

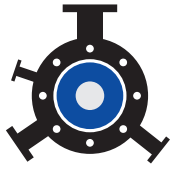
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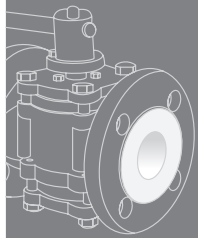


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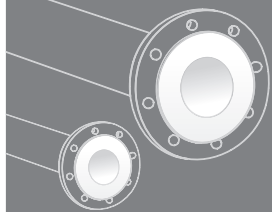
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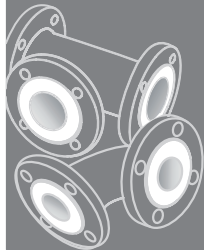
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Nitin Kalla
Founder
EXZOD India

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Indian Pharmacopoeia Commission (IPC) issues drug safety alert on Meftal

Mumbai, India: The Indian Pharmacopoeia Commission (IPC) issued a drug safety alert about Meftal painkiller, stating that its constituent, mefenamic acid, can cause adverse reactions, including drug reactions with eosinophilia and systemic symptoms (DRESS) syndrome. The mefenamic acid painkiller is prescribed for the treatment of rheumatoid arthritis, osteoarthritis, dysmenorrhoea, mild to moderate pain, inflammation, fever and dental pain.

Drug rash with eosinophilia and systemic symptoms (DRESS) syndrome is a severe, idiosyncratic, multi-system reaction characterized by the clinical triad of fever, rash, and internal organ involvement. "Healthcare professionals, patients/consumers are advised to closely monitor the possibility of the above adverse drug reaction (ADR) associated with the use of the suspected drug," according to the alert.

"In the wake of IPC issuing an alert on potential adverse effects of Mefenamic Acid, should parents worry about using Meftal syrups to treat Fever in Children? Despite its popularity, Mefenamic Acid lacks global approval for managing childhood fevers and recent warnings raise concerns. The tiered approach for medications has no scientific basis, urging caution. My practice emphasizes paracetamol or occasional ibuprofen, with close attention to danger signs. I avoid prescribing Meftal due to the lack of safety data. Parents and practitioners must prioritize trusted medications, stay informed, and exercise patience. In treating fevers, reassurance, vigilance for danger signs, and the timeless 'patience' are essential components for both the child and concerned parents," said Dr Rajath Athreya, Senior Consultant and HOD Paediatrics and Neonatology, Sakra World Hospital Bengaluru.

India's healthcare and pharma leaders set sight on disruptive innovation by 2047: EY Parthenon OPPI report

New Delhi, India: EY Parthenon (EY-P), the leading strategy consulting firm, in partnership with Organisation of Pharmaceutical Producers of India (OPPI), launched a report titled 'Reimagining pharma and healthcare for India@100' to navigate the industry's journey towards excellence over the next two decades. It explores the sector's growth potential on the back of three pivotal imperatives –transformative innovation, fortification of manufacturing and quality standards.

Between September and October 2023, EY-P and OPPI undertook primary research consulting top CXOs from leading Indian and global multinational pharmaceutical companies, to gain insights into the strategic priorities that will pave the way forward for the industry. The report identifies three key focus areas crucial for the Indian pharma and healthcare sector to reach the ambitious 2047 milestone. These include unleashing the potential for value-driven research and innovation in the pharma industry, integrating into the global pharma supply chain of the future, and ensuring sustainable and equitable healthcare access for all.

Suresh Subramanian, Partner & National Life Sciences Leader, EY Parthenon India said, "Over the past few decades, the Indian pharmaceutical sector has witnessed substantial growth. The industry has the potential and bold ambition of reaching USD 130 billion by 2030 and USD 450 billion by 2047. Our report examines the industry's potential to be an innovation powerhouse, play a crucial role in the global pharma supply chain, and ensure sustainable access to healthcare, with digitalization as a force multiplier. In navigating the challenges of a rapidly evolving landscape, the insights function as a strategic guide for industry leaders, policymakers, and stakeholders."

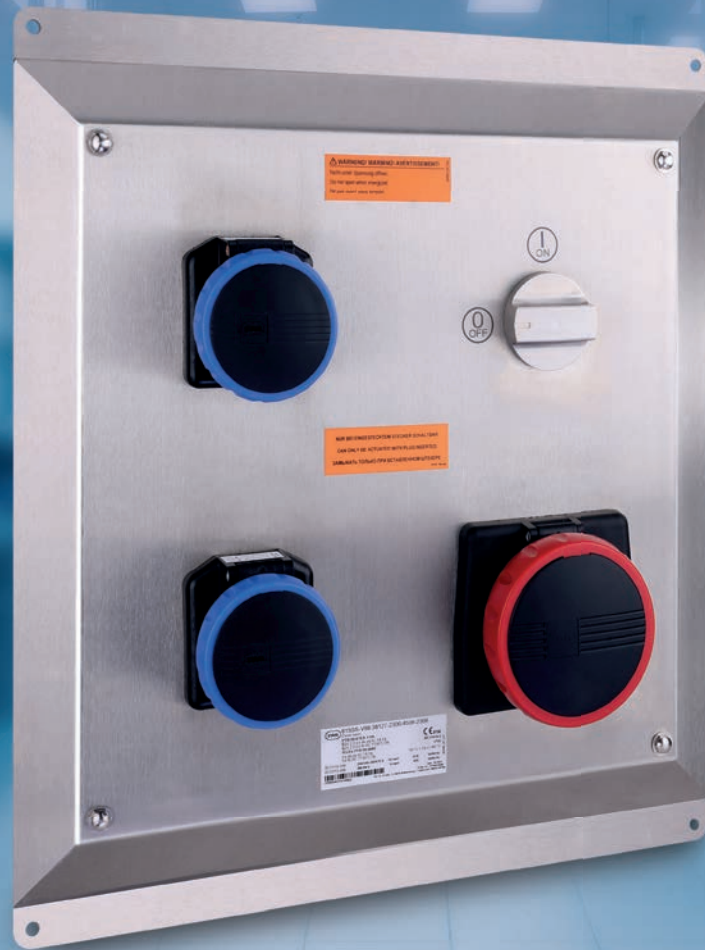
Suresh Pattathil, President, OPPI said, "At the threshold of significant change, the Indian pharmaceutical and healthcare sector is positioned to be a key player in shaping the nation's future. The report, a joint initiative by OPPI and EY-P, outlines an ambitious path for the industry. It explores the pace of reforms and the interplay of factors such as digital technologies, manufacturing, supply chain, operational efficiency, and more, shaping the industry's progress over the next two decades."

Sun Pharma arm enters into licensing agreement with Aclaris Therapeutics

Mumbai, India: Sun Pharmaceutical Industries, Inc., a subsidiary of the Company, has entered into licensing agreement with Aclaris Therapeutics, Inc., a clinical-stage biopharmaceutical company focused on developing novel drugs for immuno-inflammatory diseases.

Under the license agreement, Aclaris granted Sun Pharma exclusive rights under certain patents for the use of deuruxolitinib, Sun Pharma's JAK inhibitor, or other isotopic forms of ruxolitinib, to treat alopecia areata (AA) or androgenetic alopecia (AGA). The agreement includes an upfront payment of USD 15 million, regulatory and commercial milestones, and royalties.

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Cadila Pharma unveils API manufacturing plant at Dahej



Cadila Pharma API plant

Dahej, India: Cadila Pharmaceuticals, one of the oldest and largest privately-held drug manufacturers in the country, inaugurated its state-of-the-art Active Pharmaceutical Ingredients (API) Plant at Dahej in the Bharuch district. The facility, set up with an investment of ₹. 200 crore, is equipped with the latest Distributed Control System (DCS) automation technology, marking a significant milestone in Cadila Pharmaceuticals' dedication to innovation and excellence in drug manufacturing.

Dr. H. G. Koshia, Food Drug Commissioner for Gujarat, and Dr. M. P. Nakarani, Assistant Commissioner of FDCA, Baruch Circle, graced the event with their presence. Dr. Koshia stated, "It's truly a pleasure to visit CPL's API Greenfield state-of-the-art project at Dahej. It is a great moment for me, and my tribute to the legendary Pharma Man of India and catalyst to the Gujarat Pharma industry, late Shri IM Modi Sir. I feel and sense his presence by visiting such a beautiful creation."

Speaking on the occasion, Biswajit Mitra, Chief Mentoring Officer at Cadila Pharmaceuticals and Convener Pharma Panel, CII Gujarat State, said, "This state-of-the-art API manufacturing facility at Dahej represents our commitment to providing high-quality, cost-effective APIs to our customers worldwide. The DCS technology used in this facility will allow us to produce APIs with a high level of purity and consistency, while also reducing the environmental impact. The implementation of the plant project will further extend our impact by generating employment opportunities for both permanent and contractual positions, thereby continuing our dedication to creating positive social change."

Cadila Pharmaceuticals had earlier signed an MoU with the government of Gujarat for investing ₹ 1,000 crore

in Gujarat. The Dahej API facility is one of the projects for which the MoU was signed. The facility incorporates advanced Distributed Control System technology, enhancing greater precision and efficiency in the production process.

Lupin receives tentative approval from US FDA for Canagliflozin tablets



Nilesh D Gupta, MD, Lupin

Mumbai, India: Global pharma major Lupin Limited announced that it has received tentative approval from the United States Food and Drug Administration (U.S. FDA) for its Abbreviated New Drug Application for Canagliflozin Tablets, 100 mg and 300 mg, to market a generic equivalent of

Invokana Tablets, 100 mg and 300 mg, of Janssen Pharmaceuticals, Inc. This product will be manufactured at Lupin's Pithampur facility in India.

Canagliflozin is a sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease; to reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria Canagliflozin Tablets had estimated annual sales of USD 561 million in the U.S. (IQVIA MAT September 2023).

Lupin is an innovation-led transnational pharmaceutical company headquartered in Mumbai, India. The Company develops and commercializes a wide range of branded and generic formulations, biotechnology products, and APIs in over 100 markets in the U.S., India, South Africa, and across the Asia Pacific (APAC), Latin America (LATAM), Europe, and Middle East regions.

Strides Pharma receives USFDA approval for Generic Suprep Bowel Prep Kit



Arun Kumar, Executive Chairperson & MD, Strides Pharma

Bangalore, India: Strides Pharma Science Limited announced that its step-down wholly owned subsidiary, Strides Pharma Global Pte. Limited, Singapore, has received approval for Sodium Sulphate, Potassium Sulphate and Magnesium Sulphate Oral Solution 17.5g/ 3.13g/ 1.6g per 6 ounces (Product) from the

United States Food & Drug Administration (USFDA). The Product is bioequivalent and therapeutically equivalent to the Reference Listed Drug (RLD), Suprep Bowel Prep Kit Oral Solution 17.5g/ 3.13g/ 1.6g per 6 ounces of Braintree Laboratories Inc. (Braintree).

The approval bolsters the Company's portfolio of products in bowel preparation that spans both prescription and over the counter offerings. The Product has a market size of ~US\$143 Mn per IQVIA. The Product will be manufactured at the company's facility in Bengaluru. The company has 260 cumulative ANDA filings (including the recently acquired portfolio from Endo at Chestnut Ridge) with USFDA, of which 230+ ANDAs have been approved. The company has set a target to launch ~ 60 new products over three years in the US.

Indian Immunologicals launches Measles and Rubella Vaccine

Hyderabad, India: Human Biologicals Institute (HBI), a division of Indian Immunologicals Limited (IIL) celebrates its silver jubilee, 25 years since its establishment in 1998. HBI was created in an era where the need for indigenous vaccines is paramount and thus has contributed to a self-reliant India - "Atmanirbhar Bharat". While celebrating the occasion of 25th year of HBI with distinguished medical doctors assembled from various parts of the country in the serene precincts of Udhagamandalam (Ooty), IIL launched Mabella (Measles and Rubella) vaccine for children. This MR vaccine has been developed by IIL in partnership with Polyvac Institute, Vietnam. Through extensive human clinical trials, Mabella has been proven to be safe and effective.



