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"Our priorities will include identifying and understanding the challenges while engaging regularly with industry leaders to address their concerns"

– K Raja Bhanu, Director General, Pharmaceuticals Export Promotion Council of India (Pharmexcil)

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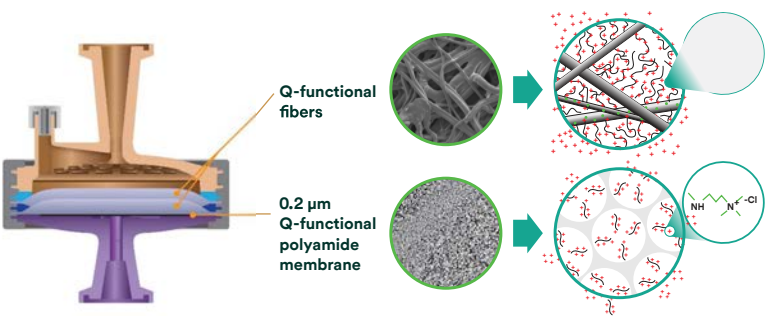

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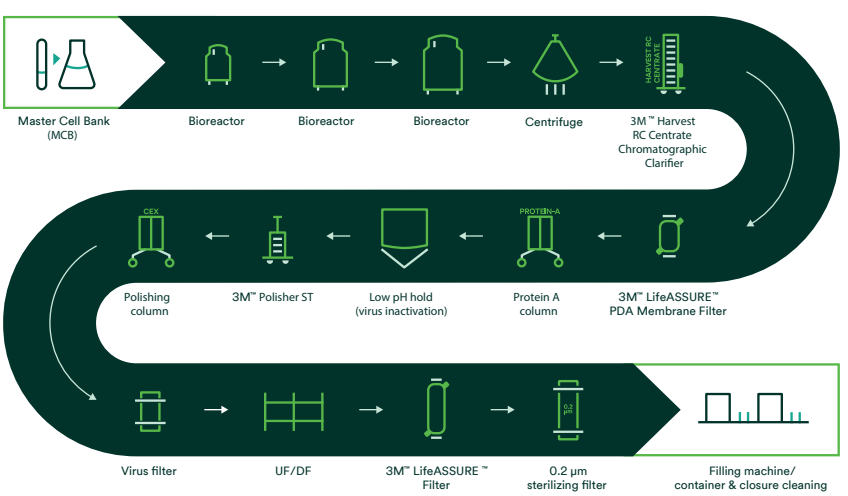

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Acknowledgement/ Feedback

Thanks a lot for the publication on the Global Capability Centres focusing on the pharma sector, in the August 2024 edition of BioSpectrum India – truly appreciate your support.

- Anil Matai, New Delhi

Thank you BioSpectrum for publishing the article on biosimilars as a part of the cover story.

- Dr Sudhira, Bengaluru

On behalf of the Blockchain For Impact (BFI), I want to extend our sincere thanks for the wonderful interview you published with our founder, Sandeep Nailwal. Your coverage was thorough and insightful, and we greatly appreciate the attention to detail you brought to highlighting our initiatives. Thank you BioSpectrum. Looking forward to further collaboration.

- Faraz Farooqui, New Delhi

The article on 'Transformative role of Indian pathology market in healthcare' has turned out well. Our endeavour with Praxis Global Alliance report is to understand, qualify, and quantify the impact that these trends will have on the Indian diagnostics market in the short to medium term.

- Shivam Bajaj, New Delhi

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Letter from Publisher

Ravindra Boratkar
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Managing Editor,
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Dear Readers,

Although India is the world's largest producer of generic pharmaceuticals, with the third-largest pharmaceutical sector by volume, it is mostly dependent on China for the importation of raw materials, Key Starting Materials (KSMs), and Active Pharmaceutical Ingredients (APIs). India produces more than 500 distinct APIs and manufactures about 60,000 generic products, spanning 60 therapeutic areas. Nonetheless, as it is a less expensive proposition to import APIs from China than to manufacture them domestically, India imports over 70 per cent of its APIs. For 58 APIs, India was largely dependent on China.

The Department of Pharmaceuticals has ranked 56 APIs in order of priority for the Make-in-India campaign. These include bulk pharmaceuticals, or APIs, that are used to make important medications, like drugs to manage HIV, antibiotics, and the ubiquitous but modest, paracetamol. Although the Council of Scientific and Industrial Research (CSIR) was just recently involved, the plan to manufacture APIs in India has been in the works for some time. The lead story of this edition delves deep into how the government initiatives are contributing to the growth of KSM and API production in India so that India can become self-sufficient in API production.

Recently the government has constituted a committee to examine the possibility of bringing nutraceuticals under the ambit of the apex drug regulator, Central Drugs Standard Control Organisation (CDSCO) instead of the food regulator Food Safety and Standards Authority of India (FSSAI) to address regulatory challenges and promote consumer safety. This has numerous implications for the nutraceutical industry and the stakeholders involved. Our team has explored the effectiveness of this change and how well the transition is managed and whether the regulatory framework can balance safety with industry growth and innovation.

Water, the essence of life, has been a subject of scientific inquiry for centuries. Yet, recent advancements in our understanding of water's molecular structure and behaviour are opening up exciting new frontiers in healthcare. We have an expert article that delves into the cutting-edge field of water structuring and its potential to revolutionise modern medicine.

Effective July 1, 2024, K Raja Bhanu has been elevated from Executive Director to Director General (DG) of the Pharmaceuticals Export Promotion Council of India (Pharmexcil). In this issue we have an interaction with him where he shared his plans on addressing many challenges before the Indian pharma industry to stay compliant with international regulations.

The BioSupplier market is growing tremendously in India with the introduction of new technologies. However, the biotech industry and researchers face challenges and gaps that need to be addressed to best utilise these technologies for developing innovative products. BioSpectrum had organised a one-day event on August 23 highlighting the efforts and initiatives of domestic and international BioSuppliers to facilitate biotech innovation in India through new technologies. As part of the mega event, we've also honoured the best technologies at the 'Supplier Excellence Award' session.

I am sure you will like this issue.

Thanks & Regards,

Ravindra Boratkar,
Publisher & Managing Editor

COVER 17

Can India Reclaim API Throne from China?

Despite having the third-largest pharmaceutical industry by volume in the world and being the largest manufacturer of generic medicines globally, India is heavily dependent on China for imports of raw materials, Key Starting Materials (KSMs), and Active Pharmaceutical Ingredients (APIs). India is the source of around 60,000 generic brands across 60 therapeutic categories and manufactures more than 500 different APIs. However, India imports about 70 per cent of its APIs from China as it's a cheaper option than manufacturing them domestically. There were 58 APIs in which India was heavily dependent on China. In the case of 45 APIs, India was dependent on China for 100 per cent of imports. Out of these 58 APIs, 29 APIs are manufactured through fermentation and 29 APIs are manufactured through chemical synthesis. The Department of Pharmaceuticals has drawn up a list of 56 APIs to prioritise them for the Make-in-India initiative. These include APIs or bulk drugs that go into the making of essential drugs, such as antibiotics, anti-HIV medicines, and the humble but indispensable paracetamol. The plan to make APIs in India has been in the works for some time but the Council of Scientific and Industrial Research (CSIR was engaged only recently. Let's see how these steps taken by the government help to promote the production of KSMs and APIs in India in the coming years.

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22 "India is well-positioned to reduce its dependence on imported APIs and potentially challenge China's dominance in the global market"

R K Agarwal,
National President, Bulk Drug Manufacturers Association (India)

Nutraceuticals

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Top Video

Dr Swati Uppal, Chief of Strategy & Growth, Vesta Elder Care, shares her opinion on how the elder care market is evolving in India.

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Recent estimates indicate that non-communicable diseases will cost India roughly $3.6 trillion by 2030. What role can homoeopathy play in easing this load? Dr Shreepad Khedekar, MD (Homoeopathy), Medical Geneticist, Teacher elaborates on this aspect.

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Event Report

Regulars

Losing the API Advantage

For those who were not very satisfied with the provisions in the budget for the healthcare and pharmaceutical sectors, there is good news. The Ministry of Chemicals and Fertilisers, under which the pharmaceutical department works, has announced that 32 projects have been completed under the production-linked incentive (PLI) scheme.

It is a significant achievement when one considers the objective of the PLI scheme in pharmaceuticals. The scheme for the industry was launched during COVID-19 to encourage domestic production of Active Pharmaceutical Ingredients (APIs), Key Starting Materials (KSMs) and drug intermediates to strengthen supply chain resilience and reduce imports of raw materials. The problem of over-dependence on imports from China and the importance of domestically produced APIs was realised very strongly particularly in the early period of COVID as the imports from China were stopped due to the pandemic.

The Indian pharma industry was dependent on imports of APIs and KSMs imported from China. In 2021-22 India imported 2.6 lakh metric tonnes (LMT) of APIs and KSMs at Rs 23,273 crore. It increased to 3 LMT at Rs 25,551 crore in 2022-23. Imports of bulk drugs have seen a steady growth of 7 per cent CAGR, the CareEdge report said. In its recent research note, rating agency ICRA said the Indian API industry will expand at a CAGR of 7 to 8 per cent between 2023 and 2029.

On this background, the development of completion of 32 projects needs to be seen. These completed projects collectively have developed an installed capacity of 56,679 MT per annum. Sixteen more projects under the PLI are still under development. They too, will add significantly to the import substitution. Still, it may take 5 to 7 years to see the real good effects of the PLI scheme in APIs and KSMs, experts feel.

However, this initiative should not stop here and all efforts should be made for complete self-sufficiency. If we produce more than our requirement, even export is possible. There are several other countries, including the US, which are interested in coming out of the clutches of China and will prefer India to China for API and other ingredients for imports. Nikkei Asia had said in a report in May 2024 that India can be a real alternative to China in pharmaceuticals. However, in another report, Nikkei Asia revealed that India's pharma quality lapses were forcing the US to turn to China for vital drugs.

Interestingly, India was self-sufficient in API production in 2000. But our dependence on China increased when the Chinese companies started dumping them at low prices, making Indian companies wind up operations. In the last few years, only one company was operating in API production. The picture started changing with the PLI scheme. Indian pharma's dependence on China for APIs must be reduced considering its volume of production of drugs. Indian pharma companies produce, though generic, as many as 60,000 drugs in 60 therapeutic categories, making India the third largest producer of drugs by volume in the world.

However, self-sufficiency in API production is just one area. Overall research and innovation in every aspect of pharmaceuticals and developing proper logistics infrastructure would be vital for the future of the sector in India. It will also be important to move from generic to developing new original drugs.

As the PLI scheme helped in APIs and KSMs, research and innovation in pharma may be befitted by one provision in the recent budget of abolishing tax on angel investment which may help a lot of startups in the healthcare area, in which startups are already playing an important role. However, the government's allocation for Ayushman Bharat Digital Mission remains unchanged at Rs 200 crore. Going by the PLI scheme's initial result, similar encouragement needs to be given for research and innovation. That may take the pharma sector to a new height than where it is today. BS

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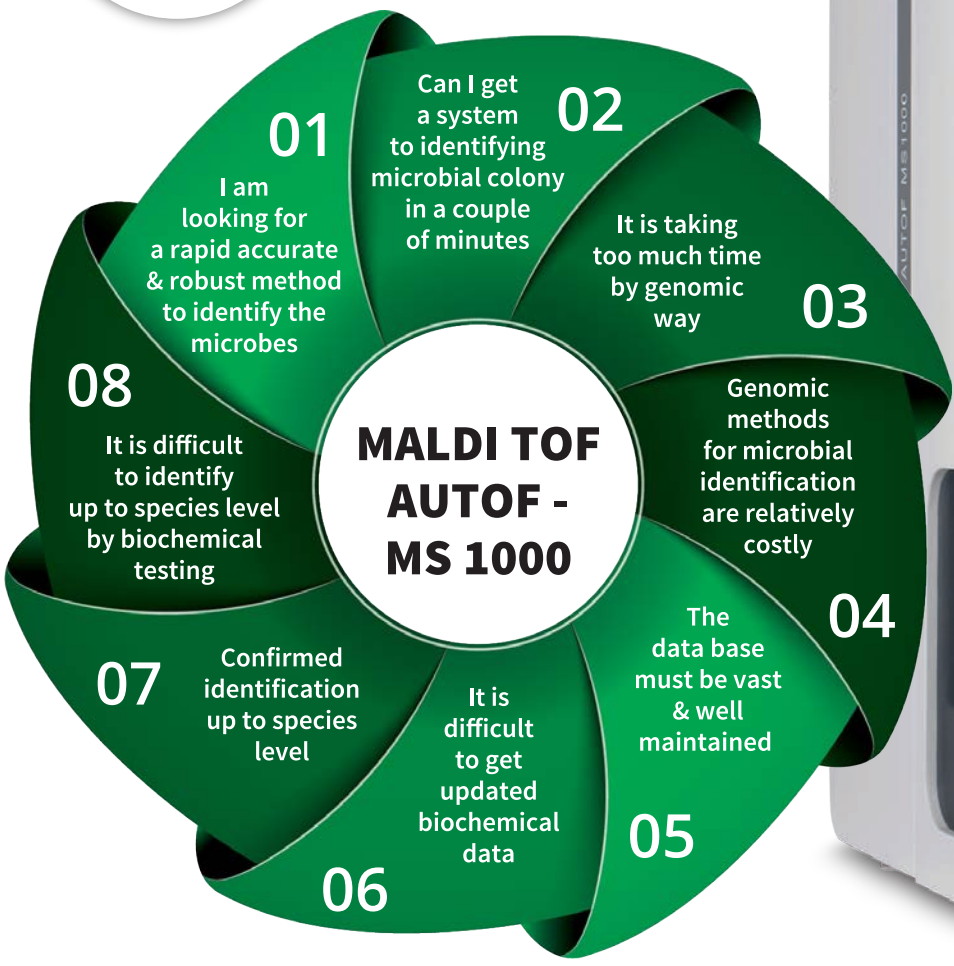

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Ministry of Ayush inks donor agreement with WHO

The Ministry of Ayush, Government of India and the World Health Organization (WHO) have signed a Donor Agreement during a signing ceremony organised at WHO Headquarters in Geneva. This agreement, which outlines the financial terms for implementing the activities of the WHO Global Traditional Medicine Centre (GTMC) in Jamnagar, Gujarat was signed by Arindam Bagchi, Permanent Representative of India to the UN, Geneva and Dr Bruce Aylward, Assistant

Director-General for Universal Health Coverage and Life Course on behalf of Ministry of Ayush and WHO respectively. Through this collaboration, the Government of the Republic of India will donate $85 million over a period of 10 years (2022-2032) to support the operations of the WHO Global Traditional Medicine Centre (GTMC) in Jamnagar, Gujarat. The Donor agreement recognises the establishment of the WHO Global Traditional Medicine Centre as a key knowledge hub for evidence-based Traditional Complementary and Integrative Medicine (TCIM) aiming to advance the health and well-being of people and the planet.

Economic Survey lays focus on mental healthcare for the first time

For the first time ever, the Economic Survey 2023-24 tabled by the Union Minister of Finance and Corporate Affairs Nirmala Sitharaman in Parliament recently, talks extensively about mental health, its significance and implications on policy recommendations. Acknowledging mental health as a principally impactful driver of individual and national development, the Survey notes that as per the National Mental Health Survey (NMHS) 2015-16, 10.6 per cent adults in India suffered from mental disorders while treatment gap for mental disorders ranged between 70 and 92 per cent for different disorders. The Survey stresses on proper implementation to accelerate the improvements made in mental healthcare on the ground and address gaps in the existing programmes to maximise their effectiveness. Important policy recommendations include re-doubling efforts to increase the number of psychiatrists, from 0.75 psychiatrists per lakh population in 2021 to the WHO norm of 3 per lakh population; Developing comprehensive guidelines for the excellence centres' services alongside mental healthcare professionals and users to understand their needs; Assessing the effectiveness of the programmes by gathering feedback from the users, professionals, and stakeholders to make necessary changes and meet the needs of a wider population.

Karnataka launches State BioEconomy Report 2024

Karnataka Innovation and Technology Society (KITS), under the Department of Electronics, IT, BT and S&T, Government of Karnataka, in collaboration with the Association of Biotechnology Led Enterprises (ABLE), has announced the launch of the Karnataka BioEconomy Report 2024. The Karnataka BioEconomy experienced a significant growth of approximately 10.7 per cent from 2022 to 2023. In specific terms, the economic value increased from $28 billion in 2022 to $31 billion in 2023. One of India's leading biotech states, Karnataka garnered more than 30 per cent of investments in the sector nationally in 2023. The state's $31 billion contributes 21 per cent to the national BioEconomy of $151 billion in 2023. It is only second to Maharashtra. Bengaluru Urban dominates the BioEconomy landscape with $15.9 billion, representing 51.17 per cent of the total BioEconomy in Karnataka. This district's substantial contributions span multiple sectors, including biopharma, diagnostics, medical devices, and BioIT & services. Further, in 2023 alone, Karnataka welcomed 202 new biotech startups, marking a staggering 113 per cent increase from 2021.

