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India is world-class cost-effective healthcare destination and global pharma leader: Jitin Prasada

New Delhi, India: Union Minister of State for Commerce & Industry Jitin Prasada said that India has emerged as a world-class cost-effective healthcare destination and global pharma leader. The Minister stated this while inaugurating the three day International Exhibition For Pharma And Healthcare Exhibition (IPHEX 2024) organised by Pharma Export Promotion Council of India (CAPEXIL) and Ministry of Commerce and Industry at Greater Noida, Uttar Pradesh. He urged the Indian Pharmaceutical industry to work towards becoming the healthcare custodian of the world.

He urged the pharma industry to increase exports and seize emerging opportunities for growth. Shri Prasada said that India is already recognized as the 'pharmacy of the world.' It's extremely important that we focus not only on our strengths in the generic sector, but also ensure our backward and forward linkages, the Minister added. He further noted that its important that we try product development and break new grounds.

The Minister urged the industry to focus on innovation, quality and work with the world market. "International competitiveness will be very important. It is important to keep abreast of new developments and good manufacturing practices", he said. He also noted that the Government has come up with many schemes like the PLI for APIs and for medical devices.

Prasada said, "The three day pharma expo IPHEX will offer the domestic industry majors from India and all across the world a great platform to connect and do business. It will provide you with an opportunity to meet new and existing customers actively looking for new suppliers, or looking to assess the current progress of existing projects."

Govt bans 156 fixed-dose combination drugs

New Delhi, India: The government has banned 156 widely sold fixed-dose combination (FDC) drugs, including antibacterial medicines used for fever, cold, allergies, and pain.

FDC drugs are those which contain a combination of two or more active pharmaceutical ingredients in a fixed ratio and are also referred to as "cocktail" drugs.

According to a gazette notification issued by the Union health ministry on August 12, the government has banned 'Aceclofenac 50mg + Paracetamol 125mg tablet,' used as pain-relieving medicines manufactured by top pharma companies.

The list also includes Mefenamic Acid + Paracetamol Injection, Cetirizine HCl + Paracetamol + Phenylephrine HCl, Levocetirizine + Phenylephrine HCl + Paracetamol, Paracetamol + Chlorpheniramine Maleate + Phenyl Propanolamine, and Camylofin Dihydrochloride 25 mg + Paracetamol 300mg.

The Centre also banned the combination of Paracetamol, Tramadol, Taurine, and Caffeine. Tramadol is an opioid-based painkiller.

"The Central government is satisfied that the use of the Fixed Dose Combination drug is likely to involve risk to human beings whereas safer alternatives to the said drug are available," the notification said.

"The FDC may involve risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale, or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940," the notification read.

JP Nadda inaugurates 'First Policy Makers' Forum' in New Delhi

New Delhi, India: Union Minister of Health and Family Welfare & Chemicals and Fertilizers, Shri J.P. Nadda inaugurated the 'First Policy Makers' Forum.' To elevate India's position in the global pharmaceutical sector, the Indian Pharmacopoeia Commission (IPC), in collaboration with the Ministry of Health & Family Welfare and the Ministry of External Affairs, hosted an international delegation of policymakers and drug regulators from 15 countries. The forum featured the launch of innovative digital platforms for pharmacopoeia and drug safety monitoring.

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Welcoming the delegates from drug regulatory authorities and the health ministries from Latin American, African, Southeast Asian, and Pacific regions participating in the program, J P Nadda stated that "this forum will provide an excellent opportunity to exchange views on the safety, efficacy, and the quality of medical pharmaceutical products amongst the participating countries that will ensure that we uphold the highest standards for the benefit of the patients". He added that "India has long been identified as the 'pharmacy of the world.' We are proud that our generic drugs help to treat diseases like malaria, HIV-AIDS, and tuberculosis which are usually considered as the health problems of developing countries."

Emphasizing India's commitment towards eradication of these diseases, Shri Nadda stated that "this contribution underscores India's commitment to global health and its responsibility in bridging the healthcare gap in developing nations". He also highlighted that "since administering drugs for HIV-AIDS is very costly and it became a burden for developing nations, the Indian manufacturers came forward and took the lead in providing effective and affordable drugs".

Nadda further added that "India has always been the world leader in the production and supply of vaccines contributing to approximately 60 percent of the global supply of vaccines." He stated that the World Health Organization procures 70 percent of its vaccine demand from India. "During the COVID-19 pandemic, India supplied COVID-19 vaccines to several countries across the world under the Vaccine Maitri Programme. This highlights India's commitment to serving humanity without any discrimination", he added.

Nadda remarked, "India has made remarkable progress in global health diplomacy and pharmaceutical leadership through various initiatives and international collaborations, embodying the vision of Prime Minister Shri Narendra Modi." Under Prime Minister Modi's leadership, India has launched several key initiatives, including the Jan Aushadhi Scheme. This program aims to provide high-quality medicines to all segments of society, especially the underprivileged, by establishing Jan Aushadhi centers nationwide. These centers offer generic medicines of equal quality to branded ones at more affordable prices, without compromising on quality. All medicines supplied through this scheme meet the standards set by the Indian Pharmacopoeia. The success of this initiative in India stands as a model that could be adapted by other countries to improve global access to affordable healthcare.

Nadda added that "as India's pharmaceuticals and the healthcare sector continue to grow, our focus remains on improving global health. India's collaboration with various countries is a testament to its dedication to this goal." He further added that "the discussions under the Policymakers' Forum will pave the way for patient safety worldwide, successful implementation of shared goals and will strengthen our healthcare systems while building lasting relationships among our countries".

Dr. Arunish Chawla, Secretary, Department of Pharmaceuticals stated that, "a global trend is emerging as patients increasingly opt for generic medicines. Generic medicines adhere to regulatory standardization equivalent to WHO standards and practices and are at least 50 to 90% cheaper than branded medicines. There is a rising feeling in the world to move towards generic medicines". Highlighting the success of the Janaushadhi Programme, he stated that, "in just a short span of 10 years, the out-of-pocket expenditure has fallen over 40% due to generic medicines which is evidence of the success of the Jan Arogya Programme and more than 10,000 Janaushadhi Kendras are running in every nook and corner of the country. Jan Arogya is a social service that we want to offer to help other countries in other parts of the world where Healthcare expenditure is a major concern."

The ADRMS software, developed as part of the Pharmacovigilance Programme of India, is India's first indigenous medical product safety database tailored to the needs of the Indian population. It facilitates the collection and analysis of adverse events related to medicines and medical devices, thereby significantly strengthening the country's pharmacovigilance infrastructure. This software not only streamlines the reporting process but also empowers consumers and healthcare professionals to directly report adverse events, ensuring a more comprehensive capture of safety information.

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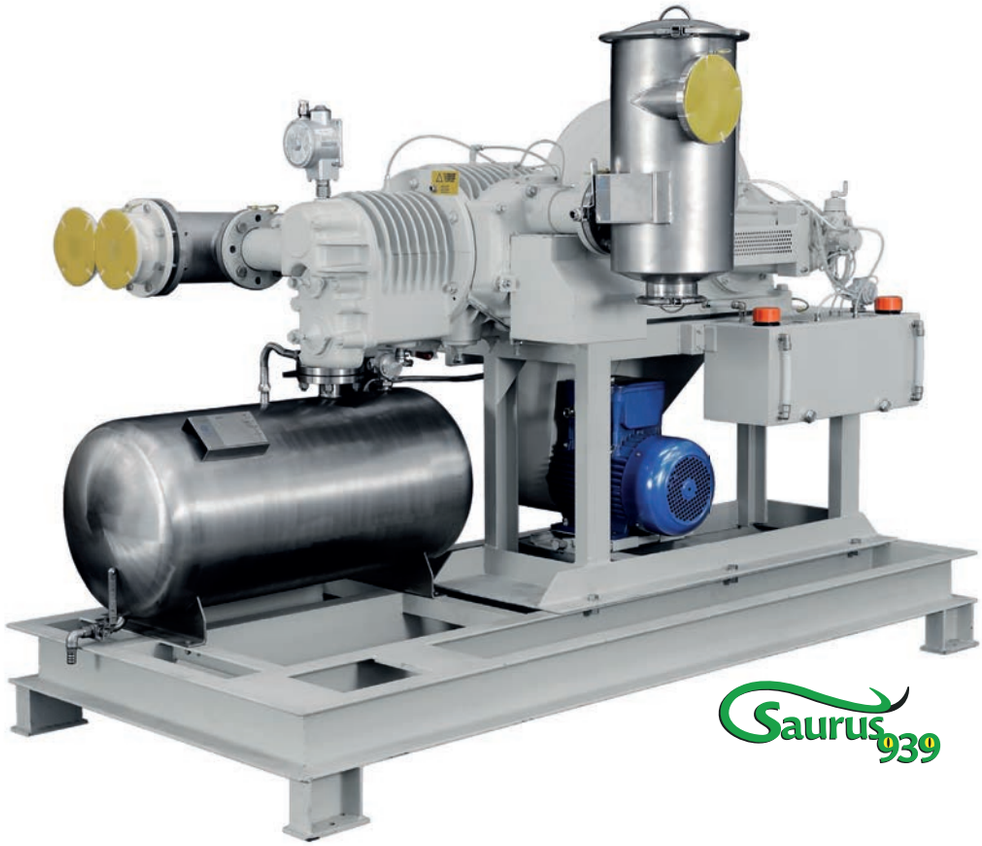

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GST Council recommends reduction in GST rates on three cancer drugs from 12% to 5%

New Delhi, India: The 54th GST Council met under the Chairpersonship of Union Minister for Finance & Corporate Affairs Nirmala Sitharaman in New Delhi.

The GST Council inter-alia made the following recommendations relating to changes in GST tax rates, provide relief to individuals, measures for facilitation of trade and measures for streamlining compliances in GST.

The GST rate on cancer drugs namely, Trastuzumab Deruxtecan, Osimertinib and Durvalumab to be reduced from 12% to 5%.

Trastuzumab deruxtecan, sold under the brand name Enhertu, is an antibody-drug conjugate consisting of the humanized monoclonal antibody trastuzumab covalently linked to the topoisomerase I inhibitor deruxtecan. It is licensed for the treatment of breast cancer or gastric or gastroesophageal adenocarcinoma.

Osimertinib is used to treat locally advanced or metastatic non-small-cell lung cancer (NSCLC), if the cancer cells are positive for the T790M mutation in the gene coding for EGFR or for activating EGFR mutations.

Durvalumab, sold under the brand name Imfinzi, is an FDA-approved immunotherapy for cancer, developed by Medimmune/AstraZeneca.[9] It is a human immunoglobulin G1 kappa (IgG1) monoclonal antibody that blocks the interaction of programmed cell death ligand 1 (PD-L1) with the PD-1 (CD279).

MK Hamied steps down as Cipla's Vice Chairman

Mumbai, India: Cipla stated that M K Hamied has resigned from the position of Vice Chairman and Non-Executive Director of the Company with effect from close of business hours of 29th October 2024 due to age and health.

M. K. Hamied is a science graduate from Bombay University and has vast and varied experience in all functions of the Company including production, technical areas, quality management and general administration. He is Non-Executive Vice-Chairman of the Company and represents the second generation of Cipla's founding family.

M K Hamied, VC and Non-Executive Director, Cipla

"It is with a heavy heart that I write to formally announce my resignation from the position of Vice Chairman and Non-Executive Director of the Company with effect from close of business hours on 29th October 2024, due to age and health. These past 47 years at Cipla have been truly a remarkable chapter in my life. Over the decades, I have seen the Company grow and evolve in ways I am immensely proud of," stated M K Hamied.

M K Hamied added, " I have had the good fortune of working with several key employees and Board members, and especially with Dr. Y. K. Hamied, who has been the guiding light of Cipla. He has greatly contributed towards making my journey at Cipla, one of the most rewarding experiences of my life. I would like to acknowledge Samina's contribution in transforming the Company into a professionally managed organization and I am pleased to see that Kamil Hamied will be joining the Board as a Non-Executive Director to maintain continuity while representing the promoter family. I would like to express my deepest gratitude to all my fellow Board members for their unwavering support and guidance. I wish Cipla continued success in the future, and I hope to see its purpose of 'Caring for Life' at the heart of everything that it does."

The Board has approved the appointment of Adil Zainulbhai and Abhijit Joshi as Additional Directors (Non- Executive) of the Company with effect from 3rd September 2024 and recommended the same to the shareholders for their approval.

Kamil Hamied is an alumnus of United World College and New York University. Kamil is a seasoned entrepreneur with extensive experience in the pharmaceutical industry and wider healthcare sectors. He has successfully navigated business across Asia, Europe, and the US. During his entrepreneurial journey, Kamil also ventured into the investment realm, establishing an investment platform focused on the broader life sciences, biotechnology, genomics, AI drug development, diagnostics, etc.

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India Ratings expects its rated pharma cos to maintain momentum on growth and profitability in US

Mumbai, India: India Ratings and Research expects its rated pharma companies to maintain their momentum on growth and profitability in the regulated markets (US), driven by new launches, ongoing drug shortages and growth opportunities in the domestic formulation business. Normalisation of drug prices in the US and a softening in raw material prices will help companies to keep revenue growth of 9% yoy and EBITDA margin of about 22% during FY25.

The agency highlights that sustainability of the US business remains key to support the low margins in other markets. However, the sector outlook for Indian pharmaceutical companies remains neutral for FY25, led by an expected volume recovery in the domestic formulations business, stability in price erosion in the US, lower input cost and overall cost optimisation efforts.

In 1QFY25, India Ratings has seen strong growth in its coverage universe of US business, led by a higher contribution from the generic Revlimid, stable price erosion and increased traction in niche products. The strong growth in the US business, if sustained, could lead to maintaining of EBITDA margins. While, the domestic formulation business coverage universe reposted low double-digit growth against high single digit growth in FY24, led by growth in acute/chronic segments.

The agency also expects an increase in United States Food and Drug Administration (USFDA) inspections in FY25; however, these are unlikely to cause significant disruptions. The agency affirmed the ratings of 53% of the entities in its universe in the eight months ended 209 September 2024 and took rating downgrade/Negative Outlook/Rating Watch with Negative Implications actions on 14% of the entities, where the margins came under pressure while rating upgrade/Positive Outlook actions on 27% of the entities where overall credit profile improved.

The agency rated a sample of 18 leading pharmaceutical companies, which reported yet another strong quarter in 1QFY25 in terms of sales growth and operating profitability, led by complex generic products launches, ongoing drug shortages in the US and healthy growth in US and India businesses. Overall, the top line grew 10.6% yoy in 1QFY25 (1QFY24: up 15.8% yoy; 4QFY24: up 9.6% yoy). The US business of companies, which are rated by India Ratings, continued to report strong growth of 11.6% yoy while domestic formulations grew 10.5% yoy. The EBITDA margin of the rated companies remained robust at 25.3% (rose 220bp yoy) in 1QFY25 (1QFY24: 23.2%; 4QFY24: 23.1%), led by the lower raw material prices and sales contribution from niche launches, and moderation in pricing pressure in the US market.

The US generic business of companies covered by Ind-Ra has continued to report a strong performance since 3QFY24 (average growth at 15.5% over the past seven quarters). In 1QFY25, the US business grew 11.6% yoy to USD2.7 billion as against 26.6% yoy in 1QFY24 and 13.5% yoy in 4QFY24, on account of a stable single-digit price erosion, shortages of drugs, and niche launches (including generic Revlimid, Mirabegron etc).

The agency highlights that the US business contribution to the coverage companies stood at around 35% over the past five years. Ind-Ra highlights that the strong pipeline of Indian companies will help maintain their sales growth momentum in the US market. The companies have increased focus on developing complex generic products (injectables, patches, inhalants, nasal, ophthalmic) over the past five to six years, which offsets the price erosion in existing molecules.

Entod Pharmaceuticals gets suspension order from DCGI for eye drop presbyopia

Mumbai, India: Entod Pharmaceuticals has received a suspension order from DCGI for treatment of presbyopia who has made no reference to any specific violation of Drugs and Cosmetics Act for this action, stated Nikkhil K Masurkar, CEO, Entod Pharmaceuticals.

"The logic applied here is the contents of our press release which has described the application of this new drug for the benefit of the lay press in more verbose terms than the exact wording of the approved indication which is – Treatment of Presbyopia. If you examine many such press announcement of other big pharma companies which are present on their website, you will always find additional descriptions about the product and condition beyond the exact approved indication, added Masurkar.

Masurkar further said"We at ENTOD Pharmaceuticals hereby declare that we have not made any unethical or false presentation of facts to the media or public when it comes to Presvu Eye Drops. All facts disclosed to the media were strictly on the basis of the recent DCGI

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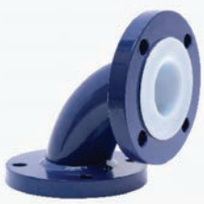

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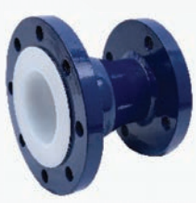

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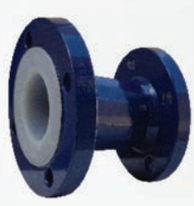

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approval for treatment of presbyopia in adults and the results of the phase 3 clinical trial conducted by us in India. Announcing the new product launch to the media is a routine industry practice followed by all pharma companies in India and in the recent past, many such announcements have been made. In our case, media reports went viral and public imagination led to an unusual escalation for which ENTOD Pharmaceuticals is not responsible.

The company said that approval by DCGI was based on a valid controlled clinical trial in 234 patients which was successful in showing efficacy and safety of these eye drops in patients of Presbyopia, who used these drops without eye glasses and could read additional lines on Snellen's chart which is a yardstick of near vision improvement. Such eye drops with same active ingredient and same concentration has been approved by the US FDA and marketed in the US for last 3 years without any serious complications. FDA didn't take any action on the companies marketing the same in USA.

