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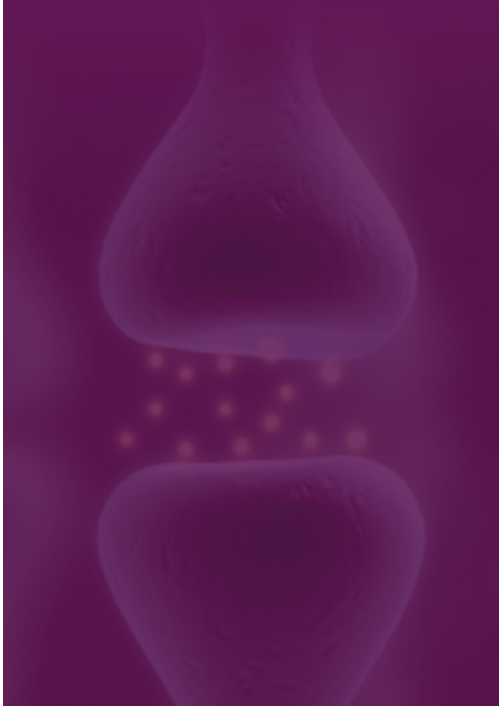
synapse

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

Volume VI | Issue II | January 2023 - March 2023

Table of Content



Dear Readers,

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

With financial sector headwinds looming large, especially considering the collapse of leading financial institutions across the US and Europe, the year 2023 has begun on a cautious note. Whilst our country's banking system has weathered such adversity in the past and come out stronger than before, it will have to be seen whether our economy, particularly the healthcare sector, will be able to withstand what experts term as 'global recession 2023'. On the public health front, the surge in H3N2 cases and resurgence of Covid-19 cases still looms large in the country. However, as we cross the milestone of three years since the pandemic first reared its ugly head, it has become abundantly clear why India has been bestowed with the epithet of 'Pharmacy of the World'. The country showed remarkable resilience and faith in the face of such terrible predicament by reducing its dependency on imports and giving impetus to domestic production, by looking at organic and inorganic opportunities, in the healthcare sector. With this, we hope to see a pick in M&A transactions in 2023, with the pharmaceutical and healthcare sectors being attractive targets for new investments.

In line with the previous few quarters, the sector witnessed important regulatory updates in the January-March 2023 quarter, which we have covered in this edition of Synapse. Most importantly, this quarter saw the notification of the Surrogacy (Regulations) Amendment Rules, 2023, which provides for amending the Surrogacy (Regulation) Rules, 2022, stipulating change in the substantive law, disallowing intending couples to commission surrogacy with donor gametes. In addition, any single woman (widow/ divorcee) undergoing surrogacy is also required to use self eggs and donor sperms to avail the surrogacy procedure. Further, the New Drugs and Clinical Trials (Amendment) Rules, 2023, were notified, which categorises non-clinical testing methods such as cell-based assays, organ chips and micro physiological systems, sophisticated and computer modelling, other human biology based testing methods and animal studies to assess the safety and efficacy of new or investigational drugs. The general requirements of non-clinical studies have also been specified. Additionally, the ICMR released the '*Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare*', with a view to guide effective yet safe development, deployment and adoption of Artificial Intelligence based technologies in the healthcare sector.

In the litigation space, the Hon'ble Supreme Court directed the Centre to file their responses on a plea seeking that Section 4(3)(I) of the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994, which prescribes an age restriction of 35 years on pre-natal and pre-conception diagnostic testing, curtails the reproductive rights of women. In another matter involving the prosecution of a doctor for unauthorised stocking of medicines, the

Court held that storage of small quantities of medicines by a registered medical practitioner cannot be punishable under the Drugs and Cosmetics Act, 1940. The SC, in a landmark matter, also eased the procedure for authorising passive euthanasia by allowing a two-tiered process, removing the earlier requirement of obtaining approval from a judicial magistrate (first class) to withdraw life support. In another matter, the Hon'ble Delhi High Court directed the National Consortium for Research and Development to consider a mechanism for increasing affordability and accessibility to therapies for rare diseases in India.

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

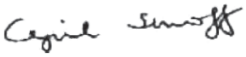
Cyril Amarchand Mangaldas, India's premier full-service law firm, has an industry leading and dedicated Pharmaceuticals, Healthcare and Life Sciences practice. Our class-leading practice specialists are always on top of the latest developments in the sector. In our endeavour to keep you abreast with the latest developments in this dynamic sector, we present to you the latest issue of Synapse. We hope you will 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 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 different 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 have enjoyed preparing it.

Regards,

CYRIL SHROFF



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Regulatory Updates

1. Notification on Assisted Reproductive Technology (Regulation) Rules, 2022[1]

The Ministry of Health and Family Welfare ("**MoHFW**"), *vide* notification no. G.S.R. 126(E), dated February 24, 2023, notified the Assisted Reproductive Technology (Regulations) Amendment Rules, 2023. The amendment provides that in case of transfer of gametes and embryos for personal use within or outside India, a declaration will be required to be furnished under Forms 16 to 24 and prior permission will be required to be obtained from the National Board.

2. Notification on Surrogacy (Regulation) Rules, 2022[2]

The MoHFW, *vide* notification no. G.S.R. 179 (E), dated March 14, 2023, notified the Surrogacy (Regulations) Amendment Rules, 2023. The said amendment to the Surrogacy (Regulation) Rules, 2022, provides for change in the substantive law as it disallows intending couples to commission surrogacy with donor gametes. The 2023 Amendment substitutes Para 1(d) of Form 2 (Consent of the Surrogate Mother and Agreement for Surrogacy) under Rule 7 of the 2022 Regulation Rules. Furthermore, a single woman (widow/ divorcee) undergoing surrogacy is required to use self eggs and donor sperms to avail the surrogacy procedure.

3. Notification on New Drugs and Clinical Trials (Amendment) Rules, 2023[3]

The MoHFW, *vide* notification no. G.S.R. 175(E), dated March 9, 2023, notified the New Drugs and Clinical Trials (Amendment) Rules, 2023 ("**NDCT Amendment Rules**"), notifying the categorisation of non-clinical testing methods such as cell-based assays, organ chips and micro physiological systems, sophisticated and computer modeling, other human biology based testing methods and animal studies to assess the safety and efficacy of new or investigational drug and the general requirements of non-clinical studies specified in the second schedule of the NDCT Amendment Rules.

4. Notification on Draft Medical Devices (Amendment) Rules, 2023[4]

The MoHFW, *vide* notification no. G.S.R. 157(E), dated March 1, 2023, notified the Draft Medical Devices Amendment Rules, 2023, that substituted "Central Medical Device Testing Laboratory" with "Medical Device Testing Laboratory" and defined the purpose of establishing State Medical Devices Testing Laboratory. It is to test and evaluate medical devices and carry out any such function as assigned. Also, no medical device testing laboratory shall be so designated without accreditation from National Accreditation Body for Testing and Calibration Laboratories.

5. The Indian Council for Medical Research issues Guidelines for Umbilical Cord Blood Banking, 2023[5]

The Indian Council for Medical Research ("**ICMR**") released the *Guidelines for Umbilical Cord Blood Banking: Collection, Processing, Testing, Storage, Banking and Release for Clinical Application,* 2023. These guidelines have been created with the objective of providing information on the scientific basis behind umbilical cord blood storage, status on its therapeutic use and guidance on allied concerns. These rules are intended to supplement the existing regulatory requirements prescribed under the Drugs and Cosmetics Act, 1940 ("**D&C Act**"), and Drugs Rules, 1945 ("**Drugs Rules**"), for Umbilical Cord Blood Banking.

