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

Volume VI | Issue III | April 2023 - June 2023

Table of Content

Dear Readers,

We hope that all of you and your families are safe and healthy.

The economic growth and well-being of a nation are intrinsically linked to the quality of its healthcare system. The Covid-19 pandemic has had a profound impact on reshaping India's healthcare landscape, necessitating a shift towards digital transformation and a revaluation of the existing healthcare practices. The recently implemented Medical Devices Policy seeks to revolutionise India's healthcare sector through its focus on regulatory mechanisms, infrastructure development, research and development, investment, human resource development, and strategic positioning, to improve healthcare outcomes. The expansion of the digital fitness & well-being and e-health sectors has been facilitated by the widespread usage of smartphones, internet connectivity and supportive government policies. Growth is driven by heightened awareness, growing demand for access to information, and an emphasis on transparent treatment and diagnosis processes. Consequently, we foresee a positive outlook for India Inc. in terms of new opportunities in the healthcare, pharmaceuticals, and life sciences sectors in the upcoming months.

Like the previous few quarters, the sector continued to witness important regulatory updates in the April-June 2023 quarter, which we have covered in this edition of *Synapse*. Most importantly, this quarter saw the notification of the Medical Device Policy, 2023, which provides for a robust regulatory, economic and legal landscape for medical device manufacturing in India. In the wake of ART and Surrogacy law reforms, Assisted Reproductive Technology Regulations, 2023 was notified, which laid down the manner of retrieving oocytes and placing embryos in the uterus of a woman. It is aimed at providing better medical care and security for donors and patients. This quarter also saw the notification of Surrogacy Regulations, 2023, which provides the procedures to be followed for transaction of business at the meetings of National Assisted Reproductive Technology and Surrogacy Board (National Board) and State Board and their quorum requirements.

Additionally, the "Accessibility Standards for Health Care" have also been notified for compliance by Government and private hospitals and other healthcare institutions and centres. Class C&D non-notified medical devices, which are currently under mandatory registration, will enter the licensing regime with effect from October 1, 2023.

In the litigation space, the Hon'ble Supreme Court has held that Ayurveda Practitioners and MBBS Practitioners do not receive equal pay since they do not perform equal work. The Court noted that allopathy practitioners perform emergency duties such as conducting trauma care and complicated surgeries, which is not true for Ayurveda practitioners and therefore Ayurveda Practitioners

cannot claim equal pay as their counterparts. The High Court of Madras in an attempt to enforce better implementation of the Surrogacy (Regulation) Act, 2021 in Tamil Nadu, noted the problems associated with the same and directed the State to constitute district medical boards for the purpose of granting eligibility certificates. In a similar pursuit, the High Court of Karnataka evolved "*triple tests*" to consider the plea of a couple to have a child through altruistic surrogacy. In another matter, the Bombay High Court held that a manufacturer of a drug cannot be penalised for not adhering to a prescribed standard if the said standard is notified post the date of manufacturing.

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

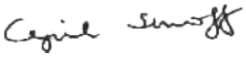
Cyril Amarchand Mangaldas, India's premier full-service law firm, has an industry leading and dedicated Pharmaceuticals, Healthcare and Life Sciences practice. Our class-leading practice specialists are always on top of the latest developments in the sector. In our endeavour to keep you abreast with 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 helps us make progress. 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 and healthcare space. We have also created a dedicated section on our website that provides up-to-date information on Covid-19 related notifications across legal sectors. We encourage our readers to visit our Covid-19 resource page at https://www.cyrilshroff.com/covid-19-know-how-cyril-amarchand-mangaldas/.

We hope that you enjoy reading our newsletter as much as we enjoy 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. Notification on Medical Device Policy, 2023[1]

The Ministry of Chemicals and Fertilizers ("**MoCF**"), *vide* notification no. 31026/91/2015-PI-II, dated May 2, 2023, notified the National Medical Policy, 2023 ("**NMP 2023**"). The NMP 2023 fits in with the Government's objective of building a robust regulatory, economic and legal landscape for medical device manufacturing in India. The NMP 2023 endeavors to balance the needs of the industry with the interests of consumers by adopting a patient-centric approach. The aim is to enhance affordability and accessibility of medical devices, to widen its use across hospitals and to provide access to better quality and affordable healthcare. To this effect, the NMP 2023 *inter alia* focuses on six core areas, i.e. (i) regulatory streamlining, (ii) enabling infrastructure, (iii) facilitating R&D, (iv) attracting investments, (v) human resource development, and (vi) brand positioning and awareness.

2. Notification of Assisted Reproductive Technology Regulations, 2023[2]

The Ministry of Health and Family Welfare ("**MoHFW**"), *vide* notification no. G.S.R. 269(E), dated April 5, 2023, notified the Assisted Reproductive Technology Regulations, 2023. The new regulations lay down the manner of retrieving oocytes and placing embryos in the uterus of a woman. Under the said regulations, the Assisted Reproductive Technology Clinics are instructed to retrieve oocytes from the donor only after obtaining consent from the doctor, with no more than seven oocytes being retrieved from the donor during one cycle, and it shall be the duty of the clinics to ensure controlled ovarian stimulation of woman in order to prevent ovarian hyperstimulation. In addition, the amendment also provides that not more than three oocytes or embryos may be placed in the uterus of a woman during the treatment cycle in such manner as may be specified.

3. Notification of Surrogacy Regulations, 2023[3]

The MoHFW, *vide* notification no. G.S.R. 270(E), dated April 5, 2023, notified the Surrogacy Regulations, 2023. The new regulations provide the procedures for the for transaction of business at the meetings of National Assisted Reproductive Technology and Surrogacy Board (National Board) and State Board and their quorum requirements. The said regulations also amend Section 4 of the Surrogacy (Regulation) Act, 2021 ("**Surrogacy Act**"), to the effect that under clause (iii) which states "no surrogacy or surrogacy procedures shall be conducted or initiated, unless the Director or in-charge of the surrogacy clinic and the person qualified to do so are satisfied, for reasons to be recorded in writing, that the following conditions have been fulfilled", the following condition under sub-clause (c) be added *"If the appropriate authority is of opinion that the eligibility condition for surrogacy other than those mentioned in the Surrogacy (Regulation) Act, 2021, the same may be sent to the National Board for consideration and approval before issuing the eligibility certificate"*.

4. Notification of Surrogacy (Regulation) Amendment Rules, 2023[4]

The MoHFW, *vide* notification no. G.S.R. 415(E) dated June 8, 2023, notified the Surrogacy (Regulation) Amendment Rules, 2023. It includes a new clause in the Surrogacy (Regulation) Rules, 2022 ("**Surrogacy Rules**"), which aims to define the term "Couple of Indian Origin" in the context of surrogacy arrangements as a couple where both the husband (male) and wife (female) are Overseas Citizens of India (OCI) cardholders in accordance with the Acts / Rules / Instructions / Guidelines being followed by the Ministry of Home Affairs from time to time, subject to fulfilment of various criteria as per the Surrogacy (Regulation) Act, 2021.

5. Notification of Cigarettes and Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Amendment Rules, 2023[5]

The MoHFW, *vide* notification no. G.S.R. 400(E), dated May 31, 2023, notified the Cigarettes and Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Amendment Rules, 2023. It seeks to amend the Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Rules, 2004. The new amendment rules provide for usage of health spots, messages and disclaimers

[1] https://egazette.gov.in/WriteReadData/2023/245630.pdf
[2] https://egazette.gov.in/WriteReadData/2023/244935.pdf
[3] https://egazette.gov.in/WriteReadData/2023/244934.pdf
[4] https://egazette.gov.in/WriteReadData/2023/245091.pdf
[5] https://egazette.gov.in/WriteReadData/2023/246178.pdf

in curated contents of cigarette and tobacco products by online publishers and the procedure to be adopted by the authority in case of non-compliance.

6. Draft notification on New Drugs and Clinical Trials (Amendment) Rules, 2022[6]

The MoHFW, *vide* notification no. G.S.R. 364(E), dated May 11, 2023, notified the Draft Rules of New Drugs and Clinical Trials (Amendment) Rules, 2022. The MoHFW, by virtue of the said amendment, has defined the term *"Clinical Research Organisation"* ("**CRO**") to mean "a body commercial or academic or of other category owned by an individual or an organisation having status of legal entity by whatsoever name called to which the sponsor may delegate or transfer some or all the tasks, duties and/or obligations regarding clinical trial, such transfer or delegation of contractual transfers or obligations must be in writing." The Draft Rules also provide the procedure related to CRO registration, validity, conditions, inspection, suspension and the requisite forms.

