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

Volume VI | Issue I | October 2022 - December 2022

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Dear Readers,

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

In the past few months, we have slowly but surely returned to our pre-pandemic lives. Although India Inc. showed resilience and performed well in the most recent financial quarter, the external financial and geopolitical environment has cast a shadow. However, as we bid goodbye to 2022 and ring in 2023, the fear of the pandemic has once again reared its ugly head, with China grappling with a surge in Covid-19 infections, leading to resurgence worries globally. With India achieving the target of administering 200 crore plus vaccine doses, the pandemic-induced curbs were relaxed and the pent-up demand for healthcare services bounced back, especially in the health-tech sector. Overall, the pharmaceutical, healthcare, life sciences and medical devices sector embraced newer challenges in 2022. We now hope that India Inc. welcomes 2023 with the anticipation of a year brimming with opportunity.

Like the previous few quarters, the sector witnessed important regulatory updates even in the October-December quarter, which we have covered in this edition of *Synapse*. Most importantly, this quarter saw the notification of new Drugs (Prices Control) Amendment Order, 2022, substituting the previous version of National List of Medicines with NLEM 2022. In the wake of the re-emergence of the Covid-19 virus, the National Pharmaceutical Pricing Authority (NPPA) and the Ministry of Chemicals and Fertilizers announced the decision to extend fixed prices of Liquid Medical Oxygen (LMO), oxygen cylinders and oxygen concentrators until March 31, 2023. A similar extension was made capping the trade margin of five medical devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer at first point of sale (price to distributor) until March 31, 2023. In another news, the formalisation of exemption of Class A non-measuring and non-sterile devices from the requirement of import license (MD-15) process has been announced. Also, the final notification amending the Drugs Rules, 1945, mandating Barcode or Quick Response (QR) Code on the label of top 300 brands of drugs, w.e.f. August 1, 2023, was also notified.

In the litigation space, the Hon'ble Supreme Court, directed the Centre and the States to file their responses on a plea seeking directions for adoption of a uniform standard of healthcare for citizens, in line with the Constitution and in terms of provisions of the Clinical Establishments Act, 2010. In another matter, the Hon'ble High Court of Delhi directed the Delhi Government to ensure compliance with the Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019. The court asked the Delhi Police to take steps to ensure that such e-cigarettes are not sold near and around schools and colleges in New Delhi. The Hon'ble court passed the order while refusing to entertain a public interest litigation seeking constitution of

a court monitored committee to review the effective implementation of the Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

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

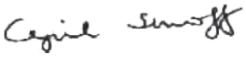
Cyril Amarchand Mangaldas, India's premier full-service law firm, has an industry leading and dedicated Pharmaceuticals, Healthcare and Life Sciences practice. Our class-leading practice specialists are always on top of the latest developments in the sector. In our endeavour to keep you abreast with the latest developments in this dynamic sector, we present to you the latest issue of Synapse. We hope you 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 in relation to 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. 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 Surrogacy (Regulation) Amendment Rules, 2022[1]

The Ministry of Health and Family Welfare ("**MoHFW**"), *vide* notification G.S.R. 772(E), dated October 10, 2022, notified the Surrogacy (Regulation) Amendment Rules, 2022, whereby in terms of Rule 5(2), the intending couple/ woman shall sign an affidavit giving guarantee in terms of Section 2(1)(q) of the Surrogacy (Regulation) Act, 2021, sworn before the Metropolitan Magistrate or a Judicial Magistrate of First Class or an Executive Magistrate or a Notary Public.

2. Notification on Assisted Reproductive Technology (Regulation) Amendment Rules, 2022[2]

The MoHFW, *vide* notification G.S.R. 771(E), dated October 10, 2022, notified the Assisted Reproductive Technology (Regulation) Amendment Rules, 2022, whereby in terms of Rule 12(2), the intending couple/ woman shall sign an affidavit giving guarantee in terms of Section 22(4)(ii) of the Assisted Reproductive Technology (Regulation) Act, 2021, sworn before the Metropolitan Magistrate or a Judicial Magistrate of First Class or an Executive Magistrate or a Notary Public.

3. Notification on New Drugs and Clinical Trials (Third Amendment) Rules, 2022[3]

The MoHFW, *vide* notification no. G.S.R. 778(E), dated October 14, 2022, notified the New Drugs and Clinical Trials (Third Amendment) Rules, 2022, to further amend the New Drugs and Clinical Trials Rules, 2019 ("**NDCT Rules**"). The amendment provides for inclusion of provisions for deemed approval for strengthening the ecosystem to boost innovation.

4. New Drugs and Clinical Trials (....Amendment) Rules, 2022[4]

The MoHFW, *vide* notification no. G.S.R. 835(E), dated November 22, 2022, notified the draft New Drugs and Clinical Trials (....Amendment) Rules, 2022. The amendment provides for substitution of clause (b) in the First Schedule that states 'General Principles and Practices for Clinical Trial' in paragraph 3 in sub-paragraph (1), which provides for non-clinical testing methods to assess the safety and efficacy of a new drug or investigational new drug.

5. Notification on Drugs (Eighth Amendment) Rules, 2022[5]

The MoHFW, *vide* notification no. G.S.R. 823(E), dated November 17, 2022, notified the Drugs (Eighth Amendment) Rules, 2022, mandating QR code/ barcode on products specified in newly inserted Schedule H2 in the Drugs Rules, 1945. The notification mandates QR code/ barcode on the label of top 300 brands of drugs with effect from August 1, 2023.

6. Implementation of Medical Devices (Fifth Amendment) Rules, 2022[6]

The MoHFW, *vide* notification no. G.S.R. 754 (E), dated September 30, 2022, notified the Medical Devices (Fifth Amendment) Rules, 2022, on October 21, 2022. Vide the amended rules, the provision for registration certificate to sell, stock, exhibit or offer for sale or distribute a medical device, including in vitro diagnostic medical device, as alternative to Drugs Sale License has been implemented with effect from September 30, 2022.

7. Notification on Medical Devices (Sixth Amendment) Rules, 2022[7]

The MoHFW, *vide* notification no. G.S.R. 777(E), dated October 14, 2022, notified the Medical Devices (Sixth Amendment) Rules, 2022, to exempt non-sterile and non-measuring Class A medical devices from the licensing regime.

8. Notice on registration of Medical Device Testing Laboratory in Form MD-40 in terms of Medical Device Rules, 2017[8]

The Central Drugs Standard Control Organization ("**CDSCO**") issued a notice dated December 22, 2022. Vide the said notice, laboratories, with capacity to test medical devices and those that are NABL accredited, are requested to submit the application in Form MD-39, along with the requisite fees and documents, through the online portal.