Masurkar added, "We strongly desist this action against a proud Indian pharma company in the MSME sector company like Entod Pharmaceuticals which is purely research and innovation driven and attempts to bring new therapeutic options to the Indian market. As a result, we have decided to challenge this suspension in the court of law to get justice. Our fight will not only allow innovative medicines to be available in India but also encourage other pharmaceutical entrepreneurs and companies in the MSME sector to continue the research drive in India without facing similar obstacles."

Sun Pharma and Moebius Medical announce Fast Track Designation granted for MM-II

Mumbai (India) & Tel Aviv (Israel): Sun Pharma and Israel-based Moebius Medical Limited announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation (FTD) to MM-II (Large Liposomes of DPPC and DMPC) for the treatment of osteoarthritis knee pain. Planning for confirmatory Phase 3 clinical trials for MMII is underway. The FDA's Fast Track program is designed to facilitate the development and expedite the review of therapies intended to treat serious conditions and address unmet medical needs in order to potentially bring important new medicines to patients earlier. Among other benefits, companies whose investigational products are granted FTD are eligible for more frequent interactions with the FDA during clinical development and potentially accelerated approval and/or priority review.

"As we enter Phase 3 development, we are very encouraged by the FDA's decision to grant Fast Track designation to MM-II and recognize its potential to fill an unmet medical need for patients suffering from Osteoarthritis," said Marek Honczarenko, MD, PHD, Senior Vice President, Head Global Development at Sun Pharma. Moshe Weinstein, CEO of Moebius Medical, added, "This Fast Track Designation, which will enable FDA to review MM-II in an expedited manner, is an important milestone in the development of MM-II, and follows our recently released Phase 2b data, which showed MMII's potential to provide effective and durable treatment for patients with knee pain of Osteoarthritis."

Glenmark Therapeutics Inc., USA launches Olopatadine Hydrochloride Ophthalmic Solution

Mahwah, New Jersey: Glenmark Therapeutics Inc., USA announced that it has launched Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1% (OTC); compare to the active ingredient in Pataday Twice Daily Relief.

According to Nielsen syndicated data for the latest 52 weeks' period ending July 13, 2024, the Pataday Twice Daily Relief (OTC) market achieved annual sales of approximately USD 26.4 million.

Commenting on the launch, Fabio Moreno, Head – OTC Sales & Marketing, Glenmark Pharmaceuticals Inc. said, "We are excited to announce the launch of Olopatadine Ophthalmic Solution USP, 0.1%, addressing the growing demand for a new supplier in this category. This addition highlights our commitment to meeting market needs and providing high-quality overthe-counter solutions for our customers."

Indian Immunologicals signs MoA with ICMR for Clinical Development of Zika vaccine

Hyderabad, India: Indian Immunologicals Limited (IIL), a leading vaccine manufacturer, has signed MoA with Indian Council of Medical Research (ICMR) for clinical development of India's first codon de-optimized live attenuated Zika vaccine.

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Sec.: 1, Vasai Taluka Industrial Estate,
Gauraipada, Vasai (East) - 401 208.
Dist. Palghar. (Maharashtra) INDIA.
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PALGHAR WORKS : Plot No. 8,
Laxmi Narayan Industrial Estate,
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Palghar (East) - 401 404. (Maharashtra) INDIA.
Mob No.+91 8007991729

CIN : U29253MH2010PTC210755
Aadhar No. : MH17B0007896
E-mail : info@chemicalequipments.com
Website : www.chemicalequipments.com

30 KL Limpeted Reactor

RANGE OF PRODUCTS

- **Reactors**
  Sizes Ranges from 0.5 KL To 40 KL.
  MOC : SS 304 / SS 316. GMP and Non GMP.
- **Heat Exchangers**
  Capacity from 1 Sq Mtr. To 150 Sq Mtr.
  Shell and Tube Type / Floating Head Type / Expanded & Double Tube Sheet Type.
- **Storage Tanks**
- **Self Stiffened Storage Tank**
  Capacity upto 95 KL.
  Available with SS Limped, Insulation and SS Cladding. Polished upto 400 Grit Mirror for Food Grade.
- **Twin Shaft Dispersor**
- **High Speed Mixers**
  Ranges from 0.5 KL To 20 KL.
  Operates at 1440 RPM.
- **Continuous Nitration Systems**
  Nitration Systems
  Operates continuously for 24X7

10 KL Twin Shaft Dispersor

25 KL SS 904L Reactor

62 KL Limpeted Storage Tank

Zika disease, a viral infection, is mostly a mosquito-borne disease transmitted by Aedes mosquitoes. It can also be transmitted to foetus during pregnancy, through sexual contact, blood transfusion and organ transplantation. The disease is usually mild and requires no specific treatment. However, it is more serious when infection occurs during pregnancy which may cause microcephaly and other congenital malformations in the infant, preterm birth and miscarriage. Few cases may also develop Guillain-Barré syndrome which is a neurological disorder.

In India, Zika cases have been reported from several states. According to Ministry of Health, Govt of India (https://mohfw.gov.in/?q=pressrelease-32), as on 22 July 2024, there are 537 Zika cases have been registered.

Emerging infectious disease are whose incidence has increased recently and could increase in the near future. The minority that are capable of developing efficient transmission between humans can become major public and global concerns as potential causes of epidemics or pandemics.

Currently there is no vaccine available for its prevention. IIL partnered with Griffith University, Australia to develop the codon de-optimized live attenuated Zika vaccine that has completed extensive pre-clinical evaluations and received permission from Indian regulatory authority to produce GMP grade materials for clinical developmental work.

As per the MoA, Indian Council of Medical Research (ICMR) will fund the Phase I clinical trial costs including the costs relating to the conduct, investigations and monitoring of clinical trial. The trial will be conducted at the ICMR network sites in India.

Speaking on the occasion, Dr K Anand Kumar, Managing Director, Indian Immunologicals Limited said, "It is a great moment for IIL to collaborate with ICMR to develop Zika vaccine. IIL has been the single largest contributor to India achieving self-sufficiency in the field of vaccines. Our foresight on the development of novel vaccine platforms including codon de-optimized viral vaccines is beginning to bear fruit. It is essential to safeguard our people from emerging diseases by developing safe and effective vaccines that are affordable".

Dr. Rajiv Bahl, DG-ICMR said "ICMR's Phase I trial network, launched last year, facilitates first-in-human safety studies for innovative and affordable Frontier MedTech, including small molecules, biologics, and vaccines. With four Phase-I sites—ACTREC Mumbai, KEM Hospital Mumbai, SRM Chennai, and PGIMER Chandigarh—fully operational, Indian innovators no longer need to go abroad for Phase-I trials. This is a significant step towards achieving Atmanirbhar Bharat and Viksit Bharat.

Dr. Priyabrata Pattnaik, Deputy Managing Director, Indian Immunologicals Limited added "We have been in the forefront of developing vaccine for emerging viral diseases. Currently we are working on developing vaccines for several neglected emerging diseases. Zika, Kyasanur Forest Disease (KFD), Chikungunya, SARS-CoV-2 intra-nasal booster vaccine are to name a few".

Indoco Remedies receives approval from USFDA for Lofexidine tablets

Aditi Panandikar, MD, Indoco Remedies

Mumbai, India: Indoco Remedies Limited announced the receipt of final approval from the USFDA for Abbreviated New Drug Application (ANDA) for Lofexidine Tablets 0.18 mg to market a generic equivalent of Lucemyra Tablets, 0.18 mg of USWM, LLC.

Indoco has been granted a Competitive Generic

Therapy (CGT) designation by the USFDA and being the first approved generic, is eligible for 180 days of CGT exclusivity for Lofexidine Tablets, 0.18 mg ("Product") in the USA. This exclusivity will begin to run from the date of the first commercial marketing of the product. Indoco intends to launch the product immediately in the USA.

This product will be manufactured by Indoco at its manufacturing facility located at L-14, Verna Industrial Area, Verna, Goa – 403722 in India. This product is indicated for mitigation of symptoms associated with acute withdrawal from opioids and for facilitation of the completion of opioid discontinuation treatment.

As per IQVIA Health data, the sales of the product are around USD 15.59 million with an expected growth of 38%.

Commenting on the achievement, Aditi Panandikar, Managing Director, Indoco Remedies said, "We are extremely pleased with this development as this strengthens our position in the US market, driving us closer to expanding our reach in the US."

Bharat Biotech announces collaboration with Alopexx for Anti-Microbial Vaccine AV0328

Dr. Krishna Ella, Executive Chairman, Bharat Biotech

Hyderabad, India: Bharat Biotech announced a collaboration with Alopexx, Inc., for the co-development and commercialization of Alopexx's proprietary broad-spectrum anti-microbial vaccine, AV0328, in India and other low income and lower middle-income countries.

As part of the collaboration, the companies will co-develop and commercialize AV0328, a synthetic vaccine targeting poly N-acetyl glucosamine (PNAG), in India and other licensed territories. Alopexx would be entitled to a one-time upfront payment and milestone payments, as well as royalties on future sales of AV0328 in the licensed territories.

Bharat Biotech is a pioneering biotechnology company known for its world-class research and development and manufacturing capabilities, and Alopexx, Inc., a clinical-stage biotechnology company focused on developing novel, broad-spectrum immune-mediated therapeutics for the prevention and treatment of bacterial, fungal, and parasitic infections.

Dr. Krishna Ella, Executive Chairman of Bharat Biotech, commented, "We are proud to collaborate with Alopexx to bring AV0328 to the regions where it is most needed. Our goal is to develop solutions to reduce anti-microbial resistance through vaccination. This collaboration aligns with our mission to provide safe, affordable, and high-quality vaccines to combat infectious diseases globally."

"We are excited to enter into this collaboration with Bharat Biotech," said Dr. Daniel Vlock, CEO of Alopexx. "To partner with a company with such vast experience and expertise in vaccine development is a significant validation of the value and potential of Alopexx's technology. This collaboration brings us one step closer to addressing the critical need for affordable, broad-spectrum antimicrobial solutions, especially in low-and middle-income countries."

Biocon Biologics signs agreement with Janssen Biotech to market Bmab 1200

Shreehas Tambe, CEO & MD, Biocon Biologics

Bengaluru, India: Biocon Biologics has signed a settlement and license agreement with Janssen Biotech Inc., Janssen Sciences Ireland, and Johnson & Johnson (collectively known as Janssen) that clears the way to commercialize its Bmab 1200, a proposed biosimilar to Stelara, in Europe, the United Kingdom (UK), Canada, and Japan.

Under the terms of this settlement agreement, Biocon Biologics has resolved patent disputes with Janssen to secure market entry dates in Europe, the UK, Canada, and Japan. Regulatory filings in these markets are currently under review.

Biocon Biologics earlier announced a settlement agreement in the United States for a Bmab 1200 launch no later than February 22, 2025, once approved by the U.S. FDA. The U.S. FDA has accepted the Company's Biologics License Application (BLA) for Bmab 1200 (bUstekinumab) for review under the 351(k) pathway.

Shreehas Tambe, CEO & Managing Director, Biocon Biologics Ltd, said: "This settlement agreement is testament to our proven track record of science and innovation and is another key milestone in our journey to bring our biosimilar Bmab 1200 (bUstekinumab) to global markets. Bmab 1200 will significantly strengthen our immunology franchise, enabling us to offer an affordable and effective treatment option for patients impacted by autoimmune diseases."

Stelara® (Ustekinumab) is a monoclonal antibody medication that prevents abnormal regulation of interleukin IL-12/23 associated immune diseases and has been approved for the treatment of psoriasis, Crohn's disease, ulcerative colitis, plaque psoriasis and psoriatic arthritis. The reference brand, Stelara®, had worldwide sales of $10.85 billion in 20231.

Lupin launches Doxorubicin Hydrochloride Liposome Injection in US

Mumbai, India: Global pharma major Lupin Limited announced the launch of Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL) and 50 mg/25 mL (2 mg/mL) Single-Dose Vials in the United States, after Lupin's alliance partner, ForDoz Pharma Corporation, USA (ForDoz) received an approval for its ANDA from the United States Food and Drug Administration (U.S. FDA).

Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL) and 50 mg/25 mL (2 mg/mL) Single-Dose Vials is a generic equivalent of Doxil® (Liposomal), of Baxter Healthcare Corporation, indicated for the treatment of Ovarian Cancer, Acquired Immune Deficiency Syndrome (AIDS)-related Kaposi's Sarcoma, and Multiple Myeloma.

Doxorubicin Hydrochloride Liposome Injection (RLD Doxil (Liposomal)) had an estimated annual sales of USD40.9 million in the U.S. (IQVIA MAT June 2024).

Granules India receives ANDA approval for Glycopyrrolate Oral Solution

Hyderabad, India: Granules India announced that the U.S. Food and Drug Administration (FDA) has approved its Abbreviated New Drug Application (ANDA) for Glycopyrrolate Oral Solution 1mg/5mL filed by Granules Pharmaceuticals, Inc. (GPI), a wholly owned foreign subsidiary of the Company. It is bioequivalent and therapeutically equivalent to the reference listed drug, Cuvposa Oral Solution, 1 mg/5 mL of Merz Pharmaceuticals, LLC.

Glycopyrrolate Oral Solution is an anticholinergic medication indicated for pediatric patients aged three to 16 years who have neurological conditions associated with problem drooling."As we strengthen Granules' footprint in the U.S. market, this approval highlights our robust quality systems, ensuring compliance with the highest regulatory standards," said Dr. Krishna Prasad Chigurupati, Chairman and Managing Director, Granules India Limited.

Zydus Lifesciences announces completion of enrollment of its Phase II(a) clinical study of 'Usnoflast (ZYIL1)

Pankaj Patel, Chairman, Zydus Lifesciences

Ahmedabad, India: Zydus, a leading discovery-based, global pharmaceutical company, announced that it has completed enrollment of its Phase II(a) clinical study of NLRP3 inhibitor 'Usnoflast (ZYIL1)' in patients with Amyotrophic Lateral Sclerosis (ALS).

ALS patients experience neuroinflammation and rapid neurodegeneration. Axonal neurodegeneration leads to formation of neurofilaments which first accumulate in CSF of ALS patients, and then slowly these neurofilaments enter blood circulation. Owing to rapid neurodegeneration, steady loss of the ability to move, speak, eat, eventually breathe, paralysis and death have been reported in ALS patients.

ALS affects approximately 32,000 people in the U.S.A and on an average 5,000 new patients are diagnosed every year with this disease in USA as per statistics from Centers for Disease Control and Prevention (CDC). More than 30,000 people are estimated to be living with ALS in Europe (European Union and United Kingdom), while India has an estimated 75,000 people living with ALS. People living with ALS have an average survival of approximately two to five years from diagnosis, with most ALS patients dying from respiratory failure.

Speaking on the development, Pankaj Patel, Chairman, Zydus Lifesciences Limited said "This is a first-in-class innovation and represents a significant scientific breakthrough in our quest for finding new medicines for treating ALS patients. We are excited to report

that Usnoflast has been able to reach therapeutic concentrations in CSF of ALS patients and reduce the neurofilaments in CSF in this initial Phase 2(a) study. Clinicians have reported improvements in ALSFRS-R score. The improvement observed in SVC (Slow Vital Capacity) in ALS patients has been encouraging in this 12-week trial. We now look forward to conducting a larger Phase 2b clinical trial in consultation with the regulatory authorities."

Alembic Pharmaceuticals receives USFDA approval for Dabigatran Etexilate Capsules

Ahmedabad, India: Alembic Pharmaceuticals Limited announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Dabigatran Etexilate Capsules, 110 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Pradaxa Capsules, 110 mg of Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer).

Dabigatran Etexilate Capsules 110 mg are indicated for prophylaxis of deep vein thrombosis and pulmonary embolism following hip replacement surgery. Refer label for a detailed indication. Alembic has a cumulative total of 211 ANDA approvals (183 final approvals and 28 tentative approvals) from USFDA.

Alembic Pharmaceuticals Limited, a vertically integrated research and development pharmaceutical company, has been at the forefront of healthcare since 1907. Headquartered in India, Alembic is a publicly listed company that manufactures and markets generic pharmaceutical products all over the world. Alembic's state of the art research and manufacturing facilities are approved by regulatory authorities of many developed countries including the USFDA. Alembic is one of the leaders in branded generics in India. Alembic's brands, marketed through a marketing team of over 5000 are well recognized by doctors and patients.

Mankind Pharma transfers OTC biz undertaking to subsidiary

New Delhi, India : Mankind Pharma stated that it has executed the Business Transfer Agreement ("BTA") to transfer Over the Counter (OTC) Business Undertaking (defined in the BTA) of the Company as a going concern on a slump sale basis to Mankind Consumer Products Private Limited (MCPPL), a wholly owned subsidiary of the Company.

The completion of slump sale of OTC Business Undertaking to MCPPL is subject to pre-conditions, closing actions and other terms and conditions as specified in the BTA.

The company focuses on the domestic market with its Pan India presence. Mankind operates at the intersection of the Indian pharmaceutical formulations and consumer healthcare sectors with the aim of providing quality products at affordable prices. The company is a leading player in the domestic pharmaceuticals business present across acute and chronic therapeutic areas including anti-infectives, cardiovascular, gastrointestinal, antidiabetic, neuro/CNS, VMN and respiratory, among others with a strategy to increase chronic presence going ahead.

Marksans Pharma Q1 net profit rises 26.5%

Mark Saldanha, MD, Marksans Pharma

Mumbai, India: Marksans Pharma Ltd. reported the financial results for the quarter ending June 30, 2024.

The company's Operating revenue was at ₹ 590.6 crore., up by 18.1% YoY driven by new launches and increase in share with existing customers in the key markets. The company's net profit stood at ₹ 89.1 crore, a growth of 26.5%

Mark Saldanha, Managing Director of the Company said "We are delighted to build on the growth momentum from the last year – the first quarter of FY25 has shown strong start with 18% YoY increase in revenue and 26% YoY increase in EBITDA. The growth is supported by increase in share from existing customers and new launches. We experienced favorable raw material prices, however surge in freight costs continue. The shipments from the new facility have commenced to our key markets, and with that we remain optimistic for a stronger performance in the coming quarters, and our journey towards achieving the next revenue goal of ₹. 3,000 crores over the next two years."