7. Notification of Accessibility Standards for Health Care[7]

The MoHFW, *vide* notification no. F. No. T.21017/20/2021-NCD.I dated May 4, 2023, notified the "Accessibility Standards for Health Care" for compliance by Government and private hospitals and other healthcare institutions and centres, in sync with the provisions of the Rights of Persons with Disabilities Act, 2016, which mandates the Central Government to formulate rules laying down standards of accessibility *inter alia* to facilities and services provided to the public in urban and rural areas.

8. Draft notification on Cosmetics Rules, (.....Amendment) Rules, 2021[8]

The MoHFW, *vide* notification no.G.S.R. 371(E) dated May 15, 2023, notified the Cosmetics Rules, (.....Amendment) Rules, 2021 to further amend the Cosmetics Rules, 2020. These rules deal with the functions of the Central Cosmetics Laboratory, including its functions, criteria for cancellation, and suspension of licences and certain amendments in relation to State Licensing Authorities to ensure better enforcement of the Cosmetics Rules, 2020.

9. Circular on licensing regime of Class C&D non-notified medical devices[9]

The Central Drugs Standard Control Organisation ("**CDSCO**") *vide* circular no. F.No.29/Misc/03/2022-DC(94) dated April 12, 2023, has declared that Class C&D non- notified medical devices, which are currently under mandatory registration, in accordance with G.S.R. 102 (E) issued on February 11, 2020, under the Medical Device Rules, 2017, will be under the licensing regime with effect from October 1, 2023.

10. Notifications/Orders by the National Pharmaceutical Pricing Authority ("NPPA") and other Price Control Related Measures

a) Corrigendum issued by NPPA in relation to ceiling price of three drugs[10]

The NPPA, *vide* order S.O. 1697(E) dated April 12, 2023, has notified modified ceiling prices for Haloperidol, Levofloxacin 250 mg and Levofloxacin 500 mg.

b) Notification of Drugs (Price Control) Amendment Order, 2023[11]

The NPPA, *vide* order S.O. 2165(E) dated May 11, 2023, has notified the Drugs (Price Control) Amendment Order, 2023, with amendments related to retail price of new drugs, which have become off patent or are about to become off patent and revision of ceiling price of scheduled formulation after expiry of patent issued under the Patents Act,1970. The said order further states that the retail price of the new drug will be calculated by reducing 50 per cent of the price calculated pursuant to Para 4(1) of the Drugs (Price Control) Order, 2013 ("**DPCO 2013**") and in case of unavailability of the drug in the domestic market, the retail price of the said drug shall be fixed pursuant to Para 3(2) of the DPCO, 2013.

c) Notification of Drugs (Price Control) Second Amendment Order, 2023[12]

The NPPA, *vide* order S.O. 2324 (E) dated May 25, 2023, has notified the Drugs (Price Control) Second Amendment

6 https://egazette.gov.in/WriteReadData/2023/245863.pdf
7 https://egazette.gov.in/WriteReadData/2023/245810.pdf
8 https://egazette.gov.in/WriteReadData/2023/245904.pdf
9 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTAwMjI=
10 https://egazette.gov.in/WriteReadData/2023/245126.pdf
11 https://egazette.gov.in/WriteReadData/2023/245818.pdf
12 https://egazette.gov.in/WriteReadData/2023/246115.pdf

Order, 2023, with amendments in Schedule II of the DPCO, 2013, such as proforma for submission of revised prices for scheduled formulations, price list, details in relation to discontinuance of the product.

d) **Corrigendum issued by NPPA in relation to ceiling price of Povidone Iodine[13]**

The NPPA, *vide* order S.O. 2168(E) dated May 11, 2023, has notified the modified ceiling price for Povidone Iodine - Solution 4%.

e) **Advisory Order on fixation of ceiling prices of twenty formulations and retail of five new drugs under DPCO, 2013[14]**

The NPPA, *vide* order S.O. 2123(E) dated May 4, 2023, has notified the fixation of ceiling prices of twenty formulations and fifteen new drugs (retail) under the DPCO, 2013 of Aceclofenac and Paracetamol Tablets, Pantoprazole (EC) and Levosulpiride (SR) Capsules, Ofloxacin and Betamethasone Sodium Phosphate Eye/ Ear Drops to name a few.

f) **Advisory Order on fixation of retail prices of twenty-three formulations under DPCO, 2013[15]**

The NPPA, *vide* order S.O. 2539(E) dated June 8, 2023, has notified the revised retail prices of twenty-three formulations, including Aceclofenac + Paracetamol + Serratiopeptidase Tablet, Atorvastatin, Clopidogrel and Aspirin Capsule, Isoniazid, and Permethrin, to name a few.

g) **Advisory Order on fixation of ceiling prices of fifteen formulations under DPCO, 2013[16]**

The NPPA, *vide* orders S.O. 2540(E) dated June 8, 2023, has notified the ceiling prices of fifteen scheduled formulations, including Thiopentone. Permethrin, Sumatriptan, Clofazimine, Dapsone, Warfarin, and Isoniazid, to name a few.

11. Notifications by the Food Safety Standards Authority of India ("FSSAI")

a) **Draft notification of Food Safety and Standards (Prohibition and Restrictions on Sales) Amendment Regulations, 2023[17]**

The FSSAI, *vide* notification F. No. REG-11027/2/2022, dated

April 27, 2023, has notified the draft Food Safety and Standards (Prohibition and Restrictions on Sales) Amendment Regulations, 2023 to further amend the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 enacted in exercise of the powers conferred by clause (l) of subsection (2) of Section 92 read with Section 26 of Food Safety and Standards Act, 2006 ("**FSS Act**"). The new draft amendment regulations provide that Multi Source Edible Oil shall not be sold in packages weighing more than 15 litres and the clauses requiring BIS certification for certain infant foods and ISI certification on condensed milk are omitted. Furthermore, the AGMARK certification mark for Multi Blended Edible Vegetable Oils and Fat spreads are omitted.

b) **Draft Notification Food Safety and Standards (Alcoholic Beverages) Amendment Regulations, 2023[18]**

The FSSAI, *vide* notification F. No. STD/SP-21/T, dated May 11, 2023, has notified the draft Food Safety and Standards (Alcoholic Beverages) Amendment Regulations, 2023 to amend the Food Safety and Standards (Alcoholic Beverages) Regulations, 2018. The amendment regulations relate to changes in the definitions of certain alcoholic beverages, including 'Ready to drink/Low alcoholic beverages', 'Country liquors', 'Honey wine', 'wine from other agricultural and plant sources (WAPS)' and 'Nitro Craft beer'. Furthermore, the amendment regulations set out the Indian liquors

[13] https://egazette.gov.in/WriteReadData/2023/245824.pdf
[14] https://egazette.gov.in/WriteReadData/2023/245710.pdf
[15] https://egazette.gov.in/WriteReadData/2023/246403.pdf
[16] https://egazette.gov.in/WriteReadData/2023/246403.pdf
[17] https://egazette.gov.in/WriteReadData/2023/245490.pdf
[18] https://egazette.gov.in/WriteReadData/2023/245867.pdf

(Distilled liquor, Undistilled liquor, Low alcoholic beverages) in Annexure-1.

c) **Press Note on prohibition of deceptive claims or advertisements under Food Safety Standards Act, 2006**[19]

The FSSAI, has released a press note on Food Safety and Standards (Advertisements & Claims) Regulations, 2018 under which deceptive claims or advertisements are prohibited and are punishable offences under Section 53 of the FSS Act. The press note specifies that every permitted nutrient based claim is required to meet the criteria stipulated under the said regulations. To ensure compliance, Food Business Operators ("**FBO**") are being directed to submit scientific evidence for health claims made on the product.

d) **Advisory Order on extension of permission to use old pre-printed packaging materials to Tea Manufacturing FBOs/ Estates**[20]

The FSSAI, *vide* an advisory order dated April 13, 2023, has decided to grant time extension of six months for 2nd permission to Tea estates/ Tea Manufacturing FBOs to use non-retail bulk tea packages. Also, FBOs who have already been granted approval letters for utilisation of pre-printed packaging material for three months will read the extension mentioned as six months.

e) **Advisory Order on re-operationalisation of the standards of Crude Corn (Maize) Oil under Section 16(5) of the FSS Act**[21]

