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

Volume VII | Issue I | October - December 2023

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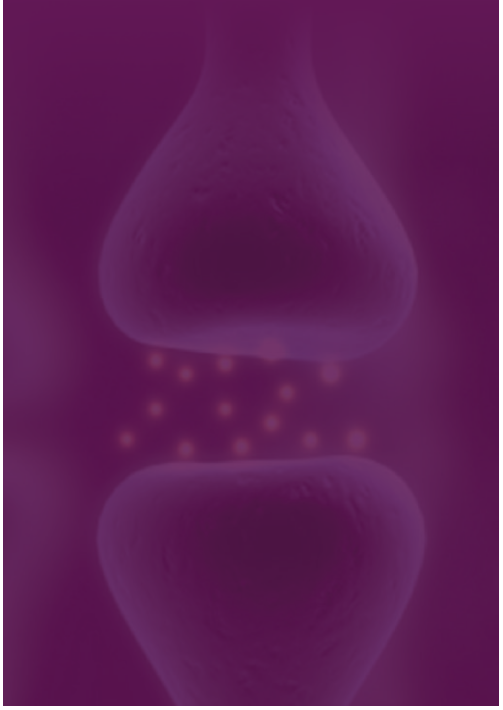


Dear Readers,

We wish you a very Healthy, Happy and Prosperous New Year.

As the Indian economy moves past the COVID shadow, the healthcare sector in India continues to grow by leaps and bounds, owing to the collaborative efforts of the regulator in the current rapidly evolving landscape, which is predominantly under the influence of the private sector. The country has garnered global acclaim as it moves forward, propelled by the thriving health tech sector, particularly in AI and telemedicine space, along with robust production capabilities and the availability of high quality, cost-effective generic medicines meeting global standards. With a simplified approach to several policies and a positive global outlook, the sector continues to draw investor attention, paving the way for rapid expansion in the future.

Like the previous few quarters, the sector witnessed important regulatory and news updates even in the October–December, 2023 quarter, which we have covered in this edition of *Synapse*. Most importantly, this quarter saw the notification of the regulation of Classes C and D non-notified medical devices, which entered the licensing regime with effect from October 1, 2023. With the intention of providing better pharmacy education in the country, the Ministry of Health and Family Welfare released the draft National Pharmacy Commission Bill, 2023, for comments from all stakeholders. The new bill seeks to repeal the *Pharmacy Act 1948* and replace the Pharmacy Council of India with a national commission. In addition, this quarter also saw the release of "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products," which substitutes the "Good Manufacturing Practices Guidelines" published under Schedule M of the *Drugs Rules, 1945*. In another news, the Centre issued an advisory to States in view of a recent upsurge in COVID-19 cases and detection of the first case of the new JN.1 variant in India. The latest advisory comes after the state of Kerala reported an increase in the number of cases, prompting the neighbouring state of Karnataka to ramp up coronavirus prevention measures. The Central Government has asked states to maintain constant vigil over the COVID situation and report and monitor district-wise SARI and ILI cases on a regular basis. We have learnt to live with this pathogen.

In the litigation space, the Hon'ble Supreme Court observed that to hold a medical practitioner liable for negligence, a higher threshold limit must be met. This is to ensure that doctors focus on deciding the best course of treatment as per their assessment rather than on the possible persecution or harassment they may face in high-risk medical situations. In another matter, the High Court of Delhi recently upheld the principle that non-scheduled drugs were outside the purview of the

price-control regime established under the *Essential Commodities Act 1955*, and *Drug Price Control Order 2013*, due to the removal of the power to fix and revise prices for non-scheduled formulations unlike in the erstwhile *DPCO 1995*.

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

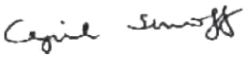
Cyril Amarchand Mangaldas, India's premier full-service law firm, has an industry leading and dedicated to pharmaceuticals, healthcare, and life sciences practice. Our class-leading practice specialists are always on top of the latest developments in the sector. In our endeavour to keep you abreast with the latest developments in this dynamic sector, we present to you the latest issue of *Synapse*. We hope you find this issue of interest. As always, your feedback makes us improve our efforts. Please feel free to send your comments, feedback, and suggestions to cam.publications@cyrilshroff.com.

We also encourage you to visit our blog at https://corporate.cyrilamarchandblogs.com for more articles on matters of interest in the Indian pharmaceutical, life sciences, and healthcare space.

We hope that you enjoy reading our newsletter as much as we have enjoyed preparing it. Your comments and feedback are most welcome. In the meanwhile, please stay safe and healthy.

Regards,

CYRIL SHROFF



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Regulatory Updates

1. Notification on *Drugs Amendment Rules, 2023*[1]

The Ministry of Health and Family Welfare ("**MoHFW**"), *vide* notification G.S.R. 922(E) dated December 28, 2023, substituted "Schedule M" of the *Drugs Rules, 1945* ("**Drug Rules**"), i.e., "Good Manufacturing Practices," with "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products." The new practice guidelines will enable licensees to evolve appropriate methodology, systems, and to document and maintain procedures for inspection and reference, as well as ensure the use of the licensed manufacturing premises exclusively for the production of drugs and no other activity. The notification introduced new concepts, *inter alia* pharmaceutical quality system (PQS), quality risk management (QRM), product quality review (PQR), qualification and validation of equipment, and a computerised storage system for all drug products.

2. Notification on regulation of all Class C & D medical devices[2]

The MoHFW, *vide* notification F.No. 29/ Misc/ 03/ 2023-DC (344), dated October 12, 2023, notified the regulation of Class C & D medical devices under the licensing regime from October 1, 2023. Further, an existing importer / manufacturer already importing / manufacturing any of the aforementioned Class C or D medical devices and having submitted an application to the Central Licensing Authority would be deemed valid. Additionally, the said importer / manufacturer could continue to import / manufacture the said devices up to six months from the date of issue of this order or until the time decision on the application was undertaken.

3. MoHFW Notification on soliciting public comments on *National Pharmacy Commission Bill*[3]

The MoHFW, *vide* notification F No. Z-28020/27/2023-AHS dated November 10, 2023, released the draft *National Pharmacy Commission Bill 2023*, which sought to repeal the *Pharmacy Act 1948* and replace the Pharmacy Council of India with a national commission. The draft bill uploaded on MoHFW website was seeking comments from the public. The proposed bill would help provide for a pharmacy education system that would improve access to quality and affordable pharmacy or pharmaceutical education, ensure the availability of adequate and high-quality pharmacy professionals across all parts of the country, promotes equitable and universal healthcare, and make the services of pharmacy professionals accessible to all citizens.