1 https://egazette.nic.in/WriteReadData/2022/239538.pdf
2 https://egazette.nic.in/WriteReadData/2022/239537.pdf
3 https://egazette.nic.in/WriteReadData/2022/239667.pdf
4 https://egazette.nic.in/WriteReadData/2022/240459.pdf
5 https://egazette.nic.in/WriteReadData/2022/240392.pdf
6 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTEzOA==
7 https://egazette.nic.in/WriteReadData/2022/239681.pdf
8 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTY4NA==

9. Notification on Establishment of Medical College Regulations, (Amendment), 2022[9]

The National Medical Commission, *vide* notification F. No. U-11022/4/2022-UGMEB, dated December 13, 2022, notified the Establishment of Medical College Regulations, (Amendment), 2022. Vide the amendment, an exception was created under the qualifying criteria, wherein the condition of "fully functional hospital for a minimum period of two years" would not be applicable to universities or deemed to be universities recognised by University Grants Commission Act, 1956, having experience of establishing and running fully functional recognised medical colleges and hospitals with 1,000 beds or more, for at least two years, anywhere in India.

10. Covid-19 vaccines approved in the country as on October 4, 2022[10]

The CDSCO issued an updated list of approved Covid-19 vaccines as on October 4, 2022. This list has been issued in addition to the previous list issued on July 8, 2022. SARS-CoV-2 vaccine containing Receptor Binding Domain (RBD) of SARS-CoV-2 gene (CORBEVAX) approved in the country for Booster (third) dose vaccination for restricted use in emergencies.

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

a) Notification on Drugs (Prices Control) Amendment Order, 2022[11]

The Ministry of Chemicals and Fertilizers ("**MoCF**"), *vide* notification no. S.O. 5249 (E) notified the Drugs (Prices Control) Amendment Order, 2022, dated November 11, 2022, which substituted Schedule I of the Drug Price Control Order, 2013 ("**DPCO 2013**"), which was originally carrying the NLEM 2011, details, with National List of Medicines, 2022 ("**NLEM 2022**"). The amendment has come into force on the date of publication of the Notification in the Official Gazette.

b) Order extending the date of Fixed Prices of Liquid Medical Oxygen (LMO)' and Oxygen Inhalation (Medicinal gas) in cylinder

The MoCF, through NPPA *vide* order no. S.O. 6175(E), dated December 30, 2022, extended the timeline for prices of 'Liquid Medical Oxygen (LMO)' and 'Oxygen Inhalation (Medicinal gas) in cylinder', fixed under Para 19 of the DPCO 2013 and powers conferred under Section 10(2)(l) of the Disaster Management Act, 2005, delegated by the MoHFW up to March 31, 2023, or till further order, whichever is earlier.

c) Order extending the capping of trade margins on Pulse Oximeter, BP Machine, Nebulizer, Digital Thermometer, and Glucometer[12]

The MoCF, through NPPA *vide* order no. S.O. 6176(E), dated December 30, 2022, extended the capping of trade margin on five medical devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, iv) Digital Thermometer, and (v) Glucometer, at first point of sale (price to distributor) up to March 31, 2023 or till further order, whichever is earlier.

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

a) Notification on Food Safety and Standards (Advertising and Claims) Second Amendment Regulations, 2022[13]

The FSSAI, *vide* notification no. F.No. Std/SP-08/A-1.2019/N-03, dated December 13, 2022, notified the Food Safety and Standards (Advertising and Claims) Second Amendment Regulations, 2022. Schedule - I, II and III were replaced with Schedule I – Nutrient Content Claim, Schedule II – Symptoms, which may be used for claims, and Schedule III - Reduction of disease risk claims. The amended regulations also laid down rules pertaining to addition of disclaimers on labels that could mislead consumers, among other things.

b) Notification on Food Safety and Standards (Food Products Standards and Food Additives) Second Amendment Regulations, 2022[14]

The FSSAI, *vide* notification no. F.No. STD/FA/A-1.30/No.1/2020-FSSAI(P-I), dated October 27, 2022, notified the Food Safety and Standards (Food Products Standards and Food Additives) Second Amendment Regulations, 2022, inserted in Table 11 A: Enzymes derived from Genetically Modified Microorganisms (GMM) after TABLE 11 under Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011,

[9] https://www.nmc.org.in/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/241078.pdf
[10] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTA4MQ==
[11] https://egazette.nic.in/WriteReadData/2022/240231.pdf
[12] https://egazette.nic.in/WriteReadData/2022/241527.pdf
[13] https://egazette.nic.in/WriteReadData/2022/241043.pdf
[14] https://egazette.nic.in/WriteReadData/2022/239918.pdf

Appendix C, under the heading "II. USE OF PROCESSING AIDS IN FOOD PRODUCTS".

c) **Notification on Food Safety and Standards (Approval for Non-specified Food and Food Ingredients) Regulations, 2017**[15]

The FSSAI, *vide* notification no. F. No. Std/EC/T(NSF-01), dated October 11, 2022, notified the Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) First Amendment Regulations, 2022. The said amendment made changes to Section 4 of the Procedure for grant of prior approval, by submission of application in FORM I, which the food authority may grant or reject as per FORM II.

d) **Notification on Food Safety and Standards (Labelling and Display) Second Amendment Regulations, 2022**[16]

The FSSAI, *vide* notification no. F. No. Std/SP-08/A-1-2020/N-01, dated October 11, 2022, notified the Food Safety and Standards (Labelling and Display) Second Amendment Regulations, 2022. The said amendment added *"Pan Masala"* in schedule II, wherein the declaration required for the same is: *"Chewing of pan masala is injurious to health. Note: The warning statement must cover 50% of the front-of-pack of the label"*. In addition, under para 2, para 2.6 *"Labelling of various types of bread"* was added, which provides that breads mentioned must comply with the requirements underlined in the mentioned paragraph.

e) **Notification on Draft Food Safety and Standards (Genetically Modified Foods) Regulations, 2022**[17]

The FSSAI, *vide* notification no. F. No. 1/ Standards/ GMO&F/ Misc/ FSSAI/ 2018, dated November 18, 2022, notified the draft Food Safety and Standards (Genetically Modified Foods) Regulations, 2022. The proposed regulations will apply to Genetically Modified Organisms (GMOs) intended for food use.

f) **Notification on Draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2022**[18]

The FSSAI, *vide* notification no. F. No. STD/39-FA/Notification/2022, dated November 2, 2022, notified the draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2022. This amendment aims to notify the standards for meat sausages. Sausage is a product obtained by stuffing minced meat (pork, poultry or meat from other food animals) and other ingredients (fat/oil, salt, water, extenders, spices, etc.) in casings (natural/artificial), which may be marketed as fresh (raw), fermented, cooked and/ or smoked. Further, the standards for Indian Mithais under regulation 2.17 has been notified.

g) **Notification on Food Safety and Standards (Labelling & Display) Amendment Regulations, 2022**[19]

The FSSAI, *vide* notification no. F. No. F. No. STD/SP-08/A1.2022/N-01, dated December 1, 2022, notified the

[15] https://egazette.nic.in/WriteReadData/2022/239592.pdf
[16] https://egazette.nic.in/WriteReadData/2022/239576.pdf
[17] https://egazette.nic.in/WriteReadData/2022/240438.pdf
[18] https://egazette.nic.in/WriteReadData/2022/239983.pdf
[19] https://egazette.nic.in/WriteReadData/2022/240705.pdf

