An MM ACTIV Sci-Tech Communications Publication

BioSpectrum

the business of Bio & Health Sciences

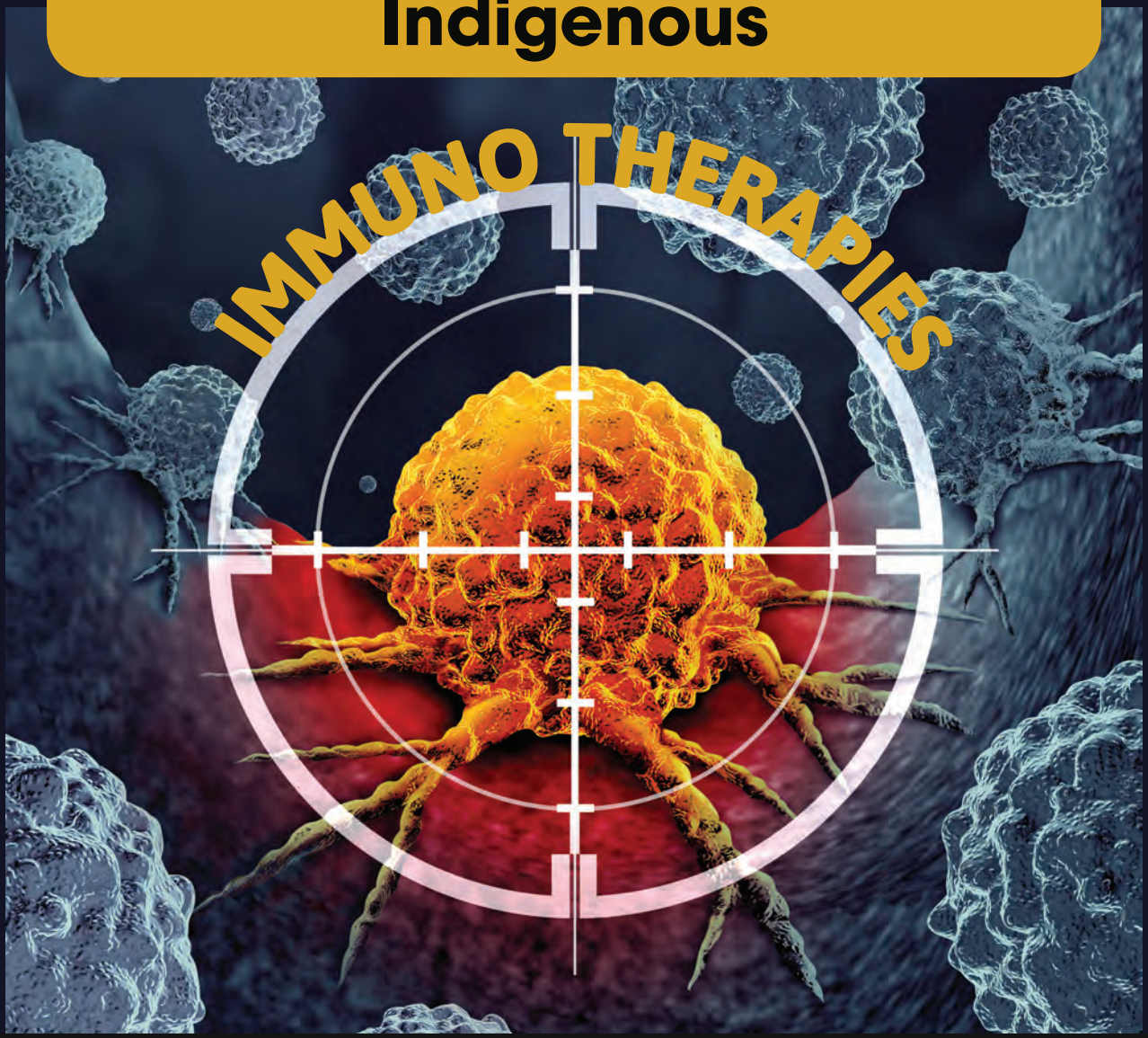
PUNE ▪ Volume 23 ▪ Issue 7 ▪ July 2025

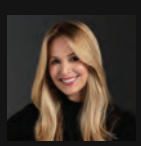
www.biospectrumindia.com

₹150

Total pages including cover 52

Advancing Affordable Indigenous





"We see India not just as a trade partner, but as a strategic collaborator for the US market and beyond"

- Ella Woger-Nieves, CEO, Invest Puerto Rico - **37**

Can Indian Companies Compete with MNCs in GLP-1 Production? - 31

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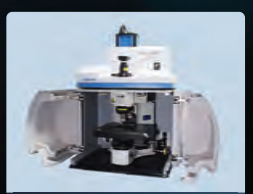

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Acknowledgement/Feedback

The cover of the June 2025 edition is indeed an in-depth story and a very informative one. A great read for me this week. Thank you for seeking responses from Dr Vikram and incorporating it in your story.

Sumathi, Bengaluru

Thank you so much BioSpectrum for the interview piece with Agilent Technologies, immensely appreciated.

Sharmistha Chattopadhyay, Delhi

We are extremely grateful to you for the feature on IDA Ireland in the BioSpectrum June 2025 edition.

Dominique Fernandes, Mumbai

Vol 23; Issue 7; July 2025

MM Activ Sci-Tech Communications

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'BioSpectrum' monthly publication is owned by MM Activ Sci-Tech Communications Pvt. Ltd., **Published and Printed by** Ravindra Boratkar, **Printed at** Spectrum Offset, D2/4, Satyam Industrial Estate, Behind CDSS, Erandawana, Pune - 411 038. and **Published at** 'Ashirwad', 36/A/s, S. No. 270, Pallod Farms, Baner Road, Near Bank of Baroda, Pune - 411 045. **Editor:** Narayan Kulkarni.
Website: www.biospectrumindia.com Reprinted for private Circulation

Letter from Publisher

Ravindra Boratkar
Publisher &
Managing Editor,
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Dear Readers,

Immunotherapy, which provides tailored, efficient, and less harmful therapies for infectious diseases, cancer, and autoimmune disorders, is revolutionising modern medicine. India is quickly establishing itself as a major participant in the development and large-scale manufacturing of these treatments as the demand for them rises globally. Thanks to its robust government support, highly qualified workforce, and expanding biotech capabilities, India is becoming a major player in the global immunotherapy market. An important turning point was reached in 2023 when NexCAR19, the nation's first domestic CAR-T treatment, was approved. The second CAR-T product, Qartemi, for patients with advanced or relapsed B-cell non-Hodgkin lymphoma, received approval in January 2025.

The field of immunotherapy in India has seen a surge in interest in recent months. The majority of CAR-T therapies/therapeutics have public domain origins. India is steadily laying the groundwork to become a worldwide hub for scalable and reasonably priced immunotherapy therapies. The nation is well-positioned to change not only its healthcare system but also make a substantial contribution to global health equity with strategic investments, legislative reforms, and an expanding talent pool. The lead piece goes in-depth into India's immunotherapy research pipeline, examining its motivations, obstacles, and potential to become a global centre for reasonably priced immunotherapy.

The patents for popular medications for diabetes and obesity, especially semaglutide, are scheduled to expire in India in March 2026, which is anticipated to cause a significant change in the market. Generic versions of these in-demand GLP-1 receptor agonist medications will be available for Indian pharmaceutical companies to introduce. At this critical juncture, the market will democratise access to costly treatments that have, up to now, been controlled by large corporations. India may become a major player in the worldwide supply of reasonably priced GLP-1 treatments with strong ecosystem support, according to our team's story, further consolidating its position as the world's pharmacy.

Americans presently pay the highest prices for prescription drugs, sometimes nearly three times more than other developed nations. To make the price of drugs affordable, the US President has signed a wide-reaching executive order (EO) on May 12 that directs drugmakers to lower the prices of medicines to align with what other countries pay. This may have an impact on the Indian pharma industry as India’s pharma export to the US is around $9 billion, contributing to about 40 per cent of the US generic market. We have covered some of the Industry leaders’ views on this.

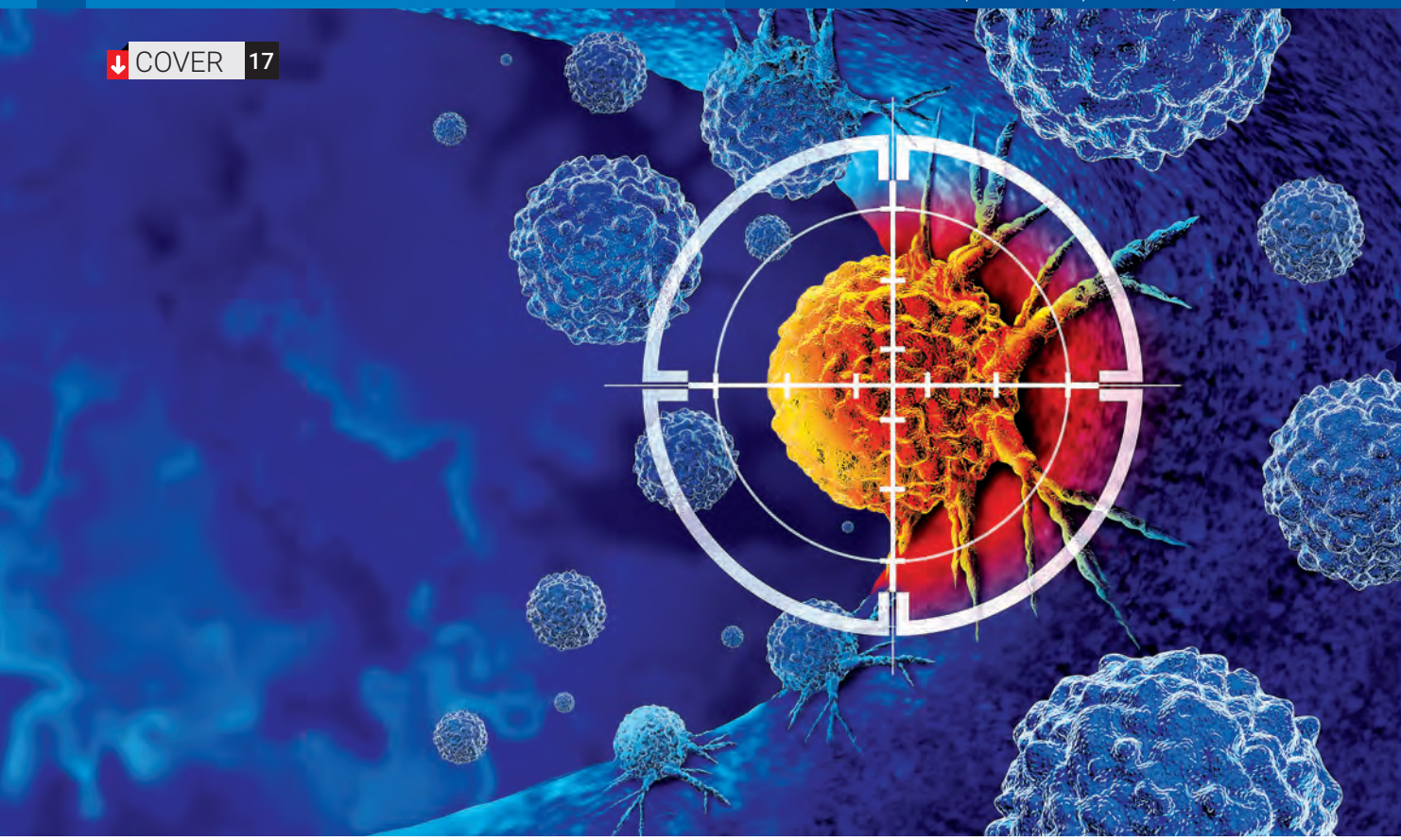
At its core, genomics enables the shift from reactive to proactive healthcare. The application of genomics in healthcare offers a multi-pronged approach to improving public health, from proactive prevention to highly targeted treatments. The benefits are vast and interconnected, creating a powerful ecosystem for medical innovation. An industry veteran explains how genomics is unfolding across emerging economies, promising to transform healthcare landscapes from Egypt to China.

I am sure you will find this edition a great read.

Thanks & Regards,

Ravindra Boratkar,
Publisher & Managing Editor

COVER 17



Advancing Affordable Indigenous IMMUNOTHERAPIES

Immunotherapy is transforming modern medicine by offering targeted, effective, and less toxic treatments for cancer, autoimmune disorders, and infectious diseases. As global demand for these therapies grows, India is rapidly positioning itself as a key player in their development and large-scale production. We shall take a deep dive into India's immunotherapy research pipeline—what's driving it, what's holding it back, and whether the country can truly emerge as a global hub for affordable immunotherapy.

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Executive Order

Pharma Patent

Speaking With

Genomics

Top Video

Dr Vinoad Bharrati, Obstetrician Gynecologist, and Director, Elite Momz unit of Rising Medicare Hospital talks about how the maternal healthcare market is evolving in India, with the advent of new technologies.

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Why generic water purification companies struggle with Ultra Pure Water? Shoeb Kurawadwala, Founder & Managing Director, CN Water Systems reveals it all.

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Schedule M

Regulars

‘Going Local’ for Med Devices

Two recent developments—one international and the other domestic—are poised to significantly benefit India’s medical equipment industry. On the global front, the European Union has voted to restrict the import of Chinese medical devices. Domestically, both the Indian government and judiciary have reaffirmed the fairness and inclusivity of the country’s procurement policies for medical equipment.

The Association of Indian Medical Device Industry (AiMeD) has welcomed both developments, viewing them as landmark steps toward creating a more equitable and self-reliant procurement ecosystem. The current regulatory, legal, and policy frameworks are better aligned to provide Indian manufacturers with a fair opportunity in public tenders, previously skewed in favour of foreign firms. This will give rise to more equitable opportunities to compete in public tenders.

A significant milestone was achieved in February 2025 when the Supreme Court of India ruled against the Gwalior Municipal Corporation (GMC) for excluding Indian manufacturers from its tender process for medical equipment, citing quality concerns and favouring multinational brands. The court criticised this bias, calling it unjustified and discriminatory. Hence, now the preference to foreign producers over Indian will no longer be even legally acceptable.

The Supreme Court ruling has been seen as a legal validation of the principle of equal opportunity for Indian manufacturers too. Beyond setting a precedent, it is expected to discourage public authorities from including such exclusionary clauses in future tenders and to strengthen the confidence of domestic manufacturers.

While it is true that over 80 per cent of India’s medical device needs are currently met through imports, this trend is beginning to shift. In a promising development, the All-India Institute of Medical Sciences (AIIMS), New Delhi, announced in April its plan to install the country’s first indigenously developed 1.5 Tesla Magnetic Resonance Imaging (MRI) machine by October this year. This project, in partnership with the Society for Applied Microwave Electronic Engineering and Research (SAMEER), marks a significant step in technological self-reliance.

Another notable initiative came in May, when the Andhra Pradesh MedTech Zone (AMTZ) launched the International Biomed Cross (IBC)—a global effort to support the maintenance and repair of medical equipment during disasters and health emergencies. This initiative brings together biomedical and clinical engineers from around the world to provide technical assistance in crisis-hit regions.

The potential for indigenous manufacturing is enormous, given the size of the domestic market. India is currently the fourth-largest medical device market in Asia—after Japan, China, and South Korea—and ranks among the top 20 globally. Valued at $14 billion, the Indian market is projected to grow to $30 billion by 2030. India also exports around $4 billion worth of medical devices.

To reduce import dependency, the government has introduced several policy measures and incentives, including a production-linked incentive (PLI) scheme for the sector. In a significant move, the government also banned the import of second-hand or refurbished medical devices from May this year. However, opinions are divided on this ban. Votaries of refurbished imports argue that such equipment helps lower the cost of treatment, making it accessible to poorer patients. They point to the lower cost of imaging tests in India compared to developed countries as an example of the benefit. These proponents advocate for regulated imports instead of an outright ban. On the other hand, opponents cite concerns over quality and patient safety.

The PLI scheme for the medical devices sector will promote domestic production. Another lingering concern for domestic manufacturers is the tariff structure. Currently, tariffs on imported medical devices are low, and reports of a possible further reduction have caused unease in the industry. AiMeD has expressed apprehension that such measures would hurt local manufacturers’ competitiveness.

If the tariff issue is resolved in favour of domestic stakeholders, India could find itself in a truly enabling environment—one that supports the vision of becoming a global hub for medical device manufacturing. BS

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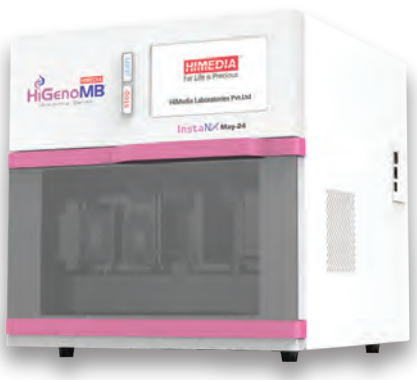

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Centre opens investor facilitation portal for traditional medicine sector

The Government of India has launched the Ayush Nivesh Saarthi portal, a dedicated, investor-centric digital platform developed by the Ministry of Ayush in collaboration with Invest India. It brings together policy frameworks, incentive structures, investment-ready projects, and real-time facilitation under one unified interface. Designed to support both domestic and global investors, the platform is a strategic tool that strengthens India's standing as a global investment destination for traditional systems of medicine.