The company's US & North America Formulation business reported growth of 29.8% YoY to ₹ 250.9 crore. in Q1FY25, on account of incremental revenue from new

product launches, and increase in the share of existing customers. The company's Australia and New Zealand business reported revenues of ₹ 65.6 crore. in Q1FY25, which grew by 12.0% YoY, due to incremental market share.

Alkem Laboratories signs agreement with Takeda Pharmaceutical


Dr. Vikas Gupta, CEO, Alkem Laboratories

Mumbai, India: Alkem Laboratories Ltd. announced that it has signed a non-exclusive patent license agreement with Takeda Pharmaceutical Company Ltd. ("Takeda") to commercialise Vonoprazan in India, under the brand name "Vonzai" as oral tablets, in 20 mg and 10 mg strengths.

Vonoprazan is a first-in-class potassium-competitive acid blocker (P-CAB), discovered and developed by Takeda. Vonoprazan has novel mechanism of action, whereby it inhibits H+,K+-ATPase activities in a reversible and potassium-competitive manner, eliciting gastric acid suppression with high serum gastrin concentration.

In India, Vonoprazan is indicated in the treatment of reflux esophagitis (RE) and other indications such as treatment of gastric ulcers (GU), duodenal ulcers (DU), prevention of recurrence of GU or DU during low-dose aspirin or NSAID administration, and adjunct to H. pylori eradication.[2]

Commenting on the development, Dr. Vikas Gupta, Chief Executive Officer, Alkem Laboratories said, "Alkem has a formidable presence in the gastrointestinal segment and this non-exclusive patent license with Takeda will help us offer a product with novel mechanism of action for a large number of patients in India who are suffering from gastro-related ailments" .

Enzene appoints new site lead for flagship US continuous biomanufacturing facility

Hopewell, New Jersey: Enzene Biosciences, a fully integrated CDMO with services spanning discovery, development and commercial supply, announced the appointment of Norm Stoffregen as SVP, site head, and head of biologics manufacturing at the company's new $50 million manufacturing facility in Hopewell, near Princeton, New Jersey.

As well as taking responsibility for Enzene's global biologics business, Stoffregen will lead the final stages of work to commission the 54,000-square-foot facility. He will then lead ongoing operations at the site, where the company intends to transfer-in existing customers' manufacturing projects and expand to add further bioreactor capacity, employing a workforce of 300 by the end of 2025. Significantly, Stoffregen brings a vast experience of building manufacturing businesses, having worked in the area since 2015 when the Hopewell facility was owned by Bristol Myers Squibb.

"I am delighted to welcome Norman to Enzene," commented Himanshu Gadgil, CEO of Enzene Biosciences. "His knowledge of the facility, our colleagues, customers and suppliers will be invaluable as we develop our customer base and expand operations, further building our reputation as a world class biologics innovator dedicated to lowering the cost of biologics production, and continually improving manufacturing techniques."

The Princeton site features EnzeneX, the company's fully-connected continuous manufacturing platform, as well as development and quality laboratories, warehousing, frozen storage and cell banking. When complete, it will complement Enzene's global network and benefit from process development expertise and the proven and flexible continuous manufacturing capabilities first developed at the company's facility in Pune, India.

"Existing and new customers see the powerful opportunities that continuous biologics technology brings, not least by providing flexibility and lowering the cost of manufacturing," commented Stoffregen. "We are already in discussion with biopharma companies keen to progress programs for the domestic market and beyond, and in the next 18-months we expect to ramp up our production capacity and capabilities, and grow our pipeline of work with biotech and pharma companies in early phases of development."

Immediately prior to joining Enzene, Stoffregen was VP-site head at PTC Therapeutics, and before that held various roles of increasing responsibility at BMS and with other biotherapeutics/bioprocessing companies, where he amassed more than 20-years' experience in leadership, quality assurance, and Chemistry, Manufacturing and Controls (CMC). Stoffregen has a bachelor's from the State University of New York at New Paltz.

Fabtech Technologies Limited files DRHP for IPO

Mumbai, India: Mumbai-based Fabtech Technologies, a turnkey engineering solutions provider for the pharmaceuticals, biotech and healthcare industry has filed its draft red herring prospectus (DRHP) with the market regulator Securities and Exchange Board of India (SEBI) to raise funds through an initial public offering (IPO).

The IPO with a face value of ₹ 10 per equity share is entirely a fresh issue of up to 1.20 crore equity shares. The offer also includes a reservation for a subscription by eligible employees and a discount is being offered to eligible employees bidding in the employee reservation portion.

The company, in consultation with the book-running lead managers, may consider a further issue of equity shares through a private placement, preferential offer, or any other method aggregating up to ₹ 10 crores and shall not exceed 20% of the size of the fresh issue. If such placement is completed, the fresh issue size will be reduced.

The Issue is being made through the book-building process, wherein not more than 50% of the net issue 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.

The proceeds from the fresh issue to the extent of ₹ 120 crore will be used for funding the working capital requirements of the company; ₹ 30 crore for pursuing inorganic growth initiatives through acquisitions; and general corporate purposes.

Established in 2018, Fabtech Technologies, part of the Fabtech Group was incorporated as Globeroute Ventures Private Ltd. The company demerged from the group company in 2021 to achieve operational efficiencies.

Pursuant to the Demerger, the order book of Fabtech Technologies International Private Ltd, which comprised twenty-seven projects with an aggregate value of Rs 287.16 cr were transferred to Fabtech Technologies Ltd

Fabtech Technologies is led Aasif Ahsan Khan, Hemant Mohan Anavkar, and Aarif Ahsan Khan who collectively have over 3 decades of experience in pharmaceutical engineering. It offers comprehensive start to finish solutions encompassing designing, engineering, procurement, installation and testing of select pharmaceutical equipment for a wide range of customers.

Its turnkey engineering solutions involves an extensive range of services such as comprehensive market analysis, disease profiling, designing and detailed engineering of equipment tailored to the manufacturing process and the applicable quality standards, leveraging the best technologies to enhance the efficiency, reliability, and sustainability of the projects and execution and commissioning strategy. It has the capability to execute green field and brown field projects.

Since incorporation and till June 30, 2024, the company has completed thirty-five projects across countries, namely Saudi Arabia, Egypt, Algeria, Bangladesh, Ethiopia, Sri Lanka, United Arab Emirates.

Its business model is considered to be asset light in nature because it procures majority of the equipment required by our customers through our Related Entities, on an arms-length basis. It is not required to make capital investment for setting up a manufacturing unit or heavy machinery for manufacturing the equipment supplied by them.

Akums Drugs and Pharmaceuticals secures Patent for Oral Suspension of Hydroxyurea

Mumbai, India: Akums Drugs and Pharmaceuticals, largest India Focused Contract Development and Manufacturing Organizations (CDMO), has been awarded a patent for its Room Temperature Stable Oral Suspension of Hydroxyurea, a breakthrough formulation aimed at managing Sickle Cell Disease (SCD). This development reinforces Akums' role as an innovator in pharmaceutical solutions, offering a significant advance in addressing the storage and accessibility challenges associated with Hydroxyurea solution.

Sickle Cell Disease, a genetic blood disorder, leads to severe health complications such as anemia, frequent pain episodes and other debilitating symptoms, affecting millions worldwide especially in India and Africa. According to the 2011 Census, 8.6% of India's population is from tribal communities, many of whom are disproportionately affected by SCD. Addressing this pressing public health issue, Akums' new formulation offers a key advantage over traditional Hydroxyurea solution that require refrigeration between 2–8°C. The new oral suspension remains stable at room temperature, providing a practical solution for widespread distribution, particularly in the tribal areas with limited access to cold storage facilities.

Commenting on this milestone, Sanjeev Jain, Managing Director of Akums, said, "We are proud to have secured this patent for a formulation that has the potential to improve the lives of countless SCD patients both in India and Africa. At Akums, we are committed to delivering innovative healthcare solutions that address real-world challenges and positively impact patient outcomes. Our constant endeavor is to work on affordable medicines for Orphan Drugs and reduce dependency on imported medicines ensuring patient safety from rare diseases with timely and necessary treatment."

Sandeep Jain, Managing Director of Akums, added, "This patent reflects our dedication to the 'Make in India' initiative and our commitment to offering affordable, high-quality pharmaceutical solutions as envisioned by Government of India. We continue to prioritize innovation to make essential treatments accessible and cost-effective for all. Tribal communities make up 67.8 million people across various states in India. Many within these communities are disproportionately affected by Sickle Cell Disease (SCD). We are happy that our R&D scientists have provided a much required formulation that is suitable for all age group especially pediatric and adolescent patients suffering from SCD. Our innovative oral suspension remains stable at room temperature, ensuring greater accessibility and providing an efficient solution for widespread distribution, particularly in tribal areas where cold storage facilities are scarce."

Akums' breakthrough aligns with India's National Sickle Cell Anemia Mission, spearheaded by Honorable Prime Minister Shri Narendra Modi Ji, which aims to enhance the quality of life for SCD patients by improving treatment options. In comparison to Hydroxy Urea Capsule (500mg), Akums Hydroxy Urea suspension offers dose flexibility based on body weight of the SCD Patients, thus offer significqant advantage for pediatric and adolescent patients.

The patented formulation will now come at fraction of the cost of imported Hydroxyurea solution, this is in line with our commitment to provide affordable quality medicines in India. With this new patent, Akums continues to advance healthcare through innovation, ensuring life-saving treatments reach those who need them the most.

Aurobindo Pharma arm gets USFDA approval for anesthetic drug

Hyderabad, India: Aurobindo Pharma announced that its stepdown subsidiary, Eugia Steriles, situated at Parawada Mandal, Anakapalli District, Andhra Pradesh, which was inspected by the US FDA from March 28, 2024 to April 05, 2024, received its first product approval from the United States Food and Drug Administration (USFDA) for Lidocaine Hydrochloride injection, USP, 1% (10 mg/mL) and 2% (20 mg/mL).

Lidocaine is a local anesthetic (numbing medication) that is used to numb an area of your body to help reduce pain or discomfort caused by invasive medical procedures such as surgery, needle punctures, or insertion of a catheter or breathing tube.

The company said that sANDA was submitted as "Prior Approval Supplement" for addition of an alternate drug product manufacturing, labeling, packaging, and testing facility

Wockhardt wins Innovator Award from Government of India

Mumbai, India: Biotechnology Industry Research Assistance Council (BIRAC), a Government of India enterprise, his behalf, the award was received by the inventor, Dr. Mahesh Patel (Chief Scientific Officer - Drug Discovery Research) during event held in New Delhi.

The award is in recognition of the highest level of innovation and research that led to successful

development of Nafithromycin (MiqnafTM), which is the first ever multi-drug resistant pathogen active respiratory antibiotic for the treatment of Community-Acquired Bacterial Pneumonia.

Miqnaf (Nafithromycin) fulfils major unmet medical need as existing treatment based on Azithromycin and Amoxicillin + Clavulanic acid have either developed resistance in contemporary respiratory pathogens or lack the coverage of entire range of respiratory pathogens involved in Community-Acquired Bacterial Pneumonia. As a result, many of these patients need to be hospitalized due to limitations of current treatment options. With once-a-day, ultra-short, 3 daycourse of oral treatment, MiqnafTM (Nafithromycin) would obviate the need of hospitalization for many such patients.

Discovery and development of Nafithromycin at Wockhardt spanned over 12 years and involved several Phase 1 and Phase 2 clinical studies which were conducted in USA and Europe. Nafithromycin has successfully completed Phase III clinical trial in India and is awaiting DCGI approval.

Globally, for the 1st time in 33 years, a new macrolide drug in the form of Miqnaf (Nafithromycin) has been developed to treat millions of community respiratory infections through a convenient home-based oral monotherapy.

Laurus Labs inaugurates new State of the Art R&D facility at IKP Knowledge Park

Hyderabad, India: Laurus Labs Ltd, a leading research and development driven pharmaceutical and biotech company in India announce the inauguration of its state of the art new R&D center at IKP Knowledge Park, Plot No DS15, Kolthur Shamirpet Medchal Telangana. The facility was inaugurated by Shri Duddilla Sridhar Babu Garu, Minister of Information Technology, Electronics & Communications, Industries & Commerce and Legislative Affairs – Government of Telangana along with Dr.Satyanarayana Chava, Founder & CEO Laurus Labs along with other senior management team. The cutting edge facility is designed to foster innovation & advance the company's mission developing 'Chemistry for Better Living.'

On the occasion of the inauguration Dr.Satyanarayana Chava, Founder & CEO Laurus Labs, said, "This will be our 5th R&D center and the new R&D center will be a testimonial to our commitment to innovation and excellence. We believe that this facility will enable us to develop ground breaking solutions that will address unmet medical needs".

Laurus has a global leadership position in select Active Pharmaceutical Ingredients (APIs) including anti-retroviral, oncology drugs (incl High Potent APIs), Cardiovascular, and Gastro therapeutics. Laurus also offers integrated Contract Development and Manufacturing Organization (CDMO) services to Global Innovators from Clinical phase drug development to commercial manufacturing.

Neuberg Diagnostics launches personalized genomics platform, "Geniee – Decode your DNA"

Chennai, India: Neuberg Diagnostics, a global leader in cutting-edge healthcare diagnostics, has launched its ground-breaking personalized genomics platform, "Geniee – Decode your DNA". This launch signifies a monumental shift in the future of personalized healthcare, positioning Neuberg Diagnostics at the forefront of genetic testing and tailored medicine.

The event was graced by Padma shri Dr. Kamal Haasan, who unveiled the Geniee brand, marking the beginning of an innovative journey that will enable individuals to unlock their genetic blueprint. Neuberg's Geniee is designed to deliver highly personalized health insights, empowering users with the knowledge needed to make informed decisions about their health and wellness based on their unique genetic makeup.

Geniee by Neuberg is more than just a risk prediction tool; it's a personalized wellness revolution. This mobile platform provides insights into how your genes influence your body's response to medications, dietary preferences, exercise routines, and nutritional needs. It enables users to take control of their health by offering comprehensive genetic insights into critical aspects of well-being. With Geniee, individuals can optimize their diets, identify nutrient deficiencies, enhance fitness plans, and take proactive steps to ensure a healthier future.

The launch of the Complete Wellness Genetics Test along with the Geniee app is at the heart of this initiative. This advanced genetic analysis dives deep into a person's DNA, offering clear guidance on how they can adjust their lifestyle to live longer, healthier lives. Whether it's determining if you are prone to be

obese, have nutritional deficiencies like vitamin A deficiency, and recommend the best foods for optimal nutrition or identifying potential health risks early on, Geniee empowers users to personalize their health strategy and transform their well-being. Considering the ever growing scientific advancement in genomics, Geniee customers will benefit from regular updates on the app that they will get based on their unique genetic make-up and recent updates.

Dr. GSK Velu, Chairman & Managing Director of Neuberg Diagnostics, addressed the audience at the launch, stating: "At Neuberg, we believe that personalized medicine is the future of healthcare. The launch of Geniee is a testament to our commitment to driving this future forward. Geniee is not just about testing—it's about giving individuals the power to take control of their health by offering them invaluable insights. We are thrilled to have Dr. Kamal Haasan with us today to unveil this milestone, as we aim to push the boundaries of medical science and deliver better healthcare outcomes for all."

Cabinet approves 'Bio-RIDE' scheme to support cutting edge research and development in Biotechnology

New Delhi, India: The Union Cabinet, chaired by the Prime Minister Shri Narendra Modi, approved continuation of the two umbrella schemes of Department of Biotechnology (DBT), merged as one scheme-'Biotechnology Research Innovation and Entrepreneurship Development (Bio- RIDE)' with a new component namely Biomanufacturing and Biofoundry.

The scheme has three broad components such as Biotechnology Research and Development (R&D); Industrial & Entrepreneurship Development (I&ED) and Biomanufacturing and Biofoundry

The proposed outlay for the implementation of the unified scheme 'Bio-RIDE' is ₹ 9197 crore during the 15th finance Commission period from 2021-22 to 2025-26.

Bio-RIDE scheme is designed to foster innovation, promote bio-entrepreneurship, and strengthen India's position as a global leader in biomanufacturing and biotechnology. It aims to accelerate research, enhance product development, and bridge the gap between academic research and industrial applications. The scheme is part of the Government of India's mission to harness the potential of bio-innovation to tackle national and global challenges such as healthcare, agriculture, environmental sustainability, and clean energy. Implementation of Bio-RIDE Scheme will -

Promote Bio-Entrepreneurship: Bio-RIDE will nurture a thriving ecosystem for startups by providing seed funding, incubation support, and mentorship to bio-entrepreneurs.

Advance Innovation: The scheme will offer grants and incentives for cutting-edge research and development in areas like synthetic biology, biopharmaceuticals, bioenergy, and bioplastics.

Facilitate Industry-Academia Collaboration: Bio-RIDE will create synergies between academic institutions, research organizations, and industry to accelerate the commercialization of bio-based products and technologies.

Encourage Sustainable Biomanufacturing: A significant focus will be placed on promoting environmentally sustainable practices in biomanufacturing, aligned with India's green goals.

Support researchers through Extramural funding: Bio-RIDE will play critical role in advancing scientific research, innovation, and technological development across diverse fields of biotechnology by supporting extramural funding to research institutions, universities, and individual researchers in areas such as agriculture, healthcare, bioenergy, and environmental sustainability.

Nurturing Human Resource in Biotechnology sector: Bio-RIDE will provide holistic development and support to students, young researchers and scientists working in the multidisciplinary areas of Biotechnology. The integrated programme of Human Resource Development will contribute towards the capacity building and skilling of the manpower and make them competent to leverage the newer horizon of technological advancements.

