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Indo Borax to acquire 64.26% stake in Kronox Lab Sciences

Mumbai: Indo Borax and Chemicals Ltd, one of the leading manufacturers of boron-based chemicals in India, along with its promoter Zenrock Chemicals Private Limited, have signed a Share Purchase Agreement (SPA) to acquire a 64.26 per cent stake in Vadodara-headquartered speciality chemicals player Kronox Lab Sciences. As per the SPA, Indo Borax would acquire 2,38,44,000 equity shares (₹10 face value each) for an aggregate consideration of ₹246.12 crore.

Indo Borax's Board also approved making an open offer, along with Zenrock Chemicals (as a PAC), to acquire up to 95,70,000 equity shares of Kronox Lab Sciences, representing a 25.79 per cent stake. The indicative time to complete the acquisition is three months from the date of signing the SPA.

Commenting on the milestone, Suresh Kalra, Managing Director and CEO, Indo Borax Chemicals Ltd., said, "It is the beginning of a new chapter for us. We are committed to creating value for our stakeholders through expansion, diversification, premiumisation, and margin improvement. The acquisition of Kronox Lab Sciences is a strategic move towards furthering our stated objectives. Kronox's rich experience and export presence will strengthen our offerings, and the synergies will help us fortify our margins going forward. We look forward to working with the team at Kronox towards a promising journey ahead."

Commenting on the acquisition, Ketan Ramani, Promoter and Director, Kronox Lab Sciences Ltd., said, "I would like to thank our investors, employees and all stakeholders for supporting us to build a reputed and growth-ready company. My co-founders, Pritesh Ramani and Jogindersingh Jaswal, have continued to shape the possibilities, and together we have had an eventful journey — from the inception to expansion to public issue and now here. Today marks the inception of a new innings for Kronox. It's time now to aim at audacious goals. Joining hands with Indo Borax would enable Kronox to accelerate its growth plans, expand its product profile, and explore new avenues. We look forward to working with Team Indo Borax and Zenrock Chemicals, and providing transition support post-acquisition."

Jogindersingh Gianchand Jaswal, Ketan Vinodchandra Ramani and Pritesh Vinodchandra Ramani are the founding promoters of Kronox Lab Sciences Limited and have led the company's manufacturing, technical, quality and commercial functions since its incorporation in 2008, through its expansion across multiple manufacturing units in Gujarat and its listing on the stock exchanges in 2024.

Incorporated in 2008 and headquartered at Vadodara, Gujarat, Kronox Lab Sciences Limited manufactures high- purity speciality fine chemicals, including excipients, reagents, buffers and intermediates, for the phamaceutical, nutraceutical, biotechnology, agrochemical, scientific research, laboratory testing, metallurgy and personal care industries. The company operates multiple manufacturing units in Gujarat and markets a portfolio of more than 185 products across dom estic and export markets. The Company reported revenue of approximately ₹101 crore and profit after tax of ~₹28 crore for FY2026.

Natco Pharma invests US$14 mn in eGenesis

Hyderabad: Natco Pharma Limited is investing US$ 14 million in eGenesis, Inc. through its wholly owned subsidiaries, Natco Pharma (Canada) Inc. for an amount of US$ 9.5 million and NATCO Pharma South Africa Proprietary Limited for an amount of US$ 4.5 million, though convertible promissory notes. Previously in 2024, NATCO Pharma Limited had invested US$ 8 million in eGenesis, Inc. through preferred stock. The total investment made by Natco Pharma Limited in eGenesis, Inc. now stands at US$ 22 million. eGenesis is pioneering a genome engineering-based approach in the development of safe and effective transplantable organs to end the global organ shortage and transform the treatment of organ failure.

The eGenesis Genome Engineering and Production (EGEN™) platform is the only technology of its kind to comprehensively address cross-species molecular incompatibilities and viral risk via genetic engineering to improve the lives of patients in need of a transplant. eGenesis is advancing development programs for kidney transplant, acute liver failure, and heart transplant. In March 2024, eGenesis announced the world's first porcine kidney transplant in a living patient. The transplant was authorized by the U.S. Food & Drug Administration (FDA) under the Expanded Access pathway. It was followed by porcine kidney transplants in additional two patients. The outcomes have been exceptionally positive.

RPG Life Sciences announces strategic API initiative to accelerate next phase of growth

Mumbai: RPG Life Sciences Limited has announced the execution of a Business Transfer Agreement for the transfer of the company's Active Pharmaceutical Ingredients (API) business to RPG Active Pharma Limited, a wholly owned subsidiary of RPG Life Sciences, as a going concern on a slump sale basis.

The proposed transfer is part of RPG Life Sciences' strategy to create a focused API business with dedicated capital, sharper management attention and greater strategic flexibility, while the company also continues to build its formulations business. This business has been created at a time when the global pharmaceutical supply chains are undergoing structural realignment and India is increasingly emerging as a preferred destination for reliable, high-quality API manufacturing.

The company has entered into an investment agreement to forge a strategic partnership with Inv Ascent, a healthcare-focused private equity investor, through an investment in RPG Active Pharma. The partnership brings together RPG Life Sciences' pharmaceutical experience, manufacturing capabilities and execution track record with InvAscent's 20-years' experience of investing in and scaling pharma businesses. Accordingly, funds managed by InvAscent will make an initial investment of an amount upto ₹243 er. in RPG Active Pharma. The agreement envisages investments by the company and InvAscent upto ₹700 er. in RPGAP in tranches. The investment is expected to provide RPG Active Pharma with the capital and strategic support required to strengthen manufacturing infrastructure, expand the product portfolio, enhance process development capabilities and pursue organic and inorganic growth opportunities.

In addition, the RPG Active Pharma has also executed a Share Purchase Agreement for acquisition of 100 per cent equity share capital of Actis Generics Private Limited - an API manufacturing company based in Visakhapatnam. The proposed acquisition is expected to expand RPG Active Pharma's manufacturing base, broaden its operating platform and support its strategic growth objectives.

The investment by India Life Sciences Fund - a life sciences focused fund - and the proposed acquisition of Actis Generics are intended to establish RPG Active Pharma as a focused API manufacturer for the next phase of RPG Life Sciences' API growth. The transactions are subject to customary regulatory approvals and pre-closing conditions.

Biodeal Pharmaceuticals raises ₹385 crore growth investment from RMB Capitalworks

Anurag Kumar (L), CMD, Biodeal Pharmaceuticals and Anshuman Malur (R), Managing Partner, RMB Capitalworks.

Delhi: Biodeal Pharmaceuticals Ltd. has announced a growth investment of ₹385 crore from RMB Capitalworks, a joint venture between Rand Merchant Bank and Capitalworks Group. The investment marks a significant milestone in Biodeal's growth journey and will support the company's next phase of expansion across specialty pharmaceuticals, manufacturing capabilities, and regulated markets.

Trusted by clients across domestic and international markets, Biodeal has built more than two decades of leadership in nasal drug delivery, supported by integrated pharmaceutical development and manufacturing capabilities. As global pharmaceutical companies increasingly seek specialized, high-quality manufacturing partners, Biodeal continues to strengthen its position as a preferred CDMO for regulated markets. The investment will support Biodeal's next phase of capacity expansion and accelerate the company's growth in high-margin markets in the US and Europe.

Anurag Kumar, CMD, Biodeal Pharmaceuticals, said, "This investment represents much more than capital - it is a strong endorsement of the platform we have built over the past two decades. At Biodeal, we have consistently focused on creating differentiated capabilities in specialty pharmaceuticals, anchored by leadership in nasal drug delivery and a relentless

focus on quality and manufacturing excellence. This milestone reflects the strength of what we've built and the scale of what lies ahead. We are delighted to welcome RMB Capitalworks as a long-term strategic partner - we chose to partner with them because of the value they bring beyond capital, and their operational expertise, governance philosophy and growth mindset align closely with our vision as we build a globally competitive specialty pharmaceutical company and advance on our path towards a planned public listing."

Anshuman Malur, Managing Partner, RMB Capitalworks, said, "We love founders passionate about building enduring businesses, and we saw that exact fire in Anurag. We work closely with founders to co-create solutions that unlock personal value and provide the long-term financial stability needed to execute ambitious growth plans. Healthcare is a core focus for us, and Biodeal fits our thesis of a differentiated player primed for rapid growth. We are proud to act as true partners, working alongside the Biodeal team to strengthen governance, accelerate expansion, and build a leading pharmaceutical powerhouse."

Merck inaugurates Global Capability Centre in Bengaluru to advance digital transformation and enterprise innovation

Merck inaugurated its Global Capability Centre (MGCC) in Bengaluru in the presence of Alessandro De Luca, Head of Digital Enterprise Solutions (DES) and Group CIO, Merck KGaA, Darmstadt, Germany, and Dr. Sanjay Tyagi, Director, STPI (Software Technology Parks of India), Bengaluru, Ministry of Electronics and Information Technology (MeitY), Government of India, among other key dignitaries.

Bengaluru: Merck, a science and technology company, opened its Merck Global Capability Centre (MGCC) in Electronic City, Bengaluru, bringing together its existing India technology and services operations.

The integrated campus will house ~3,300 professionals from across the company's data, digital, process, and technology functions, further strengthening collaboration and innovation across businesses. Purpose-built across 17,000 sq.m. at the heart of Bengaluru's technology corridor, the campus features innovation labs, neurodiversity zones and collaborative workspaces designed to attract the best technical minds and enable them to do their finest work.

The state-of-the-art campus marks a significant milestone in Merck India's journey to foster greater integration, agility, and innovation through a more connected and future-ready workplace. At the heart of the new centre is Digital Enterprise Solutions (DES). As the organisation responsible for process optimization, enterprise platforms, data and AI, technology infrastructure, hyperautomation and process excellence, DES enables Merck to operate as one connected digital enterprise rather than a collection of siloed functions.

Locating the largest concentration of DES capabilities within the MGCC reflects a strategic intent: Bengaluru is a core node in Merck's global digital operating model. From here, DES teams design, build and run enterprise wide solutions that support R&D, manufacturing, supply chains, commercial operations and enabling functions across geographies.

"The Merck Global Capability Centre is much more than an operational hub - it is a strategic engine for our digital enterprise. By bringing data, technology and process teams under one roof here, we are strengthening the foundation needed to scale innovation faster, improve agility and deliver greater impact across Merck's global businesses," said Alessandro De Luca, head of Digital Enterprise Solutions and group CIO, Merck KGaA, Darmstadt, Germany.

The Bengaluru campus also houses business technologies, teams focused on digital innovation for Merck's Life Science, Healthcare and Electronics businesses. Together, these capabilities create a cross-functional centre of excellence spanning AI, analytics, automation and enterprise technology to support innovation across healthcare, life science and electronics.

The MGCC reinforces India's growing role in Merck's global innovation ecosystem, with the country now serving as the company's fourth-largest workforce hub after Germany, the United States and China. Building on nearly six decades in India since 1967, the new centre

strengthens Merck's long-term commitment to the country, to play a larger role in shaping the company's next wave of global innovation, digital capability and business impact.

Jupiter Hospital performs first robotic kidney transplants using Toumai Robotic System

Team of doctors

Mumbai: In a significant milestone for robotic surgery, Jupiter Hospital, Thane has successfully performed the world's first robotic kidney transplant surgeries outside China using the CE-certified Toumai robotic surgical system from MicroPort MedBot. The two consecutive transplants were successfully carried out on patients with end-stage kidney disease, both of whom recovered well after surgery.

The procedures were led by senior transplant surgeon Dr. P. P. Rao, with robotic kidney transplant surgeon Dr. Lokesh Sinha performing the robotic procedures alongside the multidisciplinary transplant team. The achievement marks another milestone for Jupiter Hospital's kidney transplant programme, which is now in its 15th year and 3rd year of Robotic Kidney transplant, while reinforcing its leadership in advanced robotic transplant surgery.

Kidney transplantation demands exceptional precision while reconstructing delicate blood vessels and the urinary tract. The Toumai robotic platform provided high-definition three-dimensional visualization together with enhanced dexterity, precision, and surgical control, supporting the surgical team in performing these highly complex procedures.