4. COVID-19 vaccines approved for manufacture for sale or distribution as on November 29, 2023[4]

The Central Drugs Standard Control Organization ("**CDSCO**") on November 29, 2023, released the updated list of COVID-19 vaccines approved for manufacture for sale or for distribution in India. Both, COVISHIELD and COVAXIN were included in the list, pursuant to approval dated January 27, 2022, granted to M/s Serum Institute of India Pvt. Ltd. and M/s Bharat Biotech, respectively. The initial approval for the said vaccines was for Restricted Use in Emergency situation in the country on January 3, 2021. The CDSCO also released updated lists for approved vaccines for primary and booster (third) dose vaccination for restricted use in emergency situation in the country.

5. Drug pricing and price control: Notifications / orders by the National Pharmaceutical Pricing Authority and other price control–related measures

a) *Corrigendum issued by National Pharmaceutical Pricing Authority (NPPA) in relation to ceiling price of 438 formulations*[5]

The NPPA, *vide* order S.O. 4663(E) dated October 25, 2023, notified the modified ceiling prices for 438 (four hundred thirty-eight) formulations such as budesonide, clomiphene citrate, diazepam, haloperidol, and tacrolimus, to name a few.

b) *Advisory Order on ceiling price fixation of 29 formulations under Drug Price Control Order 2013*[6]

The NPPA, *vide* order S.O. 4660(E) dated October 25, 2023, notified the ceiling price fixation of 29 (twenty-nine)

1 https://egazette.gov.in/(S(alsy5bfpu0kh3yyski410i1s))/ViewPDF.aspx
2 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTA1NzM=
3 https://main.mohfw.gov.in/?q=newshighlights-165
4 cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTA3MDU=
5 egazette.gov.in/(S(h4pzxjh2lzpfls105jj013f3))/ViewPDF.aspx
6 egazette.gov.in/(S(h4pzxjh2lzpfls105jj013f3))/ViewPDF.aspx

formulations under the *Drug Price Control Order 2013* ("**DPCO 2013**") - sitagliptin phosphate and metformin hydrochloride tablet, nimesulide and paracetamol tablet, phenylephrine hydrochloride and chlorpheniramine maleate drops IP, to name a few.

c) *Advisory Order on retail price fixation of 33 formulations under DPCO 2013*[7]

The NPPA, *vide* order S.O. 4885(E) dated November 8, 2023, notified the retail prices of 33 (thirty-three) formulations, including the likes of vildagliptin + metformin hydrochloride tablet, metoprolol succinate extended-release, cilnidipine and telmisartan tablet, rosuvastatin + clopidogrel capsules to name a few.

d) *Advisory Order on retail price fixation of 9 formulations under DPCO 2013*[8]

The NPPA, *vide* order S.O. 4886(E) dated November 10, 2023, notified the retail prices of 9 (nine) formulations, including the likes of tacrolimus, zinc sulphate, tramadol, temozolomide, to name a few.

6) Food safety standards: Notifications by Food Safety Standards Authority of India (FSSAI)

a) *Advisory order on enforcement action in respect of products with the ingredient S-adensoyl-L-methionine under FSSAI license*[9]

The FSSAI, *vide* an order dated October 12, 2023, notified that the ingredient/products with S-adenosyl-L-methionine ("**SAMe**") could not be considered as *"food"* and directed all enforcement authorities to ensure that products containing SAMe were not available in the market with the FSSAI license. Further instructions were to be issued to the e-commerce platforms to delist products containing SAMe as an ingredient, whether alone or in combination.

b) *Advisory order on inclusion of QR codes on food products for accessibility by visually impaired individuals*[10]

The FSSAI, *vide* order dated October 12, 2023, encouraged food business operators ("**FBO**") to incorporate provisions for visually impaired individuals by incorporating QR codes on product labels that could facilitate easy access to comprehensive nutritional information on product labels, in due consonance with the provisions of *Rights of Persons with Disabilities Act 2016 and Food Safety and Standards (Labeling and Display) Regulations 2020*. The said requirement would be over and above the existing requirement of display of mandatory product label information as prescribed under relevant regulations.

c) *FSSAI clarification on restriction on adding protein binders to milk and milk products*[11]

The FSSAI, *vide* a press release dated October 5, 2023, clarified that protein binders were not permitted to be added to milk and milk products to provide users with the highest nutritional value of dairy products.

d) *Order on streamlining procedure for reactivation of auto-rejected licensing/registration applications*[12]

The FSSAI, *vide* order dated December 4, 2023, allowed FBOs to self-reactivate their auto-rejected application (due to non-response to the queries of licensing / registration authority within the specified timeline) on the FoSCos portal if they could provide a valid reason for the delay and upon payment of the requisite reactivation fees. It granted a one-time opportunity to apply for the reactivation of the new license / registration or the modification of license / registration as applicable.

[7] egazette.gov.in/(S(sbtrlsqnyvamro1jcq32tebr))/ViewPDF.aspx
[8] egazette.gov.in/(S(sbtrlsqnyvamro1jcq32tebr))/ViewPDF.aspx
[9] https://www.fssai.gov.in/upload/advisories/2023/10/652fa82aec2a6Order%20dated%2012th%20october%202023_%20SAMe.pdf
[10] https://www.fssai.gov.in/upload/advisories/2023/10/6530e9d74cd4bAdvisory-1.pdf
[11] https://www.fssai.gov.in/upload/uploadfiles/files/Press%20Release-%20Protein%20Binders_Eng(1).pdf
[12] https://www.fssai.gov.in/upload/advisories/2023/12/656ebc7a6980c20231204125427557.pdf

News Updates

1. Central advisory to states after detection of first JN.1 variant infection in Kerala[13]

The Centre issued an advisory to states in view of a recent upsurge in COVID-19 cases and the detection of the first case of the new JN.1 variant in India. The latest advisory came after Kerala reported an increase in the number of cases, which prompted neighbouring Karnataka to also ramp up coronavirus prevention measures. The Central Government advised states to maintain constant vigil over the COVID situation and report and monitor district-wise SARI and ILI cases on a regular basis. It also suggested that states ensure adequate testing (including increasing the number of RT-PCR tests) and send positive samples for genome sequencing to INSACOG laboratories.