Further, to enable Circular-Bioeconomy in the country a component on Biomanufacturing and Biofoundry is being initiated in alignment with 'Lifestyle for the Environment (LiFE)' launched by the Hon'ble PM to propel mitigation of global climate change by incorporating green and friendly environmental solutions in every aspect of life. This new component of Bio-RIDE aspires to nurture the immense potential of 'Biomanufacturing' to facilitate development of indigenous innovative solutions to improve healthcare outcomes, enhance agriculture productivity, foster growth of the bioeconomy, scale-up and commercialization of bio-based products, expanding India's cohort of highly skilled workforce, and intensifying entrepreneurial momentum. ■

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Natco Pharma (Canada) Inc. announces USD8 million investment in eGenesis

Mumbai, India: Natco Pharma Limited announce that its wholly owned Canadian subsidiary, NATCO Pharma (Canada) Inc., has made an investment of USD 8 million in eGenesis, Inc., a biotechnology company at the forefront of xenotransplantation focused on developing safe and effective human- compatible organs for transplant. In March 2024, eGenesis announced the world's first porcine kidney transplant in a living patient. The transplant was authorized by the U.S. Food & Drug Administration (FDA) under the Expanded Access pathway.

eGenesis is pioneering a genome engineering-based approach in the development of safe and effective transplantable organs to end the global organ shortage and transform the treatment of organ failure. The eGenesis Genome Engineering and Production (EGENTM) Platform is the only technology of its kind to comprehensively address cross-species molecular incompatibilities and viral risk via genetic engineering to improve the lives of patients in need of a transplant. eGenesis is advancing development programs for kidney transplant, acute liver failure, and heart transplant.

"We are excited to get involved with eGenesis, Inc. with respect to their pioneering work in xenotransplantation. We agree with the vision of eGenesis that xenotransplantation technology has the potential to end the global transplant shortage and transforming the treatment of organ failure by eliminating waitlist mortality," said Rajeev Nannapaneni, Vice Chairman and CEO of NATCO Pharma Limited. "We are thrilled to welcome NATCO as an investor. Their support will be used in advancing our research and bringing our innovative therapies to market," said Mike Curtis, CEO of eGenesis, Inc.

Zydus Lifesciences acquires Sterling Biotech's API business for ₹ 84 crore

Ahmedabad, India: Zydus Lifesciences stated that its board approved acquisition of Active Pharmaceutical Ingredients ("API") business of Sterling Biotech for ₹ 84 crore.

The Board of Directors of the Company have approved a Business Transfer Agreement ("BTA") to purchase the API business ("the Target Business") of SBL, on a going concern basis, on slump sale basis, without values being assigned to individual assets and liabilities, on cash-free and debt-free basis at a pre-defined lump-sum consideration of , subject to certain conditions precedent and closing date adjustments as provided in the BTA, with effect from such date, and in such manner and on the terms and conditions as mentioned in the BTA.

The Target Business of Sterling Biotech Limited ("SBL") is primarily engaged in manufacturing fermentation-based API products like Lovastatin, Daunorubicin, Doxorubicin and Epirubicin at its API manufacturing unit situated at village Masar near Vadodara in Gujarat.

Bora Pharmaceuticals makes Strategic Investment in Tanvex Biopharma

Taipei, Taiwan: Bora Pharmaceuticals Co., Ltd. announced that its Board of Directors has approved a strategic investment into Tanvex Biopharma Co., Ltd. whereby Bora Biologics, a wholly owned subsidiary of Bora and specialist large molecule CDMO, and Tanvex will combine their biomanufacturing facilities to create a global solution for biologics development and supply. The investment will bring together Bora's extensive CDMO capabilities and total service culture with Tanvex's scale, development expertise and USFDA-approved commercial-scale facility in San Diego, California, and, upon completion, the appointment of Mr. Bobby Sheng, Chairman and CEO of the Bora Group, as Chairman of the merged organization. Upon completion of the transaction, which is expected in Q1 of 2025, Bora will hold approximately 30.5% of Tanvex's total outstanding shares based on current shareholding structure, becoming the single largest shareholder of Tanvex.

Bora Pharmaceuticals is a leading global CDMO with 10 state-of-the-art factories around the world. Upon completion, the company will closely collaborate with Tanvex to leverage its global CDMO operations and capabilities to provide comprehensive solutions to biologics customers, including Bora 's new fill/finish capabilities in Maryland, USA. Tanvex has created a strong biologics development and manufacturing operations in both USA and Taiwan. ■

INTERVIEW

"Lincoln Pharmaceuticals eyes revenue target of ₹ 750 crore by FY26, driven by focused growth strategies and business expansion"

Mahendra Patel
Managing Director
Lincoln Pharmaceuticals Ltd

Mahendra Patel, Managing Director, Lincoln Pharmaceuticals Ltd discussed the overview of the pharma industry and strategy going ahead. He also emphasizes the plans for the global market.

Brief us about your overview of the Pharma industry?

The Indian pharmaceutical industry is a global leader in the production of generic drugs, accounting for about 20% of the world's supply by volume. Renowned for its cost-effective manufacturing and high-quality standards, the industry is a crucial player in the global healthcare system. India hosts over 3,000 pharma companies and approximately 10,500 manufacturing facilities, contributing significantly to the nation's GDP and export revenues.

Key strengths of the industry include a robust R&D infrastructure, a skilled workforce, and compliance with international regulatory standards, enabling exports to over 200 countries, including highly regulated markets like the US and EU. The sector is also a major supplier of vaccines, catering to around 60% of global demand.

What are the challenges do you face for Pharma sector?

Domestically, stringent regulatory requirements and price controls imposed by the National Pharmaceutical Pricing Authority (NPPA) often squeeze profit margins. Compliance with evolving domestic regulations can be costly and time-consuming, impacting the agility of companies to respond to market needs.

On the global front, Indian pharma companies face significant challenges in maintaining regulatory compliance with international standards such as those set by the US FDA and the European Medicines Agency (EMA). Inspections and approvals are rigorous, and any lapses can lead to bans or import alerts, affecting market access and reputation.

What is the future roadmap and strategy?

Lincoln Pharmaceuticals Limited is charting a robust future roadmap with growth and expansion strategies. The company aims to achieve a revenue target of ₹ 750 crore by FY26, driven by focused growth strategies and business expansion into value-added products and new markets. Strategic initiatives, including new product launches and further market penetration, are designed to sustain and accelerate growth, ensuring Lincoln continues to deliver value to its shareholders while solidifying its market presence both locally and globally.

The company is set to enhance its product offerings in lifestyle, chronic, women's healthcare, and dermatology

segments, alongside its existing acute care lineup. With over 1,700 registered products and 700 more in development, Lincoln is dedicated to innovation and addressing diverse healthcare needs.

Lincoln's global footprint spans over 60 countries, and recent market entries in Canada and approvals from TGA - Australia and EU GMP highlight its aggressive international expansion plans.

Could you give us an update on the expansion of the Cephalosporin plant in Mehsana, Gujarat?

We have completed the expansion of our Cephalosporin plant in Mehsana, Gujarat, with commencement of commercial production and initiating sales in domestic markets. This facility is approved by WHO-GMP, BOMRA (Botswana Medicines Regulatory Authority) and TMDA (Tanzania Medicines and Medical Devices Authority). We are now focusing on registering the product for export to multiple countries. This strategic move is expected to generate approximately ₹; 150 crore in sales over the next three years.

What is your focus area going ahead?

We are focusing on enhancing our offerings in lifestyle, chronic, women's healthcare, and dermatology

segments, alongside our existing acute care lineup. The company plans to launch new products in both domestic and export markets, strategically expanding into new territories to solidify its market presence. With over 1,700 registered products and 700 more in development, Lincoln emphasizes innovation and growth. Recent global expansion efforts include entering the Canadian market and securing approvals from TGA - Australia and EU GMP. Additionally, the company is aggressively pursuing product registration for its expanded Cephalosporin plant in Mehsana, targeting a revenue of ₹ 750 crore by FY26.

Looking ahead, Lincoln is poised to sustain and even accelerate its growth momentum. With plans for new product launches in both domestic and export markets, alongside strategic expansions into newer markets, the company aims to further solidify its market presence.

What are your plans for EU and Australian markets?

We are strategically focusing on expanding our presence in the EU and Australian markets. The company has secured EU GMP and TGA - Australia approvals, which will facilitate entry into these regulated markets. Lincoln plans to introduce a range of value-added and innovative products tailored to the needs of these regions. By leveraging its state-of-the-art manufacturing facilities and adherence to stringent quality standards, Lincoln aims to strengthen its market position in Europe and Australia. The company's strategy includes increasing product registrations and forging partnerships to drive growth and enhance market share in these key international markets.

What are your plans for export markets? What percentage of revenue comes from exports?

In FY24 exports contributed 62.4% of the total business. The company exports to over 60 countries across East & West Africa, Central & North America, Latin America, and Southeast Asia. Recent initiatives include entering the Canadian market and securing approvals from TGA - Australia and EU GMP, which will facilitate further expansion into these regions.

The company's expansion strategy involves registering new products for export, increasing its market presence, and leveraging its state-of-the-art manufacturing facilities to meet international standards. With approvals from TGA - Australia and EU GMP, the company anticipates expanding its network to over 90 countries, further enhancing its global presence.

What are your plans on the R&D front?

On the R&D front, we are committed to advancing our research capabilities and expand the pipeline. The company is currently developing 700 new products, in addition to its robust portfolio of over 1,700 registered products. Significant investments are being made in R&D to foster innovation in therapeutic areas such as lifestyle, chronic, women's healthcare, dermatology, and acute care. The company's state-of-the-art manufacturing and research facilities are equipped with the latest technology to support these efforts. Lincoln has also filed over 25 patent applications and has been awarded seven patents, demonstrating its dedication to creating proprietary and cutting-edge pharmaceutical solutions.

Brief us about the operational highlights for the quarter? What were the major drivers for growth?

In Q1 FY25, Lincoln Pharmaceuticals Limited reported a net profit of ₹ 23.67 crore, up 24.51% from the previous year. The company's total income rose by 10.03% to ₹ 157.69 crore, while EBITDA increased by 16.65% to ₹. 33.14 crore. Major drivers of this growth included strong performance across all business segments, enhanced product offerings, and successful market expansions. The company's strategic focus on value-added products, operational efficiencies, and robust domestic and international sales contributed significantly to these impressive results, reflecting its continued commitment to profitability and market expansion.

Brief us about your new product launches?

We have planned several new product launches to drive growth and expand our market presence. The company is focusing on introducing innovative and value-added products across various therapeutic areas, including lifestyle, chronic, women's healthcare, and dermatology. These new offerings will cater to both domestic and international markets, aligning with the company's strategy to enhance its product portfolio. The launches are designed to leverage Lincoln's robust R&D capabilities and manufacturing strengths, aiming to meet diverse healthcare needs and further solidify its position in key global markets. ■

Vaccine Development: An Overview

Public health plays a vital role in enhancing the productivity of a nation's workforce and its overall economic growth. Access to clean water is one of the most cost-effective means of controlling many debilitating infectious diseases within populations. Widespread vaccination is the next most crucial intervention, second only to clean water, in strengthening public health.

Dr. Rajan Sriraman, Research Director - Vaccines Reliance Life Sciences provides the overview of the vaccine development process and highlight the strategies employed by the industry to overcome challenges. Although the focus is on human vaccines, the development process for veterinary vaccines follows a very similar pathway.

Dr. Rajan Sriraman
Research Director- Vaccines
Reliance Life Sciences

Governments and donor agencies worldwide recognize the importance of vaccinating entire populations. As a result, they allocate significant funds to immunize children, thereby ensuring a healthier future workforce.

Given the significance of vaccines in public health programs, several substantial challenges must be addressed.

These challenges include cost of goods associated with vaccine manufacturing; scale of production required to meet the demand for hundreds of millions of doses annually; Ensuring vaccines are transported and stored under strictly monitored cold-chain conditions to reach the remotest areas; the speed of vaccine development and deployment to respond to emerging infectious diseases and Combating misinformation spread by vested interest groups, which discourages people from getting vaccinated.

Identifying the Causative Agent

Before a vaccine can be developed, the causative agent of the disease must be identified. This initial step is critical in creating an effective vaccine to prevent the onset of an infectious disease. Academic institutions and government health agencies play an essential role in this phase of vaccine development.

Nature of the disease-causing agent, ease of handling and operator safety determines the type of vaccine that can be developed. For instance, most of the vaccines developed for COVID-19 were recombinant sub-unit vaccine as the virus was highly infectious and against which no effective clinical management protocols were available.

Prophylactic Nature of Vaccines

Vaccines are predominantly prophylactic, meaning they are administered to healthy individuals before the onset of the disease. Unlike therapeutic agents, which are given after a person falls ill, vaccines are preventive in nature and do not generally require administration under professional supervision. This creates a higher regulatory expectation for their safety and efficacy. As a result, every vaccine, regardless of the manufacturer, is considered a "new drug" by regulatory authorities and must be rigorously tested to demonstrate both safety and efficacy. This testing involves a comprehensive clinical development program that includes non-clinical toxicology studies in laboratory animals, as well as Phase I, II, and III clinical trials in human subjects.

Regulatory Expectations and Development Timeline

Due to the stringent regulatory requirements, vaccine development and commercialization are often lengthy and resource-intensive processes. Typically, it takes between 5 to 7 years to develop a vaccine and bring it to market, depending on the number of doses required and the spacing between them. This timeline can only be shortened when the regulatory risk appetite is higher, as was the case during the COVID-19 pandemic. In such scenarios, when no existing disease management tools are available, and large populations are at risk, regulatory agencies may accelerate approval processes.

Vaccine Composition and Immune Response

Vaccines are sterile, injectable formulations designed to stimulate the immune system of an individual to recognize and combat a future invasion by a pathogen. The active ingredients in vaccines are derived from the same or similar organisms that cause the disease. The primary goal is to trigger the immune system to produce specific proteins (antibodies) or primed cells (T-cells) capable of responding to any future exposure to the pathogen. The body's ability to retain pathogen-specific information and recall it years later, when re-exposed to the infectious agent, is known as the memory response. This response is a key indicator of an effective vaccine.

Vaccines can contain a wide range of biological agents, including Live bacteria or viruses, Attenuated (weakened) bacteria or viruses, Bacterial fractions, such as toxins, toxoids, or polysaccharides, Recombinant immunogenic proteins from bacteria or viruses (subunit or virus-like particles), Bacterial polysaccharides chemically conjugated (linked) to a protein (conjugate vaccines), Nucleic acids, such as DNA or mRNA and Immunogenic proteins delivered using another virus or bacteria that are non-infectious (vectored vaccines)

The Vaccine Development Process

The development of vaccines follows a process similar to that of bio-therapeutic products. The first major step is to identify the pathogen causing the infection, which then leads to the identification and selection of a suitable antigen or immunogen. This is the foundation for developing an effective vaccine. Lead identification often takes several years, involving research conducted in academic settings or within industry. The process is highly knowledge-intensive and requires expertise in areas such as disease biology, molecular biology, immunology, bioanalytical techniques, biochemical engineering, and protein or polysaccharide chemistry.

Once a promising vaccine lead is identified, it is validated using a disease model or surrogate animal model. Following validation, a consistent manufacturing process is developed to translate the lead into an effective vaccine, which then undergoes full clinical development. Preclinical (or non-clinical) studies in animals help establish the vaccine's safety profile, and this is followed by three phases of clinical trials involving healthy human volunteers. These trials evaluate the vaccine's safety (Phase I), efficacy (Phase II), and further confirmatory efficacy (Phase III). During this process, all components of the vaccine, in-process materials, final product specifications, and the manufacturing process are established. Regulatory considerations are factored into the development process, including the manufacturing scale, which is chosen to ensure sufficient material for clinical trials and stability testing.

Vaccines required for human trials are produced in cGMP (current Good Manufacturing Practices) facilities. Three or more consistent production lots are needed for Phase III trials, which are conducted at full production scale.

Regulatory Oversight and Global Distribution

Many countries rely on the World Health Organization's (WHO) guidelines for vaccine product quality, published in its Technical Report Series (WHO TRS). Vaccine manufacturers that meet these regulatory expectations can export their products to economically disadvantaged countries through UNICEF or the Global Alliance for Vaccines and Immunization (GAVI), which support childhood immunization programs.

Vaccines undergo comprehensive analytical and bio-analytical (immunological) testing to demonstrate that both the vaccine and its key intermediates meet the specified requirements outlined in pharmacopoeias. Every vaccine must meet rigorous standards for safety, efficacy, and potency before it can be released for public use. In India, as well as other countries, national pharmacopoeias provide monographs outlining standardized requirements for each approved vaccine. Both the manufacturer and central testing laboratories must test formulated vaccines for safety and efficacy before each batch is released for use in humans.

Formulation and Technological Advancements

Multicomponent vaccines, which protect against several infectious agents, have increased compliance and reduced the number of clinic visits and needle pricks. Formulating vaccines with multiple components, each with different physicochemical properties, is a complex task that requires both scientific and practical expertise. Most vaccines, except for seasonal flu vaccines, have a shelf life of two years or more. Flu vaccines are unique because the WHO revises the list of strains to be incorporated into the vaccine annually.

Adopting new process technologies, such as single-use reactors, process automation, needle-free delivery systems, and thermostable formulations, can significantly reduce production costs and improve vaccine performance. For example, single-use reactors can lower utility consumption, reducing overhead costs, while automated processes can decrease input costs and minimize batch failures. These advancements contribute to reducing the overall cost of vaccine production, making them more accessible worldwide. Greater vaccine coverage helps prevent the emergence of infectious diseases, benefiting both public health and the global economy.

Future Trends in Vaccination

While childhood vaccination is currently the primary focus in many developing countries, there is a growing demand for vaccines for adults and the elderly, driven by increasing life expectancy worldwide. As populations age, the need for vaccines that protect against diseases prevalent in adulthood and old age will rise.

Currently most available vaccines are directed to prevent the onset of the disease – Prophylactic. Development of an effective therapeutic vaccine is also being attempted.