Upon request from Government of India, HBI indigenously developed India's 1st safe Vero-cell rabies vaccine - Abhayrab in 1998, paving way for Government of India to phase out the painful nerve tissue vaccine. Today, Abhayrab is the largest selling Anti-Rabies vaccine in the world. Millions of lives have been saved in India and across the world with HBI's Abhayrab vaccine. Subsequently, several childhood vaccines such as DPT, Pentavalent Vaccine, TT, Hepatitis-B, MR, Td vaccines were introduced by HBI.

IIL's journey of excellence in vaccine development reached its summit during the Covid 19 pandemic. IIL rose to the nation's call and contributed to the manufacturing of many million doses of vaccines. This capability of IIL was much appreciated by NITI Ayog, Ministry of Health and Family Welfare and several other agencies.

Speaking on this occasion, Dr K Anand Kumar, Managing Director, Indian Immunologicals, spoke about the significant contribution made by IIL to the nation, towards disease control and access to several lifesaving vaccines in its 25 years of existence. "IIL has now emerged as one of the largest suppliers of human vaccines to the UIP, Ministry of Health and Family Welfare, Government of India, saving many precious lives. IIL also exports quality vaccines to more than 50 countries across the globe."

Aurobindo Pharma receives USFDA approval for Darunavir tablets

Hyderabad, India: Aurobindo Pharma Limited announce that it has received final approval from the US Food & Drug Administration (USFDA) to manufacture and market Darunavir Tablets, 600 mg and 800 mg, which is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Prezista Tablets, 600 mg and 800 mg, of Janssen Products, L.P. The product will be launched on November 29, 2023. The approved product has an estimated market size of



K. Nityananda Reddy, Vice Chairman & MD, Aurobindo Pharma

USD 274.8 million for the twelve months ending October 2023, according to IQVIA. Aurobindo now has a total of 500 ANDA approvals (478 Final approvals and 22 tentative approvals) from USFDA.

Darunavir Tablets, 600 mg and 800 mg, in combination with other antiretroviral agents, is indicated for the treatment of human

immunodeficiency virus (HIV-1) infection in adult and paediatric patients 3 years of age and older.

The Company develops, manufactures, and commercializes a wide range of generic pharmaceuticals, branded specialty pharmaceuticals and active pharmaceutical ingredients globally in over 150 countries.

Suven Life Sciences announces positive topline results from a Phase-2 study evaluating Samelisant (SUVN-G3031)



Venkat Jasti, Chairman & CEO, Suven Life Sciences

Hyderabad, India: Suven Life Sciences, a clinical stage biopharmaceutical company discovering and developing novel medicines to treat Central Nervous System (CNS) disorders, announced positive topline results from its Phase-2 proof-of-concept study assessing the safety and efficacy of samelisant for the treatment of excessive

daytime sleepiness (EDS) in adult narcolepsy patients with and without cataplexy.

The study met primary endpoint, with samelisant demonstrating statistically significant and clinically meaningful reduction in EDS measured by the ESS total score compared to placebo at Day 14 ($p < 0.05$). Highly statistically significant effects were observed against placebo for the other efficacy endpoints like Clinical Global Impression of Severity (CGI-S) score related to EDS, Patient Global Impression-Change (PGI-C), and Clinical Global Impression of Change (CGI-C). Exposures of samelisant in narcolepsy patients were

observed to be in agreement with the exposures from Phase-1 studies in healthy subjects. These plasma concentrations of samelisant were projected to be sufficient for achieving receptor occupancy required to demonstrate efficacy in narcolepsy patients. Samelisant was generally safe and well tolerated. There were no serious adverse events or death reported in the study.

"We are thrilled by these compelling topline results and the magnitude of improvement observed for Narcolepsy patients in this study with Samelisant as a monotherapy," said Venkat Jasti, Chairman & CEO of Suven Life Sciences.

"These results demonstrate rapid onset of action of Samelisant and its ability to significantly address the symptoms of EDS that impair quality of life in Narcolepsy patients, we look forward to working closely with the FDA as we focus on our goal to advance Samelisant to the Phase-3 clinical development program," said Ramakrishna Nirogi, Vice President, Drug Discovery & Development, Suven Life Sciences.

Zydus receives final approval from USFDA for Ivabradine tablets

Ahmedabad, India: Zydus Lifesciences Limited has received final approval from the United States Food and Drug Administration (USFDA) for Ivabradine Tablets, 5 mg and 7.5 mg.

Ivabradine is indicated to reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with reduced left ventricular ejection fraction. It is also used in children aged 6 months and older for the treatment of stable symptomatic heart failure due to cardiomyopathy. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Zydus was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Ivabradine Tablets, 5 mg and 7.5 mg and therefore may be eligible for 180 days of shared generic exclusivity for Ivabradine Tablets, 5 mg and 7.5 mg. Ivabradine Tablets, 5 mg and 7.5 mg had annual sales of USD 136.5 mn in the United States (IQVIA MAT October, 2023). The group now has 382 approvals and has so far filed over 448* ANDAs since the commencement of the filing process in FY 2003-04.

Indoco Remedies receives tentative ANDA approval from USFDA for Canagliflozin tablets



Aditi Panandikar, MD, Indoco Remedies

Mumbai, India: Indoco Remedies Ltd. announced the receipt of tentative approval from the USFDA for Abbreviated New Drug Application (ANDA) for Canagliflozin Tablets 100 mg and 300 mg, a generic equivalent of the Reference Listed Drug, Invokana tablets 100 mg and 300 mg, of Janssen Pharmaceuticals, Inc. This

product will be manufactured by Indoco Remedies Limited, at their manufacturing facility located at Goa (Plant -I) in India.

Canagliflozin improves glycemic control in adults with type 2 diabetes mellitus. Commenting on the achievement, Aditi Panandikar, Managing Director said, "Besides reflecting the capability of Indoco Remedies to deliver products of high-quality standards, this development also provides impetus to our growth aspirations in an important market such as the US."

Indoco is a fully integrated, research-oriented pharmaceutical company with presence in 55 countries. The Company's turnover is US\$ 200 million with a human capital of 6000 employees, including over 400 skilled scientists and Field Staff who are the strength of the organization.

Rusan Pharma unveils its state-of-the-art facility for APIs in Pithampur, Madhya Pradesh

Pithampur, Madhya Pradesh, India: Rusan Pharma, a leading pharmaceutical company committed to improving healthcare globally and pioneering pain management and addiction solutions worldwide – achieved a momentous milestone with the launch of its state-of-the-art API facility in Pithampur, Special Economic Zone (SEZ), Madhya Pradesh. This achievement represents Rusan Pharma's unwavering commitment to addressing the alarming rise in pain management, drug, alcohol, and tobacco addiction while contributing to the growth of the Indian pharmaceutical industry.



Rusan Pharma API facility

With an approach to sustainable development and technological advancements, the total investment over two phases will be up to ₹ 300 crore, highlighting Rusan Pharma's commitment to the pharmaceutical sector and its potential impact on the industry's growth and development. The facility is designed to meet stringent international regulatory guidelines, ensuring the highest level of compliance. With the production capability of 400 metric tonnes of APIs annually, the facility significantly contributes to Rusan Pharma's growth and expansion plans, diversifying its portfolio and expanding its reach in India and other markets.

Dr. Navin Saxena, Founder and Chairman – Rusan Pharma, said, "The new API facility in Pithampur, will enable Rusan to significantly enhance our existing API capacity and ensure the security of supply of critical APIs to meet the growing demand for our addiction treatment and pain management products in India and globally. Rusan has invested the last 30 years and pioneered in making the treatment of addiction acceptable and accessible. We firmly believe that access to quality healthcare is a right and not a privilege. Our goal is to ensure that everyone who seeks treatment for addiction and pain management can access it."

Strategically situated within the Pithampur Special Economic Zone (SEZ), the new facility will capitalise on the support and subsidies provided by the Madhya Pradesh state government. Dr. Kunal Saxena – Managing Director, Rusan Pharma said, "At Rusan, we exemplify the 'Make in India' initiative, especially in the area of controlled substances. With an investment of about ₹ 300 crore in two phases, this new API facility will increase our current API manufacturing capacity from 40 metric tonnes in Ankleshwar to 400 metric tonnes in Pithampur. Our new plant boasts five modular API manufacturing blocks with dedicated suites for finished API manufacturing."

Akums' acquires new facility in Baddi to elevate tablet manufacturing capacity

New Delhi, India: Akums Drugs and Pharmaceuticals Limited, the contract manufacturing pharmaceutical company in India, announced the acquisition of a new formulation facility located in Baddi, Himachal Pradesh. This marks the 12th formulation facility under Akums, and the second in Baddi, a strategic move with an aim to enhance Akums' manufacturing capabilities. The newly acquired facility, sprawling across approximately 6 acres, is currently undergoing upgrades and is slated to become operational in the year 2024. Once operational, it will serve as a OSD pharmaceutical formulation facility, significantly enhancing Akums' tablet manufacturing capacity.

Sanjeev Jain, Joint Managing Director, Akums Drugs and Pharmaceuticals, speaking about the acquisition, noted, "Amidst the dynamic expansion of the pharmaceutical industry, the acquisition of the Baddi facility serves as a clear indicator of our company's planned foresight and proactive approach in contributing to market dynamics. As the industry undergoes substantial growth, our objective is to contribute not only to the Indian market but also attempting to leave a lasting imprint on the international stage." Sandeep Jain, Joint Managing Director, Akums, emphasized the significance of the expansion in light of market trends. He stated, "Acquisition of the 2nd manufacturing site in the Baddi, aligns with our goal to enhance the manufacturing capabilities across geographies, while aiming to make a substantial impact on the overall health and well-being of our communities."

InvaGen Pharmaceuticals issues voluntary nationwide Recall of Vigabatrin for Oral Solution

Hauppauge, New York: Cipla Limited announced that its wholly-owned subsidiary, InvaGen Pharmaceuticals Inc., USA is voluntarily recalling one lot of Vigabatrin for Oral Solution, USP 500mg, to the consumer level. Vigabatrin for Oral Solution, USP 500 mg has been found to have seal integrity issues allowing for powder leakage from the pouch.

An improper seal in the pouch may lead to the leakage of powder blend outside the pouch, resulting in a lower content of medicine inside the pouch compared to the label claim and result in potential underdosing. The population at risk is primarily infants and young children.

In those patients, there is a reasonable probability that inaccurate dosing might result in a serious adverse effect such as intoxication or breakthrough seizures requiring medical intervention. For a small minority of patients, who might have severe or repeated breakthrough seizures, a drop in their phenytoin blood levels could result in lifethreatening seizures requiring immediate emergency room treatment. Cipla has not received any reports of adverse events related to this recall.

The product is used for the treatment of Refractory Complex Partial Seizures as adjunctive therapy in patients 2 years of age and older who have responded adequately to several alternative treatments. Vigabatrin for oral solution is not indicated as a first-line agent. The medication is packaged in foil pouches, each containing 500mg of Vigabatrin, and there are 50 foil sealed pouches in a shelf pack. The affected lot is NB301030, with an expiration date of 03/2025. The Vigabatrin for Oral Solution, USP 500mg product was distributed nationwide to partnered distributors and consignees.

Neuberg Diagnostics announces its entry into integrated diagnostics space

Chennai, India: Neuberg Diagnostics, a leading diagnostic healthcare chain with a strong presence across India, South Africa, UAE, and the USA, has unveiled its state-of-the-art national reference laboratory which houses Genomics, Transplant Immunology, Molecular Diagnostics, Proteomics and Metabolomics testing along with integrated diagnostics in Chennai. This cutting-edge facility, hailed as "Chennai's new Healthcare landmark," represents India's First state of art total lab automation solution utilizing the Abbott GLP System, alongside the innovative WOW (Wellness on Wheels) concept.

Neuberg Diagnostics launched its national reference laboratory operations with the inauguration of its Headquarters in Chennai, in the presence of Udhayanidhi Stalin, Minister of Youth Welfare and Sports Development of Tamil Nadu, T.R.B Rajaa, Minister of Industries of Tamil Nadu, Ma. Subramanian, Minister for Health and Family Welfare of Tamil Nadu, Dr. GSK Velu, Chairman and Managing Director of Neuberg Diagnostics, Dr. Sandeep Shah, Joint Managing Director Neuberg Diagnostics and Mr. A Ganesan, Vice Chairman Neuberg Diagnostics.