I-STEM launches 'V-LABS' initiative to revolutionise R&D in India

I-STEM (Indian Science, Technology, and Engineering facilities Map), an initiative from the Office of Principal Scientific Adviser, Government of India, has launched a ground-breaking platform called 'V-LABS' (Vertically Aggregating Labs). This revolutionary programme aims to connect researchers, startups, and industries with a vast network of labs and equipment across diverse sectors. This will save the researchers, industry and startups the prohibitive capital expenditure of purchasing advanced equipment. At the national level, this prevents the duplication of scarce resources in the research institutions. The 'V-LABS' initiative represents a paradigm shift in scientific resource allocation. It facilitates this shift through a series of events and workshops. Through V-LAB, I-STEM will curate information on scientific and engineering equipment and labs. This curated data will be integrated into the I-STEM portal, enabling researchers, startups, and industries to efficiently discover and access the resources they require.

Andhra opens PTU Centres of Excellence in association with Bayer

Bayer's Pharmaceuticals division, in collaboration with the Department of Health, Medical and Family Welfare, Government of Andhra Pradesh (AP), has inaugurated the first Preserve the Uterus (PTU) Centres of Excellence in the state. King George Hospital will house one of the two Centres of Excellence. The second Centre of Excellence will be installed at Victoria Hospital. The initiative is to drive awareness about the negative impact of unnecessary hysterectomies in India. The PTU Centres of Excellence in Vizag are first-of-their-kind in the country. In recent years, hysterectomies have gained attention in India's health policy due to high prevalence. The National Family Health Survey-5 (2019-2021) shows that the rate of hysterectomy in women across India aged 30-39 years is 3.3 per cent, with the highest rate of 8.7 per cent observed in Andhra Pradesh.

Sanofi Healthcare to invest Rs 3600 Cr in Hyderabad GCC by 2030

Sanofi Healthcare India has announced a significant expansion of its Global Capability Centre (GCC) in Hyderabad, with a planned investment of Rs 3600 crore by 2030. This move is expected to bolster innovation, research, and development in the healthcare sector while substantially increasing its workforce. The announcement was made during the inauguration of the facility at Hitec City recently, attended by Telangana Minister for Industries D Sridhar Babu, Secretary of the Department of Pharmaceuticals Arunish Chawla, and Special Chief Secretary for IT Jayesh Ranjan. Sanofi's expansion in Hyderabad aligns with the Telangana government's vision to establish the state as a leading hub for healthcare innovation. The investment will enhance the GCC's capabilities, making it the largest of Sanofi's four global hubs within two years, with the workforce growing from 1,000 to 2,600 employees.

Thyrocare buys Polo Labs' pathology diagnostic biz to strengthen Northern India presence

Mumbai-based Thyrocare, a leading diagnostic and preventive healthcare service provider in India, has entered into a Business Transfer Agreement with Polo Labs to acquire their pathology diagnostic business. This strategic acquisition expands Thyrocare's footprints into the Northern part of India, further solidifying its position as a dominant player in the Indian diagnostic industry. Polo Labs, based out of Punjab, is a well-established pathology diagnostic company with 14 laboratories across Punjab, Haryana, and Himachal Pradesh. Their robust network and expertise in the region make them a valuable addition to Thyrocare's operations. Currently, Polo Labs serves a substantial client base and has a significant market presence in Northern India, contributing to the region's healthcare infrastructure.

The acquisition of Polo Labs aligns seamlessly with Thyrocare's overall business strategy in the healthcare sector, which focuses on enhancing diagnostic capabilities and extending its reach across India. By integrating Polo Labs' existing network with Thyrocare's advanced diagnostic infrastructure, the company aims to deliver improved service delivery, faster turnaround times, and unmatched patient convenience.

Mankind Pharma acquires 100% stake in Bharat Serums and Vaccines for Rs 13,630 Cr

Mankind Pharma has entered into a definitive agreement to acquire a 100 per cent stake in Bharat Serums and Vaccines Limited (BSV) from Advent International, for an enterprise value of approx. Rs 13,630 crore, subject to closing related adjustments. This strategic move marks a significant leap for Mankind Pharma, positioning it as a market leader in the Indian women's health and fertility drug market alongside access to other high entry barrier products in critical care with established complex R&D tech platforms. With over five decades of leadership in biopharmaceuticals, BSV has developed recombinant and niche biologic products in-house, demonstrating its strong R&D capabilities and boasts of a robust branded product portfolio across Women's Health, Fertility and Critical Care, with a few of its marque brands enjoying a strong leadership position in their respective therapy areas.

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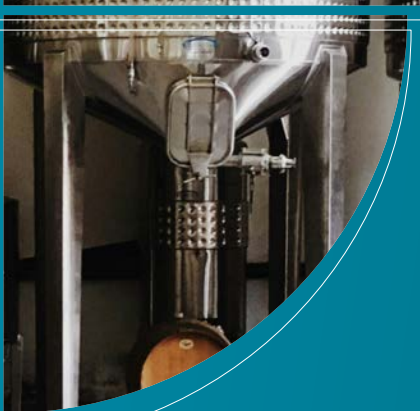

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Morepen Labs raises Rs 200 Cr through QIP

Morepen Laboratories has announced the successful subscription of a Qualified Institutional Placement (QIP) for Rs 200 crore. This strategic move underscores Morepen's commitment to accelerating growth, enhancing institutional participation, increasing market presence, and improvement in its financial position on the way to fortifying its leadership in the field of Medical Devices and APIs. The company has been growing consistently at 19.6 per cent CAGR based only on the robust internal accruals and has focused on maximising the revenue and EBITDA margins. Now, the additional fund raise of Rs 200 crore through this QIP, would accelerate the growth journey and help build large capacities and backward integration, cementing the company's leadership position in Glucometers and BP Monitors markets feeding directly to the consumers. In the API segment also, Morepen has created a niche for itself in six products where it commands leadership and has recently created extra capacities to accommodate the increasing market demand of its key products. With additional capex to be funded through the QIP fundraise the company will establish capacities for new molecules for which it has developed a strong pipeline with its R&D efforts.

Medicamen Organics expands footprint in East Africa with $75,000 investment in Rwanda

Delhi-based pharma company Medicamen Organics has taken a significant step in its global expansion strategy by signing a Memorandum of Understanding (MoU) with Depot Pharmacy Yego in Rwanda. This agreement marks the commencement of Medicamen Organics' operations in Rwanda as a subsidiary, with an initial investment of $75,000. This investment covers capital and product registration costs in the first phase. Medicamen Organics' decision to invest in Rwanda is based on the country's strategic regional positioning, low-risk factors, excellent connectivity, growing private sector, and preferential tax rates. The company plans to establish its own warehouse and depot in Kigali, Rwanda. The company will import products into Rwanda through Depot Pharmacy Yego from various countries, including the United Kingdom, France, Belgium, India, China, Kenya, Tanzania, and Uganda. In a related development, Medicamen Organics Limited recently listed its stock on NSE Emerge.

Lupin divests US commercial women's health specialty biz to Evofem for $84M

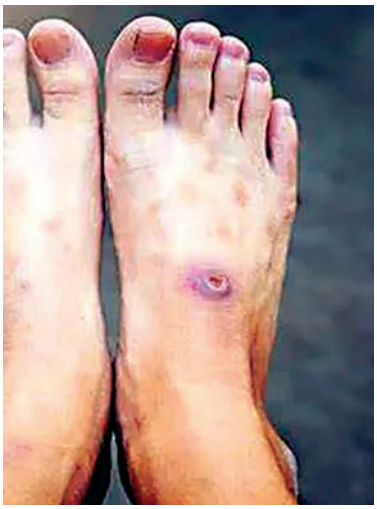
Global pharma major Lupin has divested its US Commercial Women's Health Specialty Business to Evofem Biosciences, Inc., a US biopharmaceutical company focused exclusively on Women's Health. Lupin's US Commercial Women's Health Specialty Business is primarily focused on commercialising SOLOSEC (secnidazole) 2g oral granules. This US FDA-approved single-dose antimicrobial agent provides a complete course of therapy for the treatment of bacterial vaginosis (BV) and trichomoniasis, two common sexual health infections. Under the terms of the deal, Lupin can receive a potential total consideration of up to $84 million based on future contingent milestones.

Miltenyi Biotec and THSTI collaborate to strengthen R&D in CGT

German firm Miltenyi Biotec, a global leader in biomedical solutions, has announced the signing of a Letter of Intent with the Translational Health Science and Technology Institute (THSTI), an autonomous institute of the Department of Biotechnology, Ministry of Science and Technology. With this partnership, both organisations aim to address the growing need for innovative treatments in the fight against cancer by developing innovative cell and gene therapies. The purpose of this collaboration is to focus on leveraging the strengths of both organisations to enhance research and development in cell and gene therapy (CGT) focusing on cancer and sickle cell disease. This collaboration would help in capacity building, technology transfer, training programmes, and joint research initiatives which would then be translated into medical therapies.

NovaLead's patented repurposed drug for treating DFU gets CDSCO approval

Pune-based NovaLead Pharma has announced that the drug regulator in India, Central Drugs Standard Control Organisation (CDSCO), has approved their patented Repurposed Drug for treatment of Diabetic Foot Ulcer (DFU) which is a global unmet medical need. With over 15 -25 per cent of diabetic patients suffering from DFU at least once in their lifetime, DFU is the most prevalent complication caused by chronic diabetes. The approval of NovaLead's patented repurposed drug is significant because DFU is the leading cause for lower limb amputations globally, with about 100,000 annual incidences in India alone. This drug is a novel topical gel formulation of Esmolol hydrochloride, which is already approved in several countries for cardiac conditions via intravenous injection. Thus,



this novel topical gel discovered and developed by NovaLead is a new indication as well as new formulation to be first launched in India. NovaLead has been granted patents for this drug in several countries including regulated markets of US, EU and Japan.

Stryker launches MultiGen 2 Radiofrequency Generator for chronic joint pain management

Stryker has announced the launch of MultiGen 2 Radiofrequency (RF) Generator in India. This technology provides physicians with the efficiency, control and reliability they need when performing RF ablation, a minimally invasive procedure that can provide lasting relief to those suffering from facet joint pain. With a prevalence rate of 19.3 per cent, over 180 million Indians suffer from chronic pain. Facet joint pain is a well-recognised source of pain in patients with persistent back pain. Multiple clinical studies show that for the majority of patients, RF ablation significantly reduces pain severity and frequency for one year. Engineered with double the industry standard for power, the MultiGen 2 Generator achieves target temperature faster, with fewer errors, for increased reliability and efficiency.

JRS Pharma & Gujarat Microwax open new manufacturing facility in Mehsana

JRS Pharma, a leading manufacturer of excipients, in partnership with Gujarat Microwax, has commissioned a new manufacturing facility for cotton-based croscarmellose sodium. This state-of-the-art plant is located in Mehsana and marks their fourth manufacturing facility in India. The grand opening ceremony was attended by heads of over 50 prominent pharmaceutical companies in the region, among other dignitaries. JRS Pharma, known for its plant

fiber technology innovations and with a legacy of 149 years, offers a comprehensive portfolio of solutions for the global health science industry. Their excipients portfolio includes high functionality excipients, binders, disintegrants, lubricants, functional fillers, thickeners, stabilisers, carriers, and coatings. Alongside their extensive range of excipients, JRS Pharma also offers technical support and biopharma services to address customer needs and formulation challenges. This expansion marks a significant step towards self-sufficiency in the Indian excipient industry.

Sanofi receives marketing authorisation for Beyfortus in India

Sanofi (India) has received marketing authorisation approval from the Central Drugs Standard Control Organisation (CDSCO) for Beyfortus. Beyfortus contains the monoclonal antibody nirsevimab in a prefilled injection used for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) in newborns and infants born during or entering their first RSV season. It is also administered in children up to 24 months of age, who remain vulnerable to severe RSV disease through their second RSV season. In 2019, there were approximately 33 million cases of acute lower respiratory infections globally, leading to more than 3 million hospitalisations, and it was estimated that there were 26,300 in-hospital deaths of children younger than 5 years. In March 2017, Sanofi and AstraZeneca announced an agreement to develop and commercialise Beyfortus.

Under the terms of the agreement, AstraZeneca leads development and manufacturing activities, and Sanofi leads commercialisation activities and records revenues. Beyfortus has been approved for use in the European Union, the US, China, Japan, and many other countries around the world.

Fujifilm India expands national footprint with new endoscopy centre in Mumbai

Fujifilm India's Endoscopy Division has significantly enhanced its service infrastructure by opening its second largest service centre in Mumbai. This new facility is dedicated to the rapid repair of its gastroscopes, bronchoscopes, and high-end processors, ensuring quicker turnaround times and improved service delivery across India. Over the past six years, the company has established five major service centres in key regions and cities across India, along with two satellite centres designed to accelerate endoscope repairs and accommodate an increasing installation base. The newly launched Mumbai service centre is equipped with state-of-the-art repair tools and technology, aimed at reducing service turnaround times and ensuring the swift delivery of repaired scopes. Fujifilm India plans to further expand its service centres with advanced tools, technology, and increased manpower to reach both small and large cities.

Can India Reclaim API Throne from China?

Despite having the third-largest pharmaceutical industry by volume in the world and being the largest manufacturer of generic medicines globally, India is heavily dependent on China for imports of raw materials, Key Starting Materials (KSMs), and Active Pharmaceutical Ingredients (APIs). India is the source of around 60,000 generic brands across 60 therapeutic categories and manufactures more than 500 different APIs. However, India imports about 70 per cent of its APIs from China as it's a cheaper option than manufacturing them domestically. There were 58 APIs in which India was heavily dependent on China. In the case of 45 APIs, India was dependent on China for 100 per cent of imports. Out of these 58 APIs, 29 APIs are manufactured through fermentation and 29 APIs are manufactured through chemical synthesis. The Department of Pharmaceuticals has drawn up a list of 56 APIs to prioritise them for the Make-in-India initiative. These include APIs or bulk drugs that go into the making of essential drugs, such as antibiotics, anti-HIV medicines, and the humble but indispensable paracetamol. The plan to make APIs in India has been in the works for some time but the Council of Scientific and Industrial Research (CSIR was engaged only recently. Let's see how these steps taken by the government help to promote the production of KSMs and APIs in India in the coming years.

India imported APIs and bulk drugs worth ~Rs 377 billion in 2023-24, accounting for ~35 per cent of its total API requirement, of which China accounted for ~70 per cent. Moreover, dependence on Chinese imports of APIs for certain essential medicines is as high as 80-100 per cent. Almost the entire requirement of certain fermentation-based APIs like ciprofloxacin and norfloxacin is sourced from China. The cost advantages with 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. Even where APIs are manufactured locally, KSMs are primarily sourced from China. The Chinese API industry, which accounts for ~40 per cent of the global requirement, is supported by higher economies of scale, subsidies, and fiscal incentives offered by the Chinese Government, along with lower power, fuel, and borrowing costs.

The rating agency ICRA noted that the overall API market in the country is about Rs 1100 billion with domestic sales at Rs 725 billion and exports touching Rs 375 billion to both semi-regulated and regulated markets (comprising trade supply and contract manufacturing). API exports from India have grown at a CAGR of 7.7 per cent over 2018-19 to 2023-24. Region-wise, exports are fairly diversified with Europe being the highest contributor with ~19 per cent share, followed by USA at 9 per cent.

India, one of the major producers of APIs or bulk drugs in the world, has imported Rs 353 billion worth APIs and bulk drugs in 2021-22 and also exported bulk drugs/Drug Intermediates (DIs) worth Rs 333 billion in 2021-22. The imports of APIs for 2022-23 touched Rs 362 billion.

The Centre for Market Research & Social Development in its report pointed

out that in the global API market, China is the undisputed leader, as volume wise China produces approximately 20 per cent of the world's API production. China manufactures over 2000 APIs and exports them. The percentage of API imports from China has spiked from around 1 per cent in 1991 to about 70 per cent in 2019. A study conducted by PwC shows that 50 per cent of the critical APIs are being imported and almost all the imports are from China. Domestically produced APIs cover approximately 50 per cent of the total quantity. However, KSMs for most APIs are still sourced from China.

It may be noted that in the early 90's, India was among the leading producers in API category. However, over a period of time due to many changes in the manufacturing policies and regulations and with decreasing margins and stringent environmental norms, the Indian pharmaceutical manufacturers cornered themselves from the API manufacturing and it resulted in the closure of many pharmaceutical companies. During the same period, China strengthened itself in the API sector. Today, India, which was among the leading manufacturers in the API once upon a time, now imports more than 70 per cent of the API and intermediates from China and this is truly a matter of great concern.

Government's support

To make the country Atmanirbhar in APIs and bulk drugs, drug intermediates, the government has declared "2015 as Year of API". The Department of Pharmaceuticals is implementing three schemes by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries.

1.The Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical KSMs/ DIs and APIs in India, with a financial outlay of Rs 6,940 crore and the tenure from FY 2020-2021 to FY 2029-30, provides for financial incentive for 41 identified products. A total of 48 applications have been selected under the scheme. Out of these, 27 projects have already been commissioned with the installed capacity of 41,881 metric tonnes.