India's Ayush industry has emerged as one of the fastest-growing sectors in the country, recording an annual growth of 17 per cent between 2014 and 2020. With rising global consumer interest in natural, preventive, and wellness-based healthcare, Ayush is at the forefront of a new wave in global health and lifestyle transformation. With the launch of Ayush Nivesh Saarthi, the Government of India has reaffirmed its vision of making Ayush a pillar of both public health and economic growth. This portal is expected to serve as a vital catalyst in attracting foreign direct investment, empowering entrepreneurs, and showcasing India's leadership in traditional medicine and wellness to the world.

Ayush Ministry launches portal to address issues of adverse drug reaction

In a landmark step toward strengthening consumer protection and regulatory oversight in the field of traditional medicine, the Union Minister of State (Independent Charge), Ministry of Ayush; and Union Minister of State, Ministry of Health & Family Welfare, Government of India, Prataprao Jadhav, recently launched the AyushSuraksha Portal. The Ayush Suraksha Portal has been developed in accordance with the Supreme Court's order dated July 30, 2024, in Writ Petition (Civil) No. 645/2022, wherein the Court emphasised the need for a centralised dashboard for monitoring and publishing data related to misleading advertisements and adverse drug reactions. The portal, developed with the technical support of the Central Council for Research in Siddha (CCRS) and aligned with the National Pharmacovigilance Programme, allows consumers, healthcare professionals, and regulatory authorities to report and monitor misleading advertisements and adverse drug reactions through a seamless digital process. With the launch of this portal, the Ministry of Ayush now has a centralised and accessible dashboard of reported cases, enabling real-time tracking, swift regulatory action, and detailed data analysis.

India partners with WHO to mainstream Ayush globally

In a landmark development poised to transform the global standing of traditional medicine systems, an agreement has been signed between the Ministry of Ayush and the World Health Organization (WHO). The agreement marks the beginning of work on a dedicated Traditional Medicine module under the International Classification of Health Interventions (ICHI). The ICHI, complementing WHO's International Classification of Diseases (ICD-11), documents what treatments and health interventions are administered. With the inclusion of a traditional medicine module, therapies from Ayurveda, Yoga, Siddha, and Unani systems, such as Panchakarma, Yoga therapy, Unani regimens, and Siddha procedures, will now be recognised in globally standardised terms. The combined impact of ICD-11 for diseases and the new ICHI module for interventions will ensure that Ayush becomes an integral, evidence-based, and policy-recognised part of global healthcare systems.

Shivtek Spechemi Industries invests Rs 600 Cr to set up new unit in Gujarat

Leading speciality chemicals manufacturer, Shivtek Spechemi Industries, a flagship company of the Shiva Group of Industries, focusing on innovation, sustainability, and high-quality solutions for pharmaceuticals, agrochemicals, and industrial coatings, has announced the finalisation of a new manufacturing facility near Hazira, spread across 1 million+ square feet. The new facility being built with an investment of Rs 600 crore, to be operational from 2027, will add to the production capacity of 2,50,000 MTPA by 2027-28 and offers cost-effective logistics and seamless connectivity to both domestic and international markets. The expansion is further supported by a 5000 KL storage facility and a dedicated warehousing space of 1,50,000 square feet for export orders and products from the Dahej plant.

Aster DM Healthcare to inject Rs 480 Cr in new facility in Bengaluru

Aster DM Healthcare, one of the largest integrated healthcare providers in India, has announced the signing of a lease agreement to establish its 4th Multispecialty Hospital in Bengaluru. This 430-bed state-of-the-art facility to come up in Sarjapur is set to revolutionise healthcare in the region with its comprehensive and specialised medical services. Aster DM Healthcare will be making an investment of around Rs 480 crore in this facility spreading over 4 lakh sq ft. The first phase of the project with 300 beds will be operational by the second half of FY27 and the remaining 130 beds in FY29. With the establishment of its fourth hospital in Bengaluru, Aster will strategically achieve a city-wide presence, covering all major zones and solidify its position among the top three hospital chains in the city.

Agenus and Zydus Lifesciences enter $141 M strategic collaboration for biologics manufacturing in US

US-based Agenus Inc., a leader in immuno-oncology innovation, has signed definitive partnership agreements with Ahmedabad-based Zydus Lifesciences, including its subsidiaries/ affiliates, designed to accelerate clinical development, scale global manufacturing, and expand patient access to botensilimab and balstilimab (BOT/BAL). The strategic collaboration includes an exchange of Agenus' state-of-the-art biologics CMC facilities in Emeryville and Berkeley, for upfront consideration of $75 million; Agenus to receive up to an additional $50 million in contingent payments triggered

by BOT/BAL production orders. Zydus, an India-based multinational pharmaceutical company with over 27,000 employees and operations in 55 countries, will launch a BioCDMO business using the facilities as their flagship US sites to provide biologics contract manufacturing services to biopharmaceutical companies globally. Agenus will become Zydus' first BioCDMO customer through an exclusive manufacturing agreement for BOT/BAL to ensure the combination regimen's BLA and launch readiness needs. This collaboration enables Agenus to unlock the value of its manufacturing assets and secure strategic capital to drive BOT/BAL toward global regulatory engagement and commercialisation. Agenus will also grant Zydus an exclusive license to develop and commercialise BOT and BAL in India and Sri Lanka.

Miltenyi Biotec India and BIRAC sign LoI to advance India's cell and gene therapy ecosystem

In a significant step toward strengthening India's leadership in cutting-edge biotherapeutics, Miltenyi Biotec India and the Biotechnology Industry Research Assistance Council (BIRAC) have signed a strategic Letter of Intent (LoI) at the BIO International Convention 2025. The LoI outlines a multi-pronged collaboration aimed at propelling India's capabilities in Cell and Gene therapy (CGT) by capacity building, advancing clinical research and to solve unmet medical needs by local manufacturing of Cell Therapies. Through this partnership, Miltenyi Biotec and BIRAC aim to build national capabilities and upskill scientific talent by implementing structured training and capacity-building programs for clinicians, researchers, and technicians in CGT manufacturing, analytics, and quality control; Expand translational research efforts through co-development of academic and multi-centre studies, focusing on next-generation therapies to solve India's unmet medical needs in malignancies, autoimmune diseases and rare diseases.

Nitika Pharmaceutical strengthens indigenous manufacturing of complex excipients

The Technology Development Board (TDB), Department of Science and Technology (DST), Government of India has extended financial support to Nitika Pharmaceutical Specialties in Nagpur, for their project titled "Manufacture of Complex Excipients." Excipients, though pharmacologically inactive, are critical to the functionality, stability, and delivery of medicines. As drug formulations become increasingly sophisticated, with the rise of complex generics, biopharmaceuticals, and novel delivery systems, the demand for high-quality, tailor-made excipients has surged globally. Through this project, Nitika Pharmaceutical Specialties aims to establish a state-of-the-art manufacturing facility for commercial-scale production of 14 complex excipients that cater to advanced pharmaceutical applications. These products will be developed in line with the Quality by Design (QbD) framework, ensuring precision in parameters like surface area, particle size, and stability to meet international standards.

Mapmygenome goes global with acquisition of Microbiome Insights

Hyderabad-based Mapmygenome, an artificial intelligence (AI)-driven leader in genomics and personalised health, has announced the strategic acquisition of Microbiome Insights, a global leader in microbial sequencing. The acquisition includes Microbiome Insights' CAP-accredited Canadian laboratory and rich intellectual property, boosting Mapmygenome's scientific prowess and enabling its global expansion. Having supported over 600 global clients with 1,000+ cutting-edge microbiome studies, Microbiome Insights is a leading partner for academic, clinical, and industry researchers. Microbiome Insights will maintain its role as a premier contract research organisation (CRO), empowering global research. Simultaneously, Mapmygenome will introduce its integrated genomics and microbiome testing services to North America, making holistic, data-driven health solutions more accessible.

Department of Science & Technology
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IKP Knowledge Park inks MoU with BITS Pilani Hyderabad to support startups

IKP Knowledge Park had announced the signing of a Memorandum of Understanding (MoU) with BITS Pilani Hyderabad Campus TBI Society (TBIS), a strategic collaboration to strengthen the innovation and technology transfer ecosystem. Through this partnership, IKP PRIME, the Technology Transfer Office at IKP, will spearhead efforts in IP Protection & Filing Support; Technology Transfer & Licensing; IP & Innovation Policy Guidance; Startup–Faculty Collaboration; Industry Linkages; and Capacity Building. Together, both IKP and BITS Pilani aim to empower researchers, startups, and innovators with the tools and support needed to bring groundbreaking ideas to market. This MoU marks a significant step in their shared mission to foster a dynamic, collaborative, and sustainable innovation ecosystem.

Qure.ai unveils new AI-powered co-pilot tool for frontline healthcare workers in LMICs

Leveraging its strength in digital health innovation, Mumbai-based startup Qure.ai has launched a new artificial intelligence (AI)-powered co-pilot tool for frontline healthcare workers in resource-constrained geographies. 'AIRA' is designed to optimise limited healthcare resources in Low- and Middle-Income Countries (LMICs) by supporting AI-enabled digitisation of symptoms and patient history collection; clinical protocol adherence and decision support; and aggregated population health insights. There are 17 million preventable deaths in LMICs and an estimated shortage of 11 million health workers by 2030. At the same time, more than 40 per cent of community health workers' time is spent on manual data collection, and yet countries do not have population-level data to make informed decisions. AIRA aims to solve this urgent need by freeing up precious health worker time to engage more with patients, while digitising data automatically.

Vgenomics and Dr. Shroff's Eye Hospital jointly develop unique biomarker to detect Keratoconus

Delhi-NCR based biotech startup Vgenomics has entered into a special partnership with Dr. Shroff's Charity Eye Hospital. The aim of this partnership is to detect the eye disease keratoconus at an early stage using a new technology. For this purpose, they have developed a unique tear-based biomarker, named VSP-2224. It has been developed with the help of artificial intelligence (AI) and the RgenX-LENS platform by Vgenomics. The key feature of this biomarker is its ability to detect the disease even before symptoms appear. It is completely non-invasive, allowing early diagnosis and better treatment outcomes. Keratoconus is a progressive eye disease that affects the cornea. It gradually weakens the vision and, if not treated in time, can lead to permanent vision loss. The current techniques used to detect this disease only become effective after significant corneal damage has already occurred, making timely treatment difficult. Currently, VSP-2224 is undergoing clinical validation among patients, healthy individuals, and those receiving treatment.

Novo Nordisk Foundation enters into strategic framework agreement with WHO to advance global health

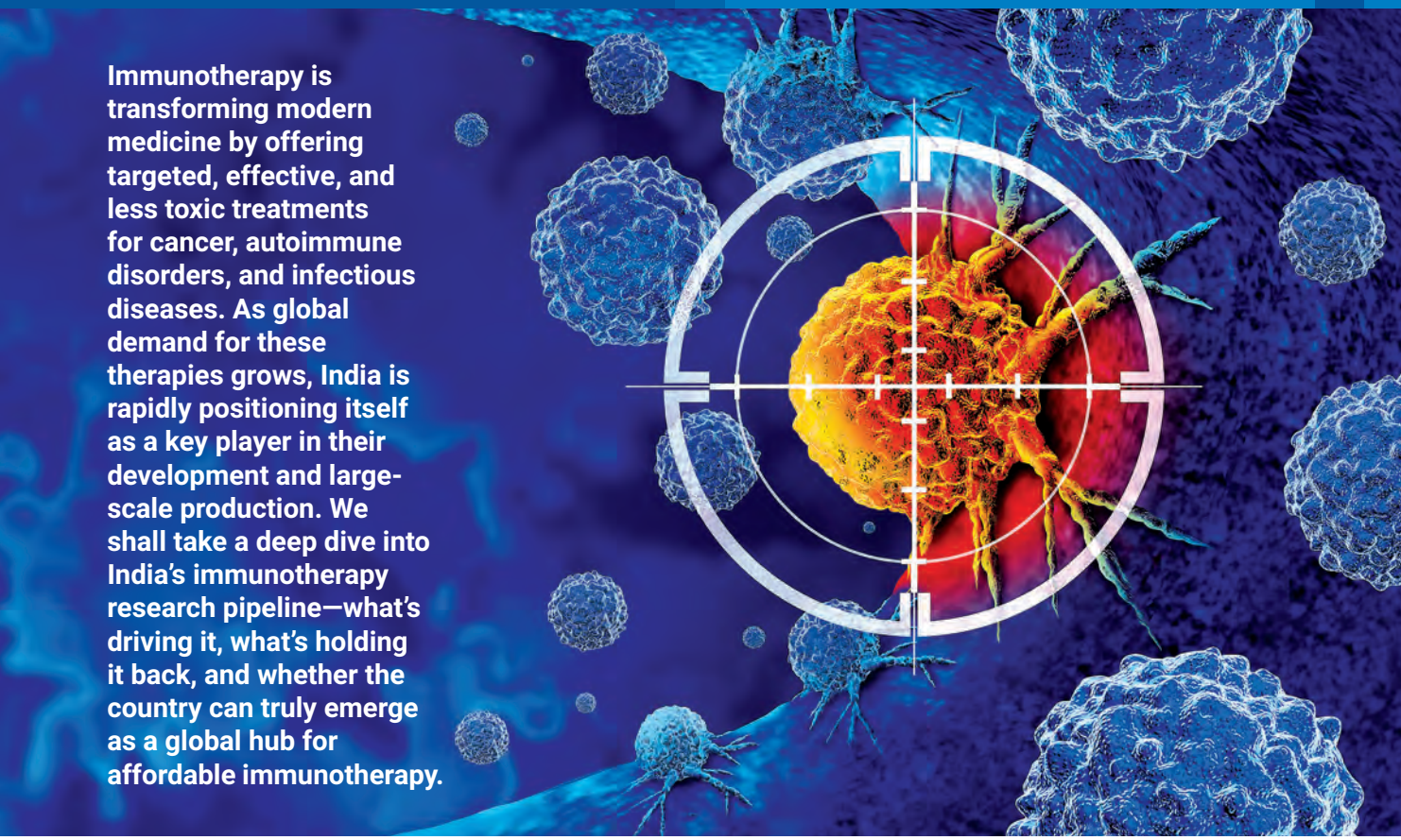
Novo Nordisk Foundation has entered into a strategic framework agreement with the World Health Organization (WHO) to advance global health. With the agreement, the Foundation expands its existing collaboration with WHO, committing to a granting frame of up to DKK 380 million over the next four years. The Foundation and WHO are deepening the partnership, adopting a more strategic approach through the signature of a framework agreement that will enable the two organisations to accelerate progress by working together. This includes opportunities to collaborate on the promotion, provision and protection of health, addressing the growing burden of non-communicable diseases (NCDs) with emphasis on cardiometabolic diseases; critical gaps in the health workforce; inequity in access to quality NCD services as well as antimicrobial resistance.

WHO outlines recommendations to protect infants against RSV

The World Health Organization (WHO) has published its first-ever position paper on immunisation products to protect infants against respiratory syncytial virus (RSV) – the leading cause of acute lower respiratory infections in children globally. Published in the Weekly Epidemiological Record (WER), the position paper outlines WHO recommendations for two immunisation products: a maternal vaccine RSVpreF that can be given to pregnant women in their third trimester to protect their infant and a long-acting monoclonal antibody nirsevimab that can be administered to infants from birth, just before or during the RSV season. WHO recommends that infants receive a single dose of nirsevimab right after birth or before being discharged from a birthing facility. If not administered at birth, the monoclonal antibody can be given during the baby's first health visit. Both products were recommended by the Strategic Advisory Group of Experts on Immunisation (SAGE) for global implementation in September 2024. In addition, the maternal vaccine received WHO prequalification in March 2025, allowing it to be purchased by UN agencies.

Africa CDC, WHO, and RKI expand unique partnership to strengthen collaborative surveillance

The World Health Organization (WHO), Africa Centres for Disease Control and Prevention (Africa CDC) and the Robert Koch Institute (RKI) have announced the expansion of the successful Health Security Partnership to Strengthen Disease Surveillance in Africa (HSPA) to seven countries on the continent. The Health Security Partnership strengthens disease surveillance and epidemic intelligence across the African Continent, enabling countries to better detect and respond to health security threats – whether they are natural, accidental, or deliberate. HSPA was launched in 2023 in six countries: The Gambia, Mali, Morocco, Namibia, South Africa, and Tunisia. The partnership will expand to other countries, including Rwanda, in its second phase which runs from 2025-2028. The partnership is supporting countries to strengthen capacities in biorisk management, event and indicator-based surveillance, genomic surveillance and epidemic intelligence.



