cyril amarchand mangaldas
ahead of the curve

synapse

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

Volume VII | Issue IV | July - September 2024

Table of Content

Dear Readers,

As India embarks on a transformative journey in healthcare following the 2024 Budget, the government now has the opportunity to boost healthcare services and expenditure as a percentage of India's GDP by prioritising healthcare infrastructure funding, innovation, and advanced skill development of medical professionals. The Budget announcement, designed to reinforce healthcare services and infrastructure, underscores India's unwavering commitment to health and wellness and heralds a new chapter in the Indian healthcare landscape through visionary policies and investments. In this quarter's issue, we explore the latest regulatory updates, important news highlights, litigation insights, and key transaction developments that will help shape the future of healthcare delivery in India.

The Indian healthcare sector saw significant regulatory and other developments in the July–September 2024 period, including the introduction of the Uniform Code for Marketing Practices in Medical Devices 2024, which aims to establish rigorous standards for promoting and marketing medical devices, ensuring compliance with ethical norms. Placing a priority on clinical trial safety, the Central Government has introduced an amendment mandating the registration of Clinical Research Organisations under the New Drug Clinical Trial Rules, 2019. The government also invoked its powers under Section 26A of the Drugs and Cosmetics Act, 1940, and banned the manufacture, sale, or distribution of 156 fixed dose combination (FDC) drugs to stem the presence of multiple and irrational FDC drugs in the country. While this has helped place reliance on the recommendations of the expert committee that identified these combinations as lacking therapeutic justification and posing potential risks to human health, it has also led to multiple legal challenges currently pending before courts. In yet another attempt to ensure availability of the latest drugs in the country, the Central Drugs Standard Control Organisation has announced local clinical trial waivers, facilitating expedited approval processes for new drugs in specific categories (e.g. orphan drugs for rare diseases and drugs demonstrating significant therapeutic advancements). This initiative aims to enhance access to innovative treatments while ensuring adherence to regulatory compliance and patient safety.

In the litigation space, aggrieved manufacturers challenges to the FDC bans by citing arbitrary and baseless reasons behind the decisions for implementing such bans. Filed before the Delhi High Court, these petitions were granted interim relief, allowing the Petitioners to dispose existing stocks while halting further manufacturing and directing them to submit stock details and affidavits on circulation. Continuing with its crackdown on improper advertising, the Supreme Court stayed the Central Government's July 2024 notification that omitted Rule 170 of the Drugs Rules, which had prohibited the advertisement of AYUSH drugs

without prior approval. The Court highlighted that this move contradicted its earlier orders and ongoing proceedings in multiple high courts. Pending a final decision, Rule 170 remains in force to ensure regulatory oversight on the promotion of AYUSH products. Readers would recollect the Apex Court's clampdown on some key industry players for making improper claims in their advertisements.

In a pivotal case on genetically modified mustard, the Apex Court delivered a split verdict on the Central Government's approval of Dhara Mustard Hybrid-11 (DMH-11), which quashed the Genetic Engineering Appraisal Committee's approval but permitted field trials to continue. The apparent difference in opinion led to the matter being referred to the Chief Justice for the constitution of a larger bench for adjudication in the matter. The Court emphasised the need for a judicial review of GEAC's decisions and directed the Central Government to formulate a national policy on GM crops within four months. In another case related to the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 the Apex Court, with a view towards curbing arbitrary searches without reasons, ruled that any search and seizure under the Act must be collectively authorised by all three members of the District Appropriate Authority, invalidating actions initiated by a single member.

In the current issue, we also shed light of some major transactions in the sector, particularly in the investment space.

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

Managing Partner

Cyril Amarchand Mangaldas

India's leading law firm

synapse

Volume VII | Issue IV | July - September 2024

cyril amarchand mangaldas
ahead of the curve

Regulatory Updates

1. The Uniform Code for Marketing Practices in Medical Devices, 2024[1]

The Department of Pharmaceuticals (**DoP**) under the Ministry of Chemical and Fertilisers, *vide* letter F. No. 31026/23/2022-Policy dated September 6, 2024, issued the Uniform Code for Marketing Practices in Medical Devices, 2024 (**UCMPMD 2024**). This code is designed to streamline and regulate the promotion and marketing of medical devices, ensuring compliance with ethical standards.

In a key difference from the previous Uniform Code for Pharmaceutical Marketing Practices – 2024 (**UCPMP 2024**), the UCMPMD 2024 has lifted restrictions on conducting events including trainings, in foreign locations, enabling medical device companies to provide travel facilities and hospitality to healthcare professionals (**HCPs**), provided they have obtained prior permission from the DoP. The UCMPMD 2024 has also included guidelines for the distribution of demonstration products to HCPs. The Apex Committee for Marketing Practices in Medical Devices can now independently address complaints should there be a delay in response from associations. Associations must form an Ethics Committee for Marketing Practices in Medical Devices to oversee the code's implementation. Companies must file details on evaluation samples and expenses on the UCPMP portal within two months of the financial year's end, with the CEO responsible for compliance and self-declaration. The UCMPMD 2024 has also addressed various marketing practices, including the relationships between medical device companies and HCPs, claims made about products, and the conduct of medical representatives. Previously, the marketing of medical devices was covered under the UCPMP 2024, which focused on drugs, but was applied to medical devices by virtue of the *mutatis mutandis* language.

We have addressed some concerns and questions with respect to the applicability of UCMPMD 2024 2024 on the industry in our Client Alert dated October 15, 2024.

2. Submission of compliance data in respect of UCPMP 2024[2]

The DoP, *vide* notification F.No. 31026/12/2024-Policy, dated August 30, 2024, has prescribed a structured format for the disclosure of particulars pertaining to distribution of free samples, as well as the expenses pharmaceutical companies incur on continuing medical education / continuing professional development / conferences / workshops / training / seminars, etc., and related activities. Such disclosures are required to be submitted on the UCPMP portal on an ongoing basis, with a mandatory filing to be completed within two months following the end of every financial year.

3. Regulation of CROs, New Drugs and Clinical Trials (Amendment) Rules, 2024[3]

The Ministry of Health and Family Welfare (**MoHFW**), *vide* notification G.S.R.581(E), dated September 19, 2024, issued the New Drugs and Clinical Trials (Amendment) Rules, 2024 (**Amendment**), which shall come into force from April 1, 2025. The Amendment provides for the procedure for mandatory registration of clinical research organisations (**CROs**) under the New Drugs and Clinical Trials Rules, 2019 (**NDCT Rules**). This mandates CROs to conduct clinical trials or bioavailability or bioequivalence studies of new drugs or investigational new drug in human subjects only after registering with the Central Licensing Authority (**CLA**).

We have addressed the key features and compliance requirements as stipulated under this Amendment in our Client Alert dated September 27, 2024.

4. Notification on draft of Drugs and Cosmetics (Compounding of Offences) Rules, 2023[4]

The MoHFW, *vide* notification G.S.R. 374(E), dated July 10, 2024, issued the draft of the Drugs and Cosmetics (Compounding of Offences) Rules, 2023 (**Compounding Rules**), for compounding of offences (whereby in lieu of undergoing prosecution and punishment, the accused can pay fine for the disposal of the prosecution) punishable under the Drugs and Cosmetics Act, 1940 (**Drugs Act**). These empower the Central and the State Governments to appoint any person as the *"compounding authority"*. The *"reporting authority"* is defined as the Licensing Authority or the CLA or the Central License Approving Authority appointed by Central Government or the Licensing Authority appointed by

[1] https://pharmaceuticals.gov.in/sites/default/files/UCMPMD_0.pdf
[2] https://pharmaceuticals.gov.in/sites/default/files/Standing%20Order%20-%20Circular%20No.%202%20of%202024.pdf
[3] https://egazette.gov.in/WriteReadData/2024/257393.pdf
[4] https://egazette.gov.in/WriteReadData/2024/255358.pdf

State Government, having jurisdiction over the place the offence has been or alleged to have been committed.

5. Inclusion of acupuncture professionals as "Other Care Professionals[5]

The MoHFW, *vide* notification S.O. 4238(E), dated September 26, 2024, in consultation with National Commission for Allied and Healthcare Profession, included *"acupuncture professionals"* under the list of *"Other Care Professionals"* in the Schedule of the National Commission for Allied and Healthcare Professions Act, 2021 (**NCAHPA**).

6. Display of anti-tobacco spots / health warnings / audio-visual disclaimers in films released on online curated content platforms. Draft changes in Rule 11 of the Cigarette and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Amendment Rules, 2024[6]

The MoHFW, *vide* notification F. No. P.16012/0E/2017-TC dated September 13, 2024, has amended Rule 11 of Cigarette and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Amendment Rules, 2024. The draft changes *inter alia* include displaying of anti-tobacco spots/health warnings/audio-visual disclaimers in films released on online curated content platforms on or after September 1, 2023, for a duration specified in the said notification. Further, it also mandates displaying non-skippable anti-tobacco health spots/audio-visual disclaimers, etc., in all content published in the online curated content platforms.