The government has received a total 249 applications across all four categories of products. Out of these applications, 48 applications have been approved with committed investment of Rs 3,938.57 crore and expected employment generation of around 9,618 persons. With the successful implementation of this Scheme, it is expected that in the coming years, the import dependence in the notified bulk drugs will get reduced over the implementation period of the scheme.

The scheme provides for financial incentive for six years to eligible manufacturers of 41 bulk drugs on their incremental sales over the base year. For fermentation based eligible products, rate of incentive for the first four years (2023-2024 to 2026-2027) is 20 per cent, for the fifth year (2027-28) it is 15 per cent and for the sixth year (2028-2029) it is 5 per cent. For chemical synthesis products, rate of incentive for entire six years (2022-2023 to 2027-2028) is 10 per cent. Industrial Finance Corporation of India (IFCI) Ltd is the Project Management Agency (PMA) for the scheme.

2.Production Linked Incentive Scheme for Pharmaceuticals, with a financial outlay Rs 15,000 crore and the tenure from 2020- 21 to 2028-29, provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. The product category two covers the APIs/KSMs/DIs except for the 41 eligible products already covered under the PLI Scheme for promotion of domestic manufacturing of critical KSMs /DIs/ APIs in India.

3. The Scheme for Promotion of Bulk Drug Parks, approved during March 2020, with a financial outlay of Rs 3,000 crore and the tenure from FY 2020-2021 to FY 2024-25, provides for financial assistance to three States for establishing Bulk Drug Parks. The Department had received proposals from 13 states namely (i) Uttar Pradesh (ii) Tamil Nadu (iii) Telangana (iv) Karnataka (v) Maharashtra (vi) Gujarat (vii) Madhya Pradesh (viii) Rajasthan (ix) Punjab (x) Haryana (xi) Himachal Pradesh (xii) Andhra Pradesh and (xiii) Odisha.

After evaluation of the proposals, Andhra Pradesh, Gujarat and Himachal Pradesh were conveyed final approval in October-November 2022 for creation of common infrastructure facilities (CIF) in the proposed Bulk Drug Parks in these three states, under the scheme. The respective State Implementing agencies (SIA) have indicated completion of these projects within next 24-28 months. An amount of Rs 900 crore has been allocated under the scheme in BE 2022-23 to release the first instalment of Rs 300 crore per state. As on December 16, 2022, first installment of Rs 300 crore were released to the SIA of Gujarat. The Ministry of Chemicals noted that first installment to the SIAs of Himachal Pradesh and Andhra Pradesh will be released, after the receipt of corresponding state shares to the SIA accounts.

In a bid to permanently address India's dependence on China for APIs, the Council of Scientific and Industrial Research (CSIR) is working with the coal and petroleum industries to generate chemicals that form the main therapeutic components in various medicines. The Department of Pharmaceuticals has drawn up a list of 56 APIs

to prioritise them for the Make-in-India initiative. These include APIs or bulk drugs that go into the making of essential drugs, such as antibiotics, anti-HIV medicines, and the humble but indispensable paracetamol. In the first phase, the focus is on about 30 ingredients. The plan to make APIs in India has been in the works for some time but the CSIR was engaged only recently. Manufacturing of 35 APIs, which have been imported earlier, has started production in India. These 35 APIs are among the 53 APIs for which India has 90 per cent import dependence. These 35 APIs are being manufactured from 32 different manufacturing plants.

Besides, the CSIR with other laboratories has developed cost-effective 25 technologies using locally available chemicals for the production of APIs under COVID API Mission and in the process of transferring the technologies to API industries. Mostly processes synthesis are completed for all. Technology transfer is yet to be done. Industries need to come forward. Lack of GMP facility in CSIR is also a gap area.

Meanwhile, continuing to support the growth of the API and bulk drugs sector the government has opened 27 greenfield bulk drug park projects on March 2 this year. Investment of Rs 3,063 crore has been grounded and employment for 2,777 persons has been generated. The sales made by the commissioned projects is worth Rs 817.33 crore which includes exports of Rs 252.62 crore.

Steady growth

ICRA noted that the Indian API industry is expected to see 7-8 per cent CAGR over CY2023–CY2029 driven by steady growth in the formulations industry, which in turn will be aided by an increasingly geriatric population, growing prevalence of chronic diseases, and rising contract manufacturing opportunities due to initiatives by export customers to diversify supply chain dependence on China to alternative destinations. At present the Indian API industry is highly fragmented with ~1,500 manufacturing facilities and several small and unorganised players in the field owing to low entry barriers. The Indian API industry contributes ~25 per cent to the Indian Pharma Industry by value. India is the third largest API manufacturer globally in terms of volume, after the US and China.

Sharing his views about the role of Foreign Direct Investment (FDI) in API sector RK Agarwal, National President of the Bulk Drugs Manufacturing Association (BDMA), said “The API sector in India is experiencing a surge in investments from both domestic and international players, reflecting the growing confidence in the country's pharmaceutical

5 Challenges before the Indian API industry

Indian API manufacturers lost their competitive edge in the manufacture of APIs at the lower end of the spectrum and fermentation technologies.

1. Stricter implementation of pollution control norms: This is leading to higher costs of manufacturing APIs in India. Under the current norms, companies have to go through a fresh approval process every time they want to make a change in the product mix, a process that can take as long as 4 months. For increase in production or addition of equipment, it could be 8 months or even more.

2. Interpretation of DPCO, 2013: In order to cope with decisions related to scheduled vs non-scheduled formulations, new drugs, demand notices for overcharging, etc., Indian pharma companies were forced to evolve business strategies to move up the value chain and focus on commercially attractive segments like finished formulations and complex-to-manufacture APIs. Local formulation players thus started sourcing raw materials and simple APIs from cost-competitive locations like China, which has led to increased dependence on a single source and huge fluctuations in API prices.

3. No tax incentives, higher utilities and borrowing cost: Non-availability of tax incentives to boost API parks, higher borrowing and utilities cost (e.g. electricity, water, steam) and low import duties have lead to cheaper imports from giant plants in China, which enjoyed economies of scale.

4. Lack of mega bulk drug parks: Lack of large clusters for bulk drug manufacturing having common facilities for pollution control, effluent treatment and single environmental clearance leads to higher capex requirement.

5. Issues faced by fermentation industry: Initially, huge capacity was created by both the public and private sector to cater to growing demand. However, because of the cheap rates, substantial quantities were being imported from China which forced local manufacturers to shut down operations owing to commercial unviability. As the sole manufacturer of penicillin, China has started manufacturing intermediates from penicillin G (6-APA, 7-ADCA and 7-ACCA) and therefore has strategically priced penicillin, which makes even the production of intermediates uneconomical in India.

Source: PwC

List of Applicants Approved under PLI Scheme for Promotion of Domestic Manufacturing of Critical KSMs / DIs/ APIs in India

(PLI Bulk Drugs as on November 6, 2023)

Target Segment I – Key Fermentation Based KSMs/ Drug Intermediates

1. Aurobindo Pharma Limited through Lyfius Pharma Pvt. Ltd. (Penicillin G)
2. Karnataka Antibiotics and Pharmaceuticals Limited (7-ACA)
3. Orchid Bio-Pharma Limited (7-ACA)
4. Kinvan Private Limited (Clavulanic Acid)

Target Segment II – Fermentation Based Niche KSMs/ Drug Intermediates/APIs

1. Macleods Pharmaceutical Limited (Rifampicin)
2. Natural Biogenex Private Limited (Betamethasone)
3. Natural Biogenex Private Limited (Dexamethasone)
4. Natural Biogenex Private Limited (Prednisolone)
5. Symbiotec Pharmalab Private Limited (Prednisolone)

Target Segment III – Key Chemical Synthesis Based KSMs/Drug Intermediates

1. Emmennar Pharma Pvt. Ltd. (1,1 Cyclohexane Diacetic Acid (CDA))
2. Hindys Lab Pvt. Ltd. (1,1 Cyclohexane Diacetic Acid (CDA))
3. Granules India Limited Dicyandiamide (DCDA)
4. Meghmani LLP (Para Amino Phenol)
5. Sadhana Nitro Chem Ltd. (Para Amino Phenol)

Target Segment IV – Other Chemical Synthesis Based KSMs/Drug Intermediates/APIs

1. Alta Laboratories Limited (Aspirin)
2. RMC Performance Chemicals Private Limited (Aspirin)
3. Amoli Organics Private Limited (Diclofenac Sodium)
4. Kreative Actives Private Limited (Diclofenac Sodium)
5. Anasia Lab Private Limited (Losartan)
6. Anasia Lab Private Limited (Olmesartan)
7. Andhra Organics Limited (Olmesartan)
8. Andhra Organics Limited (Sulfadiazine)
9. Andhra Organics Limited (Telmisartan)
10. Aviran Pharmachem Private Limited (Artesunate)
11. K P Manish Global Ingredients Pvt. Ltd. (Artesunate)
12. Centrient Pharmaceuticals India Private Limited (Atorvastatin)
13. Dasami Lab Pvt. Ltd. (Carbamazepine)
14. Dasami Lab Pvt. Ltd. (Oxcarbazepine)
15. Hetero Drugs Limited (Oxcarbazepine)
16. Global Pharma Healthcare Private Limited (Ofloxacin)
17. Globela Industries Pvt. Ltd (Ofloxacin)
18. Vital Laboratories Private Limited (Ofloxacin)
19. Globela Industries Pvt. Ltd (Norfloxacin)
20. Hazelo Lab Pvt. Ltd. (Vitamin B6)
21. Honour Lab Limited (Vitamin B6)
22. Sudarshan Pharma Industries Ltd. (Vitamin B6)
23. Hetero Drugs Limited (Carbidopa)
24. Hetero Drugs Limited (Levodopa)
25. Hetero Drugs Limited (Levofloxacin)
26. MSN Life Sciences Pvt. Ltd. (Levofloxacin)
27. Vital Laboratories Private Limited (Levofloxacin)
28. Hindys Lab Pvt. Ltd. (Acyclovir)
29. Honour Lab Limited (Levetiracetam)
30. Honour Lab Limited (Lopinavir)
31. Honour Lab Limited (Valsartan)
32. Lifetech Sciences Ritonavir
33. Rajasthan Antibiotics Limited (Meropenem)
34. Sudarshan Pharma Industries Ltd. (Vitamin B1 (Chemical Synthesis Route))

Source: Department of Pharmaceuticals

industry. FDI plays a significant role in this context, as it is permitted under the automatic route in the pharmaceutical sector up to a specified limit. This has led to several overseas investment companies acquiring substantial stakes in fast-growing Indian pharma companies, signaling their increased interest in the market."

Agarwal further pointed out that the trend is not one-sided. Indian companies are also actively acquiring stakes from overseas investors, showcasing a reciprocal interest in global collaboration. A notable example is Mankind Pharma, which has been involved in acquiring reputed brands from multinational corporations. Similarly, Dr. Reddy's Laboratories has made strategic acquisitions of brands from global giants like Novartis and Sanofi. These investments highlight the dynamic nature of the API sector, where both domestic and international players are keen to capitalise on the opportunities presented by India's growing pharmaceutical market. The influx of FDI, along with strategic acquisitions, is helping to strengthen the sector's global competitiveness and fostering innovation and growth in the industry.

"We are very much positive that the Indian API sector will definitely become self-reliant and slowly will reduce its dependence on China for its KSMs and APIs. The central government had also initiated various steps and even announced to provide incentives to manufacture more than 55 APIs and KSMs under the PLI scheme. Though we are still at the nescient stage to take advantage of all these initiatives, but I am confident that with the infrastructure, talent pool, new advancements and technology, Indian industry will definitely reach to the level of a major API global supplier in the coming days," said Raja Bhanu, Director General of Pharmaceutical Export Promotion Council of India (Pharmexcil).

Centre opens 27 new bulk drug plants

Sr. No.	Company	Bulk Drugs	Location
1	Meghmani LLP	Para Amino Phenol	Dahej, Gujarat
2	Sadhana Nitro Chem Ltd.	Para Amino Phenol	Raigad, Maharashtra
3	Emmennar Pharma Pvt. Ltd.	1,1 Cyclohexane Diacetic Acid (CDA)	Sangareddy, Telangana
4	Hindys Lab Pvt. Ltd.	1,1 Cyclohexane Diacetic Acid (CDA)	Nalgonda, Telangana
5		Acyclovir	
6	Kreative Actives Private Limited	Diclofenac Sodium	Visakhapatnam, Andhra Pradesh
7	Dasami Lab Pvt. Ltd.	Carbamazepine	Nalgonda, Telangana
8		Oxcarbazepine	
9	Hetero Drugs Limited	Carbidopa	Visakhapatnam, Andhra Pradesh
10		Levodopa	
11		Levofloxacin	Sangareddy, Telangana
12		Oxcarbazepine	
13	Honour Lab Limited	Levetiracetam	Sangareddy, Telangana
14		Valsartan	
15		Lopinavir	Visakhapatnam, Andhra Pradesh
16		Vitamin B6	
17	Anasia Lab Private Limited	Losartan	Nalgonda, Telangana
18		Olmesartan	
19	Andhra Organics Limited	Sulfadiazine	Srikukalam, Andhra Pradesh
20		Telmisartan	
21	Amoli Organics Private Limited	Diclofenac Sodium	Vapi, Gujarat
22	Symbiotec Pharmalab Private Limited	Prednisolone	Dhar, M.P.
23	Hazelo Lab Pvt. Ltd.	Vitamin B6	Yadadri Dist., Telangana
24	Aviran Pharmachem Private Limited	Artesunate	Mehsana, Gujarat
25	Centrient Pharmaceuticals India Private Limited	Atorvastatin	Nawanshahr, Punjab
26	Globela Industries Pvt. Ltd	Norfloxacin	Bharuch, Gujarat
27		Ofloxacin	

Outlook

The Indian API industry has been struggling for a long time because of high dependence on China, which accounts for the bulk of the total imports. Because of this, API prices have been very volatile and we have seen prices of APIs going up by more than 100 per cent in the recent past. High dependence on a single source can have a significant adverse impact in emergency-like situations. In the context of the recent coronavirus outbreak, it has the potential of disrupting supplies of essential medicines, resulting in price volatility and ultimately leading to a situation where medicines are not available for patients. It is time for India to revive its domestic API industry, which has been deeply affected because of policies such as stricter implementation of pollution control norms, implementation of DPCO, 2013, lower import duties, and complete collapse of the indigenous fermentation industry.

As pointed out by PwC, India needs a holistic and conducive ecosystem to rebuild its API manufacturing capabilities, which would require favourable policies from the government and a supportive financial ecosystem to boost private and foreign investment. In the immediate term, pricing policy, along with some financial incentives and faster approvals on environmental clearances, can give a required boost to the API industry. In the slightly longer term, the government may look at the Chinese model and work on developing clusters for API and fermentation, along with looking at ways to encourage alternative sources. The Indian API market is on a promising trajectory, driven by government support, increased domestic production, and a growing demand for pharmaceutical products.

However, the stringent regulations for drug approvals, various drug price policies in the country, and high competition among API manufacturers are expected to hinder India's API market growth. BS

“India is well-positioned to reduce its dependence on imported APIs and potentially challenge China's dominance in the global market”

« **R K Agarwal,**
National President,
Bulk Drug Manufacturers Association (India)

Formed in 1991 to encourage and formulate methods for developing bulk drugs indigenously for the local as well as export market, as an all-India representative body of the bulk drug industry, the Bulk Drug Manufacturers Association (India) (BDMA(I)) currently has over 350 member companies of which about 75 per cent are Micro, Small, and Medium Enterprises (MSMEs). The members of the association including the global ones such as Dr. Reddy's Laboratories, Aurobindo, Lupin, Cipla, MSN, Hetero and Laurus are supplying Active Pharmaceutical Ingredients (APIs)to about 200 countries and have been dealing with regulatory agencies in different regions / countries. The association works as an interface between the Industry & Governments both at the Central and State levels and represents all common issues affecting the API industry with the sole objective of achieving growth in this sector. In an interview with BioSpectrum, R K Agarwal, National President, BDMA spoke about the challenges before the API sector and what is expected from the government to make India self-sufficient in this sector. ***Edited excerpts:***

What are the primary challenges before the API sector in India, particularly concerning supply chain disruptions and dependency on imports?

The API sector in India is experiencing steady growth despite facing several significant challenges. One of the key issues is the storage and transportation of thermolabile drugs and cold chain-dependent pharmaceuticals, which still need improvement despite improvements in supply chain systems over the years. Additionally, compliance with newly introduced barcoding systems for API packaging presents another layer of complexity for the industry.

The Indian pharmaceutical sector continues to rely on certain imported APIs and drug intermediates, primarily due to cost considerations. While the Production Linked Incentive (PLI) schemes have been introduced to help address these issues, their impact has been limited, and the sector is still facing challenges in reducing dependency on imports.

How effective have the government's measures been in promoting domestic production?

The Indian government has implemented several strategic initiatives to strengthen the domestic production of APIs and reduce reliance on imports. One of the most notable efforts includes establishment of three Bulk Drug Parks across different states, supported by central assistance. These parks are designed to provide the necessary infrastructure and resources to facilitate large-scale API manufacturing, thereby boosting local production capabilities.