Immunotherapy is transforming modern medicine by offering targeted, effective, and less toxic treatments for cancer, autoimmune disorders, and infectious diseases. As global demand for these therapies grows, India is rapidly positioning itself as a key player in their development and large-scale production. We shall take a deep dive into India's immunotherapy research pipeline—what's driving it, what's holding it back, and whether the country can truly emerge as a global hub for affordable immunotherapy.

Advancing Affordable Indigenous IMMUNOTHERAPIES

India is emerging as a key player in global immunotherapy, backed by strong government support, skilled talent, and growing biotech capacity. A major milestone came in 2023 with the approval of NexCAR19, the country's first indigenous CAR-T therapy. This was followed in January 2025 by the approval of Qartemi from Bengaluru-based Immuneel Therapeutics—a CAR-T cell therapy for patients with relapsed or advanced B-cell Non-Hodgkin Lymphoma—marking India's second approved CAR-T product.

"From 2015 to 2025, the market is projected to grow from $0.5 billion to $4 billion. This momentum is being driven by research efforts sparked by COVID-19, innovations in cancer-focused immunotherapies and biosimilar products, as well as the growing adoption of CAR-T cell technologies and AI-based diagnostic tools—solidifying its role as an emerging centre for cutting-edge biologics and personalised medicine. However, compared to global leaders like the U.S., EU, and China, India is still in a developmental phase, with several critical capabilities under maturation," said Shalini Tanwar, Team Lead-Immunotherapy, Aurigene Pharmaceutical Services.

There has been a flurry of activity in India's immunotherapy landscape in recent months. In June 2025, Zydus Life Sciences acquired rights to Agenus' BOT/BAL cancer immunotherapy for India and Sri Lanka. Earlier, in March, Delhi-based Cellogen Therapeutics secured a patent for what is reportedly the world's first indigenously developed bi-specific 3rd generation CAR-T cell therapy. In January,

"While full commercial-scale readiness is still evolving, the foundation being built today signals a future where India plays a central role in the global immunotherapy ecosystem."

- Shalini Tanwar,
Team Lead- Immunotherapy,
Aurigene Pharmaceutical Services

CytoMed Therapeutics partnered with SunAct Cancer Institute to initiate a proposed phase 2 trial of Gamma Delta T cell therapy for solid tumours. This followed Mankind Pharma's December 2024 collaboration with Innovent Biologics to bring the PD-1 inhibitor sintilimab to India.

Immunotherapy research pipeline

Most CAR-T products have roots in public research. NexCAR19, India's first approved CAR-T product, is a prime example, developed by IIT Bombay in collaboration with Tata Memorial Centre. Qartemi, launched by Immuneel Therapeutics, was licensed from Hospital Clínic de Barcelona, highlighting the role of international technology transfer in advancing Indian immunotherapy. Similarly, IIT Kanpur is set to transfer several gene therapy assets to Laurus Labs through an in-licensing arrangement, backed by a research grant to support preclinical development.

Several key research projects funded by the Department of Biotechnology (DBT), Government of India have been instrumental in building the country's immunology and cell therapy pipeline, from advancing CAR-T cell technologies to pioneering gene-editing strategies and developing indigenous manufacturing capabilities. Given this deep academic foundation, it's only fair to take a closer look at some of the DBT funded research projects powering India's next generation of immune-based therapies.

anti-CD19 CAR-T cell therapy: This, India's first indigenously developed CAR-T cell therapy, talicabtagene autoleucel (Tali-cel), is currently undergoing a multi-centre phase II trial involving 50 paediatric patients with relapsed/refractory (r/r) B-cell acute lymphoblastic leukaemia (B-ALL). Developed through a project funded by Tata Memorial Centre, the therapy was initially evaluated in a phase I/Ib open-label single-arm study. This early-stage trial demonstrated a favourable safety profile, manageable toxicities, and promising durable remissions in heavily pretreated patients. A key objective of the programme is to provide an affordable and scalable alternative to costly global CAR-T treatments, which remain largely inaccessible in low- and middle-income countries due to high manufacturing costs, limited local production, and clinical management challenges. Based on findings from the initial study, a recommended dose of $5–10 \times 10^6$ CAR-T cells/kg was identified to balance efficacy and safety. The product is being manufactured and co-sponsored by ImmunoACT, with the ongoing Phase II trial aimed at supporting regulatory registration.

Human gene therapy for Hemophilia A: India's first gene therapy using a lentiviral vector for severe Hemophilia A has demonstrated landmark results in a single-centre study led by the Centre for Stem Cell Research (CSCR) at CMC Vellore, supported by the Department of Biotechnology (DBT). All five participants achieved zero annualised bleeding rates over a cumulative 81-month follow-up, with sustained Factor VIII production, eliminating the need for repeated infusions.

Unlike traditional therapies reliant on costly, frequent Factor VIII replacement, this first-in-human trial involved autologous haematopoietic stem cells (HSCs) transduced with a lentiviral vector carrying the Factor VIII gene—an alternative to the widely used AAV-based systems. The therapy offers a long-term, potentially curative approach to a disorder for which India bears the world's second-largest burden (~1.36 lakh cases). The results, published in the New England

Journal of Medicine, mark a significant milestone for accessible gene therapy in low-resource settings.

Gene editing based strategies for treatment of Thalassemia and Sickle Cell Disease (SCD): Another pioneering project initiated by the CSCR, Vellore, and funded by DBT focuses on applying genome editing technologies to treat β-haemoglobinopathies, including SCD and β-thalassemia. Leveraging the precision of CRISPR/Cas9, the project aims to modify a patient's own HSCs to serve as a renewable source of healthy red blood cells following autologous bone marrow transplantation.

The therapeutic strategy is centred on reversing the fetal-to-adult hemoglobin switch, thereby increasing fetal haemoglobin (HbF) production—known to mitigate clinical symptoms in both SCD and β-thalassemia. The team is targeting BCL11A, a key repressor of gamma-globin, along with other regulatory regions associated with Hereditary Persistence of Fetal Haemoglobin (HPFH) mutations. This approach not only aims to reduce sickled haemoglobin in SCD patients but also compensates for defective beta-globin in β-thalassemia by promoting the expression of gamma-globin.

Unlike hydroxyurea or HDAC inhibitors, this gene-editing platform offers a potentially curative solution by permanently reprogramming the patient's own stem cells. The CSCR-DBT collaboration represents a significant step forward in developing affordable, gene-based therapies tailored to Indian patients with haemoglobin disorders.

CAR-T cell therapy expressing BCMA-CAR and in vivo validation in the mouse model of multiple myeloma: This collaborative DBT-funded initiative, led by IIT Bombay's Department of Biosciences & Bioengineering in partnership with Tata Memorial Centre and ImmunoACT, focuses on developing a cost-effective, humanised CAR-T cell therapy targeting B-cell maturation antigen (BCMA) for relapsed or refractory multiple myeloma. Using an in-house humanisation platform, the team designed four humanised BCMA CAR constructs (h1–h4), with h2 emerging as the most promising candidate. Preclinical studies demonstrated successful lentiviral production, robust in vitro CAR-T cell expansion, and optimal binding affinity for h2. In mouse xenograft models, h2-CAR T cells achieved complete tumor elimination, extended survival (median >123 days), and showed no systemic toxicity or organ damage. These findings mark a critical milestone in India's immunotherapy pipeline and position the h2-CAR candidate for potential translation into first-in-human clinical trials.

CD19 CAR-T Cell Therapy IMN-003A in B Cell malignancies: Varnimcabtagene autoleucel (IMN-003A), developed by Immuneel Therapeutics, is India's first industry-led CD19-directed CAR-T cell therapy for relapsed/refractory B-cell malignancies (RR BCM). This autologous product, which incorporates a 4-1BB co-stimulatory domain and a novel non-FMC63 A3B1 binder, is manufactured in India. Clinical development included a preclinical and Phase 1 study in Spain and a multicentre Phase 2 study (IMAGINE) in India. The therapy demonstrated a manageable safety profile with durable, deep responses and no severe neurotoxicity. The project is supported under the Biotechnology Industry Partnership Programme (BIPP) of the DBT, underscoring public-private efforts to advance indigenous cell therapies.

Single-Cell RNA-seq analysis of hCMV-specific T Cells: In a study published in Immunology, the Immunogenomics team at The National Institute of Immunology (NII) has characterised rare human Cytomegalovirus (hCMV) antigen specific memory T cells in an unbiased manner using high throughput single-cell multi-omics. The study shows that the hCMV-specific memory T cells are highly heterogeneous and consist of different flavors of long-term and effector memory T cells. The study can serve as a knowledge base for designing vaccines and therapeutic strategies to control hCMV infections, especially in immunocompromised individuals (patients undergoing organ transplant/

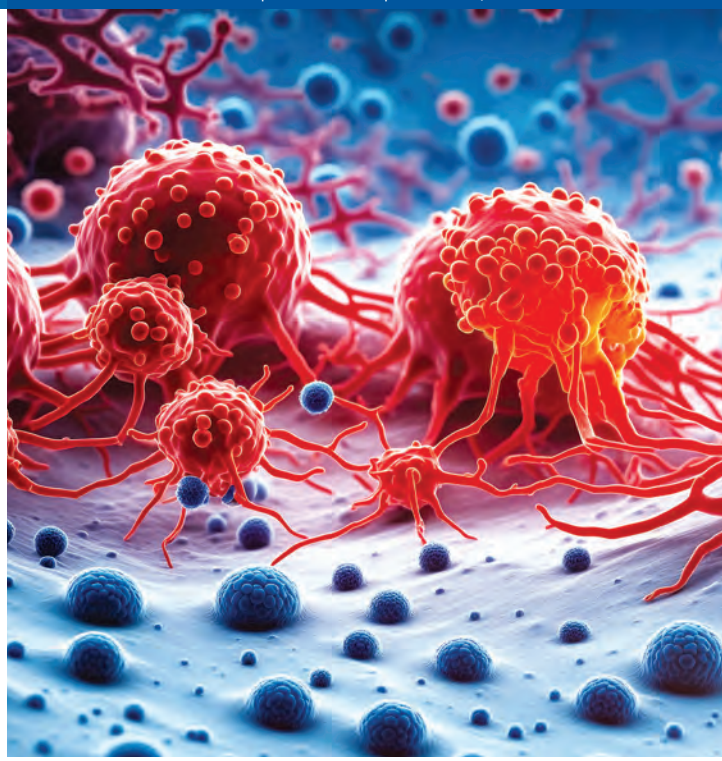
chemotherapy for cancers, etc.), and infants born to hCMV-seropositive mothers.

GMP-grade plasmid and viral vector manufacturing: The First-in-India GMP-grade plasmid and viral vector manufacturing initiative aims to establish a domestic, high-quality production facility to support CAR-T cell therapy and other gene therapy applications. Backed by the DBT, this project addresses a critical infrastructure gap by enabling the local manufacture of clinical-grade plasmids and viral vectors—essential components for gene modification in cell therapies. The initiative is expected to accelerate indigenous development, reduce dependency on imports, and support clinical translation of advanced therapies in India, especially in oncology and rare genetic disorders.

Preclinical-grade CAR-T manufacturing process: The project titled 'Chimeric Antigen Receptor (CAR) T-Cells Technology for Cancer Treatment: Development of a Pre-clinical Grade Manufacturing Process as per Industry Standards' falls under the PACE (Promoting Academic Research Conversion to Enterprise) scheme of DBT. This initiative focuses on developing a robust and standardised pre-clinical manufacturing process for CAR-T cells to meet industry-grade requirements. The goal is to bridge the gap between academic research and commercial-scale production by establishing scalable, reproducible, and quality-controlled protocols. By doing so, the project aims to create a foundation for translational research and future clinical applications of CAR-T therapies developed indigenously in India.

Anti-Nipah monoclonal antibody (mAbs): A specialised programme on the discovery and development of novel anti-Nipah mAbs with an aim to create low-cost mAb products was initiated with BRIC-Translational Health Science and Technology Institute (THSTI), Faridabad under GCI. BRIC-THSTI in collaboration with BRIC-RGCB has invented novel monoclonal antibodies from B cells of recovered individuals infected with Nipah virus during October 2023 Kerala outbreak. Engineered spike G and F antigens of Nipah virus were used to sort and clone single memory B cells.

Antigen-specific B cell clones were then screened to identify ones that bind very strongly to Nipah F and G proteins and also able to neutralise a panel of pseudoviruses encoding F and G genes of Indian, Bangladeshi, Malaysian and Flying Fox Bat origins. BRIC-THSTI also established pseudovirus neutralisation assay in this period which can be useful for vaccine studies by other researchers as well. Two top neutralising monoclonals have been identified for further development as IND products

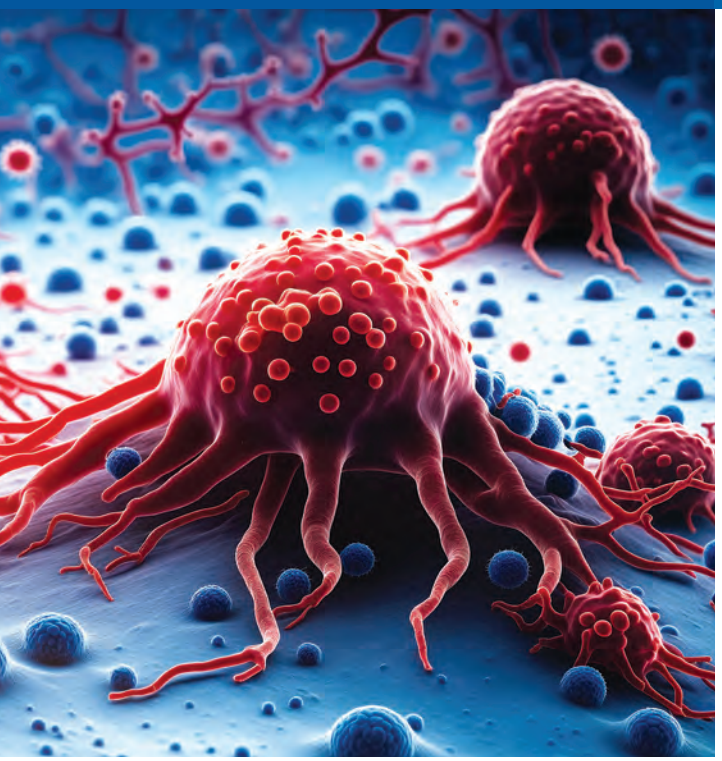


through industry-academy collaboration. This is the very first invention from India and any LMIC.

Universal CAR-T cells: All existing CAR-T cell products available globally are autologous (made with same patient-derived T lymphocytes) to avoid severe alloimmune rejection due to a mismatch of MHC between the donor and the recipient. Various studies have been implemented through the DBT's support to advance CAR-T cell therapy for a broader spectrum of cancers and reducing therapy related toxicities.

One such study aims to develop 'off-the shelf' or 'universal' CAR-T cells from healthy donors using CRISPR/Cas9 technology with specific modifications in MHC genes. Concurrently, the project focused on designing and engineering "Inducible CARs" to mitigate cytokine release syndrome, a common adverse event associated with CAR-T cell therapy. Two constructs were designed, incorporating advanced features such as syn-NOTCH domains for context-specific activation and dual-plasmid systems enabling tight regulation of IL-6 secretion. T cells were efficiently isolated using CD4 and CD8 magnetic beads, and a mCherry-luciferase expressing Raji reporter cell line was developed to evaluate the efficacy of CAR-T cells

IL-15 Cytokine for cancer immunotherapy: Another promising lead is a Chimeric Interleukin-15 (IL-15) developed using tools of genetic engineering. IL-15 is a cytokine which is a multifunctional cytokine that targets many cell types and connects the innate with the adaptive immune system. Globally, among the cytokines, IL-15 has been identified as a top candidate for cancer immunotherapy. However, the



major limitations in developing IL-15 as a therapeutic agent are its short-half life and poor bioavailability. To overcome these limitations, stable chimeric IL-15 (IL-15 coupled to IgG2 constant heavy chain) was developed with an increased half-life of 40 hours. Despite the development of a stable chimeric IL-15 with extended half-life and bioactivity, its full therapeutic potential remains to be explored. Current studies are in progress to elucidate 3D structure to investigate its role in combination therapy with checkpoint inhibitors for tumor regression and relapse prevention, as well as its potential as an adjuvant for formation of memory T and B cells. An Indian patent has been granted in 2024.

In 2024–25, DBT advanced several innovative cancer immunotherapy projects, including dual CAR-T cells, NK cell-based therapies, IL-15–enhanced CAR-T, oncolytic viruses, and RNA therapeutics. It also initiated Virtual Network Centres focused on off-the-shelf and inducible CAR-T platforms, glioblastoma-targeted T-cell therapies using non-genetically engineered MSCs, and a dedicated Cancer Immunotherapy Network to design affordable, indigenous cell-based therapies for Indian patients.