7. Notification regarding restriction on manufacture, sale, and distribution of Fixed Dose Combination (FDC) medicines

a. Notification prohibiting manufacture, sale, or distribution of 156 FDC medicines[7]

The MoHFW, *vide* multiple notifications from S.O. 3285(E) to S.O. 3440(E) released on August 2, 2024, imposed a prohibition under Section 26A of the Drugs Act on the manufacture, sale, or distribution of 156 (one hundred and fifty-six) FDC medicines including commonly used painkillers, antibiotics, antiallergy medication, and multivitamins. The notifications stated that the prohibition would be imposed with immediate effect since the expert committee considered the FDCs irrational, without therapeutic justification, and may pose risk to human beings. The banned FDCs include medicines from companies such as Torrent Pharmaceuticals, Mankind Pharma, Alkem Laboratories, Eris Life Sciences, Sun Pharmaceuticals, etc.

b. Notification prohibiting manufacture, sale, and distribution of the FDC of Naproxen IP 375 mg + Esomeprazole Magnesium Trihydrate IP 20 mg hard gelatin capsules or tablets[8] *and Naproxen IP 250/500 mg + Pantoprazole IP 20 mg hard gelatin capsules or tablets*[9]

The MoHFW, *vide* notifications S.O. 3266(E) to S.O. 3267(E), dated August 12, 2024, has restricted the manufacture, sale, and distribution of the FDC of Naproxen IP 375 mg + Esomeprazole Magnesium Trihydrate IP 20 mg hard gelatin capsules or tablets and Naproxen IP 250/500 mg + Pantoprazole IP 20 mg hard gelatin capsules or tablets, respectively. The restriction is subject to conditions that Naproxen be in an enteric coated form; the FDC be indicated in adults for the symptomatic treatment of osteoarthritis rheumatoid arthritis and ankylosing spondylitis, etc.; and the FDC's bioequivalence be demonstrated with the internationally available innovator's FDC within a year's time; and the efficacy and safety equivalence with the Naproxen Esomeprazole international innovator's FDC for the indication be demonstrated within 1 (one) year.

8. Guidelines and notifications regarding consent requirements and exemptions under the Water (Prevention and Control of Pollution) Act, 1974 (**Water Act**), Air (Prevention and Control of Pollution) Act, 1981 (**Air Act**), and the Environment Protection Rules, 1986

a. Draft Guidelines relating to the Uniform Consent Fee and Grant, Refusal or Cancellation of Consent to Establish or Consent to Operate as required under the Water Act, Air Act, and Environment Protection Rules, 1986.[10]

[5] https://egazette.gov.in/WriteReadData/2024/257549.pdf
[6] https://egazette.gov.in/WriteReadData/2024/257180.pdf
[7] https://egazette.gov.in/WriteReadData/2024/256531.pdf
[8] https://egazette.gov.in/WriteReadData/2024/256395.pdf
[9] https://egazette.gov.in/WriteReadData/2024/256395.pdf
[10] https://egazette.gov.in/WriteReadData/2024/255656.pdf

The Ministry of Environment, Forest and Climate Change of India (**MoEFCC**), *vide* notification G.S.R. 423(E), dated July 19, 2024, has published the draft guidelines relating to the Uniform Consent Fee and Grant, Refusal, or Cancellation of Consent to Establish (**CTE**) or Consent to Operate (**CTO**). These guidelines seek to develop a uniform fee structure based on factors such as the nature of the industry and amount of capital investment, across State Pollution Control Boards (**SPCB**) and Pollution Control Committees (**PCC**), for consents and approvals required under the Water Act, Air Act and the Environment Protection Rules, 1986.

b. *Exemption of certain categories of industries/activities from prior consent under the Air Act*[11]

The MoEFCC, *vide* notification G.S.R. 421(E) dated July 19, 2024, has issued the draft exemptions for certain industries and activities from the mandatory requirement of obtaining CTE and CTO from SPCB and PCC under the Air Act. Projects that require prior Environmental Clearance (**EC**) under the Environmental Impact Assessment notification, 2006 (**EIA Notification**) are now exempt from obtaining a separate CTE, provided they meet the conditions stated in the notification. Furthermore, industries categorised as *"white"* by the Central Pollution Control Board (**CPCB**) are exempt from CTE and CTO, streamlining regulatory processes for these low-pollution industries, subject to certain conditions outlined in the notification.

c. *Exemption of certain categories of industries/activities from prior consent under the Water Act*[12]

The MoEFCC, *vide* draft notification G.S.R. 425(E) dated July 19, 2024, has issued the draft exemptions for certain industries and activities from the mandatory requirement of obtaining CTE and CTO from SPCB and PCC under the Water Act. Projects requiring prior EC under the EIA Notification are exempt from the mandatory CTE requirement, subject to conditions. Additionally, *"white"* category industries, as defined by the CPCB, are exempt from CTE and CTO under the Water Act, subject to the notification's conditions.

9. Notification of draft Remediation of Contamination Sites Rules, 2024[13]

The MoEFCC, *vide* notification S.O. 3550 (E), dated August 21, 2024, released the draft Remediation of Contamination Sites Rules, inviting public comments until October 22, 2024. The proposed rules apply to sites contaminated by *"hazardous substances"* as defined under the Environment (Protection) Act, 1986, as well as those covered under the Schedules of the Hazardous and Other Waste (Management and Transboundary Movement) Rules, 2016, and in Public Liability Insurance Act, 1991. The proposed rules also seek to constitute a *"Central Remediation Committee"* that shall be tasked with outlining the procedures for identification of responsible persons, remediation costs, and supervising comprehensive investigation of contaminated sites.

[11] https://egazette.gov.in/WriteReadData/2024/255630.pdf
[12] https://egazette.gov.in/WriteReadData/2024/255621.pdf
[13] https://egazette.gov.in/WriteReadData/2024/256547.pdf

10. Public notice regarding registration of RMPs on National Medical Register (NMR) Portal of the National Medical Commission (NMC)[14]

The NMC, *vide* public notice No. R.15014/Gen/(12)/2023, dated August 30, 2024, issued notice informing the public on the launch of the NMR Portal for the registration of all Registered Medical Practitioners (**RMPs**) eligible for registration in India. RMPs with MBBS qualification registered on the Indian Medical Register are required to re-register on the NMR of NMC. The NMR is a dynamic database for all MBBS registered doctors in India, and it is linked with their Aadhaar identification.

11. Notifications/Orders/Circulars regarding food safety standards by Food Safety and Standards Authority of India (FSSAI)

a. *Order regarding introduction of new kind of business (**KoB**) for "Direct Sellers" under FoSCoS*[15]

The FSSAI, *vide* order F.No. RCD-15001/6/2021-Regulatory-FSSAI-Part(1) [Comp No. 1752], dated July 16, 2024, introduced a new KoB in Food Safety Compliance System (**FoSCoS**), seeking to differentiate between a "retailer" and a "direct seller", pursuant to which "direct sellers" can register on the FoSCoS.

b. *Notification regarding re-operationalisation of Food Safety and Standards (Licensing and Registration of Food Business) Amendment Regulation, 2021*[16]

The FSSAI, *vide* notification F. No. RCD-01002/1/2021-Regualtory-FSSAI (part-1), dated July 19, 2024, directed the re-operationalisation of Food Safety and Standards (Licensing and Registration of Food Business) Amendment Regulation, 2021 (**FSS Food Business Amendment**), which seeks to provide a detailed framework for licensing and registration procedures for e-commerce food operators, conditions for licenses for restaurants, and hygiene and sanitary requirements for all food business operators (**FBOs**), including those engaged in the catering of food services operations that apply for a license, etc.

c. *Direction regarding re-operationalisation of draft FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations, 2022*[16]

The FSSAI, *vide* F. No. SS-T003/3/2024-Standard, dated August 30, 2024, issued a directive under Section 16(5) of the Food Safety and Standards Act, 2006 (**FSS Act**) re-operationalising the draft FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022. This follows a previous directive from June 5, 2024, as the finalisation of these regulations will take more time. The re-operationalisation of the provisions is effective from July 1, 2024, with approval from the competent authority.

d. *Direction regarding re-operationalisation of Food Safety and Standards (Labelling and Display) Amendment Regulations 2022*[17]

The FSSAI, *vide* F.No. STD/SP-08/A1.2022/N-010Part (1) dated August 30, 2024, has re-operationalised the Food Safety and Standards (Labelling and Display) Amendment Regulations 2022 under Section 15(5) of the FSS Act. This includes labelling requirements for non-retail containers, minimally processed food, and pan masala warning statements. The regulations, initially operationalised on June 17, 2022, were approved excluding tolerance limits. The re-operationalisation will take effect from July 1, 2024, while final notification is pending.

e. *Direction regarding re-operationalisation of Draft Amendment Regulations for Packaged Drinking Water (excluding Mineral Water)*[18]

The FSSAI, *vide* F. No. SS-M015/1/2023-Standard, dated July 26, 2024, has issued a directive under Section 16(5) of the FSS Act on the re-operationalisation of Draft Amendment Regulations for Packaged Drinking Water (excluding mineral water). This follows earlier directives on standards for Total Dissolved Solids, Calcium, and Magnesium. Effective July 1, 2024, the permissible limits will be set at 75–500 mg/l for total dissolved solids, 10–75 mg/l for calcium, and 5–30 mg/l for magnesium to aid compliance by FBOs.

