharmaceutical company, Pharmazz entered into a license agreement with Dr. Reddy's Laboratories to commercialise its first-in-class innovative drug Centhaquine in India. Developed for potential global use, Centhaquine serves as a resuscitative agent indicated specifically for treating hypovolemic shock. This critical emergency condition characterised by severe blood or fluid loss renders the heart incapable of pumping sufficient blood to the body, causing multiple organs to stop functioning. The DCGI has approved Centhaquine for use in India following a successful phase III clinical trial.

23. Local glove makers call for stricter rules to check dumpin[45]

Domestic glove manufacturers demanded more stringent regulations to counter the surge of low-quality bulk-packaged medical gloves imported and dumped in India. Nitrile gloves have inundated the market, presenting a hurdle for domestic producers. The Indian glove market witnessed growth during the COVID-19 pandemic but is struggling to preserve the stringent quality standards, which are essential to ensure that India-manufactured gloves adhere to BIS specifications.

[41] https://www.thehindu.com/business/astrazeneca-pharma-gets-cdsco-nod-for-trastuzumab-deruxtecan-use-for-2-more-indications/article68006642.ece#:~:text=AstraZeneca%20Pharma%20India%20has%20received,Enhertu)%20for%20two%20additional%20indications
[42] https://www.cipla.com/sites/default/files/Press-Release-Cipla-partners-with-CSIR-CDRI-to-advance-Ophthalmic-Antifungal-Treatment-Development.pdf
[43] https://www.ibef.org/news/siemens-healthineers-iisc-opens-ai-lab-for-precision-medicine
[44] https://www.business-standard.com/markets/capital-market-news/dr-reddy-s-lab-enters-into-marketing-licensing-agreement-with-pharmazz-for-centhaquine-124032600301_1.html
[45] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/local-glove-makers-call-for-stricter-rules-to-check-dumping/articleshow/107271516.cms

Litigation Updates

1. Supreme Court directs Government to present a concrete proposal for fixing rates for medical procedures and services[46]

The Supreme Court (**SC**), in W.P. (C) No. 648 of 2020, *vide* order dated February 27, 2024, has directed the Central Government present a concrete proposal, in consultation with State Governments/Union Territories, to fixing rates for medical procedures and services within six weeks. The order was passed following a writ petition preferred by the Veterans Forum for Transparency in Public Life, which had sought issuance of writ of mandamus and a consequent direction be issued to Union of India (Respondent) to determine the rate of fee chargeable from the patients in terms of Rule 9 of the Clinical Establishments (Central Government) Rules, 2012 (**CE Rules**).

The crux is the interpretation of Rule 9(ii) of the CE Rules, which stipulates that clinical establishments *"shall charge the rates for each type of procedures and services within the range of rates determined and issued by the Central Government from time to time, in consultation with the State Governments"*. The CE Rules have been promulgated and notified under the aegis of the Clinical Establishments (Registration and Regulation) Act, 2010 (**CE Act**)[47]. The SC will consider issuing appropriate directives, including adoption of CGHS rates as an interim measure, is the Central Government fails to present the proposal within the stipulated duration. While issuing these directives to the Central Government, the Court reiterated that the State has a duty to provide medical assistance to its citizens.

2. SC holds Medical Council report as not determinative to establish Medical Negligence[48]

The SC, in Special Leave Petition (Civil) No. 17347 of 2018, dated February 22, 2024, set aside the orders of National Consumer Disputes Redressal Commission (**NCDRC**) and State Consumer Disputes Redressal Commission (**SCDRC**) by affirming the District Consumer Disputes Redressal Commission (**DCDRC**) order in a case involving medical negligence. The matter arose from an appeal filed by the father of a 13 (thirteen)-year-old boy (**Appellant**) who lost his eyesight because of a negligent cataract operation performed by the doctor (**Respondent No. 1**). The DCDRC allowed the Appellant's initial complaint under Section 12 of the Consumer Protection Act, 1986, but the SCDRC reversed it. Thereafter, the Appellant preferred a revision petition with the NCDRC, which too was dismissed. The Appellant

[46] Veterans Forum For Transparency In Public Life vs. Union of India, Order dated February 27, 2024 in W.P. (C) 648 of 2020.
[47] The CE Act governs the registration and regulation of clinical establishments in the country. The CE Act was enacted to prescribe minimum standards of facilities and services for improvement in public health.
[48] Najrul Seikh vs. Dr. Sumit Banerjee, Order dated February 22, 2024 in SLP (c) 17437 of 2018.

then preferred a Special Leave Petition (**SLP**) before the SC. The Apex Court allowed the appeal by upholding the DCDRC's order and held that the NCDRC and SCDRC had erred by solely relying on the Medical Council report, which had found the Respondent "not guilty".

