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# synapse

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

Volume VI | Issue IV | July 2023 - September 2023

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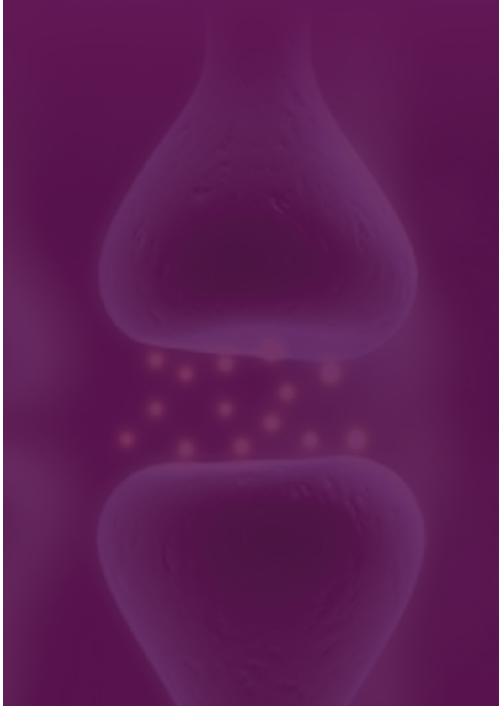


**Dear Readers,**

India's healthcare and life sciences sector fared well in the third quarter of 2023. With the Government's focus steering towards access and affordability of quality healthcare, the landscape is ripe for growth, to cater to the visible demand-supply mismatch. As disposable income among Indian households is rising, so is the demand for quality healthcare. The sector continues to embrace new technologies and AI driven diagnostics to enhance patient care and accessibility. India currently is at the cusp of embracing new challenges, in areas ranging from ART and Surrogacy to new Drugs and Medical Devices law, currently in the works, to ensure the highest possible regulatory standards and transparency. Overall, the sector is poised for rapid expansion as our economy continues to draw investor attention, owing to simplification of several FDI policies and general positive outlook.

Like the previous few quarters, the sector witnessed important regulatory updates even in the July - September 2023 quarter, which we have covered in this edition of *Synapse*. Most importantly, this quarter saw the notification of new regulations for Registered Medical Practitioners, focusing on their interactions on social media, telemedicine, replacement of continuing medical education with continuous professional development programme, and detailed guidance on prescription of generic medicine. However, owing to the strong backlash from the medical practitioners' fraternity, it was put on hold until further notice and the previously enacted Ethics Regulations, 2002 continued to stay in force. On the regulation of all medical devices, which came into effect on October 1, 2023, the remaining classes of medical devices – Class C (moderate risk) and D (high risk) – which are currently under mandatory registration, too would be brought under the licensing regime. Also, this quarter saw the notification of National Nursing and Midwifery Commission Act, 2023, which repeals the existing Indian Nursing Council Act, 1947, and National Dental Commission Act, 2023, to regulate the practice of dentistry in India and to provide quality and affordable dental education, access to high quality oral healthcare.

In the litigation space, the Hon'ble Supreme Court has held that a doctor's license cannot be suspended for contempt of court. The Apex Court has held that imposition of such a penalty would be a flagrant violation of the legislative wording of the Contempt of Courts Act, 1971, and the National Medical Commission Act, 2019, and clarified that a doctor's licence may be revoked for professional misconduct within the terms of the National Medical Commission Act itself, following an investigation and according to the rules of *audi alteram partem*, and such process being comprehensive and full. In another matter, the Hon'ble High Court of Delhi has held that the Health Ministry's decision to bring all medical devices within the ambit of the expression "drug" is a clear policy matter.

Furthermore, till the Ministry has the power to do so, no fault can be found with the impugned notification whereby all medical devices were brought within the purview of the expression "drug".

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

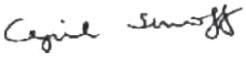
Cyril Amarchand Mangaldas, India's premier full-service law firm, has an industry leading and dedicated Pharmaceuticals, Healthcare and Life Sciences practice. Our class-leading practice specialists are always on top of the latest developments in the sector. In our endeavour to keep you abreast with the latest developments in this dynamic sector, we present to you the latest issue of Synapse. We hope that 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 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 of National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023, and subsequent suspension of operation [1]

The National Medical Commission ("**NMC**"), *vide* notification No. R-12013/01/2022/Ethics, dated August 2, 2023, notified the Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023. The said regulations introduced guidelines for Registered Medical Practitioners ("**RMPs**"), focusing on their interactions on social media, telemedicine, replacement of continuing medical education with continuous professional development programme, and detailed guidance on prescription of generic medicine. However, pursuant to the notification dated August 23, 2023, the above-mentioned regulations were put on hold until further notice and the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, continued to stay in force.

### 2. Notification on National Policy on Research & Development and Innovation in the Pharma-Med Tech Sector in India[2]

The Ministry of Chemical and Fertilizers ("**MoCF**"), *vide* notification no. No. 50020/5/2020-NIPER (R&D), dated August 16, 2023, notified the National Policy on Research & Development and Innovation in the Pharma-Med Tech Sector in India. The Policy postulates three main areas of focus; (i) to create a regulatory environment that facilitates innovation and research in product development, expansion of the traditional regulatory objectives of safety and quality; (ii) to incentivise private and public investment in innovation through a mix of fiscal and non-fiscal measures; and (iii) to build an enabling ecosystem designed to support innovation and cross-sectoral research as a strong institutional foundation for sustainable growth in the sector.

### 3. Notification on Scheme for Promotion of Research and Innovation in Pharma MedTech Sector[3]

The MoCF, *vide* notification no. No. 50018/2/2022-NIPER, dated August 16, 2023, notified the Scheme for Promotion of Research and Innovation in Pharma MedTech Sector ("**PRIP**"), to transform India's Pharma MedTech sector from cost-based to innovation-based, by focusing on strengthening the research infrastructure in the country. Notably, the PRIP scheme has two main components. The first component would focus on infrastructure building and includes establishing *'centres of excellence'* in seven campuses of National Institutes of Pharmaceutical Education and Research at a tentative cost of INR 700 crore over five years. The second component would include financial assistance to large industries, micro, small and medium industries and startups, carrying out research in collaboration with academic institutions as well as for in-house R&D.

### 4. Notification of Assisted Reproductive Technology (Regulation) Amendment Rules, 2023[4]

The Ministry of Health and Family Welfare ("**MoHFW**") released the Assisted Reproductive Technology (Regulation) Amendment Rules, 2023, *vide* G.S.R. 493(E) notification, dated July 11, 2023. The said amendment modified the qualification of Andrologist to MCh/DNB in urology or MS General Surgery or FNB/MCh/DM in reproductive medicine, with minimum two years' experience and having hands-on experience of minimum fifteen surgical sperm retrieval (namely PESA/ TESA/ TESE/ MESA/ MICROTESE procedures).

### 5. Notification of National Nursing and Midwifery Commission Act, 2023[5]

The Ministry of Law and Justice ("**MoL&J**") *vide* notification dated August 12, 2023, notified the National Nursing and Midwifery Commission Act, 2023 ("**NNMC Act**"). The said Act focuses on upkeep of nursing and midwifery practitioners' educational and service requirements, evaluation of institutions, maintenance of a National Register and State Registers, and establishment of a system to enhance adoption, research and access to the latest scientific progress. The NNMC Act repeals the existing Indian Nursing Council Act, 1947.