"Kidney transplantation is among the most challenging procedures in surgery. Our focus has always been to provide patients with the safest and most advanced treatment options available. These successful surgeries demonstrate what can be achieved through an experienced multidisciplinary transplant team supported by advanced robotic technologies. As robotic surgery continues to evolve, world-class platforms like Toumai that combine high clinical performance with greater affordability have the potential to expand patient access to complex procedures across India," said Dr. P. P. Rao.

"Robotic surgery continues to expand the boundaries of minimally invasive surgery. Successfully completing these kidney transplant procedures reflects the combined strength of surgical expertise, meticulous planning, and advanced technology, with the ultimate goal of improving patient outcomes and recovery," added Dr. Lokesh Sinha.

Eris delivers 14% YoY growth in Domestic Formulations with a 14.5% growth in Consolidated PAT in Q1 FY27

Ahmedabad: Eris Lifesciences Limited, a leading Indian branded formulations manufacturing company, has announced its earnings for the quarter ended June 30, 2026.

Commenting on the results, Mr. Amit Bakshi, Chairman & Managing Director of Eris Lifesciences Ltd, said, "Our Domestic Branded Formulations business delivered a 14 per cent YoY revenue growth in Q1 with 7 out of 10 therapies having delivered double digit growth rates. Our Insulins franchise continues to be an exciting story of market share gain, with significant headroom for growth from RHI, Glargine as well as Insulin Analogues. Our GLP-1 brand Sundae has taken off to a strong start with a rank of #1 by prescriptions and sales volume in Q1. Our consolidated revenue has grown by 13 per cent YoY in Q1 with a PAT growth of 14.5 per cent."

Eris' revenue and operating profit have grown 2.9x in the last 6 years, with FY26 revenue of ₹3,129 crore. The company has diversified its presence across geographies, technologies and therapeutic areas with an investment of ~ ₹5,000 crore over the last 3-4 years.

Jubilant Ingrevia enters into agreement with Zettaone Technologies India for acquisition of 40% stake for ₹189.2 crore

Noida: Jubilant Ingrevia Limited has entered into a binding agreement with Zettaone Technologies India Pvt Ltd. for the acquisition of a 40 per cent strategic stake for ₹189.2 crore. Following completion of the proposed acquisition, Zettaone Technologies will become an associate company of Jubilant Ingrevia Limited.

Zettaone Technologies, co-founded by Harikrishnan, Sureshkumar, Prabu and Arunkumar, is an electronics design and manufacturing platform with integrated capabilities in electronics/semicon industry. From R&D, Design and Prototyping, Manufacturing, Assembly and Box Build, the company delivers engineering excellence for Aerospace, Defence, Semi-conductor, Automotive, Medical and Industrial applications.

Commenting on the acquisition, Shyam S Bhartia, Chairman, Jubilant Ingrevia Limited and Hari S Bhartia, Co-Chairman & Whole-Time Director, Jubilant Ingrevia Limited, said, "The proposed investment is aligned with the company's pinnacle growth strategy and provides a strong platform for its play in Electronics Development and Manufacturing Services (EDMS) space. The transaction will enable the company to deliver an integrated value proposition in electronics and semi-conductor space, leading to long-term and sustainable value creation." The acquisition is proposed to be completed in two tranches, with the first tranche expected to close by November 2026 and the second tranche is expected to close by September 2027.

Commenting on the acquisition, Deepak Jain, Chief Executive Officer and Managing Director, Jubilant Ingrevia Limited, said, "We are continuously working towards advancing our strategic priorities and this acquisition is another milestone in our Pinnacle journey. We have already been expanding into high-precision semiconductor chemicals through our CDMO business and have made a great progress in last two years to establish our credibility with several global customers. The expertise in high-speed and high-power PCB design and manufacturing of Zettaone Technologies will further anchor our growing Electronics/Semiconductor business with an integrated value proposition to our customers."

Harikrishnan Gopal, CEO of Zettaone Technologies Pvt. Ltd., said, "Over the years, our team has built lasting relationships through consistency, quality, and a commitment to solving complex engineering challenges. We are happy to be a part of the Jubilant Bhartia Group and this development will reinforce our position as a trusted technology partner for mission-critical electronics solutions in aerospace, defence, semi-conductor, auto, medical and industrial spaces." Jubilant Ingrevia Limited is a leading player in specialty chemicals and CDMO globally, serving pharmaceutical, nutrition, agrochemical, consumer, semiconductor and industrial customers. It offers customised solutions that are innovative, cost-effective and conform to global quality standards and has a broad portfolio of 130+ products.

Merck expands biosafety testing laboratory in Singapore to strengthen services across Asia Pacific

Singapore: Merck, a leading science and technology company, is expanding its Singapore lab to further strengthen analytical and biosafety testing services for customers across the Asia Pacific region. Biosafety testing is a critical step in the drug development and manufacturing process, helping to ensure that biologics are safe, effective, and compliant with regulatory requirements.

The expansion builds on Merck's global testing expertise of more than 75 years and marks a significant milestone in providing an advanced, local contract testing services portfolio for the region's growing biopharma industry.

"Localizing these BioReliance® testing capabilities means our Asia Pacific biopharma customers can accelerate their development timelines, improve operational efficiency, and meet evolving regulatory and sustainability standards," said Paolo Carli, Head

of Advanced Solutions for the Life Science business of Merck. "This investment underscores Merck's commitment to empowering medicine makers by providing industry-leading analytical and biosafety testing services and technical expertise."

Merck's Singapore laboratory will become the first BioReliance® facility in Asia-Pacific to offer both Cell Line Characterization services and GMP next-generation sequencing (NGS) capabilities. It will also offer advanced molecular methods including Blazar®, a proprietary platform for rapid virus detection. The expanded facility aims to support the industry's move towards state-of-the-art quality control testing of biologics and 3Rs (Replacement, Reduction, and Refinement of animal use) through advanced molecular methods.

"Merck's expansion of the BioReliance® lab will bring world-class and next-generation testing services to biopharmaceutical companies in Singapore and the region. We look forward to continuing our partnership with Merck to strengthen Singapore's ecosystem, build new capabilities within our local workforce, and enable the delivery of innovative therapies to patients," said Goh Wan Yee, Senior Vice President and Head of Healthcare, Singapore Economic Development Board. The Singapore BioReliance® lab was opened in 2018, and the expansion will bring the total lab area to over 1,000 square meters. This expansion is also a key step in Merck's broader strategy to support the region's dynamic life science ecosystem and drive scientific progress.

Wacker Biotech & Eclipsebio announce strategic collaboration to advance RNA medicine development & production

Deutschland: Wacker Biotech, a leading contract development and manufacturing organization (CDMO) wholly owned by Wacker Chemie AG, and Eclipse Bioinnovations, Inc. (Eclipsebio), the leader in sequencing-based analytics and AI-enabled design for RNA therapeutics, have announced a strategic collaboration. The partnership will further strengthen the companies' support of RNA therapeutic developers. This collaboration unites Eclipsebio's integrated platform of AI-optimized RNA design and sequencing-based validation with the large-scale and GMP-compliant manufacturing of nucleic acid-based therapies at Wacker Biotech. Eclipsebio designs RNA for both

Lipids that are used to formulate mRNA active ingredients are stored in large steel tanks at WACKER's mRNA Competence Center in Halle, Germany. Source: WACKER

manufacturability and efficacy, focusing on high yield, integrity, purity, stability, and protein expression, while WACKER's CDMO supports the entire value chain for RNA-based therapeutic approaches, from plasmid DNA through in vitro transcription (IVT) for GMP-compliant RNA to its formulation in lipid nanoparticles (LNPs) that meet regulatory standards. Together, the companies will improve the options for drug developers to produce RNA ready for the clinic.

"We are excited to expand our collaboration with WACKER," said Peter Chu, PhD, Co-founder and CEO at Eclipsebio. "This partnership allows us to offer innovative access and better support to our partners in every stage of the drug development pipeline, whether they need initial mRNA designs that will produce high yield or are ready for IVT scale-up."

"We have been working together for a while now, and the new added RNA design services of Eclipsebio are an important feature for early-stage clients, which we are supporting with our newly launched contract research services (CRS)," said Hagen Richter, Head of Global Innovation BioPharma at WACKER. "This collaboration utilizes our complementary strengths to offer clients strong, clinic-ready RNA."

Eclipsebio is a private biotechnology company headquartered in San Diego that combines AI-powered sequence design, rapid prototyping, and sequencing-based analytics to support RNA drug development. With extensive experience supporting early-stage basic research through preclinical therapeutic development, Eclipsebio provides unparalleled support for obtaining deep insights into RNA and therapeutic biology. The company offers its solutions as end-to-end partnerships for biopharma and project-based services for academics. ■

Wockhardt Antibiotic Academy: An initiative for Patient Centric Scientific Dialogue to Tackle Multidrug Resistance

Mumbai: Since the discovery of penicillin nearly a century ago and despite the introduction of more than 300 antibiotics, Anti Microbial Resistance (AMR) has continued to emerge and accelerate, posing one of the greatest threats to global public healthcare. Around 10 lakh patients annually die in India due to multi-drug-resistant infections more than four times the number of Indian lives lost annually during the COVID-19 pandemic.

"There is an urgent need not only to have a new antibiotic like Zanyish, but also to have a science-based platform that fosters constructive dialogue on antimicrobial resistance and its appropriate management. It is essential to use the right antibiotic for the right patient at the right time. We hope this Academy will create a deeper understanding of the current realities of drug resistance and promote evidence-based solutions that enable clinicians to save patients' lives," said Dr. Habil Khorakiwala, Founder Chairman, Wockhardt.

The Wockhardt Antibiotic Academy is an open scientific learning platform accessible to the registered medical fraternity across India. It aims to facilitate continuous medical education through the exchange of knowledge, scientific discussions, and the sharing of real-world clinical experience among healthcare professionals. "Resistance is not solved by guidelines alone. It is solved at the patient's bedside, one clinical decision at a time. Those decisions improve when physicians learn from one another and build evidence together. Antimicrobial stewardship continues to evolve. Practices that were considered appropriate a decade ago have been refined by new evidence on diagnosis, dosing, treatment duration and de-escalation. Any initiative that brings clinicians together to exchange knowledge and remain closely connected to science is a step in the right direction. Resistant organisms must be defeated—and patients must win," said Dr. Subramaniam Swaminathan, President Clinical Infectious Diseases Society, India.

The Academy reflects Wockhardt's belief that advancing the fight against antimicrobial resistance requires a shared platform where knowledge, experience, and evidence can come together. Our contribution is to convene, enable, and invest in that dialogue. The science, however, belongs to the community that advances it, and to the clinicians who translate it into better outcomes for patients around the world.

This Academy is the first step in building a nationwide scientific movement. Wockhardt hopes to collaborate with clinicians across the country to strengthen the fight against antimicrobial resistance. Ultimately, the true measure of success will be the number of patients whose lives are saved through better-informed clinical decisions.

"Every breakthrough antibiotic is only the beginning. Its true value emerges through robust evidence and the judgement built by clinicians caring for patients every day. As a company dedicated to discovering, developing, and providing antibiotics, we recognise that we are part of both the challenge and the solution," said Ms. Annapurna Das, President, India & NCE Emerging Markets.

Clinicians, scientific societies, hospitals and policymakers are invited to participate in the Academy, contribute their expertise and help shape this collaborative initiative - because patients must win, and life must win.

Wockhardt is a research-based Global Pharmaceutical and Biotech company. Wockhardt's New Drug Discovery programme has focussed on unmet need of anti-bacterial drugs that are effective against the menace of untreatable superbugs. Wockhardt is the only company in the world where USFDA has given QIDP Status (Qualified Infectious Disease Product) for 6 of its anti-bacterial discovery programmes – 3 of them are Gram Negative and 3 Gram Positive effective against untreatable 'Superbugs.' ■

The Number That Stopped Falling

Prabhat Ranjan
CEO and Co-founder
ASPL Fusion

A decade into Technology Vision 2035, Indian health is the sector that has run out of easy gains — and the vision document I helped write cannot tell us what to do about it, says Prabhat Ranjan, CEO & Co - Founder, ASPL Fusion.

Eighty-eight. Eighty-eight. Eighty-seven.

Those are India's maternal mortality figures from the three most recent bulletins of the Sample Registration System — deaths per hundred thousand live births. Read them slowly, because they are among the most important numbers in Indian health today and they are being reported as good news.