The FSSAI, *vide* an advisory order dated April 24, 2023, has allowed FBO's to import crude corn (maize) pursuant to the draft Food Safety Standards (Food Product Standards and Food Additives) Amendment Regulations, 2022. The proposed draft amendment has been issued to re-operationalise 2.2.9 sub regulation relating to Solvent Extracted Crude Vegetable Oils (not for direct consumption) of the draft Food Safety Standards (Food Product Standards and Food Additives) Amendment Regulations, 2022 in relation to "solvent extracted crude vegetable oils (not for direct human consumption)".

f) **Advisory on Enforcement of Plastic Waste Management Rules, 2016**[22]

The FSSAI, *vide* an advisory dated June 16, 2023, has released a direction in reference drawn to the Ministry of Environment, Forest, and Climate Change. The advisory direction notes that the Ministry of Environment, Forest, and Climate Change has notified the Plastic Waste Management Amendment Rules, 2021, which prohibits manufacturing, import, stocking, distribution, sale, and use of single-use plastic items. Under the said advisory direction, Food Safety Officers and Designated Officers of their respective jurisdictions are directed to ensure compliance with the issued Plastic Waste Management Amendment Rules, 2021.

g) **Advisory Order to enforce the FSS Act and Rules/ Regulations made under it regarding FBO having central licenses**[23]

The FSSAI, *vide* an advisory order dated May 12, 2023, has issued an order to enforce the FSS Act and Rules/Regulations made under it regarding FBOs having central licenses. The issued order lays down the enforcement directions in case of overlapping jurisdictional issues between State and Central Food Safety Officers, keeping in view the objectives of the FSS Act as well as the overall administrative efficiency in respect of FBOs having central licenses.

[19] https://www.fssai.gov.in/upload/press_release/2023/04/64436abae6d6fPRESS_NOTE_21042023.pdf
[20] https://www.fssai.gov.in/upload/advisories/2023/04/6437f7a4673b5order13042023.pdf
[21] https://www.fssai.gov.in/upload/advisories/2023/04/64464fd4b6228Direction_Re-operationalization_Crude%20Corn%20(Maize)%20Oil.pdf
[22] https://www.fssai.gov.in/upload/advisories/2023/06/648c55b8155d620230616110757356.pdf
[23] https://www.fssai.gov.in/upload/advisories/2023/05/646b0ba9d0fe2Enforcement,%20FSSA,2006.pdf

News Updates

1. Mankind Pharma lists on the stock exchanges[24]

Mankind Pharma IPO worth INR 43,264-crore IPO was listed on the stock exchange(s) on May 9, 2023. The IPO issue had closed on April 27, 2023, with bids for 2.45 crore shares against 2.80 crore shares on offer. This is the largest IPO so far this year and one of the biggest ever by a domestic drug maker since Gland Pharma came up with its Rs 6,480 crore public issue. Mankind Pharma is the fourth-largest Indian pharmaceutical company in terms of domestic sales and the third largest in terms of moving annual total sales volume as of December 2022.[25]

2. Sanofi India approves demerger of its consumer health business[26]

Healthcare solutions provider Sanofi India has announced that its Board has approved the demerger of its consumer health care business. Pending approval from regulators and shareholders, the proposed demerged entity will be called Sanofi Consumer Healthcare India (SCHIL), which will remain a wholly owned subsidiary of Sanofi India. Once the demerger is complete, Sanofi will continue to own 60.4% shareholding in both the entities, while Sanofi India's shareholders will obtain 1:1 SCHIL equity shares of INR 10 each, for each equity share owned. As per a statement released by the company, SCHIL, which is expected to maximise Sanofi's business potential in both pharmaceuticals and consumer healthcare, is expected to be fully operational by the second half of 2024.

3. Roche Diabetes Care set to manufacture its blood glucose device in India[27]

Roche Diabetes Care India has recently announced plans to manufacture its bestselling blood-glucose monitoring device 'Accu-Check-Active' in India. The device is made in collaboration with Sanmina-SCI India Pvt. Ltd. and Parekh Integrated Services Pvt. Ltd. The devices manufactured in India will also be used to meet the market demands in the US and Germany.

4. Department of Pharmaceuticals releases Guidelines for "Assistance to Medical Device Clusters for Common Facilities (AMD-CF)" scheme[28]

The Department of Pharmaceuticals (DoP), MoCF has come out with guidelines for Assistance to Medical Device Clusters for Common Facilities (AMD-CF) Scheme. Under the AMD-CF Scheme, there are two sub-schemes, which are expected to aid the domestic manufacturing capacity and improve the quality of clusters for sustainable growth of the medical

[24] https://www.thehindubusinessline.com/markets/ipo-screener-mankind-pharma-issue-closes-today/article66782575.ece
[25] https://economictimes.indiatimes.com/markets/ipos/fpos/mankind-pharma-ipo-what-gmp-signals-ahead-of-listing-on-tuesday/articleshow/100072778.cms?from=mdr
[26] https://www.thehindubusinessline.com/companies/sanofi-india-to-demerge-its-consumer-health-care-business/article66834167.ece
[27] https://www.financialexpress.com/healthcare/medicaldevices/roche-diabetes-cares-blood-glucose-monitoring-device-to-be-manufactured-in-india/3074443/
[28] https://pharmaceuticals.gov.in/sites/default/files/Guidelines%20of%20AMD-CF%20Scheme.pdf

devices sector. Furthermore, the AMD-CF Scheme aims to strengthen Medical Device clusters by providing financial assistance and/ or establish more Testing Laboratories for Medical Devices to ensure quality and sustainable growth. The guidelines envisage a proposed financial outlay for Common Infrastructure Facilities (CIF) for the Medical Device (MD) clusters, for which the support limit will be 70% of the approved project cost or Rs. 20 crore, whichever is less, as per the Scheme Steering Committee (SSC) approval.

5. World Bank approves $82 million for prevention of zoonotic, endemic diseases in India[29]

The World Bank has approved an $82 million loan towards the adoption of global best practices for animal health management to prevent, detect, and respond to endemic zoonotic, transboundary, and emerging infectious diseases. It will strengthen India's One Health approach, which recognises that people and animals are connected, given their shared environment. The $82 million loan from the International Bank for Reconstruction and Development (IBRD) uses the Program-for-Results (PforR) financing instrument that links disbursement of funds directly to the achievement of specific programme results. The loan has a maturity of 11.5 years with a grace period of 4.5 years.

6. India pushes for global IPR waiver in case of future pandemics[30]

In the aftermath of obtaining a five-year patent waiver for the manufacture of Covid-19 vaccines in 2022, India is set to push for a global patent waiver for the development of vaccines, therapeutics, and diagnostics to deal with future pandemics. India along with 80 other World Trade Organization ("**WTO**") members had proposed an action-plan for future pandemics at the mini-ministerial meeting of the WTO.

7. DCGI grants EUA to Omicron-specific mRNA-based booster vaccine[31]

The Drug Controller General of India ("**DCGI**") has granted Emergency Use Authorisation (EUA) to Omicron-specific mRNA-based booster vaccine "GEMCOVAC-OM" for Covid-19, which was developed using the indigenous platform technology by Gennova Biopharmaceuticals. The Department of Biotechnology ("**DBT**") has facilitated establishing Gennova's mRNA-based next-generation vaccine manufacturing for developing the platform technology from proof of concept till Phase I clinical trial of the prototype mRNA-based vaccine developed against the Wuhan strain. GEMCOVAC-OM is an Omicron-specific mRNA-based booster vaccine developed using the indigenous platform technology by Gennova in collaboration with DBT.

8. DCGI gives nod to AstraZeneca Pharma India for importing cancer drug[32]

The DCGI has granted approval to AstraZeneca Pharma India to import trastuzumab deruxtecan, which is used to treat metastatic breast cancer. The drug is a specifically engineered HER2-directed antibody drug conjugate (ADC). HER-2 is a protein found in many tumours and is a biomarker found in breast cancer tumours. The approval has been granted after taking into account a global, head-to-head, randomised, open label, registrational Phase-III trial, and the drug has been approved in over 40 countries worldwide.