[1] https://www.nmc.org.in/rules-regulations/national-medical-commission-registered-medical-practitioner-professional-conduct-regulations-2023-reg/; getDocument (nmc.org.in)
[2] https://egazette.gov.in/WriteReadData/2023/248177.pdf
[3] https://egazette.gov.in/WriteReadData/2023/248170.pdf
[4] https://egazette.gov.in/WriteReadData/2023/247228.pdf
[5] https://prsindia.org/files/bills_acts/bills_parliament/2023/National%20Nursing%20and%20Midwifery%20Commission%20Act,%202023.pdf

### 6. Notification of Surrogacy (Regulation) Amendment Rules, 2023[6]

The MoHFW released Surrogacy (Regulation) Amendment Rules, 2023, *vide* G.S.R. 494(E) notification dated July 11, 2023. The said amendment modified the qualification of Andrologist to MCh/DNB in urology or MS General Surgery or FNB/MCh/DM in reproductive medicine with minimum two years' experience and having hands-on experience of minimum 15 surgical sperm retrieval (namely PESA/ TESA/ TESE/ MESA/ MICROTESE procedures).

### 7. Notification on prohibition of manufacture, sale and distribution of Ketoprofen and Aceclofenac for animal use[7]

The MoHFW *vide* notification S.O. 3448(E), dated July 31, 2023, notified prohibition on manufacture, sale and distribution of Ketroprofen and its formulations and Aceclofenac and its formulations for animal use because the said drugs pose a likely risk to animals.

### 8. Notification on National Dental Commission Act, 2023[8]

The MoL&J *vide* a notification on August 11, 2023, notified the National Dental Commission Act, 2023, to regulate the practice of dentistry in India, to provide quality and affordable dental education and access to high quality oral healthcare.

### 9. Circular on issuance of Form 11 (Test License) for Veterinary Vaccines/ Drugs[9]

The Directorate General of Health Services *vide* a circular dated July 19, 2023, has streamlined the regulatory submission procedure by introducing provision of application of issuance of Form 11 (Test Vaccine) for Veterinary Vaccines/ Drugs on SUGAM portal.

### 10. Notification of Draft Drugs Amendment Rules, 2023[10]

The MoHFW *vide* notification G.S.R. 686 (E), dated September 25, 2023, issued the draft Drugs Amendment Rules, 2023, amending the Schedule H1 of the Drugs Rules, 1945, by adding Oseltamivir and Zanamivir in the said schedule.

### 11. FAQs notified for Bar Code or QR Code on top 300 brands[11]

The Central Drugs Standard Control Organisation ("**CDSCO**") issued FAQs on July 25, 2023, on Drugs (Eighth Amendment) Rules, 2022, which notified schedule H2 drugs containing 300 brands of drugs and procedure to put bar code/ QR code on them. The list of 300 drugs included in the Schedule H2 include certain strengths of Aciloc, Actemra, Allegra, Amlokind, Ascoril D Plus New, Asthalin inhaler, Becosules capsules, Betadine ointment, solution and gargle, Calpol, Combiflam, Dolo 650 mg, Electral sachet, Fabiflu, Foracort, Gelusil, Glycomet, Janumet, Lantus, among others.

### 12. Notification on Jan Vishwas (Amendment of Provisions) Act, 2023[12]

The MoL&J *vide* a notification dated August 11, 2023, amended the Drugs and Cosmetics Act, 1940 ("**D&C Act**"), by substitution of the penalty provisions for use of Government Analyst's report (Section 29 of the D&C Act) for advertising from INR 5,000 (Indian Rupees five thousand) to would be liable to payment of penalty which may extend to INR 1,00,000 (Indian Rupees one lakh). Further, for a repeat offence under Section 29 of the D&C Act, the imprisonment which may be extended to two years, or with fine which shall not be less than INR 10,000 (Indian Rupees ten thousand) has been substituted with shall not be less than INR 5,00,000 (Indian Rupees five lakhs). Additionally, amendments were made in the Pharmacy Act, 1946, such as removal of the punishment of imprisonment and imposition of penalty of up to INR1,00,000 (Indian Rupees one lakh) for obstructing an inspector while exercising powers in line with the Act; imposing a penalty of INR 1,00,000 (Indian Rupees one lakh) for falsely claiming to be registered in the register of the State in case of first offence; and imprisonment up to three months or with a maximum fine of up to INR 2,00,000 (Indian Rupees two lakhs) or with both for subsequent convictions; punishment for dispensing by unregistered persons will be imprisonment for a term of three months or with fine which may extend to INR 2,00,000 (Indian Rupees two lakhs) or both (imprisonment and fine). A new provision too has been inserted for adjudication of penalties.

[6] https://egazette.gov.in/WriteReadData/2023/247221.pdf
[7] https://egazette.gov.in/WriteReadData/2023/247766.pdf
[8] https://main.mohfw.gov.in/sites/default/files/gazzette%20notification%20of%20NDC%20ACt.pdf
[9] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTAzNjE=
[10] https://egazette.gov.in/WriteReadData/2023/248998.pdf
[11] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTAzNzc=
[12] https://egazette.gov.in/WriteReadData/2023/248047.pdf)

### 13. Notification on revised composition of National Assisted Reproductive Technology and Surrogacy Board[13]

The MoHFW *vide* notification S.O. 4079 (E) dated September 15, 2023, notified the revised composition of National Assisted Reproductive Technology and Surrogacy Board by adding the Chairpersons of the States of Arunachal Pradesh, Assam, Uttar Pradesh and Tripura as Members, ex officio.

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

a) **Order on fixation of retail prices of 44 formulations[14]**

The NPPA *vide* order S.O. 3560(E) dated August 8, 2023, notified the fixation of retail prices of 44 formulations such as Tacrolimus Capsule (0.25 mg), Linagliptin + Metformin Hydrochloride Tablets, Levocetirizine, Montelukast & (SR) Ambroxol Hydrochloride Tablets, etc.

b) **Order on fixation of retail prices of 51 formulations[15]**

The NPPA *vide* order S.O. 4076(E) dated September 15, 2023, notified the fixation of retail prices of 51 formulations such as Linagliptin Metformin Hydrochloride Tablet, Pantoprazole Sodium (EC) & Levosulpiride (SR) Capsules, Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet, etc.

c) **Order on fixation of ceiling price of 2 formulations[16]**

The NPPA *vide* order S.O. 4077 (E) dated September 15, 2023, notified the fixation of retail prices for Piperacilin (A) – Tazobactum (B), 250 mg and 500 mg.

d) **Order on ceiling prices for Orthopaedic Knee Implant[17]**

NPPA *vide* order S.O. 4078 (E) dated September 15, 2023, directed that the ceiling prices of "Orthopaedic Knee Implants" would be reviewed after a period of one year. This order shall be applicable for the period of one year from September 16, 2023 (i.e. up to September 15, 2024), unless revised by another notification.

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

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

The FSSAI *vide* notification F. No. STD/SP-21/T(Alcohol-4), dated August 21, 2023, notified the Food Safety and Standards (Alcoholic Beverages) First Amendment Regulations, 2023, whereby it was laid down that alcoholic beverages would not be required to publish nutritional information on the label except energy content and the same would be voluntary.

b) **Notification of FSSAI manual of Methods of Analysis of Foods – Fish and Fish Products[19]**

The FSSAI *vide* order dated July 17, 2023, notified the FSSAI Manual of Methods of Analysis of Foods – Fish and Fish Products and the same superseded the Manual of Methods of Analysis of Foods - Meat and Meat Products & Fish and Fish Products issued *vide* Office Order No. 1-90/FSSAI/SP (MS&A)/2009, dated January 9, 2017. The manual has been drafted to serve as a comprehensive guide that serves as an invaluable resource for food testing laboratories, researchers and quality control professionals, food technologists, and anyone involved in the analysis of fish and fish products.

c) **Notification of FSSAI Manual of Methods of Analysis of Foods - Beverages: Tea, Coffee and Chicory[20]**

The FSSAI *vide* order dated July 17, 2023, notified the FSSAI Manual of Methods of Analysis of Foods - Beverages: Tea, Coffee and Chicory. Laboratories have been requested to use the said manual with immediate effect. The manual has been drafted to serve as a comprehensive guide that serves as an invaluable resource for food testing laboratories, researchers and quality control professionals, food technologists, and anyone involved in the analysis of Beverages: Tea, Coffee & Chicory.