2. MedTech Mitra platform launched to boost domestic medical devices industry[14]

The MoHFW launched MedTech Mitra, a platform created by Niti Aayog, Indian Council of Medical Research, and the CDSCO to accelerate the development of innovative products and aid their commercialisation. At the virtual inauguration of the platform, Union Health Minister Dr. Mansukh Mandaviya highlighted the potential of the Indian medical devices industry "to grow and become a $50 billion industry by 2030." He stated that this collaborative initiative would facilitate indigenous development of affordable, quality MedTech devices and diagnostics leading to considerable reduction in the import dependence of this sector.[15]

3. India elected member of executive committee of UN's food standard-setting body[16]

At a meeting in Rome, members unanimously elected India as a member representing the Asian region in the Executive Committee ("**EC**") of the Codex Alimentarius Commission ("**CAC**"), the UN's food safety and quality standard-setting body. The MoHFW statement suggested that this position would give India an opportunity to contribute towards the international standard-setting process for different food product categories and be included in the global decision-making process.

4. Government allows generic drugs to treat four rare diseases[17]

In a move to provide relief to patients with rare diseases across India, the MoHFW decided to make available generic

[13] https://www.financialexpress.com/healthcare/covid-19/centre-issues-advisory-to-states-after-kerala-detects-first-jn-1-variant-infection-bkg/3341736/
[14] https://www.financialexpress.com/healthcare/news-healthcare/health-min-launches-platform-to-boost-domestic-medical-devices-industry/3347233/
[15] https://pib.gov.in/PressReleasePage.aspx?PRID=1990222
[16] https://www.deccanherald.com/india/india-elected-member-of-executive-committee-of-uns-food-standard-setting-body-2794216
[17] https://www.thehindu.com/sci-tech/health/four-generic-made-in-india-drugs-to-treat-rare-diseases-offer-relief-for-patients-more-in-pipeline/article67570839.ece.

drugs to support the care and treatment of four ailments: Tyrosinemia-Type 1, Gaucher's Disease, Wilson's Disease, and the Dravet-Lennox Gastaut Syndrome. Once Indian companies start production, the cost of these drugs would drop anywhere between 60 and 100 times their current market value. The ministry, which was in the process of ensuring the availability of drugs for more such rare diseases, including Phenylketonuria and Hyperammonemia, over the following months, informed that the initiative would lead to a drop from crores annually to mere lakhs in patients' drug expenses. Additionally, the ministry also made available the Sickle Cell disease drug formulation for children.

5. Prime Minister inaugurates the 10,000th Jan Aushadhi Kendra[18]

Reaffirming the Government's commitment to providing quality and affordable medicines to the masses through the Pradhan Mantri Bharatiya Janaushadhi Pariyojana (PMBJP), Prime Minister Narendra Modi inaugurated the 10,000th Jan Aushadhi Kendra at AIIMS, Deoghar. The Prime Minister highlighted that Jan Aushadhi Kendras opened across the country made high-quality medicines available to the poor at 50%–90% cheaper than the market rates, greatly benefitting both the poor and the middle class. The Government also decided to allow 2000 Primary Agricultural Credit Societies to open Jan Aushadhi Kendras across the country.

6. Government bans anti-cold fixed drug combination for kids aged under four[19]

Prohibiting the use of a fixed drug combination ("**FDC**") containing chlorpheniramine maleate IP 2mg with phenylephrine HCL IP 5mg drop/ml, the CDSCO instructed manufacturers to print warnings on the label and package insert/promotional literature regarding the use of the said FDC in children younger than four 4 years of age. The Government took this action on basis of a Subject Expert Committee recommendation that it was inadvisable to administer the specified combination to children below four years of age. In accordance with the SEC's recommendation on June 6, 2023, the Drugs Controller General of India (**DCGI**) chief Rajeev Singh Raghuvanshi issued a letter on December 18, 2023, asking all manufacturers of the common cold FDC containing chlorpheniramine maleate IP 2mg with phenylephrine HCL IP 5 mg per ml drops to ensure that all label and package inserts cautioned against the use of the FDC in children below four years of age. Prohibition of FDCs is a hot topic in the industry as the regulator continues its efforts to weed out irrational FDCs. Many FDCs have been phased out, some replaced with drug combinations that have the CDSCO's approval, while others are the subject matter of ongoing litigation.

7. Parliamentary panel recommends Centre to support new vaccine development to address COVID-19[20]

The Department-related Parliamentary Standing Committee on Health and Family Welfare headed by Member of Parliament (Rajya Sabha) Bhubaneswar Kalita recommended that the Centre encourage vaccine development on newer and more efficient platforms and also evaluate the efficacy of the existing vaccines to address the future challenges. The Member of Parliament expressed this view in the committee's 150th report on the action taken by the Government on the recommendations and observations in the 137th report. The committee appreciated the CDSCO's role in permitting various vaccines developed on various technology / platforms for restricted use in emergency situation. In its 137th report, the committee had expressed the need for vaccine development, distribution management, and mitigation of the pandemic COVID-19.

8. Parliamentary Panel asks Department of Pharmaceuticals to make realistic assessment of funds for various PLI schemes[21]

The Department-related Parliamentary Standing Committee on Chemicals and Fertilizers headed by Member of Parliament (Lok Sabha) Dr. Shashi Tharoor, in its 45th report on the action taken by the Government on its recommendations in the 42nd report on Demand for Grants 2023–24, expressed that the Department of Pharmaceuticals ("**DoP**") find a feasible solution to issues related to the lower uptake of the Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS). It pointed to news reports that implied pharma micro, small, and medium enterprise ("**MSME**") faced hurdles in enjoying the benefits of the scheme. The Committee wanted the adequate discussion on

[18] https://pib.gov.in/PressReleasePage.aspx?PRID=1981159
[19] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/govt-bans-anti-cold-fixed-drug-combination-for-under-four-children-new-delhi/articleshow/106161125.cms
[20] https://www.pharmabiz.com/NewsDetails.aspx?aid=165344&sid=1
[21] http://www.ingredientssouthasia.com/News/parliamentary-panel-asks-dop-to-take-adequate-measures-to-make-ptuas-more-attractive

the issues with the pharma MSME industry associates and state regulators for suitable measures to make the scheme attractive for the beneficiaries.

9. Health ministry body issues alert against reactions of mefenamic acid[22]

The Indian Pharmacopoeia Commission ("**IPC**"), an autonomous body of the MoHFW, issued a drug safety alert advising healthcare professionals and patients to monitor the adverse reactions of mefenamic acid, a molecule present in Meftal and Meftal Spas, commonly used for menstrual cramps and rheumatoid arthritis. IPC, in its alert, stated that a preliminary analysis of adverse drug reactions from the Pharmacovigilance Programme of India database revealed drug reactions with eosinophilia and systemic symptoms syndrome. The mefenamic acid painkiller was prescribed in the treatment of rheumatoid arthritis, osteoarthritis, dysmenorrhoea, mild to moderate pain, inflammation, fever, and dental pain.