Dr. GSK Velu, Chairman and Managing Director of Neuberg Diagnostics, expressed his vision for the new facility, stating, "The launch of Neuberg's state-of-the-

art national reference laboratory and wellness center in Chennai is a witness to our promise to advancing integrated diagnostic healthcare in India. With cutting-edge technology like the Abbott GLP System, we are setting new benchmarks in efficiency and precision. This facility not only marks a milestone for Neuberg Diagnostics but also reinforces our dedication to providing world-class healthcare solutions to the people of Chennai and entire south India. The center will also be equipped with CT and MRI in the coming months and Neuberg Diagnostics will also bring PET scan facility in Chennai soon “

The new high-end lab offers an extensive array of over 6000 routine and specialized tests and have a capacity to process a remarkable number of 10000 tests samples per day across pathology, microbiology, genomics, proteomics, metabolomics and molecular biology, specializations, making it one of the largest clinical laboratory infrastructures in India ensuring efficiency and accuracy in diagnostic processes. The modern wellness center, focused on preventive wellness and it's fully equipped with X-ray, ECG, Sonography, TMT, Echo, Mammography, Bone Densitometry, Eye Check, Audiometry, Spirometry etc.

A Ganesan, Vice Chairman of Neuberg Diagnostics, stated “Neuberg Diagnostics network of labs is renowned for its commitment to best-in-class quality assurance and customer satisfaction at affordable cost. All our labs are equipped with best in class technology and fully automated systems that track end-to-end sample movement from collection to reporting, eliminating pre-analytical errors. The laboratory is led by highly experienced team of pathologists, microbiologists, biochemists, and molecular scientists, supported by technologists and existing network of phlebotomists for home sample collection.”

Stelis Biopharma announces closure of its transaction with Syngene International

Bengaluru, India: Stelis Biopharma & Syngene International Ltd have executed the final agreements to transfer its Unit 3 multi-modal facility in Bengaluru to Syngene with the following modifications. The gross consideration adjusted from ₹ 7,020 Million to ₹ 6,170 Million - a reduction of ₹ 850 Million. This is on account of amongst other things Stelis retaining 10 single use of 2KL (20,000 litres) reactors not currently installed in the facility.

This will support our increased focus for Mammalian Drug Substance opportunities in the CDMO space. With its current installed capacity of 8,000 litres, the near term expanded capacity at 28,000 litres will make Stelis a significant player in the space. Stelis has received a payment of ₹ 3,950 Million and the balance amount shall be received on completion of certain post-closing actions and final adjustments, if any which is expected in December 2023. The proceeds received along with cash and cash equivalents has been deployed to repay Stelis' lenders to the extent of ₹ 4,200 Million.

IIT Guwahati, Tata Medical & Diagnostics Ltd. & NHM Assam forge Partnership to revolutionize Healthcare in Assam



Guwahati, India: Indian Institute of Technology Guwahati (IIT Guwahati) has joined hands with Tata Medical & Diagnostics Ltd. (Tata MD) and National Health Mission, Assam, Health & Family Welfare Department, Govt. of Assam, to sign a Memorandum of Understanding (MoU) to implement the Tata MD's Healthcare Model for augmenting public healthcare delivery in the Kamrup district of Assam by establishing a Digital Nerve Centre. The MoU was signed on 1st December 2023 by Dr. M.S. Lakshmi Priya, IAS, MD, NHM Assam, Girish Krishnamurthy, MD & CEO, TATA MD, and Prof. Parameswar K. Iyer, Dean PRBR, IIT Guwahati. The event was graced by Keshab Mahanta, Hon'ble Minister of Health & Family Welfare and Science and Technology, Information & Technology Departments in Govt. of Assam, Shri Girish Krishnamurthy, CEO TATA MD, Prof. Rajeev Ahuja, Officiating Director, IIT Guwahati, and dignitaries from Bill and Melinda Gates Foundation, State of Assam, TATA MD and IIT Guwahati.

Speaking during the MoU signing event, Hon'ble Minister of Health & Family Welfare and Science and

Technology, Information & Technology Departments in Govt. of Assam, Shri Keshab Mahanta, said, "We are extremely excited that Tata MD, under the leadership of Hon'ble Chief Minister Dr. Himanta Biswa Sarma, is setting up the transformative Digital Nerve Centre Model in the state of Assam. We are grateful to the Bill and Melinda Gates Foundation and IIT Guwahati for partnering in this initiative. With this MoU, we mark the beginning of a unique transformative journey that holds the promise of better health outcomes, enhanced accessibility and facilitate local employment in this project."

One major highlight of this project will be Bill & Melinda Gates Foundation's involvement as the strategic partner to provide inputs and share learnings of adapting and implementing innovative models, as well as taking the learnings from the initiative to other states and globally to ensure more women and children have access to lifesaving care.

Speaking about this project, Dr. Rajani Ved, Director-Health, Bill & Melinda Gates Foundation said, "We look forward to working under the guidance of the Ministry of Health, Government of Assam and partnering with Tata MD and IIT Guwahati to help in implementing innovative ideas and accelerating the progress to reach our common vision of health for all."

Dr Reddy's Laboratories gets 3 observations from USFDA for Hyderabad facility

Mumbai, India: Dr Reddy's Laboratories announced that United States Food & Drug Administration (USFDA) completed a GMP and Pre-Approval Inspection (PAI) at R&D centre (Integrated Product Development Organisation or IPDO) in Bachupally, Hyderabad. The company stated that the inspection was conducted from December 4, 2023 to December 8, 2023.

"We have been issued a Form 483 with three observations, which we will address within the stipulated timeline," the company stated.

Merck announces winners of Merck Young Scientist Award 2023

Mumbai, India: Merck, a leading science and technology company, has announced the winners of Merck Young Scientist Award 2023, season-3 to recognise young scientists in India. Held at Bangalore, the annual awards recognise the work of young scientists who are driving positive change in the lives of millions across India through their cutting-edge research in life sciences. After an extensive selection process, the jury announced the winners at the award ceremony on November 24, 2023. The third season of the Merck Young Scientist Award Program garnered an overwhelming response with over 1500 registrations from nearly 800 institutes across India, resulting in over 500 high-quality applications.

This year's award program invited applications from three distinct categories, namely Biological Sciences, Chemical Sciences and a special category dedicated to Sustainability Research (green chemistry, renewable/alternate energy, sustainable materials and manufacturing), reflecting the growing significance of environmental consciousness in scientific research. The committee selected 3 winners each from the biological and chemical sciences categories and 1 winner in the sustainability research category. Here are the winners and runners-up: The winners include Dr. Harsha Bajaj, Dr. Debarka Sengupta, Dr. Saroj Kumar Nandi on Biological Science, Uttam Kumar Ghorai, Dr. Santanu Panda, Dr. Shobhna Kapoor on Chemical Science and Dr. John Mandal on Sustainability. The winners received a prize of ₹. 350,000, comprising a cash award of ₹ 250,000 and a travel award of ₹ 100,000. Additionally, 7 runner-up recipients, were awarded ₹ 100,000.

Announcing the winners, Dhananjay Singh, Head of Science and Lab Solutions, Merck Life Science, said, "Merck has created a platform to celebrate the brilliance of young scientists in India who are pushing the boundaries of research and contributing to the advancement of science. In Season 3, we are truly delighted to witness their passion, dedication, and innovative research, which aligns with Merck's commitment to honoring cutting-edge research that can make the world a healthier and safer place."

Granules India receives ANDA approval for Sildenafil for Oral Suspension

Hyderabad, India: Granules India Limited announced that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA), filed by Granules Pharmaceuticals, Inc. (GPI), a wholly owned foreign subsidiary of the company, for Sildenafil for Oral Suspension, 10 mg/mL. It is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Revatio for Oral Suspension, 10mg/ml, of Viatrix Specialty LLC.

Sildenafil for Oral Suspension is indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening. Granules now has a total of 63 ANDA approvals from the US FDA (61 final approvals and 2 tentative approvals).

The current annual U.S. market for Sildenafil for Oral Suspension is approximately \$43 million, according to MAT Sep 2023, IQVIA/IMS Health.

Cupid Limited to boost production capacities

Mumbai, India: In a significant strategic development, Cupid Limited, a pioneer in the personal health industry, has announced its acquisition of a new land parcel in an Industrial Area near Mumbai. This move is set to remarkably increase the company's production capabilities, enhancing its position in the global market.

The acquisition will enable Cupid Limited to amplify its production capacity by 1.5 times the existing output. As a result, the annual production capacity will be augmented by approximately 770 million male condoms and 75 million female condoms. This expansion is in addition to the current production capacity of 480 million male condoms and 50 million female condoms.

Aditya Halwasiya, Managing Director, further highlighted the prospects, "Within 18 to 24 months post-expansion, our capacity for male condoms is expected to surge to an impressive 1.25 billion units, while female condom production will rise to 125 million units. This marks a new era in Cupid Limited's journey towards global leadership in sexual wellness and reaffirms our long-standing commitment to all our stakeholders that 'We help the world play safe.' This expansion is expected to add Rs.240 crores to our revenues and Rs. 70 crores to our EBITDA."

Importantly, this capacity expansion will be funded entirely through internal accruals, with no reliance on borrowings. The company plans to invest in state-of-the-art machinery for each production stage, reaffirming its commitment to quality and innovation.

Additionally, Cupid Limited is set to expand its global footprint by forging new partnerships with international players. The Indian contraceptives market is set to grow at a healthy rate of 12.2% CAGR over the next 7-10 years, with a broader cultural shift among the younger end of the target market and population growth.

Takeda announces partnership with BIRAC in India

Mumbai, India: Takeda announced the signing of a three-year MoU with the Biotechnology Industry Research Assistance Council (BIRAC), a public sector enterprise set up by the Department of Biotechnology, Government of India. The MoU was announced in the presence of Dr. Jitendra Singh, Hon'ble Union Minister of State for Science & Technology, Minister of State for the Prime Minister Office, Government of India, and senior government and industry leaders.

The partnership will allow Takeda to extend advisory and mentoring support to innovators and entrepreneurs while assisting them from ideation to market deployment of new-age healthcare solutions. The collaboration resonates with BIRAC's vision to stimulate, foster and enhance the strategic research and innovation capabilities of the Indian biotech industry for creation of affordable products addressing the needs of the largest section of society.

Speaking of the collaboration, Sanjay Patel, Global Head of Data Digital and Technology Innovation Capability Solutions, Takeda Pharmaceuticals International AG, said, "India is one of the most vibrant and promising healthcare markets. This partnership between Takeda and BIRAC, thus, moves beyond convention, signifying a promise to further healthcare in a manner that sets the stage for lasting improvements in the years to come"

Serina Fischer, General Manager, Takeda Biopharmaceuticals India Pvt Ltd said, "At Takeda, we are committed to meeting the unmet needs of patients by discovering and delivering life-transforming treatments and innovative solutions. Our vision and mission align with the Indian Government's aspiration for local solutions to global healthcare challenges. This partnership serves as a practical blueprint, highlighting how public and private players can join forces to propel substantial and enduring advances in healthcare."

Ruchi Sogarwal, Head of Corporate Affairs, Takeda Biopharmaceuticals India Pvt Ltd, added, "Collaborations between the government, academia and industry contribute immensely to accelerating innovation and building disruptive healthcare technology solutions for addressing unmet patient needs. Our partnership with BIRAC will allow us to foster innovations, nurturing capabilities and enhancing global competitiveness translating bioscience into bioeconomy."

Wockhardt completes Phase 3 pneumonia study of its macrolide antibiotic Nafithromycin WCK 4873

Mumbai, India: Wockhardt has announced the completion of the pivotal Phase 3 pneumonia Study of its macrolide antibiotic Nafithromycin WCK 4873. Wockhardt NCE, WCK 4873 named as Nafithromycin was comparatively evaluated in multi-centre double blind Phase 3 pneumonia study employing the last-line respiratory antibiotic Moxifloxacin. The results of the study showed that an ultrashort course of three-day treatment with Nafithromycin is as effective as seven-day therapy with Moxifloxacin. The findings of Phase 3 study are in line with Phase 2 study conducted in the US and Europe.

In Phase 3 study, three-day treatment with Nafithromycin resulted in clinical cure for 96.7% of patients as against clinical cure rate of 94.5 % in Moxifloxacin arm. The Phase 3 study outcome establishes broad spectrum efficacy of Nafithromycin against Gram-positive respiratory pathogens, fastidious Gram-negative pathogens as well as therapeutically challenging intracellular atypical pathogens such as *Mycoplasma pneumoniae*, which were recently implicated for the surge of hospitalisations in China due to pneumonia.