[13] https://egazette.gov.in/WriteReadData/2023/248772.pdf
[14] https://egazette.gov.in/WriteReadData/2023/247928.pdf
[15] https://egazette.gov.in/WriteReadData/2023/248790.pdf
[16] https://egazette.gov.in/WriteReadData/2023/248790.pdf
[17] https://egazette.gov.in/WriteReadData/2023/248790.pdf
[18] https://egazette.gov.in/WriteReadData/2023/248239.pdf
[19] https://fssai.gov.in/upload/uploadfiles/files/Manual%20of%20Methods%20of%20Analysis%20for%20Fish%20%26%20Fish%20Products.pdf
[20] https://fssai.gov.in/upload/uploadfiles/files/Manual%20of%20Methods%20of%20Analysis%20for%20Beverages%20Tea%2C%20Coffee%20and%20Chicory.pdf

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## News Updates

### 1. Regulation for all medical devices with effect from October 1, 2023[21]

The Drugs Controller General of India ("**DCGI**") had previously set a deadline of October 1, 2023, for the medical devices industry to be fully brought under regulatory control. Up until October 1, 2023, only medical devices in Classes A (low risk) and B (low moderate risk) were being regulated. As per the DCGI, the new deadline will bring in the remaining classes of medical devices - Class C (moderate risk) and D (high risk), which are currently under mandatory registration, under the licensing regime. This is being done to control the quality of medical devices industry as well as to boost the revenues of manufacturers since the Indian medical devices industry accounts for just 1.5% of the total global medical devices market.

### 2. India in the final stages of introducing national policy to promote R&D in pharma-medical devices sectors[22]

In his keynote address to Indian industry leaders at the G20 Health Ministers meeting in Gandhinagar, the Union Minister of Health and Family Welfare, Mr. Mansukh Mandaviya stated that India is in the final stages of introducing a national policy to promote research, development and innovation in the pharma-medical devices sectors. The Union Health Minister invited countries, governmental bodies, industry leaders, healthcare professionals and researchers to join forces in a united effort to elevate the pharmaceutical and medical devices sectors to unprecedented heights. Mr. Mandaviya also held a bilateral meeting with Indonesia's Health Minister Mr. Budi Gunadi Sadikin and discussed several issues related to cooperation and collaboration in the healthcare sector, focusing particularly on quality, accessibility and affordability of medicines under the Jan Aushadhi Kendra model.

### 3. 143 pharma companies get show cause notices from CDSCO post inspections[23]

In a written reply to a question in Rajya Sabha, Union Minister of Health and Family Welfare, Mr. Mansukh Mandaviya stated the CDSCO, along with state licensing authorities, has conducted risk-based inspections of 162 pharmaceutical firms and issued show cause notices in 143 cases. Mr. Mandaviya also stated that orders such as stoppage of production have been issued in 40 cases, cancellation and suspension of product/ section licences in 66 cases, issuance of warning letter in 21 cases and in one case, an FIR has been lodged and three persons have been arrested as per the provisions of the Drugs Rules, 1945.

[21] https://www.thehindu.com/sci-tech/health/regulation-for-all-medical-devices-from-october-1-says-dcgi/article67044608.ece
[22] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/india-in-final-stages-of-introducing-national-policy-to-promote-rd-in-pharma-medical-devices-sectors-union-minister-mandaviya/articleshow/102873825.cms?from=mdr
[23] https://www.expresspharma.in/143-pharma-companies-get-show-cause-notices-from-cdsco-post-inspections/#:~:text=The%20Central%20Drugs%20Standard%20Control,Mansukh%20Mandaviya%2C%20Union%20Health%20Minister.

### 4. Pharma companies with over INR 250 crore turnover must adopt GMP within 6 months[24]

The Union Health Ministry has given six months to pharma companies with a turnover of more than INR 250 crore to adopt Good Manufacturing Practices ("**GMP**") and twelve months to companies with less than INR 250 crore. With a view to produce quality drugs in the country, Mr. Mandaviya stated that those who fail to follow the timelines may be penalised, in accordance with the provisions of the applicable law.

### 5. ICMR releases National List of Essential Assistive Products[25]

The Indian Council of Medical Research ("**ICMR**") has released the National List of Essential Assistive Products ("**NLEAP**") to prioritise essential assistive products to make a difference in the lives of those with functional impairments. Assistive products ("**APs**") play a pivotal role in enhancing the quality of life and promoting independence among individuals with functional impairments. The NLEAP is a list of 21 APs and technologies that are deemed essential for individuals with functional impairments to improve their quality of life and participation in the society.

### 6. Government to soon roll out U-Win portal for maintaining electronic registry of routine immunisations[26]

The Government is set to launch 'U-Win' portal, designed on the lines of the COVID-19 vaccine management system CO-WIN, for maintaining an electronic registry of routine immunisations. The U-Win programme has been designed to digitise the Universal Immunisation Programme ("**UIP**") and it is presently being run in a pilot mode in two districts of each state and Union Territory. The platform will be used to register and vaccinate every pregnant woman, record her delivery outcome, register every newborn delivery, administer birth doses and all vaccination events thereafter.

### 7. NPPA modifies guidelines for change in manufacturer to allow existing market entity to produce in its own plant[27]

The NPPA has modified the parameters in its guidelines to allow change of manufacturers after retail price of formulations are approved, allowing the existing marketing entity to produce the medicine in its own plant. The decision to modify the guidelines, as finalised in May, 2023, has come as a relief to marketing firms as they will now have the flexibility to start manufacturing the products on their own, if required. However, the Authority in its recent meeting, which approved the modification, refused to accept the industry's suggestion that the change of manufacturer may be notified by way of filing Form-V only, instead of seeking approval. The NPPA, in its meeting held on July 31, 2023, added the point allowing "Shifting of manufacturing to its own plant by the existing marketing entity," to the parameters under which the change in manufacturer may be allowed by the Authority in future cases.

### 8. First ABDM microsite under NHA '100 microsites project' launched in Mizoram[28]

The National Health Authority ("**NHA**") announced 100 microsites project to accelerate the adoption of Ayushman Bharat Digital Mission ("**ABDM**") nationwide. In India, Mizoram became the first state to operationalise an ABDM microsite. All patients can link their health records generated at these facilities with their Ayushman Bharat health accounts. As per a statement by R.S. Sharma, CEO, NHA, the 100 microsites project under the ABDM is a vital initiative for reaching out to the bulk of small and medium scale healthcare providers from the private sector and the concept of microsites was envisaged to provide a strong impetus towards healthcare digitisation efforts across the country.

### 9. Government may soon tweak PLI schemes for pharma, textiles to boost investment[29]

As per news reports, the Government may soon tweak the production-linked incentive scheme for pharmaceuticals, drones and textiles sectors to encourage investment and boost manufacturing. These sectors have been identified after inter-ministerial consultations on the performance of the scheme for various products. The PLI scheme was announced in 2021 for 14 sectors, including telecommunications, white goods, textiles, manufacturing of medical devices, automobiles, speciality steel, food products, high-efficiency solar PV modules, advanced chemistry cell battery, drones and pharma, with an outlay of INR 1.97 lakh crore.

[24] https://www.cnbctv18.com/business/companies/pharma-cos-with-over-rs-250-cr-turnover-have-to-adopt-gmp-within-6-months-mandaviya-17417831.htm
[25] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/icmr-releases-national-list-of-essential-assistive-products/articleshow/103719154.cms
[26] https://www.expresshealthcare.in/news/government-to-soon-roll-out-u-win-portal-for-maintaining-electronic-registry-of-routine-immunisations/440498/
[27] http://www.pharmabiz.com/ArticleDetails.aspx?aid=160914&sid=1
[28] https://www.business-standard.com/health/first-abdm-microsite-under-nha-100-microsites-project-launched-in-mizoram-123082300324_1.html
[29] https://www.business-standard.com/economy/news/govt-may-soon-tweak-pli-schemes-for-pharma-textiles-to-boost-investment-123091900700_1.html.