Food Safety and Standards (Labelling & Display) Amendment Regulations, 2022. This amendment added labelling requirements on non-retail container and per serve percentage contribution to RDA, and number of servings per pack may not be mentioned on infant nutrition products as defined under Food Safety and Standards (Foods for Infant Nutrition) regulation, 2020.

h) **Order clarifying application for vegan logo endorsement[20]**

The FSSAI, *vide* order no. I/5788/2022, dated October 7, 2022, clarified vegan logo endorsement in terms of sub-regulation 5(2) FSS (Vegan Foods) Regulations, 2022. For same product with multiple variants or different products, Food Business Operators ("**FBO**") have to file separate applications for each variant/ different product.

i) **Advisory order for facility of advance processing of Bill of Entry in Food Import Clearance System (FICS) of FSSAI[21]**

The FSSAI, *vide* order dated October 12, 2022, has issued an advisory to Food importers to avail the facility of advance processing of Bill of Entry in FICS while importing food consignments to facilitate faster clearance of articles of food imported at the port and minimising the clearance time and demurrage charges.

j) **Order issued for clarification on alcoholic beverages imported in India in bulk containers[22]**

The FSSAI, *vide* order dated October 20, 2022, has clarified that containers containing bulk alcoholic beverages with higher alcohol content for the purpose of manufacturing alcoholic beverages containing labels declaring the same, the upper limit of alcohol pursuant to sub-regulation 1.3.9 of FSS (Alcoholic Beverages), Regulation, 2018, now referred as FSS (Labelling and Display) Regulations, 2020, shall not apply and only safety parameters shall be tested, along with other labelling requirements.

k) **Order issued regarding clarification in respect of sale of Hemp seeds and seed products (Hemp seed, Oil extracted from Hemp seeds, Hemp seed flour)[23]**

The FSSAI, *vide* order dated November 10, 2022, has issued a clarification stating that Hemp seed and seed products are standardised under Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 (FSSR), and such products may be allowed on E-commerce websites, subject to holding an FSSAI license and compliance with standards so prescribed.

l) **Order issued regarding re-operationalisation of Food Safety and Standards (Licensing and Registration of Food Business) Amendment Regulations, 2021[24]**

The FSSAI, *vide* order no. F.No.RCD-01002/1/2021-Regulatory-FSSAI(part-1), dated June 24, 2022, issued a direction under Section 16(5) of the FSSAI Act, 2006, regarding reoperationalisation of Food Safety and Standards (Licensing and Registration of Food Business) Amendment Regulations, 2021. The FBOs are expected to follow these revised regulations.

[20] https://www.fssai.gov.in/upload/advisories/2022/10/63400fa0b1ff6Clarification_Vegan_Foods_07_10_2022.pdf
[21] https://www.fssai.gov.in/upload/advisories/2022/10/63400fa0b1ff6Clarification_Vegan_Foods_07_10_2022.pdf
[22] https://www.fssai.gov.in/upload/advisories/2022/10/635127b7c8dffClarification_Import_Alcoholic_20_10_2022.pdf
[23] https://www.fssai.gov.in/upload/advisories/2022/11/637dfe2649116Clarification_Hemp_Seed_22_11_2022_.pdf
[24] https://www.fssai.gov.in/upload/advisories/2022/12/638edf17bdbb2Direction_Licensing_28_11_2022_.pdf

News Updates

1. Dr. V.G. Somani gets another extension to continue as the DCGI[25]

The MoHFW has extended Dr. V.G. Somani's term as the Drugs Controller General of India ("**DCGI**") for another three months from November 16, 2022. The Health Ministry, in a notification, said that the competent authority has agreed to let Dr. V.G. Somani continue to hold the position of Drugs Controller (India) for a further period of three months, with effect from November 16, 2022, or until further order, whichever is earlier. This is reportedly the third time Dr. Somani's tenure is being extended as the DCGI.

2. Bharat Biotech's iNCOVACC intranasal vaccine receives CDSCO approval[26]

Bharat Biotech International Limited ("**BBIL**"), a leading multinational biotechnology company, will commence manufacturing variant-specific shots of the vaccine after iNCOVACC became the world's first intranasal Covid-19 vaccine to receive emergency use authorisation (EUA) as a primary vaccine as well as a heterologous booster for people aged 18 and above. As per the company's official press release, iNCOVACC will be rolled out in the fourth week of January and would be available on the CoWin portal.[27]

3. CDSCO orders audits of pharmacovigilance system of importers and manufacturers of human vaccines[28]

On December 23, 2022, the CDSCO ordered inspections/ audits of pharmacovigilance system of importers and manufacturers of human vaccines. As per the CDSCO order, the importer or manufacturer of any new drug for sale and distribution shall have a pharmacovigilance system in place for collecting, processing and forwarding the Adverse Drug Reaction ("**ADR**") reports to the Central Licensing Authority, emerging from the use of the new drug imported or manufactured or marketed by the applicant in the country. The pharmacovigilance system shall be managed by qualified and trained personnel and the officer-in-charge of collection and processing/ analysis of data (ADR reports) shall be a trained pharmacist or medical officer. The order further specified that importers and manufacturers of human vaccines are required to maintain qualified trained personnel and Officer-In-Charge for collection, processing of data and furnishing of PSUR as per fifth schedule of NDCT Rules, as the same may be subject to inspection at any time for compliance verification.

[25] http://www.pharmabiz.com/ArticleDetails.aspx?aid=154536&sid=2
[26] https://health.economictimes.indiatimes.com/news/pharma/bharat-biotech-to-make-variant-specific-shots-of-first-nasal-covid-19-vaccine/95845462
[27] https://www.bharatbiotech.com/images/press/incovacc-price-press-release.pdf
[28] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTczNQ

4. CDSCO and State Drugs Control Administration commence joint inspection of Drug Manufacturing Units[29]

The CDSCO, under the directions of Dr. Mansukh Mandaviya, Union Minister of Health & Family Welfare and Chemicals & Fertilizers, has started conducting joint inspection of identified Drug Manufacturing Units, along with State Drugs Control Administration as per risk-based approach. A committee of two Joint Drugs Controllers has been constituted at the CDSCO (HQ) to monitor the process of inspection, reporting and subsequent action to ensure compliance with the Drugs and Cosmetics Act, 1940 ("**D&C Act**") and Rules thereunder, especially as per the requirements of Good Manufacturing Practices (GMP). This will ensure high standards of quality compliance with respect to drugs manufactured in the country. As per a PIB press note, an action plan for nationwide inspection of manufacturing units, which are identified to be at risk of manufacturing Not of Standard Quality (NSQ)/ adulterated/ spurious drugs was made prior to carrying out the inspections.