9. Ministry of Minority Affairs grants Rs. 45.34 crore for promotion of Unani Medicine[33]

The Ministry of Minority Affairs, in an attempt to support the Central Council of Research in Unani Medicine (CCRUM) and National Institute of Unani Medicine (NIUM) Bengaluru, under the Ministry of Ayurveda, Yoga, Naturopathy, Unani, Siddha and Homeopathy Ayush ("**AYUSH**"), has approved a grant of INR 45.34 crore under the Pradhan Mantri Jan Vikas Karyakram (PMJVK), a centrally sponsored scheme (CSS). This grant will support the upgradation of Unani Medicine facilities at Hyderabad, Chennai, Lucknow, Silchar and Bengaluru. Under the approved grant, the Ministry has sanctioned a total amount of INR 35.52 crore to CCRUM and INR 9.81 crores to NIUM.

10. MoHFW launches the Comprehensive Ayush Health Management System and Education Learning Management System[34]

Union Minister of Health and Family Welfare Dr. Mansukh Mandaviya during the inaugural address at the National

[29] https://www.biospectrumindia.com/news/86/23072/world-bank-approves-82-m-for-prevention-of-zoonotic-endemic-diseases-in-india.html
[30] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/india-to-seek-pharma-ipr-waiver-for-future-pandemics/articleshow/100142635.cms
[31] https://www.businesstoday.in/coronavirus/story/covid-dcgi-grants-eua-to-omicron-specific-mrna-based-booster-vaccine-386325-2023-06-20
[32] https://www.business-standard.com/companies/news/astrazeneca-pharma-india-gets-dcgi-s-nod-for-cancer-treating-drug-123050301135_1.html
[33] https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1927151
[34] https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1925182

AYUSH Mission Conclave organised by Ministry of AYUSH, announced the launch of Information and Communication Technology initiatives namely AHMIS (Ayush Health Management Information System) and eLMS (Education Learning Management System). During the aforesaid event, Dr. Mandaviya noted "To fully empower the present healthcare system, it is important to integrate Ayush into mainstream public healthcare delivery as this integration can offer a more comprehensive and holistic approach to patient care, combining the strengths of both conventional medicine and Ayush systems of healthcare."

11. MoHFW launches SAKSHAM Learning Management Information System[35]

The MoHFW has launched SAKSHAM (Stimulating Advanced Knowledge for Sustainable Health Management), a Learning Management Information System (LMIS). This digital learning platform has been developed by the National Institute of Health & Family Welfare (NIHFW), New Delhi. SAKSHAM is a dedicated and unified platform for providing online training and medical education to all health professionals in the country. This digital learning platform will ensure inclusive capacity building of health professionals from primary health centres located in rural and remote areas all the way up to tertiary care and corporate hospitals in metropolitan cities.

12. Ministry of AYUSH and ICMR sign MoU to promote and collaborate on integrative health research[36]

A Memorandum of Understanding (MoU) has been signed between the Ministry of AYUSH and the Indian Council of Medical Research (ICMR) to promote and collaborate on integrative health research. This cooperation will focus on identified areas of national importance in healthcare to promote high impact research to generate evidence utilising modern scientific methods. This MoU shall *inter alia* explore the possibility of working on public health research, taking initiatives for addressing diseases of national importance and looking at possibilities of conducting high-quality clinical trials jointly in identified areas/ disease conditions of national importance with promising therapies of Ayush system to generate evidence for wider acceptance.

13. Cipla signs license agreement with Novartis to manufacture and market diabetes drug[37]

Cipla Ltd., a leading multinational pharmaceutical company, has signed a perpetual license agreement with Switzerland-based Novartis Pharma AG. As per the terms of the license agreement, Cipla will manufacture and market the Type-2 diabetes drug Galvus and Galvus combination brands from January 1, 2026. As per a statement released by the company, this agreement will contribute significantly to Cipla's portfolio in the diabetes care space, but will be subject to the fulfilment of certain conditions.

14. National Accreditation Board for Hospitals & Healthcare Providers launches Best Practices Club platform to encourage sustainable quality in healthcare and patient safety[38]

National Accreditation Board for Hospitals & Healthcare Providers ("**NABH**"), the national accreditation body for healthcare, has launched a platform named "NABH Best practices club" where the NABH accredited/ certified/ applicant hospitals can present and pitch best practices in their organisations. As per NABH statement, this will influence other hospitals to implement similar practices in their respective hospitals and achieve best possible outcomes.

[35] https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1922983
[36] https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1923378
[37] https://www.business-standard.com/companies/news/cipla-inks-licensing-pact-with-novartis-to-manufacture-mkt-diabetes-drug-123041000786_1.html
[38] https://nabh.co/Announcement/NABH%20Best%20Practices%20Club.pdf

15. First-ever Cannabidiol based product approved by CDSCO in India[39]

The CDSCO has given its nod to Zenara Pharma, a subsidiary of Hyderabad based Biophore India Pharmaceuticals, for the manufacture and sale of Cannabidiol active ingredient in India. Zenara Pharma has been given the approval for the manufacture and marketing of the final product: Cannabidiol Oral Solution 100mg/ml, which is used in treatment of neuro disorders. It is to be manufactured in USFDA and EU approved facilities in Hyderabad and Visakhapatnam.

16. Pharmacy Council of India issues clarification on Pharmacy profession[40]

The Pharmacy Council of India ("**PCI**") has issued a notification stating that pharmacy profession in the country is regulated by the PCI, which operates as a statutory body under the Ministry of Health & Family Welfare, Government of India. The PCI, *vide* the said notification, has clarified that the pharmacy profession is an independent profession and should not be categorised as a paramedical profession. Furthermore, it emphasises that pharmaceutical education and/ or profession should neither be linked with para-medical education nor be clubbed with para-medical profession.

17. Mansukh Mandaviya urges the Pharma Industry to establish a self-regulatory body[41]

The Minster for Health and Family Welfare, Mansukh Mandaviya speaking at the 8th Global Pharmaceutical Quality Summit, organised by the Indian Pharmaceutical Alliance, said that India should strive to maintain its reputation as the 'Pharmacy of the World', which was established during the Covid-19 crisis. In this context, he stated that the country has a zero-tolerance policy for any sort of quality compromise and a joint squad of regulators from both the states and Centre had been formed for conducting inspections at various premises. Mr. Mandaviya noted that like all other sectors there are a few people who try to compromise with the quality of the products and the Government is taking stringent actions against the companies involved in such types of malpractices. He urged the pharma industry to establish a self-regulatory body to monitor the quality of pharma products.

18. WHO Medical Product Alert: Contaminated Indian Made Cough Syrup found in Western Pacific Nations[42]

The World Health Organisation ("**WHO**") issued a Medical Product Alert N°4/2023 against substandard (contaminated) India-made cough syrup "GUAIFENESIN SYRUP TG SYRUP", which was found to cause child deaths, as found in the Marshall Islands and Micronesia. The samples of the GUAIFENESIN SYRUP TG SYRUP from the Marshall Islands were analysed by quality control laboratories of the Therapeutic Goods Administration (TGA) of Australia. The analysis found that the product contained unacceptable amounts of diethylene glycol and ethylene glycol as contaminants. As per the contents of the WHO Medical Product Alert, the stated manufacturer of the affected product is QP Pharmachem Ltd. (Punjab, India) and the marketer is Trillium Pharma (Haryana, India).

19. Generic Treprostinil injection launched by the Dr. Reddy's Laboratories[43]

Dr. Reddy's Laboratories has announced the launch of its generic Treprostinil Injection, which is the generic version of United Therapeutics Corporation's Remodulin (Treprostinil) Injection. The injection is to be used for the treatment of a variety of pulmonary arterial hypertension, as well as for reducing clinical deterioration. The injection is to be available as 20 mg/20 mL, 50 mg/20 mL, 100 mg/20 mL or 200 mg/20 mL vials.

20. Mankind Pharma geared up to inaugurate INR 300-crore facility for infertility treatment[44]

Mankind Pharma, in an attempt to become the world's maximum producer of dydrogesterone[45] and compete with *Duphaston* (dydrogesterone), a synthetic hormone brand by Abbott India, is setting up a dedicated factory in Udaipur, Rajasthan, for the manufacture of the drug which is used as a treatment for infertility and prevention of miscarriage. The

[39] https://medicaldialogues.in/news/industry/pharma/biophore-india-pharma-gets-cdsco-nod-to-manufacture-market-cannabidiol-in-india-111533
[40] https://www.pci.nic.in/pdf/10-1_circular_19062023.pdf
[41] https://bwhealthcareworld.businessworld.in/article/-Union-Health-Minister-Asks-Pharma-Industry-To-Establish-Self-Regulatory-Body/24-06-2023-481656/
[42] https://www.who.int/news/item/25-04-2023-medical-product-alert-n-4-2023--substandard-(contaminated)-syrup-medicines
[43] https://www.thehindu.com/business/dr-reddys-unveils-generic-treprostinil-injection-in-us/article66764886.ece
[44] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/mankind-setting-up-rs-300-crore-unit-to-manufacture-fertility-hormone/articleshow/99223069.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst
[45] https://medtechasia.in/mankind-setting-up-facility-to-manufacture-fertility-hormone-2/

investment in the new plant is to the tune of INR 250-300 crore, and the plant is expected to commence manufacturing of dydrogesterone key starting materials, active pharmaceutical ingredients (API) and formulations by September-October.