### 10. Government likely to extend export benefits under Remission of Duties and Taxes on Exported Products scheme for pharma, steel[30]

As per news reports, the government is expected to extend export benefits under the Remission of Duties and Taxes on Exported Products ("**RoDTEP**") scheme to iron and steel, chemicals and pharmaceutical sectors beyond September 30. In December 2022, the Government had extended the benefits under the RoDTEP Scheme to chemicals, pharmaceuticals and products of iron and steel till September 30 this year. As per a Government official statement, since exports have not been doing well recently, there is demand for extension for about six months till March 2024, which is under consideration.

### 11. NHRC sends notice to Centre, DGCI over circulation of falsified drugs[31]

The National Human Rights Commission (**NHRC**) has sent notices to the Union health Ministry and the DCGI over reported circulation of falsified liver drug, *Defitelio* and cancer drug, *Adcetris*. The NHRC has taken suo motu cognisance of a media report that after a World Health Organization ("**WHO**") alert, the CDSCO has asked state regulators, doctors and patients to remain vigilant about two medicines – Defitelio and Adcetris, as falsified versions of these drugs are circulating in four countries, including India.

### 12. Indian pharma industry to log in 8-10% revenue growth this fiscal[32]

The Indian pharmaceuticals industry is expected to log in 8-10% revenue growth in the current fiscal, aided by steady domestic growth and increased exports to regulated markets, even as semi-regulated markets face headwinds. As per news report, a study of 186 drug makers, which accounted for about half of the INR 3.7 lakh crore annual revenue of the sector last fiscal, indicated as much. The growth will be supported by price hikes allowed by the NPPA and the sale of existing drugs and new launches.

### 13. India mulls annual audit of raw material suppliers by drugmakers[33]

India is considering making it mandatory for drugmakers to audit their raw material suppliers, atleast once a year. Mooted by the CDSCO at a drugmakers' meeting earlier this month on the revised Schedule M (Good Manufacturing Practices) of Drugs Rules, 1945, the proposal came in the backdrop of World Health Organisation, beginning October 2022, flagging India-made cough syrups, which allegedly resulted in the death of several children in Gambia and Uzbekistan. In a presentation at the meeting, CDSCO stated that the proposed annual audit will replace the existing self-inspection, quality audits and supplier audits, whose frequency is routine and on specific occasions such as

[30] https://www.business-standard.com/economy/news/govt-likely-to-extend-export-benefits-under-rodtep-scheme-for-pharma-steel-123083001046_1.html
[31] https://www.business-standard.com/india-news/nhrc-sends-notice-to-centre-dgci-over-circulation-of-falsified-drugs-123091300733_1.html
[32] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/indian-pharma-industry-to-log-in-8-10-pc-revenue-growth-this-fiscal-crisil/articleshow/103571141.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst
[33] https://www.thehindu.com/business/Industry/india-mulls-annual-audit-of-raw-material-suppliers-by-drugmakers/article67327377.ece

product recall or inspection by the licencing authority. The suppliers audit will cover raw material and packaging material as well.

### 14. CDSCO approves nine more MDTLs, taking the count to 39[34]

The CDSCO has approved nine more Medical Device Testing Laboratories (MDTL) this year, including the laboratories of public sector undertakings HLL Lifecare Ltd and Atal Incubation Centre (AIC), Medivalley at Andhra Pradesh MedTech Zone. The addition takes the total number of laboratories for conducting tests under the provisions of the Medical Devices Rules, 2017 ("**MDR 2017**"), from 30 till last year to 39 across the country at present. As per news reports, the laboratories are registered to carry out tests or evaluation of medical devices on behalf of the manufacturer applied under Form MD-40, under the MDR 2017.

### 15. Industry to observe October 10 as 'cGMP Day' every year to sensitise public about drug quality[35]

Drug manufacturers in the country celebrated October 10 as 'cGMP Day' for the first time this year. 'cGMP Day' will be organised every year to sensitise the public that the industry is fully adhering to every aspect of quality assurances of medicinal products that they are manufacturing. The Indian Drug Manufacturers' Association ("**IDMA**") organised the celebration.

### 16. Sun Pharma partners with USA's Pharmazz to bring an innovative stroke drug to India[36]

Global pharma giant Sun Pharmaceutical Industries Limited has announced that it has entered into a licence agreement with American biopharmaceutical company, Pharmazz Inc., to commercialise an innovative drug, Sovateltide (**Tycamzzi™**), in India. Sovateltide, developed by Pharmazz for potential global use, is intended to treat cerebral ischemic stroke. Under the agreement, Sun Pharma obtained the rights to market Sovateltide in India under the brand name, Tycamzzi™.

### 17. Zydus Lifesciences gets USFDA nod to manufacture and market generic version of Varenicline[37]

Zydus Lifesciences has received final approval from the US Food and Drug Administration ("**USFDA**") to manufacture and market the generic version of Varenicline tablets, indicated to treat smoking addiction. As per a Zydus statement, the USFDA approval is for Varenicline tablets of strengths 0.5 mg and 1 mg. The product will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India. As per a survey data, varenicline tablets of 0.5 mg and 1 mg had annual sales of $501 million in the US.

### 18. Lupin receives US regulator's approval for Cyanocobalamin nasal spray[38]

Pharmaceutical firm Lupin announced that the USFDA had approved its abbreviated new drug application for cyanocobalamin nasal spray. Cyanocobalamin is a manufactured version of vitamin B12 used to prevent and treat vitamin B12 deficiency anaemia (low blood levels of this vitamin in the body). Lupin's nasal spray is a generic version of Nascobal nasal spray and will be made at the firm's Somerset facility in the US, the company said. According to an analytical data, Cyanocobalamin nasal spray had estimated annual sales of $69 million in the US.

### 19. Glenmark Pharmaceuticals gets USFDA nod to market generic diabetes drug[39]

Glenmark Pharmaceuticals has received the USFDA approval to market a generic diabetes drug in the American market. As per a Glenmark Pharmaceuticals' statement, the company has received final approval from the USFDA for Saxagliptin Tablets (2.5 mg and 5 mg), the generic version of AstraZeneca's Onglyza1 tablets, the Mumbai-based drug maker said in a statement.

### 20. Medanta ties-up with GE HealthCare to launch digital ICU services[40]

Medanta, a private healthcare provider group, has introduced a 24/7 remote and virtual service for ICU patients.

[34] http://www.pharmabiz.com/NewsDetails.aspx?aid=162597&sid=1
[35] http://www.pharmabiz.com/NewsDetails.aspx?aid=162568&sid=1
[36] https://www.businesstoday.in/industry/pharma/story/sun-pharma-partners-with-usas-pharmazz-to-bring-an-innovative-stroke-drug-to-india-398421-2023-09-14
[37] https://www.business-standard.com/companies/news/zydus-lifesciences-gets-usfda-nod-to-mfg-generic-version-of-varenicline-123061300552_1.html
[38] https://www.business-standard.com/industry/news/lupin-receives-us-regulator-s-approval-for-cyanocobalamin-nasal-spray-123070300568_1.html
[39] https://www.business-standard.com/india-news/glenmark-pharmaceuticals-gets-usfda-nod-to-market-generic-diabetes-drug-123080100301_1.html
[40] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/medanta-ties-up-with-ge-healthcare-to-launch-digital-icu-services/articleshow/102166675.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

It has partnered with GE HealthCare to launch the Medanta e-ICU Command Centre, which will provide 24/7 advanced consultation, care and near-real-time monitoring of critically ill patients, "without having to physically transfer them to a super-specialty hospital". The command centre is supported by Medanta's specialised critical care team. GE HealthCare has been supporting healthcare providers across Asia-Pacific in deploying digital technologies to enhance clinical outcomes and processes.