Another significant policy is the PLI scheme, which offers financial incentives for the domestic production of over 45 critical APIs and intermediates. This scheme has been widely praised for its potential to enhance the competitiveness of the Indian API sector and encourage investment in domestic manufacturing.

In addition to these initiatives, the government has provided indirect financial support for research and development by setting up Centers of Excellence at institutions like the National Institute of Pharmaceutical Education and Research (NIPERs). National labs, such as the Indian Institute of Chemical Technology (IICT) in Hyderabad and the National Chemical Laboratory (NCL) in Pune, are

also playing a voluntary role in supporting R&D efforts, contributing to innovation and technological advancement in the sector.

The Department of Pharmaceuticals (DoP) is actively supporting the API and Micro, Small, and Medium Enterprises (MSME) sectors through various schemes aimed at strengthening the Indian pharmaceutical industry. These schemes focus on upgrading the quality infrastructure in individual units and pharmaceutical clusters, ensuring that the industry remains globally competitive.

Despite various government initiatives, India still relies on China for over 80 per cent of its API needs. How can this dependence be reduced?

India's reliance on China for over 80 per cent of its APIs stems from several critical factors, primarily related to cost and scale. The Chinese pharmaceutical industry has long been able to produce APIs at a lower cost due to economies of scale, substantial government support, and a well-established manufacturing infrastructure. These advantages have made Chinese APIs more affordable and attractive to Indian pharmaceutical companies, especially those focused on producing cost-sensitive generic drugs.

Recognising the strategic vulnerability of this dependency, both the Indian API sector and the formulations industry have acknowledged the urgent need for self-reliance in critical raw materials. This is particularly crucial to ensure supply chain stability during emergencies, such as global disruptions or geopolitical tensions.

The Government of India is acutely aware of this dependency and has introduced several initiatives to encourage domestic production. One of the key measures is the PLI scheme, designed to boost local manufacturing of APIs and intermediates. This scheme not only aims to reduce dependence on imports but also to counter potential price-cutting strategies that Chinese manufacturers might employ, as was seen in the past with the production of Penicillin and 6-APA ((+)-6-aminopenicillanic acid) in India.

As a result of these efforts, India's reliance on imported APIs and intermediates is gradually decreasing. However, a significant challenge remains. For instance, the Indian formulation industry, which is heavily oriented towards cost-efficient production, requires API manufacturing costs in India to be comparable to or lower than those in China. Until this cost parity is achieved, reducing imports will be difficult.

To further mitigate this dependency, India must continue to invest in scaling up its domestic API production capabilities, enhance R&D for cost-effective production processes, and provide sustained financial and infrastructural support to the industry. Only through these combined efforts India can significantly reduce its reliance on imported APIs and strengthen its position as a global pharmaceutical leader.

What kind of support, both financial and infrastructural, have you asked from the government to improve the API sector? How is the support from state and central governments enhancing the bulk drug sector in India?

As the National President of the BDMA, I have consistently advocated for comprehensive support from both the state and central governments to strengthen India's API sector. The primary areas where we've requested government intervention include financial incentives, infrastructure development, and regulatory facilitation.

Financially, we have urged the government to expand and enhance the PLI schemes, which are currently pivotal in promoting domestic API production. While the existing PLI schemes cover a range of critical APIs and intermediates, we believe there is room for broadening the scope to include more essential raw materials and intermediates. Additionally, we have asked for increased financial support for research and development (R&D) initiatives, particularly in developing non-infringing and cost-effective manufacturing processes. Enhanced R&D funding will help Indian manufacturers innovate and stay competitive on the global stage.

On the infrastructural front, the establishment of Bulk Drug Parks with world-class facilities is a major step forward. These parks are essential in providing the necessary infrastructure, such as common effluent treatment plants, utilities, and logistics, which are critical for reducing the cost of API production and ensuring environmental compliance. The central government's initiative to set up three such parks with financial assistance is highly commendable, and we are working closely with state governments to ensure their timely and effective implementation.

Moreover, we've emphasised the need for streamlined regulatory processes to facilitate faster approvals and clearances, both for setting up new manufacturing units and for the export of APIs. Simplifying these processes will significantly reduce the time and cost involved in expanding production capacities, thus making the sector more agile and responsive to market demands.

Environmental regulations and policies often impact the API sector. How is the sector adapting to these regulations, and what are the major environmental challenges still haunting the sector?

The API sector in India has historically faced significant challenges related to environmental compliance, particularly concerning effluent treatment and waste management. Stringent environmental regulations have been implemented to ensure that the industry minimises its ecological footprint. However, these regulations have also posed substantial hurdles for manufacturers, requiring them to adopt advanced technologies and practices to meet compliance standards.

One of the major challenges has been the management of effluents, which, if not treated properly, can lead to severe environmental damage. The public perception of the API industry has often been negative due to concerns about pollution. However, the reality is that a majority of API manufacturers have made considerable strides in adopting best practices for effluent treatment. Many units have implemented state-of-the-art Effluent Treatment Plants (ETPs) that enable them to achieve zero liquid discharge, thereby significantly reducing the environmental impact.

To further support the industry in meeting these environmental regulations, the BDMA has been actively collaborating with the government. The association promotes government schemes that offer financial and technical assistance to API manufacturers for upgrading their environmental compliance infrastructure.

Despite these advancements, challenges remain, particularly in maintaining the delicate balance between stringent environmental regulations and the economic viability of API manufacturing. Continued efforts in innovation, coupled with robust support from government initiatives, are essential for the sector to overcome these challenges and sustain its growth while adhering to environmental norms.

Can India potentially lead the world in breaking China's dominance in the API market?

The Indian API industry is on a promising path towards achieving self-sufficiency and expanding its global footprint. While current capacities are growing, they are still evolving to fully meet both domestic and international demand. The PLI scheme and its forthcoming enhancements are pivotal in driving this transformation. By incentivising domestic production and reducing dependency on imports, these initiatives are expected to significantly bolster the sector's capabilities.

What opportunities lie ahead for the API sector in India, and what strategies should be adopted to capitalise on them?

The API sector in India is poised for substantial growth, driven by opportunities in cost-effective manufacturing and innovation. To capitalise on these opportunities, the sector should focus on developing non-infringing processes through low-cost research. Achieving self-sufficiency in critical raw materials and intermediates will be crucial. Strategic investments in technology and process optimisation will further enhance competitiveness and resilience.

How do you see the API sector evolving in India over the next decade?

Over the next decade, the Indian API sector is expected to solidify its position as a global leader. With ongoing advancements in technology and increased self-reliance, India is well-positioned to reduce its dependence on imported APIs and potentially challenge China's dominance in the global market. The sector's growth will contribute to India's reputation as a leading global pharmaceutical hub.

Can you provide insights into the role of technology and innovation in enhancing the efficiency and competitiveness of the API sector in India?

Technology and innovation play a pivotal role in boosting the efficiency and competitiveness of India's API sector. The government's initiatives, such as collaborations with NIPERs and CSIR labs, are instrumental in driving technological progress. Programmes like Pharma Vision 2020 and the PLI scheme are specifically designed to stimulate innovation and optimise production processes.

Hyderabad's NIPER, recognised as a centre of excellence in bulk drug manufacturing, exemplifies the impact of targeted support on industry advancement. This institute, along with similar organisations, is crucial in developing cutting-edge technologies and fostering research that enhances production efficiency.

These initiatives not only aim to improve domestic manufacturing capabilities but also position India as a competitive player in the global pharmaceutical market. By investing in technology and innovation, the Indian API sector is better equipped to meet international standards, reduce production costs, and advance its global standing. BS

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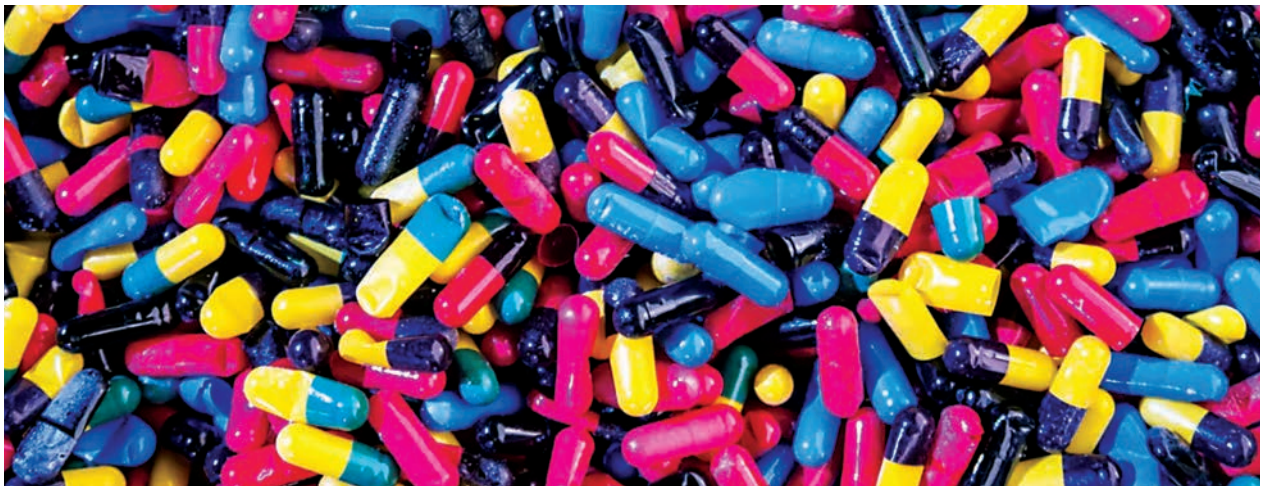


Are Nutraceuticals DRUGS? Examining a Needless Regulatory Tussle

The news has been around for a while which has put a big question mark ahead of the Indian nutraceuticals industry. The news is about changing rules, it is about switching regulations and even about reimagining the entire identity of nutraceuticals. The talk is about moving nutraceuticals from one existing regulatory body to another. Very recently, government has formed a panel to examine the possibility of bringing nutraceuticals under the ambit of the apex drug regulator, Central Drugs Standard Control Organisation (CDSCO) instead of the food regulator Food Safety and Standards Authority of India (FSSAI) to address regulatory challenges and promote consumer safety. This step taken by the centre towards nutraceuticals products has been receiving mixed reactions from the industry players and associations. According to our research, along with nutraceuticals producers, pharma players also have their own say on this particular development. Based on this, it can be said that bringing nutraceuticals under the jurisdiction of the CDSCO rather than the FSSAI could have significant implications, both positive and negative. Let's explore the numerous implications for the nutraceutical industry and the stakeholders involved.

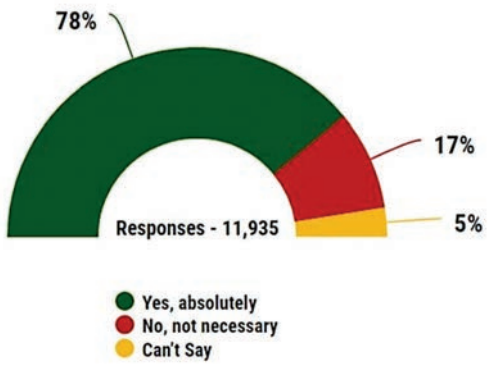
The committee formed by the government has Secretary, Ministry of Ayush; Secretary, Ministry of Food Processing Industries; Secretary, Department of Pharmaceuticals; Chief Executive Officer (CEO), FSSAI; Drugs Controller General of India (DCGI); Director General (DG), Indian Council of Medical Research (ICMR) and Director General of Health Services (DGHS) as members. Presently, the FSSAI regulates the usage of health supplements and nutraceuticals under the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022. This regulation covers food items that are specially processed or formulated for specific nutritional or dietary purposes.

Why this step and why now?

During a surveillance drive to curb the menace of spurious nutraceuticals manufactured by nutraceutical companies operating in Himachal Pradesh (HP) in June 2023, FSSAI issued a stern warning to the firms to strictly follow the regulations as according to the reports, industrial area in HP has become a hub for producing spurious vitamins, syrups, and drugs in the name of food supplements. Having said that, quality has always been one of the topics of debates in the Indian nutraceuticals

Need for capping prices of vital nutraceuticals

Should the Government cap prices of vital nutraceuticals like Vitamin A, Vitamin C and other immunity boosters?



industry. Not only HP but a number of the states in the country have been manufacturing and selling low quality, spurious nutraceuticals for a long time.

Along with quality issues, exaggerated health claims by the nutraceuticals manufacturers is also one of the pressing issues urging the government to act and take such steps. The findings presented by the recently published first-of-its-kind report on popular protein supplements sold in India is worth mentioning here. The analysis showed that nearly 70 per cent of the 36 supplements had inaccurate protein information, with some brands offering only half of what they claimed. Also, around 14 per cent of samples contained harmful fungal aflatoxins, while 8 per cent showed traces of pesticide residue.

"Several challenges associated with the development of nutraceuticals are often ignored because of a lack of authoritative control. These challenges include identification of the authentic source of raw materials, purity of the compound, presence of other active compounds, quality, lack of experimental evidence, false advertising, contamination with heavy metals, and interactions between supplements and drugs. Some manufacturers also try to use a closely related herb, which may or may not have the active ingredients. Among all the major concerns for using the nutraceuticals is the lack of scientific evidence. Some are never tested under properly controlled experimental conditions, and unlike pharmaceuticals, most nutraceuticals do not undergo "randomized controlled clinical studie", said ***Rafat A. Siddiqui, Associate Director, Agriculture Research Station and Associate Dean, College of Agriculture, Virginia State University, US.***

Many such researchers and studies have been demonstrating the need for some action at regulatory levels, ultimately leading to the appointment of a committee to rework the rules.

But why now? The pandemic is to blame! Over the last four years due to rise in lifestyle diseases and impact of pollution, poor diets, propagation of certain diets to build muscle strength, control weight gain, manage diseases like diabetes, blood pressure, etc., boost immunity as seen during COVID-19 pandemic, households have started buying different nutraceuticals products. With years passing, there is a lot of talk and 'fashion' around nutraceutical gummies, protein powders, vitamin and minerals supplements. According to the survey by the LocalCircles that was released in February 2024, 71 per cent of the consumers surveyed said that they are taking nutraceuticals (vitamin, mineral, fiber, omega, herbs & others) on a regular basis. 68 per cent of consumers buy nutraceuticals products from local medical or general stores.

Further in the report, ***Sachin Taparia, Founder, Chairman and CEO at LocalCircles*** added, "69 per cent of consumers surveyed are taking some or all the nutraceuticals without a doctor's prescription. That being the case, there is a need for more prominent advisories to be put on the labels to inform consumers which product can cause harm to those with known allergies and other medical conditions. On the question of price, 78 per cent of consumers surveyed want the government to cap prices of supplements like Vitamin A, C and immunity boosters."

The over-the-counter availability of health supplements raises the risk of consuming multiple nutrients that may counteract each other. For example, calcium from a multi-mineral supplement can interfere with the absorption of iron. Moreover, consuming supplements along with drugs which might interact with each other and may cause adverse effects is also a case. All of this is due to the lack of mandatory medical supervision for products covered under nutra regulations.

At the industry level, things are going even more complex. For example, supplements, including probiotics, vitamins, minerals, and botanicals, are increasingly being used for therapeutic purposes. Due to the blurred lines between supplements and drugs, many companies are opting to seek approval from FSSAI rather than CDSCO for ingredients that have drug-like properties, such as melatonin

and zinc carnosine. In summary, today, in 2024, nutraceuticals have become a lifestyle consumer product and at this stage, some rigid steps were the need of the hour which the government has been trying to address with such actions recently.

Positives

Moving nutraceuticals from the umbrella of FSSAI to CDSCO can have its own set of positives and negatives. Let's first have a look at some favorable outcomes.

The term 'nutraceutical' was coined from 'nutrition' and 'pharmaceutical' in 1989 by DeFelice and was originally defined as, a food (or part of the food) that provides medical or health benefits, including the prevention and/or treatment of a disease. A nutraceutical may be a naturally nutrient- rich food such as spirulina, garlic, soy or a specific component of a food like omega-3 oil from salmon. They are also known as medical foods, functional foods, nutritional supplements and dietary supplements. It ranges from isolated nutrients, dietary supplements, genetically engineered foods, herbal products, and processed products such as cereals and soups. Owing to all such terms used to describe nutraceuticals, currently, the distinction between food supplements and drugs is sometimes blurred. Under CDSCO, nutraceuticals might be better classified based on their intended use and potential health impact, leading to more clarity for consumers and manufacturers.

Nutraceuticals, often marketed as dietary supplements, have significant effects on health. Under CDSCO, which regulates drugs, there would likely be more stringent testing, quality control, and post-market surveillance. This could help in ensuring consumer safety by preventing misleading claims and ensuring that only safe, efficacious products reach the market.