10. AYUSH initiates standardisation, integrative health system in 2023[23]

The Ministry of Ayush ("**AYUSH**") stated that AYUSH and other governmental organisations have initiated the standardisation of Ayush systems of medicines and products and integrating the system with the other systems of medicines. Accordingly, as part of bringing in standards, the Bureau of Indian Standards ("**BIS**") has created a dedicated vertical for Ayush at BIS and published seven Ayush-related Indian standards. Additionally, 53 standards are in the process of development and publication. News reports have suggested that BIS was pushing for a stronger presence for Ayush in the International Organisation for Standardisation (ISO). BIS also created a dedicated Working Group (WG 10-Traditional Medicine) in ISO under ISO/TC 215–Health Informatics to formulate international standards on Ayush Informatics. This move would help Ayush gain better global acceptance and open doors for the huge export of Ayurveda products and services to more than 165 countries.

11. Pharma sector pivots from generics to innovation[24]

The changing pharmaceutical landscape in India has effected a shift in focus from generic drugs to becoming an innovation-centric pharmaceutical economy. The Contract Development and Manufacturing Organizations in the country played a large role in this transformation. The 2023 Convention on Pharmaceutical Ingredients annual report shed light on this paradigm shift. Over 250 industry executives from more than 35 countries participated in the creation of this report, which includes a pharmaceutical index. The report provides an annual overview of the global pharmaceutical industry's advancements and changes. While highlighting the progress made in the industry, it

[22] https://www.business-standard.com/india-news/health-ministry-body-issues-alert-against-adverse-reactions-of-meftal-123120700798_1.html
[23] https://www.pharmabiz.com/ArticleDetails.aspx?aid=165449&sid=2
[24] https://www.businesstoday.in/industry/pharma/story/indian-pharma-industrys-big-pivot-report-reveals-sector-transitioning-from-generics-to-innovation-402755-2023-10-20

anticipates potential trends for the year 2024. The report also evaluates the status of major pharmaceutical markets using more than ten distinct metrics.

12. Tests across 2022–23 rate over 2,900 drugs as substandard, 422 as spurious[25]

The Minister of State for Health Bharati Pravin Pawar stated in the Rajya Sabha that the CDSCO along with State Drugs Controllers ("**SDCs**") on conducting risk-based inspections of 261 premises and testing[26] 89,729 drug samples between April 2022 and March 2023 found that 2,921 were "not of standard quality" and that 422 were "spurious." He said that the state licensing authorities under the Drug Rules had undertaken more than 200 actions such as the issuance of show-cause notices, stop-production orders, suspension, and cancellation of licences/product licences. He also conveyed the information received from drugs controllers of various states and Union territories regarding the 642 prosecutions launched for the manufacturing, sale, and distribution of spurious/adulterated drugs and the arrest of 262 persons during the same period. The firms were identified based on risk criteria, such as the number of drugs declared as "Not of Standard Quality" complaints, criticality of the products, and so on.

13. DCGI approves MSD's Keytruda for two more types of cancers[27]

The DCGI approved Merck & Co's (MSD's) Keytruda (pembrolizumab) in the treatment of triple-negative breast cancer and renal cell carcinoma in adults. A statement released by MSD said that unlike chemotherapy or radiation therapy, Keytruda was an immunotherapy that worked with the immune system to help fight cancer cells. News reports also suggested that Keytruda, an important treatment option in India, and was now approved for fourteen (14) indications across eight (8) different types of tumours.

14. Zydus Lifesciences Ahmedabad facility receives 6 observations in recent US FDA inspection[28]

Zydus Lifesciences Ltd. announced that the United States Food and Drug Administration ("**US FDA**") had conducted an inspection in its active pharmaceutical ingredient site located at Changodar, Ahmedabad, from December 14 to December 22, 2023. The inspection, which encompassed pre-approval inspection and Good Manufacturing Practices (GMP), issued six observations. The company statement asserted that the observations were unrelated to data integrity and did not include repeat observations from the previous inspection.

15. Gujarat becomes first Indian state to launch FDCA-mDMLA app for online medicine licensing[29]

In a significant shift towards efficient governance, Gujarat has achieved a remarkable milestone by becoming the first state in the country to introduce online licenses for allopathic medicines through the newly launched FDCA-mDMLA mobile application. The Chief Minister of Gujarat launched this app on Good Governance Day. The app promises to streamline and expedite the licensing process for pharmaceuticals. News reports called the FDCA-mDMLA app a leap in m-governance that consolidates various online platforms into a single interface, providing stakeholders with real-time access to the status of their applications. The app also extends its benefits to Ayurvedic medicine and cosmetic manufacturers and sellers, aligning with the state's commitment to e-governance.

16. AstraZeneca receives CDSCO approval to market its inhalation aerosol[30]

AstraZeneca India announced that the CDSCO had given its approval to market its inhalation aerosol, a triple combination of budesonide (160 mcg), glycopyrrolate (9 mcg), and formoterol fumarate (4.8 mcg). The pressurised metered dose inhaler, recommended for the treatment and maintenance of patients with chronic obstructive pulmonary disease (COPD), was also beneficial for all patients with a history of multiple exacerbations.

17. Aurobindo Pharma gets "Voluntary Action Indicated" classing from US FDA[31]

Aurobindo Pharma announced that the US FDA had issued a Voluntary Action Indicated ("**VAI**") classification to its Unit IV formulation manufacturing facility, located in Menakuru Village, Andhra Pradesh, India following an inspection it

[25] https://theprint.in/india/over-2900-drugs-found-to-be-substandard-422-spurious-in-tests-conducted-in-2022-23-govt/1892593/
[26] https://www.navhindtimes.in/2023/12/20/nationalnews/over-2900-drugs-found-substandard-in2022-23
[27] https://www.thehindu.com/business/dcgi-approves-msds-keytruda-for-two-more-cancers/article67459036.ece
[28] https://www.cnbctv18.com/business/companies/zydus-lifesciences-ahmedabad-facility-receives-6-observations-in-recent-usfda-inspection-18632371.htm
[29] https://www.biospectrumindia.com/news/22/24001/gujarat-becomes-first-indian-state-to-launch-fdca-mdmla-app-for-online-medicine-licensing.html
[30] https://www.expresspharma.in/astrazeneca-receives-cdsco-approval-to-market-its-inhalation-aerosol/
[31] https://www.business-standard.com/companies/news/aurobindo-pharma-gets-voluntary-action-indicated-classing-from-us-fda-123122001032_1. html

conducted between September 13 and September 19, 2023. The VAI classification signifies deviations from GMP that do not warrant regulatory action but require voluntary corrective action by the errant party.