The Phase 3 study did not encounter any serious Adverse Event (AE), all the reported AEs were mild, and most were considered unrelated to the study drugs by the investigators except for nausea and gastrointestinal effects.

Sterling Accuris expands into pharmaceutical and analytical testing

New Delhi, India: Sterling Accuris Diagnostics, a leading chain of NABL-accredited pathology laboratories has announced the acquisition of Ahmedabad based Vaibhav Analytical Services, a leading provider of analytical testing services, including pharmaceutical/drug testing. With this acquisition, Sterling Accuris has successfully expanded its range of services offered to fields such as pharmaceutical analytical testing.

The Pharmaceutical industry in Gujarat ranks number one in India with a 33% share in drug manufacturing and a 28% share in drug exports. Established in 1999, Vaibhav Analytical Services is a service provider to the pharmaceutical industries and is acclaimed for its expertise in pharmaceutical analysis, a critical aspect of drug development and manufacturing. Vaibhav Analytical Services operates its NABL accredited laboratory, ensuring strict compliance with international standards for pharmaceutical testing at Ahmedabad and services clients from across India. The company has also received approval from the Nigerian Government (NAFDAC) as a CRIA authorised laboratory.

Rajiv Sharma, MD of Sterling Accuris Diagnostics, emphasized the significance of this acquisition "This strategic move aligns with our commitment to advance healthcare through innovation and excellence in diagnostics and analytical testing services. Analytical testing assists biotech, food, environmental, and pharmaceutical companies that provide products to consumers for safety assurance and quality control, and we want to actively collaborate with them for all their testing needs.

Ankush Gupta, CEO of Sterling Accuris Diagnostics, highlights, "Vaibhav Analytical's inclusion positions us to meet the increasing demand for comprehensive pharmaceutical testing, contributing to the highest standards of safety and efficacy."

Gaurang Oza, partner of Vaibhav Analytical Services, expressed his enthusiasm, stating, "This collaboration marks a new chapter for Vaibhav Analytical Services. By joining forces with Sterling Accuris, we aim to contribute to advancements in pharmaceutical testing and ensure the highest standards of safety and efficacy."

Molbio Diagnostics partners with Finnish innovators Testi Technologies

GOA, India: Molbio Diagnostics, a leading player in point of care diagnostics has announced its partnership with Finnish innovation leader, Testi Technologies, to manufacture its flagship product PROMILLESS - a saliva-based diagnostics test to measure body alcohol content.

PROMILLESS, an easy to use, low cost, SALIVA based self-diagnostics test that has been developed together with VTT (Technical Research Centre of Finland) is a CE approved class 1 device that is patented worldwide.

Molbio diagnostics, a pioneer in revolutionary point of care diagnostics, will strengthen its commitment to providing accessible healthcare solutions by developing a strategic collaboration with Testi Technologies in the areas of technical development, manufacturing, marketing, sales and promotion of an array of diagnostic products.

"This partnership unites Testi Technologies' innovation in enzymatic test technology with Molbio Diagnostics' technological strength, production capabilities and extensive global network. Together, we are set to revolutionize healthcare diagnostics, blending our strengths to offer advanced, accessible solutions. This collaboration is a powerful step towards making a significant impact on global health," says Tommi Vaskivuo, Chairman, Testi Technologies Ltd.

Broadening its scope, Testi Technologies is venturing into both human and pet healthcare markets with a forthcoming saliva-based glucose test. This expansion is part of a well-structured product roadmap, underlining Testi Technologies' commitment to revolutionizing healthcare diagnostics through a series of innovative enzymatic medical tests. Under the current agreement, Molbio will have the rights to commercialize, market and sell PROMILLESS under its own brand name globally.

Sriram Natarajan, Chief Executive Officer of Molbio Diagnostics Pvt. Ltd says, "We are delighted to be a joint development, manufacturing and go to market partner of Testi Technologies. Their non-invasive enzymatic testing technology enables simple, rapid and accurate detection of analytes in saliva, by just touching the test stick to tongue. The current test for alcohol, the upcoming test for glucose and many more human and veterinary tests in the pipeline will prove to be revolutionary."

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Laurus Labs arm gets 5 observations from USFDA for AP facility

Hyderabad, India: Laurus Labs Ltd announced that Laurus Synthesis Private Limited (LSPL), a wholly owned subsidiary of Laurus Labs underwent US FDA inspection for the manufacturing facility in Parawada, Anakapalli, near Visakhapatnam, Andhra Pradesh. The company said that the inspection was conducted from 4th December, 2023 to 12th December, 2023.

"We have been issued a Form 483 with five observations and the Company will address the observations within stipulated timelines," the company said.

Founded in 2005, Laurus Labs is a research-driven pharmaceutical and biotechnology company with an aim to improve the quality of life for millions around the world. We have a global leadership position in select Active Pharmaceutical Ingredients (APIs) including anti-retroviral, oncology drugs (incl High Potent APIs), Cardiovascular, and Gastro therapeutics. The company also offer integrated CMO and Contract Development and Manufacturing Organization (CDMO) services to Global Innovators from Clinical phase drug development to commercial manufacturing.

Accent Microcell Limited IPO gets overwhelming response from investors

Mumbai, India: The Initial Public Offer (IPO) of Accent Microcell Limited received an overwhelming response from the investors as it recorded 362 times subscription till the final day of bidding. The Ahmedabad-based manufacturer and exporter of pharmaceutical excipients aimed to raise Rs. 78.40 crores from the issue that was floated between December 08 – 12.

While the Qualified Institutional Buyer (QIB) portion of the issue was subscribed 119 times, the HNI/NII quota was subscribed 577 times and the Retail Individual Investors (RII) quota was subscribed 410 times, bringing the overall subscription to 362 times till the final day of bidding on Tuesday, December 12, 2023.

The price band of the issue was fixed at ₹ 133-140 per equity share with a face value of Rs. 10 apiece. The IPO consisted of a fresh issue of 56 lakh Equity Shares with a face value of ₹ 10/- through the book-building route. The minimum lot size for the application is 1,000 shares. The company is proposed to be listed on NSE Emerge. Corporate Capital Ventures Private Limited is the Book Running Lead Manager to the issue.

Accent Microcell Limited plans to utilise ₹. 54.39 crores out of net proceeds from the offering to establish a new plant at Navagam Kheda, Gujarat, India, for manufacturing Croscarmellose Sodium (CCS), Sodium Starch Glycolate (SSG) and Carboxymethylcellulose (CMC), which is expected to be commercialised by April 2025. It plans to use the remaining funds for general corporate purposes.

Shweta Rai to take over as MD of Bayer Zydus Pharma

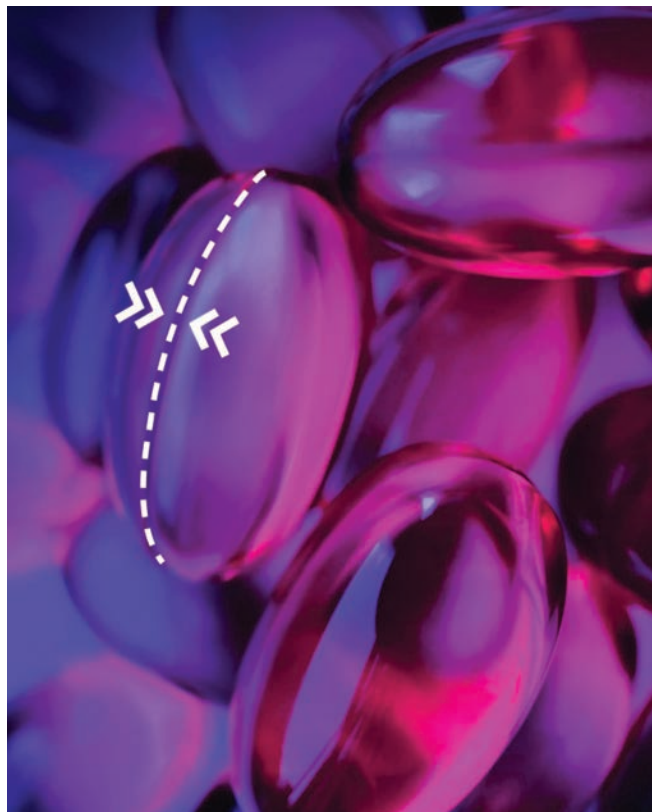
Thane, India: Bayer announced that Shweta Rai will take over as Managing Director of Bayer Zydus Pharma Private Limited and Country Division Head (CDH) for Bayer's Pharmaceuticals Business in South Asia effective, January 1, 2024. Manoj Saxena will move out of his present role to take on the role of CDH for Bayer's Pharmaceuticals Division and Senior Bayer Representative, Bayer Group for the Australia & New Zealand (ANZ) cluster, with effect from the same date.

Shweta joined Bayer in 2019 and her last assignment was Business Unit Head. With a distinguished career spanning over 22 years, Shweta has a strong track record of leading high performance diverse teams across strategic business positions in the pharmaceuticals and medical device sectors. Her expertise extends across a myriad of therapy areas, including Cardiology, Diabetes, Women's Health Care, Immunology, Virology, Anti-infectives, Vaccines, Neurology, Orthopedics and Pain Management. Prior to this, she worked with companies of repute like Johnson & Johnson, MSD Pharmaceuticals, IQVIA and Pfizer.

Shweta holds a bachelor's degree in Zoology (Honors) from Miranda House Delhi University, a Postgraduate degree in Management Studies, Mumbai and completed a Strategic Management Program from the Indian Institute of Management (IIM), Kolkata.

Speaking about taking on the leadership role, Shweta said, "I am honored to take on this new role within the organization. I am committed to build on the strong foundation that has been laid by Manoj. I am confident we can continue to build on the successes we have witnessed in the region so far and take Bayer's mission of 'Health for All, Hunger for none' forward. I am excited to work closely with internal and external stakeholders to continue delivering innovative healthcare solutions and exceptional value to our patients."

New EASYSEAL gelatin from GELITA simplifies softgel production and helps cutting costs



Birkenauer Talstr: Gelatin expert GELITA is introducing a unique solution that enables manufacturers to optimize softgel production in one easy step. By switching to the new EASYSEAL® gelatin, manufacturers can enjoy significant reductions in leakers, lower processing costs and higher quality end products.

Leakers are softgels which lose their fill due to faulty capsule seams and are a major cause of lost productivity and reduced yield for producers of softgels. EASYSEAL overcomes the issue, providing additional benefits at the same time. The highly processable pharmaceutical grade gelatin optimizes seam forming and enhances seam thickness and stability so that soft capsules are more resistant to physical stress during production and packing.

Its outstanding characteristics enable EASYSEAL to seal capsules more reliably at higher machine speeds than other gelatins. EASYSEAL can also be used at higher speeds with ingredients (e.g. suspensions) that are normally complicated to fill in softgels, and for

products that require special equipment such as double step die tooling. As well as delivering higher capsule burst strength, EASYSEAL® is less dependent on sealing temperature than other gelatins and has superior drying properties. This brings advantages in terms of energy efficiency and enhanced production capacity.

Jessica Pfoehler, Global Marketing, Business Unit Performance Solutions, GELITA AG, says: "Many manufacturers tolerate a reject rate of up to 5 percent in soft capsule production due to leakers. With EASYSEAL®, this common industry problem will be a thing of the past – simply by changing one parameter: the gelatin."

GELITA is the first gelatin manufacturer to address the problem of leakers. Its intervention comes at a time when trends in nutritional ingredients and APIs mean soft capsules manufacturers are given increasingly challenging product requests, and cost optimization is more crucial than ever. Following pilot trials conducted with the University of Heidelberg, Germany, proof-of-concept has been demonstrated under real industrial production conditions by several softgel manufacturers.