They should not be. In the decade before them, the same series fell from 212 to 88. That decline was among the fastest recorded anywhere, achieved in a country of India's size and heterogeneity, and it deserved every bit of the praise it received. What the recent bulletins tell us is that it has stopped.

I have a particular reason to care. In 2015, as Executive Director of TIFAC, I led the exercise that produced Technology Vision 2035, launched by the Prime Minister on 3 January 2016. Ten years and seven months of the twenty have gone. Our medical sciences roadmap set out six figures with baselines attached, and one was maternal mortality: 190 per hundred thousand in 2013, falling to 15 by 2035. At the pace of the last three bulletins, India reaches 15 somewhere in the twenty-second century.

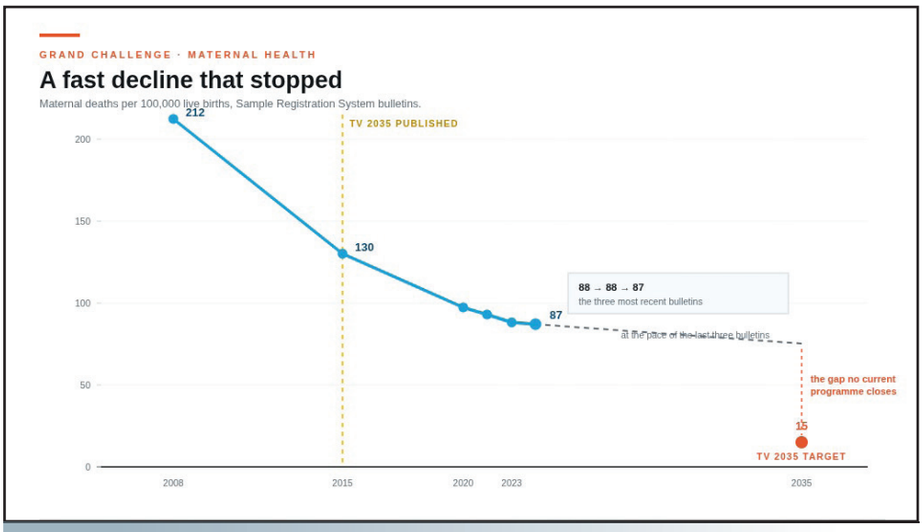
Why the Easy Part is Over

The temptation is to treat a stall as a failure of effort. It is usually the opposite — a sign that the effective interventions have been used up.

India's maternal mortality fell because of things that are, at bottom, logistics: institutional delivery pushed from a minority to a large majority of births, wider immunisation, more skilled birth attendance. These are campaigns. They work through volume, can be planned centrally, and show up quickly in the aggregate.

What remains is a different problem. The residual deaths are concentrated among women for whom the system fails on one particular night — a haemorrhage needing blood at two in the morning in a hospital that has run out, a referral chain that breaks, a woman who reaches a building but not the care inside it. These are not solved by another campaign. They are solved by a system that works reliably at its worst hour rather than its average one, which is far harder to build and almost impossible to photograph.

Under-five mortality tells a gentler version of the same story: 53 per thousand in our 2013 baseline, 31 by 2021,



Maternal deaths per 100,000 live births, from successive Sample Registration System bulletins. The decline from 212 to 88 was among the fastest recorded anywhere; the three most recent readings are 88, 88 and 87. The Technology Vision 2035 target was 15 by 2035.

against a target of 6. Life expectancy, which we set at 80 years at birth after long argument and a close look at what comparable economies such as Brazil had achieved, stands at 68.5 years for men and 72.5 for women.

What a Technology Document Cannot Say

Here I have to be critical of my own work. Our health roadmap listed the technologies it expected to matter by 2035: personalised medicine, digital health delivery, next-generation genomics, wearables, bio-printing and regenerative medicine, robotic surgical systems, controlled drug delivery. It was defensible in 2015 and most of it has advanced roughly as expected.

Not one item on it is the binding constraint on the deaths described above. That is not because the list was wrong, but because we were writing a technology document about a problem that had stopped being primarily technological. The vision document's own ambitions — a primary health centre in every gram panchayat with telemedical access, a multi-speciality hospital and air ambulance in every district, a patient reaching a well-equipped hospital within an hour — are statements about infrastructure and about time. The technology to deliver them mostly existed in 2015. What has not been built is the reliability.

This is the general lesson of auditing our own document at the halfway mark. Where the target is something the state can build, procure or count, India is at or ahead of pace: rural tap water connections went from about 17 per cent of households in 2019 to over 82 per cent by mid-2026. Where the target is an outcome requiring a system to work correctly for one person on one day, we are behind — and there, progress has decelerated rather than merely fallen short.

Spending a Smaller Share

Our roadmap projected total health spending rising from 4.0 per cent of GDP in 2013 to 5.7 per cent by 2035. The National Health Accounts put it at 3.37 per cent in 2022-23 — a smaller share of a much larger economy. Whatever the merits of the argument that efficiency has improved, the indicator we ourselves selected has moved backwards from the baseline we ourselves set.

Beside it sits the one genuinely encouraging number. Out-of-pocket expenditure — the share that comes directly from a household at the moment of illness, and the mechanism by which medical events push families into poverty — has fallen from 64.2 per cent in 2013-14 to 43.4 per cent in 2022-23, against our target of 30. That deserves more attention than it gets.

The Challenge We Ranked First

Of ten Grand Challenges in Technology Vision 2035, we placed nutritional security and the elimination of female and child anaemia at number one, noting that unlike other markers of women's health the trend was worsening.

Two years later, in March 2018, the government launched Anaemia *Mukt Bharat* (AMB) under the *POSHAN Abhiyaan.* Whether or not our document had anything to do with it, AMB was exactly what a vision exercise hopes to see: attention directed, a national mission created, machinery built behind it. Its 6x6x6 architecture reached six beneficiary groups, from children of six months to women of reproductive age, through six interventions and six institutional mechanisms. The interventions were the right ones — iron and folic acid supplementation, deworming, point-of-care testing,

fortified foods in public programmes, behaviour change communication, and attention to non-nutritional causes such as malaria in endemic pockets. The target was three percentage points a year, against the roughly one the country had been managing.

Coverage improved. Supplementation among pregnant women rose from 78 to 90 per cent in two years; among out-of-school adolescent girls, from 6 per cent to 23. Prevalence went up. In NFHS-5, anaemia among women aged 15 to 49 stood at 57 per cent against 53 in NFHS-4. Among children aged six to fifty-nine months it was 67.1 per cent. Among adolescent girls, 59.1. Then something happened that I find harder to write about than any single number here.

The NFHS-6 fact sheets, released on 29 May 2026 from fieldwork across 679,238 households in 715 districts, carry 101 indicators. NFHS-5 carried 131. Anaemia prevalence is not among them. Neither are infant and under-five mortality, sex ratio at birth, or household use of clean cooking fuel.

The government's explanation is methodological and deserves to be taken seriously rather than dismissed. Haemoglobin in earlier rounds was measured from capillary blood — a finger prick — which can be diluted by tissue fluid and vary by close to a gram per decilitre. Venous blood on an automated analyser is the internationally accepted standard. Specialists, including members of WHO guideline groups, had argued for years that India's burden was overstated for exactly this reason, and the NFHS-5 jump among young children struck many as implausible on its face. Anaemia will now be estimated through the ICMR's Diet and Biomarkers Survey, which collected some 176,000 venous samples across 183 districts. Its findings are not yet published.

I have to take that seriously, because it may mean the worsening I described is partly an artefact of the instrument. If so, I would rather know.

But two things hold regardless of how the measurement debate resolves. First, we no longer have a comparable series on the indicator we ranked first of ten: whatever the new survey finds will not be commensurable with 2015-16 or 2019-21, and "is this getting better or worse" becomes, for a period, unanswerable from the country's flagship health survey. Second, the replacement reports at state and national level, while NFHS reported at district level — and districts are where anaemia programmes are managed. The general lesson goes well beyond anaemia. We set a target in 2015. A national mission adopted a version of it in 2018. In 2026 the instrument that measured it changed, for defensible reasons, with the effect that the target can no longer be tracked against its own baseline. At no point need anyone have acted in bad faith. Accountability simply evaporated through a technical decision taken years after the target was set.

What would Help

Three things, offered to whoever is assembling *Viksit Bharat* @2047, an exercise with the considerable advantage of still being open. Label every number as a forecast or a demand. We printed both kinds and contradicted ourselves inside one exercise.

Never publish a coverage target without a service target beside it. Institutional deliveries is a coverage number. Deliveries where blood, a functioning theatre and a trained attendant were simultaneously available is a service number. India's maternal mortality stall lives entirely in the gap between the two, and no published indicator captures it.

And design the audit before the launch — fixed review dates, a named custodian, and the measurement instrument specified alongside the target rather than revised a decade later. We built no such mechanism for Technology Vision 2035, which is why this assessment is being written by one of its own authors rather than by anybody whose job it was. None of this is counsel of despair. A country that took maternal mortality from 212 to 88 in a decade can take it further. But it will not happen through the technologies our roadmap listed, and it will not happen by reading a fall from 88 to 87 as continued progress. It requires admitting that the phase which responded to campaigns is over, and the phase that responds only to reliability has begun. ■

About the Author

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GUEST COLUMN

Transforming Pharmaceutical Effluent Treatment: Towards Advanced and Sustainable Water Management

Dr. Aditi Mullick
Managing Director
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Pharmaceutical effluent management can no longer be evaluated solely through conventional parameters such as COD, BOD and TSS. Persistent pharmaceutical compounds and biologically active contaminants may remain even after substantial bulk pollution removal, creating a need for more comprehensive and targeted treatment strategies. The future lies in integrating advanced treatment with established ETP processes to address recalcitrant contaminants while balancing energy use, chemical consumption and secondary waste generation. This shift towards smarter, more resource-efficient treatment trains which are essential for making pharmaceutical manufacturing more environmentally responsible, emphasises ***Dr. Aditi Mullick, Prasinos Tech Innovations.***

A pharmaceutical effluent can meet conventional wastewater parameters and still present an environmental challenge that is largely invisible to routine monitoring. **COD, BOD, TOC, TSS and colour describe the bulk characteristics of wastewater, but they do not necessarily indicate whether biologically active pharmaceutical compounds remain in the treated stream.** This distinction is becoming increasingly important as pharmaceutical manufacturing expands and concerns over persistent contaminants and antimicrobial resistance grow.

Studies of pharmaceutical manufacturing wastewater in India have reported **pharmaceutical residues at concentrations substantially higher than those typically observed in municipal wastewater,** including antibiotics such as ciprofloxacin at concentrations of several milligrams per litre. Such findings are significant because even when the bulk organic load is reduced,

biologically active molecules may persist and enter receiving environments.

The concern extends beyond the persistence of individual molecules. Research has also identified **antimicrobial-resistant bacteria and resistance-related genetic markers associated with pharmaceutical manufacturing wastewater**, highlighting a dimension of effluent management that goes beyond conventional pollution control. These observations point to a fundamental challenge in pharmaceutical wastewater management: removing bulk organic pollution is not necessarily equivalent to removing pharmaceutical activity. A treatment system may achieve substantial COD reduction while certain chemically stable, biologically active or poorly biodegradable compounds remain in the treated water. Furthermore, partial degradation can produce transformation products whose environmental behaviour may differ from that of the parent compounds.

This creates a need to look beyond conventional treatment performance and ask a more consequential question: **what happens to the molecules that conventional treatment does not fully remove?**

The answer does not necessarily lie in replacing established effluent treatment systems. Instead, the future may involve intelligently integrating advanced treatment and polishing processes with conventional biological and physicochemical operations. Such integration can target recalcitrant contaminants while maintaining practical considerations such as energy demand, chemical consumption, secondary waste generation and operating cost.

The transition is therefore from treating wastewater primarily on the **basis of bulk pollution indicators** towards a more comprehensive understanding of chemical and biological quality. For the pharmaceutical sector, this represents an important opportunity to rethink effluent treatment—not simply as a compliance requirement, but as an essential component of responsible manufacturing and long-term environmental sustainability.

Why Pharmaceutical Effluents Challenge Conventional Treatment

Pharmaceutical wastewater is rarely a uniform stream. Its characteristics can change significantly with the **type of product manufactured, raw materials used, production stage and cleaning operations**. Unlike domestic wastewater, pharmaceutical effluents may contain compounds specifically designed to be chemically stable or biologically active, which can make their degradation more difficult.