The Apex Court ruled that while the Medical Council report could be relevant to determine deficiency of service before a consumer forum, it could not be determinative for "medical negligence", especially when it contradicts the consumer forum's evidentiary findings. In these circumstances, it is the appellate forum's duty to undertake a more thorough examination of the evidence on record. The SC noted that the DCDRC findings regarding the post-operative lapses in care remain unchallenged by other evidence on record. The Apex Court reiterated the established principle of law that in cases of deficiency of medical services, duty of care does not end with surgery. Accordingly, the Court upheld awarding the DCDRC's compensation order of INR 9 lakh to the Appellant.

3. SC directs leading Ayurvedic company's MD to appear in person over non-filing of reply to the contempt notice[49]

The SC, in W.P (C) No. 645 of 2022, dated March 19, 2024, expressed displeasure over Patanjali Ayurved Limited (**Patanjali**) not filing a reply to the contempt notice the Court had issued on February 27, 2024. The Petitioner, Indian Medical Association, had initiated a writ petition to counter the release of Patanjali's misleading advertisements for their products. The Petitioner highlighted instances where Baba Ramdev's endorsement of Patanjali's products had included controversial remarks, such as labelling allopathy as a "stupid and bankrupt science" and blaming allopathic medicines for deaths during the COVID-19 second wave without any tangible shred of evidence, and propagated vaccine hesitancy with unsubstantiated claims. The Petitioner argued that Patanjali had allegedly continued its disdain for the law and violated the ethics of advertisement, despite the Ministry of AYUSH Memorandum of Understanding (MoU) with the Advertising Standards Council of India (ASCI) for monitoring deceptive promotions of AYUSH drugs. On November 21, 2023, Patanjali's counsel had committed before the SC that the company would refrain from publishing such advertisements in the future, but the company continued with it advertising activities, prompting the Court to issue a contempt notice on February 27, 2024.

On March 19, 2024, the Court strongly rebuked Patanjali for failing to respond to the contempt notice and ordered Patanjali MD Acharya Balkrishna and Baba Ramdev to appear in person at the next hearing. Patanjali subsequently filed an affidavit the following day, tendering an unconditional apology. The Apex Court also impleaded the state licensing authority in the proceedings for neglecting its duties under the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.

4. SC allows cancellation of hospital registration under Pre-Conception and Pre-Natal Diagnostic Techniques Act, 1994 (PCPNDT Act), under public interest[50]

The SC, in its judgement dated March 4, 2024, passed in SLP (C) No. 17973 of 2015, held in favour of the hospital and dismissed the appropriate authority's appeal cancelling the registration of the hospital under the PCPNDT Act. The appropriate authority under the PCPNDT Act had suspended the license of a hospital at Ahmedabad following an inspection drive after finding some lapses against the provisions of PCPNDT Act. The authority decided to suspend the hospital's license without giving them an opportunity to be heard. The hospital then appealed before the High Court of Gujarat, which set aside the authority's order. Aggrieved, the appropriate authority preferred an appeal to the SC.

The SC, on dismissing the appeal, examined the law on Section 20(2) and 20(3) of the PCPNDT Act, where Section 20 provides for addressing cancellation or suspension of a registration. The SC noted that Section 20(2) requires giving the aggrieved party the opportunity of being heard. The Apex Court further clarified stating that if the appropriate authority deems it necessary or finds a breach of the provisions of the PCPNDT Act, it can suspend the hospital's registration, provided notice has been issued and the party facing allegations has been accorded reasonable opportunity of being heard.