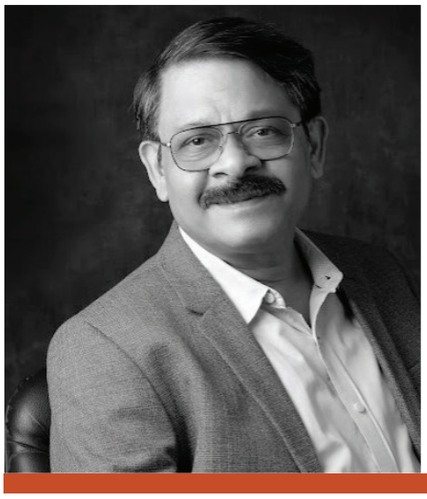
Conclusion

Vaccine development is an interdisciplinary and resource-intensive process, requiring a deep understanding of various scientific fields. As human activity continues to encroach on natural habitats, due to deforestation and urbanization, the risk of new infectious diseases, such as COVID-19, emerging from wildlife remains high. Ongoing disease surveillance and epidemiological research will be critical in preparing for and combating future infectious disease outbreaks. The need for developing and improving vaccines will always be relevant. ■

INTERVIEW

"Revolutionizing Vacuum Technology in India: The 20 years Partnership Between Italvacuum and Vacuum Drying Technology"

We had the privilege of speaking with **Mr. Jayant Joshi, CEO of Vacuum Drying Technology India LLP,** about their long-standing partnership with Italvacuum, the growing need for vacuum solutions in India, and their future plans for the industry.



Jayant Joshi
CEO
Vacuum Drying Technology India LLP

Mr. Joshi, Could you elaborate on your partnership with Italvacuum and the need for a vacuum technology revolution in India?

The partnership with Italvacuum began in 2004, driven by the rising demand for advanced vacuum technology in India's pharmaceutical and chemical sectors. At the time, there was a clear need for high-performance, reliable vacuum systems to support the industry's rapid growth. Italvacuum, with over 80 years of expertise, was the perfect partner to introduce these cutting-edge solutions. This collaboration has allowed us to bring top-tier vacuum pumps and dryers to Indian manufacturers, helping them optimize their processes and stay competitive globally.

Could you highlight some key milestones in this partnership and provide insight into the market for vacuum pumps in India?

Over the years, we have reached several key milestones. Since 2004, we have installed over 700 Italvacuum pumps across India, serving industries ranging from pharmaceuticals to chemicals. Our products are widely used by Fortune 500 companies as well as smaller

Jayant Joshi and Mr. Ennio Batissa, symbolize the relationship between Italvacuum and VDTIL

Team VDTIL and Italvacuum with Vacuum Pump "Saurus 939"

manufacturers, which speaks to their versatility and value. The Indian market for vacuum pumps has grown steadily, reflecting the country's industrial expansion. As the demand for high-efficiency, sustainable technologies increases, Italvacuum's products have set a benchmark for quality and reliability.

What distinguishes Italvacuum's vacuum pumps from other products, and how do they benefit the Indian market?

Italvacuum's pumps stand out for their innovative design, energy efficiency, and environmental compliance. They are engineered to meet stringent international standards, ensuring durability and long-term performance. In India, where regulatory demands are becoming more stringent, these features have helped our clients improve productivity while reducing operational costs and environmental impact. Their ability to customize solutions based on specific production requirements gives Indian manufacturers a competitive edge.

How do clients perceive the quality and performance of Italvacuum products, and what has been their experience with after-sales service?

Our clients consistently praise Italvacuum products for their exceptional Service, reliability, and energy efficiency. The feedback has been especially positive regarding the pumps' ability to reduce downtime and maintenance costs, significantly improving production efficiency.

A key advantage is our comprehensive after-sales service, which includes onsite technical support and maintenance to ensure optimal system performance throughout the product lifecycle. Combined with our highly trained in-house technicians, this helps minimize downtime and prevent production loss.

What are your future plans, and what message do you have for Indian manufacturers seeking vacuum solutions?

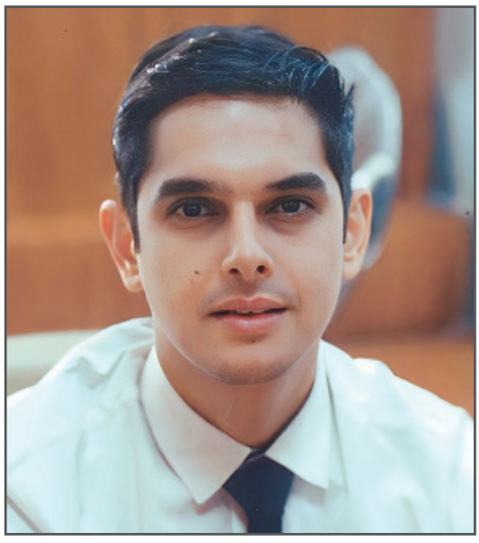
Looking ahead, we plan to expand our reach across India and into new industries that can benefit from Italvacuum's technology. As sustainability and efficiency become central to industrial operations, we are well-positioned to support Indian manufacturers in adopting advanced vacuum solutions. My message to them is simple: investing in the right vacuum technology can transform your business. With Italvacuum, you are choosing a partner that prioritizes innovation, quality, and long-term value.

The partnership between Vacuum Drying Technology India LLP and Italvacuum has played a pivotal role in revolutionizing vacuum technology in India's pharmaceutical and chemical industries. With a focus on innovation and client satisfaction, We are confident that journey will continue to shape the future of industrial processes in India. ■

Why Biologics are Important

Biologics are large, complex molecules derived from living organisms such as microbial or mammalian cells. They are unlike traditional small molecule drugs, which are chemically synthesized with simple structures.

Ishaan Bhardwaj, Senior Vice President, Anthem Biosciences emphasizes how biologics plays a role in global health and been essential in developing diagnostic tests. He also spoke about the emergence of biosimilars as a promising development in making biologic therapies more accessible and affordable.



Ishaan Bhardwaj
Senior Vice President
Anthem Biosciences

Biologics also include vaccines, stem cell therapies, gene therapies, tissues, whole blood, blood components, and cell therapies to name a few. One could fill a volume of encyclopedias with the underlying science, efficacy, regulatory and commercials of each of these vast therapeutic categories.

The impact biologics have had on the healthcare industry is obvious. By 2022 over a 100 antibody based therapeutics had been approved by the US Food and Drug Administration. In 2023 the top three pharmaceutical drugs by revenue were all biologics (Buntz, 2024). At number one Merck's Keytruda (pembrolizumab) which has indications in various cancers with USD 25 billion in sales. Despite sales decreasing significantly due to multiple biosimilars now available, AbbVie's Humira (adalimumab) for autoimmune disorders, still continues at number two with USD 14.4 billion. Easily the most famous weight-loss and diabetes pharmaceutical is at number three; Novo Nordisk's peptide semi-synthetic Ozempic (semaglutide) with USD 13.9 billion.

Biologics also played a crucial role in the 2019 COVID pandemic, particularly in the development of the Messenger RNA (mRNA) vaccines developed by Pfizer-BioNTech and Moderna. These vaccines use mRNA to instruct cells to produce a protein that triggers an immune response, providing protection against the virus.

The speed with which these vaccines were developed, tested, and distributed was unprecedented. This no doubt saved potentially millions of lives while removing the myth that biologics don't have the potential to respond rapidly to emerging global health threats. In addition, biologics have been essential in developing diagnostic tests. For instance, antibodies are used in many rapid diagnostic tests to detect the presence of viral antigens in patient samples, enabling quick and widespread testing, which was critical in controlling the spread of COVID-19.

The treatment of infectious diseases, both viral and bacterial, is another area where biologics have shown some potential. Monoclonal antibodies (MAbs) have been used to target viruses and prevent them from entering cells and target bacteria by tagging them allowing immune system to deal with them. These treatments can be particularly valuable for patients who have comorbidities and are at high risk of severe disease or those who cannot receive vaccines. In 2022, six mAbs targeting infectious diseases had been granted approval by the USFDA. The indications included the treatment of Ebola virus, prevention of respiratory syncytial virus (RSV) infection, prevention and treatment of anthrax infection caused by the bacterium Bacillus anthracis and infection and prevention of recurrence of the gram positive Clostridioides difficile bacteria.

Biologics have paved the way to more specific and effective therapies such as immunotherapy in cancer, which harnesses a patients' own immune system to fight cancer. Such treatments include monoclonal antibodies, checkpoint inhibitors, cytokines, vaccines, and adoptive cell transfer, most prominently in the form of hematopoietic stem cell transplants (HSCTs) and chimeric antigen receptor (CAR) T-cell therapies. This has attributed to the advancement of precision and personalized medicine (PPM), in which therapy selection is tailored to an individual.

However, manufacturing biologics is inherently more complex than traditional small-molecule drugs. The production of biologics begins with the expression of the protein of interest in cell-based systems such as Chinese Hamster Ovary (CHO), Escherichia coli, Pichia pastoris amongst others. This protein subsequently requires recovery and purification through multiple complex filtration and chromatography techniques. Each step in the process is intricate, from the careful selection and genetic manipulation of cells, which are then cultured under highly controlled conditions, to the isolation of the biologic from the cell culture while maintaining its structural integrity and function. Any slight deviation can affect the yield and quality of the biologic.

Biologics are held to stringent quality control measures to ensure their safety and efficacy. The manufacturing process must be highly consistent, as even minor variations can lead to significant differences in the final product. These measures include comprehensive analytical characterization methods to assess the product's structure, potency, purity, and biological activity, rigorous in-process controls and final product testing to ensure batch-to-batch consistency and use of aseptic techniques and sterile environments.

In addition, biologics and the living cells that produce them are particularly sensitive to environment and enzymatic action and therefore, require complex and thorough bioassays for batch release and stability assessments. Their sensitivity necessitates special handling, storage, and distribution processes to maintain their stability and efficacy. There is a greater chance that the biologics trigger an immune response when administered.

On the regulatory front, biologics are subject to rigorous regulatory scrutiny before they can be approved for use. In the U.S., a Biologics License Application (BLA) must be submitted to the U.S. Food and Drug Administration to gain approval for a biologic. This application includes extensive data from preclinical studies, clinical trials, and manufacturing processes to demonstrate the product's safety, efficacy, and quality. The BLA review process is more detailed and time-consuming than the New Drug Application (NDA) process for small molecules.

In the EU, companies submit an MAA to the European Medicines Agency (EMA), which undergoes a similar evaluation process. The EMA's Committee for Medicinal Products for Human Use (CHMP) assesses the application, and if approved, the biologic receives a marketing authorization valid across all EU member states. After approval, biologics are subject to ongoing monitoring to ensure long-term safety and effectiveness. Regulatory agencies require companies to report adverse events and may mandate additional studies to gather further data on the biologic's performance in the real world.

The complexity of manufacturing biologics significantly contributes to their high cost. The processes require sophisticated facilities, skilled personnel, and expensive raw materials, all of which drive up production costs. Additionally, the stringent regulatory requirements for quality control further increase expenses. These high costs present a potential barrier to patient access. While biologics can offer life-saving treatments, their price often makes them unaffordable for many patients and healthcare systems, particularly in low- and middle-income countries. The challenge lies in finding ways to reduce costs without compromising the quality or safety of these products, which is a key focus of ongoing research and innovation in the field.

The emergence of biosimilars is a promising development in making biologic therapies more accessible and affordable. Biosimilars are biologic products that are highly similar to already approved reference biologics, with no clinically meaningful differences in terms of safety, purity, or potency. They offer a cost-effective alternative to expensive biologics and have the potential to increase patient access to biologic therapies. However, it comes with regulatory and market hurdles that must be carefully navigated. Biosimilars must undergo comparative analytical studies, preclinical studies, and clinical trials to demonstrate their similarity to the reference product. In addition, for the FDA to designate a biosimilar as "interchangeable" with its reference product, meaning that it can be substituted for the reference biologic without the intervention of the prescribing healthcare provider, additional evidence is required, particularly data showing that switching between the biologic and the biosimilar does not lead to adverse outcomes. The complexity of manufacturing biosimilars means they are not as inexpensive as generic small-molecule drugs. Additionally, there may be market resistance from physicians and patients who are cautious about switching from a tried-and-true biologic to a biosimilar, despite regulatory assurances of similarity.

Advancements in genetic engineering and cell culture techniques, such as recombinant DNA (rDNA) technology, perfusion culture techniques, single-use bioreactors, de novo protein design, gene editing and CRISPR, gene amplification and stable cell lines, have revolutionized the production of biologics, leading to more efficient, scalable, and precise manufacturing processes. They have shortened development timelines, reduced costs, expanded the therapeutic possibilities and enabled more effective and personalized treatments.

Biologics are typically difficult to scale up from laboratory pre-clinical batches to large-scale commercial batches while maintaining product purity and batch-to-batch equivalence. This particular pain point can be eased with the help of Contract Development and Manufacturing Organizations (CDMOs) which have the capacity and technical know-how required to scale up. This includes bioreactors, purification systems, and filling and finishing lines that can produce biologics in the quantities required for clinical trials and commercial distribution. CDMOs ensure that the scale-up from lab to manufacturing scale is smooth and that the product retains its quality throughout the process.

CDMOs are specialized service providers in the biopharmaceutical industry that offer comprehensive support throughout the drug development and manufacturing lifecycle. These organizations provide pharmaceutical and biotechnology companies with the expertise, resources, and infrastructure needed to develop, manufacture, and bring biologic drugs to market. CDMOs play a critical role in enabling companies, especially those without in-house capabilities, to focus on core activities such as drug discovery and commercialization while outsourcing the complex and resource-intensive processes associated with biologics development and production.

In summary, biologics are playing an increasingly vital role in global health, offering new tools and strategies to combat pandemics, advance personalized medicine, and mitigate other pressing health challenges. However, realizing their full potential requires addressing challenges related to cost, accessibility, and infrastructure, particularly in resource-limited settings. ■

India's Pharmaceutical Industry – Pharmacy of the World

Over the years, India's pharmaceutical industry has made a significant mark for itself in the global market. It is estimated that India holds approximately 4% share in the global pharmaceutical economy and around 8% in the global API manufacturing industry. With low-value generic drugs constituting a large part of Indian pharmaceutical exports, India currently commands approximately 20% share in the global supply of generic medicines. Nearly 40% of generic drugs consumed by Americans are manufactured by Indian companies.

Shamsher Dewan, Senior Vice President & Group Head - Corporate Ratings, ICRA Limited emphasizes the Indian Pharma industry and how Indian companies have made a significant presence in the generics space.

Some of the leading pharmaceutical companies from India are ranked among the top-5 generic companies in many emerging markets in Africa, and Latin America among others. Today, India boasts of almost 25% of US-FDA approved plants globally and almost 44-48% of ANDAs approved by USFDA each year come from Indian companies. At USD 26.5 billion in FY2024, India's pharmaceutical exports have also grown at a healthy CAGR (%) of 6% over the past decade (i.e. FY2015-2024). It is estimated that nearly, 55% of exports are directed to developed markets in North America and the European Union, while emerging economies often known as semi-regulated markets contribute to the rest. Notably, India's pharmaceutical imports have been relatively low at USD 7.1 billion in FY2024. The majority of the imports are contributed by imports of intermediates (i.e. starting material for bulk drugs/APIs) and APIs. Overall, imports of formulation drugs are limited to relatively niche and complex drugs, which are often protected through patents.

From presence largely restricted to relatively plain vanilla oral solid drugs (OSDs) in the past, Indian companies are now proving their skills in most of the complex segments including complex therapy areas of inhalation, dermatology, advanced injectables, and even emerging areas of biosimilars. India's prominence at the global level has been aided by a combination of factors including its well-established competitive manufacturing prowess, availability of a skilled talent pool besides entrepreneurial commitment. While Indian companies have made a significant mark for themselves in the generics space, their success in the discovery and development of entirely new molecules to meet unmet medical needs has so far been dismal. Thus, the R&D achievements of Indian companies, largely comprise of development of generic formulations and APIs with innovation in areas of complex therapy areas, difficult-to-develop molecules, and differentiated drug delivery systems.

Besides proving its manufacturing capabilities, India has also been able to develop a conducive ecosystem for global innovators and start-up pharmaceutical and biotech companies to outsource their research work. Commonly, referred to as contract development and manufacturing operations (CDMO), companies, in this area, offer contract research and manufacturing services ranging right from early-stage drug identification and discovery process to large-scale manufacturing. Companies in this field differentiate themselves on their ability to commit significant capital

in setting up state-of-the-art infrastructure, attracting skilled manpower, and more importantly, ensuring stringent compliance with regard to intellectual property rights (IPR) norms for their clients.

The Indian pharmaceutical industry can be broadly classified into domestic formulations and pharmaceutical exports. The Indian domestic formulation industry can be categorised into two segments: chronic therapies and acute therapies. The rising prevalence of chronic diseases is expected to drive growth in the chronic segment over the medium to long term. A confluence of factors including changing lifestyle patterns, increasing life expectancy, expanding healthcare insurance coverage, and rising income levels are supported healthcare expenditure in India.

While over the past ten years, the domestic formulation industry has registered healthy growth, driven by a combination of volume growth, new product introduction, and price hikes, over the past 12-18 months, the volume growth has been somewhat subdued. This can be attributed to a confluence of factors including a high base (because of the Covid-19 pandemic), increased awareness towards hygiene resulting in lower water-borne diseases, and a steadily increasing share of combination dosages. In ICRA's view, the increasing focus on trade generics is also attributable as its share is not captured adequately in the various databases that publish industry sales.

The domestic formulation industry is also facing certain structural changes, which include greater focus by regulatory authorities to improve adherence to good manufacturing practices, gradual consolidation of distribution channels (including retail pharmacies and increasing sourcing by hospital chains), and the Government's continued focus on promoting cost-effective generic drugs. While focusing on stringent compliance to manufacturing practices will result in consolidation in the industry, consolidation of distribution challenge and increasing share of pure generics could pose pressure on margins of branded generic players over the medium-term.

Outside India, the United States of America (USA) is one of the most important markets for Indian pharmaceutical companies. As per ICRA's estimates, the USA contributes approximately 38% to the aggregate revenues of 13 leading pharmaceutical companies. Over the past five years (i.e. FY2020-24), the segment has witnessed a CAGR growth of 8.6%. The relatively lower growth can be attributed to limited opportunities to launch generic drugs, pricing pressure, and challenges faced by companies with respect to the issuance of warning letters and import alerts.