[14] https://www.nmc.org.in/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/4%20NMR%20Public%20Notice.pdf
[15] https://www.fssai.gov.in/upload/advisories/2024/07/6696643975b09Order%20dated%2016thJuly2024_Direct%20seller.pdf
[16] https://www.fssai.gov.in/upload/advisories/2024/07/669a5e5daca83direction%20merged.pdf
[17] https://fssai.gov.in/upload/advisories/2024/08/66d1af90f0b62Direction%20dated%2030.08.2024%20reg%20reoperationalization%20of%20draft%20FSS_Labelling%20and%20Display_Amendment%20regulations%202022.pdf
[18] https://fssai.gov.in/upload/advisories/2024/07/66a38e822bc19Direction%20regarding%20reoperationalization%20of%20permissible%20limit%20of%20Calcium%20magnesium%20and%20TDS.pdf

f. *Notification regarding omission of the sub-regulation (4) of the regulation 7 of the Food Safety and Standards (Fortification of Foods) Regulation, 2018*[19]

The FSSAI, *vide* notification F. No. SS-T018/5/2023-Standard-FSSAI, dated July 19, 2024, directed the omission the sub-regulation (4) of the regulation 7 of the Food Safety and Standards (Fortification of Foods) Regulation, 2018 with immediate effect. The sub-regulation (4) had mandated that every package of food, fortified with iron carry the label statement *"People with Thalassemia may take under medical supervision and persons with Sickle Cell Anaemia are advised not to consume iron fortified food products"*. The omission decision came after a MoHFW committee headed by Director General, Indian Council of Medical Research (**ICMR**) reviewed the advisory on Thalassemia and Sickle Cell Anaemia.

g. *Notification regarding draft amendments to Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011*[20]

The FSSAI, *vide* notification F. No. REG-11015/3/2024-Regulation-FSSAI., dated August 21, 2024, proposed amendments to the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011. The draft amendment regulations are called Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2024. This said amendment seeks to provide for permissible levels of natamycin (food additive) in "fermented milks (plain) not heat treated after fermentation". The permissible level has been set at a maximum limit of 5 mg/kg in products like *chakka* and *shrikhand*. Further, these draft regulations shall be open for public comments and suggestions for 60 (sixty) days from the date on which copies of the Gazette containing this notification are made available to the public.

h. *Letter advisory related to selling/marketing of reconstituted fruit juices as "100% fruit juices"*[21]

The FSSAI, *vide* letter bearing File No. RCD-15001/19/2024-Regulatory-FSSAI, dated August 14, 2024, has extended the deadline for using pre-printed packaging material to December 31, 2024. Further, it has clarified that FBO-manufactured products before December 31, 2024, are permitted to be sold in the market across all channels until the end of their shelf life. This letter was in reference to the advisory dated July 3, 2024, concerning the "classification regarding selling/marketing of reconstituted fruit juices as 100% fruit juices", which mandated that all the existing pre-printed material be exhausted by August 31, 2024.

a. Central Drugs Standards Control Organisation (CDSCO) Updates

a. *Circular regarding draft guidelines on Good Clinical Practices*[22]

The CDSCO, *vide* circular F. No. GCT-11/14/2024-eOffice dated September 12, 2024, has issued draft guidelines for Good Clinical Practices (**GCP**) to align with NDCT Rules and international standards. The revisions focus on incorporating digital health technologies, such as wearables, and introduce definitions for "data acquisition tool", e-consent, and decentralised trials. Key updates include computerised systems validation, enhanced security controls, and risk-based quality management. The ethics sections now address conflicts of interest, compensation, privacy, and confidentiality. Stakeholders are encouraged to provide feedback on the draft to ensure its effectiveness and relevance in clinical research.

b. *Circular regarding acceptance of data on pre-clinical toxicity studies conducted and accepted by regulatory authorities of other countries*[23]

The CDSCO, *vide* circular F. No. 12-01/24-DC dated July 29, 2024, has stated that with respect to new drugs, subsequent new drugs, and FDCs, it shall accept the pre-clinical toxicity studies for animal toxicity that have been generated and accepted by the relevant regulatory authorities of other countries. This acceptance is subject to specific conditions, such as requirement for these studies in India in instances of specific concerns. Additionally, the use of unapproved excipients in formulations will necessitate the provision of relevant safety data. For "sub-acute toxicity studies for intravenous infusions and injectables", it mandates that applicants seeking permission to import or manufacture the new drug submit the required data.

[19] https://www.fssai.gov.in/upload/advisories/2024/07/669a5493eb1baDirection%20dated%2019072024.pdf
[20] https://www.fssai.gov.in/upload/uploadfiles/files/Gazette%20Notification_270824.pdf
[21] https://www.fssai.gov.in/upload/advisories/2024/08/66bf038b82ea320240816124256461.pdf
[22] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE4OTU=
[23] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE0OTA=

c. *Circular in relation to Draft Guidelines on Good Distribution Practices for Pharmaceutical Products*[24]

The CDSCO *vide* circular F. No. QMS/41/GDP/2024, on August 9, 2024, notified the Draft Guidelines on Good Distribution Practices (**GDP**) for Pharmaceutical Products, initially published *vide* file No. QMS/04/RI/2022 on February 26, 2024. In line with the WHO Technical Report Series (**TRS**) on Good Storage and Distribution Practices, these guidelines aim to ensure the quality and identity of pharmaceutical products throughout the distribution process, covering procurement, storage, transportation, and record-keeping. Applicable to all entities involved in the trade and distribution of pharmaceuticals, including manufacturers, wholesalers, distributors, and logistics providers, these guidelines also cover biological products. The draft seeks stakeholders to provide comments and suggestions within 30 (thirty) days of publication of the circular.

d. *Circular regarding online application for issuance of New Drug permission of Bulk (API) drugs/vaccines and finished formulations for Veterinary purpose only*[25]

The CDSCO (Veterinary Division), *vide* circular VET-13014(19)/1/2023, dated September 12, 2024 has streamlined the regulatory submission procedure for applications for the issuance of New Drug permission of Vaccines/Drugs for Bulk (API) in Form-45A/46A and furnished formulations in Form-45/46 by making the service available on the SUGAM online portal.

e. *Circular regarding revision of the guidance document for functions and responsibilities of zonal, sub-zonal, and port offices*[26]

The CDSCO, *vide* circular DCGI/MISC/2024-05, dated September 12, 2024, has revised the guidance document for zonal, sub-zonal, and port offices, initially prepared in 2011. The revised guidance document has been undertaken in light of the changes resulting from the introduction of new rules and regulations, an online system through the SUGAM portal, and the delegation of certain activities to State Drugs Authorities, among other factors. Risk-based inspections within the CDSCO offices are one of the salient features of the revised document.

f. *Circular regarding streamlining the applications for registration and import of cosmetics including post-approval changes through SUGAM online portal*[27]

The CDSCO, *vide* circular COS-11018(11)/18/2024-eOffice, dated August 9, 2024, has streamlined the application process for the registration and import of cosmetics, including post-approval changes through the SUGAM online portal. The CDSCO has decided to restrict the number of products to a maximum of 50 (fifty) per online application; multiple applications can then be made. This measure is aimed at ensuring time-bound processing and disposal of applications as provided for under the Cosmetic Rules, 2020. These restrictions came into force on August 16, 2024.

g. *Circular regarding clinical trial waiver for drugs approved in well-regulated markets*[28]

The CDSCO, *vide* order DC-DT-15011(11)/85/2024, dated August 7, 2024, has specified the United States, United Kingdom, Japan, Australia, Canada, and the European Union for local clinical trial waivers under Rule 101 of the NDCT Rules. The waiver will facilitate the approval process for new drugs in specific categories, including orphan drugs for rare diseases, gene and cellular therapy products, new drugs used in pandemic situations, and new drugs with significant therapeutic advances over current standard care. This initiative is aimed at expediting access to innovative treatments while ensuring regulatory compliance and patient safety.

b. Notifications/orders/circulars by the National Pharmaceutical Pricing Authority (NPPA) regarding drugs pricing and other price-control related measures

a. *Order on revision of ceiling price of Scheduled formulations like Valganciclovir, Metoprolol, Lamivudine, and Montelukast*[29]

The NPPA, *vide* order S.O. 3216 (E), dated August 08, 2024, has fixed the ceiling price of Valganciclovir, Metoprolol, Lamivudine, and Montelukast. The ceiling price of the formulations were revised, including the wholesale price

[24] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE1OTA=
[25] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE5MzA=
[26] CDSCO Guidance Document.pdf
[27] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE1ODg=
[28] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE1ODI=
[29] https://www.nppaindia.nic.in/uploads/tender/e01968b448a02439c97bfbe66589d99d.pdf

index (**WPI**) impact @ 0.00551% for the year 2024, exclusive of goods and services tax (**GST**) applicable, if any.

b. *Order on fixation of retail price of 70 (seventy) formulations*[30]

The NPPA, *vide* order S.O. 3169(E) dated August 6, 2024, has fixed the retail price of 70 (seventy) new drug formulations, exclusive of GST applicable. The retail price was fixed pursuant to receipt of applications from individual companies, under Paras 5 and 15 of the Drugs Prices Control Order, 2013 (**DPCO 2013**). The order further clarifies that the fixed retail price is applicable only to the individual manufacturer/marketer mentioned in the order.

c. *Order regarding fixation of retail price of 62 (sixty-two) formulations under the DPCO 2013*[31]

The NPPA, *vide* order S.O. 3867(E), dated September 10, 2024, has fixed the retail price of 62 (sixty-two) drug formulations, including the Ibuprofen and Paracetamol Suspension manufactured by Innova Captab Ltd/Dr. Reddy's Laboratories Ltd.; a combination of Telmisartan, Amlodipine and Hydrochlorothiazide tablets from Sun Pharmaceuticals; a combination of Telmisartan, Cilnidipine, and Chlorthalidone tablets from Abbott Healthcare; a combination of Amlodipine, Telmisartan, and Metoprolol Succinate (Extended Release) tablets from Akums Drugs and Pharmaceuticals Ltd./Cipla Limited, and other drug combinations.

d. *Order regarding extension of ceiling price of knee implants*[32]

The NPPA, *vide* order S.O. 3869(E), dated September 10, 2024, has extended the ceiling price of the orthopaedic knee implants for knee replacement systems as applicable up to September 15, 2025.

e. *Order regarding fixation of ceiling price of chloroquine*[33]

The NPPA, *vide* order S.O. 3868(E), dated September 10, 2024, has fixed the price for chloroquine, including WPI @ 0.00551% for the year 2024. The order has also mandated the manufacturers of chloroquine to furnish quarterly returns to the NPPA, in respect of its production/import and sale in Form-III of Schedule-II of the DPCO 2013 through Integrated Pharmaceutical Data Base Management System. Any manufacturer intending to discontinue production of chloroquine must provide information to the NPPA regarding the discontinuation of production and or import of scheduled formulation in Form-IV of Schedule-II of the DPCO 2013 at least 6 (six) months prior to the intended date of discontinuation.