[49] Indian Medical Association vs. Union of India, Order dated March 19, 2024 in W.P.(C) No. 645 of 2022.
[50] District Appropriate Authority vs. Jashmina Dilip Devda, Judgement dated March 4, 2024 in SLP (C) No. 17973 of 2015.
[51] 20. *Cancellation or suspension of registration.*—(1) The Appropriate Authority may suo motu , or on complaint, issue a notice to the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic to show cause why its registration should not be suspended or cancelled for the reasons mentioned in the notice.
(2) If, after giving a reasonable opportunity of being heard to the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic and having regard to the advice of the Advisory Committee, the Appropriate Authority is satisfied that there has been a breach of the provisions of this Act or the rules, it may, without prejudice to any criminal action that it may take against such Centre, Laboratory or Clinic, suspend its registration for such period as it may think fit or cancel its registration, as the case may be.
(3) Notwithstanding anything contained in sub-sections (1) and (2), if the Appropriate Authority is of the opinion that it is necessary or expedient so to do in the public interest, it may, for reasons to be recorded in writing, suspend the registration of any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic without issuing any such notice referred to in sub-section (1).

5. SC holds that cognizance of offence under Drugs Act taken on the complaint of a police officer is invalid[52]

The SC, in SLP (Criminal) No. 10373 of 2018, dated March 19, 2024, held that the Drugs Act scheme does not permit taking cognizance of offences on the basis of a complaint by a police officer. The Appellant was aggrieved by an order of dismissal by the Patna High Court, wherein the Appellant filed a Petition under Section 482 of the Code of Criminal Procedure, 1973, challenging the order of the Judicial Magistrate of First Class who took cognizance of certain offences under the Drugs Act. The SC, while setting aside the order, held that cognizance should not have been taken on the police officer's complaint. The Court further clarified that under the scheme of the Drugs Act a drug inspector is vested with such authority, not a police officer. Additionally, the Court also quashed the proceedings against the Appellant.

6. Delhi High Court grants Union last opportunity to frame policy on online sale of drugs[53]

The High Court of Delhi (**Delhi HC**), in W.P (C) No. 11711 of 2018, dated March 4, 2024, granted the Union of India a four-month period to formulate a policy on the online sale of drugs in India. During the recent hearing, a Joint Secretary from MoHFW appeared in court following the previous order dated November 16, 2023, in which the bench had noted that more than five years had passed since the institution of the matter and that the Union of India had ample time to draft the policy. The Joint Secretary requested for an additional four months to finalise the online drug sales policy based on the draft notification of August 28, 2018.

The case originates from a petition filed in 2018 seeking a ban on the online sale of drugs. The petition argues that the "illegal" online sale of medicines could lead to drug abuse and the misuse of habit-forming and addictive drugs. On December 12, 2018, the Delhi HC issued an injunction against the sale of online drugs without a license. The Madras High Court, in WP. No. 28716/2018 and WMP. No 33542/2018, dated October 31, 2018, had recognised the gravity of the issue and granted an interim injunction against the online sale of medicines without a license. The Delhi HC, in its March 4, 2024, order emphasised this as the final opportunity given to the MoHFW, and stated that it would proceed with the matter for non-compliance.

7. Delhi HC mandates registration with Delhi Medical Council for allopathy doctors practicing in Delhi[54]

The Delhi HC, in W.P. (C) 2635 of 2024, vide order dated February 22, 2024, upheld the Delhi Medical Council (**DMC**) notice December 24, 2023 (**Notice**), which mandates that doctors practicing modern scientific system of medicine (**Allopathy**) in Delhi should register with the DMC under the Delhi Medical Council Act, 1997 (**DMC Act**). The Petitioner had

[52] Rakesh Kumar vs. State of Bihar, Judgement dated March 19, 2024 in SLP (Criminal) No. 10373 of 2018.
[53] Zaheer Ahmed vs. Union of India, Order dated March 4, 2024 in W.P. (C) 11711 of 2018.
[54] Dr. Namit Gupta vs. Delhi Medical Council and Ors., Judgment dated February 22, 2024 in W.P. (C) 2635 of 2024.

preferred a Public Interest Litigation before the Delhi HC seeking to quash the DMC's Notice and challenged its mandatory nature. The Petitioner contended that the Notice issuance would result in multiplicity of registrations and an unwarranted hassle for doctors of other states intending to practice in Delhi. The DMC, instead, highlighted that the aim of the regulations was to oversee and regulate professional misconduct by allopathy practitioners in Delhi. The National Medical Commission (**NMC/Respondent No. 2**) argued that the Notice was in line with the regulations formulated under the National Medical Commission Act, 2019 (**NMC Act**).