21. Diplomatic action by India to protect drug exports after Gambia and Uzbekistan deaths[46]

In the aftermath of the deaths caused by India-made cough syrup, Indian diplomatic officials have been in talks with foreign authorities and powers to protect Indian interests and ensure that their purchase of Indian drugs does not reduce. Drugs made in India are one of the country's biggest exports, and after the deaths of 70 children in Gambia and 19 in Uzbekistan last year, the repute of the quality of India-made medicine has declined.

22. GSK launches Shingles vaccine in India[47]

GlaxoSmithKline Pharmaceuticals has launched its globally successful shingles vaccine '*Shingrix*' in India, at one-third the price, compared to the US. Shingrix is the world's first non-live, recombinant subunit vaccine to be administered intramuscularly in a two-dose manner. The vaccine has been launched for adults only, and is recommended for age groups 50 and above, as it provides protection against shingles, a rash-causing disease, which is caused by reactivation of the Varicella Zoster virus (VZV), responsible for causing chickenpox. As per recent sero-surveys, the VZV is present in more than 90% Indians over the age of 40.

23. Novel treatment for dry eye disease launched by Sun Pharma[48]

Sun Pharmaceuticals has launched a novelty dry eye treatment in India based on nanomicellar (NCELL) technology. The Mumbai-based company has launched the treatment called CEQUA, through one of its wholly owned subsidiaries for patients who have Dry Eye Disease (DED) with inflammation, a commonly occurring condition. As per the statement issued by Sun Pharma, CEQUA is the first dry eye treatment available in India that is delivered with nanomicellar technology and is backed by years of clinical experience in the US and other geographies

[46] https://www.reuters.com/business/healthcare-pharmaceuticals/india-diplomatic-effort-protect-drug-exports-after-gambia-uzbekistan-deaths-2023-04-05/
[47] https://timesofindia.indiatimes.com/business/india-business/gsk-pharma-rolls-out-shingles-vax-shingrix/articleshow/99740732.cms?from=mdr
[48] https://sunpharma.com/wp-content/uploads/2023/04/Sun-Pharma-launches-CEQUA-a-novel-therapy-for-Dry-Eye-Disease-in-India.pdf

Litigation Updates

1. The Supreme Court holds that Ayurveda Doctors do not stand at an equal footing as MBBS doctors in terms of pay since they do not perform equal work[49]

A Division bench of the Supreme Court ("**SC**"), *vide* judgment dated April 26, 2023, held that Ayurveda Medical Officers/ Doctors are not equal to MBBS Medical Officers/ Doctors in terms of pay. The Hon'ble Apex Court was hearing a set of appeals arising out of a common order passed by the Division Bench of the High Court of Gujarat ("**Gujarat HC**") confirming the order of the learned Single Judge, holding that the two respondents possessing a degree of BAMS (Bachelor of Ayurved in Medicine and Surgery) should be treated at par with the doctors holding MBBS degrees and be entitled to the benefits of the recommendations of the Tikku Pay Commission. The Apex Court while setting aside the order of the Gujarat HC observed that while both the categories of professionals performed equal work, there existed differences between the two. While highlighting the relevant differences, the SC found that scale of pay may vary depending on the academic qualifications even if the work being done is similar. The Court noted that allopathy doctors perform emergency duties such as conducting trauma care and complicated surgeries which is not true for Ayurveda practitioners and therefore Ayurveda doctors cannot claim equal pay as their counterparts in allopathy as they do not perform equal work. The Court also referred to relevant provisions of the Code of Criminal Procedure, 1973 ("**CrPC**") to reaffirm certain medical functions which could not be performed by Ayurveda doctors.

2. SC orders States and UTs to present their menstrual hygiene plans and strategies[50]

A Three-judge bench of the SC directed States and Union Territories ("**UTs**") to submit their menstrual hygiene management tactics and plans, which are being carried out using funds provided by the Central Government. The direction arose after a petition was filed by a social worker, seeking reliefs such as free sanitary pads and separate toilets to be provided for female students in Government and Residential Schools. The Hon'ble Apex Court accordingly directed the States and UTs to ensure that procedures to safely dispose sanitary pads are accessible in school premises. The Court also directed the States and UTs to provide information relating to the ratio of female toilets for residential and non-residential schools for their territories to the Mission Steering Group of the National Health Mission. The Court noted that the Central Government should coordinate with all States and UTs to formulate a uniform national policy, with sufficient leeway being granted to them to make adjustments, based on the prevailing conditions in their respective territories.

[49] State of Gujarat & Ors. Etc. v. Dr. P.A. Bhatt & Ors. Etc., Judgment dated April 26, 2023 in Civil Appeal Nos. 8553-8557 of 2014.
[50] Dr. Jaya Thakur v. Government of India and Ors., Order dated April 10, 2023 in W.P. (Civil) No. 1000/2022.

3. Bombay High Court rules that Manufacturer cannot be punished for standards prescribed after the date of drug manufacturing[51]

A Single judge bench of the Bombay High Court ("**Bombay HC**") has held that a manufacturer cannot be penalised for not adhering to prescribed standards if the said standard is notified post the date of manufacturing. In this case, by the time the requisite standard was notified by the State's Food and Drugs Administration, the drug had already been circulated in the market. A complaint was filed under Section 18(a)(I) of the Drugs and Cosmetics Act, 1940 ("**D&C Act**") and relying on the language of this provision, the Court held that no person shall face prosecution for manufacturing a drug prior to the date when the standard was prescribed. The Court further observed that under Section 18-B of the D&C Act, the authority can only order furnishing of relevant records, but cannot order withdrawal of the drug from the market.

4. Madras High Court rules that AYUSH Doctors cannot perform Ultrasound and Ultrasonogram[52]

The Madras High Court ("**Madras HC**"), *vide* an order dated May 26, 2023, dismissed the writ petitions filed by Tamil Nadu Ayush Sonologist Association and held that doctors holding degrees in Indian systems of medicine such as Ayurveda, Unani, Homeopathy, Siddha and Naturopathy and having undergone certificate courses in ultrasonogram are not qualified to perform ultrasonogram, ultrasound techniques or related diagnostic procedures on pregnant women. The Court held that only those persons authorised under the Pre-Conception and Pre-Natal Diagnostic Techniques Act, 1994 ("**PCPNDT Act**"), are eligible to carry out the said procedures. Since Ayush doctors have not been included in the said list and do not possess the required qualification under the PCPNDT Act, the Court held that they cannot perform these diagnostic procedures.

5. Madras HC rules that recommendation from MCI or AYUSH Department essential for running a clinic[53]

A Single Judge bench of Madras HC dismissed a petition filed by diploma holders, seeking an order restraining the health department from interfering with operation of primary healthcare clinics in the State. The Court held that persons holding a diploma in community medical service and essential drugs are not entitled to run primary health care clinics without recommendation from either the Medical Council of India ("**MCI**") or the AYUSH department. The Court relied on the Tamil Nadu Clinical Establishments (Regulations) Rules, 2018, to reaffirm that a registered medical practitioner means a person who possesses any of the government-recognised medical qualifications and is enrolled with councils for medical, dental, Siddha, Ayurveda, Unani or homoeopathy or the board of Indian medicine recognised by the Government of Tamil Nadu.

6. Madras HC notes problems associated with implementation of Surrogacy Act, directs Tamil Nadu to constitute district medical boards[54]

The Madurai Bench of the Madras HC, *vide* an order dated March 31, 2023, has observed that while the constitutionality of the Surrogacy Act is *sub judice* before the Hon'ble SC, there are problems associated with its implementation. The High Court noted the lack of awareness on part of the authorities and the resulting problems for eligible persons. While directing the state health department to form medical boards in each district for the purpose of granting eligibility certificates, the Hon'ble High Court also emphasised upon the need for sensitisation of relevant authorities.