EASYSEAL is suitable for use with food supplements, Rx medicines and over the counter health and wellness products. It is available in bovine and porcine forms and is produced in line with FDA regulations, HACCP, ISO9001:2015 and FSSC22000. A respective C-DMF (China Drug Masterfile) is available to ease entering the China market. The global pharmaceutical gelatin market for soft capsules was worth more than USD 215 million in 2022 and is expected to grow at a CAGR of 6.1 percent, according to figures from MarketsandMarkets

Innova Captab Limited sets price band at ₹ 426 to ₹ 448 per Equity Share

Mumbai, India: Innova Captab Limited is an integrated pharmaceutical company in India with a presence across the pharmaceuticals value chain including research and development, manufacturing, drug distribution and marketing and exports, has fixed the price band at ₹ 426 to ₹ 448 per Equity Share for its maiden initial public offer. The Initial Public Offering of the Company will open on Thursday, December 21, 2023, for subscription and close on Tuesday, December 26, 2023. Investors can bid for a minimum of 33 Equity Shares and in multiples of 33 Equity Shares thereafter.

The Offer of Equity Shares with a face value of ₹10 consists of a fresh issue of Equity Shares worth up to ₹ 3,200.00 million and an Offer for Sale (OFS) up to 5,580,357 Equity Shares, which comprises of up to 1,953,125 Equity Shares by Manoj Kumar Lohariwala, up to 1,953,125 Equity Shares by Vinay Kumar Lohariwala (Together with Manoj Kumar Lohariwala, the "Promoter Selling Shareholders") and up to 1,674,107 Equity Shares by Gian Parkash Aggarwal ("the "Other Selling Shareholder" and together with the Promoter Selling Shareholders, the "Selling Shareholders", and such offer for sale of Equity Shares by the Selling Shareholders, the "Offer for Sale").

Innova Captab Limited is an integrated pharmaceutical company in India with a presence across the pharmaceuticals value chain including research and development, manufacturing, drug distribution and marketing and exports. Its business includes a contract development and manufacturing organization ("CDMO") business providing research, product development and manufacturing services to Indian pharmaceutical companies, a domestic branded generics business and an international branded generics business. In Fiscal 2022, among Indian formulation CDMO players considered in the CRISIL Report, it recorded the third highest operating revenue, the second highest operating profit margin, the third highest net profit margin and the second highest return on capital employed. (Source: CRISIL Report, October 2023).

The Offer is being made through the Book Building Process, wherein not more than 50% of the Offer shall be available for allocation on a proportionate basis to Qualified Institutional Buyers, not less than 15% of the Offer shall be available for allocation to Non-Institutional Bidders and not less than 35% of the Offer shall be available for allocation to Retail Individual Bidders. ■



**Quantum Leap your Business
via
Dynamic 'PharmaBio network'
platform**



**Directly Reach the Inboxes of
40,000+
Affluent Leaders & Business
Influencers' from the
Pharma Industry each
month with the
PharmaBio World
in Print and
Digital Version**

Contact: +91-22-4037 3636
Email: sales@jasubhai.com
Website: www.jasubhaimedia.com



“We intend to supplement our inorganic growth with strategic acquisitions of regional and local distributors with strong branding.”



Prabhat Agrawal

Promoter, Managing Director and Chief Executive Officer,
Entero Healthcare Solutions Limited

Prabhat Agrawal emphasizes about the overview of the pharmaceutical distribution market and spoke about synergies, expansion plans, growth strategy and about the IPO plans.

Brief us about the overview of the pharmaceutical distribution market?

The distribution of pharmaceutical products in India is extremely fragmented. There are approximately 65,000 distributors, as of March 31, 2023, that generally service limited local areas only, unlike developed markets where large nationwide distributors occupy a dominant market position.

The target addressable market for pharmaceutical distributors in India is valued at ₹2.7 trillion in FY23 and market catered by large/national distributors was valued at ₹ 150-170 billion last fiscal. As of 2021, around a fourth of the overall pharmaceutical distribution market was concentrated in tier-1 cities (Mumbai, Delhi, Hyderabad, Pune, Ahmedabad, Kolkata, Chennai and Bangalore), while the tier-2 cities and beyond markets remain relatively underpenetrated. The market is expected to grow at 10% to 11% CAGR from FY23 to FY28. The share

of large/national distributors is expected to rise to 20-30% by fiscal 2028, growing at 25-30% CAGR, with stronger inorganic growth for the large/national players in the pharmaceutical distribution segment, as a result of consolidation.

Our Company was founded in 2018 with the vision to create an organized, pan-India, technology driven and integrated healthcare products distribution platform that can add value to the entire healthcare ecosystem.

How has Entero Healthcare Solution carved a niche for themselves in the industry?

As of March 2023, we have 73 warehouses located across 37 cities in 19 states and union territories. As of March 2023, we have 424,028 square feet of warehousing space with temperature monitoring systems and modern storage solutions. In FY23, we have supply relationships with over 1,900 healthcare product



manufacturers that gives access to over 64,500 product SKUs. and we catered to 81,400 retail customers and 3,400 hospital customers spread across 495 districts.

As of March 31, 2023, Entero Direct had over 8,600 active users, with sales on Entero Direct aggregating to ₹3,687.80 million for FY23. Over the years, we have established a large footprint in the healthcare products distribution business, with relationships with key stakeholders such as healthcare product manufacturers, pharmacies, hospitals and clinics.

Brief us about your expansion plans over the next 2-3 years? What is your growth strategy to further scale up operations?

We intend to supplement our inorganic growth with strategic acquisitions of regional and local distributors with strong branding, market position and growth potential in markets where we either do not have a presence or intend to consolidate market share.

We intend to follow the growth strategies to further scale up our operations to increase customer base through the addition of new pharmacies, hospitals and clinics in both existing and new territories, expand our geographic reach through a "hub and spoke" model which connects our warehouses and supply points across districts, increase our wallet share from existing pharmacies and hospitals by offering larger product portfolios, deeper customer engagement through technology and digital solutions, and offer procurement efficiencies and economies of scale advantages.

Can you shed more light about your partnership with Roche?

We are in a position to benefit from synergies, and complement our distribution services with marketing and promotion offerings with healthcare product manufacturers to not only distribute but also market and promote their brands to provide better access to medicines for patients in India. We entered into an agreement with Roche Products (India) Private Limited for rights of promotion, marketing and distribution of its four nephrology drugs in India.

What steps do you take to integrate and establish synergies with the newly acquired smaller distributor?

When evaluating acquisition targets, we take into account a number of factors such as the size of the market where the target company operates, their customer base and catchment area, supplier relationships, product portfolio, synergies with our existing network, historic financial performance and future opportunities for growth. Subsequent to the completion of an acquisition, we deploy our growth strategies such as product portfolio expansion, increased customer reach, improved service levels, technology-based solutions to increase our market share.

Brief us about your IPO plans? What are the objects of the issue?

Our initial public offering comprises a fresh issue of up to ₹10,000 million and an offer for sale of up to 8,557,597

Equity Shares aggregating equity shares by promoters and other selling shareholders.

We propose to utilize the net proceeds from the offer for repayment/prepayment, in full or part, of certain borrowings availed of by our Company and our Subsidiaries; funding the long term working capital requirements; Pursuing inorganic growth initiatives through acquisitions and general corporate purposes.

How will you benefit from market consolidation?

We believe that we will be able to benefit from the market consolidation in India, and continue to expand our business through future strategic acquisitions of local distributors. We also believe that our technology-driven, nation-wide distribution network, relationships with over 1,900 healthcare product manufacturers that gives us access to over 64,500 product SKUs as of March 31, 2023, and experienced and professional management team, position us well to continue to grow the scale of our business in India and take advantage of the shift towards the organized Indian healthcare products distribution market.

How have you been increasing your market reach over the last five years?

We have endeavored to take advantage of the market consolidation opportunities available in the Indian healthcare products distribution market. Accordingly, we have adopted a pan-India approach towards acquiring and integrating smaller distributors to expand our geographic reach and increase the wallet share from our customers. We seek to actively explore expansion opportunities through strategic acquisitions of regional and local distributors by consolidating our position in markets in which we currently operate, by entering and growing in synergistic product adjacencies as well as entering new geographies. Since the inception of our Company in FY18, we have acquired 32 entities in the healthcare products distribution industry. ■



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Navigating the Landscape: Scope, Pitfalls, and Opportunities for Indian Generic Manufacturers in the Pharmaceutical Industry

The global pharmaceutical industry is experiencing a seismic shift, and India is emerging as a pivotal player in the domain of generic drug manufacturing. Indian generic manufacturers have played a crucial role in delivering affordable healthcare solutions globally, addressing the rising demand for cost-effective medications. However, this journey is not without its hurdles. **Dr. Sujit Paul, Group CEO - Zota Healthcare Ltd** explores the opportunities confronting Indian generic manufacturers in the pharmaceutical industry.

Scope of Indian Generic Manufacturers

Global Market Share and Growth

Over the past few decades, Indian generic manufacturers have significantly broadened their global footprint. India proudly stands among the top pharmaceutical exporters globally, wielding a substantial market share in the generic drug segment. The combination of cost advantages and adherence to stringent quality standards has empowered Indian manufacturers to compete successfully on the international stage.

Increasing Demand for Generic Drugs

The global demand for generic drugs continues to escalate, propelled by factors such as soaring healthcare costs, the expiration of patents on blockbuster drugs, and the imperative for affordable healthcare solutions. Leveraging their expertise in producing high-quality generic medications, Indian manufacturers are strategically positioned to capitalize on this burgeoning market demand.

R&D and Innovation

While Indian pharmaceutical companies have traditionally been associated with generic drug manufacturing, there's a noticeable paradigm shift towards research and development (R&D). This embrace of innovation is expanding the scope for Indian manufacturers, enabling them to venture into the development of complex generics and biosimilars. This strategic pivot fosters a more sustainable and competitive future for the industry.

Pitfalls Faced by Indian Generic Manufacturers

Regulatory Challenges

A significant challenge confronting Indian generic manufacturers is the intricate task of navigating complex and ever-evolving regulatory landscapes. Stringent regulations in key markets like the United States and Europe necessitate compliance with diverse standards, compelling manufacturers to invest substantially in regulatory expertise and quality assurance.

Intellectual Property Issues

Legal battles concerning intellectual property rights present another formidable challenge for Indian pharmaceutical companies. Patent infringement lawsuits and challenges to generic drug approvals can be protracted and financially draining. To navigate these waters, a robust legal strategy and a keen awareness of global patent landscapes are essential to mitigate the risks associated with intellectual property issues.

Quality Perception Challenges

Despite making significant strides in conforming to international quality standards, some Indian generic manufacturers still grapple with a perception challenge regarding the quality of their products. Establishing and preserving a strong reputation for product quality is indispensable to overcome barriers and secure acceptance in global markets.

Opportunities for Indian Generic Manufacturers

Strategic Partnerships and Collaborations

To surmount the challenges posed by stringent regulations and intellectual property issues, Indian generic manufacturers can strategically engage in partnerships and collaborations. Aligning with global pharmaceutical companies facilitates knowledge exchange, technology transfer, and access to new markets, offering a pathway to enhanced competitiveness.

Focus on Specialty Generics and Biosimilars

As the pharmaceutical landscape undergoes transformation, Indian manufacturers can seize the opportunity to specialize in the production of specialty generics and biosimilars. These high-value, complex products not only confer a competitive edge but also contribute significantly to the long-term sustainability of the industry.

Investment in Digital Transformation

Digital technologies are reshaping the pharmaceutical industry, providing opportunities for increased efficiency and innovation. Indian generic manufacturers can strategically invest in digital transformation initiatives, encompassing areas such as data analytics, artificial intelligence, and automation. This investment serves to streamline operations, enhance supply chain visibility, and improve overall productivity.

Challenges in Market Access

While Indian generic manufacturers have made substantial progress in global markets, challenges related to market access persist. Regulatory hurdles, trade barriers, and pricing pressures can curtail the entry and growth of Indian generics in certain regions. Overcoming these challenges requires a nuanced understanding of diverse market requirements and the establishment of strategic alliances with local partners.

Supply Chain Resilience

The COVID-19 pandemic laid bare the vulnerabilities in global supply chains, impacting the pharmaceutical industry profoundly. Indian generic manufacturers, akin to their counterparts worldwide, faced disruptions

in the supply chain, affecting the availability of essential medications. This crisis underscores the critical importance of enhancing supply chain resilience through strategic investments in technology, contingency planning, and regional diversification.

Emerging Markets and Untapped Opportunities

While Indian generics enjoy a significant presence in established markets, untapped potential lies in emerging economies. These markets present opportunities for Indian manufacturers to address unmet medical needs, forge partnerships with local healthcare systems, and contribute to the development of robust healthcare infrastructure. Successfully navigating these markets demands a deep understanding of local regulations, cultural nuances, and healthcare practices.