Furthermore, at present, these products, typically sold as over-the-counter health supplements, are not subject to price regulations. Concerns have been raised about some companies inflating prices by repurposing pharmaceutical ingredients as nutraceuticals and selling them at a premium. In the move of shifting nutraceuticals from FSSAI to CDSCO, the Indian government is said to be addressing this issue by placing nutraceuticals under price control to make them more affordable for consumers. A committee comprising representatives from various health and regulatory bodies is being formed to explore the implementation of pricing regulations to ensure fairer costs of nutraceuticals.

Another benefit could be, stricter regulations could increase consumer confidence in the safety and efficacy of nutraceuticals, which according to various research reports have been a crucial issue to address.

Proposed Shifts in Regulatory Framework of Nutraceuticals

Way back in July 2012, the Report of the 44th Meeting of the Drugs Consultative Committee was released (the Report) which raised the issue that various non-pharmaceutical companies are manufacturing supplements with vitamins that fall in the quantity specified under the Schedule V of the Drugs Rules, 1945 (the Drugs Rules). The Report went on to state that the supplements that are manufactured as per the dosage defined in the Drugs Rules should be licensed under the Drugs Rules (Drug License) instead of the FSS Act making the regulation of nutraceuticals more stringent. However, no shift in regulatory framework was implemented based on the Report.

Recently, in February of 2024, the Central Government formed another committee to analyse specifically whether nutraceuticals should be regulated by FSSAI or by the CDSCO.

Source: Lexology (global legal intelligence platform)

Negatives taking over positives

Now let's dig into another part of the chapter which seems to be opposite yet doesn't sound wrong, surprisingly.

While strongly opposing this step by the government towards nutraceuticals, ***Dr N Ramasubramanian, Director, VR FOODTECH*** said, "It is a step that I would not welcome personally. Challenges associated with nutraceutical need to be resolved within the umbrella of food and FSSAI. Nutraceutical has a great future with great employment potential, benefits to farmers, etc. Let us not nip it in the bud."

Further adding to this, Dr N Ramasubramanian quoted, "Worldwide, nutraceutical products/health supplements are categorised as foods and controlled by food regulations. Nutraceuticals are differentiated from drugs based on claims. A product claiming to cure a disease is a drug which a nutraceutical cannot do. The regulatory body can publish a detailed guideline on claims which will remove the present ambiguity so that the claims made on the label are truthful, science-based and not misleading. Another irritant could be the retail price. In my opinion, as nutraceuticals are not an essential commodity like drugs, the retail pricing should be left to the market forces."

CDSCO is one of the complex regulatory bodies of India. The CDSCO's drug approval process is more rigorous and time-consuming than FSSAI. This could slow down the introduction of new nutraceutical products, potentially stifling innovation in the sector. Most of the nutraceuticals are quite simple formulations unlike others in the market. Hence putting all of them into one single basket of CDSCO would not work.

Another factor that needs to be considered is increased regulatory burden. More stringent CDSCO regulations could lead to a higher regulatory burden on nutraceuticals manufacturers. This might increase the cost of bringing nutraceuticals to market, potentially affecting pricing and availability. This will ultimately affect the government's agenda of making nutraceuticals affordable, leaving the decision purposeless.

While sharing his thoughts on this particular move by the government, ***Shaheen Majeed, Global CEO & Managing Director, Sami-Sabinsa Group*** said, "Independently, the FSSAI through its FSS Act 2006 and FSS Regulations 2022 has streamlined the fast-growing nutraceutical sector and aligned it to global markets' requirements. We feel, more stringent regulations in terms of GAP, GMP, label claims, dosage etc. ensuring the safety and efficacy of products are required to strengthen it further. Shifting nutraceuticals from FSSAI to CDSCO will be a setback to the sector as it may lose its identity and potential, suppress the growth of nutra industry and exports, kill MSMEs fearing hard time to meet market demands during the transition period, and shift global customers to other countries and make us less competitive."

Moreover, if not clearly delineated, there could be confusion or overlap in regulatory responsibilities, especially for products that straddle the line between food and drug categories. This might lead to legal and operational challenges for companies.

"While, there are both positives and negatives in bringing the nutraceuticals under the ambit of the drug regulator, we need to examine both aspects. We should also look at global practices in this regard. India tends to lose out in this burgeoning market for food supplements and nutraceuticals if we do not align it with global practices. The weaknesses in the regulation of the nutriceuticals can be addressed by keeping it under FSSAI itself," said ***Pawan Agarwal, former CEO FSSAI and Secretary to the Government of India.***

Prioritising growth and consumer safety

The move to bring nutraceuticals under CDSCO could enhance consumer safety and regulatory clarity, but it also brings challenges related to regulatory burden and market dynamics. The effectiveness of this change will depend on how well the transition is managed and whether the regulatory framework can balance safety with industry growth and innovation.

Sandeep Gupta, Director & CEO, Nutraworks, said, "I believe Government of India and industry should come together to discuss and deliberate, understand the background of what has been designed so far for Nutraceutical Regulations and to understand what kinds of value these regulations can bring in and put Indian nutra industry on the Global Map. The Government should involve the 'Right Expert' panel, Standard Review Group (SRG), FSSAI and bodices like Expert Nutraceutical Advocacy Council (ENAC), Association of Herbal and Nutraceutical Manufacturers of India (AHNMI), Indian Drug Manufacturers' Association (IDMA), Confederation of Indian Industry (CII), Federation of Indian Chambers of Commerce & Industry (FICCI) and other such relevant groups."

Ahead of all this, prioritising voluntary self-regulation as a means of setting higher industry standards is the need of the hour. Voluntarily adhering to codes and guidelines, surpassing legal requirements to ensure the highest quality products reach consumers can enhance regulatory compliance and overall safety in the dietary supplement industry.

"Every industry player should self regulate and not over claim , and ensure effective and quality products. A $100 billion industry is the dream of the nation, government and industry needs a consensus approach. Imploring all industry stalwarts and startups alike including different bodies to align and show an united front is important at this stage," commented ***Shriram Balasubramanian, Director, Commercial and Business Development, Zuventus Healthcare.***

Moving a category from one regulatory body to another is not an overnight thing. Things will take time and execution even more. If activities start getting serious at some point, will it be a wrap for the Indian nutraceuticals industry or will it be the dawn of a new sunrise sector? What do you think? BS

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“Our priorities will include identifying and understanding the challenges while engaging regularly with industry leaders to address their concerns”

K Raja Bhanu has been elevated from Executive Director to Director General of the Pharmaceuticals Export Promotion Council of India (Pharmexcil), effective July 1, 2024. Bhanu brings a wealth of experience from his distinguished career in drug control and regulation. He has a proven track record in advancing drug quality, safety, and regulatory compliance. His leadership at the Drug Control Administration (DCA) was marked by significant initiatives that enhanced drug regulation standards and reinforced India's pharmaceutical reputation globally. In his current role, Bhanu is set to drive the expansion of India's pharmaceutical exports, boost global competitiveness, and adeptly navigate the complexities of international regulations, leveraging his extensive expertise to foster industry growth and global prominence. In an interaction with BioSpectrum, he shared his plans on addressing many challenges before the Indian pharma industry to stay compliant with international regulations. ***Edited excerpts:***

« **K Raja Bhanu,** Director General, Pharmaceuticals Export Promotion Council of India (Pharmexcil)

How do you feel after being appointed as Director General at Pharmexcil and what are your priorities?

I am truly honoured to assume the role of Director General of Pharmexcil. I am grateful to all the industry stakeholders and the government for their trust in my leadership. This position is a significant responsibility, and I am committed to addressing the key challenges facing the pharmaceutical export sector. Building on the successful initiatives of my predecessors, my priorities will include identifying and understanding these challenges, engaging regularly with industry leaders to address their concerns, and representing their interests to both state and central governments, as well as international agencies, to achieve effective solutions.

Could you provide an overview of the current export scenario of Indian pharmaceuticals in the global markets?

India’s pharmaceutical sector has experienced significant growth in recent years, with the country now exporting medicines to over 190 nations. By the end of April 2024, pharmaceutical exports had reached $27.9 billion. In the last quarter alone, we saw a growth rate exceeding 9.6 per cent, and we expect this figure to hit double digits by year-end. This growth highlights India's expanding ability to meet global healthcare needs through affordable generic drugs. When comparing India’s exports to global market trends, our sector is thriving. In the calendar year 2022-23, the global pharmaceutical market had a turnover of $1,407 billion with just a 1 per cent growth. In contrast, India’s pharmaceutical exports grew by over 3.25 per cent during the same period, reaching $25.394 billion. This growth accelerated in the following year (2023-24), reaching $27.9 billion.

Overall, India’s drug and pharmaceutical exports increased by 7.36 per cent, rising from $2.26 billion in April 2023 to $2.43 billion in April 2024. Key exporters from India include prominent companies such as Dr. Reddy’s Laboratories, Elkos Healthcare, Aurobindo, Cipla, Lupin, and Sun Pharmaceuticals, among others.

What is India's share in the global pharmaceutical export market and which are the major markets where India is growing?

India holds a 5.71 per cent share of the global pharmaceutical export market. The major portion of its exports comprises formulations and biologics, accounting for 72.54 per cent of the total, with drug intermediates and bulk drugs following. For FY24 (up

India is making significant strides to align its pharmaceutical industry with global standards. Recent improvements include the overhaul of regulatory frameworks such as Schedule M, which mandates rigorous quality and safety standards. The central govt. has also introduced regulatory reforms aimed at enhancing production practices & environmental compliance, ensuring that Indian pharmaceutical products meet international benchmarks.

to February 2024), India's pharmaceutical exports totalled $25.02 billion, compared to $25.4 billion in FY23 and $24.59 billion in FY22. The key export destinations are the USA, Belgium, South Africa, the UK, and Brazil. India has the highest number of US FDA-compliant companies with facilities outside the USA, houses about eight of the top 20 global generic companies, and directs over 55 per cent of its exports to highly regulated markets. Additionally, India is the largest global vaccine exporter, meeting approximately 65-70 per cent of the World Health Organization's vaccine needs.

Which initiatives have Pharmexcil undertaken to promote pharmaceutical exports from India? How do these initiatives facilitate Indian companies' entry into global markets?

Pharmexcil has been actively working to enhance the global presence of Indian pharmaceutical companies. We have launched several initiatives, including trade fairs, buyer-seller meets, and promotional campaigns in key markets. These activities help Indian companies understand international market demands and regulatory requirements, facilitating smoother entry into global markets.

What are the key regulatory challenges Indian pharmaceutical companies face globally? How is India addressing these challenges to stay compliant with international regulations?

Indian pharmaceutical companies face several regulatory challenges, including compliance with varying international standards and frequent updates to regulations. To address these challenges, India is continuously updating its regulatory framework and ensuring that domestic companies adhere to international standards. The implementation of stringent regulations and regular training programmes for industry professionals are steps taken to stay compliant. Apart from helping companies navigate complex global regulatory requirements, we are also giving the highest priority in addressing concerns related to quality and safety. Pharmexcil is actively involved in overcoming these challenges by organising awareness campaigns, providing industry training, and facilitating dialogue between regulatory bodies and pharmaceutical companies. Our goal is to ensure that Indian pharmaceutical products meet the highest standards globally.

In what ways is India upgrading its pharmaceutical industry to align with global regulatory standards?

India is making significant strides to align its pharmaceutical industry with global standards. Recent improvements include the overhaul of regulatory frameworks such as Schedule M, which mandates rigorous quality and safety standards. The central govt. has also introduced regulatory reforms aimed at enhancing production practices & environmental compliance, ensuring that Indian pharmaceutical products meet international benchmarks.

How is India faring in the Active Pharmaceutical Ingredients (APIs) and Key Starting Materials (KSMs) sector?

The API sector remains a challenging area for India. Currently, we rely on imports for more than 80 per cent of intermediates and KSMs, primarily from countries like China. However, there is a strong push towards achieving self-sufficiency. The government's Production-Linked Incentive (PLI) scheme is designed to boost domestic production and reduce dependence on imports, which we hope will significantly enhance our capabilities in the API sector.

How do the PLI scheme and other government initiatives contribute to the improvement of the pharmaceutical sector in India?

The PLI scheme is a crucial initiative aimed at enhancing the domestic production of APIs and other pharmaceutical products. It offers incentives to both domestic and international players to invest in India, thereby boosting our production capabilities and reducing import dependence. This scheme, along with other government initiatives, provides significant financial support and encourages technological advancements, contributing to the overall growth and competitiveness of the Indian pharmaceutical sector. BS

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Navigation Technology Trends in Healthcare

Like all other sectors, technology has become a pivotal part of healthcare, revolutionising diagnostics and treatment. This transformation extends beyond medical treatments, improving healthcare business processes and patient experiences. With the advent of technology, patients can now enjoy conveniences like online appointment scheduling, easy access to medical records, and direct communication with doctors through digital platforms. Among these advancements, navigation technology is a game-changer in minimally invasive surgical practices. This innovative approach has significantly improved the precision and safety of minimally invasive surgeries, introducing a new era in medical procedures. Navigation systems are at the forefront of a technological revolution in healthcare, reshaping surgeries by offering accuracy and better patient outcomes.

« **Arpit Paliwal,**
Director,
HRS Navigation

Expansion beyond neurosurgery

Navigation technology has revolutionised surgical procedures across multiple specialities, with its impact extending far beyond its initial applications in neurosurgery. Studies have demonstrated that navigation-assisted surgeries significantly improve screw placement accuracy and reduce reoperation rates which leads to increased demand for these advanced systems in specialities like orthopaedics and neurosurgery. In neurosurgery, this technology enables precise navigation of complex brain structures by minimising tissue damage and promoting faster recovery. For endoscopic sinus surgeries, it allows for minimally invasive techniques, improving accuracy and patient satisfaction. Spinal surgeries benefit from reduced pedicle breaches, lower radiation exposure for surgeons, and more accurate implant placement, resulting in improved outcomes and faster recovery times. With navigation technology, cranial surgeries see shorter operation times, which reduces blood loss and minimises trauma, leading to lower risks of postoperative complications.

Improved surgical accuracy

The integration of advanced navigation technology has brought about a tectonic shift in surgery by enhancing precision and patient outcomes. These technologies provide surgeons with high-definition, real-time imaging and tracking capabilities, offering a significant advantage over traditional techniques that rely heavily on experience and mental reconstruction of anatomy. By delivering a clear visual roadmap of the patient's internal structures, these systems enable surgeons to navigate complex anatomical areas accurately. Real-time instrument tracking further reduces the risk of accidental tissue damage. Studies have demonstrated the benefits of these navigation-assisted procedures by showing improved accuracy in tasks such as screw placement during spinal surgeries and overall reduced rates of repeated surgeries.

Integration with advanced technologies

Navigation technologies are the backbone of digital surgery, with their tracking systems providing crucial information that complements radiological imaging. These advanced tools significantly enhance surgeons' awareness and precision during surgeries. The true potential of surgical navigation is now being unlocked through its integration with cutting-edge technologies such as robotics, augmented reality (AR), and virtual reality (VR). This seamless convergence creates a new surgical accuracy and efficiency paradigm, particularly in spine surgery and other specialities.

Rising demand for MIS

As patients seek faster recovery times and reduced complications, the demand for minimally invasive surgeries (MIS) continues to increase. Navigation technologies are instrumental in making these procedures safer and more efficient, particularly in complex areas like spine surgery. The ability to perform intricate operations through smaller incisions is a game-changer in patient care. The advent of these advanced systems has necessitated changes in surgical training and education. Virtual and augmented reality applications integrated with navigation technologies offer opportunities for surgeons to practice and perfect their skills in risk-free environments. This evolution in training methodologies is crucial for the widespread adoption and effective use of these technologies. BS

3 Decades of Bioinformatics Advancements

« **Dr Ravi Gupta,** Vice President – Bioinformatics, MedGenome

"Bioinformatics" was first used in 1992 to refer to the creation of databases for storing genome information. Over time, its scope has expanded to include various computational techniques for gene mapping and DNA sequencing within genomic research. Paulien Hogeweg and Ben Hesper are credited with coining the term to describe "the study of informatic processes in biotic systems." This concept gained popularity as biological sequence data became accessible.

Major advancements

1. The Human Genome Project (HGP): Completed in 2003, the HGP mapped the entire human genome, requiring sophisticated bioinformatics tools for data sequencing and analysis. This project set the stage for numerous other genomic projects.

2. Next-Generation Sequencing (NGS): NGS technologies revolutionised bioinformatics by enabling rapid and cost-effective sequencing of large genomes. This has led to a deeper understanding of genetic variations and their impact on health and disease.

3. Proteomics and Metabolomics: Bioinformatics has expanded to include proteomics (study of proteins) and metabolomics (study of metabolites). Techniques like mass spectrometry and nuclear magnetic resonance (NMR) have been integrated with bioinformatics tools to analyse complex biological samples.

4. Structural Bioinformatics: This area focuses on the 3D structure of biomolecules. Techniques like X-ray crystallography and cryo-electron microscopy, combined with bioinformatics algorithms, have helped elucidate the structures of numerous proteins and nucleic acids, advancing our understanding of their functions.

5. Integration of Omics Data: Integrating genomics, transcriptomics, proteomics, and metabolomics data has provided a more comprehensive view of biological systems. This holistic approach, systems biology, is crucial for understanding complex diseases and developing targeted therapies.