6. ICMR Guidelines for use of Artificial Intelligence in health sector[6]

The ICMR with a view to "guide effective yet safe development, deployment and adoption of Artificial Intelligence ("**AI**") based technologies", has formulated and released *'Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare'*. With the growing use of AI tools in every sphere of science, including healthcare, ICMR's move aims to provide for an ethically sound policy for the regulation and application of AI in the healthcare sector. It also contributes to the dialogue on use of AI in the Indian healthcare sector, after the launch of Ayushman Bharat Digital Mission ("**ABDM**"), which seeks to create online repositories for easy transfer of health data through the creation of electronic health record ("**EHR**") for each citizen.[7]

[1] https://egazette.nic.in/WriteReadData/2023/243901.pdf
[2] https://egazette.nic.in/WriteReadData/2023/244368.pdf
[3] https://egazette.nic.in/WriteReadData/2023/244322.pdf
[4] https://egazette.nic.in/WriteReadData/2023/244036.pdf
[5] https://main.icmr.nic.in/sites/default/files/upload_documents/GUCBB_F.pdf
[6] http://www.pharmabiz.com/NewsDetails.aspx?aid=156947&sid=1
[7] https://pib.gov.in/PressReleasePage.aspx?PRID=1908041

7. The National Accreditation Board for Hospitals and Healthcare Providers issued Draft NABH Certification of ABDM Healthcare Solutions[8]

The National Health Authority ("**NHA**"), in collaboration with the National Accreditation Board for Hospitals and Healthcare Providers ("**NABH**"), *vide* a notification NABH/Notification/2023/0636, dated January 24, 2023, notified the Draft NABH Certification of ABDM Healthcare Solutions to certify the HMIS/LMIS/Clinic solutions that have been integrated with the ABDM Sandbox.

8. Notification on exemption from Customs Duty for Covid-19 vaccine until March 31[9]

The Ministry of Finance, *vide* notification G.S.R. 22(E), dated January 13, 2023, has notified that Covid-19 vaccines imported by the Central and State Government would be exempted of customs duty till March 31, 2023.

9. Central Drugs Standard Control Organisation ("CDSCO") issues list of approved PCR Kits for testing of Covid-19[10]

The CDSCO, on January 25, 2023, released a list of approved PCR Kits for Covid-19 testing. The release features the names of 272 companies.

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

a) Advisory Order on fixation of retail prices and ceiling price of 128 formulations

The NPPA, *vide* order S.O. 193(E), dated January 11, 2023, has fixed the retail and ceiling prices of 128 formulations. The ceiling prices have been fixed for antibiotic injections of Amoxicillin and Clavulanic acid; Vancomycin, Salbutamol, Trastuzumab, Temozolomide, Ibuprofen and paracetamol, among others.

b) Office Memorandum on extension of last date for filing statutory forms prescribed under Drugs (Price Control) Order, 2013[11]

The NPPA, *vide* Office Memorandum, dated February 16, 2023, has extended the last date for filing statutory forms (Form III, V and VI) prescribed under the Drugs (Price Control) Order, 2013 ("**DPCO 2013**"), to March 31, 2023.

c) Advisory Order on fixing retail prices of seventy-four formulations[12]

The NPPA, *vide* order S.O. 878(E), dated February 24, 2023, has notified the fixing of retail prices of 74 formulations.

d) Advisory Order on revised ceiling prices of eighty scheduled formulations[13]

The NPPA, *vide* order S.O. 879(E), dated February 24, 2023, has notified the revised ceiling prices of 80 scheduled formulations.

e) Advisory Order on revised ceiling prices of specific scheduled formulations[14]

The NPPA, *vide* order S.O. 881 (E), dated February 24, 2023, has notified the revised ceiling and retail prices of Methylcobalamin, Alpha Lipoic Acid, Vitamin D3, Pyridoxine Hydrochloride & Folic Acid Tablet.

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

a) Notification of Food Safety and Standards (First Amendment) Rules, 2022[15]

The MoHFW, *vide* notification G.S.R. 33 (E), dated January 16, 2023, has notified the Food Safety and Standards (First Amendment) Rules, 2022, whereby addition of designated officer position, qualification of Food Safety Officer and Food Analyst, form of notice to the Food Business Operator ("**FBO**") were made.

[8] https://www.nabh.co/Announcement/Public%20Notice%20for%20NABH%20Certification%20Of%20ABDM%20Healthcare%20Solutions%20(CAHS%20-1).pdf
[9] https://egazette.nic.in/WriteReadData/2023/241933.pdf
[10] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTgyNA==
[11] https://www.nppaindia.nic.in/wp-content/uploads/2023/02/IPDMS-2.0-date-31-03-2023-full.pdf
[12] https://www.nppaindia.nic.in/wp-content/uploads/2023/02/Retail_74_English.pdf
[13] https://www.nppaindia.nic.in/wp-content/uploads/2023/02/CP_80_English.pdf
[14] https://www.nppaindia.nic.in/wp-content/uploads/2023/02/CP_80_English.pdf
[15] https://egazette.nic.in/WriteReadData/2023/242131.pdf

b) **Notification of Aadhaar Authentication Services for Licensing/ Registration of Food Business Operators[16]**

The MoHFW, *vide* order no. S.O.333(E), dated January 16, 2023, has notified using digital platforms to ensure good governance, namely that citizens will be required to undergo Aadhaar authentication process for registration, licensing, inspection of FBOs, and verification of candidates attending training and certification programmes.

c) **Notification of Food Safety and Standards Authority of India (Financial) Regulations, 2023[17]**

The FSSAI, *vide* notification F.No. 11012/038/2016-2017/FSSAI/F&A, dated January 20, 2023, has notified the Food Safety and Standards Authority of India (Financial) Regulations, 2023, wherein the FSSAI would have to maintain a fund, i.e. FSSAI Fund to further the objectives enshrined under the Food Safety and Standards Act, 2006 ("**FSS Act**").

d) **Notification of Food Safety and Standards (Food Products Standards and Food Additives) First Amendment Regulations, 2023[18]**

The FSSAI, *vide* notification F.No. Std / Notifications / 35.1 / 2021., dated January 11, 2023, has notified the Food Safety and Standards (Food Products Standards and Food Additives) First Amendment Regulations, 2023. Vide the said amendment, the FSSAI has specified the identity standards for Basmati Rice (including Brown Basmati Rice, Milled Basmati Rice, Parboiled Brown Basmati Rice and Milled Parboiled Basmati Rice).

e) **Notification of Food Safety and Standards (Food Products Standards and Food Additives) Second Amendment Regulations, 2023[19]**

The FSSAI, *vide* notification F. No. STD/FA/A-1.30/No.1/2020-FSSAI, dated February 1, 2023, has notified the Food Safety and Standards (Food Products Standards and Food Additives) Second Amendment Regulations, 2023. Vide the said amendment, food product categories such as 'Solvent Extracted Crude Vegetable Oils', 'Desiccated Coconut', 'Wheat Flour' and 'Papad' were added. Furthermore, the authority framed and notified comprehensive group standards for 15 millets, based on eight major criterias, *i.e.* maximum limits for moisture content, uric acid content, extraneous matter, other edible grains, defects, weevilled grains, and immature and shrivelled grains, to ensure availability of good quality (standardised) millets in domestic and global markets.

f) **Advisory Order issued on instant renewal of license/ registration of FBOs[20]**

The FSSAI, *vide* an order dated January 11, 2023, has issued an advisory to streamline the process of licensing/ registration and its renewal of Food Business Operators ("**FBO**"). The order states that renewal of license/ registration would be granted instantly upon submission of the application by the FBO, without requiring any scrutiny/ approval from the concerned authority.