Patient-Centric Healthcare Models

The evolving healthcare landscape emphasizes a shift towards patient-centric models. Indian generic manufacturers can capitalize on this trend by actively engaging in patient education, advocacy, and support programs. Establishing a positive connection with end-users not only enhances brand perception but also contributes to improved medication adherence and patient outcomes.

Government Initiatives and Policy Support

The Indian government has been proactive in promoting the pharmaceutical industry through various initiatives and policy measures. The 'Make in India' campaign, coupled with efforts to streamline regulatory processes, creates a conducive environment for the growth of generic manufacturers. Continued collaboration between industry stakeholders and policymakers is crucial to address evolving challenges and leverage policy support for sustainable growth.

Environmental Sustainability

In an era where sustainability is a central concern across industries, including pharmaceuticals, Indian generic manufacturers can explore environmentally friendly practices. Implementing green manufacturing processes, reducing carbon footprints, and adopting eco-friendly packaging contribute to a positive corporate image and align with global sustainability goals.

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Human Capital and Skill Development

A skilled workforce forms the bedrock of success for any industry. Indian generic manufacturers need to invest in continuous training and skill development programs to keep pace with evolving technologies and industry best practices. Developing a talent pool well-versed in regulatory compliance, advanced manufacturing techniques, and research capabilities is vital for sustaining competitiveness.

Conclusion: Charting the Future Course

In conclusion, the journey for Indian generic manufacturers in the pharmaceutical industry is both challenging and promising. The global demand for affordable healthcare solutions, coupled with India's manufacturing capabilities, positions the industry for significant growth. However, to fully realize this potential, addressing regulatory challenges, embracing innovation, and navigating emerging trends are imperative.

Strategic collaborations, a focus on specialty generics and biosimilars, and investments in digital transformation are key pillars for success. Furthermore, actively engaging with patients, exploring untapped markets, and ensuring supply chain resilience contribute to a robust and sustainable future. Government support and environmental consciousness add additional dimensions to the industry's growth trajectory.

Indian generic manufacturers, with their resilience and adaptability, are well-equipped to navigate the complexities of the pharmaceutical landscape. By staying attuned to global trends, leveraging opportunities, and continuously evolving, the industry can not only meet the current demands but also play a pivotal role in shaping the future of accessible and innovative healthcare solutions worldwide. ■

Author



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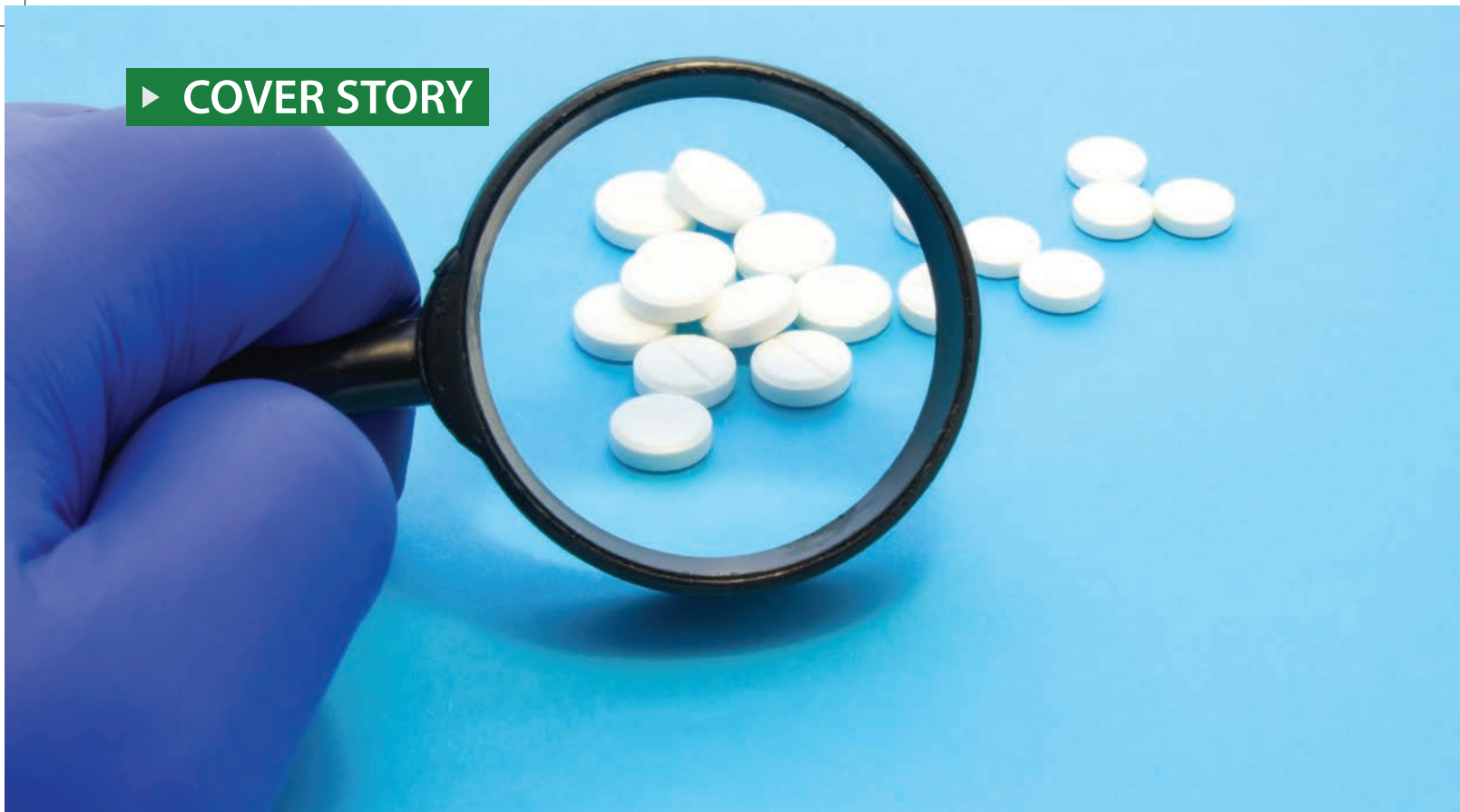


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Research and development will continue to be a major focus area in 2024: Saransh Chaudhary



Saransh Chaudhary

President, Global Critical Care
Venus Remedies Ltd, and
CEO, Venus Medicine Research Centre

Year 2023 has turned out to be a good one for the Indian pharmaceutical sector with the policy thrust on innovation and technology widening the ambit of the pharma industry from volume-based generics to value-based products driven by R&D. The government's move to promote research and innovation through centres of excellence and collaboration with laboratories run by the Indian Council of Medical Research has given a fillip to research-driven pharmaceutical organisations like Venus Remedies.

Investments in pharma R&D have also received a big boost with the Central government rolling out a Rs 5,000-crore research-linked-incentive (RLI) scheme for pharmaceuticals. The decision to set up Centres of Excellence in National Institutes of Pharmaceutical Education and Research presents huge opportunities to the Indian pharma sector to move up the value chain. Furthermore, the six priority areas identified by the government for promotion of research—new chemical entities, complex generics, precision medicine, medical devices, orphan drugs and drug development for

antimicrobial resistance (AMR)—has widened the scope for growth of the Indian pharmaceutical industry. The production-linked incentive (PLI) scheme announced by the government to boost domestic manufacturing capacity, which includes high-value products across the global supply chain, has also come as a shot in the arm for the pharma manufacturing segment.

Emerging trends and key focus areas and outlook for 2024

Focus areas: Research and development will continue to be a major focus area in 2024 with the pharma industry poised to introduce many innovative medicines and generic drugs in both domestic and international markets. The special emphasis on pharmaceutical manufacturing capabilities and cost-effective production processes will enable India to further cement its position as a global pharmaceutical hub.

Improving quality standards is a key area of focus for the Indian pharmaceutical industry. The industry is adopting best global practices and digitising its processes for better tracking and traceability, which will help eliminate counterfeit drugs from the market. The Union Health Ministry has been working towards upgrading the quality standards of Indian Pharmaceuticals by introducing barcodes for all drugs, conducting API quality checks and supporting SMEs through the Pharmaceuticals Technology Upgradation Assistance Scheme. The implementation of revised Good Manufacturing Practices (GMP) guidelines is a significant step towards achieving global quality standards in the pharmaceutical industry.

Enforcing stronger regulatory oversight on drug manufacturing is another critical focus area. The Central Drugs Standard Control Organisation (CDSCO) is considering rationalising the regulations as a measure to improve the ease of doing business, while also addressing the problems in the way of uniform implementation and interpretation of rules and regulations across the industry.

This coordinated strategy can ensure uniform regulatory enforcement, consistent standards and effective industry oversight, thus contributing towards improved patient safety and medicines of better quality for patients in both India and abroad.

New drug development, personalised medicine and improvements in operational efficiencies will be among the other focus areas. Another priority for next year should be to ensure the growth of the Indian generics market. We should concentrate on correcting the information asymmetry about generic drugs, which can lead to suboptimal prescribing and purchasing decisions, thus impacting both healthcare costs and patient outcomes. Addressing this information symmetry among patients and doctors can help build more trust in generics, enhance competition, reduce healthcare costs and improve patient access to medicines.

▪ **Trends:** Technology and technological advancements will be a major trend shaping the course of the Indian pharmaceutical industry in 2024. Innovative advancements in artificial intelligence, data analytics, automation, real-world data integration and Internet of Things will turn out to be the game changers for the pharma sector next year, and so will quality control benchmarks, drug discovery and development, R&D and innovation, advancements in manufacturing, biopharmaceuticals, sustainability and collaborations at both national and international levels.

▪ **Outlook:** As per Crisil Ratings, the revenue of the Indian pharmaceutical industry is expected to increase at a rate of 8-10 per cent in Financial Year 2024. According to the Frost & Sullivan report on the Union Budget for 2023-2024, India is expected to attract an investment of \$419.2 million in pharmaceutical R&D in the current fiscal. Given the growing emphasis on new innovative therapies, the market outlook for the pharmaceutical industry appears promising indeed. The incentives focused on R&D are expected to result in investments in innovation and outcome-based financing to drive public-private partnerships. ■

Diagnostics healthcare sector is positioned for substantial growth and transformation: Dr. Nilesh Shah



Dr. Nilesh Shah

President and Chief of Science and Innovation,
Metropolis Healthcare Limited

In the upcoming year of 2024, the diagnostics healthcare sector is positioned for substantial growth and transformation, driven by key trends and developments. Increased healthcare spending, rising life expectancy, growing incomes, and a heightened awareness of preventive testing will collectively create ample business opportunities in the healthcare and diagnostic space.

A noteworthy trend gaining momentum is the intensified focus on research and development to usher in new and advanced diagnostic technologies within the healthcare industry. This surge is marked by innovative approaches to disease detection and treatment, with a robust emphasis on precision medicine. Companies are investing heavily in the development of diagnostic tools capable of identifying individual patient characteristics, paving the way for more personalized and effective treatment strategies. The integration of data analytics and artificial intelligence is proving to be a game-changer, enhancing diagnostic precision and operational efficiency. Collaborative efforts with healthcare institutions and technology partners are expected to catalyse the creation of groundbreaking diagnostic solutions. This collaborative approach is integral to staying at the forefront of technological advancements in the rapidly evolving healthcare landscape.

Genetic testing and molecular diagnostics are expected to make personalized medicine mainstream, enabling

tailored treatments and preventive care. At Metropolis, our commitment to staying at the forefront of innovation is evident in our continuous expansion of capabilities in Molecular Diagnostics, Oncology, Cytogenetics, and other crucial domains. Throughout the year, Metropolis has successfully introduced cutting-edge tests leveraging Next Generation Sequencing (NGS) Technology. These tests cover a spectrum of critical areas, including pre-natal screening, Breast Cancer, Bone Marrow Transplant, and Allergy Component Testing powered by Artificial Intelligence. This strategic integration of advanced technologies positions us to revolutionize the diagnostics sector, elevating accuracy, accessibility, and overall efficiency.