Conventional effluent treatment plants, typically incorporating equalisation, chemical treatment and biological processes, remain essential for reducing bulk pollution loads. However, achieving a lower COD or BOD does not necessarily mean that all **pharmaceutical-specific contaminants have been eliminated.** Certain compounds may persist through biological treatment because of their low biodegradability, while others may inhibit microbial activity at elevated concentrations.

Some of the key treatment challenges include:

- **Recalcitrant organic compounds:** Certain APIs, intermediates and related compounds can resist conventional biological degradation.
- **Variable wastewater characteristics:** Changes in production campaigns can cause significant fluctuations in organic load, pH, salinity and toxicity.
- **Microbial inhibition:** Solvents, active compounds, disinfectants and other constituents may interfere with biological treatment processes.
- **Incomplete degradation:** A reduction in COD may represent removal of bulk organic matter without complete destruction of specific pharmaceutical molecules.
- **Transformation products:** Partial degradation can produce intermediate compounds whose toxicity and environmental persistence may require further assessment.
- **Sludge and secondary waste:** Chemical treatment can transfer contaminants from the liquid phase into sludge, creating an additional waste-management requirement.

These challenges do not imply that conventional ETPs are inadequate; rather, they highlight the importance of **treatment-train design.** Biological

and physicochemical processes can provide effective bulk pollutant removal, while appropriately selected advanced processes can be incorporated as polishing or intensification steps for contaminants that are more difficult to degrade.

The future of pharmaceutical effluent treatment therefore lies not in a single "universal" technology, but in **integrated treatment strategies designed around the characteristics of the specific wastewater.** The focus is increasingly shifting towards processes that can improve contaminant degradation while controlling energy demand, chemical consumption, secondary waste generation and overall environmental footprint.

Advanced Oxidation: Moving Beyond Conventional Pollutant Removal

When conventional treatment is unable to adequately address persistent or poorly biodegradable compounds, **advanced oxidation processes (AOPs)** provide an additional treatment pathway. Rather than primarily separating contaminants from water, AOPs are designed to chemically transform complex organic molecules through highly reactive species, with the objective of reducing their persistence, toxicity or chemical complexity.

AOPs encompass several approaches, including **ozonation, Fenton and photo-Fenton processes, photocatalysis, electrochemical oxidation and UV-based oxidation.** Their effectiveness depends strongly on the characteristics of the wastewater, the nature of the contaminants and the operating conditions. Therefore, AOPs are best considered as application-specific treatment or polishing processes rather than universal replacements for conventional ETPs. For pharmaceutical effluents, their potential lies particularly in addressing compounds that are difficult to biodegrade or that remain after primary and biological treatment. Important considerations include:

- **Transformation of recalcitrant organic compounds** that persist through biological treatment.
- **Improvement in biodegradability,** allowing subsequent biological processes to treat partially oxidised compounds more effectively.
- **Reduction of specific trace contaminants,** where conventional bulk parameters may not adequately represent treatment performance.
- **Control of transformation products,** ensuring that degradation does not simply replace one problematic compound with another.
- **Integration with existing ETPs,** allowing advanced processes to be applied where they provide the greatest benefit.
- **Balancing treatment efficiency with sustainability,** including energy demand, chemical consumption, sludge generation and overall operating cost.

The effectiveness of an AOP therefore depends not only on the oxidant or reaction chemistry, but also on h**ow efficiently the process is engineered and integrated into the overall treatment train.** Factors such as mass transfer, contact efficiency, reaction kinetics, wastewater composition and oxidant utilisation can significantly influence performance.

This brings an important engineering question to the forefront: **how can advanced oxidation be made more efficient and practical for complex pharmaceutical effluents?** One promising direction is to improve the interaction between the gaseous oxidant and the liquid phase, creating more favourable conditions for mass transfer and reaction. This provides the basis for exploring intensified gas–liquid treatment approaches in pharmaceutical wastewater management.

Ozone–Nanobubble Technology: Intensifying Advanced Treatment

Ozone is a highly efficient and feasible AOP widely used for effluent treatment and disinfection, However, the effectiveness of ozonation depends not only on the oxidative strength of ozone but also on how efficiently it is transferred from the gas phase into wastewater. Conventional gas–liquid contact systems can be influenced by bubble size, mixing, contact time and the composition of the wastewater. Consequently, improving gas–liquid mass transfer is an important consideration when designing efficient ozone-based treatment systems.

Nanobubble technology offers an emerging approach to this challenge. Owing to their submicron dimensions,

nanobubbles provide a high gas–liquid interfacial area relative to conventional bubbles and can remain dispersed within the aqueous phase for extended periods. These characteristics create favourable conditions for the transfer and utilisation of gases in water-treatment applications.

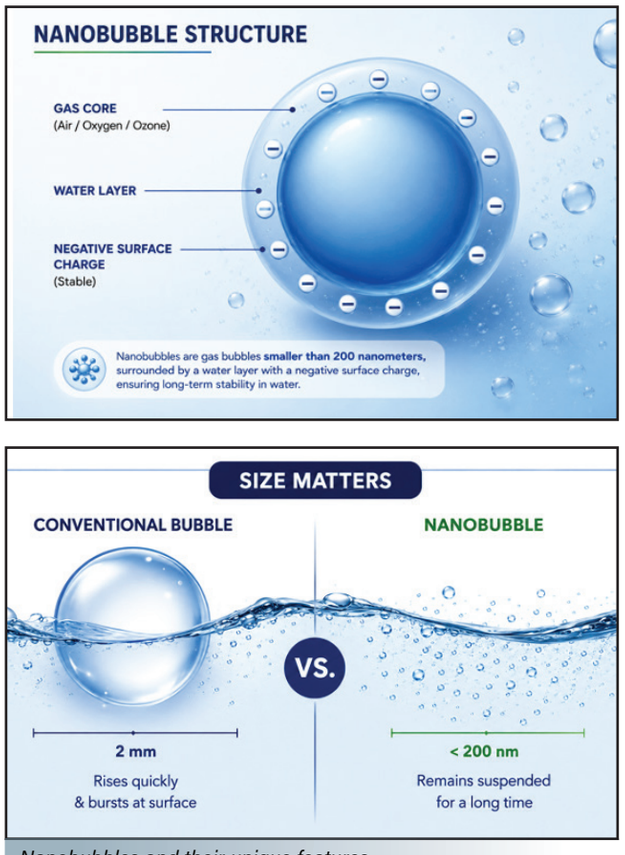
When ozone is delivered through a nanobubble-based system, the two mechanisms can work in a complementary manner:

- Ozone provides the oxidative potential required to transform susceptible organic contaminants.
- Nanobubbles enhance gas–liquid interfacial contact, potentially improving ozone transfer into the aqueous phase.
- Greater dispersion can facilitate more uniform interaction between the oxidant and wastewater.
- Improved oxidant utilisation may provide an opportunity to optimise ozone dosage rather than relying solely on increasing the quantity of ozone supplied.
- The process can potentially be incorporated as an intensification or polishing stage alongside conventional biological and physicochemical treatment.

For pharmaceutical effluents, this approach is particularly relevant because treatment performance must be considered in relation to both bulk organic pollution and specific persistent contaminants. The objective is therefore not simply to generate more ozone, but to improve the efficiency with which the available oxidant is delivered and utilised within the treatment environment.

This principle of engineering for treatment efficiency and resource efficiency is also reflected in the work of **Prasinos Tech Innovations,** which has been developing ozone–nanobubble-based approaches for challenging water and wastewater applications. The company's approach places emphasis on integrating advanced treatment with existing systems rather than viewing emerging technologies as isolated replacements for established treatment processes. Such integration is intended to improve treatment performance while considering operational practicality, resource consumption and long-term sustainability.

However, the performance of ozone–nanobubble treatment remains highly dependent on the characteristics of the wastewater and the configuration of the treatment system. Ozone concentration, gas flow, organic load, pH, hydraulic conditions, contact time and reactor design can all influence the outcome. Consequently, site-specific evaluation and optimisation remain essential before large-scale implementation.



Nanobubbles and their unique features

The broader significance of this technology lies in this balance between treatment intensity and sustainability. Advanced treatment should not be judged solely by percentage pollutant removal; its energy demand, oxidant utilisation, chemical requirements, secondary waste generation and potential for water reuse must also be considered. This perspective can help move pharmaceutical effluent treatment towards systems that are not only technically effective, but also more aligned with the principles of sustainable manufacturing.

Nano-Ozonation at ETP site

Integrating Advanced Treatment into the Pharmaceutical ETP

Advanced treatment technologies are unlikely to function most effectively as isolated replacements for conventional effluent treatment. Their greater potential lies in **strategic integration within a treatment train**, where each stage performs the function for which it is best suited. Conventional physical, chemical and biological processes can address bulk pollutants, while advanced processes can be positioned to target residual or recalcitrant contaminants.

For pharmaceutical wastewater, such integration can provide greater flexibility because effluent characteristics may vary considerably between manufacturing processes and production cycles. The location and operating intensity of an advanced treatment step should therefore be determined by the **specific contaminant profile, treatment objective and downstream water-quality requirement.**

A well-designed treatment train may consider:

- **Equalisation and pre-treatment** to manage fluctuations and remove materials that could interfere with subsequent processes.
- **Biological treatment** for the removal of readily biodegradable organic matter and reduction of bulk pollution loads.
- **Advanced oxidation or polishing** for compounds that persist after conventional treatment.
- **Post-treatment and monitoring** to verify water quality and assess suitability for discharge or potential reuse.

This approach also changes how treatment performance should be evaluated. Percentage reduction in COD alone may not adequately describe the effectiveness of an advanced process. Depending on the application, assessment may also need to consider **specific pharmaceutical residues, toxicity, biodegradability, transformation products, oxidant utilisation and overall energy demand.**

An important consideration is therefore **process intensification rather than process multiplication.** Adding more treatment stages does not automatically result in a more sustainable ETP. The objective should be to achieve the required water quality with the minimum reasonable combination of energy, chemicals, equipment and operational complexity.

For this reason, the integration of ozone–nanobubble systems should be approached as an engineering decision based on wastewater characteristics and treatment objectives. Properly positioned, such technologies may serve as an intensification or polishing step within a broader treatment system, creating opportunities to improve contaminant removal while maintaining focus on **resource efficiency, reliability and environmental sustainability.**

The Road Ahead: Towards Smarter Pharmaceutical Effluent Management

The future of pharmaceutical effluent treatment will require a shift from **treatment as an end-of-pipe obligation to treatment as an integral part of sustainable manufacturing.** As pharmaceutical processes become more complex and environmental expectations continue to evolve, effluent management systems will need to address not only conventional pollution indicators but also persistent and biologically active contaminants.

The next generation of treatment systems is likely to be characterised by **greater process integration, better contaminant-specific treatment and more efficient use of energy and chemicals. Advanced oxidation, membrane technologies, biological processes,** adsorption and intensified gas–liquid systems need not compete with one another; their greatest value may lie in combining them according to the characteristics of a particular effluent.

Equally important will be the ability to monitor and optimise treatment in real time. Moving towards **data-driven operation, automated control and condition-specific treatment** can help avoid unnecessary chemical and energy consumption while maintaining consistent effluent quality.

For emerging technology developers, the opportunity is therefore not simply to introduce another treatment technology, but to rethink how individual processes can work together to create **more efficient, adaptable and sustainable treatment trains**. Prasinos Tech Innovations is pursuing this direction through the development and application of advanced oxidation and nanobubble-based technologies, with an emphasis on improving treatment efficiency while considering resource and environmental impacts.