The number of warning letters and import alerts issued by the USFDA to Indian pharmaceutical manufacturing companies has increased in the past year. These have led to delays in product launches, translating into failure to supply penalties and entailing significant cost burden towards remedial measures like hiring consultants and consuming additional management bandwidth, thus impacting the profit margins. As a result of heightened scrutiny by the USFDA, regulatory risks persist.

Given the relatively challenging phase over the past few years in the US generics market, companies have been gradually altering their business strategies, which includes a) greater focus on complex therapy areas, b) selective phasing out less margin accretive products, especially in the oral solid dosage segments from their portfolio and c) optimisation of R&D investments. Some of the leading companies have also been trying to build a portfolio of specialty products, which offer relatively superior and stable earnings profile albeit comes at the risk of committing significant investments in acquiring such products during the development or pre-approval stage.

These factors coupled with changing disease patterns and advancements in clinical therapies are entailing companies to focus on segments like novel molecules (in areas of oncology, immunology, plasma therapy, and biologics), digital therapies, and consumer health (including nutrition). Notwithstanding the challenges brought about by the consolidation of distribution networks in the US, the outlook remains stable in the near term aided by continued focus on the adoption of generic drugs to contain healthcare costs. In addition, the US market has also been facing drug shortages in select categories, and servicing those white spaces is also likely to be a growth engine for generic companies. Over the medium term, the growth for generic companies in the U.S. will be driven by the upcoming patent cliff with an estimated US$ 120 billion

worth of drugs expected to go off-patent between CY2025-2030.

Apart from the US, Europe is another important market for Indian companies. Compared to the US, the performance of Indian companies in the European markets has been relatively stable albeit it generates lower profitability vis-à-vis in general. In the European market, revenue growth will be aided largely by the uptick in the base business (both branded and generics segment), new product launches (especially injectables), and incremental revenues from new tender wins (in countries such as Germany).

In terms of backward integration, although India has strong capabilities in manufacturing APIs and Bulk drugs, it continues to remain import-dependent for sourcing KSMs. In FY2024, India imported APIs and bulk drugs worth ~Rs. 377 billion, accounting for ~35% of its total API requirement, of which China accounted for ~70%. Moreover, dependence on Chinese imports of APIs for certain essential medicines is as high as 80-100%. Almost the entire requirement of certain fermentation-based APIs like ciprofloxacin and norfloxacin is sourced from China. The cost advantages of the Chinese API industry and the volatility in the prices of APIs have made domestic production of certain APIs unviable for Indian manufacturers, resulting in continued dependence on China. India has witnessed favourable traction in the production linked incentive (PLI) scheme launched by the Central Government for the bulk drugs industry. The scheme particularly focuses on select molecules such as Penicillin G and 7-ACA, which require sizeable investments and involve high energy consumption during the manufacturing process. ■

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Advanced Filtration

Filtration in the pharma/chemical/chemical industry is used to remove impurities from products and ensure they meet quality standards. Some time to separate the desired/ required product from two different mixture. Different types of filtration systems are used, depending on the product, the desired quality, and the manufacturing process.

M. H. Choudhary, Managing Director, Advanced Expertise Technology Pvt. Ltd emphasizes the different types of filtration systems used in pharmaceutical industry. He also spoke about the various filtration techniques to meet regulatory requirements.

Pharma/Chemical industries offer various filtration techniques with the respective filters to meet different requirements. The important types of filtrations used in the pharma/chemical industry are bag filtration, self-cleaning filtration and ultrafiltration.

These filtration techniques provide the pharma/chemical industry with efficient and reliable means of purifying and separating substances. They also contribute to maintaining product integrity and meeting regulatory requirements, ensuring the production of high-quality pharma/chemical products.

Bag Filtration

Bag filtration is a valuable filtration method widely employed in the pharma/chemical industry for the purification of fluids and air. It utilizes bags made of various types of fabric as the filter media. In liquid bag filtration, the fluid suspension passes through the bag, and the fabric's pores act as a filter, entrapping larger particles. Over time, the accumulation of oversized particles leads to the formation of a filter cake, which further enhances filtration by reducing the effective pore size.

Bag filtration can help in pharma/chemical applications where the removal of solid impurities or particles from liquids is necessary to achieve desired product quality. It is commonly used in processes such as pre-filtration of raw materials, clarification of solutions and removal of particulate matter during the production of pharma/ chemical formulations. Bag filtration helps maintain the cleanliness and purity of fluids, ensuring that the final pharma/chemical products meet stringent quality standards.

Self-Cleaning Filtration

Self-cleaning filtration is an advanced filtration method that offers automatic removal of accumulated contaminants from the filter membrane. There are different mechanisms used for self-cleaning filtration, including direct flushing, back flushing and automatic self-cleaning.

It is particularly important in pharma/chemical processes where continuous filtration is required without frequent interruptions for manual cleaning or replacement of filter media. It helps maintain consistent filtration performance and reduces the downtime associated with filter maintenance. Self-cleaning filtration finds application in various pharma/chemical processes, including the filtration of process fluids, solvents, suspensions and formulations. It is commonly used in pharma/chemical manufacturing operations such as active pharma/chemical ingredient (API) production, formulation processing and sterile filtration of pharma/chemical preparations.

Ultrafiltration

Ultrafiltration is a highly significant filtration technique extensively employed in the pharma/chemical industry. It operates through pressure-driven transport, where the suspension is passed across a membrane. This process is utilized both in laboratory settings and on an industrial scale.

This process plays an important role in pharma/chemical applications where the separation and concentration of macromolecules are required. It is commonly used for the purification of proteins, enzymes, antibodies and other biomolecules. Ultrafiltration helps remove contaminants such as aggregates, impurities and smaller molecules while retaining the desired macromolecules based on their size or molecular weight. ■

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Pharmacy of the world

The Indian pharmaceutical industry, a global powerhouse in drug manufacturing and distribution, continues to evolve amidst a rapidly shifting landscape. Known for its robust production capabilities, cost-effective solutions, and significant role in global supply chains, India's pharma sector is at a pivotal juncture in 2024, marked by both opportunities and challenges.

Tina Nitin Parikh, Practice Leader, Pharma & Lifesciences, PINC Insurance emphasizes the recent development, challenges and trends in the Pharma sector. She also spoke about the Perspective of Insurance towards Pharma Industry in India.

A Global Player in Pharmaceuticals

India has long been a critical player in the global pharmaceutical market. The country is often referred to as the "pharmacy of the world" due to its extensive production of generic drugs and active pharmaceutical ingredients (APIs). Indian pharmaceutical companies supply a substantial portion of the world's generics, particularly to developing countries, and have been instrumental in making affordable medicines accessible globally.

Recent Developments and Trends

Regulatory Changes and Compliance

India's pharmaceutical industry has faced significant regulatory changes over the past few years. The Central Drugs Standard Control Organization (CDSCO) has implemented stricter guidelines to enhance drug safety and efficacy. In 2024, ongoing reforms focus on improving compliance with international standards, particularly for exports to the U.S. and European markets. Companies are investing heavily in quality control and regulatory affairs to meet these heightened requirements.

Focus on Innovation and R&D

The Indian pharmaceutical sector is increasingly emphasizing research and development (R&D). Traditionally known for its strength in generics, the industry is now investing in innovative drug development and biotechnology. Indian companies are exploring novel drug delivery systems, biosimilars, and personalized medicine. The government's push for the National Biopharma Mission and the establishment of biotech parks have provided crucial support for this transformation.

Increased Mergers and Acquisitions

The Indian pharmaceutical landscape has seen a surge in mergers and acquisitions (M&As) as companies seek to consolidate resources, expand portfolios, and enter new markets. This trend is driven by the need for economies of scale and the desire to enhance competitive positioning in a global market. High-profile deals and strategic partnerships are reshaping the industry, enabling firms to access new technologies and capabilities.

Expansion into Emerging Markets

Indian pharmaceutical companies are increasingly targeting emerging markets in Africa, Latin America, and Southeast Asia. These regions offer significant growth potential due to rising healthcare demands and expanding healthcare infrastructure. Companies are tailoring their strategies to local needs and regulatory environments, which involves building partnerships with local stakeholders and navigating diverse regulatory landscapes.

Emphasis on Digital Transformation

Digital transformation is becoming a key driver of efficiency and innovation in the pharmaceutical industry.

Companies are adopting advanced technologies such as artificial intelligence (AI) and machine learning (ML) for drug discovery, clinical trials, and supply chain management. Additionally, digital health platforms and telemedicine are gaining traction, reflecting broader trends in healthcare delivery.

Challenges and Areas of Concern

Intellectual Property Issues

Intellectual property (IP) rights remain a contentious issue, particularly concerning patents and proprietary technologies. Indian pharmaceutical firms face challenges related to IP enforcement and protection, both domestically and internationally. Balancing the need for innovation with the protection of intellectual property is an ongoing concern for the industry.

2. Price Control and Policy Regulations

Price control regulations imposed by the Indian government to make medicines affordable have sparked debate within the industry. While these regulations aim to ensure accessibility, they can impact profitability and incentivize companies to invest in high-risk, high-reward research. The industry advocates for a balanced approach that supports both affordable healthcare and sustainable business practices.

Supply Chain Disruptions

Global supply chains have been disrupted by various factors, including geopolitical tensions, pandemics, and natural disasters. The Indian pharmaceutical industry, which relies on a complex network of suppliers and logistics, faces challenges in maintaining consistent production and distribution. Companies are working to build more resilient supply chains through diversification and strategic sourcing.

Perspective of Insurance towards Pharma Industry in India

The relationship between the insurance sector and the pharmaceutical industry in India is integral and multifaceted, with each influencing the other in significant ways. As the pharmaceutical industry continues to grow and evolve, insurance companies must navigate a range of challenges and opportunities that impact their operations and strategic decisions. Here's an in-depth look at how insurance companies view and interact with the pharmaceutical sector in India.

Key Areas of Interaction

Coverage and Risk Management

Insurance companies play a crucial role in managing the risks associated with the pharmaceutical industry. These risks include product liability, regulatory compliance, and supply chain disruptions.

- **Product Liability Insurance:** Pharmaceutical firms require robust product liability coverage to protect against claims related to drug safety and efficacy. This insurance is critical, given the high stakes involved in drug development and the potential for adverse effects on patients.

- **Regulatory Compliance:** As the pharmaceutical industry faces stringent regulatory standards, insurance companies need to understand and adapt to the evolving compliance landscape. Coverage may include protection against fines and legal costs associated with regulatory breaches.

- **Supply Chain Risks:** With global supply chains increasingly complex, insurance companies must account for risks related to supply chain interruptions. This includes coverage for disruptions caused by geopolitical events, natural disasters, or logistical issues.

Impact of Drug Pricing and Reimbursement Policies

Insurance companies in India are directly affected by drug pricing and reimbursement policies, which can influence their operational and financial strategies.

- **Drug Pricing Controls:** The Indian government's price control measures, which aim to keep medicines affordable, can impact insurers' cost structures. Lower drug prices can reduce the financial burden on insurance providers, but stringent controls might also lead to shortages or limitations in drug availability.

- **Reimbursement Policies:** The reimbursement landscape is evolving, with insurers increasingly focusing on value-based care models. This shift impacts how pharmaceutical companies price and market their products. Insurers are interested in cost-effectiveness and clinical outcomes, which can influence drug coverage decisions and negotiation strategies.

Rising Healthcare Costs and Insurance Premiums

As the pharmaceutical industry innovates and develops new treatments, healthcare costs can rise, affecting insurance premiums and coverage.

- **High-Cost Drugs:** The introduction of advanced therapies, such as biologics and personalized medicine, often comes with high price tags. Insurers need to assess the cost-benefit ratio of covering such treatments, which can lead to higher premiums for policyholders.
- **Healthcare Inflation:** Rising drug costs contribute to overall healthcare inflation, which in turn affects insurance premiums. Insurers must balance the need to provide comprehensive coverage with the financial sustainability of their policies.

Investment Opportunities and Collaborations

Insurance companies are also exploring investment opportunities within the pharmaceutical sector.

- **Equity Investments:** Some insurers invest directly in pharmaceutical companies or related ventures as part of their investment portfolios. These investments can yield significant returns, given the growth potential of the pharma industry.
- **Collaborations:** Partnerships between insurers and pharmaceutical companies can lead to innovative solutions in healthcare delivery. For example, collaborations on patient assistance programs or health management initiatives can improve patient outcomes and reduce overall costs.

Challenges and Future Outlook

Regulatory and Compliance Risks

Navigating the complex regulatory environment poses challenges for both insurers and pharmaceutical companies. Insurers must stay informed about changes in regulations that affect drug approval, pricing, and safety standards. Effective risk management strategies are crucial to mitigate potential financial impacts.

Evolving Healthcare Models

The shift towards value-based healthcare models is reshaping how insurance companies interact with the pharmaceutical industry. Insurers are increasingly focusing on outcomes-based contracts and performance-based reimbursement, which require pharmaceutical companies to demonstrate the effectiveness and cost-efficiency of their products.

Technological Advancements

Advancements in technology, including digital health and telemedicine, are transforming the healthcare landscape. Insurers must adapt to these changes by integrating new technologies into their coverage models and exploring innovative ways to manage risks and costs.

Conclusion

The insurance industry's perspective on the pharmaceutical sector in India is shaped by a complex interplay of risk management, cost control, and strategic investment. As the pharmaceutical industry continues to innovate and expand, insurance companies must adapt to new challenges and opportunities. By understanding and anticipating the evolving dynamics of the pharma sector, insurers can better manage risks, optimize coverage solutions, and contribute to the overall efficiency and effectiveness of healthcare delivery in India.

The Indian pharmaceutical industry stands at a crossroads in 2024, characterized by dynamic growth and transformation. As it navigates the complexities of regulatory compliance, innovation, and global market demands, the sector remains a crucial contributor to global healthcare. The industry's ability to adapt to emerging trends and address ongoing challenges will determine its future trajectory and continued prominence on the world stage.

In this evolving landscape, India's pharmaceutical sector exemplifies resilience and adaptability, positioning itself as a key player in shaping the future of global healthcare. ■

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Trends in Pharma 4.0: Addressing the Unspoken Challenges of Business Growth

The Indian pharmaceutical industry has long been a global healthcare powerhouse, renowned for producing affordable, high-quality medicines. Yet, this success has not come without challenges. Issues of quality and intellectual property disputes have occasionally jeopardized its reputation.

Ashutosh Parasnis- Founder, NewBox Consulting emphasizes the latest trends in Pharma 4.0, and shares an actionable methodology to navigate this new era of data-driven manufacturing and benefit from digital transformation.

The healthcare landscape is witnessing a significant and rapid shift toward personalization, with a laser-like focus on outcomes and value. Pharma companies cannot afford to ignore these market forces.

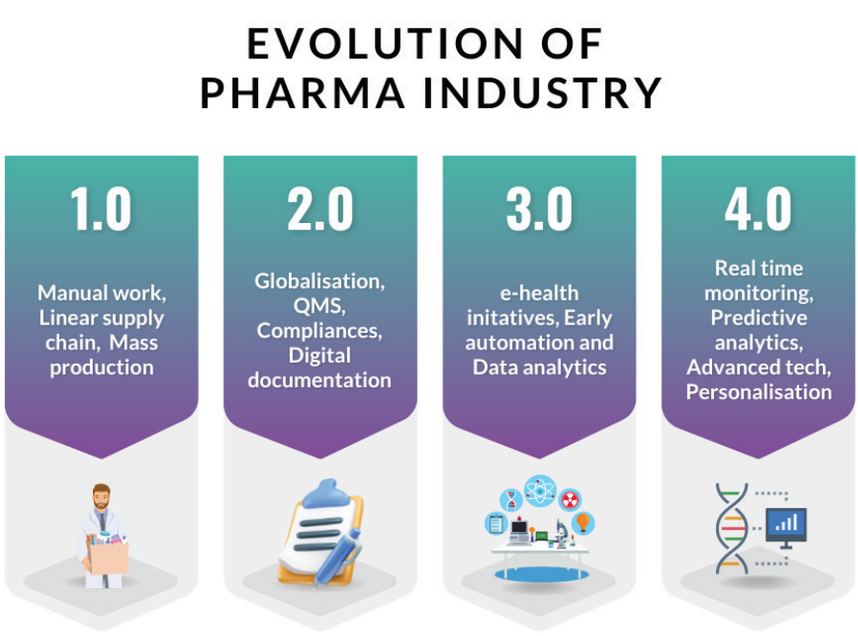
They must reassess how these forces impact their core pillars: cost, speed, quality, compliance, and competitiveness which ultimately determine the financial performance.

Meanwhile, the emergence of Industry 4.0 around the mid-2010s, heralded a new era of smart, automated, and data-driven manufacturing. This seismic shift laid the groundwork for what we now call Pharma 4.0. These shifts have been significant enough for the government to focus on ensuring the adherence of companies to global quality norms and allocating budgets for skilling people in Industry 4.0.

The industry stands at a pivotal juncture, where the need for adaptation is not just important—it's imperative. The old adage, "What got you here won't get you there," has never been more relevant.

The Essence of Pharma 4.0

Pharma 4.0 isn't just a technological leap; it's the



culmination of centuries of evolution within the pharmaceutical industry, transitioning from manual, smallscale production to a highly automated, data-driven, and patient-centric model. It represents how technology can help discover and develop targeted drugs faster, reduce manufacturing costs while maintaining flexibility, assure unwavering quality, optimize supply chains, and ensure the industry remains responsive to a rapidly changing world.

Yet, most companies are still grappling with the earlier stages of this evolution, not even achieving Pharma 3.0 maturity. The key takeaway for growth-oriented businesses is to not get lost in nomenclature but to ensure they stay ahead.