[30] https://www.nppaindia.nic.in/uploads/tender/58eddec8232e4ada093b846e5b5ccb7f.pdf
[31] https://www.nppaindia.nic.in/uploads/tender/78cea45800398a2ae1223b33bbdbb016.pdf
[32] https://www.nppaindia.nic.in/uploads/tender/132fe3f8a8ee7fa7714f16a7d21a28bb.pdf
[33] https://www.nppaindia.nic.in/uploads/tender/94e7d6893e1a2d97d0ff93f3682926ba.pdf

News Updates

1. 2024 Union Budget: Highlights for the pharmaceuticals industry[34]

The Central Government, in its Union Budget 2024 as presented by Finance Minister, Nirmala Sitharaman on July 23, 2024, allocated INR 89,287 crores to the healthcare sector. It also exempted 3 (three) cancer treatment drugs – Trastuzumab Deruxtecan, Osimertinib, and Durvalumab –from customs duty. It will also promote vaccination for girls aged between 9 and 14 years to prevent cervical cancer. The Budget also introduced a comprehensive healthcare program prioritising maternal and child healthcare, with plans to unify various schemes for maternal and childcare under one program to ensure synergy in implementation. Also on the anvil is the upgradation of Anganwadi centres under "Saksham Anganwadi and Poshan 2.0" for improved nutrition delivery, early childhood care, and development.

2. 2024 Union Budget: Highlights for the medical devices industry[35]

For the medical devices sector, the Budget reduced basic customs duty on X-ray tubes and flat panel detectors used in medical X-ray machines under the phased manufacturing program. It increased the production linked incentive (**PLI**) scheme for the pharmaceutical industry from INR 1,200 crores to INR 2,143 crores. To foster innovation and R&D, the Budget proposed creation of a mechanism for promoting private-sector-driven research and innovation at a commercial scale. A funding pool of INR 1 lakh crore, with interest-free loans for 50 (fifty) years, has been set aside for long-term financing of technological research. Additionally, the Anusandhan National Research Fund will be operationalised to support basic research and prototype development.

3. 2024 Union Budget: Highlights for the agriculture and other allied industries[36] [37]

Allocating INR 1.52 lakh crore for the agriculture and allied sectors, the Budget announced the launch of biomanufacturing and biofoundry initiatives aimed at developing environment-friendly polymers, bio-agricultural inputs, and biopharmaceuticals. It also focused on developing an Aatmanirbhar strategy to boost oilseed production (including mustard, groundnut, soybean, etc.), while promoting modern farming technologies. Emphasizing an increase in milk and dairy production, it plans to enhance the productivity of milch animals.

[34] https://www.expresspharma.in/decoding-budget-2024-25-a-lacklustre-budget-for-pharma/
[35] https://pib.gov.in/PressReleasePage.aspx?PRID=2036143
[36] https://prsindia.org/files/budget/budget_parliament/2024/DFG_Analysis_2024-25_Agriculture_and_Farmers_Welfare.pdf
[37] https://pib.gov.in/PressReleaseIframePage.aspx?PRID=2035609

The Budget aims to introduce 109 high-yielding and climate resilient varieties of field and horticulture crops for farmers and initiate 1 (one) crore farmers into natural farming over the next 2 (two) years, besides establishing 10,000 bio-input resource centres. The newly designed U-WIN platform for managing immunisation efforts and the intensified rollout of Mission Indradhanush will be expedited nationwide. Additionally, under the Matsya Sampada Yojana (Fisheries), the Department of Fisheries plans to increase seafood exports to INR 1 lakh crore and establish 5 (five) integrated aquaparks.

4. Central Government approves schemes for farmers[38]

The Central Government has approved seven schemes with an outlay of INR 14,235.30 crores to boost farmers' livelihoods and incomes. Key schemes include the Digital Agriculture Mission to enhance productivity through technology, Crop Science for Nutritional Security to build climate resilience, and Sustainable Livestock Health and Production to increase income from livestock and dairy. Other initiatives focus on horticulture development, strengthening agricultural education, Krishi Vigyan Kendra, and natural resource management. These efforts aim for sustainable agricultural growth and improved farmer welfare.

5. Central Government announces health cover for senior citizens aged 70 years and above[39]

The Central Government introduced the Pradhan Mantri Senior Citizen Health Scheme (**PMSCHS**) under the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB PM-JAY) for senior citizens aged 70 (seventy) years and above. The PMSCHS will cover around 6 (six) crore seniors, providing each family with INR 5 (five) lakh in free health insurance for secondary and tertiary conditions. It covers medical consultations, diagnostic tests, and more. Eligible seniors will receive a unique card (registration requires a valid Aadhaar number) and a dedicated portal link for those aged 70 (seventy) years and above.

6. Draft guidelines for passive euthanasia[40]

The MoHFW has issued draft guidelines titled *"Guidelines for Withdrawal of Life Support in Terminally Ill Patients"*. These specify conditions under which passive euthanasia can be permitted; for example, when a patient is brain dead as per the Transplantation of Human Organs Act, 1994, shows no improvement in their condition or when the patient or their surrogate provides informed refusal to continue life support. The guidelines emphasise that life-support should not be withdrawn from terminally ill patients who are unlikely to suffer significant pain or lose their dignity. The draft also includes provisions for "Do Not Attempt Resuscitation" (**DNAR**), where cardiopulmonary resuscitation (**CPR**) should not be performed in cases with no realistic chance of survival or recovery. The guidelines state that for patients lacking the capacity to make decisions, a primary medical board consisting of three doctors will determine the withdrawal of life support, ensuring that decisions are made carefully and with medical expertise. This framework aims to provide clear guidance on end-of-life care while maintaining the dignity and rights of terminally ill patients.

7. DoP revises guidelines for PLI scheme[41]

The DoP has revised guidelines for the PLI scheme to boost domestic bulk drug manufacturing. The successor-in-interest clause has been updated to allow beneficiary firms to transfer their business to a wholly owned subsidiary, enabling the transfer of scheme benefits in such cases. With a total budget of INR 6,940 crores, the scheme targets the production of 41 bulk drugs between 2020–21 and 2029–30.

8. Niti Aayog recommends making CDSCO an independent regulatory authority[42]

An expert committee report by NITI Aayog titled *"Future Pandemic Preparedness and Emergency Response: A Framework for Action"* has recommended making the CDSCO an independent regulatory authority. The expert committee also proposed appointing a technically proficient chief regulator, reporting directly to the Health Minister, to enable faster regulatory approvals with pre-approved pathways and protocols, ensuring readiness for future health emergencies within 12–24 months.

9. New guidelines for drug inspectors for uniform drug sampling[43]

The Drugs Controller General of India (**DCGI**) has issued new guidelines to ensure uniformity in drug sampling by

[38] https://pib.gov.in/PressReleasePage.aspx?PRID=2050900
[39] https://www.thehindu.com/sci-tech/health/ayushman-bharat-health-insurance-how-to-apply/article68637461.ece
[40] https://www.livemint.com/news/india/health-ministrys-draft-guidelines-says-withdrawal-of-life-support-in-terminally-ill-patients-includes-4-conditions-11727584424661.html
[41] https://www.pharmaceuticals.gov.in/sites/default/files/Corrigendum%20Under%20PLI%20scheme%20for%20Bulk%20Drugs%2025.09.2024.pdf
[42] https://www.pharmabiz.com/NewsDetails.aspx?aid=172418&sid=1
[43] https://www.livemint.com/companies/dcgi-issues-fresh-code-for-drug-inspectors-to-keep-market-vigil-11726385509670.html

inspectors, focusing on cosmetics, medical devices, and drugs. Under these guidelines, inspectors must prepare annual and monthly sampling plans. A centralised monthly list of substandard or spurious drugs will also be public to prevent their use and ensure the availability of genuine products. This initiative aims to enhance market surveillance and prompt action against substandard products as identified by government analysts.

10. Revised guidelines for Non-Alcoholic Fatty Liver Disease (NAFLD) released[44]

The MoHFW has released revised operational guidelines and a training module for NAFLD management. These guidelines focus on improving patient care by using evidence-based procedures, highlighting the public health significance of NAFLD, which is linked to obesity, diabetes, and cardiovascular diseases. The guidelines promote early detection, health promotion, and a multidisciplinary approach, ensuring comprehensive care. The training module will equip HCPs with the necessary skills to diagnose, treat, and prevent NAFLD, particularly at the primary-care level.

11. Committee revising Rule 64 of Drugs Rules, 1945, to present report[45]

The CDSCO has established an ad hoc committee to revise Rule 64 of the Drugs Rules, which outlines the conditions for granting licenses for drug sales (excluding homeopathic drugs). The committee is preparing its report for further deliberation by the Drugs Consultative Committee (**DCC**). This initiative stems from DCC recommendations aimed at incorporating GDP guidelines into the existing regulations. The revision aims to address previous loopholes that allowed manufacturers to overlook proper storage conditions for drugs during transit to wholesale and retail levels.

12. Proceedings against companies not using QR codes in their medications[46]

The CDSCO is set to initiate legal action against pharmaceutical companies that have not implemented barcodes on their top 300 medication brands. This measure is part of a broader initiative to combat counterfeit and contaminated drugs. Additionally, it is considering a collaborative task force to address these issues. The drug regulator has mandated that companies include barcodes on their product labels, enabling the scanning of vital information, such as batch numbers and manufacturing licenses, to enhance traceability. Notable brands identified for non-compliance include Unisvet, Calpol, Limsee, Sumo, Saridon, Eabiflu, Ecgapzin, Dolo, and Thyronorm.