Digital technologies continue to play a crucial role in the evolution of the healthcare industry, a trend expected to persist in 2024. The incorporation of digital tools and platforms has enhanced patient care, streamlined workflows, and improved data management. Metropolis is at the forefront of leveraging digital technologies to enhance healthcare in 2024. The company's robust technological advancements include the development of an integrated API and CRM stack, spanning Service, Sales, and Marketing. This strategic investment positions Metropolis for accelerated growth and seamless integration with key stakeholders, aligning with government initiatives such as Ayushman Bharat Digital Mission.

In addition, Metropolis has transformed its B2C application, offering a comprehensive 360-degree approach to health management. This initiative, part of the Metropolis 3.0 strategy, emphasizes Direct-to-Consumer (D2C) engagement. The strategy includes health check-up camps, digital channel enhancements, and a modernized Patient Mobile App with personalized testing recommendations and user-centric features. Data analytics plays a pivotal role in customer segmentation and lifecycle management, reinforcing Metropolis' commitment to digital innovation.

Telemedicine and remote patient monitoring are gaining popularity, making healthcare services more accessible and efficient, particularly benefiting underserved areas. Largest national players like us have various network expansion plans in setting up labs and increasing patient collection centres across the country to ensure accessibility to high-quality diagnostic tests. Metropolis currently operates 180 labs and 3934 collection centres nationwide. We are on the course of adding 90 labs and 1800 service centres over the next three years. We have been bolstering our marketing efforts and strengthening our B2C connection, particularly in specialized testing. The imminent integration of automation, artificial intelligence, and advancements in data analytics is set to revolutionize laboratory processes. This transformation promises not only faster and more precise diagnostic results but also holds the potential to significantly enhance patient outcomes. As we continue to expand our network and reach out to an increasing number of doctors and patients, these technological strides underscore our commitment to delivering cutting-edge and impactful healthcare solutions.

As we say goodbye to the current year, the diagnostics and healthcare industries are on the verge of profound change. Entrepreneurs and businesses that embrace these trends and capitalise on emerging opportunities will enjoy significant success in the evolving healthcare landscape.

Glenmark Pharma will continue to work towards meeting the evolving healthcare needs of patients across the world: Glenn Saldanha



Glenn Saldanha

Chairman and Managing Director,
Glenmark Pharmaceuticals Ltd.

The Indian pharmaceutical industry has made significant strides globally, driven by 8% YoY increase in exports over the last five years. The 'Make in India' initiative together with the National Pharmaceutical Policy 2023 and the Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) along with the successful Production linked incentive (PLI-2) schemes underscore the government's commitment towards making India self-reliant while also encouraging the industry to further strengthen its position internationally.

With an emphasis on innovation and developing complex generics as part of our strategy of moving up the value chain, we will continue to work towards meeting the evolving healthcare needs of patients across the world.

Navigating the Pharma Landscape: Sibaji Biswas



Sibaji Biswas

CFO, Syngene International

As we bid farewell to 2023, the pharmaceutical industry finds itself at the crossroads of transformation, with India emerging as a prominent player in the global supply chain. Over the past few years, discussions about India complementing China as a sourcing destination for innovative pharmaceutical companies were gaining traction.

The year unfolded with increased interest from global pharmaceutical giants looking to build a robust supply chain out of India, aiming to reduce dependence on China for chemicals, APIs, research services, and manufacturing. While the shift has been gradual, the signs of progress are evident; we saw inquiries and engagements increasing, thereby setting the stage for a significant transformation in the next 12-24 months.

2023 has been the year of international pharma exploration in India, and the year witnessed a surge in curiosity about the opportunities India presents. This signals a paradigm shift, positioning India as an integral element of the global pharma supply chain. This trend mirrors the broader shift seen in various industries, such as electronics, as India steps into a role previously dominated by other nations.

However, challenges lie ahead. The pharmaceutical industry in India has relied heavily on China for key starting materials and intermediates. Breaking free from this dependence requires industry and government collaboration to build an ecosystem, and sustained support and encouragement from the government. The journey towards self-reliance will be gradual, demanding careful attention and strategic planning.

One significant catalyst accelerating this shift is also likely to be the Inflation Reduction Act in the United States. This initiative aims to control drug prices, compelling pharmaceutical companies to scrutinize their budgets closely. The pressure to reduce the time and cost of drug discovery is prompting a global search for outsourcing partners, and India is reinforcing its position as a skill-rich, cost-effective alternative.

The biotech funding landscape has experienced significant fluctuations over the last few years. A surge in funding in the past decade, accentuated by the pandemic and subsequent investor flight and drying up of funds, led to a phenomenon termed the 'biotech funding winter' in 2023. Many biotech companies faced challenges, impacting the research and the early-stage development business of the Contract Research Development and Manufacturing Organizations (CRDMOs). There is increasing optimism in the air as we are observing the funding gradually returning to the pre-pandemic levels, offering hope for a revival in the biotech sector towards the end of 2023.

Looking ahead to 2024, the CRDMO industry anticipates growth from contract manufacturing and the revival of the biotech sector. We also expect to see larger contract research opportunities materializing from the Big Pharma companies. The long-term trends remain solid, contingent on global economic stability and geopolitical factors.

Syngene, a key player in the pharmaceutical and life sciences R&D and contract manufacturing landscape, remains optimistic and committed to expansion plans, particularly in Hyderabad. The company acknowledges the cyclical nature of the industry and is prepared for the anticipated growth in the latter part of 2024.

In the realm of manufacturing, the focus on biologics remains strong, with an increasing number of molecules gaining attention globally. Syngene's success in biologics sets a precedent, positioning it well to capitalize on the continuous momentum in the sector.

The pharmaceutical and life sciences contract research landscape is evolving, transitioning from a cost-led market to one of value-added thought leadership. India's journey from being a major player in generics to a hub for innovative drug discovery is underway, necessitating a paradigm shift in entrepreneurial efforts, skill development and overall government support.

As we step into 2024, the pharmaceutical industry stands resilient, navigating challenges and embracing opportunities, with India poised to play a pivotal role in shaping the future of global pharmaceuticals.

2023: A Transformative Year for Indian Pharma Industry



Sudarshan Jain

Secretary General,
Indian Pharmaceutical Alliance

The Indian pharma industry is a knowledge-driven and strategic sector for the nation with the advantage of depth and scale. The year 2023 has been a transformational year for the sector which witnessed multiple initiatives catalysing innovation, quality and access. The Government announced the Promotion of Research & Innovation Program (PRIP) Scheme, MedTech Policy, Approach Paper on National Pharma Policy and displayed thrust on “One Health” during the G20 Summit. These initiatives are in continuation of Production Linked Incentive (PLI) 1.0, Bulk Drug Park and PLI 2.0 Schemes and are aimed at self-reliance and making global champions from India. The convergence of policy thrust, and India’s entrepreneurial vigour will propel the sector’s growth and ensure a consistent supply of quality-assured affordable medicines for patients both in India and globally.

Pharma industry is poised for continued growth in the coming years: Nikhil Chopra



Nikhil Chopra

CEO & Whole Time Director, JB Pharma

The year 2023 has proven to be pivotal for the Indian pharmaceutical sector, surpassing expectations with an impressive overall performance. Chronic therapies have emerged as the primary drivers of growth, contributing approximately 38 to 40 percent. Government regulations and initiatives have been effective in addressing issues related to spurious and substandard drugs, leading to significant enhancements in quality measures, manufacturing facilities, processes, and quality assurance and control mechanisms. Additionally, the government’s focus on promoting digital health and strengthening healthcare infrastructure is expected to further contribute to the industry’s growth.

The rising demand for high-quality pharmaceutical products is driven by the increasing burden of diseases and a growing awareness of the importance of healthcare. The Indian pharmaceutical industry is globally recognized as a supplier of high-quality, affordable medicines. Through a dedicated collaborative approach across the stakeholder community, the industry aims to solidify the ecosystem and reinforce the reputation of Indian Pharma as a reliable supplier in both domestic and international markets. Demonstrating resilience, the Indian Pharma industry has quickly adapted to changing patient needs in the post-pandemic world, providing timely and effective healthcare solutions. The industry is poised for continued growth in the coming years, solidifying its position as the ‘Pharmacy to the World.’

Revolutionizing Digital Healthcare Delivery: Transforming Patient Care through Innovation

Digital Technology in healthcare has the potential to reduce costs, improve productivity and efficiency, and improve outcomes. A smarter, faster, more efficient and convenient healthcare system can provide optimal care to millions across the globe who have remained underserved. In the healthcare industry, pharmaceuticals and medical equipments have already seen use of advanced digital technology.

In the dynamic landscape of modern healthcare, the infusion of digital technologies can completely transform and revolutionize the delivery of healthcare services. **Dr. Sabahat** and **Shailesh Kumar** emphasize about the application-oriented aspects of digital transformation in healthcare delivery.

Telehealth and Remote Patient Monitoring

Telehealth has emerged as a cornerstone in the digital transformation of healthcare, fundamentally altering the patient-provider dynamic. Virtual digital consultations have democratized access to medical expertise, overcoming geographical barriers and significantly improving healthcare accessibility. Nurse or paramedic assisted digital healthcare can deliver comprehensive primary healthcare. Using point of care and Internet of Things (IoT) devices with rich and real time data transfer, today it is possible for doctors to examine a patient remotely, get rapid tests done, prescribe treatment and even dispense medicines through an automated dispenser. Patients, regardless of their location, can now access timely primary care and medical opinions without the need for physical travel, thereby reducing costs, time and environmental footprint. This is already a reality in India and a boon for millions of underserved people in remote areas of the developing world.

Concurrently, remote patient monitoring (RPM) has fortified the continuum of care. With the advent of e-ICUs critical patients can be monitored and even managed remotely. The best of medical expertise can be leveraged from anywhere in the globe to augment local

capacities. Wearable devices and mobile applications empower patients to actively participate in their health management by providing real-time data on vital signs and health metrics.

This wealth of information not only allows for more proactive intervention by healthcare professionals but also promotes a patient-centric approach to treatment plans. Digital technologies now enable real time management of chronic conditions such as diabetes and hypertension by constant monitoring, generating alerts and administering precise dose of medicine automatically. Very soon it will be possible to do invasive procedures remotely. Eventually, invasive and surgical procedures would be done in situ using nano bots or nano delivered precision medication.

Electronic Health Records (EHRs) and Interoperability

The digitization of health records through Electronic Health Records (EHRs) has ushered in an era of enhanced efficiency and coordination in patient care. EHRs serve as centralized repositories for comprehensive medical histories, allowing healthcare providers seamless access to critical information.

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Interoperability further ensures that this information is accessible across diverse healthcare settings, fostering collaboration among healthcare professionals.

Patients stand to benefit significantly from the interconnectedness facilitated by EHR systems. The seamless sharing of medical data among different healthcare providers ensures a more holistic and streamlined approach to patient care. Real-time access to up-to-date medical histories empowers healthcare professionals to make informed decisions, reducing redundancies in testing and minimizing the likelihood of medical errors.

Blockchain for Data Security and Integrity

However, digital health records also throw up concerns related to patient privacy and unauthorised access of protected health information. Blockchain technology, synonymous with decentralized and secure data management, has emerged as a robust solution for ensuring the security and integrity of healthcare data. By decentralizing data storage and employing cryptographic techniques, blockchain fortifies the security of health records, making them resistant to tampering and unauthorized access.

Artificial Intelligence (AI) Enabled Process Based System

Artificial Intelligence (AI) can help healthcare providers by automating administrative and communication processes, freeing up valuable time for clinical and patient-centric activities. AI can enable virtual triage, improve convenience and experience for both providers and patients. Chatbots and Generative AI are already extensively used in various industries.

It is humanly impossible for a doctor to remember everything from years of rigorous study. It is not an issue of competence but an issue of data processing capability. The doctor's ability to memorize and effectively recall, not only affects the diagnosis and treatment, but a small error may have serious implications. In today's hi-tech world, this is simply unwarranted. The doctor can be aided by AI enabled algorithm based clinical decision support system (CDSS), leading to efficiency, accurate diagnosis and adherence to most updated treatment protocols devoid of medical errors. By processing and evaluating enormous amounts of historic and real-time

data, AI can help medical professionals in chalking out a more evidence based and individualized treatment, forecast risk for individuals as well as populations and ensure proactive intervention. A CDSS, combining data science and evidence based medicine, can help take healthcare to all the underserved population. This is also a pragmatic approach to expanding doctor capacities than trying to mass produce new doctors by opening hundreds of new medical colleges.