### 21. Serum India to launch dengue vaccine in India soon[41]

Pune-based Serum Institute of India will be launching vaccines for dengue in approximately a year's time as the disease is spreading rapidly in the country as well as worldwide. Furthermore, an executive for the Serum Institute also stated that the dengue vaccine, in the pipeline, is in partnership with the National Institutes of Health in the United States.

### 22. BDR Pharma launches generic drug for fungal infections at 1/3rd cost[42]

BDR Pharmaceuticals, a leading pharma company, has announced the launch of Zisavel capsules for treating invasive aspergillosis and mucormycosis, both fungal infections. This generic medication, classified under azole antifungals, is offered at one-third the price of the current therapy provided by the innovators. According to news reports, BDR Pharmaceuticals aims to make invasive fungal diseases' treatment with isavuconazole as affordable as voriconazole and posaconazole, two new-generation antifungal agents. Notably, this initiative aims to widen access to these crucial medications, ensuring they are within the reach of patients who are currently struggling to afford them.

### 23. India finds 'violations' at cough syrup maker linked to Cameroon deaths[43]

India has found violations related to manufacturing and laboratory practices at drugmaker Riemann Labs, whose

cough syrup was linked to the deaths of children in Cameroon. Riemann Labs is the fourth Indian cough syrup maker to stop production after regulators found lapses. A batch of cough syrups manufactured by the company was linked to the death of at least six children in Cameroon by the country's authorities. Consequently, samples of all the company's products were sent for testing. Further action would be decided based on the results. Indian authorities have tightened their testing of cough syrup exports since June 2023, making it mandatory for companies to obtain a certificate of analysis from a Government laboratory before undertaking exports of such products.

### 24. CDSCO issues alert against 51 substandard drug samples; three declared spurious[44]

The CDSCO has flagged 54 commonly used medicines as they failed the latest drug safety alert issued by the drug regulator in July 2023. According to the July alert list released by the CDSCO, 51 samples were declared as "Not of Standard Quality". Meanwhile, three samples were flagged as "Spurious". Folic Acid Tablets, Paracin Plus Suspension, Norfloxacin Tablets, Amoxycillin & Potassium Clavulanate Tablets, Albendazole Tablets and Telmisartan Tablets are some of the drugs that were flagged by the regulator.

[41] https://www.indiatoday.in/india/story/malaria-vaccine-launch-soon-dengue-cure-in-one-year-serum-institute-chief-cyrus-poonawalla-2428843-2023-08-30
[42] https://www.business-standard.com/industry/news/bdr-pharma-launches-generic-drug-for-fungal-infections-at-1-3rd-the-cost-123092900309_1.html
[43] https://www.business-standard.com/companies/news/india-finds-violations-at-cough-syrup-maker-linked-to-cameroon-deaths-123080200264_1.html
[44] https://www.financialexpress.com/healthcare/pharma-healthcare/cdsco-issues-alert-against-51-substandard-drug-samples-3-declared-as-spurious/3222773/


## Litigation Updates

### 1. Supreme Court holds that a Doctor's License cannot be suspended for Contempt of Court[45]

The Hon'ble Supreme Court ("**SC**"), in Civil Appeal No. 4725 of 2023, has set aside an order issued by the Hon'ble Calcutta High Court, by virtue of which a RMP's licence was suspended due to contempt of court. The SC determined that imposition of such a penalty would be a flagrant violation of the legislative wordings of the Contempt of Courts Act, 1971 ("**Contempt of Courts Act**"), and the National Medical Commission Act, 2019 ("**NMC Act**"), which govern the grant, regulation, and suspension of medical licences. A RMP's licence may be revoked for professional misconduct within the terms of the NMC Act itself, following an investigation and according to the rules of *audi alterum partem*, and the process is comprehensive and full. The Contempt of Courts Act, on the other hand, expressly specifies penalty under Section 12(1) as a fine of no more than INR 2,000 or a term of simple imprisonment of no more than six months. Accordingly, the SC held that suspension of the doctor's ability to practise medicine is wholly inconsistent with the Contempt of Courts Act, and hence unjustifiable.

### 2. Supreme Court awards INR 1.6 crore to individual in HIV medical negligence case[46]

The Hon'ble SC in Civil Appeal No. 7175 of 2021, dated September 26, 2023, ordered the Indian Air Force (**IAF**) to pay approximately INR 1.6 crore as compensation to a veteran who contracted the human immunodeficiency virus (**HIV**) during a blood transfusion at a military hospital and slammed the IAF and the Army for their conduct and held them vicariously liable, both jointly and severally. The SC was hearing an appeal against a judgment of the National Consumer Disputes Redressal Commission (**NCDRC**), which had dismissed a plea by the veteran for INR 95.31 crore as compensation for the medical negligence that had led to him being infected by HIV. The SC took critical note and inferred that only superficial attention was paid during the blood transfusion on several aspects and noted that there was lack of adherence to or breach of relevant standards of care, reasonably expected from a medical establishment and systemic failure in ensuring safe transfusion of blood to the veteran. The SC opined that these facts establish medical negligence, and therefore, vicarious liability on the part of

[45] *Gostho Behari Das vs Dipak Kumar Sanyal* dated July 28, 2023 in Civil Appeal No. 4725 of 2023.
[46] CPL Ashish Kumar Chauhan Retd vs. Commanding Officer and ors. dated September 26, 2023 in Civil Appeal No(S). 7175 of 2021.

the IAF and the Indian Army. Furthermore, the IAF and Army were also directed to cooperate during future medical treatments and bear the veteran's travel expenses for bi-monthly check-ups.

### 3. Delhi High Court upholds MoHFW's notifications categorising all medical devices as 'drugs'[47]

The Division Bench of the Hon'ble Delhi High Court, in W.P.(C) Nos. 10514/2019 & 10478/2020, has upheld the MoHFW decision to bring all medical devices within the ambit of the expression *"drug"* in terms of the D&C Act. The Court heard the two petitions filed by the Surgical Manufacturers and Traders Association ("**Association**"), challenging the MoHFW's Notifications dated February 11, 2020 ("**2020 Notification**"), and December 3, 2018 ("**2018 Notification**"), along with a challenge to Section 3(b)(iv) and Section 5(2) of the D&C Act. The 2018 Notification had brought four medical devices within the ambit of "drug" as defined under Section 3(b)(iv) of the D&C Act, while the 2020 Notification had brought all medical devices within the ambit of *"drug"* as defined under Section 3(b)(iv) of the D&C Act.

The Court held that MoHFW's decision to bring all medical devices within the ambit of the expression *"drug"* is a clear policy matter. Furthermore, as long as MoHFW has the power to do so, no fault can be found with the 2020 Notification, whereby all medical devices were brought within the purview of the expression *"drug"*. Furthermore, the Court noted that the MoHFW's reasons for doing so are manifold, *inter alia* the desire to align itself with the international regulatory regime and to further the interest of patients. The Court also noted that mere errors, if any, in an otherwise robust policy, which has been devised bearing in mind patient safety, cannot be upturned by the Court while exercising the power of judicial review under Article 226 of the Constitution, unless there is a clear case of demonstrable violation of fundamental rights, including Article 14 and 21 of the Constitution.

### 4. Gujarat High Court voices concern over authorities wrongly arresting doctors under the PCPNDT Act and upholds discharge order of patient[48]

The Hon'ble Gujarat High Court, in the matter of Special Criminal Application No. 8286 of 2019, dated July 26, 2023, discussed the issue of officers and authorities registering complaints under the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 ("**PCPNDT Act**"), and the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996 ("**PCPNDT Rules**"). The Court observed that the authorities may be right in taking action against erring doctors, but mostly their actions prove non-application of mind, causing genuine doctors to suffer. A complaint was filed against the owner of the hospital and two visiting doctors for offences under Sections 4(3), 5(1-b), 19(4) and 29 of the PCPNDT Act and Rules 6(2), 9(1), 10 and 17(2) of the PCPNDT Rules. The allegations were in relation to non-fulfilment of provisions regarding maintenance of records and non-filling up of forms provided under the PCPNDT Act and the PCPNDT Rules. The Court *inter alia* observed that the object of the PCPNDT Act was to prohibit prenatal diagnostic techniques for sex determination of a foetus, leading to female foeticide; and noted that there was no *prima facie* evidence of breach of Rule 10 of the PCPNDT Rules, which provides for 'conditions for conducting pre-natal diagnostic procedures', thus discharging the accused 1 (the visiting doctor). The Court also noted that Form 'F' is to be maintained by the authority and/or staff of the clinic and it is not the duty of the visiting gynaecologist to maintain such records and Form 'F'.