Key challenges

Despite the growing momentum, India faces several critical challenges that must be addressed to achieve commercial-scale readiness in immunotherapy manufacturing.

"One of the foremost barriers is the high capital investment required to establish GMP-compliant facilities. While biotech hubs such as Hyderabad and Bengaluru are witnessing infrastructure growth, India still lags behind the scale and technological sophistication seen in the U.S., EU, and increasingly, China. The financial burden of setting up advanced manufacturing units—including infrastructure, equipment, and quality systems—is particularly daunting for startups and small-to-medium enterprises (SMEs), which often struggle to secure funding due to long return-on-investment cycles and limited access to biotech-focused venture capital," said Shalini.

Another significant constraint is the limited domestic availability of critical raw materials and enabling technologies. The production of immunotherapies relies heavily on imported reagents, viral vectors, and cell lines, making the supply chain both fragile and costly. The absence of a robust local ecosystem for these components creates bottlenecks that hinder scalability and responsiveness.

"Regulatory complexity further compounds these

India's Leading Immunology Firms

ImmunoACT (Mumbai)
- **Focus:** Academic spin-off (IIT Bombay); CAR-T platforms for B-cell malignancies and multiple myeloma.
- **Notable:** Developed NexCAR19, India's first indigenously developed CAR-T product.

Immuneel Therapeutics (Bengaluru)
- **Focus:** CAR-T cell therapies (e.g., Qartemi for B-NHL)
- **Notable:** First Indian company to launch a commercial CD19-directed CAR-T therapy

Laurus Labs (Hyderabad)
- **Focus:** In-licensing of gene therapy platforms, expansion into immuno-oncology.
- **Notable:** Partnered with IIT Kanpur to develop gene therapies.

NKure Therapeutics (Bengaluru)
- **Focus:** Off-the-shelf NK cell-based immunotherapies, allogeneic CAR-T therapies
- **Notable:** Partnered with CRISPR Therapeutics to co-develop and co-commercialise CTX112, an allogeneic CAR-T therapy, in India

Cellogen Therapeutics (Delhi)
- **Focus:** Advanced CAR-T platforms, including bi-specific 3rd generation constructs.
- **Notable:** Secured a patent for India's first bi-specific 3rd-gen CAR-T cells.

challenges. Navigating approvals from multiple agencies such as the Central Drugs Standard Control Organisation (CDSCO), DBT, and the Indian Council of Medical Research (ICMR) can be time-consuming and lacks harmonisation. While efforts are underway to streamline biologics approval pathways, India's regulatory framework is still evolving. In contrast, regulatory bodies in the U.S. and EU benefit from decades of experience and integrated innovation ecosystems that facilitate faster approvals and clearer guidance for novel therapies like CAR-T and gene editing," said Shalini.

The skill gaps in specialised areas also poses a barrier. Although India has a strong foundation in bioprocessing and engineering, expertise in niche domains such as viral vector production, gene editing, and advanced analytics remains limited. Industry-academia collaboration for hands-on training and workforce development is still in its early stages and needs significant scaling.

"Logistical challenges, particularly in cold chain and last-mile delivery, remain a concern. Immunotherapies require stringent temperature control, which is difficult to maintain in rural and remote regions. Fragmented logistics networks and the lack of real-time monitoring systems increase the risk of compromising product integrity during transport," said Shalini.

She further added, "The innovation ecosystem remains fragmented. Many startups and academic labs lack access to pilot-scale facilities and structured tech transfer mechanisms. This disconnect between lab-scale innovation and commercial production delays the time-to-market for promising therapies."

Capitalising on opportunities

India is rapidly laying the groundwork to become a major player in global immunotherapy manufacturing. Building on its established strengths in generics and vaccines, the country is now making strategic moves into the more complex arena of biologics and cell therapies. This transition brings both challenges and significant opportunities.

One example is the cost of CAR-T therapy. While globally the treatment can cost upwards of Rs 2–3 crore per patient, India's indigenously developed alternatives are being offered at a much lower price point—from Rs 25 to Rs 50 lakh.

"To bridge the gap between research and commercialisation, the Government of India, through the DBT, has launched the BioRIDE initiative. This includes the development of Biofoundries, Bio-AI Hubs, and Biomanufacturing Hubs - shared platforms designed to accelerate innovation and scale-up," said Shalini.

Biopharmaceutical clusters are emerging in cities like Hyderabad, Bengaluru, and Pune, with Hyderabad's Genome Valley becoming a focal point for biologics and cell therapy infrastructure. Across the country, GMP-compliant facilities are being established to support the production of biologics and cell-based therapies at scale. At the same time, India has significantly upgraded its cold chain logistics to support the transport of temperature-sensitive immunotherapies, although last-mile delivery in rural and tier-2/3 cities remains a logistical hurdle.

"India's scientific ecosystem is also evolving to support the full lifecycle of immunotherapy development. Leading research institutions are actively engaged in immunotherapy R&D, and the country has hosted clinical trials for CAR-T therapies and monoclonal antibodies, including homegrown innovations. A major milestone was the approval of NexCAR19, India's first indigenous CAR-T therapy, which marked a leap in local manufacturing capabilities. The country is also nurturing a growing talent pool in bioprocessing, cell culture, and downstream processing, though there remains a need for specialised training in areas like viral vector manufacturing and gene editing," said Shalini.

Public–private partnerships are playing a catalytic role in this transformation. Initiatives like BioNEST and BIRAC are supporting biotech startups with infrastructure, mentorship, and funding. The National Biopharma Mission, co-funded by the World Bank and DBT, is driving the development of biopharmaceuticals through support for translational research and manufacturing scale-up.

"Academic collaborations with institutions such as IIT Bombay, IISc, and Tata Memorial Centre are further accelerating the co-development of CAR-T therapies and novel delivery systems. Additionally, the Production-Linked Incentive (PLI) scheme is incentivising investment in high-end biomanufacturing infrastructure, reinforcing India's position as a rising global player in immunotherapy," said Shalini.

"While full commercial-scale readiness is still evolving, the foundation being built today signals a future where India plays a central role in the global immunotherapy ecosystem," signs off Shalini.

India is progressively building the foundation to establish itself as a global center for cost-effective and scalable immunotherapy solutions. With strategic investments, regulatory reforms, and a growing talent base, the country is poised to transform not only its own healthcare landscape but also contribute significantly to global health equity. BS

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How Immune Cell and Gene Therapies are Transforming Treatment in India

Immune cell and gene therapies are redefining treatment for cancer, genetic disorders, and autoimmune diseases in India. Once considered the realm of science fiction, these living medicines are now at the forefront of clinical care, offering hope for previously untreatable or poorly managed conditions.

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Sudeep Krishna,
Co-Founder & President,
Healthark Insights

Immuno-gene therapies represent a transformative frontier, combining genetic engineering with the body's natural defenses to treat complex diseases like cancer and genetic disorders. Immuno-cell therapy boosts immune response by collecting, activating, and expanding a patient's own immune cells outside the body, then reinfusing them to better target abnormal cells.

CAR-T cell therapy, one of the most advanced forms, modifies T cells with Chimeric Antigen Receptors (CAR) to identify and destroy cancer cells. In India, this segment is projected to grow from $710.9 million in 2024 to $2.5 billion by 2033, at a 15.1 per cent CAGR. CAR-NK therapy, another form, uses modified Natural Killer (NK) cells - either autologous or donor-derived - to target tumors, potentially offering safer and more effective outcomes.

In parallel, Gene Therapy modifies or replaces defective genes to treat cancer, inherited disorders, and chronic conditions. It includes Somatic gene therapy, which targets non-reproductive cells and affects only the treated person, and can be delivered ex-vivo (outside the body, then reinfused) or in-vivo (directly inside the body). Germline gene therapy alters reproductive cells or embryos, resulting in heritable genetic changes.

Immune cell and gene therapies increasingly intersect, with engineered immune cells like in CAR-T therapy offering better disease targeting and response durability. This convergence is advancing personalized medicine and unlocking new options for conditions once deemed untreatable.

Competitive Landscape in India

India's cell and gene therapy ecosystem is expanding, with both established players and emerging innovators:

Company/ Organisation	Notable Products/ Technologies	Indications/ Focus Areas
ImmunoACT	NexCAR19 (CAR-T therapy)	Blood cancers
Immuneel Therapeutics	Qartemi (CAR-T therapy)	Lymphoma
CyGenica	GEENIE platform (Gene therapy – non-viral protein-based gene delivery)	Glioblastoma Multiforme
Stempeutics Research	Stempeucel (Cell therapy)	Critical Limb Ischemia (CLI) & Knee Osteoarthritis (OA)
Reliance Life Sciences	CardioRel (Cell therapy)	Cardiac disorders
Dr. Reddy's Laboratories	Ribrecabtagene autoleucel (DRL-1801) (CAR-T therapy)	Multiple Myeloma
Cellogen Therapeutics	Bi-Specific 3rd Generation CAR-T cell therapy (CAR-T therapy)	Blood Cancers

India's first homegrown CAR-T therapy, developed by IIT Bombay and Tata Memorial Hospital, was approved in October 2023, marking a major milestone.

Strategic Partnerships and Collaborations

Recent collaborations are accelerating India's cell and gene therapy landscape:

1. Bharat Biotech & University of Wisconsin: Bharat Biotech launched India's first

dedicated cell and gene therapy facility at Genome Valley, Hyderabad, expanding its expertise beyond vaccines into regenerative and personalised medicine. The company is collaborating with University of Wisconsin to develop next-generation CAR therapies using AI

2. PM-STIAC Initiative: The Prime Minister's Science, Technology & Innovation Advisory Council (PM-STIAC) is driving government-industry partnerships to accelerate cell and gene therapy commercialisation, focusing on rare diseases and cancer treatments

3. NexCAR19 Launch: Hinduja Hospital, Khar, partnered with ImmunoACT to bring NexCAR19 (Actalycabtagene autoleucel)- India's first homegrown CAR-T cell therapy to cancer patients in Mumbai

4. NKure Therapeutics and CRISPR Therapeutics: Co-develop CTX112, an allogeneic (donor-derived) CAR-T therapy targeting CD19-positive B-cell cancers. Unlike traditional CAR-T, CTX112 uses CRISPR gene editing to create an off-the-shelf solution with faster turnaround and lower cost

5. Miltenyi Biotec and Translational Health Science and Technology Institute (THSTI): The partnership aims to boost R&D, technology transfer, training, and capacity building to make CGT more accessible and affordable in India

6. Caring Cross and ImmunoACT: This partnership aims to develop and commercialise TriCAR-T cell therapy in India for leukemia and lymphoma. Unlike conventional CAR-T therapies that target a single antigen, TriCAR-T targets multiple tumor antigens, reducing the risk of relapse due to antigen escape

7. Qartemi CAR-T Launch Milestone: Immuneel Therapeutics launched Qartemi, India's first globally benchmarked CAR-T therapy for B-cell Non-Hodgkin Lymphoma, developed in collaboration with Hospital Clínic de Barcelona. With strong clinical results and lower pricing, it marks a major step in making advanced cancer therapies more accessible in India

Recent Advancements in India

India is making strides in gene therapy and cell-based treatments:

1. CAR-T Therapy for Solid Tumors: Indian researchers presented evidence of CAR-T therapy effectiveness against gastric and brain tumors at the American Society of Clinical Oncology (ASCO) 2025 conference, highlighting India's growing expertise in solid tumor immunotherapy

2. Nagpur's First CAR-T Therapy Center: A private hospital in Nagpur successfully performed CAR-T therapy for blood cancer patients, marking a major leap in regional cancer care

3. Hemophilia-A Gene Therapy Trial: A lentiviral-transduced autologous gene therapy trial in Tamil Nadu has demonstrated restoration of Factor VIII production, offering hope for hemophilia patients

4. NexCAR19 Clinical Results: The IIT Bombay–Tata Memorial–ImmunoACT collaboration reported showed a 73 per cent response rate in leukemia and lymphoma patients, demonstrating strong clinical efficacy

5. Bharat Biotech CGT Facility Milestone: Bharat Biotech inaugurated a $75 million state-of-the-art Cell and Gene Therapy facility in Hyderabad's Genome Valley, focused on producing viral vectors (AAV, lentivirus, adenovirus) essential for cell and gene therapies

6. Cellogen Bi-Specific CAR-T Milestone: Cellogen Therapeutics, a Delhi-based biotech startup, secured a patent for India's first indigenously developed bi-specific 3rd generation CAR-T cell therapy. Unlike conventional CAR-T therapies that target a single antigen, Cellogen's platform targets two tumor-specific antigens simultaneously

Cost and Reimbursement Landscape

In India, CAR-T therapy (such as NexCAR19) is available at approximately Rs 50 lakh (about $60,000) including hospital fees. This pricing is more than 80 per cent lower than the $500,000–$700,000 range in countries like the United States, and substantially lower compared to options available in Europe and China.

However, the Government of India is taking gradual steps toward reducing the financial burden. Recent press releases and governmental factsheets indicate that pilot schemes under Ayushman Bharat are being considered to eventually cover high-cost procedures - including therapies like CAR-T for conditions such as relapsed leukemia.

Gene therapy costs in India vary, with pricing models evolving to include outcomes-based reimbursement and staged payments. The Indian government is exploring financial assistance programmes to improve affordability.

Conclusion

India's cell and gene therapy sector is rapidly evolving, driven by academic research, biotech innovation, and government support. With affordable CAR-T therapy, expanding gene therapy trials, and cutting-edge advancements, India is poised to become a global hub for immuno-cell and gene therapy. BS

India-Japan Synergies in CAR-T and ADCs

Cancer remains the leading cause of death globally. As per the World Health Organisation (WHO), there were approximately 9.7 million deaths from cancer in 2022, and around 20 million cancer cases were reported. It is estimated that by 2050, global cancer cases will be around 50 million globally. The rising incidence of cancer has led to a growing focus on individualised and targeted care.

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Frost & Sullivan

Immunotherapies like CAR-T therapy and antibody-drug conjugates (ADCs) have demonstrated strong clinical efficacy in oncology and continue to be widely adopted within precision medicine practices. The FDA has approved 17 ADCs and 7 CAR-Ts to date. Despite emerging as the most effective therapies for cancer treatment, the broader adoption of CAR-T is hampered by complex manufacturing processes and financial burdens.

The cost of CAR-T globally ranges from $373,000 to $475,000. While Indian CAR-T treatments cost around Rs 30-50 lakh, it is still not accessible to most patients as they are not covered by insurance. Other than affordability, the lack of rural healthcare facilities offering infusion set-ups for CAR-T limits its adoption in India. Thus, there is a need to make CAR-T more accessible.

India ranks second globally in cancer-related mortality and third globally in cancer incidence. As cell and gene therapies (CGTs) can provide improved cancer care, there is a need to establish affordable manufacturing centres for CGTs. Asian nations like Japan and India can capitalise on this opportunity by creating new manufacturing hubs for CGTs. India needs to focus more on developing its own IP to support developments in CAR-T and ADCs and lead the biopharma industry, particularly CAR constructs for Indian cancers (oral, gallbladder, and stomach).

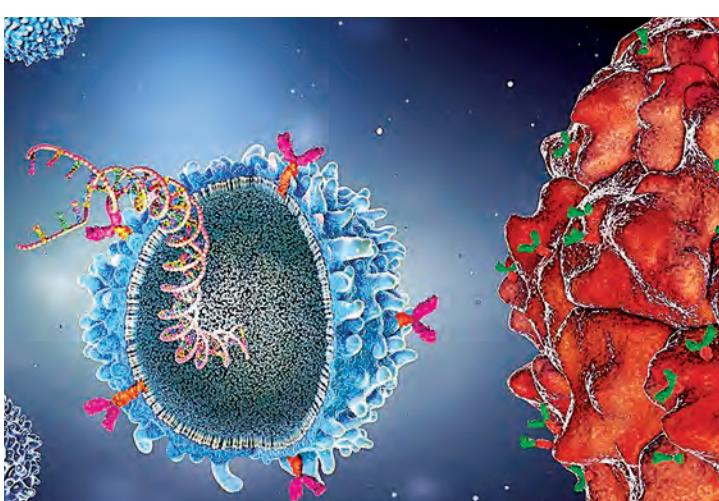
India also needs to focus on innovative technologies like manufacturing cost-effective viral vectors, non-viral delivery methods, smart linker-payload design, AI-driven target discovery, simulated cytotoxicity, and CRISPR-based editing for next-gen CAR. Growth in the biopharma sector will allow India to emerge as a global innovation hub, save lives, and establish strategic independence in next-generation therapies.