g) **Advisory Order issued for mandating manufacturers to upload lab testing reports every six months[21]**

The FSSAI, *vide* order dated January 13, 2023, has made it mandatory for manufacturers (including 'Repacker' and 'Relabellers') to either upload six monthly lab testing reports of Food Safety Compliance System ("**FoSCoS**"), or link such lab reports from InFolNet – Indian Food Laboratory Network, whenever sample analysis takes place in labs.

h) **Advisory Order issued for reducing initial license[22] application fee**

The FSSAI, *vide* order dated February 10, 2023, has issued an advisory for promoting new businesses/ start-ups and providing ease in obtaining FSSAI license for FBOs. It has

[16] https://egazette.nic.in/WriteReadData/2023/242104.pdf
[17] https://egazette.nic.in/WriteReadData/2023/242176.pdf
[18] https://egazette.nic.in/WriteReadData/2023/241910.pdf
[19] https://egazette.nic.in/WriteReadData/2023/243823.pdf
[20] https://www.fssai.gov.in/upload/advisories/2023/01/63bfa4c0d8679FSSAI%20Order%20dated%2011-01-2023.pdf
[21] https://www.fssai.gov.in/upload/advisories/2023/01/63c123ad24b17Order_Manufacturer.pdf
[22] https://www.fssai.gov.in/upload/advisories/2023/02/63e60f8240016FSSAI_Order.pdf

also reduced the initial application fee for such license to Rs. 1000. However, the total fee to be submitted by the FBO is exactly the same as provided under Schedule 3 of the FSS (Licensing and Registration of Food Businesses) Regulations, 2011.

i) **Advisory Order issued for de-recognition and de-notification of in-house testing laboratories[23]**

The FSSAI, *vide* order dated February 14, 2023, has issued an advisory stating that it shall not notify in-house testing laboratories of FBOs because of conflict of interest, location of such labs within the manufacturing area of the FBO, presence of directors of the FBO in the constitution of Board of Management, and difficulties caused due to regular monitoring and verification of minor details of in-house laboratories.

j) **Advisory Order issued for implementation of traceability application under Repurpose Used Cooking Oil initiative[24]**

The FSSAI, *vide* order dated February 24, 2023, has issued an advisory to streamline the Repurpose Used Cooking Oil ("**RUCO**") initiative and promote ease of doing business. It has developed the RUCO Traceability application, which is designed to inter alia track the RUCO ecosystem, generate disposal requests, and enrol Non Food Product units.

k) **Notification on Food Safety and Standards (Advertising and Claims) Second Amendment Regulations, 2022[25]**

The FSSAI, *vide* notification dated February 27, 2023, has issued directions under Section 16(5) of the FSS Act to enforce the FSS (Advertising and Claims) Second Amendment Regulations, 2022, to extend the implementation of Section 7(4) therein, stating the requirement of disclaimer on the front of the pack of the label in case trade mark contains adjectives such as "natural", "fresh", etc.

l) **Notification on revised guidelines for submission of applications for vegan logo and formats[26]**

The FSSAI, *vide* notification dated February 24, 2023, has issued revised guidelines for submission of applications for vegan logo and formats. The revised guidelines provide for application for endorsement under Food Safety and Standards (Vegan Foods) Regulations, 2022, approval/ rejection of endorsement of vegan logo and proforma for self-declaration.

m) **Notification Press Release prohibited the use of calcium carbide as fruit[27] ripening agent**

The FSSAI, *vide* press release dated March 10, 2023, has prohibited the use of calcium carbide, also referred to as "*masala*", as a ripening agent for artificially ripening fruits. Instead, Ethylene has been recognised as a safe ripening agent by the FSSAI, provided it does not come in contact with the fruit directly. The standard procedure for use of the same has also been issued by the FSSAI.

n) **Notification on FSS (Labelling and Display) Amendment regulations, 2022[28]**

The FSSAI, *vide* notification dated January 6, 2023, has reoperationalised select provisions provided in the annexure of draft FSS (Labelling and Display) Amendment regulations, 2022, such as; (1) optional provision regarding declaration of RDA per servings for Infant Nutrition Products; (2) insertion of explanation defining minimally processed foods in the context of raw agricultural minimally processed food, such as wheat, rice, pulses, etc.; (3) provision for labelling requirement on packaged food for non-retail sale; and (4) substituting the term pregnant and lactating mothers to pregnant and lactating women throughout the FSS (Labelling and Display) Amendment Regulations, 2022.

o) **Notice on Rapid Analytical Food testing (RAFT) Kit/ equipment/ Method[29]**

The FSSAI, *vide* notice dated January 9, 2023, has approved the RAFT Kit/ equipment/ Method with a format for revised application form. The application is required to be submitted within a period of thirty days, and failure to do the same will result in rejection of the application. Application for instruments used for analysis of general parameters like pH, density or routine laboratory equipment and accessories, etc., will be rejected. For renewal of RAFT application, declaration form and fees are to be sent to the FSSAI not less than 60 days prior to the expiration date on the certificate.

[23] https://www.fssai.gov.in/upload/advisories/2023/02/63edbdbfbfdfeDrecognition.pdf
[24] https://www.fssai.gov.in/upload/advisories/2023/02/63f8a90fd0d77RUCO.pdf
[25] https://www.fssai.gov.in/upload/advisories/2023/02/63fc929b699bbDirection_Enforcement.pdf
[26] https://www.fssai.gov.in/upload/advisories/2023/02/63fc4d9d71c4dGuidelines%20dated%2024th_February.pdf
[27] https://www.fssai.gov.in/upload/press_release/2023/03/640eb634762f0Press%20Release-%20Fruits%20English.pdf
[28] https://www.fssai.gov.in/upload/advisories/2023/01/63bcddfe6bdfaDirection_Reoperationalisation.pdf
[29] https://www.fssai.gov.in/upload/advisories/2023/01/63bcf01a746b6RAFT_Notice.pdf

News Updates

1. Dr. Rajeev Singh Raghuvanshi appointed as the new Drugs Controller General of India[30]

Dr. Rajeev Singh Raghuvanshi has been appointed as the new Drugs Controller General of India ("**DCGI**") for a three year period, ending February 28, 2025. He was previously serving as the Secretary and Scientific Director of the Indian Pharmacopeia Commission, a government mandated body that regulates standards for drugs in the country. Mr. Raghuvanshi takes charge as DCGI from Dr. PBN Prasad, who held the charge of the DCGI on a temporary basis after the expiry of the tenure of the erstwhile DCGI, Dr. VG Somani on February 15, 2023. Dr. Raghuvanshi has previously worked with the National Institute of Immunology and in the private sector.

2. E-pharmacies probed through show cause by DGCI over licence issue[31]

The DCGI served show-cause notices to around 20 e-pharmacy companies, alleging that they had flouted the provisions of the D&C Act and Drugs Rules, by selling and distributing drugs without license. The notices demanded response from e-pharmacies on why action should not be initiated against them for sale and distribution of medicines in contravention of the applicable law, within a two-day period. The DCGI has alleged that even after e-pharmacies were asked to comply with the Delhi High Court order dated December 12, 2018, passed in the matter of *Dr. Zaheer Ahmed vs. The Union of India,* they were found to be selling medicines online without a licence.