Ultimately, the road ahead is not about finding a single solution for pharmaceutical wastewater. It is about building **smarter treatment systems that are technically effective, economically viable and environmentally responsible**. As the pharmaceutical industry continues to grow, such an approach can help ensure that progress in healthcare is accompanied by equally responsible management of the water and ecosystems on which that progress depends. ■

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GUEST COLUMN

How India's Regulatory Modernisation Is Unlocking Access to Complex Global Markets

Jeevan Kasara
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The regulation of the Indian pharma industry has sufficed for its basic role, which is to ensure the quality and safety of medicines within the country. However, it has not been developed enough to help the Indian pharma industry make its mark in the international market. This is being altered through several steps taken by the Central Drugs Standard Control Organisation (CDSCO). In order for India to have the ability to produce and export biosimilars, complex injectables, innovative drug delivery systems, and specialist active pharmaceutical ingredients to the international markets, it needs to evolve its regulatory regime from merely being a compliance issue to being an enabling one, emphasizes ***Jeevan Kasara, Chairman, Steris Healthcare.***

India's drug regulatory system, in the past, used to be marked by lack of coherence in its regulatory structure with drug regulations being managed by both the central CDSCO and various state licensing authorities in such a manner that the standards set were inconsistent. The existing regulatory framework concerning introduction of new drugs and clinical trials had not changed much over decades. The regulatory rules were not suited for handling biologics, biosimilar or even complex drug delivery systems. Inconsistent timelines for granting approval were also not helpful in attracting foreign companies to develop their products in India.

From an export perspective, the more consequential gap was in manufacturing regulation. Import alerts issued by the US FDA against several Indian facilities exposed weaknesses in data integrity practices, documentation standards, and quality management systems. While these alerts affected a minority of manufacturers, their reputational impact was significant, underscoring the need for India to move from a compliance culture that prepared for inspections to one that embedded quality as an operational principle. Addressing this gap has been central to India's regulatory modernisation agenda ever since.

Constructing a Framework Fit to Be Trusted Globally: *The Central Drugs Standard Control Organisation of India has carried out one of the biggest restructurings in its regulatory framework in generations by incorporating timeliness of approvals, digital systems of submission, and international standards which are gradually establishing India as a trusted partner in the global pharma industry.*

Rules Regarding New Drugs and Clinical Trials: A Modern Approach

The Rules Regarding New Drugs and Clinical Trials, 2019 marked the most important modernization of India's pharmaceutical regulatory regime since the beginning of the last decade. These rules brought in a time-bound process of regulatory clearance, unlike the flexible approach earlier adopted which made it hard to predict outcomes for the industry. There were provisions for new drug applications, fast track approval for drugs treating medical needs, and specific provisions for biologic and biosimilar drugs recognizing their special scientific and clinical considerations.

It was critical that the guidelines also covered the issue of clinical trials in India, which had become a subject of considerable debate after the clinical trial moratorium of 2013 led to a dramatic drop in clinical trials conducted in the country. The revised guidelines included provisions for improved safety monitoring, ethics committee registration, and compensation of clinical trial injuries that were essential for restoring India's reputation as a reliable destination for clinical trials. The inclusion of the 30-day deadline for approval of clinical trials provided the element of predictability which was missing before. Even though implementation has not always been easy in all cases, there has been a move towards rule-based and predictable approval of clinical trials.

WHO-GMP and Transformation of the Quality Infrastructure

One of the biggest infrastructures of pharmaceutical manufacturing facilities in the world which have got the certifications of US FDA, EMA, and WHO-GMP belongs to India. But the compliance infrastructure was divided into two categories - big companies having their manufacturing facilities according to the global standards and small companies having their manufacturing facilities according to the older standards of Schedule M. Narrowing down the difference between these two segments of companies became an ongoing structural concern.

But the most crucial action that the Indian Government has done for that matter is revising the Schedule M to come closer to WHO-GMP standards. The revised schedule of 2023 has stricter rules about quality management systems, documentation procedures, equipment qualification, and process validations. The phased implementation of the new schedule, from the bigger companies to the medium and then to the smaller ones, is meant to set a higher standard of quality among many more manufacturing facilities. The result of this trend will be substantial, not only large exporters but also additional facilities gain the ability to satisfy the international regulatory standards.

Biosimilars, Complex Generics and High-Value Export Routes

Regulatory upgrading in India carries significant strategic implications when it comes to biosimilars and complex generics, both of which are the high-value segments of the pharmaceuticals export business. The Guidelines on Similar Biologics, which were first issued in 2012 and later amended, provided a regulatory framework for developing and approving biosimilar products in India, which Indian companies have utilised for developing products in oncology, autoimmune disorders and supportive care, successfully competing in the international market at far lower cost levels than

The Convergence of Global Standards and Indian Manufacturing Scale: *The update of India's Schedule M standards to conform to WHO-GMP standards will increase the quality floor across a wider spectrum of the pharmaceutical industry – that is, the number of manufacturing facilities that can meet the exacting standards expected by regulated markets in the US, Europe, and elsewhere.*

the innovators' products. The regulations governing complex generics including liposomal, modified-release formulations, inhaled medications and transdermal drug delivery in India, however, have not been as well-defined thus far. There is considerable scope for developing more product specific guidelines along the lines adopted by the US FDA that would help improve development predictability for companies working in these spaces. The CDSCO has started exploring these issues, and it could have commercial implications for the continued evolution of such guidelines. Complex generics earn much higher margins compared to conventional oral solid dosage forms and encounter less competition based on pricing in global markets, making them quite relevant for the future of Indian pharma exports.

ICH Harmonization and International Regulatory Convergence

The Indian involvement in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use as an observer since 2016, along with subsequent initiatives toward greater engagement with this group, is indicative of the desire of the Indian regulators to make their regulations consistent with the standards required for gaining access to the markets of the US, Europe, and Japan. The ICH guidelines, which cover all aspects of pharmaceutical regulation from stability testing, impurity standards, clinical trials, and pharmacovigilance, serve as a universal language of pharmaceutical regulation in the most challenging markets of the world. Indian firms that are developing under ICH guidelines can use one development program for several regulatory submissions, making drug development a lot more efficient.

Mutual recognition arrangements with major regulatory authorities represent the next significant frontier. Reduced duplicative inspections and streamlined review processes for manufacturers with established compliance track records would lower market entry costs and timelines in ways that directly improve competitiveness. Progress on this front has been gradual, reflecting the complexity of the negotiations involved. However, the direction is clear and the commercial rationale is compelling. Even a limited mutual recognition arrangement covering specific product categories or facility types would have material practical implications for Indian pharmaceutical exporters.

Digital Systems and Data Integrity

Regulatory reform entails not just policy and standard setting but also the provision of investment in digital technology, which facilitates the implementation of regulations. The country has achieved significant success in implementing the reforms through its Sugam website, where drug applications are processed digitally and one can track their status of approval. A fully functioning and integrated digital regulatory system ensures transparency in the process and makes dealing with the Indian regulatory framework easier for both local and foreign companies.

Data integrity, the guarantee that pharmaceutical data generated in the process of research and manufacturing are true and complete, has become the key issue of international regulatory interest and the one in which India has made many investments. Guidance on data integrity has been released by the CDSCO, which complies with international standards, and the industry has invested heavily into electronic tools and audit

Indian Involvement in the Regulatory Debate: *Involvement of India in the ICH harmonization framework and the attempt to establish mutual recognition agreements with leading regulatory bodies has been helping in reducing the barriers of market entry for Indian companies, as one single development program can cater to many regulatory markets simultaneously.*

trails. Data integrity forms the basis of regulatory trust, which forms the basis of market access. The progress achieved in this field within the last ten years has been the key factor for India's successful presence in the international pharmaceutical markets.

What Remains to Be Done

India's regulatory modernisation is genuine and consequential, but it remains a work in progress. The CDSCO's capacity to review complex applications, for biologics, advanced therapy medicinal products, and novel drug delivery systems, needs to continue growing to match the increasing sophistication of products India's industry is developing. Recruitment and retention of scientific expertise within the regulatory system, and investment in the training and analytical infrastructure that complex product review requires, are areas where sustained commitment is essential. Product-specific guidance for complex generics, a body of work built over decades at the US FDA, is at an early stage in India and needs to accelerate meaningfully.

The Digital Infrastructure of Trust in Regulation: *Data integrity and the digital regulatory infrastructure underpin the construction of access to international markets. Investments made by India in electronic submissions, audit trails, and quality culture transformation have played an important role in allowing India to retain and increase its footprint in the most stringent global pharmaceutical markets over the past ten years.*

What Needs to Be Done Next

India's regulatory reform process is real and significant, but there is still a lot of work to be done. The ability of the CDSCO to evaluate sophisticated products like biologicals, advanced therapies, medicinal products, and drug delivery systems must keep evolving to keep pace with the complexity of the products being developed by Indian industry. Attracting and retaining scientific talent in the Indian regulatory system and creating the necessary infrastructure to evaluate complex products are critical needs. Guidelines for evaluating complex generics, a long-term endeavor at the US FDA, are just getting started in India.

A Regulatory Foundation for Global Aspirations

There has been much improvement in the modernisation of India's pharmaceutical regulatory system, and the results of these changes in terms of access to global markets are very tangible indeed. Companies that are producing under ever improving and more international standards find that when the level of trust in their regulatory system has been established, this unlocks many opportunities that were not available before. Approval of biosimilars, registrations of complex injectables in the USA and Europe and greater involvement in WHO prequalification of essential medicines are all results, at least in part, of the increasing credibility of India's modernising regulatory efforts. Not everything is yet done, but the platform that is being built, standard by standard, is the one on which India's pharmaceutical aspirations will be based. ■

GUEST COLUMN

Bridging the Gap Between Microbiome Research and Product Development

Pranshul Aggarwal
Founder
LivLively

The microbiome has become one of the most exciting frontiers in health science, linking the trillions of microbes living in the human body to digestion, immunity, metabolism, and mood. Yet the industry built on top of that science has narrowed itself to a single idea, which is that a healthy gut is something added from outside. The more compelling question, and the harder one to build products around, is how to make the gut a place where a person's own microbes can thrive, explains ***Pranshul Aggarwal, Founder, LivLively.***

Gut health has moved from the laboratory to the living room. Published research on the human microbiome now runs well into six figures, and the commercial response has been just as rapid. In India, the gut health supplements market stood at around USD 565 million in 2025 and is projected to more than double by 2034[1], while the wider global microbiome market is forecast to grow past USD 7 billion by 2035[2], with Asia-Pacific the fastest-growing region. The demand is real. By some estimates, one in four[3] urban Indians lives with a gut-related complaint. But the gap between what the science says and what sits on the shelf remains wide, and it is not simply a gap of volume. It is a gap of interpretation.

The Rapid Growth of Microbiome Research, and What the Evidence Actually Shows

Two decades of work have established something the supplement aisle has been slow to absorb. The gut is not a container waiting to be filled with beneficial bacteria. It is an ecosystem, and like any ecosystem, its health depends on conditions rather than headcount. Diversity of resident species, the integrity of the gut lining, the balance of metabolites those microbes produce, and the level of inflammation in the

surrounding tissue all determine whether a microbial community flourishes or falters.

This distinction matters because it changes what a product should be trying to do. Research increasingly points to the microbiome as a partner in host physiology converting food into compounds the body uses, training immune responses, and maintaining the barrier that separates gut contents from the bloodstream. A product that ignores these conditions and simply introduces more organisms is answering a question that science has not asked.

Crucially, every person's microbial community is unique. Two healthy adults can host strikingly different populations and both be well. That variability is not a nuisance to be engineered away. It is the central fact of the field, and it has direct consequences for how products should be designed.

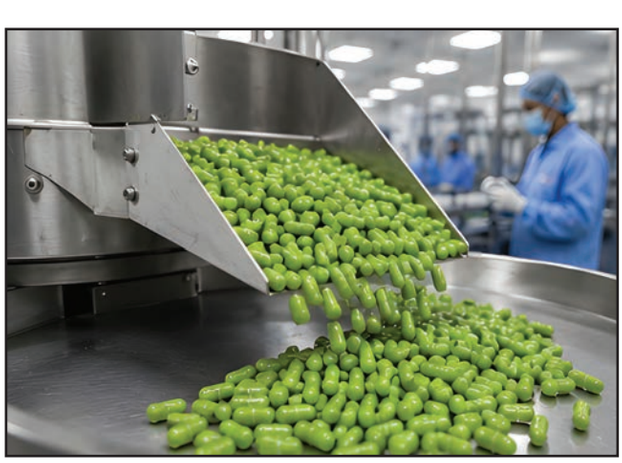
Turning Scientific Discoveries into Evidence-based Products

Promising research alone is never enough. Ingredient selection, clinical validation, formulation, and stability testing sit between a compelling paper and a product that consumers can trust, eliminating ideas that seemed excellent in a journal at each stage.