5. Ministry of AYUSH and DST sign a MoU[30]

A Memorandum of Understanding ("**MoU**") was signed between Ministry of Ayush, Government of India ("**AYUSH**"), and the Department of Science and Technology ("**DST**"), Ministry of Science and Technology & Earth Sciences, to identify prospective areas of research to explore cooperation, convergence, and synergy for evidence-based scientific intervention in the AYUSH sector and for further integration of these into the public healthcare system. Through the MoU, AYUSH and DST have agreed to jointly undertake R&D activities aimed at scientifically validating Ayush concepts, practises, and products. They have also agreed to develop a platform for information exchange and apply contemporary science to understand Ayush-related concepts and principles.

6. Three National AYUSH institutes inaugurated by Hon'ble Prime Minister Narendra Modi[31]

The Hon'ble Prime Minister Narendra Modi inaugurated three National Ayush Institutes with the goal of improving infrastructure and advancing research in traditional medicine. The three National AYUSH Institutes – All India Institute of Ayurveda (AIIA), Goa; National Institute of Unani Medicine (NIUM), Ghaziabad; and National Institute of Homeopathy (NIH), Delhi; were virtually launched during the valedictory ceremony of the ninth World Ayurveda Congress (WAC) at Panjim, Goa.

7. Cost of 127 medicines to go down post the fifth price cap by the NPPA in 2022[32]

As per reports, NPPA had capped the prices of 127 medicines. Among the 127 medications on the NPPA's list are paracetamol, amoxycillin, rabeprazole, and metformin. Many patients frequently make use of these medicines.

8. Roche Pharma India launches patient support app[33]

Roche Pharma India recently launched a new digital platform, The Blue Tree 2.0 mobile app, for patients enrolled in Roche's Blue Tree patient support programme in India. The mobile application, which is available on both the Android and iOS platforms, will make it easier for patients to access a variety of patient support services, such as drug assistance, expert consultation booking, diagnostic support services such as genomic profiling, and notifications about upcoming infusion schedules and other appointments. Other benefits include digital programme enrolment, home drug delivery, and access to reliable and validated disease information. The company's flagship patient assistance programme Blue Tree caters to cancer, haemophilia, and rare disease patients. Over 11,000 patients are currently enrolled in this programme.

9. Mylab launches first indigenous TB diagnostic kit in India[34]

Mylab Discovery Solutions, a Pune-based diagnostic kit manufacturer, has launched India's first indigenously developed Tuberculosis detection kit and has received approvals from the CDSCO, TB Expert Committee, and the ICMR. Through a single test, the PathoDetect kit can identify various medication resistance to isoniazid and rifampicin. With 4.93 lakh confirmed deaths in 2020, TB is one of the most potent killers in India. The automated approach, unlike

[29] https://pib.gov.in/PressReleseDetailm.aspx?PRID=1886842
[30] https://dst.gov.in/mou-signed-between-ministry-ayush-and-department-science-and-technology
[31] https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1882546
[32] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/costs-of-127-medicines-set-to-go-down-post-nppas-5th-price-cap/articleshow/96416516.cms
[33] https://medtechasia.in/roche-pharma-india-launches-patient-support-app-2/
[34] https://www.tbonline.info/posts/2022/11/30/mylab-launches-first-indigenous-tb-diagnostic-kit-single-test.

existing PCR solutions, which requires 2-8 degrees Celsius cold storage, helps carry out testing procedures even in rural regions and mobile labs with low infrastructure requirements.

10. Glenmark and Pfizer sign Settlement Agreement for Cancer Drug[35]

Glenmark Pharmaceuticals, a leading Mumbai-based pharmaceutical company, and its US-based subsidiary have reached a settlement agreement with Pfizer Inc. for a cancer therapy drug, namely Axitinib tablets (1 mg and 5 mg). Glenmark's product is the generic version of Pfizer's Inlyta tablets, which are used to treat kidney cancer. Glenmark's current portfolio includes 177 medications that are approved for distribution in the United States, as well as 47 abbreviated new drug applications (ANDAs) awaiting clearance from the US Food and Drug Administration (FDA).

11. Indian Immunologicals enter the fish vaccine market[36]

Indian Immunologicals Limited ("**IIL**") has become the first vaccine maker in India to venture into fish vaccine development. The Hyderabad-based firm announced a partnership with Central Institute of Fisheries Education, Mumbai, for the commercial development of a vaccine against common bacterial diseases in freshwater fishes. Presently, India has no fish vaccine available on a commercial scale to prevent aquaculture infections.

12. Hetero's Covid-19 oral drug Nirmacom gets WHO nod[37]

Hetero Drugs has received the World Health Organization ("**WHO**") prequalification of medicines programme (WHO PQ) approval for its generic version of Covid-19 oral antiviral treatment candidate 'Nirmatrelvir'. As per reports, the company has stated that it is the first prequalification for a generic version of Pfizer's Covid-19 oral antiviral drug 'PAXLOVID', which the WHO called the best therapeutic choice for high-risk patients to date. Hetero's 'Nirmacom' (Nirmatrelvir) is co-packaged with ritonavir tablets.

13. Due to low take-up, 50 million doses of Covaxin set to expire in early 2023[38]

BBIL has halted the production of Covaxin, a two-dose vaccine, earlier this year due to lack of demand. The company has over 200 million doses of Covaxin in bulk and approximately 50 million doses in ready-to-use vials. On July 23, 2021, BBIL announced the termination of its MoU with Precisa Medicamentos and Envixia Pharmaceuticals LL.C for its Covid-19 vaccine Covaxin for the Brazilian market. In December 2021, CDSCO had approved the extension of Covaxin's shelf life up to 12 months.

14. Eli Lilly launches Ramiven in India[39]

Eli Lilly and Company has announced the launch of the additional indication for Ramiven (*abemaciclib*), following approval from the DCGI, in combination with endocrine therapy for adjuvant treatment in adult patients with hormone receptor - positive, human epidermal growth factor receptor - negative and node-positive early breast cancer at high risk of recurrence. Abemaciclib is a CDK 4/6 inhibitor, which has now been approved for HR+ HER2 node positive high-risk early breast cancer. CDK 4/6 inhibitors are a class of medicines used to treat certain types of metastatic breast cancer. Every year, more than 50,000 patients in India are given the diagnosis of HR+/HER2- early breast cancer.

[35] https://medtechasia.in/glenmark-and-pfizer-sign-pact-for-cancer-drug-2/
[36] https://www.deccanherald.com/national/south/in-a-first-hyderabad-based-firm-to-develop-fish-vaccines-1166513.html
[37] https://www.livemint.com/news/india/indiabased-hetero-s-covid-19-oral-drug-nirmacom-gets-who-backing-11672185871258.html
[38] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/50-million-doses-of-covaxin-set-to-expire-early-2023-due-to-poor-off-take/articleshow/95332309.cms
[39] https://www.expresspharma.in/eli-lilly-introduces-ramiven-abemaciclib-in-india/

15. CDSCO approves AstraZeneca's Dapagliflozin with additional indication for treating CKD and heart failure patients[40]

The CDSCO has approved Dapagliflozin, AstraZeneca's anti-diabetic drug, for the treatment of adults suffering from Chronic Kidney Disease ("**CKD**"). As per the press statement released by the company, Dapagliflozin is the first and only approved anti-diabetic drug to reduce the risk of sustained estimated Glomerular Filtration Rate (eGFR), cardiovascular deaths and hospitalisations, due to heart failure in adults with progressive CKD. This approval is applicable for both diabetic and non-diabetic CKD patients.