7. Delhi HC issues directions for effective implementation of PCPNDT Act[55]

Emphasising the need for a "safe womb for the female foetus", a Single Judge bench of the Delhi HC issued directions for effective implementation of the PCPNDT Act. The Court noted that the purpose of the PCPNDT Act is to protect the female foetus and the mother from violence. The Court observed that women face immense pressure to bear sons and emphasised that sex-determination-based abortion perpetuates misogyny and gender inequality. Accordingly, the Court directed that the PCPNDT Act and Rules should be made known to District authorities, investigation officers, and prosecutors to inform them of the mandatory provisions of Section 28 and the protocol for filing a complaint under the Act. The Court also observed the need for *inter alia* online complaint portals, as well as training and sensitisation programmes for authorities under the PCPNDT Act.

[51] Kirti Kumar Jayantilal Patel and Ors v. State of Maharashtra, Judgment dated March 31, 2023 in Crim W.P. No. 912/2023.
[52] Tamil Nadu Ayush Sonologist Association v. Union of India, Order dated May 26, 2023 in Writ Petition Nos. 33547-33549 of 2017.
[53] K. Ganesan v. Government of Tamil Nadu and Ors., Judgment dated March 31, 2023 in W.P. 9708/2023.
[54] Priya Dharshini v. State of Tamil Nadu, Order dated March 31, 2023 in WP(MD) No. 4714 of 2023 and WMP(MD) No. 4371 of 2023.
[55] Manoj Krishna Ahuja v. State of NCT of Delhi & Anr., Judgment dated April 24, 2023 in CR.M.C. 1352/2023 and CRL.M.A. 5184/2023.

8. Karnataka High Court develops a three-pronged test to check eligibility under the Surrogacy Act[56]

The Karnataka High Court was faced with a petition filed by a married couple seeking to have a child through altruistic surrogacy. The situation gave rise to two significant legal hurdles – *first*, that the husband was 57 years old, thus having crossed the 55-year age criteria prescribed by the Surrogacy Act; and *second*, that the proposed surrogate was a family friend of the couple and thus not *'genetically related'* to them as required by the Surrogacy Act. The High Court observed that the provision in the Surrogacy Act which states that the "surrogate mother should be genetically related" to the couple, "defeats both altruism and logic". Accordingly, the Court developed the triple tests – genetic test, physical test, and economic test – which the Petitioner-husband has to pass to become eligible as a father by surrogacy. Thus, the Court directed the relevant authority to consider the couple's plea after using the triple tests and after ascertaining the details of the intending surrogate mother.

9. Delhi High Court seeks response from Centre on exclusion of "infertile couples" from surrogacy[57]

The Delhi High Court ("**Delhi HC**"), *vide* an order dated May 9, 2023, issued notice to the Central Government with respect to a petition challenging the notification dated March 14, 2023, which introduced an amendment to the Surrogacy Rules. The impugned notification (which amended Para 1(d) of Form 2 under Rule 7 of the Surrogacy Rules) excluded "*infertile couples*" from accessing surrogacy services by disallowing use of donor gametes and requiring that the couple undergoing surrogacy must have both gametes from the intending couple. The petition pointed out that such a condition violates the fundamental rights guaranteed under Articles 14 and 21 of the Constitution of India. The Petitioners further pleaded that genetic purity of the embryo cannot be the basis for depriving an infertile couple of their legal right to parenthood and surrogacy.

10. Delhi HC upholds ban on flavored tobacco as it is 'food' under FSS Act[58]

The Delhi HC was faced with a batch of appeals filed by the Commissioner, Food Safety against a decree passed by the Single Judge quashing various notifications issued by the State government prohibiting the manufacture, storage, distribution or sale of Gutka, Pan Masala, flavoured tobacco and similar products in the national capital. The Delhi HC observed that the prohibition which was sought to be enforced was the addition of tobacco or tobacco products to a food product, namely, Pan Masala because tobacco when mixed with other ingredients and additives mentioned therein, is *'food'* as defined under the FSS Act. Hence, the Court noted that the impugned notification only prohibited sale of tobacco as a mixture or combination with other products but did not prohibit tobacco *per se*. Thus, regulatory power exercised under the FSSAI cannot be invalidated merely because it is viewed as incidentally entrenching upon a provision in another statute. The Court noted that this was a policy decision and accordingly set aside the judgment of the Single Judge and upheld the impugned notifications.

11. Delhi HC issues notice in case relating to mandatory QR code for medical and food products[59]

The Delhi HC, *vide* an order dated May 9, 2023, sought response from the Central Government on a plea seeking compulsory use of QR codes on all food and medicinal products to make them accessible to visually impaired persons. The plea highlighted that a smartphone could scan the code on the label and convert the same to speech using the accessibility feature. The Petitioners further stated that this measure would increase the efficacy of healthcare in the State and reduce the risk of side effects and errors. The Petitioners accordingly stated that the concerned authorities have failed to take comprehensive measures or frame guidelines in this regard.

12. Gujarat HC observes Article 21 covers right to consume food with hygiene[60]

Dismissing a plea brought by owners of slaughterhouses and meat shops to reopen their establishments in Surat, the Gujarat HC held that the fundamental right to trade is subject to compliance with public health norms and food safety requirements. Earlier, the State authorities had shut down certain meat shops and slaughterhouses on account of non-compliance with licencing and regulatory norms, food and safety standards, hygiene imperatives, etc. The Court clarified that consumers have a fundamental right to consume safe and hygienic food under Article 21 of the Constitution of India. Thus, the Petitioners were rightly prevented by the State authorities from selling unstamped meat and operating unlicensed slaughterhouses. Accordingly, the Court directed that the meat shops and slaughterhouses cannot be reopened until they become fully compliant.

[56] H. Siddaraju v. Union of India, Judgment dated April 21, 2023 in W.P. No. 5861/2023 (GM-RES).
[57] Dr. Ravikant Chauhan and Anr v. Union of India and Ors., Order dated May 9, 2023 in W.P. (C) 6020/2023.
[58] Commissioner, Food Safety, GNCTD v. Sugandhi Snuff King Private Limited and Ors., Judgment dated April 10, 2023 in LPA 742/2022 and CAV 462/2022, CM APPL. 56085/2022, CM APPL. 56087/2022 and CM APPL. 56088/2022.
[59] The Kapil and Nirmal Hingorani Foundation and Ors. v. Union of India and Ors., Order dated May 9, 2023 in W.P. (C) 5985/2023.
[60] Patel Dharmeshbhai Naranbhai v. Dharmendrabhai Pravinbhai Fofani, Judgement dated April 11, 2023 in C/WPPIL/133/2021.

Transaction Updates

1. Temasek acquires controlling stake in Manipal Hospitals[61]

Temasek Holdings, Singapore state-owned investment arm, has acquired an additional 41% stake in Bengaluru-based Manipal Health Enterprises Private Ltd. This transaction takes Temasek's shareholding in Manipal Hospitals up to 59%, having held an 18% stake already. While the deal amount remains undisclosed, Temasek is said to have paid approximately INR 16,400 crore for the additional stake. This transaction will mark the exit of asset management firm TPG, and India's sovereign wealth fund, the National Investment and Infrastructure Fund (NIIF), which will sell their stakes to Temasek Holdings. As per news reports, this deal has valued Manipal Hospitals at INR 40,000 crore (USD 5 billion) of enterprise value, making this transaction one of the biggest in the Indian healthcare sector.

2. Sun Pharma to acquire Israel-based Taro Pharmaceutical Industries[62]

Sun Pharmaceutical Industries Ltd., India's biggest drug manufacturer, has announced its intention to acquire Israel-based Taro Pharmaceutical Industries through an all-cash deal. After the proposed acquisition, Taro will become a wholly owned subsidiary of Sun Pharma and will be delisted at the New York Stock Exchange (NYSE). Currently, Sun Pharma holds 78.48% stake in Taro and has proposed to acquire the outstanding ordinary shares for a purchase price of USD 38 per ordinary share. As per a statement released by Sun Pharma, the transaction, if fructified, will take the form of a reverse triangular merger under the Israeli Companies Law, 1999.

3. Ipca Labs acquires 33.38% stake in Unichem[63]

Ipca Laboratories Ltd., a leading Indian pharmaceutical company, announced that it has acquired 33.38% stake in Mumbai-based Unichem Laboratories for approximately INR 1034 crore. As per a statement released by Ipca, it is also preparing an open offer to Unichem's shareholders to acquire a further 26% stake for approximately INR 805 crore. Unichem is engaged in the manufactureing of branded generic drugs, while Ipca primarily produces active pharmaceutical ingredients ("**APIs**"). The deal is subject to approval from the Competition Commission of India and other regulatory approvals.