3. DCGI directs State drug controllers to ensure that sale of drugs is made under direct supervision of pharmacists[32]

The DCGI has directed drug controllers of all States and Union territories and the Pharmacy Council of India to ensure that pharmacists are physically present in retail medical stores and that medicines are sold under their direct supervision. In the letter issued on March 9, 2023, the DCGI has sought strict implementation of Section 42 (a) of the Pharmacy Act, 1947, and Rule 65 of the Drugs Rules in retail pharmacies. The directive was issued in furtherance to a letter received from Mr. Suresh Khanna, National General Secretary, IPA, Mumbai, who had highlighted issues pertaining to the implementation of certain provisions of the Pharmacy Act, 1947, and the D&C Act and Drugs Rules.

[30] https://health.economictimes.indiatimes.com/news/pharma/dr-rajeev-singh-raghuvanshi-is-new-drugs-controller-general-of-india/98156450
[31] https://www.business-standard.com/article/companies/india-s-drug-regulator-serves-show-cause-notice-to-online-pharmacies-123021000651_1.html
[32] https://www.deccanherald.com/national/dcgi-says-medicines-should-be-sold-only-under-direct-supervision-of-pharmacists-in-retail-medical-stores-1201090.html

4. 2023 Budget: Highlights for the Pharmaceuticals sector[33]

Significant Budget updates for the pharmaceuticals sector include; launch of Sickle Cell Anaemia Elimination mission to eradicate the disease by 2047, plans to introduce National Data Policy, establishment of nursing homes with 157 medical colleges established since 2014, as well as setting up three centres of excellence for enabling use of AI in health and agriculture. The Government announced plans for a new programme for research in pharmaceuticals, dealing in dedicated multidisciplinary courses on medical device and high-end manufacturing research. It also announced several plans to boost innovation and research, such as strengthening of the private and public partnership ecosystem as well as making the Indian Council for Medical Research Labs available for research by medical college faculty and R&D teams. Finally, the Government also exempted customs duty on denatured ethyl alcohol, increased customs duty on two chemicals – Styrene (from 2% to 2.5%) and Vinyl chloride monomer (from 2% to 2.5%), and reduced customs duty on acid grade fluorspar from 5% to 2.5% and on crude glycerine from 7.5% to 2.5%.

5. 2023 Budget: Highlights for the Food industry[34]

Major updates announced for the food industry in 2023 Budget include; the setting up of Agriculture Accelerated Fund to encourage start-ups in rural areas, targeted funding of Rs. 20 lakh crore for agricultural credit, setting up of open-source digital public infrastructure for agriculture, which will be a public good, and use of PAN as common identifier for all governmental agencies. The 2023 Budget also aims to transform India into a global hub for millets (Sri Anna) and hence support IIMR Hyderabad for boosting research on it. For ease of doing business, and in line with the proposed Jan Vishwas Bill, 2022, 39000 compliances have been reduced and 3400 legal provisions decriminalised. Finally, the 15% import duty on frozen krill, squid and mussels has been removed and basic customs duty on goods, other than textile and agriculture, has been reduced from 21% to 13%.

6. Special courts set up under D&C Act for speedy disposal of cases[35]

Dr. Bharati Pravin Pawar, the Minister of State for Health and Family Welfare, proposed the establishment of several fast track special courts in all states across the country for trial of offences under the D&C Act. The move aims to ensure that cases brought under the D&C Act are disposed on an expedited basis.

7. MoHFW is planning a uniform and coherent organ allocation policy[36]

The MoHFW has announced that it is in the process of developing a 'One Nation One Organ Allocation' policy, which would lay down a blanket uniform framework for organ allocation process. This comes after the Apex Court's directions to the MoHFW to act on the inconsistent policy nationwide, with various states having differential requirements and compliances for registration and other parts of the organ allocation process. The move would allow for a pan-India framework, increasing accessibility.

8. Tele-MANAS: Centre allocates Rs 120 crore for mental health programme[37]

The National Tele Mental Health Programme ("**NTMHP**") was launched in October, 2022, by the Government, to boost mental health services in India. Under this programme, the Government also launched the Tele Mental Health Assistance and Networking Across States ("**Tele-MANAS**"), to provide free tele-mental health services. For financial year 2022-23, a total of Rs. 120.98 crore has been allocated by the Government towards this scheme. And as on January 31, 2023, Tele-MANAS had received 43,861 calls from across India.

9. India spearheading G20 – an opportunity to strengthen talks on AMR[38]

With India at the forefront of the G20 summit and setting the agenda for several working groups, it is anticipated that one of the Health Working Group's priorities will be antimicrobial resistance ("**AMR**"), among others. AMR happens when the genetic makeup of germs is altered, resulting in drugs previously used to treat them becoming ineffective. India launched its National Action Plan on containment of Antimicrobial Resistance ("**NAP-AMR**") on April 19, 2017. To achieve the same, a national AMR surveillance network ("**NARS-Net**"), comprising state medical college labs, was established, to obtain high-quality data on AMR[39].

[33] https://www.pib.gov.in/PressReleasePage.aspx?PRID=1895315
[34] Ibid
[35] https://pib.gov.in/PressReleasePage.aspx?PRID=1909084
[36] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/health-ministry-working-on-one-nation-one-organ-allocation-policy/articleshow/97988751.cms
[37] https://pib.gov.in/PressReleasePage.aspx?PRID=1896958
[38] https://timesofindia.indiatimes.com/blogs/voices/indias-g20-presidency-a-perfect-opportunity-to-catalyse-deliberations-on-antimicrobial-resistance-amr/
[39] https://pib.gov.in/PressReleasePage.aspx?PRID=1896028

10. Sun Pharmaceuticals to recall 34,000 bottles of a drug due to manufacturing issue[40]

Sun Pharmaceuticals is recalling more than 34,000 bottles of Diltiazem Hydrochloride extended-release capsules (used in the treatment of angina, high blood pressure and some types of irregular heartbeats). The Mumbai-based drug major is recalling the lot due to "Failed Impurity (Desacetyl Diltiazem Hydrochloride) specification during stability testing and failed dissolution testing at the US Food and Drug Administration ("**USFDA**") laboratory." The affected lot had been produced at its Halol-based manufacturing facility in Gujarat and was being distributed in the US.

11. WHO alert against two cough syrups after death of 18 children in Uzbekistan[41]

The World Health Organisation ("**WHO**") issued Medical Product Alert N°1/2023[41] against two cough syrups (AMBRONOL syrup and DOK-1 Max syrup) manufactured by Noida-based Marion Biotech Private Limited as the same had resulted in the death of 18 children in Uzbekistan. Laboratory analysis undertaken by the Ministry of Health of the Republic of Uzbekistan revealed that these syrups contained "unacceptable" amounts of diethylene glycol and/or ethylene glycol, which prove toxic when consumed by humans and can be fatal.

12. Marion Biotech's license revoked after WHO alert[43]

In the aftermath of the Medical Product Alert issued by the WHO against two cough syrups made by Noida-based pharmaceutical firm, Marion Biotech Private Limited, the Uttar Pradesh Drugs Controlling and Licensing Authority has cancelled its manufacturing license, thereby ceasing their right to manufacture the two cough syrup concoctions. The Company's cough syrup Dok-1 was linked with the death of 18 children in Uzbekistan. As per reports, the firm's license was under suspension since January, after which a detailed inquiry was initiated.

13. SII seeks inclusion of Covovax on CoWIN portal after approval as booster dose by DCGI[44][45]

The DCGI has approved the market authorisation of Serum Institute of India's ("**SII**") Covovax (the Novavax vaccine made in India), as a heterologous booster dose for adults in India who have received two doses of Covishield or Covaxin. Hence, Mr. Prakash Kumar Singh, Director, Government and Regulatory Affairs at SII, wrote to MoHFW, requesting the inclusion of the vaccine as a booster shot on the CoWIN Portal.