13. CDSCO framing guidelines for disposal of unused medicines[47]

The CDSCO, in its effort to reduce anti-microbial resistance (**AMR**) brought on by improper drug and chemical discharge into the environment, is framing guidelines for disposal of expired and unused medicines to prevent their misuse, in accordance with the report prepared by the subcommittee of DCC. The DCC suggested that the subcommittee investigate the protocols outlined in the draft guidance document concerning disposal of unused or expired medications by the public, before finalising. AMR is the process through which bacteria, fungi, and viruses develop drug resistance over time, making the treatment of diseases more difficult. This action is significant given the threat that AMR poses to public health in India.

14. National Accreditation Board for Hospitals and Healthcare Providers (NABH) releases sixth edition of accreditation standards for hospitals[48]

The NABH has launched the sixth edition of its accreditation standards for hospitals, effective starting January 1, 2025. This revised edition represents a significant advancement, addressing the rapidly changing healthcare landscape, and aligning the same with international standards. It incorporates improved procedures that respond to emerging challenges and trends in healthcare, safety, and hospital management, ensuring that Indian healthcare providers remain competitive globally even as they deliver high-quality care.

15. Amendment proposed in Legal Metrology (Packaged Commodities) Rules, 2011[49]

The Department of Consumer Affairs is considering amendments to the Legal Metrology (Packaged Commodities) Rules, 2011, aimed at establishing uniformity for packaged goods sold across offline and online platforms.

[44] https://pib.gov.in/PressReleasePage.aspx?PRID=2059351
[45] https://www.pharmabiz.com/NewsDetails.aspx?aid=172751&sid=1
[46] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/drug-regulator-to-crack-down-on-pharma-companies-not-using-barcodes/articleshow/111615168.cms?from=mdr
[47] https://www.livemint.com/politics/policy/drug-regulatory-body-guidelines-disposal-expired-and-unused-medicines-misuse-cdsco-11724836208609.html
[48] https://www.pharmabiz.com/PrintArticle.aspx?aid=172394&sid=1
[49] https://pib.gov.in/PressReleasePage.aspx?PRID=2033114

The proposed changes will stipulate that all packaged products sold in retail settings comply with these rules, except for items packaged for institutional or industrial use. This amendment seeks to enhance transparency and standardisation in the labelling and sale of packaged commodities.

16. Fund for agricultural startups set up[50]

The Ministry of Agriculture and Farmers' Welfare, along with the Ministry of Rural Development, has launched "AgriSURE – Agri Fund for Start-Ups and Rural Enterprises" to stimulate investment in the agricultural sector, aiming to empower farmers and enhance the rural economy. The AgriSURE fund focuses on technology-driven, high-risk, high-impact ventures to promote innovation and growth within agricultural and rural startup networks. The total fund amounts to INR 750 crores, with contributions from the Government of India (INR 250 crores), NABARD (INR 250 crores), and an additional INR 250 crores from banks, insurance companies, and private investors.

17. National Health Accounts (NHA) estimates for 2020–21 and 2021–22 released[51]

The MoHFW has released the NHA estimates for the years 2020-21 and 2021-22. These estimates are based on the globally accepted framework of "A System of Health Accounts, 2011," which facilitates inter-country comparisons. The report provides a methodical account of the financial inflows and outflows from various sources into India's health system, along with details on how healthcare is delivered. The Government's efforts to raise public investments in the health sector are underscored by the NHA estimates for 2020-21 and 2021-22, which demonstrate an unprecedented increase in government spending on healthcare by 37 percent.

18. Standard operating procedure for product traceability[52]

To curb the rising cases of counterfeit and spurious medicines, the DCGI has established standard operating procedures and guidelines to ensure product traceability throughout the supply chain. As lack of proper documentation along the distribution channel complicates

traceability efforts, the DCGI has disseminated GDP to assist authorities in pinpointing the exact location within the supply chain where the medication was contaminated or where counterfeit drugs were introduced in cases of adulteration.

19. DCGI suspends permission given to eye drop over false claims[53]

The DCGI has indefinitely revoked authorisation for "PreAVA", which was developed by Ented Pharmaceuticals, a Mumbai-based pharmaceutical company. This revocation is due to the unfounded and unapproved promotion claims that it can cure presbyopia, an age-related vision condition. The drug regulator noted that the product had received approval as an eye drop for the treatment of presbyopia but denied the assertion that it could improve vision in 15 minutes. According to the DCGI, the company violated the NDCT Rules by making claims for which it did not have approval from the Central Licensing Authority.

20. Central Government approves clean plant programme to promote horticulture[54]

The Central Government has approved the Clean Plant Programme (**CPP**) with an investment of INR 1,765.67 crores to promote horticulture in the country. The initiative aims to redefine the horticulture industry in India and establish new benchmarks for sustainability and quality. Under this initiative, reliance on imported planting materials will

[50] https://www.business-standard.com/industry/agriculture/govt-launches-rs-750-cr-fund-agrisure-for-support-to-agriculture-startups-124090301130_1.html
[51] https://pib.gov.in/PressReleasePage.aspx?PRID=2058791
[52] https://www.livemint.com/industry/indias-apex-drug-regulator-frames-guidelines-to-ensure-product-traceability-11723357074980.html
[53] https://www.outlookindia.com/national/dcgi-suspends-permission-to-entod-pharmas-eye-drop-that-claims-to-dependency-on-reading-glasses
[54] https://economictimes.indiatimes.com/news/economy/policy/cabinet-approves-rs-1766-cr-clean-plant-programme-to-boost-horticulture-exports/articleshow/112410765.cms?from=mdr

decrease, while encouraging environmentally friendly and sustainable agricultural practices. According to news reports, the CPP will also play a vital role in making India a prominent exporter of fruits globally. The National Horticulture Board, in collaboration with Indian Council of Agricultural Research (**ICAR**), will implement the programme.

21. Researchers invited by ICMR to create evidence based protocol for empirical use of anti biotics[55]

The MoHFW, in collaboration with the Department of Health and Family Welfare, the Directorate General of Health Services, and the Department of Health Research, is spearheading an initiative to develop evidence-based protocols for the empirical use of antibiotics. This project aims to ensure the proper administration of antibiotics in various clinical settings and combat the growing issue of antibiotic resistance. The ICMR has invited expressions of interest from researchers, scientists, and academicians to create guidelines specifically for treating dental infections, sepsis, and vaginal discharge. The initiative will compile data from existing literature on critical decisions regarding antibiotic therapy, such as duration and initiation of treatment. To evaluate the strength of the recommendations made, the evidence will be systematically reviewed and analysed using the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach, ultimately enhancing antibiotic stewardship in clinical practice.

22. ICMR enters into partnerships for human clinical trials[56]

The ICMR has entered into Memorandum of Agreements with several organisations to advance human clinical trials. These partnerships include collaborations with Aurigene Oncology Limited to develop a small molecule for multiple myeloma, Indian Immunologicals Limited for a Zika vaccine, Mylab Private Limited for seasonal influenza, and ImmunoACT for CAR-T cell therapy targeting chronic lymphocytic leukaemia. These initiatives reflect ICMR's commitment to fostering a robust clinical trial ecosystem in India, aimed at facilitating drug development from inception to commercialisation and promoting access to affordable, high-quality healthcare.

23. ICMR invites expression of interest to commercialise CRISPR Cas-Based TB-detection system[57]

The ICMR, aiming to enhance the detection of Mycobacterium tuberculosis, the causative agent of tuberculosis (**TB**), has invited companies, manufacturers, and organisations to participate in the "Transfer of Technology" for a CRISPR Cas-based TB-detection system. The ICMR-RMRCNE Institute in Dibrugarh, one of ICMR's constituent institutions, developed this cost-effective diagnostic tool to facilitate early TB detection. The initiative seeks to grant licenses for further advancement and commercialisation of the technology while ensuring that it reaches a broader population. Collaborations with various stakeholders will adhere to ICMR's Intellectual Property policy to ensure transparency. While the ICMR will provide expert guidance, the participating companies will be responsible for obtaining regulatory approvals, production, and the commercial success of the product.

24. ICMR and Panacea Biotech initiate phase 3 clinical trial for indigenous dengue vaccine[58]

The ICMR, in collaboration with Panacea Biotech, a multinational manufacturer of specialty and generic pharmaceuticals and vaccines, has commenced the phase 3 clinical trial for DengiAll, India's first indigenous dengue vaccine. The company holds a process patent related to the vaccine. According to news reports, the formulation's phase 1 and phase 2 clinical trials, completed in 2018–19, showed promising results. The development of DengiAll aims to address the gap created by the absence of antiviral treatments or licensed vaccines against dengue in India.

25. ICMR invites expression of interest to create collaborative centres of excellence[59]

In its efforts to identify and encourage partnerships with research teams excelling in biomedical research, the ICMR has invited expressions of interest for the establishment of ICMR Collaborating Centres of Excellence (**ICMR-CCRE**) for the year 2024. The recognition granted to these centres will be valid for 5 (five) years, subject to extension upon review. However, designation as an ICMR-CCRE will not result in funding from ICMR. Both public and private sector

[55] https://www.icmr.gov.in/icmrobject/uploads/Documents/1724743558_eoi_empirical_use_of_antibiotics_rh.pdf
[56] https://pib.gov.in/PressReleasePage.aspx?PRID=2054864
[57] https://main.icmr.nic.in/sites/default/files/seminars/Revised_EoICRISPR_19072024.pdf
[58] https://www.livemint.com/science/health/icmr-and-panacea-biotec-begin-phase-3-clinical-trial-of-indias-1st-indigenous-dengue-vaccine-dengiall-11723626004153.html
[59] https://epms.icmr.org.in/extramuralstaticweb/ccoedocs/CCoE_Call_for_Interest_2024.pdf

institutions, along with academic and research institutions, are eligible to participate in the initiative, provided they meet the necessary requirements.