[61] https://www.reuters.com/markets/deals/temasek-acquires-41-stake-indias-manipal-health-2023-04-10/
[62] https://economictimes.indiatimes.com/markets/stocks/news/sun-pharma-offers-to-acquire-100-stake-in-taro-in-an-all-cash-deal/articleshow/100544807.cms
[63] https://www.reuters.com/markets/deals/indian-pharma-ipca-labs-buy-over-33-stake-unichem-2023-04-24/

4. Serum Institute doubles investment in Biocon's unit[64]

Serum Institute of Life Sciences (SILS), a subsidiary of Indian biotechnology and biopharmaceuticals company Serum Institute of India, has expanded its investment in Mumbai-based Biocon Biologics. As per news reports, SILS will convert its USD 150 million loan into equity, for an undisclosed stake. In November 2022, Serum had invested USD 15 million into Biocon. With the present transaction, SILS' aggregate equity investment in Biocon amounts to USD 300 million. As per this arrangement, Biocon's unit will also get access to Serum's 100 million vaccine doses annually, in addition to the distribution rights to Serum's vaccine portfolio. As per a statement released by Biocon, this transaction will help Biocon to reduce the USD 1.2 billion debt, which it had raised to acquire Viatris' biosimilars business last year.

5. Nirma Group acquires Stericon Pharma[65]

Nirma Group, an Ahmedabad-based diversified group, has acquired 100% stake in the Stericon Pharma, a Bengaluru-based eye-drop and contact lens solutions provider. Nirma Group operates in the healthcare industry through its subsidiary, Aculife Healthcare Pvt. Ltd., which sells medical devices and critical care medicines under its "Nirlife" and "Oneuse" brands. While the deal amount remains undisclosed, news reports suggest that the deal is within the INR 350-380 crore range. This transaction fits in with Nirma Group's wider objective to expand its presence in the healthcare sector in India.

6. Fortis to acquire Medeor Hospital for INR 225 crore[66]

Fortis Healthcare Limited announced that it has signed definitive agreements with VPS Group for the acquisition of Gurugram-based Medeor Hospital for an overall purchase consideration of INR 225 crore. This deal will be financed through a mix of debt and internal accruals. As per a statement released by Fortis, this transaction is likely to make Fortis the second largest healthcare services provider in Gurugram with over 850 beds and fits with Fortis' larger strategy to expand its presence in focus geographic clusters. The deal is expected to close by July 2023, pending completion of certain conditions stipulated in the definitive agreements.

7. Sun Pharma acquires 60% in Vivaldis Animal Health[67]

Sun Pharma announced that it is set to acquire 60% in Vivaldis Health & Foods Pvt. Ltd. in an all-cash deal of INR 143.30 crore. As per a statement released by Sun Pharma, it also intends to acquire the remaining 40% shareholding in Vivaldis in the future. Vivaldis is involved in the business of trading, distributing, manufacturing and marketing of drugs, food supplements and over the counter products in the companion animal segment of animal healthcare industry. This transaction comes soon after Sun Pharma's acquisition of US-based Concert Pharmaceuticals, and forms part of the company's larger strategy to expand its specialty portfolio.

8. Redcliffe Labs acquires Medicentre Sonography & Clinical Lab[68]

Redcliffe Labs, one of India's fastest growing technology-based diagnostics service providers, has acquired Rajasthan-based Medicentre Sonography and Clinical Lab. Medicentre is one of the biggest independent diagnostic labs in Rajasthan, having 10 labs and 40 collection centres in the region. As per news reports, while the valuation details and deal amount remain undisclosed, the pay-out structure will be a mix of cash and equity. As per a statement released by Redcliffe Labs, this acquisition blends with the company's larger strategy to expand its operations in India and establish a one-stop diagnostic services business with a wide selection of tests, especially for patients living in Tier-2 to Tier-4 cities of India.

9. Lupin set to acquire French pharma company Medisol for INR 160 crore[69]

Lupin Ltd., an Indian multinational pharmaceutical company, announced its plans to acquire French pharmaceuticals company, Medisol, for a purchase consideration of EUR 18 million (approximately INR 160 crore). The deal is expected to be completed by July 2023 and remains subject to approval from the French Ministry of Economics and Finance. Through

[64] https://www.businesstoday.in/industry/pharma/story/serum-institute-to-double-its-investment-in-biocon-unit-to-300-million-378706-2023-04-25
[65] https://www.livemint.com/companies/news/nirma-group-acquires-stericon-pharma-for-healthcare-expansion-deal-worth-350-380-crore-11680545214958.html
[66] https://www.businesstoday.in/industry/top-story/story/fortis-teams-up-with-vps-group-to-acquire-manesar-based-medeor-hospital-for-rs-225-crore-378193-2023-04-20
[67] https://www.cnbctv18.com/business/companies/sun-pharma-to-acquire-60-stake-in-animal-healthcare-company-vivaldis-16259911.htm
[68] https://www.financialexpress.com/healthcare/news-healthcare/redcliffe-labs-acquires-rajasthans-integrated-diagnostics-chain-medicentre-sonography-clinical-lab/3028596/
[69] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/lupin-to-acquire-french-firm-medisol-for-around-rs-160-cr/articleshow/100019680.cms?from=mdr

this acquisition, Lupin will gain access to Medisol's portfolio of seven generics injectable products in areas including pain management and cardiovascular diseases. As per a statement released by Lupin, this acquisition enables the company to expand its footprint into the European Union and strengthen its injectables franchise.

10. Fortis Healthcare to divest Vadapalani Hospital business[70]

Fortis Healthcare Limited has announced the signing of a definitive agreement for sale of its hospital business operations at Vadapalani, Chennai, to Sri Kauvery Medical Care (India) Limited for a sale consideration of ₹152 crore. The healthcare company informed about the all-cash deal in an exchange communication on June 22, 2023. The divestment deal is expected to fructify by the end of July 2023. The aforesaid divestment is a part of Fortis' ongoing portfolio rationalisation strategy to focus on deepening its presence in select geographic clusters where it has a sizeable presence.

11. SRL Diagnostics acquires Lifeline Laboratory[71]

SRL Diagnostics, a subsidiary of Gurgaon-based Fortis Healthcare Limited, has completed the acquisition of Lifeline Laboratory, a Delhi NCR-based technology-based pathology testing and services company for an undisclosed amount. The "Lifeline" brand will continue under the management of SRL Diagnostics. As per a statement released by Lifeline Laboratory, this strategic partnership is expected to accelerate the next phase of growth for the overall business.

12. Somerset Indus Capital acquires minority stake in Emil Pharmaceuticals[72]

Somerset Indus Capital Partners, a Mumbai-based healthcare focused private equity firm, has acquired a minority stake in Emil Pharmaceuticals Industries Pvt. Ltd., a Mumbai-based contract manufacturer of medicines, for a purchase consideration of INR 150 crore. While the size of the minority stake remains undisclosed, the deal will take place through a mix of primary and secondary sale. The investment outlay may increase in the near future. As per a statement released by Emil Pharmaceuticals, the funds raised will be used to widen its product basket, including expanding into nutraceuticals, as well as to modernise its pharmaceutical formulations' capacities and increase its global footprint.

13. Verlinvest acquires controlling stake in Ferty9 Fertility Center[73]

Verlinvest, an international, family-backed evergreen investment company, has announced its entry into India's healthcare sector, with the acquisition of a controlling stake in Ferty9 Fertility Center, a chain of fertility clinics in the Telangana region. This investment will enable Ferty9 to expand its reach across India and support the development of newer technologies and medical innovations, further strengthening Ferty9's position as a leading fertility clinic chain. Verlinvest's acquisition of a controlling stake in Ferty9 Fertility Centre marks their first foray into the healthcare sector in India, having spent several decades investing in the healthcare sector in Europe. Verlinvest aims to leverage its expertise in backing market-leading consumer focused brands and apply it to the healthcare industry.