Emerging Trends Shaping Pharma 4.0

When discussing Pharma 4.0 trends, the focus often gravitates toward technology. While some understand it, many find it complex and overwhelming, particularly smaller businesses that may not even be aware of the term. Here's a look at two dimensions of these trends.

The Research World Technological Trend

Technology is often the star of the show.

Basic technologies such as Sensors, Automation, Connectivity and Basic Data Analysis have delivered reduced costs, increased revenue and waste reduction.

Common applications in manufacturing include managing records like EMRs, Batch Records, Compliance Reports, Optimizing Machine Productivity, Quality Management, and Supply Chain Traceability. Other applications include lab automation, clinical trials, distribution etc.

On the horizon are advanced technologies such as Artificial Intelligence (AI), Machine Learning (ML), Robotics, Cloud Computing, 3D Printing, and Digital Twins.

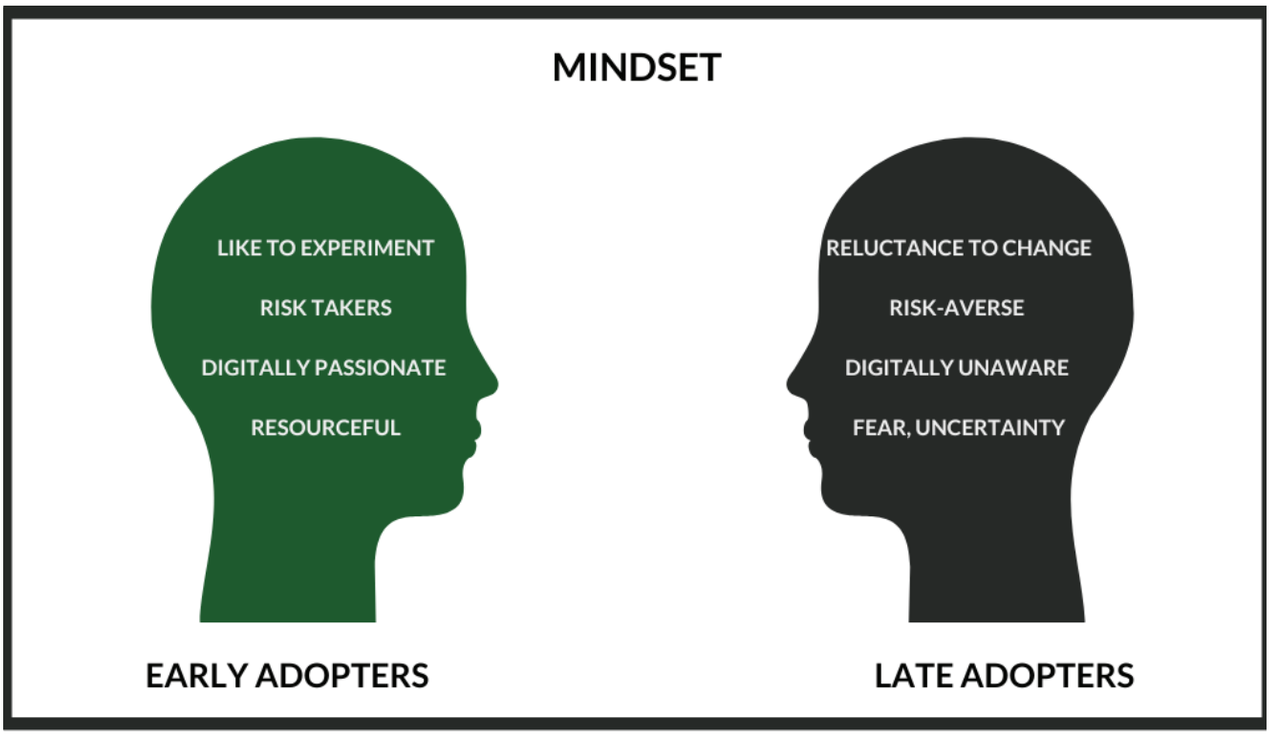
Together, these technologies not just help in understanding what is happening but in anticipating what may happen opening doors to more opportunities.

However, access to an appropriate technology, its cost-effectiveness and people's capability to use it effectively matters a lot in business.

Unless everything comes together in a meaningful manner, businesses will not adopt them.

The Real World Business Trend

The industry thus faces several hurdles: understanding the technology, developing industry-specific use cases, and overcoming issues like the lack of established



policies, digital infrastructure, financial and talent constraints, and data security concerns. Transitioning from traditional processes to digital ones demands a significant mindset shift, which is neither quick nor easy.

Mindset is the biggest challenge that organisations face:

For Pharma 4.0 to be widely adopted, businesses need a clear vision to overcome these obstacles. The journey toward digital business transformation is largely a function of mindset. Innovators and early adopters, driven by growth and a thirst for innovation, spearhead this change. These trailblazers are often a small group, but they create differentiation and value that fuel their growth. On the other hand, late adopters, who prioritize risk avoidance and do not prepare themselves for upcoming change, find themselves in a constant game of catch-up. By the time they adopt, the growth opportunity is lost as early adopters capture the market.

How Companies are Fast-Tracking Pharma 4.0 for Early Gains with Minimal Risk.

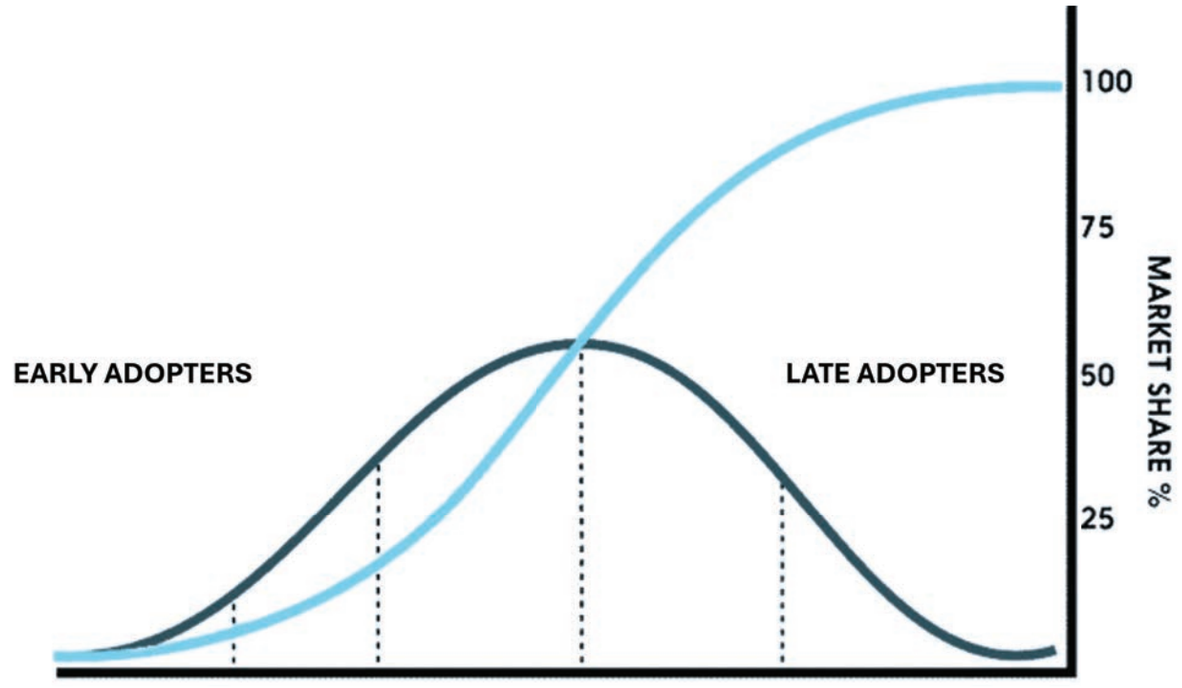
Here's the trend we see among companies successfully growing with Pharma 4.0.

- Workforce development, including leadership on business, tech and regulations.
- Collaborating with technology partners, consulting firms and startups as needed. (to identify and implement meaningful innovation)
- Phased implementation with small projects and small wins. (generating real business benefits)

This trend is most relevant to Pharma companies. It allows them to move quickly while protecting their interests and mitigating risks.

Achieving the needed organisational mindset becomes easier. The focus is more on business leveraging technology and not technology driving your business. Successful adopters are thus well-placed to dominate the market as compared to those who prefer the wait-and-watch game.

For example, a company might start with an immediate project to improve quality through technology, reducing costs and enhancing brand recognition. These short-term wins help the organization pace its transformation confidently. At the same time, it can define long-term objectives like accelerating drug discovery through AI/ML or digital twins or positioning itself as a dominant player in the export market.



Recommendations for the Indian Pharma Industry

While large Indian pharmaceutical companies like Cipla, Dr. Reddy's, Sun Pharma, and Emcure have begun embracing Pharma 4.0, the overall adoption remains in its infancy. Globally, only 15-20% of companies have made significant progress, with North America and Europe leading the charge, driven by regulatory pressures, a focus on innovation, and access to advanced technology infrastructure. China and India, both aspiring global players, are adopting these practices more slowly while emerging markets lag even further behind.

According to our research, successful implementers of technology follow a series of steps that require time but yield a healthy compound annual growth rate (CAGR) year after year. In contrast, those who rush through or skip these steps create an illusion of speed but rarely achieve satisfying results.

5 steps to adopt Pharma 4.0 without breaking the bank or losing momentum in their current business:

Pause and Reflect

Business leaders should dedicate quality time to understanding the changes impacting their business. This reflection is critical to developing a clear, actionable vision for the future.

Prioritize People

Invest in skilling your entire team to navigate new business and technological dynamics. Communicate the need for change clearly and effectively. This approach preserves existing talent and helps address the industry's talent shortage.

Focus on Meaningful Improvement

Learn and deploy problem-solving and innovation techniques to identify which initiatives will make sense for your specific business. This ensures allocation of resources where they can have the most significant impact.

Adopt Practical Technology

Don't get bogged down by complex tech jargon. Seek assistance to understand and implement simple, cost-effective solutions. You need to begin with an understanding of smart sensors, basic automation, and data analysis methods that can drive immediate benefits in the initiatives identified above.

Develop a Strategic Roadmap

As you gather suggestions and ideas, put a process in place to evaluate, prioritize, and align them with your business needs. It's unrealistic to execute everything in one year, but a well-defined roadmap will help you stay on track and monitor progress effectively.

In Conclusion

This straightforward approach offers a twofold advantage. It provides an agile, cost-effective pathway to kickstart your Pharma 4.0 journey while simultaneously driving both business and workforce growth. By cultivating a forward-thinking team adept at leveraging technology, your business will not only navigate the anxiety of digitization but also carve out a position as a global leader in the Pharma 4.0 revolution. ■

Author

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Pharmacovigilance and Drug Safety: Evolution, Challenges and Future

The word 'Pharmakon' in Greek means 'Drug' & 'Vigilare' in Latin means "To keep watch awake or alert'. Pharmacovigilance is noble and important clinical science with an end objective of rational and safe use of medicines. It intends to educate and share information with patients for informed decisions and take appropriate actions when required.

Dr. Prabhu Kasture (MD, DPH), Director Medical Services & Pharmacovigilance, Blue Cross Laboratories Pvt Ltd shares insights about the evolution of Pharmacovigilance and its challenges. He also spoke about the future of pharmacovigilance in India.

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Director Medical Services & Pharmacovigilance,
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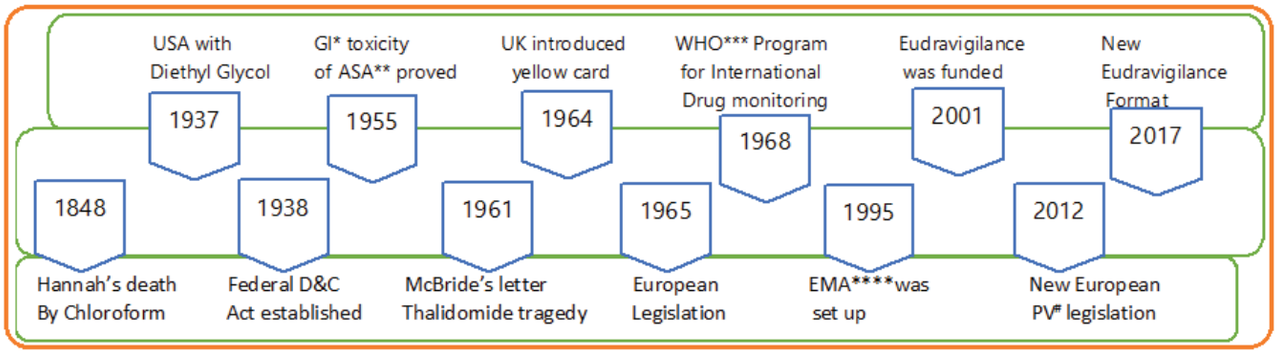
Adverse drug reaction (ADR) is one of the known leading cause of death, thus highlighting the need to monitor safety aspect of a drug available for use throughout its life cycle & thus making it necessary to protect the public health by promoting safer drug therapy.

Pharmacovigilance is defined by the World Health Organization (WHO) as 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem' & it's of paramount importance for doctors and patients to have enough information to make an informed decision while choosing medicine for treatment.

The history of pharmacovigilance is more than 170 years, although it wasn't termed until 1961. Post the Thalidomide disaster the WHO in 1968 took cognizance on the safety issues related to the consumption of drugs and there by established the program of pharmacovigilance for international drug monitoring.

In India, this program is still at the dawning stage and require concerted efforts from all the stakeholders. Pharmacovigilance in India was initiated in 1986 with a formal adverse drug reaction (ADR) monitoring system, under the supervision of the Drug Controller of India. In 1998, India had joined the World Health Organization (WHO) for drug monitoring. The National Programme of Pharmacovigilance was launched in 2005 and later



Historical evolution of Pharmacovigilance.* GI: Gastrointestinal **ASA: acetylsalicylic acid; ***WHO: World Health Organization; ****EMA: European Medicines Agency #PV: Pharmacovigilance

renamed to Pharmacovigilance Program of India (PvPI) in 2010. Currently, the PvPI is implemented through the National Coordination Centre at Ghaziabad under the aegis of Indian Pharmacopoeia Commission (IPC). Materiovigilance for medical devices has been initiated since 2015.

Numerous challenges have prevented the successful implementation of PV program in India. Lack of awareness, regarding the occurrence of adverse reactions with the medicines amongst the general population and lesser participation from the healthcare professionals have led to underreporting.

The knowledge, attitude and practice of PV is lacking even amongst the health care professionals. Half of the HCPs are not aware of PvPI and out of those aware, two-thirds of HCPs are not aware from where to obtain an ADR reporting form contributing to lesser reporting of spontaneous adverse cases.

The unprecedented pandemic that the world witnessed in 2020 highlighted the importance of robust pharmacovigilance systems during the mass vaccination campaigns and numerous repurposed drugs for covid treatment which left many adverse events go unreported. Thus, the Central Drugs Standard Control Organization (CDSCO) continued to enhance the PvPI by integrating more advanced technologies and expanding its network of institutions and stakeholders in pharmacovigilance.

The emphasis has been on strengthening the data management systems, improving transparency, and fostering collaborations with professional & international bodies for better global harmonization. A strong public private partnership for providing quality training to all the stakeholders and regular monitoring of program by the regulatory authority can help improve the implementation of PV program in India.

Challenges

- **Scant Resources:** Limited resources of finances and human resources pose a significant challenge. We have often struggled to allocate sufficient funding and trained personnel to pharmacovigilance activities, hindering their ability to establish comprehensive monitoring systems.

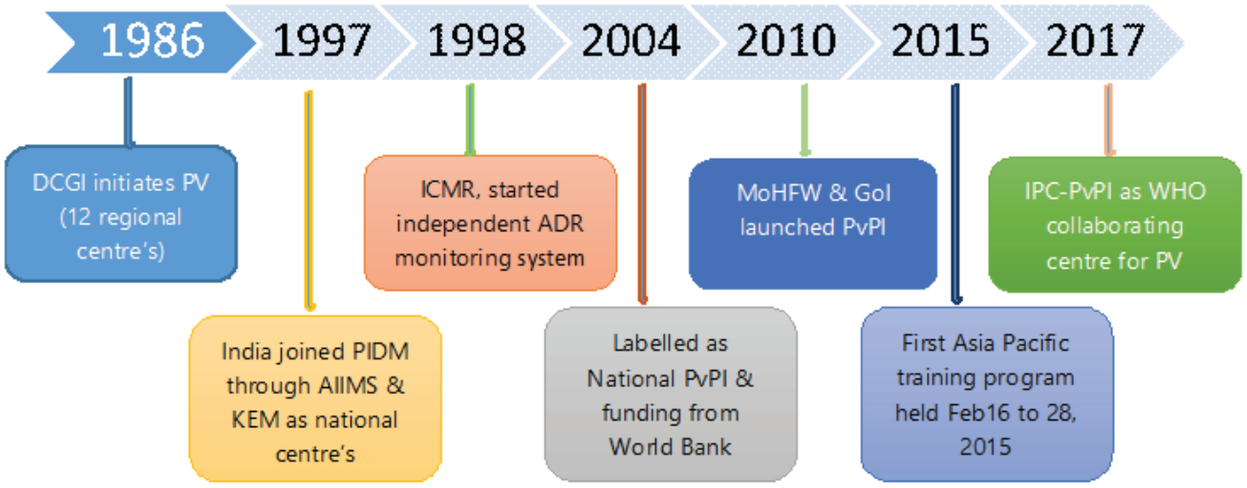
- **Poor Infrastructure:** Inadequate healthcare infrastructure, especially in rural areas, restricts the seamless flow of information.

- **Data Quality and Reporting Culture:** Inaccurate or incomplete reporting, coupled with a lack of reporting culture, affects the reliability of the collected data, making it challenging to derive meaningful insights.

- **Integration of Traditiona l Medicine:** India's rich tradition of alternative medicine, including Ayurveda, Unani, and Siddha, adds a layer of complexity to pharmacovigilance. Integrating these traditional practices with conventional pharmacovigilance systems is challenging but essential for comprehensive safety monitoring.