Ruling in favor of the Respondents, the Delhi HC held that the impugned Notice issued under Section 15 of the DMC Act was *intra vires* and in consonance with the provisions of the NMC Act. Explaining that the law aimed to bring the practitioners under a regulatory framework based on their place of practice, the Court held that registration with DMC would help discipline the medical practitioners who have indulged in malpractice or unethical conduct.

8. Delhi HC takes *Suo Moto* cognizance of the poor condition of Delhi's state-run hospitals and sets up a committee to give recommendations[55]

The Delhi HC, in W.P.(C) 8548/2017, *vide* order dated February 13, 2024, took *suo moto* cognizance of the poor conditions of the Delhi's state-run hospitals and, among other things, the shortage of healthcare professionals in Delhi's hospitals. The Court noted the incident wherein a person, Pramod, was denied treatment by three Government hospitals (including one Central Government hospital) in Delhi citing non-availability ICU beds and CT scan machines, which resulted in his demise. Mr. Ashok Agarwal, learned Amicus Curiae appointed by the Delhi HC, apprised the Court that ICU beds were totally absent and the medical equipment were non-functional in nine Delhi state-run hospitals. He also emphasised that the Department of Radiology and Imaging of the Government of National Capital Territory of Delhi hospitals, were issuing appointments to the patients between May 2025 and March 2027, rendering access to medical care illusory.

After considering the inputs of the Court-appointed Amicus, the Delhi HC directed forming a committee to examine and suggest remedial actions to enhance both infrastructure and personnel in state-run hospitals. The Court reiterated the importance of providing quality medical services for the health and well-being of urban residents, underscoring the State's obligation under Articles 47 and 21 of the Constitution of India. The Court also stressed on the need for substantial investments and structural reforms in the operations of Government hospitals to address years of neglect and indifference towards patient welfare.

[55] Court on its Own Motion vs. Union of India and Others, Judgement dated February 13, 2024 in W.P.(C) 8548 of 2017 and CM Appl. 985 of 2024.

Transaction Updates

1. Eris acquires "branded formulations" business from Biocon Biologics[56]

Eris Lifesciences, a company focused on chronic therapy drugs, acquired Biocon Biologics' India-branded formulation business for INR 1,242 crore. This includes portfolios in insulin, oncology, and critical care. The collaboration aligns with Biocon Biologics' strategy to unlock value from its legacy branded formulations business. This deal grants Eris entry into the INR 30,000-crore injectable market, establishing a significant presence in insulin through the acquisition of "Basalog" and "Insugen" from Biocon Biologics. This acquisition also marks Eris's foray into the fields of oncology and critical care pharmaceuticals.

2. Eris acquires majority stake in Swiss Parenterals[57]

Eris Lifesciences announced its acquisition of a majority stake (51 per cent) in Swiss Parenterals Limited for a consideration of INR 637.5 crore. Swiss Parenterals, founded in 1997, is a prominent player in the sterile injectables sector across over 80 emerging markets spanning Africa, the Asia Pacific, and Latin America. It has two facilities in Gujarat, which are accredited by over 50 regulatory authorities worldwide. Eris, backed by ChrysCapital and Kuwait Investment Authority, will pay INR 200 crore at closing of acquisition, with the remainder due 12 months later. A statement released by Eris suggested that the deal is expected to close by March 31, 2024.

3. Max Healthcare acquires Nagpur-based Alexis hospital for INR 412 crore[58]

Max Healthcare, India's leading private healthcare provider, announced the acquisition of 100 per cent stake in Alexis Multi Speciality Hospital Private Limited (Alexis) for an Enterprise Value of INR 412 crore. The company statement implies that this acquisition will strengthen Max Healthcare's footprint in Western India and enable providing the best in class clinical care to all patients in the region. The 200-bedded hospital owned and operated by Alexis is a JCI-accredited facility located on a land parcel of approximately 2 acres at Mankapur, North of Nagpur.