India's Emergence

NexCAR19, India's first manufactured CAR-T, was approved in 2023. It was developed by ImmunoACT in collaboration with IIT Bombay and Tata Memorial Centre. NexCAR19 showed a 70 per cent overall response rate, a notable halt in the spread of the cancer, manageable toxicity, and cost around Rs 30-40 lakh, which is one-tenth of the cost of other approved CAR-T therapies.

Cellogen Therapeutics, established in 2021, is developing bi-specific, 3rd and 4th generation CAR T-cell therapies, in line with the latest innovations happening in the field. The CAR-T would be able to target CD19 and CD20 simultaneously, preventing the risk of antigen-escape mediated relapses.

In January 2025, the Central Drugs Standard Control Organisation (CDSCO) authorised Imuneel Therapeutics' Qartemi, a CD19-targeted CAR T-cell therapy, for adult patients with relapsed or refractory B-cell non-Hodgkin's lymphoma. This approval represents a breakthrough in the country's cancer treatment landscape. This Indian CAR-T is expected



to be priced at about $60,000. This would provide an affordable solution to the growing number of cancer patients in India.

Aurigene Oncology is developing India's first novel autologous BCMA-directed CAR-T cell therapy for patients with relapsed / refractory multiple myeloma. Aurigene's BCMA-targeted CAR-T trial is a major advancement in Indian biotechnology and shows the innovative spirit of the country. In early studies, it was shown that 100 per cent of patients achieved a clinical response and a stringent complete response was achieved in 62.5 per cent of patients. Its Phase 2 approval by the Drugs Controller General of India (DCGI) demonstrates the expanding scientific legitimacy and governmental backing for transforming cancer therapies in India.

Enhancing global reach

India is also making strides in the Antibody-drug Conjugates (ADCs) space with companies like Sun Pharma, Biocon exploring ADC development. With an IND application submitted to the US FDA, Sun Pharma's first ADC, SBO-154, which targets MUC1-SEA in advanced solid tumours, will soon initiate its Phase 1 testing. Biocon is investigating ADCs through international collaborations as well. Although their development stages lag behind those of their international counterparts, which are exploring specific antigens like FRα and CD37, Indian companies' efforts demonstrate their expanding oncology capabilities.

The Contract Development and Manufacturing Organisation (CDMOs) are playing an important role in strengthening India's position in ADCs landscape. CDMOs like Piramal Life Sciences, Aurigene Pharmaceutical Services, Suven Pharmaceuticals are providing ADCs development and manufacturing services.

Indo-Japan Collaborations

Japan has a comparatively strong ground in the ADC and CAR-T space. Japan's Daiichi Sankyo's ADC drug, Enhertu, for treating HER2-positive cancers is one of the leading approved ADC drugs. Daiichi Sankyo has a strong ADC pipeline with 7 ADCs in the pipeline and 2 ADC platforms in clinical development. Takeda is also developing CAR-T TAK-007 for multiple myeloma, which is in clinical phase 2 studies. With these active developments, Japan is positioning itself in the global CAR-T and ADCs landscape. There is an opportunity for India to collaborate with Japan through the existing partnership between Japan Science and Technology Agency (JST) and Department of Science and Technology (DST) to take advantage of Japan's expertise in CAR-T and ADC technologies.

Harmonising Regulatory Policies

At the 6th Asia Partnership Conference on Regenerative Medicine, 2023, both countries discussed regulatory harmonisation in CAR-T cell therapies, with a focus on biodistribution and safety assessment. This is a step towards standardised regulatory frameworks.

In 2024, the 7th India-Japan Medical Product Regulatory Symposium organised by CDSCO and the Pharmaceuticals and Medical Devices Agency (PMDA), continued the regulatory cooperation under the 2015 Memorandum of Cooperation. The symposium was attended by key leaders from the pharmaceutical, medical device, and biologics-biosimilars industries. Discussions focused on the harmonisation of regulations between the two countries. This represents a step forward for promoting developments in CAR-T and ADCs.

The Way Forward

India is gaining attention as an emerging economic developer of CAR-T therapies and a provider of top-level contract development services for ADCs. With approvals of CAR-Ts like Qartemi and NexCAR19 catering to the needs of the Indian population, India is in a strong position to become a prominent global player in the immunotherapy landscape, supported by a solid foundation of startups, clinical trials, and regulatory initiatives.

The partnership between India and Japan will boost innovations and speed up the development in the immunotherapy space and expand healthcare access across Asia. There is a need for more structured India-Japan collaboration, such as co-development research and development partnerships, consortia for translational research, and academia-company partnerships across nations. This collaborative environment will unlock the significant innovation potential in the CAR-T and ADC landscape.

Both nations will benefit by combining their expertise in technological know-how, R&D capabilities and cost-effective development frameworks. India has the potential to transform itself from just an "affordable manufacturer " to a "global innovator".

India needs to engage more actively in commercial and research partnerships with countries making significant progress in this space, such as the US, Europe, and Japan and promote academic-industry-government consortia to accelerate translational research. BS

Indian Pharma Exporters Recalibrate Strategies Amid US Drug Price Cuts

US President Donald Trump's recent announcement to cut the cost of prescription drugs has jolted Indian and APAC manufacturers. While this new development comes a few months after the initial pharma tariff move, Indian pharmaceutical companies aren't left with much choice except to strategise their next steps pragmatically. Here we seek some clarity about what stance the Indian manufactures might take to counter such economic bullying tactics of countries like the United States.

The Trump administration is at it again and after the pharma tariff saga, the US President has signed a wide-reaching executive order (EO) on May 12. The EO directs drugmakers to lower the prices of medicines to align with what other countries pay. The price cut range may be from 30 to 80 per cent. Drugmakers are required to make the price changes within a month from the date of issuance of the order, failing which, punitive action would be taken. This is all part of the so-called Most Favoured Nation (MFN) pricing framework by the US that has set alarm bells ringing. The US pays the highest prices for prescription drugs, sometimes nearly three times more than other developed nations.

Impact if any?

India's pharmaceutical export to the US is around $9 billion contributing to about 40 per cent of the US generic market. It may be noted that the policy was initially floated during Trump's first presidency but was blocked by numerous legal challenges. Big Pharma's contention is that drug discovery research is very expensive and risky and takes about $2 billion to discover a new molecule, in which the US is the world leader.

Talking about the 30-day deadline announced that seems to be a short notice, ***Ravi Shah, Partner, Cyril Amarchand Mangaldas,*** stated, "The 30-day deadline places significant pressure on global pharmaceutical supply chains, but for most Indian generic drugmakers, the immediate operational impact is likely to be limited since the order is primarily aimed at branded medicines. However, the constantly evolving position of the US government underscores the need for Indian companies to remain agile and closely monitor the US regulatory and trade policy changes to be able to suitably adapt its strategy for the US market."

Sharing his views ***Dr Ajit Dangi, President and CEO, Danssen Consulting,*** observed, "While it is difficult to assess the full impact of this policy, since Indian generics are already priced competitively compared to prescription drugs, this EO is unlikely to have a major impact on Indian generic drugs exporters. However, Indian companies who have significant US exports like Sun, Dr. Reddys, Cipla, Lupin, among others, may need to recalibrate their export strategies. Apart from pricing, Indian pharmaceutical companies are also likely to face tariff increase and therefore need to explore possibilities of putting up manufacturing facilities in the US or acquire small generic companies or have a tie up there. Non-tariff barriers like stricter cGMP compliance by US FDA, already flagged by Trump, is likely to be another challenge, increasing the cost of manufacturing. To guard their export revenues, Indian companies will have to cast their net wider and explore markets other than the US."

Shedding more light on the impact of the policy, ***Chakravarthi AVPS, Senior Vice President (National) and Chairman of AP and Telangana, Federation of Pharma Entrepreneurs (FOPE)*** clarified, "The policy seems to target expensive branded drugs more than generics, and our low-cost

production gives us an edge. Plus, legal fights and delays, like what happened in 2020, could push the real effects to 2026 or later. I see some companies trying to set up factories in the US to avoid possible tariffs, but that's super expensive—hundreds of crores—so it's not easy. In the long run, I believe leaning on government programmes, like those pushing local raw material production, will keep us competitive. Indian generic makers will face tougher times and need to adapt, but they're in a better spot than US companies selling pricier drugs. Smaller firms might struggle, though. We should watch for updates on US rules and any tariff talks to know what's next."

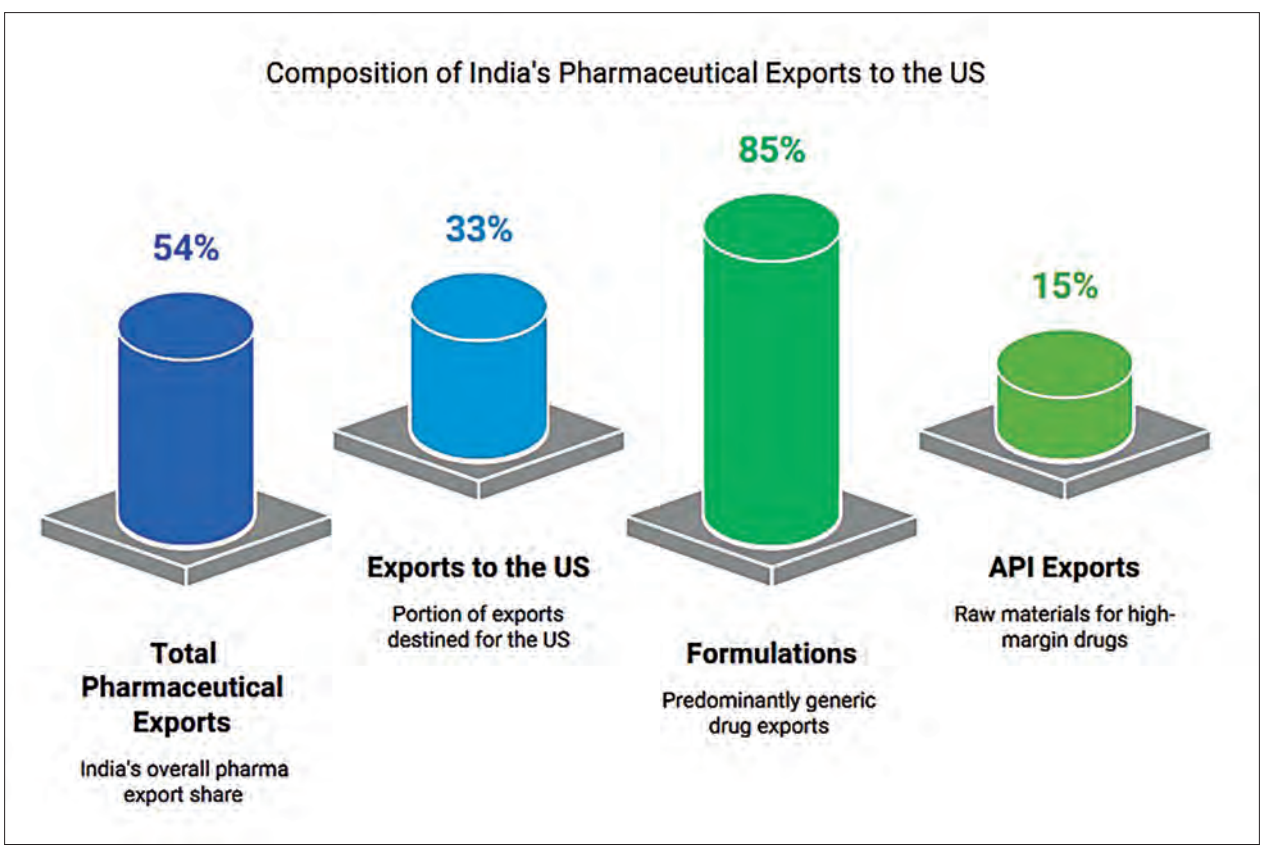
Kiran Mazumdar Shaw, Chairperson, Biocon Group said, "I believe this order does not target generics and biosimilars, which already provide affordable alternatives under the Affordable Care Act (ACA). It also does not aim to equalise drug prices with developing economies. The Indian pharmaceutical industry, particularly in the generics and biosimilars sector, is well-positioned to support this shift with its proven capabilities in cost-efficient, high-quality manufacturing. This executive order therefore strengthens the greater adoption of generics and biosimilars."

Time for clarity and recalibration

Donald Trump's announcement is not the first price reform and probably will not be the last. Indian and APAC pharma companies need a shift from being price warriors to becoming innovation-led, quality-focussed, globally responsive organisations. Trump's MFN policy directly targets pricey branded medicines, but its impact on generics cannot be overlooked. Reduced benchmark prices in the OECD nations will apply global pricing pressure on suppliers, reducing margins, and in turn cause reimbursement bottlenecks in the future.

Indian pharma companies are primarily involved in generic drugs which are very low in prices, than the prescription drugs cost and already over 80 per cent cheaper for insurance payors. From antiretrovirals for HIV to affordable cancer therapies, India's pharmaceutical industry is vital to global health.

Expressing his views ***Ranjit Barshikar, CEO – QbD International, United Nations Advisor, Member of Editorial Board of Journal of Generic Medicine UK*** said, "While the global pharma giants are surprised by the price cut executive order, Indian industry voices suggest that domestic



drugmakers are unlikely to be affected. The generics industry is not likely to be impacted, as it operates on very low margins already. The President's order stresses on the cost of innovation / R&D should be shared equitably among all stakeholders and with a 30-day window to align their US prices with MFN pricing, giant companies are expected to be affected. India's generic drug industry, which is not only a source of low-cost medicines in India but also in the US and UK."

Hyderabad-based HRV Global Life Sciences has invested in a virtual manufacturing model that brings flexibility, cost-efficiency, and rapid regulatory adaptability. The convergence of AI, predictive inventory tools, and federated compliance intelligence is what the company expects to help win in a margin-sensitive world.

Hari Kiran Chereddi, Managing Director, HRV Global Life Sciences and CEO, New Horizon Global Pharma mentioned, "Instead of panicking, I believe the time is for clarity—and for recalibration. We must map a structural shift towards volume-based approaches to value-based models. This is an urgent invitation to diversify. We have already begun increasing our presence in geographies beyond the US—namely the EU, LATAM, MENA, and Southeast Asia. The MFN pricing shock affirms that a globally diversified portfolio is no longer optional; it is strategic insurance. If US Big Pharma is forced to scale back on marginal therapies, Indian and APAC firms can become global go-to partners for value-priced substitutes. The cost advantage that sets our positioning can now be focused on building trusted therapeutic relationships."

Umang Vora, MD and Global CEO, Cipla while announcing the financial results recently mentioned that the US government's order to pharma firms to lower the cost of prescription medicines within 30 days will not impact Indian generic drugmakers. The EO is probably going to impact branded drugs. Vora said, "What we understand is that this is largely targeted towards branded drugs. As of now, what we understand is that this is a voluntary measure that perhaps the companies will be taking. There are aspects of MFN clauses etc and it is not clear as of now how and in which manner the EO will be implemented."

MFN model unlikely to significantly affect bulk of India's pharma exports: Crisil

Crisil Ratings has undertaken a study of its rated pharmaceutical portfolio comprising 190 companies and accounting for ~53 per cent of overall Indian pharma industry revenues of Rs 4.5 trillion estimated for fiscal 2025.

India exports ~54 per cent of its pharmaceutical production, of which nearly a third is to the US. Around 85 per cent of the exports to the US comprises formulations, largely generics while sales from biosimilars and innovator drugs remains low. Generics account for ~90 per cent of the prescription volume sales but only ~13 per cent of the value spending in the US as generic prices in the US are very low and are already below their economic peer countries.

Consequently, the Most Favoured Nation (MFN) model is unlikely to significantly affect the bulk of India's exports. However, the potential indirect impact, through lower growth prospects for upcoming generic versions of innovator drugs going off patent, due to lower price differential post price reductions of the innovator drugs, would bear watching.

A few formulation companies with niche presence in the branded innovator drug segment can face some pricing risk, though the share of these drugs in their overall revenue mix is limited at present (~10 per cent). The impact will also depend on the final pricing and the proportion to be absorbed across the value chain.

Crisil further mentions that the potential business impact of the MFN model is expected to be limited on Indian pharma players and the balance sheet strength of these companies is expected to support their credit profiles. If the MFN pricing model is enacted into law and takes effect, there are several monitorables, including the determination of the drug list, the extent to which pricing cuts are to be absorbed across the value chain, and the timelines to be adhered to.

Nilesh Patel, Managing Director, Kashmik Formulation opined, "The downward trend in Indian pharmaceutical stocks is more sentiment-driven than a reflection of long-term industry fundamentals. The branded drugs represent a different segment than the generic pharmaceuticals exported by India. As a result, the immediate impact on the Indian generic drug segment is limited. Trump also mentioned implementing a MFN policy, but the specifics of this policy remain unclear. Without concrete guidelines, the broader implications for foreign drug manufacturers, including those from India, are speculative. Indian-manufactured medicines constitute only about 11 per cent of the total US pharmaceutical market. Hence, even if price reforms are implemented, the overall impact on the Indian pharmaceutical industry is expected to be moderate in the short to medium term."