### 5. Kerala High Court quashes case against clinical establishment and nine doctors accused of misconduct[49]

The Hon'ble Kerala High Court in CRL.MC No. 1019 of 2022, dated July 26, 2023, quashed a criminal case against Aster Medcity (a hospital) and nine doctors accused of flouting organ transplantation protocols. The cases were in relation to the commission of offences in terms of the provisions of the Indian Penal Code, 1860, and the Transplantation of Human Organs and Tissues Act, 1944. The complaint stated that Aster Medcity and its practicing doctors had not adhered to the prescribed protocols for certifying brain death and harvesting organs for transplantation. This despite the Government of Kerala introducing new guidelines to enhance transparency in brain stem death certification and organ donation processes within the state's hospitals, which made it mandatory for Government doctors to be present during the certification of brain stem deaths in Kerala's hospitals. The Court's decision

[47] *Surgical Manufacturers & Traders Association v. Union of India* dated September 1, 2023 in W.P.(C) Nos. 10514/2019 & 10478/2020.
[48] *Pappu Kumar Singh v. Dharmesh Bharatbhai Patel*, Judgement dated July 26, 2023 in R/Special Criminal Application No. 8286 Of 2019.
[49] *Aster Medcity & Ors. v State of Kerala & Anr.*, Judgement dated July 2023 in CRL.MC No. 1019 of 2022.

acknowledges Aster Medcity and its practicing doctors' compliance with the established protocols and emphasises the importance of adhering to the guidelines set forth by the government to ensure transparency and accountability in organ transplantation processes.

### 6. Punjab and Haryana High Court approves bail to Ayurvedic Gynaecologist involved in a pregnancy termination case[50]

The Hon'ble Punjab and Haryana High Court, in the matter of CRM-M-31863 of 2023, granted interim anticipatory bail to an Ayurveda gynaecologist accused of performing an unauthorised pregnancy termination. This decision was made after considering the submission made on behalf of the Ayurvedic practitioner that it was debatable whether the case was one of pregnancy termination or premature delivery.

The Ayurveda practitioner's counsel argued that if it is found to be a case of pre-mature delivery, the petitioner would be entitled to get the benefit of a 2017 communication issued by the Government of India, permitting certain practitioners of Indian medicine to perform such deliveries. Furthermore, the case involved allegations of criminal conspiracy and offences under the Medical Termination of Pregnancy Act, 1971. According to the authorities, confidential information was received about an illegal abortion being performed by a doctor at a hospital in Kaithal.

[50] *Dr. Mehak v. State of Haryana,* Judgement dated July 6, 2023 in CRM-M-31863-2023.

## Transaction Updates

### 1. Baring Asia to acquire India's largest fertility chain Indira IVF[51]

BPEA EQT, an Asia focused private equity fund, is set to acquire about 60% in Indira IVF for $656.6 million. Indira IVF is the largest provider of fertility services in India and is among the top five globally in terms of annual IVF cycles. As per news report, global investors such as Baring PE Asia EQT and Blackstone had submitted non-binding bids to acquire majority stake in India's largest fertility clinic chain, Indira IVF, valuing it at $1-1.2 billion. Further, the new investor is likely to end up owning about 60% stake, with the existing investor TA Associates selling its 47% holding and the promoters diluting additional stakes.

### 2. Torrent likely to buy out Cipla, in talks with PEs, banks for funds[52]

Torrent Pharma, a leading pharma player in the country, is actively working to secure financing to buy out the promoter family of Cipla, and thus, positioning itself as a key contender in what could become the largest pharma sector acquisition in the country to date. Ahmedabad-based Torrent had approached PE funds such as Warburg Pincus, CVC, among others, to raise around $1 billion before submitting a binding offer by early October. According to a news report, rival contenders such as Blackstone, Baring Asia hit pause mode as Cipla valuations soared.

### 3. Cipla to acquire Actor Pharma for $49 million[53]

Pharma major Cipla is all set to acquire Actor Pharma, a privately owned consumer health and generic medicine company, for $48.6 million, in an attempt to expand its presence in the South African market. As per a statement issued by Cipla, the transaction was executed through its wholly-owned subsidiary in South Africa, that signed a binding term-sheet with Actor Holdings to acquire 100 percent of the issued ordinary shares of Actor Pharma.

### 4. Lupin acquires two brands from Boehringer Ingelheim India[54]

Lupin Ltd., a leading Indian pharmaceuticals company, has announced the acquisition of diabetes brands *"ONDERO"* and *"ONDERO MET"* from Boehringer Ingelheim International GmbH, including the associated trademark rights with these brands for €26 million. As per a statement issued by Lupin, this move will solidify its position as a market leader in the

[51] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/baring-asia-to-acquire-largest-fertility-chain-indira-ivf/articleshow/102191385.cms?from=mdr
[52] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/torrent-in-top-gear-to-close-out-cipla-buyout-in-talks-with-pes-banks-for-funds/articleshow/103258025.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst
[53] https://www.cnbctv18.com/business/cipla-acquires-south-africas-actor-pharma-for-49-million-17717251.htm
[54] https://www.thehindu.com/business/lupin-acquires-two-brands-from-boehringer-ingelheim-boosts-diabetes-portfolio/article67210186.ece

anti-diabetes segment. Lupin had been marketing these brands in India since 2015 as part of a co-marketing agreement with Boehringer Ingelheim India.

### 5. Biocon Biologics takes over commercialisation of Biosimilars Business from Viatris[55]

Biocon Biologics, a subsidiary of biopharmaceutical company, Biocon, has announced that it has completed the integration of the biosimilars business acquired from American pharma company Viatris in over 70 countries. As per a statement by Biocon Biologics, all biosimilar products previously commercialised by Viatris and co-developed with Biocon Biologics, such as Glargine (Semglee), Pegfilgrastim (Fulphila), Trastuzumab (Ogivri), Bevacizumab (Abevmy), and Adalimumab (Hulio), which is in-licensed by Mylan, will continue to meet patients' needs.

### 6. Biocon acquires Eywa Pharma's US-based manufacturing facility for $7.7 million[56]

Biocon's wholly-owned subsidiary, Biocon Generics, has acquired oral solid dosage manufacturing facility of US-based Eywa Pharma Inc., located in Cranbury, New Jersey, for $7.7 million. As per a statement issued by Biocon, the US facility could further expand its capacity up to two billion tablets or capsules per year. The company further stated that the acquisition of this USFDA approved facility will complement Biocon's existing manufacturing capabilities, allow addition of oral solid dosage capacities for new products earlier than originally planned, ensure supply continuity and strengthen foothold in the United States.

### 7. Fortis Healthcare expands footprint with Rs. 225-crore acquisition of Medeor Hospital, Manesar[57]

Fortis Healthcare is set to acquire Medeor Hospital, Manesar, for INR 225 crore. As per a Fortis Healthcare statement, the acquisition involves the procurement of both Medeor Hospital, Manesar (asset), as well as all the moveable assets housed within the hospital asset, making Fortis the second-largest healthcare services provider in Gurugram with over 850 beds. As per news reports, this will enable Fortis to offer top-tier healthcare services to residents in the burgeoning areas of New Gurgaon, Dwarka Expressway, IMT Manesar, and along National Highway - 48.