6. Metagenomics: This field, established in the late 1990s and early 2000s, uses DNA sequencing to study entire microbial communities directly from environmental samples. This approach allows researchers to analyse the genetic material of all microorganisms in each sample, regardless of whether they are cultured. Metagenomics has opened new avenues of research in environmental microbiology and biotechnology.

Transformative trends

1. Cloud Computing: The vast amount of data generated by bioinformatics requires significant computational resources. Cloud computing offers scalable solutions for storing and processing this data, making it accessible to researchers worldwide.

2. Personalised Medicine: One of the most promising bioinformatics applications is personalised medicine. By analysing an individual's genetic makeup, bioinformatics can empower clinicians with specific information that can help them design customised treatment plans, improving efficacy and reducing the side effects of therapies. The future of bioinformatics in this area is bright, with the potential to revolutionise healthcare by providing tailored treatments based on a patient's unique genetic profile.

3. Chemoinformatics: This emerging field combines chemistry and bioinformatics to streamline drug discovery. Advanced computational models can predict the interaction of drug molecules with biological targets, accelerating the development of new therapeutics.

4. Ethical and Privacy Considerations: As bioinformatics continues to evolve, ethical and privacy concerns surrounding the use of genetic data are becoming increasingly important. Developing stringent and conducive frameworks to ensure data security and patient privacy is crucial.

Bioinformatics has grown a lot since it started in the early 1990s. It has helped us understand biology and medicine better, leading to big developments in studying genes, proteins, and finding new drugs. As we move forward, using deep learning, storing data online (cloud computing), and focusing on treatments designed for individuals will greatly change healthcare. This means better and more tailored treatments for everyone around the world. BS

Beyond H2O: How Water Restructuring Could Reshape Modern Healthcare

Water, the essence of life, has been a subject of scientific inquiry for centuries. Yet, recent advancements in our understanding of water's molecular structure and behaviour are opening up exciting new frontiers in healthcare. This article delves into the cutting-edge field of water structuring and its potential to revolutionise modern medicine.

« **Madhusudan Rajagopalan,** CEO, Analemma Coherent Water

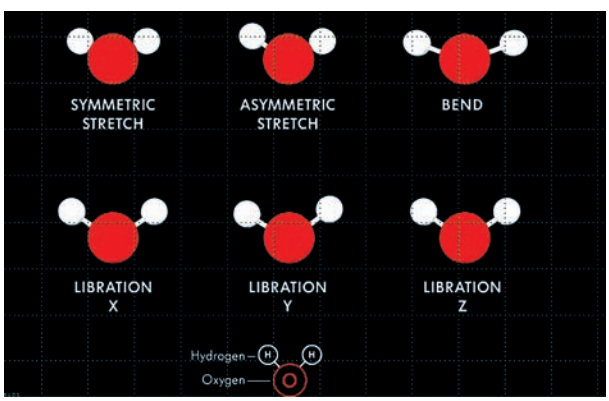
At first glance, water seems simple – two hydrogen atoms bonded to one oxygen atom. However, the behaviour of water molecules en masse is far more complex. Water molecules form hydrogen bonds with each other, creating clusters and networks that are constantly shifting and rearranging. These molecular arrangements give water unique properties, such as its high boiling point and ability to dissolve many substances. But there is also still a lot that is less known about water.

In the last decades, several important, and new scientific discoveries about water have been made. We now understand how water actually is a great energy converter, the most important carrier of electromagnetic energy on earth. Renowned scientists such as Luc Montagnier, Gerald Pollack, Marc Henry, Pierre Madl, and Emilio del Giudice offer new explanatory models for the 'miraculous' behaviour of water.

Water absorbs around 70 per cent of all the electromagnetic energy in our atmosphere, making water the most important electromagnetic energy carrier on Earth. Water absorbs, and/or reacts to electromagnetic waves of 106 Hertz with wavelengths of about 100 metres to waves of 1021 Hertz with wavelength sizes of atomic nuclei. Water has the unique ability to interact with and react to electromagnetic frequencies, by constantly adapting its molecular structures. Beyond its 'simple' chemical composition 'H2O', water has a dynamic and self-organising structure.

When it absorbs energy, water doesn't simply contain and transport the received energy. Any interaction with electromagnetic frequencies - whether electromagnetic radiation or the interaction with the frequencies emitted by chemical substances - has its effects on the physical structure of water.

Prof. Martin Chaplin (Emeritus Professor, London South Bank University) has been one of the first to describe the different movements of water molecules. The movements illustrate the flexibility of water-structures.



Water owes many of its unique properties to the polarity of its molecules and, specifically, to their ability to form hydrogen bonds with each other and with other molecules. These connections unfortunately also mean that with 'normal' chemical cleaning of water, polluting chemicals can mostly be removed, but the stressing frequencies and radiation, which came with the chemicals, and which the water has absorbed, will remain: water will hold these unhealthy structures.

Based on general Quantum Field Theory, Prof. Emilio del Giudice has explained how the molecule structures of water are actually not homogeneous. Water is composed of a mixture of two entirely different types of molecular order: so called 'coherence domains' and incoherent regions. In the incoherent regions, the quantum oscillations of water molecules are independent from each other, which means the oscillations produce little energy.

In Coherence Domains the molecules are ordered and display collective quantum oscillations with high energy. In Prof. Del Guidice's words: "Water has the possibility to produce extremely sophisticated

Water Restructuring

Water restructuring involves altering the molecular configuration of water clusters to alter the coherence. In ancient traditions, healing practices have been used to restore the natural properties of polluted or disturbed water, though this was not accepted by Western scientific methods. Today, there is a growing body of work that is establishing that generating natural, restorative frequencies will allow water to reorganise and restore its structures. Water's structure can be influenced through various methods, including: Exposure to specific minerals or crystals; Acoustic waves; Electromagnetic fields; Vortexing or structured flow patterns, or A combination of methods noted earlier.

electromagnetic fields i.e. over the course of time the system changes from one configuration into another, which it can do with tiny leaps of energy. From where can water take this energy? From the environment! Water can take energy from the environment, from ambient noise that is chaotic, and turn it into very precise vortexes of electrons: by means of an ordered excitation, water thus generates a spontaneous decrease in entropy."

Modern science is utilising methods such as Near Infrared Spectroscopy and Aquaphotonomics to measure the exact way in which water absorbs electromagnetic waves. By looking at ultra-weak photon emissions, science is showing us the vital role of coherence in water for homeostasis. Thus, the importance of 'energetic cleaning' of water, and restoring water to its 'natural order' should be considered of increasing importance to health.

Potential Applications in Healthcare

1. Enhanced Hydration and Nutrient Absorption: Coherent water is more easily absorbed by cells, potentially improving hydration at a cellular level. This could be particularly beneficial for athletes, the elderly, or patients recovering from illness. Moreover, improved cellular absorption could enhance the delivery of nutrients and medications throughout the body, potentially increasing their efficacy.

2. Higher mitochondrial activity and energy levels : Clinical studies have shown the impact of coherent water on ATP concentration levels in whole blood for humans. Regular consumption of coherent water leads to better mitochondrial activity, thereby leading to an increase in energy levels. Studies have shown a 20%+ increase in ATP levels, thereby boosting performance and fighting fatigue more effectively.

3. Detoxification and Waste Removal: The altered molecular structure of restructured water might improve its ability to bind to and remove toxins from the body. This could have applications in treating conditions related to environmental toxin exposure or supporting liver and kidney function. However, more research is required to establish this phenomenon.

4. Reducing Inflammation: The Glycanage study conducted by our team showed an improvement in the anti-inflammatory markers and reduction in the pro-inflammatory markers, indicating a clear improvement in inflammation levels within the body. The larger implications of this need more research studies though.

5. Improved gut health: Coherent water has been seen to have a clear relationship to a balanced microbiome. Studies have shown a stark improvement in the quality of the microbiome in soil, as well as of that in the human gut. This has vast implications for health, as this is a subject of much concern for health professionals, and being able to influence it with just a change in water could mean significant changes in their approach.

6. Brain coherence: The human brain is over 80 per cent water and a change in the structure of water to coherence shows up almost immediately in brain scans (QEEG) as more balance. This has implications for people going through stress as well as for those afflicted with disorders of the brain. This is also interlinked with the impact on gut health, given the gut-brain axis and that factor's impact on overall health of an individual.

Outlook

Water restructuring represents a fascinating frontier in healthcare research. While more aspects of coherent / structured water come to light, the potential benefits are too significant to ignore. As our understanding of water's complex behaviour grows, we may find ourselves on the cusp of a new era in medicine – one where the most abundant substance on Earth becomes our most powerful ally in promoting health and fighting disease.

The journey from laboratory curiosity to clinical application is often long and fraught with challenges. However, if the promises of water restructuring can be realised, it could usher in a paradigm shift in how we approach healthcare, offering new hope in the field of wellness and new tools for practitioners and healthcare providers. As we continue to unlock the secrets of water, we may find that the key to many of our medical challenges has been flowing through our rivers all along. BS

(L-R) D. K. Shivakumar, Deputy Chief Minister of Karnataka; Dr Ekroop Caur, Secretary to Government, Dept of E, IT, Bt and Science & Technology, Govt of Karnataka; Prof. Navakanta Bhat, Chair, VGNT, Govt of Karnataka, and Jagdish Patankar, Executive Chairman, MM Activ, Sci- Tech Communications inaugurated the Exhibition Centre at 13th Bengaluru INDIA NANO 2024.

13th Bengaluru INDIA NANO 2024 brings together 1018 delegates, 3,000+ visitors

The 13th edition of Bengaluru INDIA NANO 2024, organised by the Department of Science & Technology, Government of Karnataka, Karnataka Science & Technology Promotion Society (KSTePS), and Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR) concluded on August 3 with participation of 1018 delegates, 11 countries including Korea, Morocco, USA, UK, France, Canada, Germany, Netherlands, Russia, Japan, and Poland, 49 exhibitors comprising 21 startups and 28 industry and institutes, and 200 posters. The exhibition had a footfall of 3,000+ visitors.

The conference featured 81 distinguished speakers across 41 sessions, exploring a broad range of topics from cutting-edge research to practical industry applications in nanotechnology. Over 200 young attendees participated in the pre-conference tutorials.

During the two days sessions on “Nano in Healthcare”, Prof. Dhirendra Katti, Director, IIT Goa spoke on 'Development of a Vaccines/Nano vaccines for Multi-drug Resistant Diarrhoea'; Dr Jiban Jyoti Panda, Associate Professor, Institute of Nano Science and Technology, Mohali spoke on 'Brain targeting Small Molecular Nanomedicines', Prof. Biman B. Mandal, Professor, IIT Guwahati shared his views on ‘Nano-Composite Silk Hydrogel for Spatiotemporal, Targeted and On-Demand Controlled Release of Chemotherapeutics: An In Vivo Approach toward Suppressing Solid Tumour Growth’, This session was chaired by Prof. Swaminathan, Professor & Director, SASTRA University.

Dr Praveen Kumar Vemula, Faculty, DBT – INSTEM chaired a second session on Nano in Healthcare in which Prof. Neetu Singh, Professor & Head, Center for Biomedical Engineering, Indian Institute of Technology Delhi shared her views on the topic '3D Liver Platforms For In-Situ Disease Staging' and in his presentation Prof. Bikramjit Basu, Professor, IISc Bangalore touched upon 'Size-tailored Gold Nanoparticles: Novel electroactuators to guide stem cell differentiation and as bacteriotoxic agents' and Prof. K. Uma Maheswari, Professor, Sastra University spoke on Smart Non-intervention for Therapy.

Dr Taslimarif Syed, CEO and Director, C- CAMP, moderated a panel discussion on 'Healthcare & Medical Electronics' with Dr Aditya Kulkarni,

“Scientists should innovate solutions in nanotechnology for critical areas including healthcare”

(L-R): Priyank Kharge, Minister for Information Technology & Biotechnology, Government of Karnataka (GoK); Rizwan Arshad, Member of the Legislative Assembly, Shivajinagar Assembly Constituency, Karnataka; N S Boseraju, Minister of Minor Irrigation and Science & technology, GoK; Siddaramiah, Chief Minister of Karnataka; Prof. Arindam Ghosh from the Indian Institute of Science, Bengaluru; Prof. C.N.R. Rao, Honorary Chairman, VGNT, Govt of Karnataka, National Research Professor & Linus Pauling Research Professor, Honorary President, JNCASR, Bengaluru; Dr Indumati Rao, Hon. Coordinator, ETU, INCASR, Bengaluru; Dr Kiran Mazumdar-Shaw, Executive Chairperson, Biocon Ltd; Chairperson Vision Group on Biotechnology, GoK; Dr Shalini Rajnesh, Chief Secretary, GoK; felicitated Dr Arindam Ghosh at the Bengaluru INDIA NANO 2024 with the Prof. C.N.R. Rao Bengaluru INDIA NANO Science Award.

“Our scientists and engineers should innovate solutions in nanotechnology for critical areas such as food and energy security, water purification, healthcare, and waste management,” urged Siddaramaiah, Chief Minister of Karnataka.

Speaking after inaugurating the 13th edition of Bengaluru INDIA NANO 2024 on the theme, ‘Nanotechnology for Sustainability: Climate, Energy, and Healthcare’, on August 2, he said “Addressing the challenges posed by urbanisation and environmental hazards requires robust international collaboration and a strong link between academia, industry, and research to advance this promising technology for the benefit of humanity."

In his address, N S Boseraju, Minister of Science & Technology and Minor Irrigation, Government of Karnataka said, “This prestigious nanotech event in India serves as a platform for networking and exchange knowledge on the new frontiers of science and technology. The nanotechnology sector has a crucial role in making the world more sustainable. Beyond climate, energy, and healthcare, two other significant global challenges are food and water security. Our government, is making all-out efforts to develop Karnataka as a major player in the Nanotechnology sector. We will provide all the necessary support for growth of this sunrise industry in the state.”

In recognition of his contribution in advancing science and celebrating his 90th birthday year Bharat Ratna Prof. C.N.R. Rao, Honorary Chairman of Vision Group on Nanotechnology and Linus Pauling Research Professor, and Honorary President of JNCASR, Bengaluru, who has been the driving force behind this event was felicitated at the event.

Prof. Arindam Ghosh from the Indian Institute of Science, Bengaluru, who is also the recipient of Prof. C.N.R. Rao Bengaluru INDIA NANO Science Award, delivered a compelling and insightful plenary talk. The "Nano for the Young" lecture, an initiative by Bharat Ratna Prof. C.N.R. Rao, FRS, aimed at inspiring nanotechnology students, was led by Prof. Ashok K Ganguli, Director & Professor of Chemical Science at IISER Berhampur, and Dr B L V Prasad, Director of the Centre for Nano and Soft Matter Research, India.

D K Shivakumar, Deputy Chief Minister of Karnataka inaugurated the exhibition that showcased the latest innovations, products, and technologies in nanotechnology. With over 50 leading companies, research institutions, and startups presenting their cutting-edge nanotech products and services, it was a brilliant display of scientific and industry advancements. BS

Founder and CSO, Avammune Therapeutics, Dr Ashwin Lal, Founder & CEO, Shilps Sciences, Dr Subhasis Sarangi, Founder, SAIMAF Healthcare, Md Lateefuddin Shariff, Director, India DM Lead, AstraZeneca as panel members.

Speaking at the valedictory of the event, Dr Devi Shetty, Founder, Narayana Hrudayalaya said, "I firmly believe that India will be the first country in the world to dissociate healthcare quality from wealth, demonstrating that every citizen can access top-tier healthcare regardless of financial status. This transformation is not a distant dream, it is set to happen in the next five to ten years, propelled by rapid advancements in healthcare technology and the dedication of brilliant innovators."

In his address NS Boseraju, Minister of Science & Technology and Minor Irrigation, Government of Karnataka said, "Our government is dedicated to fostering innovation, as seen in our support for both nanotechnology and emerging fields like quantum technology. We are investing in science centers across Karnataka and constructing a state-of-the-art facility in Bangalore to promote scientific inquiry and curiosity. These efforts are aimed at addressing critical global challenges such as climate change, food security, and water security. As we move forward, let us harness these technologies to drive sustainable development and ensure that scientific advancements serve humanity with compassion and responsibility."

The Bengaluru INDIA NANO Innovation Award 2024 was bestowed upon the JNCASR-CeNS-SGRI Team for their breakthrough Smart Glass Technology, accompanied by a trophy, a certificate, and a cash award of Rs 1,00,000. Besides the Karnataka DST Nanoscience Fellowships were awarded to five scientists: Sumita Mukherjee from the Indian Institute of Science Education and Research (IISER), Berhampur; Soumi Mondal from the New Chemistry Unit, JNCASR, Bengaluru; Dr Kenneth Lobo from the Centre for Nano and Soft Matter Sciences, Bangalore; Manisha Bungla from the Indian Institute of Technology, Delhi; and Sourav Rudra from the Chemistry and Physics of Materials Unit, JNCASR, Bengaluru. Each recipient received a certificate and a cash prize of Rs 50,000.