18. Sun Pharma and Lupin recall drugs from US market over manufacturing issue[32]

Leading drug makers, Sun Pharma and Lupin, initiated recall of products from the US market over manufacturing issues, as per the US FDA. According to the latest US FDA enforcement report, Princeton-based Sun Pharmaceutical Industries Inc., a unit of the Mumbai-based Sun Pharmaceutical Industries, India, had started the recall of 96,192 bottles of liothyronine-sodium tablets used for treating an underactive thyroid. News reports suggested that the lot produced at the drug maker's Dadra-based facility in India contained impurities. According to the US FDA, the company commenced the voluntary nationwide Class II recall of the lot on December 4, 2023, because of "failed impurities/degradation specifications." The US FDA also stated that Mumbai-based Lupin also started recalling an unspecified number of penicillamine tablets from the US.

19. Zydus Lifesciences gets US FDA nod for cancer drug[33]

Zydus Lifesciences Ltd has announced that it has secured final approval from the US FDA for its cyclophosphamide capsules USP, available in 25 mg and 50 mg variants. The approved capsules, equivalent to the US Reference Listed Drug cyclophosphamide capsules, 25 mg and 50 mg, are poised to offer effective therapeutic solutions for a spectrum of cancers, including lymphoma, myeloma, leukaemia, breast cancer, and ovarian cancer.

20. Granules India gets US FDA nod for generic pantoprazole sodium tablets[34]

Granules India Limited announced the approval of its abbreviated new drug application by the US FDA for pantoprazole sodium delayed-release tablets USP in both 20 mg and 40 mg strengths. These tablets, identified as bioequivalent and therapeutically equivalent to the protonix delayed-release tablets of Wyeth Pharmaceuticals LLC, will help treat erosive oesophagitis associated with gastro-oesophageal reflux disease. A statement by the company suggested that the tablets were prescribed to maintain healing in such conditions and to address pathological hypersecretory conditions, including the Zollinger-Ellison syndrome.

21. Zydus Lifesciences inks licensing pact with Daewoong Pharma for leuprolide in Us[35]

Zydus Lifesciences Ltd. announced the entry of its arm Zydus Worldwide DMCC into a licensing agreement with Daewoong Pharmaceutical to develop and market the leuprolide injectable in the United States. Lupride injection is used for the treatment of advanced prostatic cancer, endometriosis, and uterine leiomyomata (fibroids) depending on its dosage regime. As per the agreement, Zydus would assume full responsibility for the clinical development and commercialisation in the US market, and Daewoong would handle the pre-clinical studies, production, and supply.

22. US FDA issues warning letter to Intas Pharma for manufacturing lapses at Ahmedabad plant[36]

The US FDA has issued a warning to Intas Pharmaceuticals for manufacturing flaws, including violations of current GMP regulations at its Ahmedabad factory. News reports suggest that the US FDA's warning letter to the company's CEO and MD Nimish Chudgar cited multiple production flaws at the Matoda-Sanand, Ahmedabad-based factory. The US health agency also discovered that a manufacturer had seriously violated its regulations and issued a warning letter pursuant to the manufacturing facility that was under inspection from May 1 to May 12, 2023.

23. Lupin gets US FDA nod smoking-cessation treatment drug copy[37]

Leading drugmaker Lupin has received US FDA approval for its generic copy of smoking-cessation treatment medicine chantix tablets, 0.5 mg and 1 mg, of PF Prism CV. As per news reports, Lupin will manufacture the product at its Pithampur facility in India for its abbreviated new drug application for varenicline tablets, 0.5 mg and 1 mg. A statement released by

[32] https://www.deccanherald.com/india/sun-pharma-lupin-recall-drugs-in-us-market-over-manufacturing-issue-2814557
[33] https://www.cnbctv18.com/business/companies/zydus-lifesciences-gets-us-fda-nod-for-cancer-drug-18569231.htm
[34] https://www.cnbctv18.com/market/granules-india-receives-usfda-nod-for-acid-reflux-treatment-tablets-18556891.htm
[35] https://www.cnbctv18.com/business/zydus-life-inks-licensing-pact-with-daewoong-pharma-for-leuprolide-in-us-to-treat-prostate-cancer-18533811.htm
[36] https://www.indiainfoline.com/article/news-top-story/usfda-issues-warning-letter-to-intas-pharma-for-manufacturing-lapses-at-ahmedabad-plant-1702284379145_1.html
[37] https://www.thehindu.com/business/lupin-gets-us-fda-nod-smoking-cessation-treatment-drug-copy/article67611719.ece

Lupin said that Varenicline tablets, indicated for use as an aid to smoking cessation treatment, had estimated annual sales of $ 430 million in the United States.

24. KIMS Hospital and Pfizer India establish CoE for adult vaccination[38]

Pfizer India launched a Center of Excellence ("**CoE**") for adult vaccination in collaboration with Krishna Institute of Medical Sciences (KIMS) Hospital in Hyderabad. The CoE aims to promote the adoption of adult vaccination within the local community to protect patients against vaccine-preventable diseases. The CoE at KIMS Hospitals, situated in Secunderabad, was established to set up a comprehensive ecosystem within the hospital premises to equip healthcare professionals with the means to educate patients about the long-lasting benefits of vaccination for individuals with comorbidities, advanced age, occupational hazards, and lifestyle-related disorders.

[38] https://health.economictimes.indiatimes.com/news/pharma/pharma-industry/kims-hospital-pfizer-india-establish-coe-for-adult-vaccination/104646490

Litigation Updates

1. Supreme Court observes that a higher threshold must be met to hold a medical practitioner liable for negligence[39]

The Supreme Court of India ("**SC**") in the matter of Civil Appeal No. 3975 of 2018 with Civil Appeal No. 4847 of 2018 dated October 19, 2023, observed that to hold a medical practitioner liable for negligence, a higher threshold limit must be met. The intent was to ensure that doctors focus on deciding the best course of treatment as per their assessment rather than being concerned about the possible persecution or harassment they could face in high-risk medical situations. The SC was hearing the appeals pertaining to medical negligence matter filed under the *Consumer Protection Act 1986*, assailing the impugned decision passed on February 16, 2018, by the National Consumer Disputes Redressal Commission ("**NCDRC**") in a consumer case filed by Mrs. Sunita Parvate.