A multi-pronged strategy

Indian companies will have to move up the value chain and work on complex generics and biosimilars where price erosion after patent expiry is minimal. In fact, India should capitalise on drugs like GLP -1 receptor agonist, a current block buster weight loss drug, which is aggressively priced in the US, and whose patent in India is likely to expire in 2026. A multi-pronged strategy is the only answer to face this challenge.

Not just relying on cheap labours, a proper implementation of technology should be in place. This will help to reduce cost significantly in the long run and improve the quality of medicine and in an environment-friendly way. Focus on value and not volume and investing on value-based products, innovations will help Indian pharma companies bypass these threats. Or it will make the pharma industry difficult to survive.

Dr Ranjan Chakrabarti, Advisor-Drug Discovery and Biopharma, Ex VP-Drug Discovery, Dr. Reddy's Laboratories and US Pharmacopeia is of the opinion that this move should be considered as an opportunity to produce quality medicines and also expand home grown capabilities. "Top Indian pharma companies have their manufacturing units in the US, they can exploit this provision. Most of our SE Asian neighbours are already ahead of us in this aspect. Pharma companies should always be prepared for audit, i.e., their quality system should be developed enough to face audit any time. There is a need to fast-track US-based manufacturing through streamlined permitting and technical assistance", remarked Dr Chakrabarti. "Also, unannounced foreign inspections can be eliminated where it will benefit more than 600+ Indian facilities exporting to America. This will ensure production of better-quality medicine, which is a problem in many of our SMEs", he added.

Dr Chakrabarti recommended detailed reporting of ingredient origins with potential cross-contamination penalties. According to him, it will boost the effort to produce an API inside India. The Government of India has certain specific plans to bring back API production to India and the industry with the government can work together to speed up the implementation.

What lies ahead?

Any form of threat perception resulting in panic is nothing new from a country like the US. Post the tariff announcement by the Trump administration, within a month came the executive order to slash the price of prescription drugs. And more such EO's must be waiting in line to be announced.

Economist Intelligence Unit, the research and analysis division of the Economist Group, differs, wherein it maintains that Donald Trump's move to improve price transparency has already helped to cut prices. Whether the EO will be effective enough to cut prices depends on negotiating acts. Drug imports have drastically risen due to stockpiling of prescription drugs with long shelf lives. Though there are mentions of high investment plans, no mention was made about Indian pharma companies.

It is best to wait, watch and take proactive strategic steps to ensure that India pharma does not succumb to any pressure or economic arm twisting. BS

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Can Indian Companies Compete with MNCs in GLP-1 Production?

With the patents for blockbuster diabetes and obesity drugs, particularly Semaglutide set to expire in India in March 2026, it is expected to trigger a major shift in the market. Indian pharmaceutical companies will be able to launch generic versions of these high-demand GLP-1 receptor agonist drugs. This is a pivotal moment in the offering that will democratise access to expensive therapies that has been till now dominated by multinational companies.

The patent war can become uglier at times and the pharma industry is no exception to this. Indian and MNC pharma companies are at loggerheads when it comes to global patent disputes. That Indians get affordable and accessible medicines is what the Government of India prioritises. However, MNC pharma companies want to dominate the market armed with patents.

The global pharmaceutical industry is bracing itself for the upcoming patent cliff which is touted to put an estimated $236 billion in drug sales in jeopardy for the innovator companies. Between 2025 and 2030, the patents on a number of blockbuster drugs spanning therapeutic areas including diabetes, cardiovascular, oncology immunology, and ophthalmology are set to expire, thereby opening up the market for generic and biosimilar manufacturers.

While patent cliffs by themselves are not unprecedented, they have previously involved relatively simple chemical entities. By contrast, the current wave of expiries includes several biologics, structurally complex small molecules, and drugs which require novel delivery systems.

India's patent history

India supplying 20 per cent of the world's generics and exporting to over 200 countries is being supported by the current patent regime. It has ensured access to affordable medicines for diseases like cancer, TB and HIV AIDs. Also, pharma companies have been able to invest more on R&D. The Patents Act of 1970 initially only allowed process patents for pharmaceuticals, enabling Indian companies to manufacture generic versions of patented drugs using alternative processes. The Patents (Amendment) Act, 2005, brought India into compliance with the WTO's TRIPS agreement, introducing product patents for pharmaceuticals and strengthening IP protection.

Patent disputes

The patents of many blockbuster diabetes and obesity drugs like Semaglutide will expire from 2026 onwards. Many Indian pharma companies are in the fray to grab the market share that has been dominated by MNC companies for years. Incentives are in place to promote local manufacturing of GLP-1 drugs by 2026. This may lead to more nasty court cases.

The Delhi High Court has issued an interim order restraining Dr. Reddy's Laboratories and OneSource Specialty Pharma from marketing Semaglutide, the active ingredient in Novo Nordisk's weight loss drug Wegovy, in India.This is an ongoing case. The order was passed following a patent infringement suit filed by the Danish pharmaceutical company, which is preparing to launch the blockbuster drug in the Indian market.

In a statement, Novo Nordisk said it is taking active steps to protect its inventions in India. The company added that its Semaglutide patents are protected in the country and that it expects continued support for innovation and intellectual property protection. "This will help stimulate companies' motivation to develop innovative medicines and bring new treatments to patients," it said, adding that it would not comment further on a sub-judice matter.

In another episode, the Delhi High Court rejected Swiss MNC F. Hoffmann-La Roche's petition seeking to restrain Hyderabad-based Natco Pharma from infringing its product patent for Risdiplam compound used for treating spinal muscular atrophy.

In a majority of the cases, the originator is aware of the impending loss of patent and therefore erosion of market share and loss of profit. And remains constantly engaged in research and development much before the loss of patent to have a robust pipeline to be able to introduce follow-on molecules which provide better efficacy, and safety compared to the earlier molecules.

Is this a golden opportunity?

The forthcoming patent expirations of blockbuster GLP-1 receptor agonists present a transformative opportunity for Indian pharma companies. As patents for Semaglutide and Tirzepatide are set to expire

between 2026 and 2027, Indian firms are positioned to capitalise on a rapidly expanding market.

With India's diabetes population projected to reach 212 million and obesity cases at 70 million, the convergence of patent cliff events, government production incentives, and the rising disease burden creates unprecedented market entry opportunities. The Indian GLP-1 market is expected to reach $350 million by 2030, representing a 25 per cent CAGR, while global markets could expand to $156 billion at a 30 per cent CAGR.

Piyali Chatterjee Konar, Executive Vice President, Head – CX/UX/B2B, Hansa Research Group mentions, "India can capitalise on this opportunity through big Indian pharma giants like Biocon, Sun Pharma, Cipla, Dr. Reddy's and Lupin are already preparing to manufacture generic versions of GLP-1 drugs post-patent expiry. Indian pharmaceutical companies have a massive opportunity to disrupt the industry and establish themselves as key players. If they get this right it can be a game changer for Indian pharma business."

Sharing his thoughts on this ***Hari Kiran Chereddi, Managing Director, HRV Global Life Sciences and CEO, New Horizon Global Pharma*** mentions, "GLP-1 analogues such as Semaglutide are India's next chance to dominate complex generics. For this, India must deepen its capabilities in peptide synthesis, submit early-stage DMFs and collaborate with regulators extensively, invest in regulated market-capable CDMO platforms and encourage PPPs to create innovation. Many companies are exploring long-chain peptide intermediates and the GLP-1 ecosystem actively to create a high-trust regulatory map. It is not reverse engineering that is on their mind but rather designing for global scalability and compliance."

Says ***Girdhar Balwani, Director - Cadila Pharmaceuticals and Hypothalamus,*** "It is expected that in the post-patent-expiry environment, we will witness the launch of newer molecules over time from many originator / international research companies. Based on an analysis of the international R&D pipeline, these new products will offer advantages over the earlier products in terms of efficacy and safety. We should expect that these products will be aggressively marketed in India in the future given the size of the Indian market."

Start of leadership test

Domestic players are rapidly enhancing their expertise in biosimilars and peptide-based biologics, bolstering R&D capabilities, expanding production infrastructure, and pursuing strategic collaborations. The approaching patent expirations of blockbuster GLP-1 receptor agonists like Semaglutide provide an unprecedented opportunity for Indian pharmaceutical companies.

Historically, MNCs have dominated these molecules due to patent protections, strong R&D, and brand loyalty. However, as these patents expire, the entry barrier dissolves. Indian pharma, with its established manufacturing base, wide field force, price advantages and vast domestic market, is perfectly positioned to take over the market.

Dr Karishma Atul Shah, Founder and Managing Partner, Pronto Consult, market research firm, says "Patent expiries are not just some events, they are market resets. When exclusivity ends, new players can enter the field, pricing drops, and patient access increases. But not all players benefit equally. Those who act fast, position smartly, and engage doctors meaningfully are the ones who stand to win. This is not just about launching brands it is about launching new brands in new forms for a new healthcare consumer. First-to-market launches are critical. Early brand activation, regulatory readiness, and supply chain alignment will define success. The expiry of patents is not the expiry of opportunity, it is the start of a leadership test for Indian pharma."

Indian firms can leverage their manufacturing scale, regulatory agility, and global supply chain networks to rapidly enter the GLP-1 market post-patent expiry. Strategic alliances, in-licensing deals, and co-development partnerships with global firms can further enhance market reach and innovation. Indian companies can differentiate through affordable GLP-1 formulations, patient support programmes, and localised distribution strategies. Companies that effectively leverage this patent cliff window while addressing affordability and accessibility barriers will not only transform the domestic diabetes and obesity treatment landscape but establish India as a global leader in GLP-1 therapeutic manufacturing and innovation.

A competitive edge

Indian players are not the only ones viewing

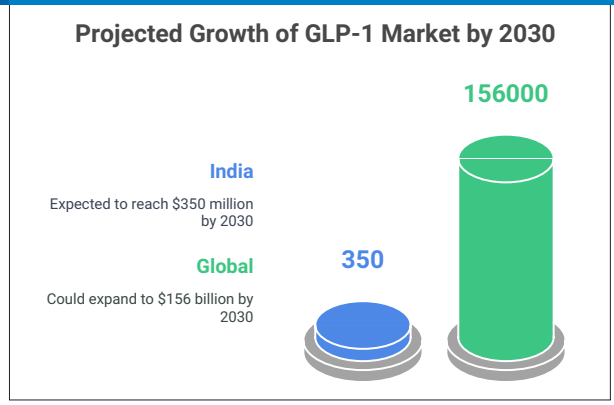
this environment favourably. Innovator companies are also shifting their strategies to leverage this opportunity. Innovators and generic companies are collaborating to launch new products. These strategic collaborations are taking on a diverse range of shapes and forms including out-licensing of brands, contract research and manufacturing services partnerships, co-marketing and co-promotion arrangements, technology transfers to enable domestic manufacturing, and even co-development of the generic drug or biosimilar.

Eshika Phadke – Leader, Pharmaceutical, Lifesciences & Healthcare, Nishith Desai Associates, an innovative law firm opines, "The innovator companies can retain value beyond patent expiry, while Indian companies gain a competitive edge against other generic manufacturers, which becomes especially relevant given the recent quality-related concerns that have emerged about drugs manufactured in India. From a regulatory strategy perspective also, both parties stand to benefit substantially, especially when the manufacturing activities are taking place domestically. Depending on the type of collaboration, these arrangements could potentially result in more streamlined approvals, wider access to government buyers and temporary relief from price control."

Dr Rashmi Chaturvedi Upadhyay, Pharma & Biotech Strategy Consultant, Dialectica, a global B2B information services firm, says, "The convergence of patent expiries for blockbuster GLP-1 drugs, India's substantial disease burden, and supportive government policies creates an unprecedented opportunity for Indian pharmaceutical companies. Companies that effectively leverage this patent cliff window while addressing affordability and accessibility barriers will not only transform the domestic diabetes and obesity treatment landscape but establish India as a global leader in GLP-1 therapeutic manufacturing and innovation. The projected market expansion signifies potential democratisation of life-changing therapies for millions of patients across India and emerging markets globally."

Probable challenges

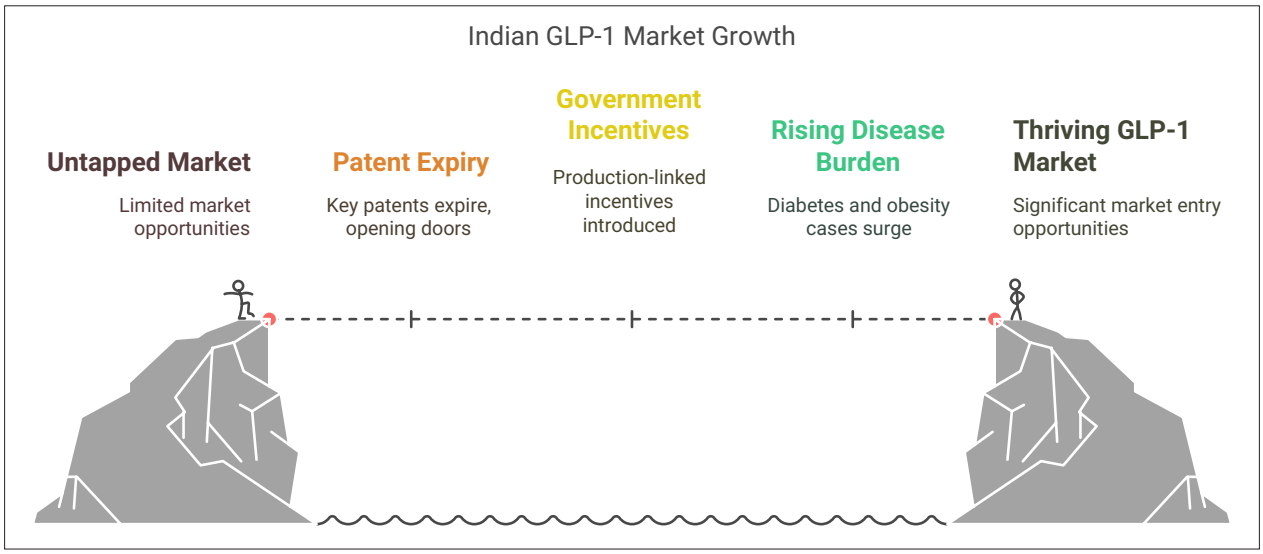
Indian pharma companies need streamlined regulatory frameworks, enhanced clinical trial infrastructure, and supportive financial mechanisms such as government incentives or public-private partnerships to foster innovation and ensure affordable patient access.



Saransh Chaudhary, President, Global Critical Care, Venus Remedies and CEO, Venus Medicine Research Centre (VMRC) says, "Developing GLP-1 receptor agonists at scale involves significant challenges, including high manufacturing costs, limited domestic expertise in complex peptide synthesis, and the necessity of specialised infrastructure to comply with stringent regulatory standards. Additionally, anti-diabetic medications typically require extensive and lengthy clinical trials, significantly raising development costs and risks. Moreover, India's current reimbursement landscape, characterised by low insurance penetration and high out-of-pocket expenses, poses further obstacles to patient access to these advanced therapies.

Munjal Patel, Director, Lincoln Pharmaceuticals is convinced that with the right mix of innovation, investment, and policy support, Indian pharma is capable not just of repeating success in generics but of becoming a hub of excellence in high-quality, affordable metabolic medicines globally. However, he mentions, "GLP-1 drugs are complex peptide-based biologics that require advanced manufacturing capabilities, cold-chain logistics, and strict quality control. The development and scale-up of generics in this segment demand significant R&D investments and regulatory expertise with strict adherence to protocols. Moreover, building trust in global markets will require consistent demonstration of efficacy, safety, and affordability — for which large-scale trials and rigorous testing are essential."

Says ***Vishal Manchanda, Sr VP, President Institutional Research, Systematix Group,*** "The key challenge as of now for companies is to have their



manufacturing/supply chain and regulatory approval in place so that they go full throttle when the market formation begins. While companies have initiated clinical trials and regulatory filings to launch timely, they are yet to garner regulatory approval. Since Semaglutide is a peptide, the regulatory hurdles are likely to be higher and we might not see everyone reach the market on day one. The other core challenge to commercial success is pricing as it would be crucial to create a larger scale acceptance in the market."

Sreekanth Muttineni, President, Formulations Operations, MSN Laboratories, mentions, "Big companies fiercely protect their patents, which include the manufacturing process, methods, and functionalities of their products, by resorting to court battles. Consequently, new products might not be released to the market for an extended period, even after their patents expire. Indian players will face intense pressure from payers demanding ever-lower prices while offering discounts. This pressure could squeeze margins, even with increased volume. To defend market share, MNCs will aggressively employ contracting strategies, introduce next-generation products, and potentially authorise generics."