14. First lot of iNCOVACC shipped across India[46]

Bharat Biotech has rolled out the first shipment of the world's first intranasal Covid-19 vaccine, iNCOVACC across various cities in India. iNCOVACC is a "*recombinant replication-deficient adenovirus vectored vaccine with a pre-fusion stabilized spike protein*". The vaccine a heterologous booster dose, which is to be administered in a two-dose schedule. The vaccine has been evaluated in three phases of clinical trials with successful results in each.

[40] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/sun-pharma-recalls-over-34k-bottles-of-generic-drug-in-us-due-to-manufacturing-issues/articleshow/97819610.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst
[41] https://www.businesstoday.in/latest/in-focus/story/india-may-issue-alert-on-marion-cough-syrup-exports-after-toxins-found-372259-2023-03-04
[42] https://www.who.int/news/item/11-01-2023-medical-product-alert-n-1-2023-substandard-(contaminated)-liquid-dosage-medicines
[43] https://www.livemint.com/news/india/up-cancels-marion-biotech-s-license-firm-linked-with-uzbek-cough-syrup-deaths-11679535158480.html
[44] https://www.livemint.com/news/india/covovax-gets-dcgi-nod-as-heterologous-booster-for-those-who-got-2-doses-of-covishield-covaxin-11673520423718.html
[45] https://www.thehindu.com/news/national/sii-seeks-inclusion-of-covid-jab-covovax-in-cowin-portal-as-heterologous-booster-dose-for-adults/article66397884.ece
[46] https://health.economictimes.indiatimes.com/news/pharma/bharat-biotech-dispatches-first-shipments-of-incovacc-across-india/97688683

15. India's first vaccine against cervical cancer launched by Serum Institute of India[47]

Serum Institute of India, a leading Indian biotechnology and biopharmaceuticals company, in partnership with the Department of Biotechnology, has launched indigenously developed human papillomavirus vaccine ("**HPV**") – "CERVAVAC", against cervical cancer in women. India accounts for nearly a fourth of all cervical cancer deaths globally. Government analysis shows that this vaccine provides prevention against 6, 11, 16 and 18 strains by generating antibodies against HPV.

16. Institute of Veterinary Biological Products signs MoU with Centre for commercial production of Lumpi-ProVac[48]

The Government of India has signed a pact with Pune based Institute of Veterinary Biological Products for mass production of Lumpi-ProVac, the indigenously developed vaccine to cure lumpy skin disease in cattle. Department of Agriculture Research and Education, Agrinnovate India Ltd has granted 'non-exclusive rights' for commercial production of Lumpi-ProVac for a period of 10 years. The vaccine has been developed by Haryana-based National Centre for Veterinary Type Culture and ICAR-National Research Centre on Equines, in collaboration with Uttar Pradesh-based ICAR-Indian Veterinary Research Institute. Prior to this, the Goat-pox vaccine was being used for lumpy skin disease.

17. DCGI grants approval to Akums to roll out anti-diabetes drug in India[49]

Akums Drugs and Pharmaceutical Limited, a leading contract manufacturing pharmaceutical company, has received DCGI's nod to launch 'Lobeglitazone' drug, which is used to treat type 2 diabetes. The drug is a new and improved formulation and promises significantly lower risk of hypoglycemia. Hence, Akums claims to be the first Contract Drug Manufacturing Organisation ("**CDMO**") to sell Lobeglitazone commercially.

18. CDSCO grants approval to AstraZeneca for cancer drug[50]

AstraZeneca has recently received CDSCO nod for its new drug – Durvalumab. The drug is used to treat biliary tract cancer in India. The drug promises better results and lower risks than the earlier treatment – chemotherapy. As per the statement issued by Dr Anil Kukreja, vice-president (Medical Affairs and Regulatory), AstraZeneca India, "This milestone approval now becomes the only immunotherapy-based combination treatment option in the country that offers significantly improved survival rates".

19. New anti-cancer agent discovered in India[51]

An alternative drug molecule called 'Ruthenium-Ferrocene Bimetallic', displaying antitumor properties (antiproliferation effect), with exceptional ability to inhibit the growth of blood vessels (anti-angiogenic effect) has been discovered by a team of scientists from IIT Hyderabad, Tata Institute of Fundamental Research in Mumbai, and the Agharkar Research Institute in Pune. This discovered molecule can be used to treat cancers that resist platinum drugs.

20. MSD India's Keytruda receives DCGI nod for use in cervical and esophageal cancer treatments[52]

Keytruda, a brand of MSD India, originally pembrolizumab, has received approval from the DCGI for use in persistent, or recurring cervical cancer with PD-L1 tumours, having a CPS of 1 or more. While this is the first cancer immunotherapy that has been approved in India for cervical cancer, Keytruda has also, as a first, been approved as the first line of treatment, other than chemotherapy for esophageal cancer patients.

21. Fujifilm India and Manipal Hospitals enter into agreement to store medical records for global access[53]

Fujifilm India and Manipal Hospitals have signed a long-term agreement, whereby Manipal Hospitals will be permitted to

[47] https://www.livemint.com/science/health/serum-institute-launches-country-s-first-hpv-vaccine-against-cervical-cancer-adar-poonawalla-11674574562639.html
[48] http://bwhealthcareworld.businessworld.in/article/Centre-Signs-Pact-With-IVBP-For-Commercial-Production-Of-Lumpy-Skin-Disease-s-Vaccine/02-01-2023-460037/
[49] https://theindianpractitioner.com/akums-gets-dcgi-approval-to-launch-anti-diabetic-drug-lobeglitazone-in-india/
[50] https://www.livemint.com/companies/news/astrazeneca-gets-cdsco-approval-for-cancer-treatment-drug-durvalumab-11676616728352.html
[51] https://thehealthmaster.com/2023/01/04/indian-scientists-discover-new-anti-cancer-agent/
[52] https://www.expresspharma.in/dcgi-approves-msd-indias-keytruda-for-treating-cervical-and-esophageal-cancers/
[53] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/manipal-hospitals-signs-up-with-fujifilm-for-storing-medical-records-for-global-access/articleshow/97278285.cms

utilise Fujifilm India's digital technology storage tool called Picture Archiving and Communication System ("**PACS**"), for storing sensitive medical documents and images. This move is expected to strengthen Manipal Hospitals' digital infrastructure, which would allow increased and easier access to medically sensitive information. As per a press statement issued by Manipal Hospitals, this agreement would allow 23 hospitals and 45 teleradiology centres under the aegis of Manipal Health Enterprises to benefit from global accessibility of sensitive medical data through PACS as well as storage of medical documents on secure off-site servers.

22. NIPER Hyderabad[54] receives lung cancer drug patent

The National Institute for Pharmaceutical Education and Research, Hyderabad ("**NIPER**"), has received patent approval for nano-formulation of lung cancer drug, Osimertinib Mesylate, by the Indian Patent Office. The patent for nano-formulation is for dealing with acquired resistance that is observed among patients during the first year of treatment.

23. AstraZeneca to venture into rare disease therapy[55]

AztraZeneca India is set to expand its portfolio drastically and enter the market for rare disease therapy in India, on receipt of regulatory approval for its drug 'Selumetinib'. The move will help address the severe unmet needs of patients living with rare diseases and transform their quality of life, especially when not much is known about the mortality rate associated with such diseases.