4. Temasek sells minority stake in Manipal Health Enterprises[59]

Abu Dhabi's Mubadala Investment Company, along with two other funds, has acquired an 8 per cent minority stake in Manipal Health Enterprises from Singapore's Temasek. Temasek, the majority shareholder, reduced its stake to 59

[56] https://www.business-standard.com/companies/news/eris-acquires-india-branded-formulation-business-of-biocon-biologics-124031401073_1.html
[57] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/eris-acquires-51-pc-stake-in-swiss-parenterals-for-rs-637-5-cr/articleshow/107665426.cms
[58] https://max-website20-images.s3.ap-south-1.amazonaws.com/PR_Max_Nagpur_acquisition_1_d987a04e0f.pdf
[59] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/mubadala-buys-8-stake-in-manipal-health-enterprises/articleshow/107424489.cms?

per cent following the transaction. The deal values Manipal Health Enterprises at INR 40,000 crore. Temasek's stake reduction is part of a broader sale of about 8 per cent to various investors, including Mubadala, Novo Holdings, and California Public Employees' Retirement System (**CalPERS**).

5. Bajaj Finserv health arm to acquire Vidal Healthcare[60]

Bajaj Finserv Health, a wholly owned subsidiary of Bajaj Finserv, announced that it would acquire a 100 per cent stake in Vidal Healthcare Services for INR 325 crore. Bajaj Finserv Health is a digital-first healthtech company with a network of over 1 lakh doctors, 5,500 lab touch points, and 2,100 hospitals. Vidal Healthcare is one of India's largest healthcare administrators and provides Insurtech solutions and Knowledge Process Outsourcing (**KPO**) services to global insurance and health administrators as part of its international business. The acquisition will enable Bajaj Finserv to offer OPD, wellness, and hospitalisation benefits to customers, thereby providing continuum of care.

6. Tata Consumer signs definitive agreements to acquire Capital Foods[61]

Tata Consumer Products has signed definitive agreements to acquire 100 per cent equity shares of Capital Foods, owner of the brands "Ching's Secret" and "Smith & Jones", in a phased manner. The company statement suggested that 75 per cent of the equity shareholding will be acquired upfront and the balance 25 per cent within the next three years. This move aligns with Tata Consumer's strategic intent to expand its product portfolio and its target addressable market in fast-growing/high margin categories and strengthen its pantry platform.

7. Tata Consumer signs definitive agreements to acquire Organic India[62]

Tata Consumer Products has signed definitive agreements to acquire up to 100 per cent of the issued equity share capital of Organic India, which has a portfolio of over 100 products in the Health & Wellness space. The Tata Consumer Products statement implied that the strategic intent behind the acquisition was to expand their product portfolio and its target addressable market in fast-growing/high margin categories and create a health & wellness platform.

8. Thyrocare to buy ECG service provider Think Health[63]

Thyrocare, a leading diagnostics player, backed by Pharmeasy, announced that it would acquire 100 per cent stake in Chennai-based Think Health Diagnostics to provide electrocardiogram (**ECG**) services at home. The deal, finalised on February 1, 2024, marks Thyrocare's expansion into diagnostics-at-home healthcare services and presents opportunities in the insurance sector. This acquisition enables Thyrocare to offer a complete solution for blood and ECG testing to insurance partners, strengthening its position in the Pre-Policy Medical and Annual Health check-up market.

9. Yatharth Hospital acquires Faridabad based hospital for INR 116 crore[64]

Yatharth Hospital and Trauma Care Services has announced the acquisition of Faridabad-based Asian Fidelis Hospital for INR 116 crore. This acquisition will help the hospital chain, which runs hospitals in Noida, Greater Noida, and Noida Extension, strategically expand its footprint in the Delhi NCR region. Asian Fidelis Hospital, situated on 1.25 acres, is equipped with modern medical facilities and currently has 175 operational beds, expandable to 200 beds.

10. NATCO Pharma invests USD 2 million in Cellogen Therapeutics[65]

NATCO Pharma Limited has invested USD 2 million in Cellogen Therapeutics Private Limited, a Delhi based biotech startup primarily involved in two R&D programs for cell and gene therapy solutions. Cellogen's research interests include innovative and cost-effective cell and gene therapies for addressing various oncological, hematological, and metabolic diseases. The statement issued by Rajeev Nannapaneni, Director and CEO of NATCO Pharma, expressed excitement about the upcoming partnership and suggests that Cellogen's research aligns with their core values.