Agilent Technologies sees a strong and sustained growth trajectory for the GLP-1 drug segment and the broader biopharmaceutical industry. Despite the promising market outlook, scaling R&D and manufacturing for GLP-1 receptor agonists in India presents several complex challenges. Says ***Nandakumar Kalathil, Country General Manager (CGM) - India, Agilent Technologies,*** "These biologics require precise analytical characterisation to ensure structural integrity; rigorous quality control to meet international regulatory standards; scalable manufacturing processes that maintain consistency across batches etc. Indian pharmaceutical companies often face limitations in access to high-end instrumentation, the technical complexity of biologics handling, and the need for rapid scale-up to meet market timelines. These challenges are compounded by evolving regulatory landscapes and the long biosimilar development timelines, especially as key patents for some GLP-1 drugs extend to 2033."

Future

Indian pharma companies have a unique opportunity to disrupt the GLP-1 drug market. If they focus on affordability, innovation, and regulatory approvals, they could emerge as key players in diabetes and obesity treatment worldwide. Indian manufacturers can leverage their cost-effective production capabilities to export GLP-1 drugs globally, particularly to emerging markets with a high prevalence of diabetes and obesity. Incentives for local manufacturing and policy reforms could. This further boosts India's position in the global pharmaceutical industry. Leveraging its proven capabilities in generics, expanding peptide manufacturing expertise, and strategic investments, India can gain a competitive advantage in this dynamic global market. With robust ecosystem support, India can become a formidable player in the global supply of affordable GLP-1 therapies, further solidifying its status as the pharmacy of the world. Exploring ways to overcome patent challenges can be a win-win situation for Indian pharma players. BS

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"There is a huge gap in corporate engagement and government procurement of innovative products within Telangana"

Dr N Madhusudhana Rao, Chief Executive Officer, Atal Incubation Centre (AIC), CSIR-Centre for Cellular and Molecular Biology (CCMB), Hyderabad

According to the world's leading real estate consulting firm, CNRE's latest report, 'Global Life Sciences Atlas', Hyderabad has emerged as a prominent global centre of life sciences manufacturing activity in India. This positions Telangana to play a defining role in shaping the next decade of biotech innovation and entrepreneurship. In alignment with this development, Hyderabad-based Atal Incubation Centre (AIC), hosted in one of the premier research institutes, CSIR-Centre for Cellular and Molecular Biology (CCMB), seeks unique schemes and proposals from the government to strengthen biotech entrepreneurship in the state. Dr N. Madhusudhana Rao, Chief Executive Officer, AIC-CCMB, spoke with BioSpectrum India, highlighting the dynamic growth trajectory of the biotech innovation ecosystem in Telangana. ***Edited excerpts:***

How is AIC-CCMB contributing towards strengthening Telangana's position as a life sciences innovation hub of India? What are the challenges that lie ahead in this direction, particularly for the startups?

AIC-CCMB in the past several years has been standing top of the list of life science incubators locally and nationally by joining hands with larger stakeholders in the domain. Since COVID times, AIC-CCMB has created various avenues for startups and innovators in product development as well as validation. In particular, AIC-CCMB partnered with Telangana Innovation Cell (TGIC) & tHUB to engage two programmes, REGIG and Mission 10X (SIG), where several startups in life sciences and medtech have been engaged for mini-acceleration and micro-funding. Other than local strong partnerships and collaboration with fellow incubators and stakeholders, AIC-CCMB, along with tHUB is engaging the NHS Manchester ecosystem, TANDEM programme with German Centres for Research and Innovation (DWIH Germany) and other global ecosystems to strengthen the life sciences ecosystem as a whole for the state.

The major challenge lies in accelerating these life science startups with enough quantum of funding from both the government side and the private investment side. A match-making between such players is a greater challenge at the moment. Secondly, unique platforms for market access and regulatory support from the local Central Drugs Standard Control Organisation (CDSCO) office would be greatly helpful to augment the technology development.

AIC-CCMB, in its seven years of existence, has focused primarily on establishing a good infrastructure for life science startups, an effective mentorship network and high-quality scientific counsel to the startups. In addition to supporting startups that come to us, we also feel it is important to generate startup ideas based on the discoveries in academic institutions. It is important to curate, package and showcase these discoveries so that commercial partners may take this into a product. In this focus, we generated a reasonable momentum in the area of the usage of animals in drug discovery and promoting non-animal methods. Secondly, we find engagements where technologies at CCMB are adapted for field applications. Incubators like ours, associated with an academic institute, should play a larger role in taking science to benefit society.

What are your views on the upcoming life sciences policy to be launched by the Telangana government?

Telangana's startup and innovation ecosystem is up to the mark, having rich educational, research institutes and also a number of incubators and co-working spaces. However, there should be unique schemes and incentives from the government catering to the needs of innovators, not only

Telangana's startup and innovation ecosystem is up to the mark, having rich educational, research institutes and also a number of incubators and coworking spaces. However, there should be unique schemes and incentives from the government catering to the needs of innovators, not only from Tier I cities like Hyderabad, but other Tier II and Tier III areas and rural sectors. Unless there is monetary commitment and other such incentives, infrastructure alone cannot meet the needs of nurturing creativity and innovation to solve local problems, contributing to a larger impact.

from Tier I cities like Hyderabad, but other Tier II and Tier III areas and rural sectors. Unless there is monetary commitment and other such incentives, infrastructure alone cannot meet the needs of nurturing creativity and innovation to solve local problems, contributing to a larger impact. Moreover, there is a huge gap in corporate engagement and government procurement of innovative products within the state. The policy should include such incentives, e-procurement policies, piloting platforms, Intellectual Property (IP) and regulatory incentives and platforms, and scale-up platforms for the innovators and startups emerging out of the state.

Are there any specific challenges in biotech products commercialisation that AIC-CCMB is actively addressing through mentorship or partnership programmes? How many new products/technologies were launched by your startups in 2024?

AIC-CCMB is under its limited capacity, building connections with potential partners locally and globally for commercialising biotech-based products. We mediate some of the global partnerships, like Montgomery County, Maryland, to help our startups set up their companies overseas. Similarly, welcoming global players who look for local partners for marketing similar products. Having immense engagement with various mentors and advisors, we engage our startups through specific programmes. However, more stringent startup mentorship programmes are in the plans for this year.

Our startups have soft-launched three innovative products: the Pheezee Device by Startoon Labs, indiMeat by Svastha Samriddhi, and Suraksha by Briota.

What lies ahead for the life sciences startups at AIC-CCMB in 2025?

This year, we are planning to expand our operations in other places like Andhra Pradesh, Karnataka, Maharashtra, and North Eastern states to promote skill development and entrepreneurship in life sciences and healthcare. We seem to place ourselves in incubators and accelerators like tHUB, Nadathur S Raghavan Centre for Entrepreneurial Learning (NSRCEL), FORGE, Andhra Pradesh MedTech Zone (AMTZ), Wadhwani Foundation to cross-learning and launching programmes together with those agencies suiting life sciences and biopharma domains.

We recently started engaging with the HDFC Parivartan programme and engaged theme-specific startups working in 3D bioprinting and microphysiological systems/organoids and smart and alternative proteins. In addition to this, we have started an international partnership with Blockchain for Impact (BFI) to support innovators and startups with fellowships and Kickstarter grants, respectively. We have also designed the fellowship programme for PhDs and postdocs to bridge the innovation funding for young innovators. Some of the fellowships are also to cater the MBBS and MDs who feel the taste of entrepreneurship through this programme.

Currently there are 26 physical startups and over 40 virtual startups incubated with AIC-CCMB. There are 7 physical startups and over 20 startups, virtually incubated since 2024, in particular, 4 physical and 12 virtual startups incubated in 2024.

Are you planning more collaborations with industry leaders or research institutions to accelerate the growth of biotech/ life sciences startups?

Yes. Thermo Fisher is a strong partner that we have planned several engagements with since their support of the Centre of Innovation at AIC-CCMB. Currently, there are several workshops and training sessions planned through this centre. We are planning to engage the Gopalakrishnan-Deshpande Centre for Innovation and Entrepreneurship (Indian Institute of Technology Madras) to accelerate life sciences startups, especially those founded by academics. BS

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"We see India not just as a trade partner, but as a strategic collaborator for the US market and beyond"

Ella Woger-Nieves, Chief Executive Officer of Invest Puerto Rico, spoke BioSpectrum India on the sidelines of BIO 2025, offering insights into how Puerto Rico has firmly positioned itself as the leading pharmaceutical exporter in the United States. With $54.3 billion in annual life sciences exports to over 120 countries, the island is leveraging its strategic location, FDA-aligned manufacturing ecosystem, and robust talent base to attract global biopharma investments. In this interaction, Ella Woger-Nieves discusses Puerto Rico's infrastructure, policy incentives, global outreach including recent engagements in India, and its long-term vision as a hub for next-generation therapeutics. ***Edited excerpts;***

« **Ella Woger-Nieves,** CEO, Invest Puerto Rico

Puerto Rico has become the #1 pharmaceutical exporter in the United States, with $54.3 billion in total life sciences exports annually to over 120 countries. What are the key factors that have enabled Puerto Rico to become such a vital player in the U.S. pharmaceutical supply chain?

Puerto Rico is home to world-class businesses such as Amgen, Bristol Myers Squibb, Johnson & Johnson, and Eli Lilly's manufacturing operations. Puerto Rico's prominence as the No.1 producer and exporter of pharmaceuticals in the U.S. supply chain is no coincidence—it's the result of decades of infrastructure investment, regulatory alignment, and talent development. We offer a unique combination of a highly skilled, bilingual workforce with deep expertise in FDA-regulated manufacturing, world-class facilities that meet the highest GMP standards, and full compliance with U.S. laws and regulations. Our strategic geographic location also allows us to serve U.S. markets swiftly, securely, and tariff-free, making Puerto Rico not only a reliable but also a resilient supply chain partner. This has enabled us to play a critical role in ensuring continuity of care for U.S. institutions like the Department of Defense and the VA.

Given that approximately 90 per cent of air cargo leaving Puerto Rico consists of bioscience products, how has the San Juan Airport's pharmaceutical certification enhanced Puerto Rico's competitiveness in the global biopharma logistics landscape?

The pharmaceutical certification of San Juan's Luis Muñoz Marín International Airport, particularly its IATA CEIV Pharma certification, is a game changer. It affirms that Puerto Rico's logistics infrastructure meets the highest standards for temperature-controlled, time-sensitive biopharma shipments. This has significantly strengthened our value proposition to global life sciences companies by ensuring safe, compliant, and efficient movement of critical products. It also reinforces Puerto Rico as not just a manufacturing hub, but a strategic node in the global biopharma logistics network. Additionally, Governor Gonzalez was at the helm to secure a two-year exemption from federal air cabotage laws, allowing foreign airlines to transfer cargo freely and ultimately increase efficiency and reduce costs.

You've emphasized that as a U.S. territory, Puerto Rico avoids import tariffs imposed on foreign trade partners. How are you communicating this strategic advantage to global pharmaceutical and biotech companies—especially those in emerging markets like India?

We emphasize Puerto Rico's unique position as a US jurisdiction with global reach. Unlike offshore locations, companies manufacturing in Puerto Rico have duty-free access to the US market while operating under a legal framework fully aligned with U.S. standards. This is particularly attractive to firms in emerging markets like India that are

seeking secure and tariff-free entry into the US. Our messaging is reinforced through targeted outreach, international roadshows, and high-level engagements where we demonstrate how Puerto Rico can de-risk market expansion while enhancing speed to market. The India visit was one example of our proactive approach in fostering bilateral collaboration rooted in mutual growth. Invest Puerto Rico also recently attended SelectUSA, a US Commerce Department event that promotes foreign direct investment. There, we announced the arrival of Dot Ai, a company that transforms supply chain and asset management. Dot Ai's leadership team chose to expand to Puerto Rico instead of Mexico. This is the most recent example of a company seeing the value of operating in the US.

What types of pharmaceutical products or therapeutic areas—such as insulin, vaccines, or cancer therapies—are you particularly prioritizing for manufacturing expansion on the island?

Puerto Rico is actively focusing on high-value, complex biologics and pharmaceuticals, particularly in areas such as oncology, diabetes, and vaccine production. These segments require sophisticated capabilities, regulatory rigor, and technical know-how—all of which Puerto Rico offers. We are also seeing rising interest in gene therapies, biosimilars, and advanced drug delivery systems. Our goal is to be a strategic base for next-generation therapeutics, supporting innovation while addressing critical public health needs. Puerto Rico is the perfect place for companies large and small.

Invest Puerto Rico recently visited India to attract business partnerships. Could you share key outcomes or takeaways from your visit, and how you see India fitting into Puerto Rico's strategic vision for biopharma collaboration?

Our visit to India confirmed a strong mutual interest in deepening pharmaceutical and biotech ties. India has a world-class generic drug industry and a growing footprint in complex biologics—two areas that complement Puerto Rico's strengths in advanced manufacturing and regulatory excellence. Key outcomes included high-level dialogues with leading pharma players, new interest in site selection opportunities, and a clearer path for collaboration on R&D and supply chain resilience. We see India not just as a trade partner, but as a strategic collaborator in building a more agile, diversified, and secure pharmaceutical ecosystem for the US market and beyond.

Looking ahead, what support mechanisms—such as tax incentives, infrastructure investment, or workforce development—does Puerto Rico offer to life sciences companies considering expansion or relocation?

Puerto Rico offers incentives designed for manufacturers that work well in the life science industry. These incentives include no US federal tax on eligible income, up to 50 per cent tax credit on R&D expenditures, and Foreign Trade Zones that provide duty-free storage, processing and distribution of imported medical components. We are also investing significantly in infrastructure—such as our grid—and bolstering our STEM talent pipeline through partnerships with universities and technical training centres. We have a holistic, business-ready environment where life sciences companies can scale efficiently and sustainably. Currently, Puerto Rico's legislators have re-introduced an incentive to Congress, called the Medical, Manufacturing, Economic Development and Sustainability (MMEDS) Act. We're excited for the potential of this bill to bring companies back to America.

Finally, how does Invest Puerto Rico plan to strengthen the island's positioning in the broader US and global pharmaceutical ecosystem over the next five years?

Our vision is to position Puerto Rico as the premier reshoring hub for pharmaceutical innovation and manufacturing in the Western Hemisphere. Over the next five years, we're focused on three pillars: attracting investment in emerging therapeutics, enhancing infrastructure and workforce capacity, and forging international partnerships that align with our long-term goals. We're also working closely with federal stakeholders to align Puerto Rico's capabilities with US supply chain resilience initiatives. Governor Jennifer González-Colón's executive order promotes the relocation of overseas pharmaceutical manufacturing products to Puerto Rico, and Governor Gonzalez reached out to top White House officials to offer Puerto Rico's well-established, yet currently underutilised, manufacturing capacity as an economic engine to help grow American prosperity. Through strategic branding, global outreach, and continuous ecosystem development, Invest Puerto Rico is committed to ensuring the island remains a cornerstone of pharmaceutical production and innovation globally. BS

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How genomic revolution is reshaping healthcare in emerging markets

A new frontier in medicine, powered by genomics, is unfolding across emerging economies, promising to transform healthcare landscapes from Egypt to China. The application of genomics in healthcare offers a multi-pronged approach to improving public health, from proactive prevention to highly targeted treatments. The benefits are vast and interconnected, creating a powerful ecosystem for medical innovation. Let's explore further.

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At its core, genomics enables the shift from reactive to proactive healthcare. It allows for the prediction and prevention of diseases by identifying individuals at high risk for conditions such as diabetes, heart disease, and cancer long before any symptoms manifest, facilitating early, life-saving interventions.

This predictive power is complemented by the rise of precision medicine, which tailors treatments directly to a person's unique genetic profile. This personalised approach significantly improves the effectiveness of therapies while minimising adverse side effects, moving away from a one-size-fits-all model of care.

Furthermore, the field is dramatically accelerating the discovery of new treatments. Rapid genomic sequencing allows researchers to identify drug targets more quickly and efficiently, enabling faster and more affordable drug development. This is particularly crucial for emerging markets, as it can lower healthcare costs by reducing the reliance on expensive imported medications.

In the realm of infectious diseases, genomics has become an indispensable tool. Genomic data is vital for combating infectious diseases by helping scientists track viral and bacterial mutations, control the spread of outbreaks, and guide the development of effective vaccines and treatments in real-time.

Collectively, these advancements work to strengthen public health systems. By enhancing disease surveillance, informing evidence-based policymaking, and improving outbreak response, genomic data empowers governments and healthcare organisations to build more resilient and effective healthcare infrastructures for better long-term outcomes.

Opportunity in emerging economies

The genomics market across emerging economies is experiencing a period of dynamic growth. This expansion is fueled by improvements in healthcare infrastructure, a surge in research and development investment, and a growing public demand for the benefits of personalised medicine. Nations like China, India, Brazil, Egypt, and South Africa are at the vanguard of this transformation, each demonstrating remarkable growth projections.