AI in Diagnostics

The most immediate use of AI is in diagnostic capabilities within the healthcare domain. Machine learning algorithms, capable of processing vast datasets at unprecedented speeds, have become instrumental in the early detection of diseases. In diagnostic imaging analysis, AI applications enhance image recognition, expediting the diagnostic process and improving the accuracy of interpretations.

Moreover, AI's impact extends to genomics, where it aids in unravelling complex genetic codes to identify predispositions to diseases. Tailored treatment plans based on an individual's genetic makeup promise to optimize therapeutic outcomes while minimizing adverse effects.

Virtual Reality (VR) in Rehabilitation

Beyond diagnostics and treatment, digital innovations have penetrated the realms of rehabilitation and therapeutic interventions. Virtual Reality (VR), once a staple of the gaming industry, is now proving its mettle in physical and mental health rehabilitation programs. VR environments offer immersive experiences that contribute to pain management, cognitive rehabilitation, and physical therapy.

In the context of post-surgery recovery or chronic pain management, VR-based interventions provide a non-pharmacological avenue for engaging patients in their rehabilitation journey. The gamification of rehabilitation exercises through VR not only enhances patient adherence to treatment plans but also injects an element of enjoyment into an otherwise challenging process. The application of VR in rehabilitation exemplifies how digital technologies can redefine and elevate the patient experience.

The ongoing digital revolution in healthcare isn't a distant promise; it is a tangible force reshaping the foundations of patient care. From the democratization of healthcare through telehealth to the precision of AI-driven diagnostics, the immersive experiences of VR-based rehabilitation, and the security ensured by blockchain, these innovations collectively represent a paradigm shift toward a more patient-centric, efficient, and interconnected healthcare ecosystem. There are voices that are fearful of the negative implications of technology such as Generative AI. However, regulation has to be mindful enabling innovation, while protecting citizens. Hasty regulations can stall healthcare innovation, pushing the healthcare revolution by decades and exacerbating health inequity.

As we navigate this digital transformation, collaboration between healthcare professionals, policymakers, and technology developers becomes increasingly paramount. This collaboration ensures that these innovations are not only cutting-edge but also ethically applied to real-world healthcare scenarios. The application-oriented focus on these technologies underscores their practical significance, marking the trajectory toward a future where healthcare is not just a service but a personalized, accessible, and seamlessly integrated experience for all. ■

Authors



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Embracing Sustainable Practices for Innovation and Growth of the Life Sciences Sector in India

In an era defined by rapid advancements in technology and a growing awareness of environmental responsibility, the life sciences sector in India stands at a crucial juncture. As businesses navigate through the complex landscape of global challenges and opportunities, the integration of sustainable practices has emerged as a key driver for innovation and growth. The life sciences industry in India has witnessed remarkable growth in recent years: Valued at USD 92.3 billion in 2022, the Indian Biotechnology Industry is likely to reach US \$300 billion by 2030. **Vishal Goel, MD, RX Propellent** talks about the key environmental concerns for life sciences companies.

Environmental Impact of Life Sciences Sector

The life sciences sector is a significant contributor to environmental degradation, from the manufacturing of pharmaceuticals to the disposal of biomedical waste. Recognizing the urgent need for change, leading companies in India are adopting sustainable practices to minimize their environmental footprint. A Jones Lang Lasalle report titled *Embracing Sustainability* notes that Life Sciences real estate uses up to 10 times the energy and 4 times the water of a traditional office, and plastic waste that can cover as much as 138,000 hectares every year.

Some of the key environmental concerns for life sciences companies include:

- High energy consumption in laboratories as they often operate around the clock. This includes activities such as operating cold storage units, chemistry fume hood air extraction, and utilizing specialized equipment at various intervals. These equipment commonly require heating or cooling, utilizing water baths or running water, resulting in substantial water usage.
- Additionally, significant plastic waste is generated from single-use items like pipette tips, conical tubes, and gloves, with historically low rates of recycling. Biomedical waste generated in labs, which is often costly to dispose of effectively or recycle, typically ending up in landfills after sterilization.
- Since many life sciences companies are situated away from the cities, many employees commute by car, especially last mile. With low uptake of no-carbon transport options like electric-run vehicles or lower-carbon, public transport options such as trains or buses, this leads to increased Scope 1 or 3 emissions, depending on whether the service is provided directly by the company or through a vendor, and an overall environmental burden.

Challenges for developers include the need for specialized construction to accommodate equipment loading, vibrations, and specific air handling requirements in laboratories. The construction process often involves substantial embodied carbon and energy usage, making retrofitting and refurbishment more expensive with similar or higher carbon emissions. Location is a significant factor in transitioning to sustainability, relying on innovation, especially when space is limited. In established areas like London, new Life Sciences real estate may involve repositioning existing structures, making sustainability considerations complex. Retrofitting remains a challenge due to pre-existing infrastructure complexities. Energy performance regulations require laboratory buildings to meet criteria similar to other building types, posing a challenge due to their high resource usage. As performance criteria tighten, laboratories may struggle to meet standards unless there is flexibility for the life sciences sector, which is unlikely given the expected trend of increasingly stringent legislation over time.

Innovation for sustainability

Five United Nations Sustainable Development Goals (SDGs) constitute the pillars of the commitment of life sciences companies towards sustainability – SDG3 (Good Health & Well-Being), SDG8 (Decent Work and Economic Growth), SDG9 (Industry, Innovation and Infrastructure), SDG12 (Responsible Consumption and Production), and SDG13 (Climate Action) – underscoring dedication to creating a positive impact on health, the economy, innovation, responsible production, and climate action. Here are a few ways:

- **Innovation in R&D:** Sustainable practices extend beyond environmental concerns to encompass research and development (R&D) activities within the life sciences sector. Companies are increasingly focusing on developing eco-friendly products and processes that align with global sustainability goals. A prime example is the rising trend of green chemistry in pharmaceutical R&D. Companies are investing in research to replace traditional, resource-intensive chemical processes with more sustainable alternatives. This not only minimizes environmental impact but also enhances the reputation of the companies as responsible corporate citizens.
- **Sourcing and supply chain:** The life sciences sector heavily relies on intricate supply chains that span across the globe. Ensuring ethical and sustainable practices throughout these supply chains is crucial for maintaining industry integrity and meeting the demands of conscious consumers and investors. Companies are now placing a stronger emphasis on responsible sourcing of raw materials, fair labor practices, and transparency in the supply chain. This approach not only mitigates reputational risks but also fosters long-term relationships with suppliers and creates a resilient and sustainable ecosystem.
- **Sustainable design principles:** Incorporating sustainable principles in design and construction of life sciences infrastructure can go a long way to minimize environmental impact. From the choice of building materials to heating, cooling, plumbing, waste, and ventilation systems, prioritizing sustainability

can help optimize building orientation to reduce heat, integrate shading devices into windows for adequate daylight, and employ high-performance insulation to contribute to energy efficiency and reduced cooling needs.

- **Harnessing renewable energy:** Choosing renewables, especially offgrid sources, automatically improves the sustainability quotient of operations. Exploring innovative solutions, including Building Integrated Photovoltaics (BIPV) materials on vertical facades and solar panels on terraces, can prove to be beneficial. These initiatives aim to reduce reliance on grid-supplied electricity that often has a large share of power generated from fossil fuel sources. By incorporating renewable technologies, companies can contribute to a greener environment while aligning with the global shift towards renewable energy sources.
- **Water and waste management:** Water sustainability is a critical aspect of the commitment of life sciences companies to environmental stewardship. Using recycled wastewater to meet non-potable water requirements is a proven way to make a head start. Additionally, adopting an integrated waste management, especially for segregation of municipal solid waste (MSW) from biomedical and hazardous waste, can help achieve zero waste to landfill during construction and operational phases. In addition to sustainability, these measures also resonate with our tenants' growing emphasis on environmental, social, and governance (ESG) mandates. ■

Author



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Pallets keep the pharma supply chain moving



Nitin Kalla

Founder
EXZOD India

Pallets give pharmaceutical firms the power they need to handle their products, increase storage efficiency, and protect products in the warehouse. They are used to stack, store, protect, and transport a variety of pharmaceutical materials. According to a McKinsey analysis, the pharmaceutical business has a rare opportunity thanks to a number of local producers of branded generics. The industry has had amazing expansion, going from being non-existent to having a global pharmacy.

The pandemic's ensuing supply chain problems had an influence on pallet availability. The new normal has shown, however, that pharma supply networks need to be resilient and agile, driving manufacturers and suppliers to improve their pharmaceutical product storage, shipping, and supply chain management capabilities in order to add value for consumers.

The events of the pandemic have really opened people's eyes to the relevance of the pallet industry and the role it plays in the supply chain.

Digitalisation: The supply chain can be streamlined and its agility and flexibility increased by implementing technologies like automation, blockchain, and artificial intelligence.

Fragmented logistics network: The supply chain management can become complex due to the fragmented logistics network, leading to inefficiencies.

Regulatory compliance: The sector is governed by regulations, and it can take up a lot of time to make sure that all the rules are being followed. Adhering to

regulations like Good Manufacturing Practice, Good Distribution Practice, and Good Clinical Practice can have an effect on the supply chain.

Cold chain management: Pharmaceutical products demand storage and transportation at controlled temperatures, which can pose a challenge. In India, the cold chain infrastructure does not meet the desired standards and necessitates significant investment in constructing temperature-controlled areas. The extreme temperatures in several parts of India add to the complexity of maintaining cold chains.

Transportation challenges: Pharmaceutical products require special storage and transportation conditions, particularly temperature control, which must be strictly adhered to. Any deviation from these requirements can have adverse effects on the quality and effectiveness of the products. Transportation issues like delays, damage, or loss pose a significant threat to the supply chain, causing disruptions.

Creating infra for better pharma handling: In recent years, India has made significant advancements in the handling and logistics infrastructure of the pharmaceutical industry. These improvements have contributed to India's rise as a top supplier of generic pharma products worldwide. The development of new technology and facilities, including the use of cold chain logistics, has enhanced the storage and transportation of pharma products. Although there is still scope for further improvements, these advancements have solidified India's position as a leading global manufacturer and supplier of pharmaceuticals. The National Logistics Policy has set out a clear roadmap for India to establish itself as a dominant player in the global logistics industry.

Quality control: Quality control is an essential aspect of the pharmaceutical supply chain. India, however, has encountered issues with counterfeit and substandard medications, as well as regulatory non-compliance. It is crucial to tackle these problems to uphold the supply chain's credibility.

Crucial role of technology: The transportation and storage of pharmaceutical products heavily rely on the advancements in technology and innovation.

The safety of pharma shipments is at risk due to various factors, such as temperature, humidity, and light, making it necessary for shipment and storage facilities to have automated tracking systems, proper temperature-controlled storage, advanced handling equipment, and procedures. The utilisation of Artificial Intelligence, Internet of Things, and Blockchain enables real-time tracking of temperature and humidity levels, which brings transparency and enhances the entire process of pharma cargo handling and transportation.

Technology and automation: Technology and automation, like GPS tracking and real-time temperature monitoring, are effective tools for preserving the quality of time-sensitive pharmaceutical shipments. By using these tools, temperature fluctuations can be prevented, resulting in less wastage and on-time delivery of the shipments.

Minimize carbon footprint: The importance of supply chain sustainability is increasing day by day, leading to a rise in demand for reusable and recyclable pallet materials in the pharmaceutical industry. Although wood is an inherently sustainable material, the newer plastics and composites offer even higher levels of sustainability. This trend is driven by the collective desire of companies and consumers to reduce their carbon footprint.

Adoption of agile supply chain strategies: Supply chain agility is essential to ensuring that pharmaceuticals are delivered to clients quickly. To respond to shifting consumer expectations, supply chain disruptions, and regulatory changes, we created flexible supply chain methods.

Pharmaceutical companies should prioritize enhancing their supply chain efficiency to stay ahead in the industry since every life is valuable. We have taken steps to improve our supply chain and respond to evolving customer demands by developing flexible solutions that meet their requirements. Managing pharmaceutical supply chains demands expertise, and we have a team of professionals who are knowledgeable in handling shipments that require special handling conditions. Our size and variety of pallets allow us to cater to this industry effectively. ■

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