Live organisms illustrate the difficulty better than anything else. Probiotics are genuinely challenging to make and harder to deliver. The active ingredient is alive, which means it can weaken in the fermenter, degrade in transit, and die on the shelf. Unprotected cultures can lose substantial viability during ambient storage, with losses accelerating as temperatures rise, a serious constraint in Indian supply chains where cold storage is inconsistent. Even when the organisms survive the journey, they must then survive the stomach. Studies of simulated gastric digestion have recorded losses large enough to leave residual counts too low to produce a meaningful effect, and encapsulation improves this without solving it.

Then comes the deeper problem. Even when live strains arrive intact, they may not settle. In a placebo-controlled trial at the Weizmann Institute, researchers found that people cluster into those who are permissive and those who are resistant to mucosal probiotic colonization, with patterns that are specific to the individual, the strain, and the region of the gut. In other words, the same product can take hold in one person and pass straight through another. Because everyone's microbiome differs, supplying identical live strains to every consumer is not a universal solution, and the researchers themselves concluded that empiric supplementation is limited in its ability to affect the gut lining consistently.

None of this makes probiotics worthless. Well-characterized strains with genuine clinical data behind them have a clear role, particularly in specific conditions. But they are just one tool, not the whole toolbox, and the industry has treated them as if they were the entire category.



Feeding the Residents rather than Importing New Ones

If colonizing a gut with foreign organisms is unreliable, the alternative is to improve conditions for the organisms already living there. This is where polyphenols, the pigmented compounds found in plants such as *amla,* green tea, berries, and spices, have become one of the most interesting areas in applied microbiome science.

Polyphenols work in a way that seems, at first, like a flaw. Only five to ten per cent[4] of dietary polyphenols are absorbed in the small intestine, meaning that 90 to 95 per cent travel onwards to the colon, which is precisely where the densest microbial populations live. What looks like poor bioavailability is in fact targeted delivery. Resident bacteria break these compounds down into smaller phenolic metabolites that the body can then absorb, and the relationship runs both ways. The microbes make the polyphenols usable, and in return, the polyphenols shift the microbial balance.

That shift is measurable. Evidence indicates polyphenols encourage beneficial populations such as Lactobacillus and Bifidobacterium while reducing pathogenic species, and animal work has shown polyphenol extracts strengthening the tight junction proteins that hold the gut lining together and lowering inflammatory signaling. The organisms being encouraged are the person's own, already adapted to that individual, which sidesteps the colonization problem entirely. The compounds are also stable, since they are not alive and therefore cannot die in a warehouse.

This approach is a meaningfully different proposition from conventional prebiotics too. Fermentable fibers feed bacteria, but in sensitive individuals they can also produce gas and bloating, which is why so many people with irritable bowel symptoms abandon them. Gentler polyphenol-rich approaches aim to nourish the community and repair its environment without overstimulating it.

Balancing Innovation with Consumer Trust

The commercial risk in this category is not scientific failure. It is credibility. Gut health has attracted claims that outrun the evidence, from vast colony counts printed on labels without survival data to promises of transformation that no serious researcher would make.

Responsible development means three things. Ingredients should be selected for documented mechanisms rather than marketing familiarity. Claims should reflect what has actually been demonstrated in humans, in the dose and format being sold. And manufacturing should be held to pharmaceutical discipline, with real stability testing and honest potency at the end of shelf life rather than at the moment of production. Companies working to global quality standards while formulating for Indian diets and stress patterns have an advantage here, provided they resist the temptation to oversell.

Transparency is not a constraint on growth in this category. It is the only durable route to growth, because consumers who feel misled once rarely return.

Collaboration Between Researchers and Product Developers

Very little of this can be achieved by one discipline working alone. The microbiologist who identifies a mechanism, the formulator who must keep an active compound stable and palatable, the clinician who tests whether any of it changes how a person feels, and the manufacturer who must reproduce it batch after batch are solving different halves of the same problem.

When these functions operate as a sequence of handovers, promising science stalls somewhere in the middle. When they work as one team, .a laboratory finding becomes a product that performs consistently in real-world settings as it did in clinical trials. Partnerships between Indian manufacturers and international research groups have been particularly useful, combining domestic formulation skills and cost advantages with the deep characterization work that credible claims require.

The Future of Microbiome-driven Nutrition

The direction of travel is towards precision. Targeted formulations aimed at defined outcomes rather than general wellness, personalized approaches informed by an individual's own microbial profile, and combinations that pair well-evidenced strains with the compounds needed to sustain them all point in the same direction.

The underlying logic is shifting from replacement to cultivation. A gardener who scatters seeds on poor soil gets very little. A gardener who improves the soil finds that what is already there grows. Applied to the gut, this means the next generation of nutraceuticals will be judged less by what they introduce than by the environment they create.

The microbiome will deliver on much of its promise. But the products that endure will be those built on the whole science rather than one convenient part of it, made by companies that recognize that lasting gut health comes from supporting the microbiome with well researched, evidence based formulations rather than relying on simplistic claims. ■

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About the Author

Pranshul Aggarwal is the Founder of LivLively, a gut health and microbiome-focused wellness brand committed to delivering science-backed, sustainable health solutions. With experience across the pharmaceutical and nutraceutical ecosystem, he brings hands-on expertise in product development, business strategy, and scaling healthcare ventures. He plays active leadership roles across businesses within the Medicef ecosystem, with LivLively operating alongside Purobien Lifesciences.

GUEST COLUMN

Precision Extraction: Turning India's Botanical Wealth into High-Value Global Ingredients

Dr. S. Vijaya Kumar
CEO – Wellness
Agrizy

For centuries, India has known the power of plants. Turmeric, Ashwagandha, Boswellia, Coleus, Moringa, Ginger, Holy Basil, Silymarin and hundreds of other botanicals have been part of traditional health practices for generations. Today, the opportunity is much bigger. The global food, nutrition, pharmaceutical, personal-care and wellness industries are rapidly moving toward plant-derived ingredients, emphasizes ***Dr. S. Vijaya Kumar, CEO – Wellness, Agrizy.***

Consumers increasingly want products that are natural, clean-label, traceable and supported by credible science. For ingredient manufacturers, however, simply having access to a medicinal plant is no longer enough.

The real value lies in converting a variable plant into a consistent, measurable and application-ready ingredient. That is where precision extraction, standardization, advanced analytical science and scalable manufacturing come together.

A Rapidly Expanding Opportunity

The global plant-extract market was estimated at approximately USD 46.37 billion in 2025 and USD 52.12 billion in 2026, with a projected CAGR of around 12.4 per cent through 2034. Other studies that use narrower definitions produce significantly smaller market estimates — for example, botanical extracts alone have been estimated at USD 6.91 billion in 2025.

These differences are important: the botanical industry contains several overlapping market definitions, from crude herbal materials and extracts to phytochemicals, standardized ingredients and finished botanical supplements. But regardless of the definition used, the direction is clear: demand for plant-derived functional ingredients is expanding across food, nutraceuticals,

pharmaceuticals, beverages, cosmetics and personal care.

The next question is therefore not whether the market will grow. It is - Who will capture the highest-value part of that growth?

India has Raw Material Advantage but not Full Value-Chain Advantage

India possesses one of the world's richest pools of medicinal and aromatic plants. It has farmers, traditional knowledge, diverse agro-climatic conditions and a large domestic market for Ayurveda and natural products.

The country is already a major global supplier of medicinal and aromatic plant materials. Yet a significant portion of India's exports still consists of raw herbs and relatively basic extracts rather than highly standardized, differentiated ingredients. This represents both a challenge and an enormous opportunity.

Selling a botanical primarily as a commodity means competing largely on:

- Availability
- Price
- Extraction cost and
- Short-term supply conditions.

Selling a standardized ingredient changes the equation. The customer begins paying for:

- Defined active-marker content
- Technology
- Batch-to-batch consistency
- Validated analytical methods
- Traceability
- Clinical or scientific substantiation
- Bioavailability
- Formulation performance
- Regulatory documentation
- Sustainability and
- Supply chain reliability

In other words, the value of a botanical increases dramatically as science and quality are added to the supply chain.

From Plant Material to Precision Ingredient

Traditional extraction often starts with a simple proposition: take the plant, add a solvent, apply heat or agitation, separate the extract and concentrate it. At laboratory scale, this may appear straightforward. Industrial production is very different.

Raw botanical material changes with geography, cultivar, soil, rainfall, harvesting time, storage conditions, drying temperature and particle size. The same botanical purchased from two different suppliers can therefore behave very differently during extraction.

This variability can affect extraction yield, colour, moisture, marker concentration, impurity profile, stability and ultimately the performance of the finished ingredient. Modern extraction technologies are changing the equation.

Depending on the botanical and target compound, manufacturers can use technologies such as:

- Optimized solvent extraction
- Counter-current extraction
- Supercritical CO_2 extraction
- Pressurized extraction
- Membrane-based concentration
- Enzymatic pre-treatment
- Microwave- or ultrasound-assisted extraction
- Adsorption and resin purification, and
- Advanced drying and encapsulation technologies

The objective is not simply to obtain 'more extract.' The objective is to obtain the right molecules, at the right concentration, with the right purity and physical properties, at the lowest sustainable cost. That is the essence of precision extraction.

Yield is Important but Recovery is not Whole Story

One of the most common mistakes in botanical processing is to judge a process simply by extraction yield. A process may generate a high percentage of extract but still be commercially inferior if the concentration of the desired active is low.

For example, a 20 per cent extraction yield containing 5 per cent of the target marker may be less attractive than a 10 per cent yield containing 20 per cent of the desired marker. Therefore, industrial process development increasingly needs to consider the complete equation:

Raw material quality → extraction yield → recovery → purification → concentration → stability → final specification → cost per kilogram of active ingredient.

This is particularly important for high-value standardized ingredients such as *curcuminoids, berberine, forskolin, silymarin,* boswellic acids, carotenoids and other phytochemicals. The commercial question is ultimately: How much value can be recovered from each kilogram of good-quality botanical raw material?

The Laboratory-to-Factory Gap

One of the biggest challenges in botanical extraction is the gap between laboratory success and industrial reproducibility. A process that produces an excellent extract from 1 kg of material may behave differently at 100 kg, 1 tonne or 10 tonnes.

- Heat transfer changes.
- Mass transfer changes.
- Solvent-to-solid ratios change.
- Mixing characteristics change.
- Filtration behaviour changes.
- Drying characteristics change.

Even the physical behaviour of the botanical material can change dramatically. This is why scale-up cannot be treated as simply making a laboratory process bigger. A robust development pathway should normally progress through laboratory experimentation, process optimization, pilot-scale validation and finally commercial-scale qualification.

The global plant-extract market was estimated at approximately USD 46.37 billion in 2025 and USD 52.12 billion in 2026, with a projected CAGR of around 12.4 per cent through 2034. Other studies that use narrower definitions produce significantly smaller market estimates — for example, botanical extracts alone have been estimated at USD 6.91 billion in 2025.

Pilot plants therefore play a critical role. They provide the bridge between scientific feasibility and manufacturing reliability. Increasingly, process modelling and digital tools can also help predict how extraction, heat transfer, solvent recovery and other operations may behave during scale-up.

The result is a more disciplined approach:

Discover → Optimize → Pilot → Validate → Scale → Continuously Improve.

Standardization: Converting Biological Variability into Commercial Consistency

Extraction alone does not create a high-quality ingredient. The second major challenge is standardization. Plants are biological systems. Their chemistry is inherently variable. The concentration of an active compound can change with:

- Species and cultivar
- Geographic origin
- Soil conditions
- Climate
- Season
- Maturity
- Harvesting time
- Drying conditions
- Storage and
- Post-harvest handling

A modern botanical ingredient manufacturer therefore needs to control variability from the farm all the way to the

finished powder or liquid. This begins with raw-material specifications and supplier qualification and continues through extraction, purification, concentration, drying, packaging and storage.

Analytical Science becomes the Backbone

Marker-based standardization is one of the foundations of the modern botanical industry. Instead of simply stating that an ingredient is 'turmeric extract' or *'Boswellia extract',* manufacturers increasingly need to demonstrate quantitatively what the extract contains.