The SC, in its judgment, *inter alia*, penned down the three essential ingredients in determining an act of medical negligence: (i) a duty of care extended to the complainant; (ii) breach of that duty of care; and (iii) resulting damage, injury, or harm caused to the complainant attributable to the said breach of duty. However, it observed that only those medical practitioners whose conduct fell below the standards of a reasonably competent practitioner would be held liable for negligence. Furthermore, the SC stated that unique circumstances and complications arising in different individual cases and the constant advancement in the medical field and its practices could always naturally lead to differences in opinions, including contesting views regarding the chosen line of treatment or the course of action to be undertaken. In such circumstances, doctors could not be held liable for negligence if they opted for a particular line of treatment but did not achieve the desired result, provided the said course of action undertaken was recognized as sound and relevant medical practice. This could include a procedure entailing a higher risk element as well that a doctor might have opted for after due consideration and deliberation.

2. SC holds pregnancy crossing the statutory limit of 24 (twenty-four) weeks cannot be terminated[40]

The SC, in Miscellaneous Application No. 2157 of 2023 in Writ Petition (Civil) No. 1137 of 2023, did not accede to the prayer for the medical termination of pregnancy in the case of the petitioner, a married woman of twenty-seven years. The Petitioner had preferred the petition under Article 32 of the Constitution of India praying for directions to the

[39] M.A Biviji vs. Sunita & Ors., Judgement dated October 19, 2023 in Civil Appeal No. 3975 of 2018 with Civil Appeal No. 4847 of 2018.
[40] X vs Union of India and Anr., Judgement dated October 16, 2023 in Miscellaneous Application No. 2157 of 2023 in Writ Petition (Civil) No. 1137 of 2023.

Respondents to permit a medical termination of her ongoing pregnancy. The Petitioner had averred that she and her husband attempted to terminate the pregnancy medically at various hospitals but were unable to do so because of the *Medical Termination of Pregnancy Act 1971* ("**MTP Act**") read with the *Medical Termination of Pregnancy Rules 2003*, leaving them with no other option but to approach the SC by invoking its writ jurisdiction. She had sought permission for medical termination of her pregnancy on the following grounds: (i) having suffered from post-partum depression and her mental condition did not permit her to raise another child; (ii) her husband is the only earning member of their family, and they already have two children to care for. Additionally, the couple had other family members who depended on them. The Petitioner had submitted that she did not discover that she was pregnant until after 20 weeks of the pregnancy had elapsed because she had lactational amenorrhea. The Petitioner argued that she had visited the gynaecologist for the first time after the delivery of her second child because she was feeling weak, nauseous, dizzy, and experiencing abdominal discomfort. She realized she was pregnant only after she underwent the ultrasound scan. The pregnancy was estimated to be around 24 weeks at the time.

The matter came up before the three-judge bench after a two-judge bench gave a split verdict on the Centre's application for the recall of an order dated October 9, 2023. The two-judge bench had allowed the petition and permitted the medical termination of the pregnancy on the ground that continuing with the pregnancy could seriously imperil the Petitioner's mental health. The three-judge bench of the SC, in its judgement, observed that the length of the pregnancy had crossed 24 weeks and did not permit the medical termination of the pregnancy. The Apex Court based its observation on the following reasons:

i) The crossing of the statutory limit of 24 weeks mandated meeting the requirements in either of section 3(2B)[42] or section 5[43] of the *MTP Act*.

ii) No "substantial foetal abnormalities" were diagnosed by a Medical Board, in terms of section 3(2B) of the *MTP Act*. The Apex Court called for a second medical report from All India Institute of Medical Sciences to ensure that the facts of the case were placed accurately before it and that no foetal abnormality was detected.

iii) Neither of the two reports submitted by the medical boards indicated that a termination was immediately necessary to save the life of the petitioner, in terms of Section 5 thereto.

3. High Court of Delhi hold market forces to determine the MRP of non-scheduled formulations[44]

The High Court of Delhi ("**Delhi HC**"), in LPA 118 of 2023, held that non-scheduled drugs were outside the purview of the price-control regime established under the *Essential Commodities Act 1955* ("**EC Act**") and DPCO 2013, due to the removal of the power to fix and revise prices for non-scheduled formulations as was allowed in the earlier DPCO 1995. Furthermore, the Court clarified that the DPCO 2013 only provided the Government with the power to fix the MRP for scheduled formulations. As far as non-scheduled formulations were concerned, it could only monitor their MRP. The Court thus held that with respect to non-scheduled formulations, the Government was authorized solely to oversee the increase in MRP, ensuring it did not exceed the permissible 10% threshold as set out in DPCO 2013. If the increase surpassed this threshold, penalties outlined in Para 20 of the DPCO 2013 would become applicable.

The Delhi HC also expressed reluctance in accepting that Para 20 of the DPCO 2013, as a whole, is penal in nature. This was evident from the language contained in sub-para (2) of Para 20 in DPCO 2013, which specifically required manufacturers to reimburse any amount exceeding the 10% increase in the MRP, as allowed by Para 20, along with applicable interest. Moreover, the term *"penalty"* in sub-para (2) of Para 20 pertains to the penalty as outlined under Section 7 of the *EC Act*. The DPCO 2013 was enacted under the authority granted by Section 3 of the *EC Act*. The penalties for breaching orders issued under the *EC Act* were outlined in Section 7, but not within the DPCO 2013 itself. Thus, the term *"penalty"* in Para 20 of the DPCO 2013 did not introduce an additional penalty beyond that already contemplated under the *EC Act*.

4. Delhi HC grants favourable order to pharma company for alleged overcharging[45]

The Delhi HC, in the matter of WP (C) No. 39 of 2005, *vide* judgement dated December 26, 2023, quashed two of NPPA's orders/communications - October 5, 2004 and December 17

[41] As a result of lactational amenorrhea, women who are breastfeeding do not menstruate
[42] http://www.bareactslive.com/ACA/ACT139.HTM
[43] Ibid.
[44] Union of India vs. Bharat Serums and Vaccines, Judgement dated November 8, 2023 in LPA 118/2023, LPA 229/2023, LPA 119/2023, LPA 142/2023, and LPA 227/2023.
[45] Glaxo SmithKline Pharma Pharma Ltd. v. UOI & Anr., Judgement dated December 26, 2023 in WP (C) No. 39 of 2005.

2004 respectively, demanding a deposit of around INR 5.59 crore from GlaxoSmithkline Pharma's ("**GSK**") for allegedly overcharging their anti-asthmatic medicine, Ventolin (salbutamol) Inhaler. The Delhi HC, in an interim order, had stayed the enforcement of the demand on condition that the company deposit the principal amount of INR 4.35 crore and furnish a bank guarantee for the interest of INR 1.23 crore.