### 8. Krensavage declines Sun Pharma's lowball bid to increase stake in Taro Pharma[58]

Sun Pharma, the majority shareholder of Taro Pharma, with a 78.5% stake, made an offer to acquire the remaining stake, valuing the company at $1.4 billion. However, as per news reports, Krensavage, the largest minority shareholder of Taro Pharma, claimed that Sun Pharma's offer was inadequate, amounting to a 17 percent discount. As per Krensavage, the tangible assets' value amounts to $38 per share of net cash, whereas Taro's liquidation could potentially provide shareholders more than $45 a share.

### 9. Corona Remedies buys Sanofi India's ortho brand Myoril[59]

Ahmedabad-based Corona Remedies Private Limited has announced the acquisition of muscle relaxant brand "Myoril" from Sanofi, a global pharmaceutical giant, at INR 234 crore. As per news report, with the *Myoril* brand becoming a part of its portfolio, Corona is all set to gain its first offering in the muscle relaxant category, strengthening its existing line-up of more than 80 brands.

### 10. Morgan Stanley PE Asia purchases controlling stake in ClearMedi Healthcare[60]

Morgan Stanley PE Asia has acquired a controlling stake in ClearMedi Healthcare, a Delhi based oncology hospital and radiation therapy centre chain, for approximately $35 million. As per news report, the deal involves buy out of 100% stake from Italy's KOS Group and injection of fresh equity into the company, in a move marking Morgan Stanley's debut in the Indian healthcare landscape. ClearMedi Healthcare manages complex clinical services, including oncology, nuclear medicine and radiology, and operates standalone super specialty hospitals with over 350 hospital beds across different locations.

[55] https://www.businesstoday.in/latest/corporate/story/biocon-biologics-takes-over-biosimilars-business-from-viatris-in-over-70-countries-388374-2023-07-05
[56] https://www.business-standard.com/companies/news/biocon-acquires-eywa-pharma-s-us-based-manufacturing-facility-for-7-7-mn-123090200623_1.html
[57] https://www.cnbctv18.com/business/companies/fortis-healthcare-expands-footprint-with-rs-225-crore-acquisition-of-medeor-hospital-manesar-17678181.htm
[58] https://www.cnbctv18.com/market/stocks/krensavage-declines-sun-pharmas-lowball-bid-to-increase-stake-in-taro-pharma-17269281.htm
[59] https://www.thehindubusinessline.com/companies/corona-remedies-acquires-myoril-brand-from-sanofi-for-234-cr/article67019725.ece
[60] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/morgan-stanley-pe-acquires-controlling-stake-in-clearmedi-healthcare/articleshow/101806216.cms?from=mdr

### 11. Sigachi Industries forays into API business, acquires majority stake in Trimax Bio Sciences[61]

Sigachi Industries has ventured into the active pharmaceutical ingredient ("**API**") business by acquiring a majority stake i.e. 80% in Trimax Bio Sciences, an API manufacturing company located in Raichur, Karnataka. As per a Sigachi Industries statement, the API unit is equipped with cutting-edge technology and follows stringent international quality standards of the USFDA, EMEA and WHO. Further, the company also stated that the API unit is approved by the USFDA for advanced and critical intermediates, and that the acquired API unit will synergise seamlessly with Sigachi's existing portfolio of excipients to provide a one stop solution for customers' API and non-API needs.

### 12. IHH Healthcare to acquire remaining stake in Ravindranath GE Medical Associates[62]

Malaysia's IHH Healthcare Bhd is likely to acquire the remaining stake in hospital chain operator Ravindranath GE Medical Associates ("**RGE**"), held by Ravindranath Kancherla and his affiliates, for around INR 740 crore. IHH Healthcare has inked the agreement to acquire the stake in RGE through its wholly-owned subsidiary Gleneagles Development, a leading tertiary and quaternary healthcare chain. As per news reports, this transaction will strengthen IHH's position as a tertiary and quaternary care platform, including multi-organ transplants, in India and across its key markets.

### 13. India Resurgence Fund in talks to acquire Ind-Swift's API business[63]

India Resurgence Fund, an India-focused distressed and special situations investment platform, sponsored by the Piramal Group and Bain Capital Credit, is in talks to acquire the API business of debt ridden Ind-Swift Laboratories, according to sources familiar with the matter. As per news reports, the investment size could be in the range of INR 1,000 crore. Earlier in July 2021, Ind-Swift Laboratories had agreed to sell its API business to PI Industries on a slump sale basis, for INR 1,530 crore. However, the said deal was terminated by PI Industries in November 2021.

### 14. Asia Health in talks to acquire kidney care hospital Asian Institute of Nephrology and Urology[64]

Asia Healthcare Holdings, an India-based investment platform, is negotiating with kidney care hospital chain, Asian Institute of Nephrology and Urology ("**AINU**"), to acquire a majority stake, approximately 70%, at a valuation of INR 500-520 crore, while the current management will continue to operate the business. Notably, Singapore's sovereign wealth fund GIC had invested $170 million for a minority stake in Asia Healthcare Holdings last year.

### 15. Warburg in advanced talks to buy medical equipment manufacturer Appasamy[65]

Warburg Pincus, a leading private equity firm, is in advanced discussions to acquire Chennai-based medical equipment producer, Appasamy Associates. The US-based Warburg Pincus has signed an exclusivity agreement with Appasamy Associates. The due diligence process has already begun. According to news reports, Appasamy promoters are expecting a valuation of INR 4,000-4,500 crore, while Warburg Pincus plans to acquire a 65-70% stake in the company and have the current management run the company. Appasamy Associates is the market leader in the Indian intraocular lens market, with approximately seventy-five percent market share.

### 16. Norwest likely to buy 40% in Regency Health for INR 600 crore[66]

Norwest Venture Partners, a leading American venture and growth equity investment, is close to buying 40% stake in Regency Healthcare for up to INR 600 crore in a deal involving both an expansion of the equity base and transfer of existing shares to the Wells Fargo-backed buyer. US banking giant Wells Fargo is the main institutional limited partner in Norwest Venture Partners. According to news report, Norwest and Regency Healthcare could finalise an agreement within two weeks. As per the new arrangement, International Finance Corporation (**IFC**) and HealthQuad, which had earlier invested around $14 million in Regency Healthcare in 2016, will now be exiting.

[61] https://www.expresspharma.in/sigachi-industries-forays-into-api-business-acquires-majority-stake-in-trimax-biosciences/#:~:text=Sigachi%20Industries%20has%20forayed%20into,%2C%20located%20in%20Raichur%2C%20Karnataka
[62] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/ihh-healthcare-to-acquire-remaining-stake-in-ravindranath-ge-medical-associates-for-rs-740-cr/articleshow/103063799.cms
[63] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/india-resurgence-fund-in-talks-to-acquire-ind-swifts-api-business/articleshow/101996048.cms
[64] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/asia-health-in-talks-to-acquire-kidney-care-hospital-ainu/articleshow/101678032.cms
[65] https://www.medicalbuyer.co.in/warburg-in-talks-to-buy-appasamy/
[66] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/norwest-set-to-buy-40-in-regency-health-for-600-cr/articleshow/103998389.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

### 17. Apollo acquires under-development hospital asset from Future Oncology in Kolkata for Rs 102 crore[67]

Apollo Hospitals has acquired a partially built hospital in Sonarpur, Kolkata, with a total capacity of 325 beds. The acquisition is being fully funded by Apollo Multi Speciality Hospitals. The hospital will offer high-end specialties, including comprehensive oncology services with radiotherapy. As per news reports, the acquisition is being fully funded by Apollo Multi Speciality Hospitals, a 100% wholly owned subsidiary of Apollo Hospitals, through internal accruals. This acquisition strengthens Apollo's position as the largest healthcare provider in the eastern region, with over 1,800 beds across Kolkata, Bhubaneshwar and Guwahati.