[60] https://www.thehindubusinessline.com/money-and-banking/bajaj-finservs-healthtech-arm-to-acquire-vidal-healthcare-for-325-crore/article67793225.ece
[61] https://www.tataconsumer.com/news/tata-consumer-products-acquire-capital-foods-owner-chings-secret-and-smith-jones-brands
[62] https://www.tataconsumer.com/news/tata-consumer-products-acquire-organic-india-better-you-organic-brand-spanning-food-beverages
[63] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/thyrocare-to-buy-home-ecg-service-provider-think-health/articleshow/107422962.cms
[64] https://theprint.in/economy/yatharth-hospital-acquires-faridabad-based-facility-for-rs-116-crore/1963178/
[65] NATCO Pharma Limited invests around US$ 2 million in Cellogen Therapeutics, ET HealthWorld (indiatimes.com).

11. Pulsar Capital-owned TruDoc buys Mumbai's Wellthy Therapeutics[66]

Dubai-based TruDoc Healthcare has acquired Indian healthtech startup Wellthy Therapeutics to combine its advanced behavioural science and digital therapeutic solutions with TruDoc's virtual and in-home healthcare services. This integration aims to provide 24-hour access to customised treatment plans to enhance health outcomes and reduce healthcare costs. Rooted in patient-centric care, the alliance aims to deliver a seamless healthcare experience, solidifying TruDoc's leading position in the GCC region as a tech-enabled primary care provider.

12. Fireside Ventures invest INR 50 crore in mental health startup Amaha[67]

Amaha, a mental health startup, secured more than INR 50 crore (about USD 6 million) in an extended Series A funding round led by Fireside Ventures. Reports suggest that while Fireside Ventures contributed INR 36.4 crore, other investors provided an additional INR 15 crore to support the company's expansion plans. Founders psychiatrist and healthcare entrepreneur Dr. Amit Malik and social entrepreneur Neha Kirpal had set up Amaha to address a broad range of mental health conditions, including anxiety, depression, bipolar disorder, ADHD, OCD, schizophrenia, and addiction.

13. Wellness brand Zingavita secures Series A funding of INR 10 crore[68]

Zingavita, a health and wellness startup, secured INR 10 crore in Pre-Series A funding led by Anicut Capital. The investment will encourage new product development, particularly in targeted nutrition. Established in 2022,

Zingavita offers health products, including natural supplements, and plans to expand into premium ayurvedic supplements with the fresh infusion.

14. Olympus Capital divests stake in Aster DM Healthcare[69]

Olympus Capital Asia sold 9.8 per cent of its stake in Aster DM Healthcare for INR 1,978 crore in open market transactions. Its affiliates, Olympus Capital Asia Investments Ltd and Olympus ACF Pte., executed this divestment. By December 2023, Olympus Capital Asia Investments Ltd. held an 18.96 per cent stake in Aster DM Healthcare. Additionally, Capital Group, along with affiliates like SmallCap World Fund Inc., SBI Mutual Fund, Nippon India MF, and ICICI Prudential MF, acquired approximately 3.13 crore shares of Aster DM Healthcare.

[66] https://www.biospectrumasia.com/news/46/23740/trudoc-acquires-wellthy-therapeutics-to-deliver-digital-health-services-in-gulf-and-expand-to-india.html
[67] https://yourstory.com/2024/01/amaha-50-crore-fireside-ventures-mental-health-funding
[68] https://www.thehindubusinessline.com/companies/d2c-wellness-zingavita-raises-10-crore-in-pre-series-a-round-led-by-anicut-capital/article67744481.ece
[69] https://economictimes.indiatimes.com/markets/stocks/news/olympus-capital-asia-divests-9-8-stake-in-aster-dm-healthcare-for-rs-1978-cr/articleshow/108828251.cms

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cyril amarchand mangaldas
ahead of the curve

List of Contributors

Ashwin Sapra
Partner (Head - Pharma & Healthcare)

Biplab Lenin
Partner

Akshat Razdan
Principal Associate

Kartik Jain
Principal Associate

Priyam Rajkumar
Senior Associate

Kritika Asawa
Associate

Anant Mishra
Associate

Shivansh Vishwakarma
Associate

Cyril Amarchand Mangaldas
Advocates & Solicitors

100⁺ years of legacy | **1000** Lawyers | **Over 170** Partners

Peninsula Chambers, Peninsula Corporate Park, GK Marg, Lower Parel, Mumbai – 400 013, India
T +91 22 2496 4455 **F** +91 22 2496 3666 **E** cam.mumbai@cyrilshroff.com **W** www.cyrilshroff.com
Presence in Delhi-NCR | Bengaluru | Ahmedabad | Hyderabad | Chennai | GIFT City | Singapore | Abu Dhabi