24. Pune's Enzene Biosciences launches adalimumab biosimilar[56]

Enzene Biosciences, a subsidiary of Alkem Laboratories, has begun commercial production and supply of its fourth biosimilar in the last eighteen months – adalimumab biosimilar. The launch is said to be competitively priced and since the biosimilar is used to treat autoimmune diseases

such as rheumatoid arthritis and ankylosis spondylitis, it is expected that the treatment cost will be reduced.

25. Ayushman Bharat aids in speedy OPD registrations in 365 hospitals[57]

In October 2022, as part of ABDM, the NHA had launched a 'scan & share' service for efficient OPD registrations. The MoHFW has confirmed that the service has been adopted by more than 365 hospitals across the country since then and has helped over five lakh patients, by cutting down on the waiting and registration time for OPD services.

26. PMNDP: 17.27 lakh beneficiaries reported by states[58]

As per the data reported by states, the number of people who have availed services under the Pradhan Mantri National Dialysis Programme ("**PMNDP**") stood at 17.27 lakh till December 31, 2022. Originally launched in 2016, the PMNDP provides free dialysis services to BPL patients in the country. The programme, which has been implemented in all 36 States/UTs in 641 districts, has led to the establishment of 1,350 dialysis centres and the deployment of 8,871 haemodialysis machines as on December 31, 2022.

[54] http://pharmabiz.com/NewsDetails.aspx?aid=156447&sid=1
[55] https://www.thehindubusinessline.com/companies/astrazeneca-expands-its-portfolio-by-bringing-rare-disease-therapy-in-india/article66563627.ece
[56] https://theindianpractitioner.com/alkem-subsidiary-enzene-launches-adalimumab-biosimilar-in-india/
[57] https://www.livemint.com/news/india/ayushman-bharat-facilitates-quick-opd-registrations-in-365-hospitals-through-scan-and-share-11677162553417.html
[58] https://pib.gov.in/PressReleasePage.aspx?PRID=1896035

Litigation Updates

1. Supreme Court eases procedures to withhold life support of a terminally ill patient[59]

The Hon'ble Supreme Court ("**SC**"), in WP (C) No. 215 of 2005, admitted an application filed by the Indian Council for Critical Care Medicine, which paved the way for simplification of guidelines for executing a Living Will/ Advance Medical Directive with respect to 'passive euthanasia'. The erstwhile procedure laid down in *Common Cause (A Registered Society) v. Union of India and Another (2018) 5 SCC 1*, required not only that the advance medical directive be made in the presence of two independent attesting witnesses, but also that the directive be countersigned by a Judicial Magistrate of First Class. Noting that the current procedure to withdraw life support of a terminally ill patient is unworkable, the Constitution Bench of the Hon'ble SC simplified the procedure by allowing a two-tiered process for authorising passive euthanasia, removing the requirement to obtain approval from a judicial magistrate (first class) to withdraw life support.

2. SC holds that doctors cannot be punished for storing small quantities of medicines[60]

The Hon'ble SC, dealing with a case of prosecution of a doctor under Section 18(c) of the D&C Act for unauthorised stocking of medicines, held that storage of small quantities of medicines by a registered medical practitioner cannot be punishable under the said provision. The Hon'ble Court relied on Rule 123 of the Drugs Rules, read with Entry 5 of Schedule K to the Rules, which exempts certain drugs from Chapter IV of the D&C Act (including the penal provisions in Sections 18 and 27) and provides an exception in favour of doctors in respect of the same. The Court further clarified that Sections 18 and 27 are intended to prevent exploitation of ordinary citizens by unethical medical practitioners and cannot be invoked as a matter of course where a doctor stores small quantities of drugs of standard quality, which may also be required for emergency uses. The Court declared that as long as a medical practitioner is not keeping an open shop or selling across the counter, he/ she cannot be prosecuted on these grounds.

3. SC issues notice to FSSAI on a contempt plea related to adulteration of milk[61]

The Hon'ble SC, *vide* an order dated February 17, 2023, issued notice to the FSSAI in a Contempt Petition arising from its judgment dated August 5, 2016, in *Swami Achyutanand Tirth & Ors. v. Union of India & Ors., WP (C) No. 159 of 2012*. The Apex Court in its judgement has clarified that the said notice shall not be construed as a contempt notice and is simply intended to ensure that FSSAI exercises its statutory powers to duly implement the directions of this Court. The SC judgement had directed the Union of India to revisit the food safety standards and revise the punishment for adulteration

[59] Common Cause (A Regd. Society) v. Union of India, Order dated January 24, 2023 in Misc. App. No. 1699 of 2019 in WP (C) No. 215 of 2005.
[60] S. Athilakshmi v. The State Rep. By The Drugs Inspector, Judgement dated March 15, 2023 in SLP (CRL.) No. 9978 of 2022.
[61] Swami Achyutanand Tirth v. Ajay Kumar Bhalla & Ors., Order dated February 17, 2023 in Contempt Petition (Civil) Diary No. 4296/2022.

to make it a penal offence. The Court had also directed States to undertake proactive steps to inform dairies, dairy operators, and retailers that if any chemical adulterants are found in milk, it will attract stringent action.

4. SC directs UP to procure Ayurvedic medicines by tenders, as opposed to nominations[62]

The Hon'ble SC dismissed an appeal from the Indian Medicines Pharmaceutical Corporation Limited, challenging an order issued by the Allahabad High Court, which had stated that the State of Uttar Pradesh cannot purchase medicines from the PSU without inviting tender. The SC observed that the State of Uttar Pradesh should instead purchase Ayurvedic medicines by adopting a transparent process, after invitation of tenders. Referring to the process of invitation of bids as the most transparent and non-arbitrary method of allocation, the Hon'ble SC emphasised that the Government cannot act arbitrarily while dealing with the public. The Apex Courtin its judgement directed that the State must henceforth purchase Ayurvedic medicines only through a free and transparent procedure such as tenders, barring exceptional circumstances, which have to be demonstrated on the basis of cogent material.

5. SC seeks response from the Centre on age restriction of 35 years prescribed under the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994[63]

The Hon'ble SC, *vide* an order dated January 16, 2023, has granted the Central Government a period of four weeks to file a counter-affidavit in a plea filed before the court, which asserts that Section 4(3)(l) of the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 ("**PCPNDT Act**"), which prescribes an age restriction of 35 years on pre-natal and pre-conception diagnostic testing, curtails the reproductive rights of women.

6. Delhi High Court directs National Consortium to consider a mechanism for increasing affordability and accessibility to therapies for rare diseases[64]

The Delhi High Court, *vide* an order dated March 6, 2023, has directed the National Consortium for Research and Development on therapeutics for Rare Diseases ("**National Consortium**") to consider conducting clinical trials to develop indigenous therapies for Duchenne Muscular Dystrophy (DMD) and Gaucher Disease. This order was passed after several petitions were filed before the High Court concerning children suffering from these rare diseases, highlighting issues of cost and accessibility. The Court directed the National Consortium to hold a meeting in this regard on or before March 20, 2023, and place the report before the court before the next date of hearing. The Court clarified that the report must be comprehensive and must consider aspects including age of the affected children, negotiations with pharmaceutical companies to offer approved therapies to affected children in India, expenses involved in the treatment, and feasibility of indigenous therapies in already approved trials.

7. Gujarat High Court issues notice to National Medical Commission ("NMC") in a PIL filed for framing of rules for doctors to prescribe generic medications[65]

A Division bench of the Gujarat High Court was faced with a Public Interest Litigation ("**PIL**") wherein the Petitioner, one Anang Manubhai Shah, prayed that doctors must be directed to prescribe only generic medicines rather than particular brands. It was prayed that the patient must have the choice to decide between different brands selling medicines of the same composition. Vide an order dated January 12, 2023, the High Court directed that a notice be served upon the NMC to send its response to the petition. The Court noted that while the Medical Council of India was a Respondent in the case, it has since been replaced by the NMC (PIL was filed in 2016), which had not been notified of the matter. Thus, the Court issued a direction to issue a fresh notice.