16. Dr. Reddy's completes phase-I study of Tocilizumab proposed biosimilar[41]

Dr. Reddy's Laboratories Ltd, a leading pharmaceutical company, has successfully completed Phase-1 study of its proposed biosimilar of Tocilizumab, to be used in the treatment of rheumatoid arthritis in adults. The company's Tocilizumab biosimilar candidate 'DRL_TC' successfully met its primary and secondary endpoints in a Phase I study, the company said in a regulatory filing. Tocilizumab is an important anti-rheumatic agent that has a unique place in treating patients with rheumatoid arthritis and other diseases. Dr Reddy's is developing the proposed Tocilizumab biosimilar as both subcutaneous and intravenous formulations.

17. Serum Institute submits application for grant of market authorisation for Covovax as booster dose[42]

Serum Institute of India ("**SII**") has sought the drug regulator's approval for market authorisation of its Covid-19 vaccine, Covovax as a booster dose. The vaccine will be administered to those aged 18 years and above, and those who have been administered two doses of Covishield or Covaxin. Covovax is the indigenous version of a Covid-19 vaccine developed by Novovax Inc. and manufactured under the SII licence.

18. Biological E's Corbevax safe and immunogenic for children aged five to eighteen[43]

Vaccine maker Biological E announced the publication of Corbevax Covid-19 vaccine phase-II/III clinical trials conducted in paediatric population (five to <18 age group). Corbevax is India's first indigenously developed RBD protein sub-unit vaccine for Covid-19. It has demonstrated excellent safety profile in children and adolescents. The findings of the study have been accepted and published in the Vaccines, a peer-reviewed international publication. In February 2022, DCGI had approved Corbevax for limited emergency usage in people aged 12 to 18. The apex drug regulator had authorised the use of the vaccine on April 25, 2022, for kids between the ages of five and twelve.

19. Centre unveils India's first national repository for life science data[44]

The Indian Biological Data Centre ("**IBDC**"), developed from publicly funded research in the country, was unveiled in Faridabad as India's first national repository for life science data. The facility houses the 'Brahm' High Performance Computing facility and has a data storage capacity of four petabytes. IBDC began nucleotide data submission services through two data portals, the 'Indian Nucleotide Data Archive (INDA)' and the 'Indian Nucleotide Data Archive - Controlled Access (INDA-CA)' and has collected over 200 billion bases from 2,08,055 submissions from more than 50 research labs across the country.

20. Manipal Hospital, Isansys Lifecare launch new Patient Status Engine (PSE) initiative in collaboration[45]

Manipal Hospitals and Isansys Lifecare launched a new initiative of Patient Status Engine ("**PSE**") to constantly monitor high risk patients across areas. The PSE is approved internationally as a vital solution for wirelessly and remotely monitoring patients. PSE monitors health indicators like heart rate, temperature, saturation, blood pressure and ECG with minute-by-minute Early Warning Score (EWS).

[40] https://www.expresspharma.in/cdsco-approves-astrazenecas-dapagliflozin-with-additional-indication-for-treating-ckd-and-heart-failure-patients/
[41] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/dr-reddys-lab-completes-phase-1-study-of-proposed-arthritis-drug/articleshow/96339880.cms
[42] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/serum-institute-seeks-drug-regulators-approval-for-market-authorisation-of-its-covid-vaccine-as-booster-dose/articleshow/96425495.cms
[43] https://www.expresspharma.in/biological-es-corbevax-safe-and-immunogenic-in-five-to-18-age-group/
[44] https://www.business-standard.com/article/economy-policy/centre-unveils-india-s-first-national-repository-for-life-science-data-122111000935_1.html
[45] https://health.economictimes.indiatimes.com/news/medical-devices/manipal-hospitals-isansys-lifecare-partner-to-launch-patient-status-engine/94892625

21. HCG Cancer Hospital, Bengaluru, launches India's first AI-based radiation treatment technology[46]

HealthCare Global Enterprises (HCG) cancer hospital has announced the launch of the first Varian EthosTM therapy, an AI-driven holistic solution designed to increase radiotherapy capability, flexibility, and efficiency. This innovative technique aims to deliver an adaptable treatment based on tumour and anatomical changes in 15 minutes.

22. Intuitive India debuts 'Xi experience centre', a robotic-assisted surgery experience centre at FICCI Heal 2022[47]

Intuitive Surgical, pioneers in robotic-assisted surgery ("**RAS**") and a global technology leader in minimally invasive care, has launched a first-of-its-kind project to educate healthcare professionals on RAS, its capabilities, and clinical applications. The centre is outfitted with Intuitive's latest Da Vinci Xi technology, as well as other cutting-edge amenities like the 'wet lab'. The centre also showcases cutting-edge technologies such as real-time visual assistants, dual grip technology, and suturing and simulation exercises.

23. IISc develops smartphone-linked artificial pancreas to monitor blood sugar levels for Type-1 diabetes patients[48]

Researchers from the Indian Institute of Science's ("**IISc**") Robert Bosch Centre for Cyber-Physical Systems have collaborated with doctors at MS Ramaiah Medical College to create an artificial pancreas system that monitors and controls blood sugar levels in real time. The device is made up of three parts: a coin-sized sensor that continuously monitors glucose concentrations in subcutaneous tissue, an insulin pump that infuses insulin beneath a user's skin, and an Android app that controls both the sensor and the pump to determine the amount of insulin needed.

24. OXYAid launches India's first IoT-enabled mobile medicinal oxygen plant[49]

OxyAid, India's first mobile containerised oxygen generator truck with IoT capabilities, is part of the National Medical Oxygen Grid initiative and intends to provide last-mile supply and accessibility of medical oxygen in rural and isolated areas.

25. MUHS inaugurates genetic lab-cancer research centre in Pune[50]

Maharashtra University of Health Sciences ("**MUHS**") and the Indian Drug Research Association and Laboratory ("**IDRAL**") have collaborated to set up MUHS GeneHealth, a unique genetic institute to provide affordable care, featuring a diagnostic centre, research facility, and genetic clinic. The cutting-edge lab, which was launched on November 11, 2022, will offer a wide range of tests to evaluate and diagnose congenital abnormalities, prenatal disorders, and hematologic and oncologic disorders by analysing DNA, RNA, chromosomes, and proteins using biochemical, cytogenetic, and molecular methods.