14. Laurus Labs expands investment in ImmunoACT[74]

Laurus Labs Ltd., a Hyderabad-based pharmaceutical and biotechnology company, has announced the acquisition of an additional 7.24% stake in Immunoadoptive Cell Therapy Pvt. Ltd. (ImmunoACT). ImmunoACT is a Mumbai-based company engaged in developing novel cell and gene therapy technologies for treatment of cancer. The said acquisition will take place for a purchase consideration of INR 80 crore, and will take Laurus' stake in ImmunoACT up to 33.86% (on a fully diluted basis). As per a statement released by Laurus Labs, the infusion of capital will allow ImmunoACT to expedite the additional supply of its lead candidate for leukaemia, HCAR-19, as well as to expand its multi-location cGMP facilities and R&D of new product portfolios.

15. Zydus acquires 6.5% stake in Mylab[75]

Zydus Animal Health and Investments, a wholly owned subsidiary of Zydus Lifesciences, has entered into a Share Purchase Agreement with Rising Sun Holdings (an investment company owned by Adar Poonawalla, CEO, Serum Institute of India) and Mylab Discovery Solutions to acquire

[70] https://www.livemint.com/companies/fortis-healthcare-to-divest-vadapalani-hospital-business-for-rs-152-crore-11687490925668.html
[71] https://health.economictimes.indiatimes.com/news/diagnostics/srl-diagnostic-completes-acquisition-of-lifeline-laboratory/99403401
[72] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/emil-raises-rs-150-cr-from-somerset-indus-capital/articleshow/99741074.cms?from=mdr
[73] https://www.biospectrumindia.com/news/86/22977/verlinvest-acquires-controlling-stake-in-ferty9-fertility-center.html
[74] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/laurus-labs-invests-rs-80-crore-in-cell-gene-therapy-firm-immunoact/articleshow/100655546.cms
[75] https://www.biospectrumindia.com/news/86/23259/zydus-acquires-6-5-stake-in-mylab-for-rs-106-cr.html

65,06,500 equity shares, representing 6.5% of the total paid-up equity share capital of Pune-based startup Mylab. Mylab is engaged in the business of researching, developing, manufacturing, marketing and selling in-vitro diagnostics kits, equipment, reagents and related therapeutic products that are linked to its diagnostic portfolio and providing portfolio solutions to other labs and hospitals. The proposed investment will help Zydus to participate in the growing diagnostics space, which is expected to witness increased penetration through in-clinic solutions with Point of Care Testing (POCT) devices.

16. Tricog raises $8.5 million to scale business across Asia and Africa[76]

Tricog Health, a heart-focused healthtech startup based in Bengaluru, has secured $8.5 million in new series funding round from investors including Omron Healthcare and Sony Innovation Fund. The funding round also saw participation from existing investors The University of Tokyo Edge Capital, Inventus Partners, and SG Innovate, bringing Tricog's total funding to $30 million. The healthtech startup's TriCare platform provides an integrated solution for chronic disease management, enabling remote management of heart disease using medical data from connected devices at home and wearable devices like the Apple Watch. The healthtech startup plans to deploy the incoming funding to expand its geographical presence in Asia and Africa.

17. PAG to invest $200 million for minority stake in RK Pharma[77]

PAG, a Hong Kong based private equity firm, has acquired a significant minority stake in the US-headquartered pharmaceutical company, RK Pharma Inc. Terms of the deal remain undisclosed. Having operations in US and India, RK Pharma focuses on the development, manufacturing, and sale of high-quality and affordable generic pharmaceutical products. This transaction represents PAG's fifth India-focused private equity deal. According to a statement released by RK Pharma, this deal will help accelerate its growth plans, partnerships, and develop further innovative medicines alongside strengthening RK Pharma's position as a leading fully vertically integrated specialty injectable and ophthalmic pharmaceutical company.

18. PI Health Sciences set to acquire TRM India, Solis Pharma and Archimica[78]

PI Health Sciences (PIHS), a wholly owned subsidiary of Mumbai-based PI Industries, an agri-sciences company, has entered into agreements with Therachem Research Medilab LLC (TRM), to acquire TRM's Indian subsidiaries, namely TRM India and Solis Pharma Chem, as well as its assets in the US. PIHS focuses on research & development into pharmaceutical technologies, while TRM is a solutions provider catering to pharmaceutical and biopharmaceutical

[76] https://inc42.com/buzz/tricog-health-raises-8-5-mn-help-hospitals-clinics-diagnose-heart-problems/
[77] https://www.livemint.com/companies/start-ups/asian-investment-firm-pag-to-acquire-minority-stake-in-injectables-firm-rk-pharma-for-200m-in-latest-pharma-deal-11685986977226.html
[78] https://www.business-standard.com/markets/news/pi-industries-surges-10-on-twin-acquisitions-into-pharma-api-cdmo-space-123042800209_1.html

companies in the preclinical and clinical stages of rare diseases. The purchase consideration for this deal is USD 50 million with an additional payment of up to USD 2.5 million over the next six years in performance-linked payouts.

19. LTS Investment Fund acquires further stake in Evexia Lifecare[79]

As per news reports, LTS Investment Fund is set to acquire 40,00,000 shares in India's leading manufacturer of pharma and agricultural chemicals, Evexia Lifecare Ltd. This transaction is set to take place at an average price of INR 2.69 per share. Earlier, LTS had purchased 55,00,000 shares in Evexia at an average price of INR 2.43 per share. Evexia Lifecare manufactures a wide range of petrochemical downstream products, including *inter alia* special oils, petroleum sulphates, special chemicals and solvents for industrial applications like ink, leather, rubber and paint industries.

20. IvyCap Ventures invests INR 100 crore in Celsius start-up[80]

Celsius, a Mumbai-based start-up cold chain solutions provider, has raised INR 100 crore in a funding round led by IvyCap Ventures – one of India's leading homegrown venture capital funds. As per a statement released by Celsius, the company intends to use these funds to invest in food security, establish an unbroken cold supply chain, and develop smart-tech innovations to address challenges in the pharmaceuticals sector. Celsius presently owns approximately 4,500 reefer vehicles, seven distribution centres, 107 cold storage facilities, and 100 hyperlocal riders.

21. OrbiMed invests growth capital in Innvolution[81]

Orbimed, an American investment firm focused on making public and private investments in the Healthcare and Biotechnology industries, has announced investment of an undisclosed sum of growth capital into Innvolution Group, an Indian business group focused on interventional cardiology with a comprehensive portfolio of imaging and consumable products. The Innvolution Group comprises two companies – Innvolution Healthcare Private Limited (IHPL) and Innovation Imaging Technologies Private Limited (IITPL). Both these companies have announced a merger to form a single entity, which will operate under the Innvolution brand name. As per news reports, these funds will help Innvolution to invest further into its R&D initiatives, develop new products, and expand its footprint into foreign markets.

22. Glenmark Pharma considers selling stake in Glenmark Life Sciences[82]

As per news reports, Indian pharmaceutical company Glenmark Pharmaceuticals Ltd. is weighing the possibility of selling most of its 82% stake (worth approximately INR 4110 crore) in its subsidiary entity Glenmark Life Sciences (GLS). GLS is a developer and manufacturer of high value, non-commoditised APIs in chronic therapeutic areas. This move is an attempt by the company to lower its debt load, which amounted to nearly INR 2615 crore as on December 2022. To this effect, the company has hired experts to oversee the sale and has approached buyout funds to gauge interest.

23. Apollo Hospitals to sell stake in digital healthcare platform[83]

Apollo Hospitals Enterprise Ltd., an Indian multinational healthcare group operating the largest hospital chain in India, has announced its plans to sell up to 6% stake in its omnichannel healthcare platform, Apollo HealthCo Ltd. The company seeks to raise approximately USD 200 million from the said sale and is expecting a valuation of around USD 2.5 billion to USD 3 billion for its healthcare services platform.

[79] https://www.timesnownews.com/business-economy/companies/bulk-deal-lts-investment-fund-buys-additional-stake-in-evexia-lifecare-details-article-100124347
[80] https://www.businesstoday.in/entrepreneurship/story/mumbai-based-celcius-raises-rs-100-cr-from-ivycap-ventures-in-series-a-funding-376814-2023-04-10
[81] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/innvolution-secures-growth-capital-from-orbimed-to-advance-rd-expand-product-line-and-enter-global-markets/articleshow/99436679.cms?from=mdr
[82] https://www.reuters.com/markets/deals/indias-glenmark-pharma-weighs-selling-stake-glenmark-life-mint-2023-04-11/
[83] https://www.reuters.com/world/india/indias-apollo-hospitals-sell-stake-healthcare-platform-2023-06-02/

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Volume VI | Issue III | April 2023 - June 2023

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