Depending on the ingredient, analytical platforms can include:

- HPLC and UHPLC
- HPLC-MS/MS
- GC and GC-MS
- Quantitative NMR
- UV-visible spectroscopy
- FTIR
- ICP-MS for elemental analysis
- Microbiological testing, and
- Increasingly sophisticated chemometric and data-analysis tools.

The future is likely to be even more data-driven. A particularly interesting direction is the combination of multiple analytical techniques with machine learning. Research involving 78 batches of a botanical injectable demonstrated that combining HPLC-UV, HPLC-ELSD and quantitative proton NMR data with a machine-learning model could distinguish normal and abnormal batches with very high reliability.

The implication extends beyond one product. The botanical industry is moving from testing individual parameters toward building a multidimensional chemical fingerprint of an ingredient. That could eventually enable manufacturers to detect subtle changes in raw materials or processes before they become a commercial quality problem.

Traceability will become a Competitive Advantage

Quality does not begin inside the extraction plant. It begins in the field. For global customers, the question is increasingly: Where did this botanical come from, how was it cultivated, how was it harvested, and can you prove it?

This is particularly relevant as international customers place greater emphasis on:

- Traceability
- Sustainable sourcing
- Organic certification
- Good agricultural and collection practices
- Pesticide control
- Heavy-metal management
- Authenticity
- Geographical origin and
- Responsible farmer engagement

Government initiatives supporting medicinal-plant cultivation, quality systems and good agricultural and collection practices can therefore have a direct commercial impact. The more demanding the international market becomes, the more important the connection between farm-level controls and finished-ingredient specifications will become.

From Standardized Extract to Application-ready Ingredient

There is another major shift taking place. Customers are no longer necessarily looking for a drum of botanical extract. They are increasingly looking for an ingredient that can work inside their formulation. That distinction is commercially significant. A nutraceutical company developing a gummy may require a specific particle size, taste profile, stability and dispersion. A beverage manufacturer may require water dispersibility and low sedimentation. A capsule manufacturer may prioritize flowability, bulk density and dose concentration. A cosmetic company may require colour, odour, solubility and compatibility with its formulation system. A pharmaceutical customer may require an even higher

level of characterization, impurity control and regulatory documentation.

Therefore, the next generation of botanical companies will increasingly compete not merely on extraction capability, but on formulation and application science.

Bioavailability is Becoming the Next Battleground

Standardization tells the customer how much of a marker is present. It does not necessarily tell them how much the human body can use. This is why the industry is increasingly moving toward technologies designed to improve:

- Solubility
- Dissolution
- Absorption
- Stability
- Permeability and
- Ultimately bioavailability

Approaches such as micronization, amorphous dispersions, phospholipid complexes, liposomes, nanoemulsions, cyclodextrin complexes and other delivery systems are creating opportunities to transform conventional extracts into differentiated ingredients. This is an important transition - The future premium may not belong to the company selling the highest-purity extract, but to the company that can demonstrate superior performance in the finished application.

Rise of Evidence-Backed Botanical Ingredients

The market is also becoming more sophisticated about claims. 'Natural' is no longer enough. Customers and consumers increasingly want evidence. This is encouraging a shift from:

Botanical → Extract → Standardized Extract → Clinically Supported Ingredient → Application-Specific Solution

The strongest ingredient platforms can combine:

1. A defined botanical source
2. Controlled extraction
3. Reproducible standardization
4. Safety and quality data
5. Mechanistic research
6. Bioavailability information
7. Formulation compatibility and
8. Where appropriate, human clinical evidence

This creates a significant barrier to entry — and therefore a significant opportunity for companies willing to invest in science.

India can Move from Supplier to Global Ingredient Innovator

India's competitive advantage is not simply its biodiversity. It is the combination of:

Biodiversity + Traditional Knowledge + Agricultural Capability + Process Engineering + Analytical Science + Manufacturing Scale + Cost Competitiveness.

The future of botanical manufacturing will not be defined by how many tonnes of herbs India exports. It will be defined by how much value, science and intellectual property India can build into every kilogram it produces.

The missing link has often been integration. A globally competitive botanical ingredient platform needs to connect the entire chain:

Farm → Quality Raw Material → Extraction → Purification → Standardization → Characterization → Formulation → Clinical Evidence → Regulatory Support → Global Customer

When these capabilities operate independently, value is lost at every interface. When they are integrated, the same botanical can generate substantially greater economic value.

What will Separate the Winners?

Over the next decade, the botanical industry is likely

to become increasingly polarized. At one end will be commodity suppliers competing primarily on raw material and manufacturing cost. At the other will be specialized ingredient companies offering differentiated, evidence-backed solutions. The winners are likely to share several characteristics:

1. **Strong raw-material control:** They will build long-term relationships with growers and establish clear specifications at source.
2. **Superior extraction economics:** They will optimize recovery, solvent consumption, energy use, cycle time and waste generation — not just laboratory yield.
3. **Deep analytical capability:** They will understand the complete chemical profile of their ingredients rather than relying on one marker alone.
4. **Pilot-scale and process-development capability:** They will know how to convert laboratory innovation into reproducible commercial manufacturing.
5. **Application expertise:** They will understand how their ingredients behave in capsules, tablets, gummies, beverages, foods and personal-care products.
6. **Evidence:** They will invest in scientific and, where commercially justified, clinical substantiation.
7. **Traceability and sustainability:** They will be able to demonstrate where their raw materials came from and how they were produced.
8. **Regulatory readiness:** They will design products with the requirements of target markets in mind from the beginning rather than treating regulatory compliance as an afterthought.

Real Opportunity: Moving up the Value Chain

The global botanical opportunity is therefore not simply about extracting more plants. It is about extracting more value from every plant. India already possesses much of the raw-material advantage required to become a global powerhouse in botanical ingredients. The next stage is to build the scientific, technological and commercial infrastructure needed to convert that advantage into differentiated products.

The industry is moving from 'herb supply' to 'ingredient science.' And eventually, from ingredient science to 'solution science.'

A company that can tell a customer: *"Here is the botanical source. Here is how we control it. Here is how we extract it. Here is exactly what is in it. Here is how consistently we can manufacture it. Here is how it performs in your formulation. And here is the evidence supporting its intended application,"* is no longer simply an extract manufacturer. It is an ingredient technology company. That is the opportunity ahead for India.

The country's botanical wealth has already created the raw-material foundation. The next chapter is to add precision extraction, advanced analytics, process engineering, formulation science and evidence. The future of botanical manufacturing will not be defined by how many tonnes of herbs India exports. It will be defined by how much value, science and intellectual property India can build into every kilogram it produces.■

About the Author

Dr. S. Vijaya Kumar is widely recognized in the industry for his expertise in business development, technology and product innovation, greenfield project execution, and operational transformation. He has held strategic and senior leadership roles at organizations such as Aurobindo Pharma, Dr. Reddy's, Jubilant, McKinsey, Novartis, and GlaxoSmithKline. In the recent past he has held CXO positions in Biocon, Sami-Sabinsa and Botanic Health.

GUEST COLUMN

Why Prediabetes Could Be Ayurveda's Next Prevention Frontier!

Shafiulla Hirehal Nuruddin
Founder & MD
Greenspace Herbs

Prediabetes is treated as a cautionary sign, rather than a condition necessitating immediate action. Prediabetes provides an opportunity to slow or even reverse metabolic deterioration. Instead of waiting for blood glucose to cross the threshold of diagnosis, the focus can be shifted on detecting metabolic stress early and addressing its underlying factors, emphasizes ***Shafiulla Hirehal Nuruddin, Founder & MD, Greenspace Herbs.***

According to the latest IDF Diabetes Atlas[1], 89.8 million adults aged 20-79 years in India were living with diabetes in 2024, and this figure is expected to rise to 156.7 million by 2050. In addition, an estimated 136 million[2] Indians, or 15.3 per cent of those aged 20 years and above, had prediabetes.

Prediabetes provides an opportunity to slow or even reverse metabolic deterioration. Instead of waiting for blood glucose to cross the threshold of diagnosis, the focus can be shifted on detecting metabolic stress early and addressing its underlying factors.

The encouraging part is that progression is not inevitable. Structured lifestyle intervention, including healthier eating, physical activity and weight management, is recommended for people with prediabetes by the American Diabetes Association's 2026 Standards of Care. Long-term findings from the Diabetes Prevention Program reinforce the value of such interventions. Over a median follow-up of more than 21 years[3], cumulative diabetes incidence was 24 per cent[3] lower among those originally assigned to intensive lifestyle intervention and 17 per cent[3] lower among those assigned to metformin, compared with the placebo group. The original trial found a 58 per cent[3] reduction in diabetes risk with intensive lifestyle intervention after a mean 2.8 years[3].

Prediabetes is More than Elevated Blood Sugar

Prediabetes reflects changes in the way the body handles glucose. Insulin resistance can develop before blood glucose crosses the threshold for diabetes, while excess abdominal fat, inflammation, inactivity and poor dietary patterns can further increase metabolic stress.

That complicates prevention more than just trying to lower a glucose reading. The bigger picture is to improve insulin sensitivity, support a healthy body composition, reduce inflammation and build sustainable dietary and physical activity habits.

There is growing recognition that metabolic dysfunction is regulated by multiple interconnected pathways. Changes in insulin signalling, chronic low grade inflammation, oxidative stress, lipid metabolism and gut health can all contribute to the effectiveness of glucose management in the body. Understanding the contribution of these interrelated factors may be a better indicator of metabolic risk than just one number.

This is where Ayurveda provides an interesting viewpoint. Its traditional approach does not view metabolic health through a single laboratory marker. Concepts such as *Prameha, Agni* and individual constitution place considerable emphasis on digestion, diet, daily routines and the broader balance of the body. Modern metabolic science can provide a different language for investigating some of these ideas.

Where Ayurveda Meets Metabolic Science

Several Ayurvedic botanicals are now being studied for their potential effects on glucose metabolism, insulin sensitivity and inflammation. Research has examined ingredients including *Gymnema sylvestre, Tinospora cordifolia, Momordica charantia, Curcuma longa and Trigonella foenum graecum***,** among others.

A systematic review and meta-analysis of Ayurvedic medicines for type 2 diabetes examined 199[4] randomised controlled trials involving 21,191[4] participants. It found evidence of improvements in measures such as HbA1c and fasting blood glucose with several botanicals. However, the authors also highlighted limitations in study quality and called for better designed clinical trials.

For the Ayurveda sector, this is an important distinction. The value of a botanical cannot be judged only by its traditional reputation. Researchers increasingly need to establish its phytochemical composition, biological activity, safety profile, dosage, bioavailability and interaction with relevant metabolic pathways. This shift from traditional use to measurable evidence could determine how botanical interventions are integrated into future metabolic care.

That caveat is important. Evidence from diabetes management cannot automatically be transferred to diabetes prevention. A botanical that improves glucose levels in people who already have diabetes has not necessarily been proven to stop prediabetes from progressing.

Early evidence is encouraging, but not conclusive

There are studies specifically examining Ayurvedic interventions in people with prediabetes. A randomised, double blind, placebo controlled study[5] evaluated an Ayurvedic polyherbal combination containing Tinospora cordifolia, Pterocarpus marsupium, Gymnema sylvestre, Zingiber officinale and Momordica charantia alongside lifestyle modification in people with prediabetes.

Another randomised controlled study[6] examined Nisha Amalaki, a combination of turmeric and amla, in prediabetic participants over six months. The researchers reported improvements in fasting glucose, post meal glucose, HbA1c, insulin resistance and oxidative stress markers.

More recently, a 2024 randomised controlled clinical trial[7] evaluated an integrated Ayurveda treatment protocol in people with HbA1c between 5.7 per cent and 6.4 per cent. The study compared an Ayurveda based intervention with standard prediabetes care over 90 days.

One reason prevention needs a broader approach is that prediabetes does not look identical in every person. Two people with similar glucose readings may have different contributors to their metabolic risk. Diet, physical activity, body composition, family history, sleep, stress and insulin sensitivity can all influence the trajectory. The 2026 ADA guidelines therefore emphasise individualised nutrition and diabetes prevention programmes rather than a single universal diet.

Taken together, these studies show that Ayurveda is moving into a more structured research environment. They also highlight why larger, well controlled and longer duration trials are necessary. Prevention is a long term outcome, so short term improvements in glucose markers cannot by themselves establish that progression to diabetes has been prevented.