26. FSSAI withdraws advisory on A1 and A2 milk claims[60]

The FSSAI has formally withdrawn its advisory dated August 21, 2024, which had instructed food businesses to remove claims regarding "A1" and "A2" milk types from their packaging. The food authority, FSSAI, announced its intention to conduct further consultations with stakeholders to address concerns surrounding these classifications before issuing any new guidelines. In the original notification, the regulator had expressed that the differentiation between A1 and A2 milk does not conform to the FSS Act, raising questions about the validity of such claims. This withdrawal reflects the FSSAI's commitment to ensuring comprehensive dialogue and stakeholder engagement on this significant issue in the dairy industry. The authority aims to balance consumer protection with the interests of food business operators in light of emerging research and market demands.

27. Manufacturing license of 111 spice producers revoked[61]

The FSSAI has revoked the manufacturing licenses of 111 spice producers, mandating an immediate halt to their manufacturing processes. The samples collected for testing included products from brands such as Everest, MDH, Catch, and Badshah, focusing on parameters such as rodent and insect contamination, heavy metal and moisture content, aflatoxins, and pesticide residues. FSSAI conducted random testing on 2,200 spice samples, of which 117 spice manufacturers failed to meet the basic quality standards required for their products.

28. FSSAI launches project to tackle microplastic contamination[62]

In recognition of microplastics as an emerging threat to public health, the FSSAI has introduced an initiative aimed at determining the frequency and degree of exposure to micro and nano plastics in Indian food products. Additionally, the project seeks to develop and validate analytical methods for this purpose. This initiative, titled "Micro-and Nano-Plastics as Emerging Food Contaminants: Establishing Validated Methodologies and Understanding the Prevalence in Different Food Matrices", was rolled out in March 2024. The project is being conducted in collaboration with several institutions, including the CSIR-Indian Institute of Toxicology Research (Lucknow), ICAR-Central Institute of Fisheries Technology (Kochi), and the Birla Institute of Technology and Science (Pilani).

[60] https://www.businesstoday.in/latest/economy/story/fssai-withdraws-advisory-on-removal-of-claims-of-a1-a2-milk-from-packaging-443111-2024-08-27
[61] https://timesofindia.indiatimes.com/life-style/food-news/fssai-cancels-manufacturing-licences-of-111-spice-producers-across-india/articleshow/111400965.cms
[62] https://retail.economictimes.indiatimes.com/news/food-entertainment/fssai-launches-project-to-address-microplastic-contamination-in-indian-food-products/112616525

Litigation Updates

1. Supreme Court issues notice in PIL mandating Braille Labels for medicines, consumer products, tickets etc.[63]

The Supreme Court (**SC**), in W.P.(Civil) No 516 of 2024, *vide* order dated August 27, 2024, issued notice on a petition seeking guidelines for implementing a Braille Integration System on medicine prescriptions, consumer products, and currency notes for visually impaired individuals. Filed by Medhansh Soni, a visually challenged Petitioner, under Article 32 of the Constitution, the Public Interest Litigation (**PIL**) highlights the difficulties faced by the visually impaired in identifying currency notes, reading product labels, and managing medicine prescriptions. It also raises issues regarding their accessibility to public spaces and information, contending that the absence of Braille violates their rights to equality and dignity under Articles 14, 16, 19, and 21 of the Constitution.

The plea emphasises that the lack of Braille language on key items, such as prescriptions and currency notes, forces visually impaired individuals to rely on others for basic information. It further notes that demonetisation, which changed the size of currency notes, worsened the situation. The matter has been listed for hearing on November 5, 2024.

2. SC stays Central Government notification directing omission of Rule 170 under Drugs Rules[64]

The SC, in W.P.(Civil) No. 645 of 2022, *vide* order dated August 27, 2024, issued a stay on the Central Government notification dated July 1, 2024, which had introduced the Drugs (Fourth Amendment) Rules, 2024, omitting Rule 170 of the Drugs Rules. Rule 170 prohibits the advertisement of Ayurvedic, Siddha, or Unani (**AYUSH**) drugs without prior approval.

The Apex Court noted that this notification contradicted its earlier order from May 7, 2024. In that order, the court pointed out that Rule 170 was under challenge in separate proceedings before the High Courts of Delhi, Bombay, and Kerala. The High Court of Delhi (**Delhi HC**), in a leading case (W.P.(C) No. 320 of 2019), had explicitly ruled on May 1, 2023, that no decision by the Union of India, based on the recommendations of the Ayurvedic Siddha and Unani Drugs Technical Advisory Board (**ASUDTAB**), should be implemented for four weeks, maintaining an interim arrangement. However, ASUDTAB proceeded to recommend the omission of Rule 170, and the notification was forwarded to the Ministry of Law and Justice for approval and

[63] Medhansh Soni vs. Union of India & Ors, Order dated August 27, 2024 in W.P. (Civil) 516 of 2024.
[64] Indian Medical Association vs. Union of India, Order dated August 27, 2024 in W.P. (Civil) 645 of 2022.

publication. This was not carried out despite the Apex Court's directive to withdraw the notification.

The Apex Court, pending a final judgment, has stayed the government's action to omit Rule 170, ensuring that the rule remains in force.

3. SC upholds overcharging recovery against Sun Pharma under the Drugs (Price Control) Order[65]

The SC, in Civil Appeal No. 7209 of 2019, *vide* judgment dated July 15, 2019, upheld that the demand raised by the NPPA against M/s Sun Pharma for overcharging on Rosciles, a Cloxacillin-based drug formulation, despite the price being fixed under the Drugs (Price Control) Order, 1995 (**DPCO 1995**). Sun Pharma had challenged the demand notices issued by NPPA for INR 4.65 crore, which included INR 2.15 crore as the principal for overcharging between April 1996 and July 2003, and INR 2.49 crore as interest. Both the single and division benches of the Delhi HC had dismissed Sun Pharma's arguments, leading the company to approach the SC.

The SC ruled that there was no clear distinction between the terms *"dealer"*, *"distributor"*, and *"wholesaler"* under the DPCO. It observed that the definitions were not mutually exclusive, and a distributor could also act as a wholesaler or retailer, thereby qualifying as a dealer. Furthermore, the court found that Sun Pharma had provided inconsistent explanations regarding its arrangement with Oscar Laboratories Pvt. Ltd. and concluded that regardless of whether Sun Pharma was a dealer or distributor, it fell within the scope of Para 13 of DPCO 1995, allowing the NPPA to recover the overcharged amount.

Based on these reasons, the Apex Court concluded that Sun Pharma fell within the ambit of Para 13 of the DPCO 1995, and recovery of the overcharged amount was warranted.

4. SC directs Centre and States to implement NCAHPA[66]

The SC, in W.P. (Civil) No. 983 of 2023, *vide* order dated August 12, 2024, has directed Union and State Governments to implement NCAHPA[67], which had not been enforced despite over two years since its enactment. The PIL, filed by the Joint Forum of Medical Technologists of India, highlighted that NCAHPA required State Councils to be established within 6 (six) months, but repeated extensions by the Government had delayed this. The Petitioners emphasised the need for an institutional framework to standardise certifications, curriculum, and institutions, which was vital for improving job opportunities.

The SC noted that most States had yet to set up the required councils, and those that did were non-functional. Only 14 out of 28 States and Union Territories had formed councils, and even these were ineffective. The Apex Court raised concerns about the proliferation of unregulated healthcare institutes, emphasising that the NCAHPA was intended to address this issue. The bench noted that the petition specifically called for the implementation of Section 22(1) of the NCAHPA, which mandates the creation of professional and state allied healthcare councils. The Apex Court has directed the Union and State Governments to implement the NCAHPA within 2 (two) months. Additionally, the Apex Court has called for an online meeting between the MoHFW and State Secretaries to be convened within 2 (two) weeks. The States have been instructed to establish the requisite infrastructure to ensure the full operationalisation of the NCAHPA.

5. PIL filed seeking implementation of Front-of-Package Warning Labels on packaged foods[68]

The SC, in W.P. (Civil) No. 437 of 2024, *vide* order dated July 29, 2024, issued notice to the Union Government in a PIL filed by 3S and Our Health Society Public Charitable Trust, an NGO, seeking the implementation of Front-of-Package Warning Labels (**FOPL**) on packaged foods concerning fat, sugar, and salt content. The petition highlighted that diabetes has affected millions and has become a silent epidemic. It also pointed out that food advertising often promotes unhealthy products without disclosing their sugar, salt, or fat content. The petition further noted that companies like Nestlé do not use sugar in infant milk in Europe and other countries, a practice it does not follow in India.

The PIL referenced aggressive marketing practices and their influence on consumer behaviour, particularly concerning the promotion of unhealthy products. The petitioner had previously written to the MoHFW, urging action on this issue, but had received no response, prompting the approach to the Apex Court. In light of these concerns, the SC directed the Union Government to furnish its response in the mater, with the matter tentatively listed for hearing on November 8, 2024.

[65] M/s Sun Pharma Industries Ltd. vs. Union of India and Ors., Judgement dated July 15, 2019 in Civil Appeal 7209 of 2019.
[66] Joint Forum of Medical Technologists of India JFMTI & Ors vs. Union of India, Order dated August 12, 2024 in W.P. (Civil) 983 of 2023.
[67] National Commission for Allied & Healthcare Professions Act, 2021.
[68] 3S and Our Health Society vs. Union of India & Ors. Order dated July 29, 2024 in W.P. (Civil) 437 of 2024.