In the Nano SparX Startup Pitch, a total of 18 startups from across the country participated in the competition. Out of these, five finalists—Neer Shakti Systems Pvt Ltd, Pradaan Innovation Labs LLP, Vimano, Trinano Technologies Pvt Ltd, and Shilps Sciences—showcased their groundbreaking ideas. After a rigorous evaluation, Vimano and Neer Shakti Systems Pvt Ltd startups were selected as winners for their outstanding pitches, demonstrating their potential to make significant contributions to nanotechnology winning Rs 50,000 cash prize each.

(from L-R) Jagdish Patankar, Executive Chairman, MM Activ, Sci-Tech Communications; Dr Ekroop Caur, Secretary to Government, Dept of E, IT, Bt and Science & Technology, Government of Karnataka; Dr Devi Shetty, Founder, Narayana Hrudayalaya Pvt Ltd; N S Boseraju, Minister of Minor Irrigation and Science & technology, Govt of Karnataka; Prof. Navakanta Bhat, Chair, Vision Group on Nanotechnology, Govt of Karnataka and Dean, Division of Interdisciplinary Sciences, Professor, CeNSE, IISc, Bengaluru; Prof. P S Anil Kumar, Chair, CEC, 13th Bengaluru INDIA NANO 2024 and Dean, Administration & Finance, Professor – Dept of Physics, IISc, Bengaluru; Pawan Kumar Malapati, Director, Dept of Science and Technology and Managing Director Karnataka Science and Technology Promotion Society, Govt of Karnataka along with winners of Poster Awards at 13th Bengaluru INDIA NANO 2024.

The Best Poster Awards, a highlight of Bengaluru India Nano, showcased innovative research from over 200 young researchers. With participation from 35 cities, 19 states, 3 entries from abroad, and 70 institutions—including 145 posters from Bengaluru—the event was a vibrant platform for emerging talent. The top 15 posters were honored with a cash prize of Rs 20,000 and a certificate. Notable institutions among the winners included the National Institute of Technology, Rourkela; IIT Roorkee; Indian Institute of Science, Bengaluru; ICAR-National Bureau of Agricultural Insect Resources; Centre for Nano and Soft Matter Sciences; Jawaharlal Nehru Centre for Advanced Scientific Research; and the Institute of Nano Science and Technology.

At the Valedictory, several exhibitors were recognised for their exceptional showcase. The Exhibitor Awards featured various categories, with Park Systems winning in the Interactive & Best Managed category. Indian Oil Corporation Limited was honored for its Content & Information, while the Ray Nano Science & Research Centre received the award for Innovative Display.

The 13th edition of Bengaluru INDIA NANO has not only showcased the latest advancements in nanotechnology but has also fostered collaboration and innovation among the brightest minds in the field. The event's success highlights its importance as a global platform for knowledge exchange and networking, paving the way for future breakthroughs in sustainability, climate, energy, and healthcare. The 14th edition of Bengaluru INDIA NANO has been announced for July 2026. BS

BIOTECH INNOVATIONS & SUPPLIERS CONCLAVE'24
23rd AUGUST 2024

"Indian BioSupplier sector needs capacity and capability building to strengthen local presence"

The experts from the BioSupplier industry discussed the need of the hour on August 23, 2024 at the Biotech Innovations & Suppliers Conclave 2024, organised by BioSpectrum, in Navi Mumbai, to develop cost-effective and best quality solutions for the Indian market, as a strategy to boost domestic production and maintain an overall global competitiveness. The importance of bringing global technologies to India and adapting them to local needs, as well as introducing innovations around existing technologies are some of the key agendas of the biotech industry-based suppliers in India currently.

The biosupplier market is undoubtedly a critical part of the biotech industry catering to the different requirements in public and private sectors comprising academia, pharma and biotech companies, contract/ clinical research organisations (CROs) etc. While the Indian biosupplier market is growing at a rapid pace, a large chunk of it is governed by global players. Thus, it becomes imperative to strengthen local development of analytical instruments and supplies required for biotech innovation in the country because the biotech innovation ecosystem's potential and its rapid growth are recognised as the key contributor to the growth of the global bioeconomy. However, many hurdles need to be addressed before we achieve that.

During a panel discussion at the event which focused on the challenges being faced by the biosuppliers for developing new age technologies and instruments locally, an intriguing point was brought forth by ***V Sankaranarayanan, Managing Director, VFL Sciences*** where he mentioned that there is a requirement of institutions focusing on the building and development of complex, new-age analytical instruments in India. "Compared to the density of such facilities in the Western counterparts in the US or Europe, the Indian biosupplier sector has not seen enough of such institutions yet, except for one in Chandigarh", he said.

Adding to this crucial element of building the 'Capacity and Capability' to strengthen domestic development of advanced analytical instruments, ***Yogeendra Dawalkar, General Manager-Commercial, Premas Life Sciences*** further extrapolated, "The amount of encouragement or scope required for doing that in India is not there. Although certain initiatives are being taken by the industry and the government, I think a lot more needs to be done in this direction."

A key takeaway of the discussion also broadly highlighted the idea that suppliers are currently working on developing cost-effective tools and technologies that enable Indian players to compete with multinational corporations.

Sharing a global perspective in this direction, ***T. Anil Kumar, President, Waters India*** said, "If we have to help the industry to go into the similar way of the generics for biosimilars, we need collaborations, partnerships with the government. We are also making efforts to establish centres of excellence, where we can partner with academic institutions. For example, recently we established a centre of excellence at the Indian Institute of Toxicology Research, where we are addressing risk assessment of carcinogenic drugs. So, partnerships with the government, and initiatives from the

government's side are essential. As a biosupplier in the instruments area, we are ready to come to the Indian market. We want the Indian industry to produce biosimilars because these are the need of the hour, to tackle chronic diseases in the India centric scenario."

Critical for novel research

Given the rapidly evolving landscape of the biosupplier sector, emphasising its critical role in advancing biotech and biopharma manufacturing in India is impertinent. While India has made strides in small molecule generics, the trajectory graph for biosimilars, and other trending innovative biopharma and biotech products, such as cell and gene therapy technologies, remain comparatively underdeveloped to their full potential. Case-in-point made during another panel discussion at the Biotech Innovations & Suppliers Conclave 2024, focused on the challenges encountered and the way forward in accelerating biotech, pharma research, and innovation with new technologies.

"While the biopharma companies in India are looking at reducing the cost, the yields and titres of many of the companies manufacturing biosimilars are relatively lower, close to, or even less than a gram per litre, as compared to giants like Samsung that are operating at five grams, eight grams, 20 grams titres. So, you cannot only keep on reducing the cost. You need to bring your titres up. But things are shaping up now, and as suppliers, this is where we can bring in a lot of value, for making Indian companies a lot more competitive, especially if you need to compete with Taiwanese or Koreans or even Chinese, it's not an easy market", pointed out ***Aditya Sharma, Head Process Solutions, Merck Life Science, India.***

Panelists spoke about the complexity of the research and innovation environment of the biopharma, and biotech sectors, as well as the need for multiple players to work together. The discussion also focused on the importance of developing the right infrastructure for innovators, emphasising the need for a conducive environment and collaboration between government, private partners, and scientists. Experts also advocated for increasing communication between the researchers and suppliers so that the right technology is made available to the innovator in the best way possible.

Another significant factor that the panelists highlighted is the role of academic research and young scientists as important flag-bearers of biotech innovations. The conversation highlighted the importance of capacity building, innovation, and partnerships between academia, industry, and suppliers to drive scientific advancements and commercialisation in India.

"Suppliers are the ones who really accelerate the pace of the biotech sector, and we must recognise their efforts and challenges. Although BioSpectrum has been recognising the efforts of the life sciences industry players across verticals since 2014 in the form of our Excellence Awards programme, it is for the first time that we have organised an elaborate programme to recognise the efforts of the biotech industry suppliers in detail".

- Ravindra Boratkar,
Publisher and Managing Editor, BioSpectrum, and Managing Director, MM Activ Sci-Tech Communications

Highlighting the government's role in strengthening the biosupplier sector for promoting biotech innovation, in his inaugural address ***Dr Jitendra Kumar, Managing Director, Biotechnology Industry Research Assistance Council (BIRAC),*** talked about the critical role of innovation clusters and robust R&D institutions in driving the growth of the biosupplier and biopharma/biotech markets. He emphasised that a dense network of vendors and suppliers for advanced equipment is a crucial factor in fostering innovation, as seen in the thriving ecosystems of Hyderabad, Bengaluru, and Pune. He also underscored the need for India to better showcase its innovations to a global audience. Dr Kumar also touched upon the collaborative challenges in India's ecosystem, noting that there is still a need for stronger cooperation across the ecosystem. "The world is moving towards sustainable bio-manufacturing, including advancements in green chemistry, precision fermentation, and AI-enabled technologies. With continued cooperation and

The biosupplier market is undoubtedly a critical part of the biotech industry catering to the different requirements in public and private sectors. While the Indian biosupplier market is growing at a rapid pace, a large chunk of it is governed by global players. Thus, it becomes imperative to strengthen local development of analytical instruments and supplies required for biotech innovation in the country because the biotech innovation ecosystem's potential and its rapid growth are recognised as the key contributor to the growth of the global bioeconomy. However, many hurdles need to be addressed before we achieve that.

innovation, India's bio-economy is poised for significant growth in the coming years", he said.

The event also took into consideration a few more aspects of biotech and pharma research such as quality assurance, cleanroom technology, hygiene, and sterility, as these are foundational pillars of the biopharma and biotech sector, ensuring the safety, efficacy, and reliability of products. As regulatory standards continue to evolve, maintaining high levels of hygiene and sterility is essential for compliance and for upholding the industry's commitment to producing safe and effective therapeutics.

Sharing his views about the supplier sector, ***Manas Kumar, Global Director Pharma & Director Strategic Marketing and Business Development- APAC at Lindström Oy*** pointed out the new trends towards outsourcing sterilisation for ready-to-use products and adopting newer techniques like E-beam and X-ray. The discussion with other industry experts around this topic, focused on the current rapid advancements in sterility testing. As it turns out, this acceleration is crucial for getting products, especially in cell and gene therapy, to market faster while maintaining high-quality standards.

"When talking about portraying ourselves as a pharmacy of the world, I would say that basic thing about quality is adherence to ethics, adherence to integrity, and finally, adherence to everything concerning the data and concerning the research which goes into that", said ***Shyam Khante, President, Shyam Khante & Associates.***

This panel discussion also addressed the global perception of Indian biopharma quality, noting significant improvements and the potential for future innovations, such as digital therapeutics and artificial intelligence (AI) in clinical trials. The industry's ability to adapt to emerging technologies and business models, including potential partnerships with tech giants as critical for maintaining global competitiveness was a key takeaway from the conversation.

Suppliers Excellence Awards 2024

Another key highlight of the event was the debut of Suppliers Excellence Awards 2024, which was organised for the very first time to recognise the efforts of the biotech industry based suppliers, across categories such as Analytical Instruments, Next generation technology, Research softwares, etc.

"Suppliers are the ones who really accelerate the pace of the biotech sector, and we must recognise their efforts and challenges. Although BioSpectrum has been recognising the efforts of the life sciences industry players across verticals since 2014 in the form of our Excellence Awards programme, it is for the first time that we have organised an elaborate programme to recognise the efforts of the biotech industry suppliers in detail", said Ravindra Boratkar, Publisher and Managing Editor, BioSpectrum, and Managing Director, MM Activ Sci-Tech Communications.

The awards were jointly presented to the winners by Ravindra Boratkar, and Dr Milind Kokje, Chief Editor, BioSpectrum. "There is immense potential for innovation that India holds for its biotech and biopharma industries, and the supplier market is a critical part of it. India hopes to take the lead in the bio-supplier sector, especially with the domestic players occupying the large chunk of the market in the coming years", said Dr Kokje in his welcome address.

The first edition of the Biotech Innovations & Suppliers Conclave 2024 played its part by bringing industry captains together who deliberated on a number of thought provoking topics, and sharing their knowledge on the same. The event was well supported by BIRAC as the Title Partner, and Eppendorf, Plasmid factory, Takara, Revvity, Lindstrom, HiMedia, and Biomerieux as industry partners. BS

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Panelists

L-R- Dr Prudwidhar S, Director of Medical Affairs, Miltenyi Biotec; Aditya Sharma, Head Process Solutions, Merck Life Science, India; Dr Neelima Khairatkar Joshi, Founder & President, Promethean Drug Ideas, Ex- Sr VP & Head, NCE Research, Glenmark Pharmaceuticals; Dr Ashutosh Kumar, Professor, Department of Biosciences and Bioengineering, IIT Bombay; Chaitanya Gundu, Country Leader, Sales & Marketing, Beckman Coulter Life Sciences; and Dr Asad Shahzada, Principal Product Specialist, Revvity Inc.

L-R- Shivani Thakkar, Content Creator, BioSpectrum; Manas Kumar, Global Director Pharma & Director Strategic Marketing and Business Development-APAC, Lindström Oy; Vivek Gupta, Chief Operating Officer, Symbio Generrics; Shyam Khante, President, Shyam Khante & Associates; and Naresh Kumar, Application Support Manager, BioMérieux Industrial Applications, South Asia.

L-R- Dr Manbeena Chawla, Executive Editor, BioSpectrum; Dr Girish Mahajan, Senior Vice President - Microbiology Division, HiMedia Laboratories; V Sankaranarayanan, Managing Director, VFL Sciences; Yogeendra Dawalkar, General Manager Commercial, Premas Life Sciences; Raghavendra Goud Vaggu, Executive Director, PharmNXT; and T Anil Kumar, President, Waters India.

Winners of Suppliers Excellence Awards 2024

BioTek Gen6 from Agilent Technologies receives Best Software for Biotech Research 2024 Award.

End-to-End Gene Synthesis Technology by Barcode Biosciences gets Special Recognition Technology 2024 Award.

Spectrum Compact CE System by Promega Corporation bags Best Analytical Instrument 2024 Award.

CytoFLEX Nano Flow Cytometer from Beckman Coulter Life Sciences receives Best Advanced Technology 2024 Award.

XELTA 3D from PharmaNXT Biotech bags Best Sustainable Solution for Biotech Research 2024 Award.

Olink's Proximity Extension Assay from Premas Life Sciences gets Best Advanced Technology 2024 (Distributor) Award.

Xevo TQ Absolute IVD Mass Spectrometer by Waters Corporation bags Next Generation Technology 2024 Award.

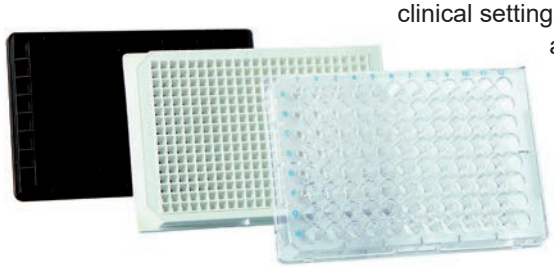
Ravindra Boratkar, Publisher and Managing Editor, BioSpectrum, and Managing Director, MM Activ Sci-Tech Communications; and Dr Milind Kokje, Chief Editor, BioSpectrum handed over the Suppliers Excellence Awards 2024 to all the winners.

β irradiated plasticware in PCR, RT-PCR, and cell biology experiments helps maintain a controlled and contamination-free environment

β -irradiation and γ - irradiation are both methods of sterilizing plasticware, but they utilize different types of radiation. Each method has its advantages and disadvantages.

β - irradiation, which involves the use of β - particles (high-energy electrons) emitted from a radioactive source, offers several advantages over γ irradiation:

• **Depth of Penetration:** β particles have a lower penetration power compared to γ rays. This means that β irradiation primarily affects the surface of the material being sterilized. In the context of plasticware, this can be advantageous, as it minimizes potential damage to the bulk properties of the plastic.



• **Uniformity:** β irradiation can provide a more uniform dose distribution across the irradiated surface. This uniformity is essential to ensure consistent sterilization without creating weak points in the material.

• **No Residual Radiation:** β irradiation does not leave residual radiation in the material after the sterilization process is complete. This is a significant advantage in applications where residual radiation is a concern.

• **Environmentally Friendly:** β irradiation doesn't rely on the use of radioactive isotopes, making it more environmentally friendly and easier to handle from a regulatory perspective.

• **Reduced Contamination Risk:** β irradiation effectively sterilizes plasticware, minimizing the risk of contamination in sensitive experiments like PCR and cell culture. Contamination can lead to inaccurate results, making sterilized plasticware crucial in maintaining experimental integrity.

• **Consistent and Reliable Results:** Sterile plasticware ensures consistent experimental conditions, leading to reliable and reproducible results in PCR and RT-PCR experiments. Contaminants from non-sterile plasticware can interfere with reactions, affecting the outcome of the experiments.

• **Preservation of Enzyme Activity:** β irradiation's surface sterilization method helps preserve the activity of enzymes used in PCR and RT-PCR reactions. Enzyme activity is essential for the success of these techniques, and minimizing the risk of contamination ensures optimal enzymatic reactions.

• **Cell Viability:** In cell biology experiments, sterile plasticware is critical for maintaining cell viability and ensuring that cell cultures are not compromised by microbial contamination. β irradiated plasticware provides a controlled environment for cell growth and experimentation.