These findings are worth following, but they should not be presented as proof that Ayurveda can independently prevent diabetes. The evidence is still evolving.

Opportunity is in Personalised Prevention

One reason prevention needs a broader approach is that prediabetes does not look identical in every person. Two people with similar glucose readings may have different contributors to their metabolic risk. Diet, physical activity, body composition, family history, sleep, stress and insulin sensitivity can all influence the trajectory. The 2026 ADA guidelines therefore emphasise individualised nutrition and diabetes prevention programmes rather than a single universal diet.

The next generation of botanical research can advance by studying specific phytochemicals, their molecular targets, bioavailability and effects on pathways such as AMPK and insulin signalling. Advanced analytical tools, computer modelling and clinical biomarkers can help to define which compounds work, for whom and under what conditions.

This presents a significant prospect for the modern Ayurveda practice. Traditional knowledge can provide a framework for individualised dietary and lifestyle recommendations, while contemporary science can help identify measurable biological responses. The next generation of botanical research can advance by studying specific phytochemicals, their molecular targets, bioavailability and effects on pathways such as AMPK and insulin signalling. Advanced analytical tools, computer modelling and clinical biomarkers can help to define which compounds work, for whom and under what conditions.

Such an approach could also help move botanical research away from the idea of a single herb being universally beneficial. Different people can respond differently to the same intervention. Understanding those variations through metabolic markers, phytochemical profiling and individual health characteristics could eventually support more precise botanical strategies.

Prevention needs Evidence, not Promises

The future of Ayurveda in metabolic health should therefore not be framed as choosing between traditional medicine and modern medicine. It should be about testing traditional knowledge with the same scientific discipline expected from any health intervention. For someone with prediabetes, lifestyle change and regular medical monitoring remain fundamental. Ayurveda may have a complementary role, particularly when its dietary, behavioural and botanical approaches are evaluated through rigorous clinical research.

This is also where collaboration between Ayurvedic practitioners, phytochemists, clinicians and biomedical researchers becomes important. Traditional knowledge can help identify promising botanical candidates, while modern research can investigate their active constituents, mechanisms and safety. The result can be a more credible evidence base for deciding where Ayurveda has a meaningful role in prevention.

The larger opportunity lies in moving from broad claims about 'natural diabetes control' towards validated, measurable and personalised metabolic support. Its tradition of individualised health practices can be combined with modern tools capable of testing what works, understanding why it works and identifying who would most likely benefit. ■

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India Runs the World's Clinical Trials; AI Is About to Raise the Stakes on Who Owns the Data

Dr. Keyur Jathal
Executive Director
Ishan Technologies

India has not traditionally been where the intellectual property gets created. It is where the hypothesis gets tested. The molecule is designed elsewhere; the proof happens here. Artificial Intelligence (AI) changes the economics of that equation, emphasizes ***Dr. Keyur Jathal, Executive Director, Ishan Technologies.***

For decades, India has played a particular role in global pharma. Not as the country where the next blockbuster molecule is dreamed up, but as the place where the world comes to test it.

A new compound discovered in Basel or Boston still has to prove itself on real patients, across real genetic diversity, at a cost and speed that few other geographies can match. India carries roughly 18 per cent of the world's population and close to 20 per cent of its disease burden, giving it a scale and diversity of patients that few countries can offer. It is already among the world's largest clinical trial destinations, with trial activity growing rapidly over the past few years.

And yet, for all that weight, India's share of global clinical trials and pharma Research & Development (R&D) remains disproportionately small. That gap is the real story. India is essential to the global pipeline, but it is not yet capturing a proportionate share of the value created through it. It is also, if we are honest, still largely a supporting role. India has not traditionally been where the intellectual property gets created. It is where the hypothesis gets tested. The molecule is designed elsewhere; the proof happens here. Artificial Intelligence (AI) changes the economics of that equation.

AI Doesn't Care Where the Lab Is. It Cares Where the Data Is

Drug discovery has always been slow because biology is complicated and expensive to test. AI can change the economics of that search. Machine learning models can scan enormous compound libraries, predict how a molecule might behave before it is synthesised, and identify likely failures earlier. On the clinical trial side, AI

is being used to match patients to trials, predict which trial sites are likely to under-enrol, and make sense of real-world data that previously sat in silos.

A 2025 study published in Nature Medicine[1] described an AI-discovered drug and target combination that had reached a randomised Phase 2a trial. McKinsey[2] estimates that generative AI could unlock $60 billion to $110 billion of annual value for pharma and medical products globally.

That value does not materialise simply because an AI model exists. It materialises where there is enough high-quality data to train, validate and improve those models. That is where India needs to pay attention.

Every clinical trial conducted in India adds to a growing pool of clinical, genomic and real-world evidence. As AI makes that data more valuable, the question is no longer simply who generates it, but who controls where it is processed and who captures the value created from it.

India does not need to prevent global pharma from using this data. It needs to ensure that using Indian data does not automatically mean exporting the data, the compute or the resulting intelligence outside India's control.

Data Sovereignty is the Strategic Opportunity

Data sovereignty is often presented as a question of where data is stored. It is much bigger than that. For India, sovereignty should mean control over where sensitive clinical and genomic data resides, who can access it, where it can be processed, and what happens to the intelligence created from it.

Indian pharma companies, hospital networks, CROs and research institutions should be able to process sensitive clinical and genomic datasets within controlled, auditable environments in India, while still participating fully in global research collaborations.

India does not need to lock its data away from the global research community. That would defeat the purpose of its position in global pharma. The objective should be to change the architecture of how that collaboration happens.

Instead of sending sensitive clinical or genomic datasets to wherever the compute happens to be, India should increasingly enable compute to come to the data.

Sensitive datasets can remain within controlled, India-based environments. Approved researchers and global pharma partners can run authorised workloads against them. Access can be governed, monitored and audited. Data does not necessarily have to leave the country simply because the algorithm does. The same principle should extend to the value created from that data. Clinical trial agreements and data-sharing arrangements need to become much more explicit about secondary use, derived datasets, trained models and downstream commercialisation. If data generated in India helps train a model that subsequently contributes to a drug discovery programme worth billions of dollars, the question cannot end with whether the original dataset was legally transferred.

The question should be whether India retained sufficient control and participation in the value chain. That is what data sovereignty should mean in practice. It is not about hoarding data. It is about ensuring that the country generating a strategically valuable resource does not permanently remain only its supplier.

The Keystone, Not Just the Testing Ground

The opportunity is not simply to be a low-cost clinical trial destination. It is to become a keystone in the global drug discovery and clinical research value chain. That positioning will require more than regulation. It will require infrastructure.

India has already demonstrated what can happen when it builds digital rails that others can build on top of. The same instinct now needs to be applied to health data and AI compute.

Indian pharma companies, hospital networks, CROs and research institutions should be able to process sensitive clinical and genomic datasets within controlled, auditable environments in India, while still participating fully in global research collaborations.

That means data centres, cloud, high-bandwidth connectivity, cybersecurity and AI compute cannot be treated as separate technology purchases. They need to operate as one sovereign data and compute fabric for workloads where control matters as much as performance.

This is where infrastructure becomes strategic. The objective is not simply to host Indian data on Indian soil. It is to create an environment where sensitive data can be processed, models can be trained and research can be conducted under Indian-controlled governance, while global collaborators can still participate.

The economics make the case for this even stronger. IBM's[3] 2026 Cost of a Data Breach report puts the average cost of a data breach in India at ₹255 million, up from ₹220 million in 2025. The problem is not simply the cost of a breach. It is the strategic exposure created when sensitive clinical, genomic and proprietary research data sits across infrastructure and AI environments that an organisation does not fully control. For an industry built around patient privacy and proprietary intellectual property, sovereignty is therefore not a philosophical question. It is an operating model.

The world will continue to come to India to test its medicines.
The strategic question is whether India remains the place where the world generates evidence or becomes the place where that evidence is transformed into intelligence, intellectual property and economic value.

Where This Goes Next

The next phase of pharma's AI story will not be written only in discovery labs. It will also be written in data centres, contracts, governance frameworks and infrastructure choices. India already has the raw material: scale, patient diversity, clinical expertise and a trial ecosystem that global pharma understands.

What it needs now is control. That does not mean preventing global pharma from accessing Indian data. It means creating the conditions under which that access happens without requiring India to surrender control of the underlying data, the compute environment or the value created from it.

The world will continue to come to India to test its medicines.

The strategic question is whether India remains the place where the world generates evidence or becomes the place where that evidence is transformed into intelligence, intellectual property and economic value.

That is the real opportunity in sovereign AI for pharma. India has spent decades building the scale to run the world's clinical trials. The next decade should be about building the sovereignty to capture the value in the data they generate. ■

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About the Author

Dr Keyur Jathal is a business leader with 24 years of experience in the IT sector and a successful track record in creating and optimizing business ecosystems for Fortune 100 companies, including IBM, HP, and SAP, particularly in emerging markets.

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- **Company's total installed capacity exceeds 24,000 MT per annum.**


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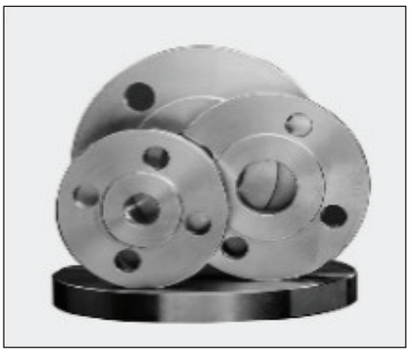
Stainless Steel Seamless Heat Exchanger U-Tubes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Thermo Fisher Scientific launches first Orbitrap Mass Spectrometers for Isotope Ratio Analysis

New Orbitrap Isora workflow integrates mass spectrometry, Vanquish Duo UHPLC System and Isotope Discoverer Software to bring molecular-level isotope ratio analysis to more researchers worldwide

Waltham: Thermo Fisher Scientific has introduced the Thermo Scientific™ Orbitrap™ Isora™ Mass Spectrometer and Orbitrap Isora Pro Mass Spectrometer, the company's first Orbitrap instruments with a dedicated isotope ratio analysis mode. Together with the Thermo Scientific™ Vanquish™ Duo UHPLC System and new Isotope Discoverer™ Software, the instruments form an integrated workflow designed to make molecular-level isotope ratio analysis accessible to more laboratories and researchers worldwide.

Unlike traditional isotope ratio techniques that require samples to be converted to a simple gas, the Orbitrap Isora workflow measures isotope ratios directly at the molecular level, providing a more detailed picture of a sample's origin and history. At the same time, the workflow simplifies an analysis that previously required multiple script-based tools and complex manual data processing. The Orbitrap Isora workflow brings these steps together, delivering results in hours instead of days and making isotope analysis more practical for a broader range of laboratories. The workflow includes:

- **The Orbitrap Isora MS and Orbitrap Isora Pro MS,** which combine electrospray ionization (ESI) with high-resolution accurate-mass (HRAM) detection to measure isotopologues and isotope ratios directly from intact molecular ions. The instruments capture multiple isotopes in a single run and offer researchers different levels of analytical capability, with up to 240K maximum resolution (at m/z 200) on Orbitrap Isora MS and up to 480K maximum resolution (at m/z 200) on Orbitrap Isora Pro MS.
- **The Vanquish Duo UHPLC System,** which automates the introduction of samples and reference materials, using known standards to help ensure accurate, reliable isotope ratio measurements.
- **New Isotope Discoverer Software,** which turns the resulting isotope data into usable results by extracting isotope ratios, filtering data and applying corrections, all in one environment.

The Orbitrap Isora workflow expands what researchers can investigate with isotope ratio analysis across a range of fields:

- **Environmental research:** Helps trace pollution back to its source and helps track the paths PFAS and other contaminants take through watersheds, soil and food supplies, so remediation teams can target the source.
- **Geology, climatology and archaeology:** Helps reconstruct the past oxygen levels and microbial activity preserved in the geological record, giving earth and climate scientists a more detailed account of how the planet behaved in the past.
- **Bioscience and metabolism:** Provides insights into how the body uses and transforms nutrients and metabolites at the molecular level, opening new lines of study in nutrition, metabolic disease and drug development.
- **Food and beverage authenticity:** Helps distinguish synthetic ingredients from natural ones and helps confirm whether a product matches its label, catching adulteration before it becomes a recall. ■

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