6. SC view on genetically modified crops in "genetically modified mustard" case[69]

The SC, in W.P. (Civil) No. 115 of 2004, delivered a split verdict on July 23, 2024, regarding the Union Government's approval of genetically modified mustard, Dhara Mustard Hybrid-11 (**DMH-11**). The case involved multiple PILs challenging the 2022 decision by the Genetic Engineering Appraisal Committee (**GEAC**), which had granted conditional approval for the environmental release of this transgenic mustard hybrid. In the split decision, Justice BV Nagarathna quashed the GEAC's approval, while Justice Sanjay Karol permitted field trials of DMH-11 to proceed. Given the divergence in opinions, the matter has now been referred to the Chief Justice of India to constitute a larger bench to resolve the issue.

However, the bench reached consensus on several important aspects. First, the Court affirmed that the GEAC's decisions on genetically modified organisms are open to judicial review, ensuring oversight on regulatory approvals. Second, it directed the Central Government to develop a comprehensive national policy on genetically modified (**GM**) crops, involving relevant stakeholders and ensuring wide public dissemination. The MOEFCC has been given four months to finalise this policy, including taking inputs from State Governments and formulating necessary rules. Additionally, the Apex Court mandated that the import of GM foods, including edible oils, meet packaging and labelling requirements under Section 23 of the FSS Act.

7. SC rules search and seizure under Pre-Conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 illegal, without authorisation from all members of District Authority[70]

The SC, in its judgment dated September 12, 2024, in Criminal Appeal No. 3747 of 2024, ruled that any search and seizure under the Pre-Conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (**PCPNDT Act**), be collectively authorised by all three members of the District Appropriate Authority. Any action initiated by a single member is illegal. This case involved the Appellant and others accused of engaging in illegal foetal sex determination using ultrasound. The Appellant petitioned the Punjab and Haryana High Court to quash the complaint and FIR against them, but the High Court refused.

Under Section 30 of the PCPNDT Act, the Appropriate Authority may initiate search and seizure if there is "reason to believe" that an offence has been committed. The SC clarified that the intent of this provision is to prevent arbitrary searches and seizures, requiring that all members of the Appropriate Authority share the same opinion before proceeding. The Apex Court further stated that while the Appropriate Authority need not record the reasons behind their belief of an offence, search and seizure actions must be a joint decision of all three members. Therefore, any search conducted on the authorisation of a single member is illegal and in violation of Section 30(1) of the PCPNDT Act.

[69] Gene Campaign & Anr. vs. Union of India & Ors., Judgments dated July 23, 2024 in W.P. (Civil) 115 of 2004.
[70] Ravinder Kumar vs. State of Haryana, Judgment dated September 12, 2024 in Criminal Appeal no. 3747 of 2024

8. Delhi HC provides interim relief against notification banning 156 FDCs[71]

The Delhi HC, *vide* order dated August 29, 2024, in the batch matter of *Vilco Laboratories Private Limited & Ors. vs. Union of India,* WP (C) 11882 of 2024 and other connected petitions, granted interim relief against the Government's notification banning 156 FDCs. The notifications, issued on August 2, 2024, prohibited the manufacture, sale, or distribution of FDC medicines, including common painkillers, antibiotics, antiallergy drugs, and multivitamins, under Section 26A of the Drugs Act, citing irrational combinations and potential risks to human health.

The Court, relying on the coordinate bench order in *Lupin Limited vs. Union of India* (June 28, 2023 in W.P (C) No. 8593 of 2023), emphasised the absence of clear evidence linking these FDCs to significant human health. While permitting existing stock to remain in circulation, the Court prohibited further manufacturing until the next hearing. The petitioners in the batch matter were directed to provide details of their available stock and submit an affidavit regarding stock circulation.

In light of the prior order of the coordinate bench, the Court directed that this interim relief would apply similarly to the all the drugs covered in the writ petitions before them. The matter is next listed on December 10, 2024.

9. Delhi HC directs Ram Kishan Yadav and others to take down claims pertaining to Coronil and against allopathy[72]

The Delhi HC, *vide* its judgment dated July 29, 2024, passed in CS(OS) No. 320 of 2021 and I.As 13602 of 2022, and 1724 of 2024, directed Ram Kishan Yadav (**Baba Ramdev**) and certain other defendants to take down claims against allopathy and those related to Coronil. The judgment followed a suit filed by the Resident Doctors Association, AIIMS Rishikesh, and individual resident doctors and office bearers of other doctors' associations, seeking a direction to restrain the defendants from distributing, transmitting, publishing, re-publishing, or releasing statements to the public that spread misinformation, prompt people to avoid medical help and hospitalisation, and attribute COVID-19 deaths to allopathy. They also sought a direction to remove/take down all active URLs and videos pertaining to the impugned statements.

The Delhi HC directed social media intermediaries to delete and take down from their respective platforms the statements/claims related to allopathy, COVID-19, and the promotion of "Coronil" if Baba Ramdev failed to comply. It noted that the product's license was never updated to reflect it as a "medicine for COVID-19" and remains approved only as an "immunity booster". The High Court further emphasised that if the contesting defendants were permitted to continue to promote and advertise the *"Coronil"* tablet, not only would the public be at risk of their health, but the ancient and venerated system of Ayurveda may itself come into disrepute. As a corollary, the High Court directed the removal of the claims made by Baba Ramdev.

10. Kerala High Court upholds right to unadulterated food as a fundamental right[73]

The High Court of Kerala (**Kerala HC**), in its judgment dated September 4, 2024, in Criminal MC No. 8950 of 2016, directed the Central Government to address the lacuna in the FSS Act and its regulations, emphasising the government's duty to enact laws that ensure citizens have access to unadulterated food. The matter arose when the complainant purchased four identical and sealed bottles of "Mint & Lemon Flavoured Green Ice Tea" from a hypermarket, with one part of the sample sent for examination as per the provisions of the FSS Act and Regulations.

The issue before Kerala HC was whether prosecution could be initiated against Pepsico India Holdings Private Limited (PepsiCo), Accused No. 4, under the FSS Act and relevant regulations, for allegedly selling a misbranded and an unsafe product. The food analyst found the food product sample to contain saccharin, deeming it unsafe. Upon appeal, the referral food laboratory's director also found the sample unsafe due to the undisclosed presence of caffeine. However, the Court noted the divergent views between the two examinations and ruled that prosecution could only proceed when the food laboratory confirms the food analyst's findings, not when there is a difference of opinion. It directed the Central Government to address the lacunae in the legislation and incorporate appropriate amendments and forwarded the judgment to the relevant competent authority for compliance. The proceedings against PepsiCo were quashed accordingly.

[71] Vilco Laboratories Pvt. Ltd & Ors vs. Union of India, order dated August 29, 2024 in W.P (C) 11882 of 2024 and CM Appl. 49475 of 2024, CM Appl. 49476 of 2024, CM Appl. 49477 of 2024 and other connected petitions.
[72] Resident Doctors Association, All India Institute of Medical Sciences (AIIMS), Rishikesh and Ors. vs. Ram Kishan Yadav Alias Swami Ramdev and Ors., Judgment dated July 29, 2024 in CS(OS) 320 of 2021, I.A 13602 of 2022 and I.A 1724 of 2024.
[73] Pepsico India Holding Pvt Ltd. vs. State of Kerala, Order dated September 4, 2024 in CRL.MC No. 8950 of 2016.

Transaction Updates

1. Mankind acquires Bharat Serums and Vaccines[74]

Mankind Pharma (**Mankind**), a leading Delhi-based pharmaceutical company, has completed the acquisition of Bharat Serums and Vaccines Limited (**BSV**), a leading biopharmaceutical company with expertise in women's healthcare, from Advent International, securing a 100 percent stake in BSV for approximately INR 13,630 crores, subject to closing adjustments. A statement by Mankind implies that BSV's specialised R&D platforms, encompassing a diverse portfolio in women's health, fertility, critical care, and immunoglobulin therapies, aligned well with Mankind's strategic goal of expanding its presence in high-entry-barrier segments.

2. AI healthcare start-up Qure.ai India raises Series D round[75]

Indian start-up Qure.ai (**Qure**) raised USD 65 million in its Series D funding round from investors led by Lightspeed Venture Partners and 360 ONE Asset Management to expand its artificial intelligence (**AI**) products for disease detection. Based in Mumbai, Qure has deployed its AI technology at over 3000+ imaging sites in over 90 countries. Founded in 2016, the company claims its solutions outperform human radiologists and physicians in diagnosing critical conditions such as tuberculosis, lung cancer, and stroke. Reports indicate that the company intends to use the proceeds to expand into the United States and other markets, improve its generative AI models, and fund acquisitions.

3. Redcliffe Labs raises Series C round[76]

Redcliffe Labs (**Redcliffe**), a Noida-based omnichannel diagnostics service provider, has raised USD 42 million in a Series C funding round led by the Denmark-based investment firm, IFU, which contributed USD 20 million. The existing investor, LeapFrog, added USD 15 million, with additional capital coming from shareholders HealthQuad and Spark Growth Ventures. As per news reports, this fresh capital will enable Redcliffe to expand its operations, particularly in tier II and III cities across India, where the company plans to open more labs and collection centres. Currently, Redcliffe services 220 cities through a network of 80 labs and more than 2,000 collection centres, having served over 7 million patients across various urban tiers.