• **Standardization and Quality Control:** Sterilization through β irradiation can be precisely controlled and monitored, ensuring standardized quality across batches of plasticware. This consistency is particularly important in research and clinical settings where reproducibility and accuracy are paramount.

• **Compliance with Regulations:** β irradiation methods often comply with regulatory standards, ensuring that plasticware used in PCR, RT-PCR, and cell biology experiments meets industry and research-specific guidelines for sterility and safety.

However, it's important to note that the choice between β and γ irradiation depends on the specific requirements of the application and the type of material being sterilized. Factors such as the thickness and composition of the plasticware, regulatory guidelines, and cost considerations also play a crucial role in the selection of the appropriate sterilization method. At BRAND all BRANDplates® are produced in clean room class 7 according to ISO 14 644 -1 and pre-sterilization according to Ph. Eur. and USP requirements. β radiation according to ISO 11137 and AAMI Guidelines using minimal dose of 25kGy to obtain SAL 10-6 .Overall, the use of β irradiated plasticware in PCR, RT-PCR, and cell biology experiments helps maintain a controlled and contamination-free environment, leading to accurate, reliable, and reproducible results in scientific research.

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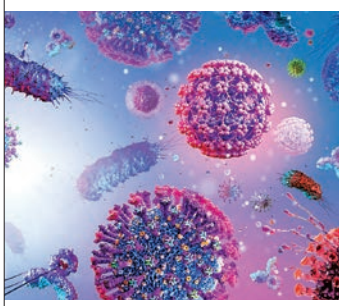
IIT Delhi transfers indigenous healthcare technologies to industry

Two indigenous healthcare technologies developed under the Ministry of Electronics and Information Technology (MeitY)-funded project Nanoelectronics Network for Research and Applications (NNetRA) have been transferred to the industry at an event recently hosted by Indian Institute of Technology (IIT) Delhi. Foundation for Innovation and Technology Transfer (FITT) at IIT Delhi has played an instrumental role in fostering this technology transfer. The technology named DNA Aptamer for Prostate Cancer Detection has been transferred to Dr Swapnil Sinha, Hummsa Biotech in Kolkata. The aptamer is developed by Prof. Prashant Mishra and his team from IIT Delhi and is capable of binding to the specific oncogenes and could be useful as theranostics for prostate cancer. On the other hand, the technology Photonic Chip based Spectrometric Biosensor for pathogen detection has been transferred to Nitin Zaveri, Unino Healthcare in Mumbai. This new technology has been developed by Prof. Joby Joseph and his team from IIT Delhi and will enable quick and accurate detection of the pathogens, thereby aiding in the prevention of infectious diseases.

IIT Kanpur paves way for new drugs against infectious diseases

A research team from the Indian Institute of Technology Kanpur (IIT-K), led by Prof. Arun K. Shukla of the Department of Biological Sciences and Bioengineering, has made a significant scientific breakthrough with the first-ever visualisation of the complete structure of the Duffy antigen receptor. This receptor protein, found on the surface of red blood cells and other cells in the human body acts as a gateway into the cell, facilitating infections by destructive pathogens like the malaria parasite, Plasmodium vivax and the bacterium, Staphylococcus aureus. While the Duffy antigen receptor is common in most populations, a significant percentage of people of African descent do not produce the Duffy receptor on their red blood cells due to a genetic variation. This makes them naturally resistant to certain types of malaria parasites that rely on that specific 'gateway' to infect those cells. This shows how important the Duffy antigen receptor is for these diseases and how targeting it could lead to new treatments.



Protein interaction study can help treatments for Alzheimer's & Parkinson's

Small molecules called osmolytes help proteins maintain their structure and function under stressful conditions, according to a recent study, which provides important insights that could aid in the development of treatments for diseases like Alzheimer's and Parkinson's. A research team at Kolkata's S.N. Bose National Centre for Basic Sciences, an autonomous institute of the Department of Science and Technology, used a technique called covalent magnetic tweezers to observe how individual protein molecules fold and unfold under different conditions and interact with osmolytes. They focused on a protein called Protein L and tested its interaction with two osmolytes, Trimethylamine N-oxide (TMAO) and trehalose. At higher concentrations, TMAO significantly increased the strength of Protein L, making it more resistant to unfolding. At low concentrations, TMAO had little effect on the unfolding force of the protein. High levels of TMAO are linked to heart diseases, so knowing how it interacts with proteins can lead to better treatments. Osmolytes are small molecules that help cells survive stress by stabilising proteins and preventing them from misfolding.

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Study of Kindlins proteins reveal novel pathways for cancer treatment

A new study has investigated the influence of Kindlins, adapter proteins that exist inside cells of vertebrates, in various cancers. Since this protein is central to many signaling pathways, targeting it could lead to new cancer treatments that address multiple aspects of the disease at once. A team from S. N. Bose National Centre for Basic Sciences in Kolkata collected data of 10,000 patients with 33 cancer types from The Cancer Genome Atlas, to understand the role of Kindlins in turning normal cells into cancerous ones. The researchers found that Kindlin 1 (belonging to the Kindlin family) regulates the immune microenvironment in breast cancer and that cancer-specific metabolic regulation, such as TCA cycle and glycolysis, is governed by Kindlin 2. The researchers employed structural and functional genomics tools on this data to investigate the influence of Kindlin family proteins on mechano chemical signaling in various cancers. The study strongly suggests that Kindlins participate in essential mechano-sensitive pathways. This study also suggests a potential link between Kindlin dysfunction and adverse survival outcomes.

IIT-G discovers RNA-destroying function of p30 protein in African Swine Fever Virus

Indian Institute of Technology Guwahati (IIT-G) researchers have investigated the biochemistry of the African Swine Fever Virus (ASFV) protein, focusing on understanding the biochemical processes of infection to devise effective control strategies. This protein plays a crucial role in the attachment of the virus to host cells by binding to specific receptors on the cell surface and facilitating the merging of viral and cell membranes. Membrane proteins also help viruses evade detection by the host cell's immune system. Understanding how the p30 protein in ASFV affects host cell RNA helps illustrate how the virus manipulates cellular functions to survive and spread. This insight could inform future research into therapies that target these viral mechanisms, potentially leading to new ways to combat ASFV infections.

Novel computational model to help in early detection of cervical cancer

A new computational model that can improve the diagnosis of cervical dysplasia or abnormal cell growth on the surface of the cervix, has the potential for use in early detection of cervical cancer. Scientists from Guwahati-based Institute of Advanced Study in Science and Technology (IASST) set out to develop a model that would be practically applicable in real-world situations and have unmatched accuracy while requiring the least amount of computation time. Researchers

experimented with different colour models, transform techniques, feature representation schemes and classification methods to develop a powerful machine learning (ML) framework. This comprehensive analysis and experimentation aimed to identify the optimal combination for detecting cervical dysplasia. The model's performance was tested on two datasets: one collected from healthcare centres in India and a publicly available dataset. The innovative model could revolutionise the detection of cervical dysplasia and provide healthcare professionals with highly accurate tools for better diagnostic precision and improved treatment outcomes.

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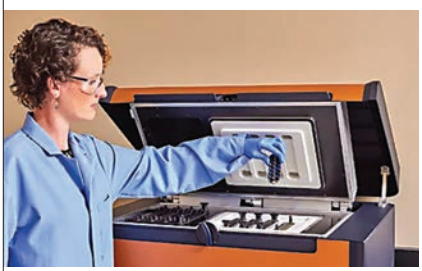
Thermo Fisher Scientific introduces novel pre-transplant risk assessment assay

Thermo Fisher Scientific has introduced a new pre-transplant risk assessment assay via its CLIA laboratory that helps assess risk of early acute rejection in kidney transplant recipients, providing data that may inform a more personalised approach to post-transplant immunosuppression management. Standardised immunosuppression protocols based on broad clinical and demographic features are a routine part of care for most of the 250,000 Americans living with a kidney transplant. While effective in reducing overall rates of rejection, such protocols can also result in over-immunosuppression, which may lead to poor long-term outcomes; patient complications such as toxicity, cancer and serious infections; and considerable costs to the healthcare system. The PTRA Assay utilises an mRNA signature of 29 markers to help stratify patients into high- and low-risk categories for early acute rejection. A recent clinical validation study observed that patients with high PTRA scores were six times more likely to experience early acute rejection than patients with low-risk scores, a statistically significant finding.

Waters releases new Differential Scanning Calorimeter

Waters Corporation has announced the global release of the TA Instruments Rapid Screening-Differential Scanning Calorimeter (TA Instruments RS-DSC), designed for biopharmaceutical developers. The TA Instruments RS-DSC is a high-throughput DSC for precise thermal stability testing of high-concentration biologic formulations specifically for antibody drugs and engineered proteins. The TA Instruments RS-DSC offers a more convenient and accurate solution to assess biological drug stability and quality by employing disposable, low sample volume microfluidic chips (MFCs) that enable up to 24 simultaneous measurements. This reduces or eliminates the need for sample dilution, repetitive instrument cleaning, and lowers contamination risk. Its unique design avoids the sensitivity challenges of DSF methods, enabling it to produce more accurate data on high-concentration samples. Additionally, the TA Instruments RS-DSC features state-of-the-art automated software that provides rapid, effortless, precise, and in-depth insights about a sample's thermodynamic properties.



Agilent acquires Sigsense, creator of AI-enabled lab operations technology

Agilent Technologies Inc. has acquired Sigsense Technologies, a US-based startup that uses artificial intelligence (AI) and power monitoring to help optimise lab operations. Sigsense technology is already available to Agilent customers through CrossLab Connect, a suite of digital applications such as inventory management, service management, asset monitoring, smart alerts, and asset lifecycle analytics, that improve lab performance. Integrated into the Agilent CrossLab Connect asset monitoring solution, Sigsense's algorithm tracks instrument utilisation and status across all scientific assets, regardless of vendor or manufacturer. The operational insights collected from the technology alert lab managers of assets that are underperforming and how to optimise them. Asset monitoring is particularly important for commercial labs with large instrument fleets, intense testing schedules, and quick turnaround times. CrossLab Connect monitors a wide range of instruments, including chromatography, mass spectrometry, spectroscopy, liquid handlers and plate readers, flow cytometry, centrifuges, NMR, sequencers, PCR, and more.

Effectively Addressing Growing Rare Diseases Burden

The Central Drugs Standard Control Organisation (CDSCO) stated recently that certain categories of drugs which have already been approved in specified developed countries such as US, UK, EU, Canada, Japan and Australia, can be directly launched in India without local clinical trials, including orphan drugs for rare diseases.

Considering the fact that many crucial drugs have been launched 10-20 years after being approved in the US and European Union, it might be a very positive step in the direction of promoting collaboration between local and global pharma majors to manufacture, market or distribute the drugs locally. This can particularly prove fruitful for the Indian pharma sector to address the growing burden of rare diseases in the country.

With a staggering 400 million cases worldwide, rare diseases seem anything but rare. India alone accounts for some 72-96 million such patients. This means one in every 20 Indians suffers from a rare disorder. Additionally, individuals with rare diseases face numerous challenges, including late diagnosis and misdiagnosis, improper or no response to therapies, and lack of accurate monitoring tools. Misdiagnosing rare diseases is a significant obstacle that can lead to worsened symptoms along with the development of other health problems.

As a result, with the third consecutive term win of the government, rare disease patients and their caregivers are now writing to the newly appointed Union Health Minister JP Nadda to draw the Ministry's attention to the critical gaps that remain in the implementation of the National Policy for Rare Diseases (NPRD) 2021.

For instance, the lives of many patients (mostly children) suffering from chronic rare genetic disorders, such as Lysosomal Storage Disorders (LSDs), are still fraught with uncertainty due to the lack of sustainable funding and delays in the effective utilisation of the allocated funds. While the recent development by CDSCO might turn out to be a good development, the industry and academia researchers must still continue their search for novel and innovative drugs to treat rare diseases.

And to support the ecosystem in this search, artificial intelligence (AI) can make a big difference, in both diagnosing and finding treatments for rare diseases. The ability of AI-based technologies to integrate and analyse data from different sources such as multi-omics, patient registries, etc. can be used to overcome the challenges associated with rare diseases.

To give an example, investigators from Harvard Medical School and Brigham and Women's Hospital have developed a deep learning algorithm that can teach itself to learn features that can then be used to find similar cases in large pathology image repositories. Known as SISH (self-supervised image search for histology), the new tool acts like a search engine for pathology images and has many potential applications, including identifying rare diseases and helping clinicians determine which patients are likely to respond to similar therapies.

On the other hand, researchers from Canada's London Health Sciences Centre (LHSC) and Lawson Health Research Institute are using a technology called EpiSign that leverages AI to measure a patient's epigenome, which is a unique chemical fingerprint that is responsible for turning genes on or off. EpiSign can currently be used to help diagnose over 100 genetic diseases that were previously difficult to diagnose. Using this technology, the researchers are currently studying and developing biomarkers for over 700 rare disorders.

Another kind of interesting work is being done by a Bengaluru-based startup called Peptris. This AI-based drug discovery company is focusing on helping develop drugs for muscle-related rare diseases like Duchenne muscular dystrophy (DMD), a genetic disorder characterised by progressive muscle degeneration and weakness.

With AI making significant strides in furthering our understanding of different diseases, this might be the right time for the industry to invest more into the technology, with support from the government, to improve diagnosis and treatment of rare diseases. BS

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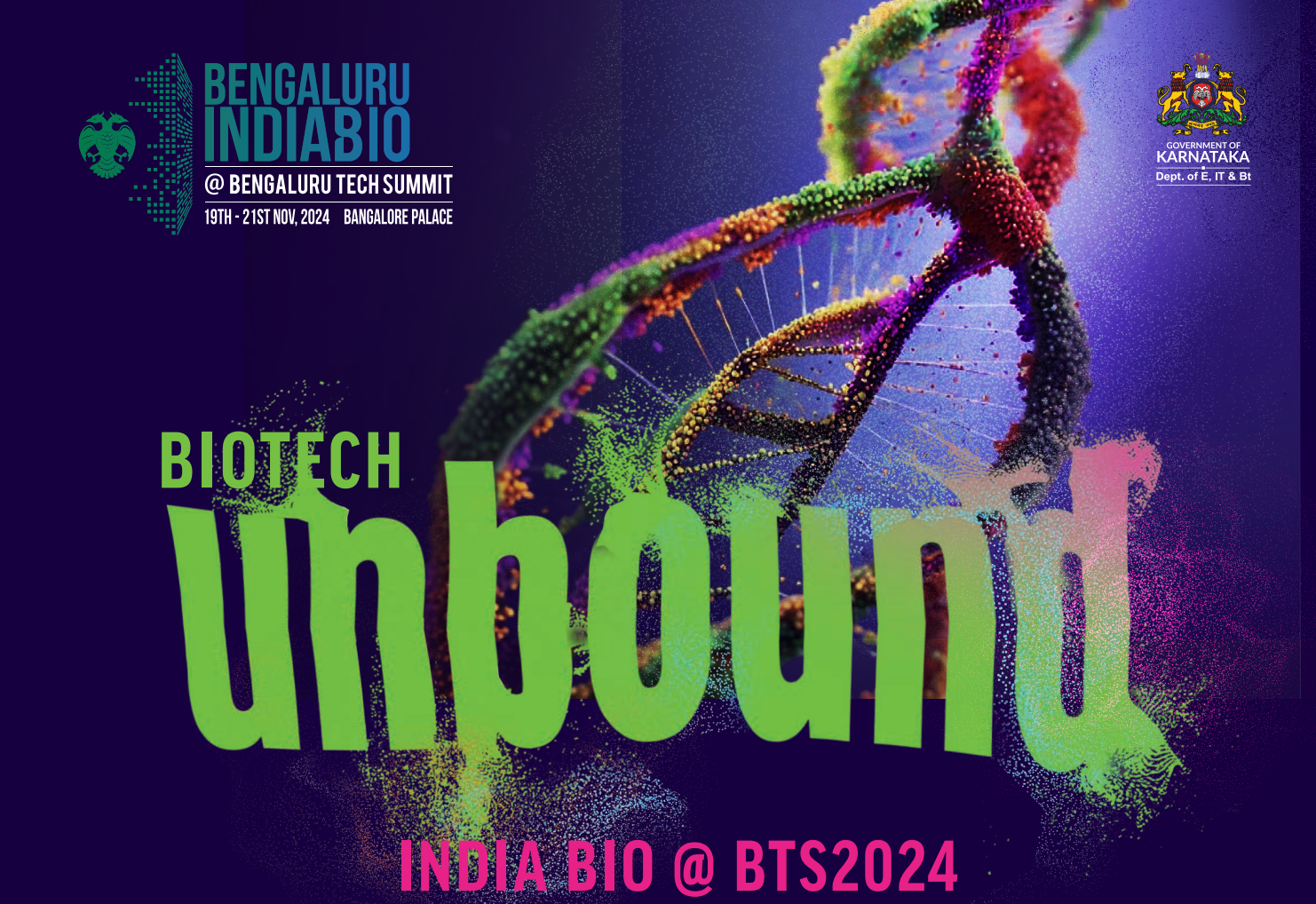

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