### 18. CVC may sell controlling stake in Indian hospital chain HealthCare Global[68]

CVC Capital Partners, a leading global private equity and investment advisory firm, may sell controlling stake in Indian cancer hospital chain, HealthCare Global Enterprises Ltd. As per news report, CVC Capital is looking to identify buyers for its 60.4% stake in the Mumbai-listed company. Currently, the private equity firm's stake is worth about $358 million, according to data compiled by Bloomberg. Notably, CVC Capital may seek a premium of at least 20% for the shares, potentially even up to 50%, depending on market conditions. HealthCare Global owns 24 cancer centres across India and serves over 2,00,000 patients annually.

### 19. Manipal completes Kolkata's AMRI Hospitals acquisition[69]

Manipal Hospitals, the second-largest hospital chain in India, has completed the acquisition of 84% stake in AMRI Hospitals Ltd. As per a Manipal Hospitals' statement, the acquisition fits into the growth strategy of Manipal Hospitals to have a larger footprint and expanded presence in eastern India as the largest hospital chain in that region. The deal valued at around INR 2,400 crore was finalised after prolonged negotiations, which first started in 2018.

### 20. Cabinet clears Advent's acquisition of Suven Pharma for INR 9,589 crore[70]

The Cabinet Committee on Economic Affairs, headed by Hon'ble Prime Minister Narendra Modi, has approved a foreign direct investment ("**FDI**") proposal worth INR 9,589 crore in Suven Pharmaceuticals Limited. Private equity firm Advent International, through its Cyprus based Berhyanda Ltd., will acquire a 50.1% stake in the company for INR 6,313 crore, with plans to launch an open offer for an additional 26%. The deal necessitated government approval as currently, under the existing policy, FDI of up to only 74% is allowed in brownfield pharma projects under the automatic route. The approval, however, is subject to fulfilment of all applicable rules and regulations.

### 21. Asia Healthcare Holdings acquires majority stake in Asian Institute of Nephrology and Urology for INR 600 crore[71]

Asia Healthcare Holdings ("**AHH**"), a single specialty healthcare delivery platform backed by TPG Growth, has announced that it has acquired a majority stake in Asian Institute of Nephrology and Urology, by investing INR 600 crore in the company through a mix of primary and secondary

[67] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/apollo-acquires-under-development-hospital-asset-in-kolkata-for-rs-102-crore/articleshow/103984521.cms
[68] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/cvc-may-sell-controlling-stake-in-indian-hospital-chain-healthcare-global/articleshow/103978053.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst
[69] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/manipal-completes-kolkatas-amri-hospitals-acquisition/articleshow/103815942.cms
[70] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/cabinet-clears-advents-acquisition-of-suven-pharma-for-rs-9589-crore/articleshow/103638601.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst
[71] https://www.thehindu.com/business/Industry/asia-healthcare-holdings-to-acquire-majority-stake-in-asian-institute-of-nephrology-and-urology-for-600-crore/article67325482.ece

infusion. AHH, launched in 2017, owns and operates Motherhood Hospitals' network of 23 women and children's hospitals across 11 cities and Nova IVF Fertility chain of 68 IVF centres in 44 cities in India and South Asia. It also built oncology hospital chain CTSI, before exiting the company in 2019.

### 22. India Resurgence Fund picks up majority stake in Punjab-based hospital chain Ivy for Rs 525 crore[72]

India Resurgence Fund ("**Indiarf**") has announced INR 525 crore investment to acquire majority stake in Ivy Health and Life Sciences, a Punjab-based corporate hospital chain. As per a statement by the company, the Piramal Enterprises and Bain Capital investment platform will acquire Ivy's facilities at Mohali, Amritsar, Khanna, Hoshiarpur and Nawanshahr as part of the transaction. According to news reports, the transaction includes a sizeable infusion of growth capital, which will be used by Ivy to improve existing facilities and expand its footprint to other cities in Punjab and adjoining regions.

### 23. Neuberg Diagnostics completes merger of Supratech and Anand Reference Laboratory[73]

As per news reports, Neuberg Diagnostics Pvt. Ltd. has completed the merger of Neuberg Supratech Reference Laboratory, Ahmedabad, and Neuberg Anand Reference Laboratory, Bengaluru, thereby setting the ball rolling for its IPO plans by 2024 or 2025. With a strategic vision to streamline operations and enhance efficiency, the merger brings together two entities under Neuberg Diagnostics Pvt Ltd. As a result of the acquisition, Neuberg Diagnostics' gross revenue is expected to cross INR 1,000 crore during the current financial year. The company can leverage its enhanced capabilities to expand and offer an extensive range of cutting-edge diagnostic services to patients across India and beyond.

### 24. Glenmark to divest majority stake in Glenmark Life Sciences to Nirma[74]

Glenmark Pharmaceuticals has entered into a share purchase agreement with Nirma to divest 75% stake in its subsidiary, Glenmark Life Sciences, at a price of INR 615/- per

[72] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/indiarf-picks-up-majority-stake-in-punjab-based-hospital-chain-ivy-for-rs-525-cr/articleshow/103613937.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst
[73] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/neuberg-diagnostics-completes-merger-of-supratech-anand-reference-laboratory/articleshow/103815144.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst
[74] https://www.expresspharma.in/glenmark-to-divest-majority-stake-in-glenmark-life-sciences-to-nirma/

share for an aggregate consideration of INR 5,651 crore, subject to closing adjustments. After the divestment, Glenmark Pharmaceuticals will own only 7.84% in Glenmark Life Sciences. The transaction is subject to customary closing conditions precedent, including receipt of regulatory and shareholder approvals. Pursuant to the transaction, Nirma will make a mandatory open offer to all public shareholders of Glenmark Life Sciences.

### 25. Aurobindo Pharma forays into Indonesian market with brand acquisitions[75]

Aurobindo Pharma has announced its foray into the Indonesian market with the acquisition of 15 branded products from Viatris Inc. and Pfizer Inc. The acquisition has been done for a cash consideration of $48 million or around INR 400 crore, according to an exchange filing. The sales revenue generated from the specified brands in the Indonesian market was $30.5 million in 2022, $28.3 million in 2021 and $25.1 million in 2020. Aurobindo Pharma's entry into the branded formulation market of Indonesia is in line with most Indian pharma companies looking beyond the US as part of their capital-allocation strategy to attain consistent growth after a gestation period.

### 26. Dabur scion Gaurav Burman buys 7.5% in healthtech startup Mitsu[76]

FMCG and consumer healthcare group Dabur India scion Gaurav Burman has acquired 7.5% strategic stake in healthcare start-up, Mitsu. Mitsu is a mental health tech start-up that offers self-therapy programmes. The app, Mitsu.care, was launched this summer and provides programmes at one-third the cost of in-person therapy. As per a statement by Mr. Burman, the investment is part of his mission to invest in companies shaping the future of healthcare.

### 27. Lupin inks pact to acquire five drug brands from Menarini for Rs 101 crore[77]

Pharma major Lupin has inked a pact to acquire five drug brands from Italian firm Menarini for INR 101 crore. The company also stated that it has signed an agreement to acquire five legacy brands, catering to gastroenterology, urology and anti-infective segments. The brands are *Piclin* (Picosulfate Sodium), *Menoctyl* (Otilonium Bromide), *Sucramal O* (Sucralfate + Oxetacaine), *Pyridium* (Phenazopyridine) and *Distaclor* (Cefaclor).

[74] https://www.expresspharma.in/glenmark-to-divest-majority-stake-in-glenmark-life-sciences-to-nirma/
[75] https://www.bqprime.com/markets/aurobindo-pharma-forays-into-indonesian-market-with-brand-acquisitions
[76] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/dabur-scion-gaurav-burman-buys-7-5-in-healthtech-startup-mitsu/articleshow/103598582.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst
[77] https://www.business-standard.com/companies/news/biocon-acquires-eywa-pharma-s-us-based-manufacturing-facility-for-7-7-mn-123090200623_1.html

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