[46] https://medtechasia.in/hcg-cancer-hospital-launches-ai-based-radiation-treatment-technology-2/
[47] http://www.pharmabiz.com/NewsDetails.aspx?aid=153833&sid=2
[48] https://www.mobihealthnews.com/news/asia/indian-researchers-develop-smartphone-app-predicts-optimal-insulin-amount
[49] https://medtechasia.in/oxy-aid-launches-indias-first-iot-enabled-medical-oxygen-plant-on-wheels-2/
[50] https://indianexpress.com/article/cities/pune/bhagat-singh-koshyari-inaugurates-muhs-genehealth-centre-in-pune-8263763/

Major Litigation Updates

1. SC directs the Centre and States to file responses on plea seeking directions for Uniform Healthcare Standard[51]

The Hon'ble Supreme Court ("**SC**"), in Civil Writ Petition No. 289 of 2021, directed the Centre and the States to file their responses on a plea seeking directions for adoption of uniform standard of healthcare for citizens, in line with the Constitution and the provisions of the Clinical Establishments Act, 2010 ("**CE Act**"). The petition filed by Jan Swasthya Abhiyan, Patients' Rights Campaign and KM Gopakumar[52], contended that the public healthcare system suffers from lack of public health infrastructure and human resources, non-availability of medicines, lack of public investment and forced dependency on the private sector. The plea had sought directions for notification and implementation of the conditions for registration of clinical establishments, such as observance of minimum standards, display of rates for procedures and services, compliance with the standard treatment protocol as provided for under Sections 11 and 12 of the CE Act, read with Rule 9 of the Clinical Establishment Rules, 2012.

2. SC observes that if seized contraband is found to contain 'morphine' and 'meconic acid', it is sufficient to establish that it is 'opium poppy'[53]

The Hon'ble SC, in Criminal Appeal No. 959 of 2012, observed that once it is found that the seized material contains '*morphine*' and '*meconic acid*', it is sufficient to establish that it is an 'opium poppy' as defined under Section 2(xvii) of the Narcotic Drugs and Psychotropic Substances Act, 1985 ("**NDPS Act**"). The Hon'ble High Court of Himachal Pradesh had acquitted the accused by allowing their appeals on the ground that the prosecution had failed to establish that the seized material was the genesis of a plant of 'Papaver somniferum L' or any other plant, which is notified by the Central Government in terms of Section 2(xvii) of the NDPS Act. The apex court noted the judgement in *State of Himachal Pradesh vs. Nirmal Kaur alias Nimmo*[54], set aside the High Court judgement and remitted the same back to be considered afresh in accordance with the judgement in *State of Himachal Pradesh vs. Nirmal Kaur alias Nimmo*.

[51] Jan Swasthya Abhiyan & Ors. vs. Union of India & Ors., order dated December 2, 2022 in Civil Writ Petition No. 289 of 2021.
[52] https://health.economictimes.indiatimes.com/news/policy/sc-directs-centre-states-to-file-responses-on-plea-seeking-directions-for-uniform-healthcare-standard/95938798
[53] State of Himachal Pradesh vs. Angejo Devi, Order dated November 23, 2022 in Criminal Appeal No. 959 of 2012.
[54] State of Himachal Pradesh vs. Nirmal Kaur alias Nimmo and Others, Judgement dated October 20, 2022 in Criminal Appeal No.956 of 2012.

3. Delhi High Court directs the Delhi Government to ensure compliance with the law prohibiting the manufacture and sale of e-cigarettes[55]

The Hon'ble High Court of Delhi has directed the Delhi Government to ensure compliance with the Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019 ("**PEC Act**"). The court has asked the Delhi Police to take steps to ensure that such e-cigarettes are not sold near and around schools and colleges in New Delhi. The court passed the order while refusing to entertain a public interest litigation, seeking constitution of a court monitored committee to review the effective implementation of the PEC Act. The court observed that the authorities are taking adequate action by conducting raids to ensure that e-cigarettes are not manufactured and sold.

4. Delhi High Court order permitting Natco Pharma to manufacture and roll out pest control products incorporating Chlorantraniliprole (CTPR) upheld[56]

The Hon'ble High Court of Delhi, in FAO No. 301 of 2022, upheld its single judge's order[57], permitting Natco Pharma to manufacture and roll out insecticides containing Chlorantraniliprole (CTPR), while observing that the same does not infringe upon FMC Corporation's patent. CTPR is an active ingredient used in pest management products for crops. The single judge had observed in the September 19, 2022, order that there was no infringement of FMC Corporation's patent process as the reagents – sulfonyl chloride (used by FMC) and thionyl chloride (used by Natco Pharma) play a different and distinct role in accomplishing the same task and achieve substantially the same result. The division bench dismissed FMC Corporation and its subsidiary FMC Agro Singapore Pte's appeal and refused to interfere with the preliminary findings of the single judge. The court also imposed a cost of INR 2.70 lakh on FMC Corporation, which is to be paid to Natco Pharma within two weeks.

5. Madras High Court observes that all directors of a pharma company are liable for production of substandard drugs[58]

The Hon'ble High Court of Madras, in the matter of *Vikas Rambal and others vs. The State*, has dismissed a petition filed by the directors of Sunrise International Labs for quashing a criminal proceeding initiated against them, alleging that the company had supplied drugs of substandard quality. The case against the petitioners was that the company was manufacturing and supplying sub-standard medicine to government hospitals. The petitioners were prosecuted under Section 34 of the D&C Act. The court rejected the contention of the directors that the prosecution should be quashed against them since they were not involved in the day-to-day functioning of the company. The court further observed that the decision to manufacture drugs was a collective decision of the board of directors and thus all the directors will be made liable. The directors could not merely claim that they were not involved in the production of drugs.

[55] Shiv Vinayak Gupta & Anr. vs. Union of India and Others, Order dated December 12, 2022 in Writ Petition (Civil) No. 16952 of 2022.
[56] FMC Corporation & Ors. vs. Natco Pharma Limited, order dated December 5, 2022 in FAO(OS) No. 301 of 2022.
[57] FMC Corporation & Ors. vs. Natco Pharma Limited, order dated September 19, 2022 in Civil Suit (Comm.) No. 349 of 2022.
[58] Vikas Rambal and others vs. The State, Judgement dated October 12, 2022 in Criminal Original Petition No. 11184 of 2019.

Major Transactions

1. Advent to acquire Suven Pharma[59]

Advent International, a global private equity major, has agreed to acquire 50.10% stake in Suven Pharmaceuticals from the promoter Jasti family. Post the acquisition, Advent intends to explore the merger of Suven Pharma with Cohance Lifesciences, a portfolio company of Advent, to build a leading end-to-end CDMO and merchant API player, servicing the pharma and specialty chemical markets. The merger will be evaluated by the board taking into consideration the strategic rationale and accretiveness to Suven's public shareholders and will be subject to regulatory approvals and other customary approvals.

2. Hetero acquires Johnson & Johnson's manufacturing plant in Telangana[60]

Hetero Drugs, an Indian Pharmaceuticals firm, has acquired the manufacturing plant of Johnson & Johnson at Penjerla, Telangana. According to the news reports, the plant, which is spread across 55.27 acres, was acquired for INR 130 crore. As per a Hetero statement, the company has committed to an investment upwards of $75 million to upgrade and enhance existing facilities at the site and expand manufacturing of global biologics and sterile pharmaceutical products. The facility is expected to add 2,000 new jobs in biochemistry, pharmaceutical sciences, molecular biosciences, engineering, and ancillary services.