The Petitioner company argued that the period of dispute was during the time the judgement of the High Court of Bombay ("**Bombay HC**") striking down the inclusion of the drug under the *Drug Price Control Order 1995* ("**DPCO 1995**") was in operation. Moreover, the SC had not stayed this order while granting leave in the Special Leave Petition of the Union of India against the Bombay HC order. It was only for this period that the Petitioner company had increased the price of salbutamol. Consequent to the SC setting aside the Bombay HC judgement on August 1, 2003, the Petitioner company had reduced the price of the drug in accordance with the *DPCO 1995*. The Central Government Standing Counsel argued that considering the SC order operated retrospectively and not prospectively, this order allowed the Union of India the liberty to recover 50% of the overcharged amounts pending fresh determination by the Bombay HC. The Central Government also argued that the company had no rights to increase the price even if the SC did not stay the Bombay HC order, as it was aware that the Centre was in appeal before the SC.

The Delhi HC, after hearing arguments from both the sides, agreed with the Petitioner company's argument that no demand could be raised under Para 3 of the *DPCO 1995* as Ventolin Inhaler was not overcharged. The Delhi HC also observed that the Apex Court's order allowing the Centre to recover 50% of the overcharged amount was applicable only on those companies that increased the price before the Bombay HC's order. The Court observed that the Petitioner company had never charged any amount in excess of the price fixed by the NPPA.

5. High Court of Kerala refuses compensation to woman claiming conception and delivery despite sterilization surgery[46]

The High Court of Kerala ("**KHC**"), in the matter of R.F.A. No. 9 of 2003 dated November 28, 2023, refused the compensation claim of a woman who alleged that she conceived and gave birth to a fifth child despite having undergone the post-partum sterilization ("**PPS**") surgery due to the negligence of the doctor who performed the same. The Kerala HC noted that the appellant had failed to discharge the initial burden of *prima facie* proving negligence and carelessness on the part of the doctor in performing the surgery. The Court further noted that the lack of evidence in proving that the doctor did not possess the requisite skill and competence to perform the surgery before venturing into performing the same. Additionally, considering the possibility of pregnancy even after PPS surgery in rare cases and the time gap of 5 years in the delivery of the appellant's fifth child after the surgery, the Court asserted that no negligence could be attributed to the doctor.

[46] XXX. v District Collector & Ors., Judgement dated November 28, 2023 in R.F.A. No. 9 of 2003-A.

Transaction Updates

1. Blackstone completes majority stake acquisition of Care Hospitals[47]

Blackstone, the US-based private equity major, completed the acquisition of the 72.5% stake in Quality Care India Ltd. ("**QCIL**"), the operator of a network of Care Hospitals. The company acquired the majority stake in QCIL from Evercare, a platform backed by TPG Rise funds. TPG would continue to hold the remaining 27.5% stake in QCIL. The acquisition deal, estimated at about INR 4,800 crore ($580 million), marked Blackstone's foray into India's healthcare services sector.

2. Blackstone-backed Care Hospitals set to acquire KIMSHealth[48]

Blackstone, through QCIL signed a definitive agreement to acquire around 80% in KIMSHealth, a Thiruvananthapuram-headquartered quaternary care hospital network offering end-to-end healthcare services. KIMSHealth runs four hospitals in Kerala with around 1,400 beds. The valuation of KIMSHealth was estimated at INR 3,300 crore ($ 400 million).

3. Aster DM Healthcare sells stake in GCC business[49]

Aster DM Healthcare Ltd, a leading hospital chain with business interests in India and the Gulf, announced the divestment of its Gulf Cooperation Council (GCC) business and consequent sale it to its Indian promoters (Moopen family) and a Dubai consortium for INR 8,215 crore ($1.001 billion) in a move to unlock shareholder value and attract more institutional investors. News reports suggested that a consortium led by United Arab Emirates Government-backed Fajr Capital and Dr. Azad Moopen, the promoter of Aster DM, would have a shareholding ratio of 65:35 in the new entity. The enterprise value of the GCC business was at $1.7 billion (INR 13,540 crore).

4. Max Healthcare to acquire Sahara Hospital for INR 940 crore[50]

Max Healthcare, India's leading private healthcare provider announced the acquisition of 100% stake in Starlit Medical Centre, which had entered into a business-transfer

[47] https://www.business-standard.com/companies/news/blackstone-tpg-backed-quality-care-india-to-acquire-kims-for-400-mn-123103000921_1.html
[48] Ibid.
[49] https://www.livemint.com/companies/aster-dm-healthcare-divests-gulf-business-for-1-01-bn-11701182090788.html
[50] https://indianexpress.com/article/cities/gandhinagar/max-healthcare-to-buy-sahara-hospital-for-rs-940-crore-9060510/ strict Collector & Ors., Judgement dated November 28, 2023 in R.F.A. No. 9 of 2003-A.

agreement with Sahara India Medical Institute (Sahara Hospital) for the purchase of the healthcare unit on a slump-sale basis. News reports suggested that Max Healthcare Institute would buy Starlit Medical Centre for an enterprise value of INR 940 crore, thus acquiring the ownership of 550-bed Sahara Hospital in Lucknow.

5. Zydus Lifesciences acquires UK-based LiqMeds group[51]

Zydus Lifesciences acquired the UK-based LiqMeds Group for GBP 68 million (around INR 689 crore). News reports suggested that the Ahmedabad-based group, through its wholly owned subsidiary Zydus Pharmaceuticals UK Ltd., would also pay yearly earn-outs until 2026 depending on the achievement of certain agreed milestones towards the acquisition. The LiqMeds Group of companies specialises in the development, manufacturing, and supply of oral liquid products for global markets. The group's subsidiary, LM Manufacturing Ltd., which manufactured the oral liquids at Weedon, Northampton, UK, supplied products to the United States and United Kingdom markets.

6. Sun Pharma to buy out local partner in Mexican arm[52]

Sun Pharma announced that it would buy out local partner Indi Pharma from its Mexican arm for MXN 161.85 million (over INR 75 crore). News reports suggested that the company had signed a binding letter of intent to acquire the 25 outstanding shares of Sun Pharma de Mexico, SA de CV, a subsidiary where it currently held 75per cent shares. Furthermore, the acquisition would enable Sun Pharma to acquire the remaining 25 per cent stake held by the local partner, as it would be done through a wholly owned subsidiary Sun Pharma (Netherlands) B.V. The cost of acquisition was reportedly MXN 161.85 million.