8. Jammu and Kashmir High Court holds that retailer cannot evade liability for spurious drugs on the ground that it was obtained from a licensed dealer[66]

A Single bench of the Jammu and Kashmir and Ladakh High Court, *vide* its judgement dated February 9, 2023, has clarified that obtaining drugs from a licensed dealer by itself is not sufficient for the retailer to escape liability in cases of spurious or sub-standard quality drugs. Instead, the retailer must satisfy three conditions in terms of Section 19(3) of the D&C Act, i.e. (a) that he obtained the drug from a licensed manufacturer; (b) that he could not have reasonably ascertained violation of the provisions of applicable law; and (c) that the drug/ cosmetic was properly stored and was sold in the same state as when he had acquired it.

[62] M/s Indian Medicines Pharmaceuticals Corporation Ltd. v. Kerala Ayurvedic Co Operative Society Ltd. & Ors., Judgement dated January 3, 2023 in Civil Appeal No. 6693 of 2022.
[63] Meera Kaura Patel v. Union of India & Anr., Order dated January 16, 2023 in WP (C) No. 1327/2019.
[64] Master Arnesh Shaw v. Union of India & Anr., Order dated March 6, 2023 in W.P.(C) 5315/2020.
[65] Anang Manubhai Shah v. Union of India, Order dated January 12, 2023 in R/WP (PIL) No. 270 of 2016.
[66] Sundaram Surgicals v. Drug Inspector Doda., Judgement dated February 9, 2023 in CRMC No. 396/2018 with CRM(M) No. 93/2021 (O&M).

Transaction Updates

1. Sun Pharmaceutical acquires US based Concert Pharma for $576 million[67]

Sun Pharmaceutical Industries Ltd., the country's biggest drug manufacturer, has completed the acquisition of Concert Pharmaceuticals, a US based late-stage clinical biopharmaceutical company, through a $576 million tender offer. Sun Pharma's strategic move was motivated by its interest in getting access to Concert's lead product – Deuruxolitinib – an experimental drug used in the treatment of Alopecia Areata.

2. Carlyle Group acquires majority stake in VLCC Healthcare[68]

Carlyle Group, a leading private equity firm, has acquired a majority stake in VLCC Healthcare Limited for nearly $300 million. VLCC is an Indian beauty care and wellness solutions provider. As per a Carlyle Group statement, entities affiliated with Carlyle Asia Partners will provide equity for the transaction. The transaction comes after the online sales of VLCC jumped to 22% from 7% in the preceding three years. As per a statement made by Carlyle India, VLCC's online sales, along with their product efficacy and brand value, presented a distinct value proposition for Carlyle Group.

3. TA Associates acquires majority stake in Synokem Pharmaceuticals[69]

TA Associates, a leading private equity firm, has announced the acquisition of majority stake in pharmaceutical manufacturer Synokem Pharmaceuticals, in a deal worth Rs. 1000 crore ($125 million). As per the press statement released by TA Associates, Synokem's founders would continue as shareholders in the company. The move is intended to not only boost TA's market share and growth, but also elevate Synokem as an industry leader, with combined experience and knowledge.

4. Tata Capital Healthcare Fund infuses $10 million in Mumbai Oncocare Centre[70]

Tata Capital Healthcare Fund ("**TCHF**"), a private equity fund sponsored by Tata Capital Ltd., has infused approximately Rs 82.6 crore ($10 million) in Mumbai Oncocare Centre ("**MOC**"), a chain of cancer day care centres and subsidiary of Cellcure Cancer Center Pvt Ltd. This capital was raised during MOC's Series A funding. As per a statement issued by MOC, the funds will be utilised to expand their presence across the country in the next 18 months. However, the equity stake acquired by TCHF remains undisclosed.

[67] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/sun-pharma-completes-acquisition-of-concert-pharmaceuticals/articleshow/98458017.cms
[68] https://www.reuters.com/markets/deals/carlyle-group-buys-majority-stake-indias-vlcc-2023-01-10/
[69] https://www.businessworld.in/article/Ta-Associates-Acquires-Synokem-Pharma-For-125-Mn/20-01-2023-462728/
[70] https://www.business-standard.com/article/companies/tata-capital-healthcare-fund-infuses-10-mn-in-cancer-care-unit-123011400891_1.html

5. NephroPlus raises funds from Asian Development Bank[71]

NephroPlus, India's largest provider of dialysis centres, has signed a financing package worth Rs. 69.5 crore ($8.39 million) with the Asian Development Bank ("**ADB**"), to expand its presence by building four new dialysis centres in Uzbekistan. The transaction comes as part of a broader collaboration between Nephroplus and the Uzbekistan's Ministry of Health. As part of this partnership, Nephroplus had earlier secured a contract worth $100 million to operationalise these centres. The financing package consists of a loan of Rs. 41.7 crore from ADB's ordinary capital resources as well as a loan of INR 27.8 crore from Leading Asia's Private Infrastructure Fund.

6. MediBuddy acquires vHealth by Aetna[72]

MediBuddy, an Indian digital healthcare platform, in an all cash deal of an undisclosed amount, has acquired the Indian operations of 'vHealth by Aetna' a subscription-based primary healthcare provider. The business will shortly be rebranded into 'MediBuddy vHealth'. As per MediBuddy's statement, this acquisition is in line with their goal of gaining market leadership and improving the quality of and access to healthcare through the integration of primary and digital healthcare.

7. Sun Pharmaceutical acquires three brands of Aksigen Hospital Care[73]

Sun Pharmaceutical has acquired three brands of Mumbai-based research-driven pharmaceutical company, Aksigen Hospital Care, namely, Disperzyme, Disperzyme-CD, and Phlogam. As per Sun Pharmaceutical's statement, this acquisition is aimed at enhancing the company's anti-inflammatory portfolio. These three brands, used majorly in treating post-operative inflammation resulting from dental procedures and minor surgeries, have already been approved by DCGI. The deal value, however, remains undisclosed.

8. Max Healthcare announces acquisition of 26% stake in Eqova Healthcare[74]

Max Healthcare Institute, one of India's leading private healthcare providers, has announced the acquisition of Eqova Healthcare for a deal value of Rs. 47.18 crore. Eqova Healthcare is a private company with long term exclusive rights to develop and provide medical services to a to 400-bed hospital in Patparganj, Delhi, owned by Nirogi Charitable and Medical Research Trust. As per news reports, the first part of the acquisition involves purchase of 26% stake upfront, while the second part involves an escrow mechanism for an additional 34% under call/ put options exercisable, subject to the achievement of certain milestones. As per a Max Healthcare statement, this move is expected to enhance the quality of healthcare provided in East Delhi.

9. MO Alternates acquires minority stake in Pan Healthcare[75]

Motilal Oswal, through its investment arm, MO Alternate Investment Advisors, has acquired minority stake in Rajkot-based Pan Healthcare, in a deal worth Rs. 400 crore (approximately $48.3 million). Pan Healthcare is largely known for manufacturing sanitary napkins and diapers. As per news reports, the acquisition was motivated by Motilal Oswal's desire to penetrate into the sanitary and hygiene products' market, which is majorly dominated by multi-national companies. Further, a statement provided by Pan Health clarified that the funds will be utilised for investing in the brand, ramping up the distribution infrastructure and building a robust organisation.