3. Biocon Biologics completes the acquisition of Viatris' biosimilar business[61]

Biocon Biologics Ltd. has successfully completed the acquisition of the global biosimilars business of its partner Viatris Inc. As per company's official release, this acquisition builds on Biocon's long-standing, strategic partnership with Viatris and is a historic milestone in Biocon Biologics' value creation journey. This acquisition strengthens the company's commitment to expand affordable access to lifesaving biosimilars worldwide, thus addressing global health inequities.

4. Gland Pharma announces acquisition of 100% equity stake in Cenexi Group[62]

Gland Pharma, a generic injectable-focused company, has announced signing of a Put Option Agreement to acquire Cenexi Group, a France-based Contract Development and Manufacturing Organisation firm, for an equity value of 120 million euros through its wholly-owned subsidiary, Gland Pharma International, Singapore. As per reports, Cenexi, along with its subsidiaries, is engaged primarily in the business of Contract Development and Manufacturing Organisation (CDMO) of pharmaceutical products, with

[59] https://www.thehindu.com/business/pe-major-advent-to-acquire-suven-pharma/article66306601.ece
[60] https://www.thehindu.com/news/cities/Hyderabad/hetero-acquires-johnson-johnson-plant-in-telangana/article66021899.ece
[61] https://www.biocon.com/biocon-biologics-acquires-viatris-global-biosimilars-business/
[62] http://bwhealthcareworld.businessworld.in/article/Gland-Pharma-To-Acquire-France-based-Cenexi-Group-For-Rs-1014-Cr/30-11-2022-456062/

expertise in sterile liquid and lyophilised fill-finished drug, including capabilities in oncology and complex products.

5. BSV to acquire Firstline Pharma and Genomicks[63]

Bharat Serums and Vaccines ("**BSV**") has entered into a definitive agreement to acquire Firstline Pharma and Genomicks to augment its presence in women's health and reproductive therapy in Malaysia, as per BSV's official statement. While Firstline Pharma is one of the leading distributors of fertility treatment in Malaysia, Genomicks currently distributes medical devices in the country. The companies distribute a wide range of products, which include FoliculinTM, Hucog, Humog, Profortil, Fortelle+Omega 3, the statement added.

6. JB Pharma to acquire Razel brand from Glenmark[64]

JB Chemicals & Pharmaceuticals Ltd. ("**JB Pharma**") said it had entered into an agreement with Glenmark Pharmaceuticals Ltd. to acquire the entire Razel (*Rosuvastatin*) franchise for India and Nepal region for a consideration of ₹313.7 crore. As per reports, the acquisition of the Razel franchise would result in JB Pharma's expansion into Statins, which is the largest therapeutic segment in cardiology.

7. Indegene acquires CultHealth[65]

Indegene, a Bengaluru based technology firm that provides solutions for life sciences companies in commercialization of their drugs and medical devices, has acquired CultHealth, a US-based full-service healthcare marketing agency for many life sciences brands. This acquisition is expected to propel Indegene's commercialisation portfolio spanning drug discovery and development to marketing and sales, adding brand strategy and market development capabilities, along with patient engagement platforms.

8. HCAH acquires RPG-owned e-commerce platform Seniority[66]

HCAH, an out-of-hospital care provider, has acquired an online store named Seniority from the RPG Group. Seniority is touted to be India's largest geriatric-centric digital platform. Health-tech company HCAH, earlier known as Healthcare at home, operates in the out-of-hospital healthcare segment and has raised investments from the Burman family (promoters of Dabur), founders of Healthcare at Home UK, Singapore-based healthcare fund Quadria Capital, and ABC Impact.

9. Viatris Acquires Taparias' eyecare business[67]

Viatris Inc., a global pharmaceutical company, has acquired Famy Life Sciences, an eyecare business owned by the Taparia family for a total cash of around INR 2,460 crore. The portfolio consists of six new chemical entities (NCEs or molecules) that are under phase 3 trials and will be developed further by Viatris.

10. Mankind Pharma acquires majority state in Upakarma Ayurveda[68]

Mankind Pharma, a leading Indian pharmaceutical company, has acquired a majority stake in Upakarma Ayurveda. Upakarma Ayurveda is in the business of developing, manufacturing, and selling ayurvedic and herbal products. This acquisition would allow Upakarma Ayurveda to widen its product offering and enhance its market penetration, leveraging upon Mankind's distribution network.

11. MedQuimica acquires rights to nine brands from Bausch Health[69]

Lupin Limited announced that its wholly-owned subsidiary, MedQuímica Indústria Farmacêutica (MedQuímica), has signed a definitive agreement to acquire all rights in relation to nine medicines from BL Indústria Ótica Ltda., a subsidiary of Bausch Health Companies Inc. As per the company's press statement, as part of the transaction, MedQuímica will acquire rights to nine products, including Limbitrol, Melleril and Dalmadorm for Central Nervous System related conditions, Bacrocin, Glyquin, Solaquin, Oxipelle and Efurix as topical oncological treatments, and Cuprimine for the treatment of Wilson's disease.

[63] https://www.expresspharma.in/bsv-to-acquire-firstline-pharma-and-genomicks/
[64] https://www.thehindu.com/business/jb-pharma-to-acquire-razel-franchise-from-glenmark-for-314-cr/article66262754.ece
[65] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/health-tech-firm-indegene-acquires-us-based-culthealth/articleshow/94969131.cms
[66] https://www.thehindubusinessline.com/companies/home-healthcare-services-hcah-buys-rpg-groups-digital-platform-seniority/article66119263.ece
[67] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/vitaris-buys-taparias-eyecare-business-for-rs-2300-crore/articleshow/95360653.cms
[68] https://www.livemint.com/companies/news/mankind-pharma-acquires-majority-stake-in-upakarma-ayurveda-11669635976909.html
[69] https://www.lupin.com/lupins-brazilian-subsidiary-medquimica-acquires-rights-to-nine-brands-from-bausch-health/

12. Lupin signs agreement to acquire two inhalation brands of Sun Sunovion Pharma[70]

Lupin, a leading drug maker, has announced an agreement to acquire two inhalation brands - namely Brovana (arformoterol tartrate) inhalation solution and Xopenex HFA (levalbuterol tartrate) inhalation aerosol – of Sun Sunovion Pharmaceuticals Inc, a US-based company, for a consideration of USD 75 million. This acquisition brands expands Lupin's portfolio of inhalation products in the US.

13. Apollo Hospitals acquires majority stakes in AyurVAID[71]

Apollo Hospitals Enterprise Ltd has acquired a 60% stake in leading classical Ayurveda hospital chain AyurVAID for a consideration of INR 26.4 crore. As per reports, the investment will be used to upgrade existing centres, set up new ones, strengthen enterprise platforms, and for digital health initiatives, as mentioned by Apollo in their regulatory filing.