Drivers to overcome these challenges

- Raising awareness and education: There is a need to raise awareness and education



DCGI: Drugs Controller General of India; ICMR: Indian council of medical research; PIDM: Program for international drug monitoring; MoHFW: Ministry of health & family welfare;IPC: Indian pharmacopoeia commission; PvPI: Pharmacovigilance program of India; WHO: World Health Organization

about pharmacovigilance among healthcare professionals and the general public in India. Training programs through partnerships, information education communication (IEC) campaigns, wiser dissemination of pertinent information through social media and influencers.

- **Promoting collaboration and partnerships:** Collaboration between the various stakeholders like governments, international organizations, the pharmaceutical industry, academia and professional bodies is essential & can facilitate better pharmacovigilance practices

- **Advancements in Technology:** The digital revolution shall help streamline the collection and analysis of adverse event through electronic health records (EHRs) thus enhancing the efficiency of pharmacovigilance practices, making all the stakeholders more accessible and responsive. Further AI/ML shall augment the quality of data ingestion and enhance the reporting.

- **Regulatory Reforms**: strengthening regulations and enforcing compliance standards ensure that pharmacovigilance becomes an integral part of the healthcare system.

The future of pharmacovigilance in India looks promising and dynamic, with several key trends and developments shaping its evolution:-

- **Regulatory Advancements**: The Indian regulatory landscape for pharmacovigilance is becoming increasingly sophisticated. The Central Drugs Standard Control Organization (CDSCO) is working towards aligning with international standards and enhancing regulatory frameworks to improve drug safety monitoring.

- **Integration of Technology**: The use of technology, including artificial intelligence and machine learning, is expected to play a significant role in pharmacovigilance. These technologies can help in analyzing large datasets, predicting adverse drug reactions, and improving signal detection.

- **Strengthening Data Collection and Reporting:** Efforts are being made to improve the quality and consistency of data collection and reporting mechanisms. This includes the adoption of electronic reporting systems and better training for healthcare professionals and patients on reporting adverse drug reactions.

- **Public Awareness and Education**: Increasing awareness among healthcare professionals and the public about the importance of pharmacovigilance is crucial. Educational initiatives and training programs are likely to expand, fostering a culture of safety and vigilance.

- **Collaborations and Global Integration:** India is

expected to further integrate its pharmacovigilance practices with global standards. Collaborations with international organizations and participation in global pharmacovigilance networks will enhance the country's ability to monitor and respond to drug safety issues effectively.

- **Patient-Centric Approaches:** There will likely be a greater focus on patient-centric approaches, involving patients more directly in the reporting and monitoring of adverse drug reactions. Patient engagement can improve the quality of data and the overall effectiveness of pharmacovigilance efforts.

- **Improved Risk Management:** Enhanced risk management strategies, including more sophisticated risk assessment and mitigation plans, will become more prevalent. This will help in better managing the risks associated with new and existing medications.

Current and Future Directions

Overall, the future of pharmacovigilance in India is geared towards greater efficiency, accuracy, and global integration, aiming to ensure the safety and well-being of patients through robust and innovative monitoring systems. The ongoing development of digital tools and databases, along with increased awareness and training among healthcare professionals, is likely to drive further improvements in pharmacovigilance practices in India. ■

Biosecure Act accelerated the need for supply chain resilience: Jonathan Hunt

Jonathan Hunt, MD and CEO, Syngene International

Regarding Statement on Biosecure, Jonathan Hunt MD and CEO, Syngene International Ltd stated that the recent news in the USA has accelerated the need for supply chain resilience, which is expected to be a long-term strategic shift. The change in the Biosecure Act around the timeline of implementation has lessened the urgency with which they are looking for alternatives, but it hasn't changed the direction of travel.

"We have been observing a steady change since the pandemic, where global pharma companies are increasingly looking to India and Southeast Asia as alternative supply chain destinations. We see this as a positive development. Other CROs and CDMOs outside of China are also observing the same shift -- Pharma companies are now exploring new partnerships among multiple suppliers to evaluate capabilities and service quality. India boasts of a significant pool of skilled scientists, researchers and technicians, with a high output of STEM graduates annually. Additionally, India's adoption of advanced technologies, such as digitization and automation, enhances manufacturing efficiency and quality, instilling confidence in global pharma companies, and the numerous US FDA-approved facilities here underscore the commitment to meeting global quality standards, stated Jonathan Hunt.

Jonathan Hunt added that the Indian Government has been supportive in fostering a conducive environment for the sector, introducing various initiatives to promote research, development and innovation. This includes incentives and policies that encourage local manufacturing, reduce dependency on imports, and foster collaboration between the government and the private sector. It is good to see the national initiatives being embedded by the States as well, like the Biotechnology Policy 2024-2029 recently announced by the Karnataka Government; the Telangana Government has also made commitments like the expansion of existing R&D clusters and the establishment of integrated greenfield pharma villages. Other states like Haryana, Odisha, and Gujarat have also announced various incentives under their biotechnology policies, stated Jonathan Hunt.

Jonathan Hunt added, "The quality of science is perhaps the biggest differentiator for an outsourcing partner. At Syngene, our growth is built on our reputation for high quality standards and the depth of our capabilities to drive scientific innovation from discovery right through to commercial supply, which puts us in a strong position. These aspects have led to us building strong partnerships with 11 of the top 15 pharmaceutical companies in the world, including GSK, Zoetis and Merck KGaA, Amgen, Baxter and Bristol-Myers Squibb."

"One significant area that we are offering to our clients is the resilience of their entire manufacturing supply chains. We have led the industry in India in introducing a China-independent supply chain, whereby the entire manufacturing of a potential drug is done without resources from China-based suppliers. This approach helps mitigate risks associated with overreliance on China. More generally, we focus on evaluating all supply partners to ensure lower risks and greater resiliency. This direction in the industry is being adopted by big pharma and we are empowering our biotech partners to take the same robust approach," added Hunt.

The company continue to remain focused on our strategy, continue to deliver growth, gain market share relative to many of our closest competitors, invest in new capabilities, clear multiple client and regulatory audits, and position ourselves well for the future." ■

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UPCOMING ISSUE - OCTOBER 2024

PBW-QA & QC: Lab & Analytical Solutions

Quality Assurance & Quality Control is of more importance for pharma manufacturers who rely on lab & analytical technologies to ensure the safety & compliance of products before these reach the market & to the final consumers. QA and QC is also crucial for effective quality management and continuous improvement.

The October edition of **Pharma Bio World (PBW)** on the theme of "Quality Assurance & Quality Control" will have compilation of articles authored by subject matter specialists in this domain.

The magazine will carry regular updates on the industry through Interviews, Business News & Feature Articles.

Send Editorial submissions to editorial@jasubhai.com

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Website: www.jasubhaimedia.com

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EVENTS

DOMESTIC

Bio Pharma and Lab Analytix World Expo 2026

Dates: 3-6 February, 2026

Venue: Bombay Exhibition Centre, Goregoan East, Mumbai, India

Details: The Bio Pharma and Lab Analytix World Expo 2026 will bring together the stakeholders and leaders for the pharma industry, which will focus on emerging trends and technologies.

Contact: 022-40373636
Email: sales@jasubhai.com
Website: www.chemtech-online.com

International Conference on Pharmaceutical Chemistry (ICPC)

Dates: 6th October 2024

Venue: Trivandrum, India

Details: ICPC-24 will create a global platform to researches, scientists, academicians, policymakers, industry experts to share experiences, discuss research findings and acquire and the desired knowledge in the subject from around the world with many networking opportunities.

Contact: 9677007228
Email: info@sfe.net.in
Website: https://www.sfe.net.in/

World Congress on Advanced Pharmacy and Clinical Research (WCAPCR)

Dates: 5th October, 2024

Venue: Delhi, India

Details: WCAPCR-24 will create a global platform to researches, scientists, academicians, policymakers, industry experts to share experiences, discuss research findings and acquire and the desired knowledge in the subject from around the world with many networking opportunities.

Contact: 9677007228
Email: info@sfe.net.in
Website: www.sfe.net.in

World Pharma IP Conclave

Dates: 3-4th October, 2024

Venue: Sahara Star , Sahara Hospitality Limited, Opp Domestic Airport, Mumbai

Details: Step into the spotlight of intellectual property dialogue of the pharmaceutical realm at the “World Pharma IP Conclave” by Durva Media Services. An exclusive event to convene India’s Top 100 Pharma IP minds for two days of unparalleled insights into pharmaceutical intellectual property rights global regulations and interactive sessions with leading law firms.

Contact: 99303 07433
Email: dk@durvamedia.com
Website: worldpharmaip.com

The Pharma India Expo 2024

Dates: 24-25-26th October 2024
Venue: Hitex Exhibition Center, Hyderabad, India

Details: Pharma India Expo - An International Exhibition & Conference on Pharma and Healthcare Technologies focusing on the Future of the Pharma & Healthcare Industries transitioning to a fully digitized industry worldwide. Professionals from across the globe will converge to share their knowledge, and experience in creating future assets using cutting edge technologies. This international event will be a focused and dedicated platform for professionals from all the major industries including Pharma, IT, Healthcare, & Biotech Start-ups to discuss, and share knowledge, expertise and experience.

Contact: 8448193089
Email: milan@ies-india.com
Website: https://pharmaindiaexpo.com/

INTERNATIONAL

Executive Decision Making for Pharma & Biotech 2024

Dates: 8 - 10 October 2024

Venue: Royal Sonesta Boston, Cambridge, USA

Details: Executive Decision Making, portfolio prioritization, agile capacity management, resource allocation, risk mitigation, and overall strategic decision-making are becoming increasingly difficult in today's ever-changing pharma R&D landscape. Days of high-level content, interactive discussions and networking, breakout roundtables, 1:1 meetings, and much more. Attendees will leave with new tools and organizational strategies to improve strategic decision-making, optimize portfolio prioritization and resource planning, and drive value and resilience.

Contact: (+1) 781-972-1343
Email: chi@healthtech.com
Website: www.executivedecisionmaking.com

SCOPE Europe - Summit for Clinical Operations Executives 2024

Dates: 29 - 30 Oct 2024

Venue: InterContinental Barcelona, an IHG Hotel, Barcelona, Spain

Details: This event brings together leaders from large, mid-sized, and small pharma, specialty pharma, biotech, CROs, vendor companies, and academic research centers who come together to share best practices and discuss the new era of decentralized, analytics-driven and patient-centric trials. The event features four conference tracks, shared plenary keynotes, interactive panels, networking, and tapas, of course. Topics to be discussed include the digitalization of trials, decentralized/hybrid trial operations (DCTs), protocol optimization, global site selection, feasibility, study start-up, patient engagement, and more.

Contact: +1 781.972.5418
Email: mdolen@healthtech.com
Website: www.scopesummiteurope.com

International conference on Pharmacy, General drug categories and Drug action

Dates: 8-9th October 2024

Venue: Lima, Peru

Details: The event will serve as an excellent networking opportunity, providing delegates with the chance to form business and research relationships, engage in high-level discussions, and foster future international collaborations. These experiences will significantly enrich your professional growth and development.

Contact: info@worldacademics.net
Email: info@worldacademics.net
Website: worldacademics.net

International conference on Nano Biotechnology and Pharmacy

Dates: 8-9th October 2024

Venue: Durban, South Africa

Details: The focal point of this conference is to provide attendees with a chance to share their knowledge and insights with a worldwide audience. The comprehensive program will include industry-driven presentations, expert panels, and keynote speeches from global thought leaders.

Contact: 9344550460
Email: info@worldacademics.net
Website: worldacademics.net

One stop solutions supplier with a focus on sustainability

Karlsruhe/Germany: Romaco will be taking advantage of this year's CPhI in Milan to present one stop solutions for manufacturing, filling and packaging pharmaceuticals. Sustainable components and processes are a key development priority with all of the pharmaceutical machinery manufacturer's products.

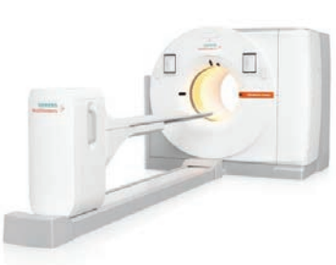
From powder processing to the finished pallet, Romaco has the right technology for every process step. The pharmaceutical machinery manufacturer's portfolio includes fluid bed processors, granulation lines, tablet presses and drum coaters as well as various primary, secondary and tertiary packaging solutions for processing and filling liquids, powders and solid dosage forms.

All Romaco machines are developed and manufactured in accordance with the Group's high sustainability standards. Featuring energy-efficient systems and designed using recycled or recyclable materials, they actively contribute to reducing carbon dioxide emissions worldwide. Romaco recently earned a silver medal in the EcoVadis Sustainability Rating for its commitment to climate protection.

Among other things, Innojet fluid bed processors can be equipped with heat recovery systems that reduce heat energy consumption by up to 70 percent, depending on the product and the process. The VENTILUS® Lab fluid bed processor from Romaco Innojet will be on show at CPhI Milan. ■

Siemens Healthineers introduces Biograph Trinion

Siemens Healthineers introduces the Biograph Trinion, a high-performance, energy-efficient positron emission tomography/computed tomography (PET/CT) scanner with a wide range of clinical capabilities and a low lifetime operational cost.



"With the Biograph Trinion, Siemens Healthineers is proud to offer customers a high-performance PET/CT scanner that delivers the precision and speed needed for clinical demands," said James Williams, PhD, head of Molecular Imaging at Siemens Healthineers. "This new system is designed to be user- and patient focused as well as a sustainable investment in terms of reduced installation and operational costs and easy, on-site scalability." ■

Syntegon develops Versynta microBatch

Waiblingen, Germany / Minneapolis, USA: Syntegon developed Versynta microBatch with these requirements in mind: the gloveless isolator with integrated air treatment significantly reduces operator intervention and the risk of contamination. 100 percent in-process control (IPC) ensures high quality.

Five integrated inline inspection systems provide special safety, while optional network cameras ensure continuous monitoring of production in the isolator via remote access.

"During my 35 years of working in the pharmaceutical packaging and processing business, it is rare to experience the partnership Syntegon and Kindeva enjoy. With our joint successes, their experience, and high level of technical capabilities, Kindeva is a perfect partner for our technology-leading Versynta microBatch," said Kerry Fillmore, Managing Director of Syntegon Pharma Technology in North America. ■

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Scope for ChemTECH World Expo 2026

- Plant Machinery & Industrial Consumables
- Engineering Consultants
- OEMs for Chemicals & Pharmaceutical Processing Equipment
- Metals & Metallurgy
- Bioprocessing Equipment
- Construction Services Providers
- Plant Maintenance Services Providers
- Logistics & Supply Chain Solutions Providers
- Instrumentation & Process Control
- Industry Automation (Process & Factory)
- Systems Integration & ERP Solutions Providers
- Water & Waste Water Treatment Consultants
- Environment Solutions Providers
- Waste Management Consultants
- Financial Institutions
- Fire & Safety Solutions Providers
- Material Handling Solutions
- Certification Bodies
- Welding Solutions
- Quality Health & Environment Solutions
- Analytical & Laboratory
- Packaging Materials, Machinery & Systems
- Business Consultants

Scope for Specialty Chemicals World Expo 2026

- Agrochemicals Intermediates
- Adhesives & Sealants
- Agrochemicals & Crop Protection
- Bulk Drugs & Intermediates
- Enzymes
- Colorants, Dyes & Pigments
- Cosmetics & Personal Care Ingredients
- Hygiene & Cleaning Chemicals
- Laboratory Chemicals
- Surfactants
- Water Treatment Chemicals
- Catalysts
- Electronic Chemicals
- Flavours & Fragrances
- Contract Manufacturers

Scope for Biopharma World Expo 2026

- Materials Processing
- Pharma Machinery
- Pharma Ingredients
- Plant Engineering, Process Plants & Equipment
- Laboratory & Analytical Solutions
- Process Measurement & Inspection
- Sterilization & Clean Room Solutions
- Biopharma R&D And Manufacturing
- IT Solutions
- Water & Waste Treatment Solutions

FACT & FIGURES 2024

- **750** EXHIBITORS FROM 15+ COUNTRIES
- **25871** VISITORS FROM 53 COUNTRIES
- **8** TECHNICAL CONFERENCES
- **250+** GLOBAL SPEAKERS
- **1500+** BUSINESS DELEGATES
- **2500+** ENGINEERING PHARMA & SCIENCE STUDENTS AT STUDENT OUTREACH PROGRAM FROM 28 STATES & UNION TERRITORIES
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HIGHLIGHTS OF BIO-PHARMA WORLD EXPO 2024

Bio Pharma World Expo 2024

NAVIGATING THE PATH TO LEADERSHIP IN BIOPHARMA EXCELLENCE

(L to R) Guest of Honour Dr Krishna Ella , Executive Chairman, Bharat Biotech International Ltd, Prof (Dr) Samir Kulkarni , Head, Department of Biological Sciences & Biotechnology, Coordinator, DBT – ICT Centre, Dr Rajesh Gokhale, Secretary , DBT, Ministry of Science & Technology, Govt. of India & Chief Guest, Mr Suresh Prabhu Former Union Minister, Govt. of India & Chief Patron & Brand Ambassador, ChemTECH World Expo 2024

Biotech is one of the fastest-growing industries in the world right now, especially in India. The Indian bioeconomy registered a remarkable 28% growth in 2022. The past three years have been enormously successful, especially considering the challenges posed by the COVID-19 pandemic. The Indian bioeconomy is forecasted to reach USD 300 billion by 2030, a significant increase from its current valuation of USD 140 billion, which constitutes 4% of the total GDP of our country's growth. The BioPharma industry contributes approximately 43% to the economy and extends beyond pills; it encompasses aspects of healthcare, wellbeing, and cognitive enhancement. To capitalize on green growth and the bio economy, we are establishing Bio enablers in the form of Bio manufacturing hubs through Public-Private Partnerships.

Dr Rajesh Gokhale
Secretary, DBT, Ministry of Science & Technology, Govt. of India

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