10. Max Healthcare to inject Rs. 400 crore for expansion[76]

Max Healthcare Institute has announced its intent to expand its Mohali-based hospital by infusing an investment of Rs. 400 crore. As per news reports, the investment and expansion move is intended to enhance its existing healthcare infrastructure in Punjab, along with providing job opportunities in the region.

[71] https://www.financialexpress.com/healthcare/news-healthcare/nephroplus-signs-rs-695-crores-loan-with-asian-development-bank-to-expand-in-uzbekistan/2937425/
[72] https://www.thehindubusinessline.com/companies/medibuddy-acquires-vhealth-by-athena-in-an-all-cash-deal/article66489968.ece
[73] https://www.businesstoday.in/industry/pharma/story/sun-pharma-acquires-three-brands-from-mumbai-based-aksigen-hospital-care-to-boost-anti-inflammatory-portfolio-368132-2023-01-30
[74] https://www.business-standard.com/article/news-cm/max-healthcare-acquires-26-stake-in-eqova-healthcare-122021100344_1.html
[75] https://www.business-standard.com/article/finance/motilal-oswal-arm-announced-to-invests-rs-400-crore-in-pan-heathcare-123020700560_1.html
[76] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/max-healthcare-lines-up-rs-400-cr-to-expand-mohali-facility/articleshow/97583306.cms

11. Owners of Indira IVF in talks to sell their stake[77]

As per news reports, a group of the largest shareholders of Indira IVF, an Indian in-vitro fertilization clinic operator, are in talks with advisers to sell their holdings in Indira IVF, in a deal which could value the company at around $1 billion. As per the said reports, Indira IVF's founders, along with TA Associates, a private equity firm, have conducted preliminary talks on this proposal and may also consider holding their stakes for a longer period of time.

12. Sun Pharmaceutical announces acquisition of minority stake in two healthcare companies, Agatsa and Remidio[78]

Sun Pharmaceutical has announced the completion of a 26.09% stake acquisition in Agatsa Software Pvt. Ltd. for Rs 30 crore. The acquisition was completed in two tranches. Further, Sun Pharmaceutical announced the completion of a 27.39% stake acquisition in Remidio Innovative Solutions for Rs. 149.9 crore. While Agatsa provides innovative medical devices and solutions, Remidio provides eye-care solutions through its flagship product – the portable fundus camera.

13. Eris Lifesciences set to acquire a host of dermatology brands from Glenmark[79]

Eris Lifesciences Ltd., a Gujarat based drugmaker, has announced plans to acquire nine dermatology brands from Glenmark Pharmaceuticals Ltd, including Halovate, Demelan and Onabet. As per a statement released by Eris, this acquisition is aimed at expanding the company's portfolio and deepening its presence in the anti-fungal and anti-psoriasis segments. The company further stated that the acquisition of brands from Glenmark will have an annual revenue base of Rs. 85 crore and will be financed through borrowings. Eris is set to invest Rs. 340 crore ($41.63 million) on the acquisition.

14. Kotak set to invest $129 million in Biocon to help fund Viatris biosimilars deal[80]

Biocon Ltd., a leading Indian biopharmaceutical company, has raised Rs. 1070 crore ($129 million) from Kotak Investment Advisors (Kotak Mahindra Group's asset management arm) to fund its biosimilars deal with global healthcare company Viatris Inc. As per a statement issued by Biocon, the company plans to use the funds to acquire Viatris' biosimilars business in the United States. Earlier in November 2022, Biocon acquired Viatris' biosimilars business in a deal worth $3.34 billion. As per news reports, the Kotak investment, along with an earlier move by Biocon to sell 10% stake in its research firm Syngene International Ltd., are intended to help fund the Viatris deal. Biocon aims to become a leading player in the biosimilars market and expects the acquisition to enhance its product portfolio, manufacturing capabilities, and R&D expertise.

15. Eris Lifesciences acquires nine cosmetic derma brands from Dr. Reddy's[81]

Dr. Reddy's Laboratories has sold nine cosmetic dermatology brands to Eris Lifesciences in a deal valued at Rs. 275 crore ($36.4 million). The divested portfolio had clocked Rs. 60 crore sales in 2022, according to an IQVIA MAT report dated December 2022. As per a statement released by Dr. Reddy's, this move is in line with the company's strategy of growing brands organically, making strategic acquisitions and divesting non-core brands. Further, Eris Lifesciences said the acquisition would help with the expansion of its cosmetic dermatology business by increasing its product offerings.

16. TPG Capital seeks to exit Sai Life Sciences for $500 million[82]

TPG Capital, a leading US based private equity firm, is seeking to exit its minority stake of 43.4% in Hyderabad-based pharmaceutical contract development and manufacturing organisation, Sai Life Sciences. Established in 1999, Sai Life Sciences entered the contract manufacturing services business in 2005 and has expanded its global footprint to cater to the growing demand for outsourcing in the pharmaceutical industry. This move could generate up to $500 million for the US based private equity firm.

17. Athulya Senior Care receives funding from Morgan Stanley[83]

North Haven India Infrastructure Partners, a fund managed by Morgan Stanley India Infrastructure, has provided funding

[77] https://www.bloomberg.com/news/articles/2023-01-31/indira-ivf-s-owners-weigh-stake-sale-at-1-billion-valuation
[78] https://www.businesstoday.in/latest/corporate/story/sun-pharma-acquires-minority-stakes-in-two-healthcare-companies-for-rs-180-crore-370739-2023-02-19
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[83] https://www.thehindu.com/news/national/tamil-nadu/athulya-senior-care-raises-rs-77-crore-from-morgan-stanley-india-infrastructure/article66357018.ece

of Rs. 77 crore to Athulya Senior Care, which provides assisted living and healthcare services to senior dependents. As per a statement released by Athulya Senior Care, the funds will be utilised towards expansion and establishment of new facilities in various cities, along with investing in talent acquisition and skill training.

18. Hindustan Antibiotics and LordsMed enter into distribution partnership[84]

Hindustan Antibiotics Ltd. ("**HAL**"), a public sector manufacturer of drugs, has entered into a distribution agreement with LordsMed, the global healthcare division of Lords Mark Industries. As per news reports, this agreement lays down a framework whereby HAL will procure a range of rapid antigen test kits at subsidised rates (10% less than average market rates) and distribute it to government hospitals pan-India. These kits are used to detect a variety of diseases such as Malaria, HIV, Syphilis, and Hepatitis C Virus.

19. Safex Chemicals acquires Briar Chemicals for Rs. 728 crore[85]

Safex UK Holdings Limited, an agrochemical firm and a wholly-owned subsidiary of Safex Chemicals (India) Ltd, has acquired UK-based Briar Chemicals for approximately Rs. 727.8 crore (GBP 73 million) from Aurelius Equity Opportunities, a pan-European alternative investment firm. As per news reports, Safex is backed by private equity firm ChrysCapital. Briar Chemicals is one of UK's independent and largest agrochemical CDMO solutions providers. As per a statement released by Safex, this transaction being the company's first overseas acquisition, contributes to the company's objective of expanding into the global agrochemicals market.

20. Kedaara Capital acquires majority stake in Oliva[86]

Kedaara Capital, a Mumbai-based private equity firm, has acquired a majority stake in Oliva Skin and Hair Clinic, a dermatology chain based out of Hyderabad. As per a statement released by Kedaara Capital, this investment is intended to grow Oliva's business, with a vision to make Oliva one of the most trusted brands in the country for world-class medico-aesthetic dermatology services. As per news reports, this investment would allow InvAscent, an early-stage investor with an approximate 30% stake in Oliva, to exit fully. The deal amount remains undisclosed.

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