4. Onsurity raises Series B round[77]

Onsurity, a subscription-based employee healthcare provider, has raised USD 45 million in a Series B finding round

[74] https://www.mankindpharma.com/media/press-release/mankind-pharma-clinches-bharat-serums-deal-for-164-billion
[75] https://economictimes.indiatimes.com/tech/funding/lightspeed-leads-65-million-round-by-india-ai-diagnostics-startup-qure-ai/articleshow/113607128.cms?from=mdr
[76] https://entrackr.com/2024/09/redcliffe-labs-raises-42-mn-in-series-c-round/
[77] https://www.vccircle.com/insurtechstartup-onsurity-raises-45-mn-in-series-b-round.

led by private equity firm, Creaegis, with existing investors including International Financial Corporation (IFC), Nexus Venture Partners, and Quona Capital also participating. Founded in 2020, Onsurity offers a health insurance management platform tailored for various clients. New reports suggest that the start-up plans to deploy the funds to launch additional digital offerings and product lines aimed at small and medium enterprises (**SMEs**) in India while also enhancing the company's technological capabilities.

5. Zydus acquires 50 percent stake in Sterling Biotech[78]

Zydus Animal Health and Investments Ltd (**Zydus**), wholly owned subsidiary of Zydus Lifesciences Ltd, has completed the acquisition of 50 percent stake in Sterling Biotech Ltd (**SBL**) from Perfect Day Inc. This acquisition signifies Zydus' entry into the fermentation-based protein business. The joint venture intends to set up a state-of-the-art facility for producing animal-free fermented protein for international markets. News reports suggest that after the acquisition, SBL will operate as a 50:50 joint venture, featuring equal representation on the board.

6. Redcliffe set to acquire Celara Diagnostics[79]

Redcliffe is set to acquire Bengaluru-based Celara Diagnostics in a deal valued at up to INR 60 crore (USD 7 million). This transaction marks Redcliffe's second acquisition in the diagnostics space this year. Celara Diagnostics, which reported INR 25 crore in revenue and INR 1.5 crore in profit for FY 23, offers advanced diagnostic services in radiology and pathology, including MRI, CT scans, and speciality services in neurology and cardiology. Earlier this year, Redcliffe, through Medcentre, acquired Kota-based Prime Sonography & Diagnostic Centre for an undisclosed amount.

7. Max Healthcare announces acquisition of Jaypee Healthcare[80]

Max Healthcare, India's leading private healthcare provider, announced the acquisition of a 63.65 percent stake in Jaypee Healthcare Limited (**JHL**) for a consideration of INR 398 crore. In its filing to the stock exchanges, Max Healthcare confirmed the execution of share purchase agreement for acquisition of 27,21,09,231 equity shares of JHL, free of encumbrances, with call-option right to acquire the remaining stake from the sellers. New reports suggest that in addition to the consideration price, Max Healthcare will also manage the debt repayment for JHL's financial creditors. JHL currently operates three Jaypee hospitals, a flagship 500-bed hospital facility in Noida, a 200-bed hospital in Bulandshahr, and a 100-bed facility in Anoopshahar, currently not operational.

8. Birla Fertility & IVF acquires BabyScience IVF clinics[81]

Birla Fertility & IVF (**Birla Fertility**), India's third-largest IVF network and a division of the CK Birla Group, announced the acquisition of 12 (twelve) BabyScience IVF clinics, further solidifying its presence in the fertility and IVF space. In a company statement, Birla Fertility stated that this strategic move marks its entry into Karnataka, Maharashtra, and Tamil Nadu, expanding its network to 50 clinics nationwide. This acquisition is part of Birla Fertility's ongoing expansion strategy, which includes continued investment exceeding INR 500 crore in this area. Notably, this acquisition follows closely on the heels of company's acquisition of the ARMC IVF Chain in Kerala earlier this year.

9. KKR enters into agreement with Baby Memorial Hospital[82]

KKR has entered into a definitive agreement with Baby Memorial Hospital (**BMH**), a leading regional multi-specialty hospital chain based in Kozhikode. New reports indicate that under the terms of the definitive agreement, funds managed by KKR will acquire a controlling stake in BMH. According to KKR, this investment is expected to strengthen BMH's initiatives to meet the rising demand for high-quality and accessible healthcare in India by facilitating the development of a premier hospital network across the country, leveraging both organic growth and strategic acquisitions.

[78] https://www.thehindubusinessline.com/markets/zydus-completes-acquisition-of-50-stake-in-sterling-biotech/article68584554.ece
[79] https://entrackr.com/2024/09/exclusive-redcliffe-labs-acquires-celara-diagnostics-for-7-mn/
[80] https://www.businesstoday.in/industry/pharma/story/max-healthcare-acquires-majority-stake-in-jaypee-hospitals-447815-2024-09-27
[81] https://bwhealthcareworld.com/article/birla-fertility-ivf-expands-to-50-clinics-with-acquisition-of-babyscience-ivf-530469
[82] https://www.pharmabiz.com/NewsDetails.aspx?aid=170054&sid=2

10. Krsnaa Diagnostics acquires minority stake in Apulki Healthcare[83]

Krsnaa Diagnostics Ltd (**Krsnaa**), a Pune-based diagnostic services provider, has announced the acquisition of a 3.53 percent stake in Apulki Healthcare Private Limited (**Apulki**), which operates cancer and cardiac care hospitals. News reports suggest that the partnership will involve Krsnaa offering a comprehensive range of integrated diagnostic services at Apulki's facilities, thereby improving access to advanced and super-specialised diagnostics. The financials of this acquisition remain undisclosed.

11. Acko General acquires OneCare[84]

Acko General Insurance (**Acko**) acquired OneCare, a digital chronic-care management company, in its attempt to enter the healthcare service-providing sector. Details of the price of the all-cash acquisition have not been disclosed. The acquisition is a central element of Acko's strategy to develop a comprehensive healthcare ecosystem that addresses all facets of a customer's health insurance needs, including protection, prevention, care, and recovery.

12. Glenmark Pharma divests stake in Glenmark Lifesciences[85]

Glenmark Pharmaceuticals Limited divested a 7.84 percent stake in its subsidiary Glenmark Lifesciences Limited (**Glenmark Lifesciences**), a listed company, by undertaking an offer for sale on the stock exchange. The offer comprised up to 96,09,571 equity shares of Glenmark Lifesciences. The sale will be undertaken via the Stock Exchange platform, in compliance with relevant legal regulations. This divesting of stake was preceded by Nirma Limited acquiring 75 percent majority stake in Glenmark Lifesciences, amounting to 91.9 million shares. The estimated value of the deal is INR 845 crores.

13. Thyrocare enters into business transfer agreement with Polo Labs[86]

Thyrocare, a leading diagnostics player, has entered into a business transfer agreement with Polo Labs Private Limited (**Polo Labs**), a Punjab-based pathology diagnostic company, to acquire their pathology diagnostic and pathological business, as a going concern on a slump-sale basis. By integrating Polo Labs' established network with Thyrocare's advanced diagnostic infrastructure, the company seeks to enhance service delivery, reduce turnaround times, and provide exceptional patient convenience. The acquisition is contingent upon the fulfilment of condition precedents and the timeline of completion is subject to a 60-day-long stop period beginning on the execution date of the business transfer agreement.

14. MedGenome picks up stake in Odisha-based GenX Diagnostics[87]

MedGenome, a genomics-driven diagnostics and research services company with headquarters in Bengaluru, has acquired a stake in GenX Diagnostics, a well-known diagnostic lab chain in Odisha. New reports suggest that this strategic partnership aims to leverage MedGenome's advanced scientific and technological capabilities alongside GenX's established leadership in the region. Together, this collaboration intends to empower clinicians in Odisha to derive actionable insights from genetic data, enabling more precise and targeted treatment for patients, improving healthcare outcomes.

15. Suven Pharmaceuticals receives approval from BSE and NSE for merger with Cohance Lifesciences[88]

Suven Pharmaceuticals Limited, a contract development and manufacturing organisation (**CDMO**) backed by Advent International, has received approval from the BSE and NSE for its proposed merger with Cohance Lifesciences. Both companies have also filed an application before the NCLT for the proposed merger, the expected timeline for which is 12–15 months. The merged entity will have three verticals – pharma CDMO, agrochemicals CDMO, and active pharmaceutical ingredients. It will become an integrated CDMO player with strong development and manufacturing capabilities. Advent International will own a 66.7 percent stake in the combined entity.

[83] https://www.thehindubusinessline.com/news/national/krsnaa-diagnostics-makes-strategic-investment-in-apulki-healthcare/article68686987.ece
[84] https://www.livemint.com/companies/news/acko-onecare-acquisition-insurance-healthcare-multiples-pe-11721813473596.html
[85] https://www.business-standard.com/companies/news/glenmark-pharmaceuticals-to-sell-7-84-stake-in-glenmark-life-sciences-124071000812_1.html
[86] https://investor.thyrocare.com/wp-content/uploads/2024/07/SELetterPoloLabs02072024Final.pdf
[87] https://health.economictimes.indiatimes.com/news/diagnostics/medgenome-acquires-stake-in-odisha-based-genx-diagnostics/111653516
[88] https://pharma.economictimes.indiatimes.com/news/mergers-and-acquisitions/cohance-lifesciences-merger-with-suven-pharma-gets-nse-bse-nod/112074655?utm_source=top_news&utm_medium=sectionListing

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

Vatsala Parashar
Associate

Anam Chowdhary
Associate

Kartik Agrawal
Associate

Cyril Amarchand Mangaldas
Advocates & Solicitors

100⁺ years of legacy | **1000** Lawyers | **Over 200** Partners

Peninsula Chambers, Peninsula Corporate Park, GK Marg, Lower Parel, Mumbai – 400 013, India
T +91 22 6660 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