14. Medi Assist Healthcare Services set to acquire majority stake in Mayfair We Care[72]

Medi Assist Healthcare Services Ltd., India's leading insurtech/ health tech and one of the largest health benefits administrators, has announced its intention to acquire 60% stake in Mayfair We Care ("**Mayfair**") for an undisclosed amount. Mayfair is a UK-based healthcare-focused administration service provider, with global presence. This acquisition will help Medi Assist to expand beyond India and provide medical benefits globally.

15. Cipla and Ethris partner to develop mRNA-based therapies[73]

Cipla has announced that its wholly-owned UK subsidiary, Cipla EU, has signed definitive agreements for EUR 15 million equity investment in Ethris GmbH, a global leader in delivering mRNAs directly to the respiratory system, including administration by inhalation. As per the company's statement, the investment will facilitate a long-term strategic partnership between the two companies for the development of messenger RNA (mRNA)-based therapies

and fast-track Cipla's participation in the mRNA space, enabling it to provide access to cutting-edge solutions developed by Ethris for developing countries.

16. Nikon India enters healthcare sector[74]

Nikon India Pvt Ltd, an imaging products firm, announced its foray in to India's healthcare sector through the System Product Microscopy business, by launching the AXR Point scanning confocal microscope. According to the company's statement, the company is aiming to facilitate direct sales, services, and distribution for its Microscopy Solutions. As per reports, the product is targeted at premiere research institutes, research centres funded and established by the government, academic educational institutions, clinical centres, hospitals, and medical research institutes to boost research and development in medicine.

17. IHH Healthcare attempts to acquire more stake in Fortis[75][76]

IHH Healthcare, a leading Malaysian healthcare company, has said that it is committed to the Indian market on a long-term basis and Fortis Healthcare remains its main platform for growth in India. There was a freeze put on an open offer by IHH to acquire additional 26.1 per cent stake in Fortis. The company has already acquired 31.17 per cent stake in Fortis, by infusing fresh capital of INR 4,000 crore in November 2018, and is currently waiting a go-ahead from capital

[70] https://www.lupin.com/lupin-signs-agreement-to-acquire-two-inhalation-brands-from-sunovion
[71] https://health.economictimes.indiatimes.com/news/mergers-and-aquisitions/apollo-hospitals-acquires-60-pc-stake-in-ayurvaid/94668978
[72] https://bwdisrupt.businessworld.in/article/Medi-Assist-Acquires-Majority-Stake-In-Mayfair/18-11-2022-454552/
[73] https://www.expresspharma.in/cipla-and-ethris-partner-to-develop-mrna-based-therapies/
[74] https://www.financialexpress.com/healthcare/medicaldevices/nikon-india-forays-into-healthcare-sector-in-india-to-focus-on-microscopy-business/2816201/
[75] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/ihh-healthcare-says-fortis-remains-its-main-platform-for-growth-in-india/articleshow/95486186.cms
[76] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/in-talks-with-sebi-for-fortis-open-offer-ihh-healthcare-ceo/articleshow/95387030.cms

markets regulator SEBI to proceed with its stalled open offer to acquire additional 26.1 per cent stake. IHH Healthcare is still in talks with SEBI to proceed with its open offer for Fortis Healthcare.

18. Rx Propellant deployed Rs. 1,100-crore for developing a lab in Hyderabad[77]

Rx Propellant, a life-sciences real estate development platform, has deployed INR 1,100 crore to develop a 9,00,000 square feet lab space at Genome Valley in Hyderabad, which is expected to be operational in 2025. It is the first expenditure from the total of USD 200 million that global fund Actis had infused in it.

19. Vedanta's BALCO and Anuva collaborate to conduct cancer research in India[78]

Vedanta's BALCO Medical Centre (BMC), one of India's leading cancer hospitals, and Anuva, a translational research company, have jointly announced a strategic collaboration to build a Cancer Genomics Biobank for cancer research in India. As per reports, this collaboration is expected to leverage on the strengths of both the organisations – the clinical expertise of BMC and Anuva's biobanking and genomic expertise.

20. Blackstone and Sheares Healthcare top contenders to buy Care Hospitals[79]

Blackstone, the world's largest private equity group, and Sheares Healthcare, a Temasek-owned Singapore platform, have emerged as the top contenders for Care Hospitals, one of India's largest hospital chains. The deal is estimated to be between INR 8,000 crore and INR 8,200 crore.

21. Dr. Reddy's Labs to spend INR 1,500 crore capex on biosimilars and injectables[80]

Dr. Reddy's Laboratories, a leading multinational pharmaceutical company based out of Hyderabad, is all set to spend a capex of around INR 1,500 crore in the next financial year, with focus on biosimilar and injectable businesses. The money will also be utilised towards addition of capacities to their existing plants, firming up their R&D activities, and further investments in digitisation projects.

22. Launch of Cohance Lifesciences[81]

Advent International, a global private equity firm, has announced the launch of Cohance Lifesciences as a new brand identity for its active pharmaceutical ingredient (API) and contract development and manufacturing services (CDMO) platform. It would comprise three portfolio companies – RA Chem Pharma, ZCL Chemicals and Avra Laboratories. As per reports, the new Cohance Lifesciences brand brings its API-focussed assets together under one platform. The platform is also forward integrated into pellets, formulations, and clinical research to provide end-to-end offerings to its customers.

23. Max Healthcare and Evex Hospitals collaborate to set up a Bone Marrow Transplant programme in Tbilisi, Georgia[82]

Max Healthcare and Evex Hospitals have entered into an agreement to set up a Bone Marrow Transplant programme at two hospitals in Tbilisi, Georgia. It has taken approximately 18 months to set up the programme, which will be led by personnel(s) appointed by Max Healthcare.

24. Abdul Latif Jameel Health and Wellesta Holdings Pte Ltd collaborate for marketing and distribution of Butterfly iQ+ ultrasound device in India[83]

Abdul Latif Jameel Health and Wellesta Holdings Pte Ltd have entered into an agreement for marketing and distribution of Butterfly iQ+, a kind of ultrasound device in India. Butterfly iQ+ is a first of its kind single probe, whole-body handheld point-of-care device. It is a step forward in medical imaging.

[77] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/rx-propellant-plans-rs-1100-crore-lab-in-hyderbad/articleshow/94973306.cms?from=mdr
[78] https://www.aninews.in/news/business/business/anuva-and-vedantas-balco-medical-centre-bmc-announce-strategic-collaboration-in-cancer-genomics20221007183111
[79] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/blackstone-temaseks-sheares-lead-race-for-care-hospitals/articleshow/95344072.cms
[80] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/dr-reddys-labs-lines-up-rs-1500-cr-capex-with-focus-on-biosimilars-injectables/articleshow/95333033.cms
[81] https://www.expresspharma.in/advent-international-launches-cohance-lifesciences/
[82] https://health.economictimes.indiatimes.com/news/hospitals/max-healthcare-evex-hospitals-sign-agreement-to-set-up-bmt-program-in-tbilisi/95913031
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