7. Zenex announces acquisition of Ayurvet[53]

Zenex, a leading animal healthcare company announced the 100% acquisition of Ayurvet, a provider of natural ayurvedic and herbal medicines, feed supplements, and topical treatments for farm and companion animals. Reports suggested that this move would enable Zenex to strengthen its portfolio of offerings by adding herbals and furthering the quality of its overall animal health portfolio globally. A news release by Zenex stated that the acquisition would augment its growth, considering the new endeavour complemented its current operations and was likely to fuel its geographical expansion.

8. Akums acquires new formulation facility in Baddi, Himachal Pradesh[54]

Akums Drugs and Pharmaceuticals Limited, a contract manufacturing pharmaceutical company, announced the acquisition of a new formulation facility in Baddi, Himachal Pradesh, for an undisclosed amount. Reports suggested that this would be the company's twelfth formulation facility and the second in Baddi. A statement issued by the company informed that the facility, likely to be operational in 2024, would augment the company's tablet manufacturing business and improve time-to-market.

9. IQuest Enterprises to acquire Viatris' active pharma ingredient business[55]

Multisector investment firm IQuest Enterprises had entered into a definitive agreement to acquire the active pharmaceutical ingredients (API) operations of the global pharmaceutical major Viatris in India for an undisclosed amount, a statement by the company disclosed. As part of the deal, the company would acquire six API manufacturing facilities - three each in Vizag and Hyderabad, an R&D facility in Hyderabad, and third-party API sales.

10. Biocon Biologics to sell two non-core branded formulation businesses to Eris Lifesciences for INR 366 cr[56]

Biocon Biologics Ltd., a subsidiary of Biocon, has entered into a definitive agreement with Eris Lifesciences to divest its dermatology and nephrology-branded formulations business units in India for INR 366 crore. Reports suggested that the total transaction value of the divestment included the working capital conveyed as part of the deal and represented an accretive multiple of 4X on revenues and 22X on EBITDA. A "slump sale," the transaction was expected to

[51] 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
[52] https://www.business-standard.com/companies/news/sun-pharma-to-buyout-local-partner-indi-pharma-in-mexican-subsidiary-123092800990_1.html
[53] https://www.expresspharma.in/zenex-announces-acquisition-of-ayurvet/
[54] https://www.thehindubusinessline.com/companies/akums-buys-new-facility-in-baddi-to-augment-tablet-output/article67606924.ece
[55] https://www.business-standard.com/companies/news/iquest-enterprises-to-acquire-active-pharma-ingredient-business-of-viatris-123100200569_1.html
[56] https://www.thehindubusinessline.com/companies/biocon-biologics-to-sell-2-non-core-branded-formulations-businesses-to-eris-lifesciences-for-366-cr/article67512732.ece

enable a seamless transfer of the product brands and employees associated with these businesses.

11. Genpharmasec acquires stake in Derren Healthcare, shares down[57]

Gujarat-based Genpharmasec Limited executed a share-purchase and share subscription-cum–shareholders' agreement with Derren Healthcare Private Limited, as per a statement by the company. Genpharmasec would acquire a 70% stake in DHPL in a phased manner over a period of one year. Reports suggested that the acquisition would be consistent with Genpharmasec's long-term strategic goals and, consequently, the company expected to create significant value. The transaction included a 70% in DHPL covering all manufacturing plants along with land and buildings.

12. JB Chemicals inks deal to buy ophthalmology brands from Novartis[58]

JB Chemicals & Pharmaceuticals Ltd., the Mumbai-based drugmaker majority-owned by private equity firm KKR, acquired a portfolio of ophthalmology brands from Novartis to enter the growing eyecare market in India. Reports suggested that JB Chemicals approved signing a Trademark License Agreement to acquire the brands for INR 964 crore ($ 116 million), effective January 2027. In the interim, it entered into a three-year promotion and distribution agreement for the brands, beginning December 2023, with Novartis by making an additional payment of INR 125 crore. During the three-year in-licensing agreement period, Novartis would maintain drug manufacturing, while JB Chemicals would focus on the marketing and sales.

13. DRL partners with Coya Therapeutics to develop nerve disorder therapy[59]

Dr. Reddy's Laboratories announced that it had entered into an exclusive collaboration with the US-based Coya Therapeutics for the development and commercialisation

of an investigational combination therapy named COYA 302 for a neurological disorder. Dr. Reddy's agreed upon obtaining the commercialisation rights for COYA 302 in the United States, Canada, the European Union, and the United Kingdom, for patients with amyotrophic lateral sclerosis. Consequently, Coya would be responsible for development, including the conduct of the Phase 2 clinical trial and for obtaining regulatory approval in the United States. In early 2023, Coya entered into an in-licensing agreement with Dr. Reddy's to license its proposed biosimilar abatacept for the development and commercialisation of COYA 302.

14. IHH Healthcare seeks acquisitions in Indonesia and Vietnam; eyes turnaround in China[60]

IHH Healthcare, an operator of private hospitals in Asia with more than 12,000 beds, is looking for acquisitions in new markets such as Indonesia and Vietnam. A company statement pointed towards its intent to expand in markets such as India and Turkey, where it already has a presence, and to turn around underperforming assets in China. News reports suggested that IHH intends to grow organically by adding 4,000 new beds across Malaysia, India, Hong Kong, Turkey, and Europe over the next five years.

[57] https://www.thehindubusinessline.com/markets/genpharmasec-limited-acquires-stake-in-derren-healthcare-shares-down/article67325663.ece
[58] https://www.vccircle.com/kkrcontrolled-jb-chemicals-acquires-eyecare-brands-from-novartis
[59] https://www.business-standard.com/companies/news/drl-partners-with-coya-therapeutics-to-develop-nerve-disorder-therapy-123120601115_1.html
[60] https://health.economictimes.indiatimes.com/news/pharma/mergers-acquisitions/ihh-healthcare-seeks-acquisitions-in-indonesia-vietnam-eyes-turnaround-in-china/105655798

List of Contributors

Ashwin Sapra
Partner

Biplab Lenin
Partner

Akshat Razdan
Principal Associate

Kartik Jain
Senior Associate

Priyam Rajkumar
Associate

Kritika Asawa
Associate

Preksha Mehndiratta
Associate

Cyril Amarchand Mangaldas
Advocates & Solicitors

100+ years of legacy | **1000** Lawyers | **Over 170** Partners

Peninsula Chambers, Peninsula Corporate Park, GK Marg, Lower Parel, Mumbai – 400 013, India
T +91 22 2496 4455 **F** +91 22 2496 3666 **E** cam.mumbai@cyrilshroff.com **W** www.cyrilshroff.com
Presence in Mumbai | Delhi-NCR | Bengaluru | Ahmedabad | Hyderabad | Chennai | GIFT City | Singapore