Market data indicates upward trajectory:

- China stands as the dominant market, projected to grow from $2,721 million in 2024 to an astounding $8,314 million by 2030, reflecting a compound annual growth rate (CAGR) of 20 per cent.
- India's market is set for a 19 per cent CAGR, expected to expand from $841 million in 2024 to $2,434 million by 2030.
- Egypt shows a strong CAGR of 18 per cent, with its market projected to grow from $110 million in 2024 to $296 million in 2030.
- Brazil's market is forecast to grow at a 9 per cent CAGR, from $662 million in 2024 to $1,135 million by 2030.
- South Africa, a key player in African genomics, is expected to see its market grow from $88 million in 2024 to $136 million by 2030, at a CAGR of 8 per cent.

Pioneering initiatives in emerging markets

These market figures are underpinned by ambitious and impactful initiatives on the ground. Emerging nations are not just adopting genomic technologies; they are adapting them to solve specific, regional healthcare challenges.

In a landmark public health achievement, Egypt's Hepatitis C elimination initiative utilised nationwide PCR-based screening and HCV genotyping to screen 50 million people, successfully curing over 2 million and drastically reducing the disease's prevalence.

China is making significant headway in precision oncology and the management of rare diseases. A major breakthrough in lung cancer research identified that nearly half of non-small cell lung cancer patients share the same genetic mutation, paving the way for targeted therapies like Tyrosine Kinase Inhibitors (TKIs) and avoiding broader chemotherapy. Simultaneously, the country's National Rare Disease Registry, established in 2018, has compiled data on 62,000 cases across 166 rare diseases, supporting diagnostics and treatment research.

In South Africa, a hub for infectious disease research, genomic studies are providing new hope for HIV treatment. Research focusing on individuals who naturally suppress the HIV virus has identified specific immune-related genetic variations that could guide the development of new treatment strategies.

Brazil is investing in building a foundational data resource with its "DNA do Brasil Project." Launched in 2019, this large-scale initiative aims to sequence the genomes of 15,000 Brazilians to create a representative genomic database, which will advance research, disease prevention, and national health policies.

Meanwhile, India took a significant step by opening South Asia's first advanced genomics research center in Hyderabad in 2021. The center is tasked with ambitious goals, including the sequencing of thousands of COVID-19 genomes and hundreds of human genomes to bolster regional research capabilities.

Key challenges to widespread adoption

Despite the immense potential and ongoing progress, the journey toward the widespread integration of genomics in emerging markets is fraught with significant challenges.

A primary obstacle is the high cost of equipment. Although the cost of sequencing has plummeted by orders of magnitude over the past two decades, the price of the necessary machinery remains prohibitive for many, often exceeding $100,000 and thus limiting access in developing countries.

Severe infrastructure and talent gaps also hinder progress. There is a critical shortage of skilled professionals, such as medical geneticists and bioinformaticians, stemming from limited funding and inadequate training pipelines. The disparity is stark: the United States has approximately 27 times more medical geneticists per million people than South Africa, highlighting a deep-seated gap that must be addressed. This shortage has tangible consequences; in 2021, African nations collectively sequenced only 7,000 COVID-19 genomes in 50 days, a fraction of the 590,000 sequenced by EU countries in half that time.

A third major challenge is the underrepresentation of local genomic data. The populations of Africa and Southeast Asia account for a quarter of the world's population but contribute less than 15 per cent of the genomic data used in research. This lack of diversity in global databases limits the scope and applicability of scientific findings for these populations, creating a risk of deepening health inequities.

Finally, regulatory barriers present another significant hurdle. Many developing countries lack the robust institutional frameworks and national policies needed to oversee genomic research and its clinical application. For instance, while the US has over 2,000 institutional review boards for research and experiments, a country like Nigeria has fewer than 20, constraining the pace and governance of scientific advancement.

Strategic imperatives for growth

Realising the full potential of genomics in emerging markets requires a concerted and strategic effort. While these nations are already active contributors to global research, surmounting the existing challenges is paramount. The next phase of growth will be contingent on several key pillars: increased investment in both public and private sectors, the cultivation of public-private partnerships to drive innovation, dedicated programs for workforce training, the development of supportive and clear regulatory frameworks, and a major push to expand the collection of diverse genomic data that truly represents the populations of these regions.

As technology continues to evolve and costs inevitably decline, genomics is set to revolutionise healthcare, making the promise of personalised medicine a tangible reality for millions across the globe. The coming years will be a pivotal period. The nations that choose to embrace this transformation, invest strategically, and build collaborative ecosystems will not only enhance the well-being of their own citizens but will also lead the global charge in reshaping the future of health for all. BS

Why the New Schedule M Is a Game Changer for Indian Pharma and How the Industry Is Adapting

The Indian pharmaceutical industry stands at a pivotal moment. With the government's notification of the revised Schedule M in January 2024, the sector is undergoing a structural and cultural transformation. The updated regulations, which bring India's Good Manufacturing Practices (GMP) in line with global standards, are not just compliance mandates, they represent a paradigm shift towards consistent quality, operational excellence, and global competitiveness.

« **Nilesh Patel,**
Managing Director,
Kashmik Formulation

Schedule M of the Drugs and Cosmetics Rules, 1945, outlines the GMP requirements for manufacturing pharmaceutical products in India. The revised version enhances and broadens these requirements, integrating principles that focus on quality risk management, validated systems, contamination control, and comprehensive documentation. Key components include upgraded infrastructure norms, air handling systems, water quality management, and stricter environmental monitoring. These reforms aim to ensure that every medicine manufactured in India is safe, effective, and of assured quality.

Phased Compliance Deadlines

The regulatory shift is being rolled out in a phased manner to ensure smoother implementation. Large manufacturers are expected to comply within six months from the date of notification, while micro, small, and medium enterprises (MSMEs) have been given a twelve-month window. This phased timeline recognises the capacity differences across enterprises and allows room for technical and financial preparedness.

Why This Move Matters

India is one of the world's largest suppliers of generic medicines, catering to both domestic needs and export markets across more than 200 countries. In recent years, increased global scrutiny and rising quality expectations from importing countries have underlined the need for stronger, harmonised manufacturing practices. The revised Schedule M is thus a timely intervention that will help elevate India's global standing in pharmaceutical manufacturing.

Strengthening Quality Assurance

The new guidelines promote a risk-based approach to quality management. This involves implementing quality control checks at every stage - from sourcing raw materials to finished product dispatch. By institutionalising quality at the core of operations, the sector can minimise deviations, reduce batch failures, and improve patient safety outcomes. Importantly, it also establishes a uniform benchmark for all manufacturers, regardless of size or geography.

Alignment with Global Benchmarks

The updated norms are closely aligned with standards set by international regulatory agencies such as the World Health Organization (WHO) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S). This alignment ensures that Indian manufacturers can better integrate into the global pharmaceutical supply chain, particularly in regulated markets like the US, EU, and Japan.

Notably, several companies in India had already adopted WHO-GMP standards even before the revised Schedule M was introduced. These early adopters—many of whom cater to export markets—have demonstrated that adherence to international GMP guidelines not only improves quality but also opens access to new markets and partnerships.

Building a Data-Driven Compliance Culture

The new guidelines encourage a shift from paper-based systems to digitised operations. Electronic batch manufacturing records (eBMR),

digital logbooks, audit trails, and track-and-trace mechanisms are becoming increasingly prevalent. These systems enhance traceability, ensure real-time monitoring, and improve response times during inspections or deviations. They also foster a culture of accountability and transparency, which is critical for sustaining regulatory compliance.

For instance, in active pharmaceutical ingredient (API) manufacturing, digital quality records help ensure that every step from synthesis to storage is monitored and traceable. This reduces the scope for errors and improves product recall efficiency if needed.

Enhancing Investor and Market Confidence

The introduction of clearer, more enforceable quality guidelines under Schedule M is likely to boost investor confidence. Investors, both domestic and global, often view regulatory compliance as a proxy for operational maturity and long-term viability. A transparent and harmonised regulatory framework signals policy stability and strengthens trust among stakeholders.

How the Industry Is Adapting

Recognising the long-term benefits of the revised norms, pharmaceutical companies are proactively initiating changes across their operations.

Facility Upgradation: Many manufacturing units are undertaking major infrastructure revamps, including redesigning production layouts, improving cleanroom classifications, installing advanced HVAC systems, and enhancing utilities like purified water generation and waste management.

Digital Transformation: Digital tools are being deployed to manage inventory, track production stages, and monitor lab data. Platforms such as Laboratory Information Management Systems (LIMS), ERP software, and quality management systems (QMS) are playing a central role in driving compliance efficiency.

Workforce Training: A critical pillar of GMP compliance is a skilled and aware workforce. Companies are prioritising employee training programs that focus on the revised regulatory requirements, standard operating procedures, hygiene protocols, and documentation practices. Continuous skill development is ensuring that personnel are not just trained once but are regularly updated on evolving best practices.

Global Certifications: Many companies are actively pursuing WHO-GMP certification and PIC/S compliance to signal quality readiness to international regulators. These certifications also help secure entry into regulated markets and foster export growth.

Challenges on the Road to Compliance: While the industry is committed to embracing the new standards, the transition is not without challenges.

Financial Constraints: Infrastructure upgrades, technology investments, and training programs require significant capital outlay. For MSMEs in particular, accessing affordable finance for these improvements remains a hurdle.

Technical Expertise: Complying with global GMP standards demands specialised knowledge in validation protocols, cleanroom design, quality risk assessment, and regulatory documentation. Smaller firms may lack access to such expertise, necessitating partnerships or external consultants.

Operational Disruptions: Retrofitting facilities or installing new systems often requires partial or complete halts in production. These interruptions, though temporary, can affect supply chain commitments and increase operational costs.

Government Support and Ecosystem Efforts

Acknowledging these challenges, the government has introduced support mechanisms. Schemes such as the Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) offer financial aid and soft loans for facility modernisation. Technical guidance is also being provided through national regulatory agencies and industry associations.

Industry bodies such as the Indian Drug Manufacturers' Association (IDMA) and Organisation of Pharmaceutical Producers of India (OPPI) are playing an active role in capacity building through webinars, workshops, and compliance toolkits. These collective efforts are fostering a more prepared and cooperative compliance ecosystem.

A Defining Moment for the Sector

The revised Schedule M is more than a regulatory update - it is a strategic inflection point for the Indian pharmaceutical industry. By elevating the manufacturing landscape to global benchmarks, it strengthens India's position as a trusted healthcare partner to the world.

The companies that prioritise compliance, adopt digital tools, invest in talent, and seek global certifications are likely to lead the next phase of growth. The transition may be demanding, but the long-term benefits—increased credibility, expanded market access, and improved patient outcomes—make the journey worthwhile.

As the implementation progresses, the industry is expected to become more resilient, quality-focused, and innovation-driven. Ultimately, this transformation will contribute to not just business success, but also to public health advancements in India and beyond. BS

IIT-KGP inks MoU with German University to foster academic collaboration

The Indian Institute of Technology Kharagpur (IIT-KGP) has signed a Memorandum of Understanding (MoU) with the Technische Universitat Darmstadt, Germany, to foster collaboration in academic, research and innovation initiatives. Both parties have discussed a range of disciplines, including robotics, AI, mechanical, aerospace, computer science & engineering, electrical, electronics engineering disciplines, political science, biological sciences, medical sciences, biotechnology, industrial engineering, and others. The MoU sets a framework for both institutions to explore innovative opportunities for cooperation, including student and faculty exchange programmes, joint research projects, and shared academic ventures. It is envisaged that several collaborative academic and research programmes will emerge from this strategic partnership.

Chandigarh University, UP emerges as new hub for pharmacy education in AI and research

Chandigarh University, Uttar Pradesh (UP) Campus, continues to break new ground in AI-augmented multidisciplinary education with a major milestone- its School of Pharmacy has received formal approval from the Pharmacy Council of India (PCI) for its Bachelor of Pharmacy (B. Pharma) programme. The curriculum is designed to balance theoretical foundations with hands-on training, ensuring that students graduate as competent and industry-ready healthcare professionals. The PCI has granted formal approval to Chandigarh University, Lucknow Campus to begin offering 60 seats in the Pharmacy course from the academic session 2025. Students at the School of Pharmacy can pursue careers in diverse fields such as Clinical Research, Intellectual Property Management, Regulatory Affairs, Quality Control, and Medical Writing.

P. D. Hinduja Hospital, King's College London commence first training programme for nurses

P. D. Hinduja Hospital & Medical Research Centre has entered into a strategic services agreement with King's College London, Guy's and St Thomas' NHS Foundation to deliver training in clinical and non-clinical courses for doctors and nurses, research capacity building and executive education to health professionals in India and the UK. The 12-week course, titled "Clinical Nursing Leadership," is being conducted by the faculty of the Florence Nightingale Faculty of Nursing,

Midwifery & Palliative Care at King's College London. Structured as a hybrid programme, it combines online and in-person instruction and follows a synchronous, activity-based teaching methodology designed to engage and elevate experienced nursing leaders. A cohort of highly qualified nurses currently serving in senior leadership roles at P. D. Hinduja Hospital has enrolled in this inaugural batch. The curriculum is designed not only to enhance clinical acumen but also to cultivate the strategic thinking and leadership competencies required to manage modern healthcare environments.

IDMA names Nikkhil K Masurkar as Vice Chairperson of R&D and Innovation Committee

Nikkhil K Masurkar, Chief Executive Officer of Mumbai-based Entod Pharmaceuticals, has been appointed Vice Chairperson of the R&D and Innovation Committee of the Indian Drug Manufacturers Association (IDMA) for the 2025–2026 term. As India's largest pharmaceutical industry body, IDMA represents over 1,100 member companies, the majority of which are Micro, Small, and Medium Enterprises (MSMEs). Masurkar's strong leadership qualities, dynamic entrepreneurial spirit and sharp business acumen together with impressive pharmaceutical & research skills have made Entod Pharmaceuticals into one of the fastest growing speciality pharmaceutical & healthcare companies in India and abroad. Under the leadership of Chairperson Sanjiv Navangul (MD & CEO, Bharat Serums & Vaccines), and alongside an esteemed committee, Masurkar will help mobilise collaborative initiatives that promote research-led development, facilitate strategic engagement with scientific institutions, and accelerate the innovation momentum among MSMEs.

Practo appoints Shoumyan Biswas as Global Chief Strategy & Marketing Officer

Practo, India's largest and most trusted health services platform, has announced the appointment of Shoumyan Biswas as its new Global Chief Strategy & Marketing Officer. Biswas brings over two decades of extensive leadership experience and a proven track record of building customer-centric growth engines across diverse industries. His expertise will be invaluable in advancing Practo's mission to help people live healthier, longer lives through strategic clarity and driving innovation to improve health outcomes. In his new role, Biswas will lead Practo's global business expansion along with focusing on deepening customer engagement and accelerating profitable growth in India. He will play a key role in shaping the company's global growth strategy plans, with a strong emphasis on category expansion and a sharper consumer focus. His career includes positions such as CMO & Group Loyalty Head at Tata Digital, CBO at Rebel Foods, and CMO at Flipkart.

Gagandeep Singh Bedi joins Smile Group to lead HealthTech Venture Builder

Smile Group, a technology investor and operator, is launching a Healthtech Venture Builder and has appointed Gagandeep Singh Bedi as Managing Partner to lead the initiative. This strategic move signals Smile Group's entry into the fast-growing and rapidly evolving health tech sector, leveraging its full-stack approach of bringing in capital and operational expertise to venture build, and driving the expansion of globally disruptive market leaders into Asia. With over 25 years of experience at AstraZeneca, Boehringer Ingelheim, Baxter, and Eli Lilly, Bedi has driven growth, built high-performing teams, and shaped market strategies across India, Africa, and global markets. At AstraZeneca India, he led a turnaround, doubling market growth and tripling market capitalisation to $1 billion, while contributing to India's COVID-19 vaccine response. He has also actively engaged with India's startup ecosystem through the India-Sweden Healthcare Innovation Centre to accelerate tech adoption in clinics; a partnership with IIT Kanpur's SIIC for dementia-care innovation; and early-stage investments in health tech ventures targeting acute coronary syndrome and lung cancer.

Sharda Care Healthcity ropes in Dr Chirag Tandon as Director of Internal Medicine

Reinforcing its leadership in comprehensive internal medicine and integrated patient care, Sharda Care Healthcity has appointed renowned physician Dr Chirag Tandon as Director of the Department of Internal Medicine at its state-of-the-art facility in Greater Noida. With close to two decades of clinical experience, Dr Tandon is widely recognised for his expertise in managing complex adult medical conditions. His appointment strengthens Sharda Care Healthcity's capabilities to offer holistic, patient-centric care across a broad spectrum of general medicine services. Dr Tandon brings with him deep proficiency in areas including diabetes and thyroid disorders, infectious diseases, metabolic and rheumatologic illnesses, geriatric medicine, gastroenteritis, and critical care. He is adept in ICU and ICCU management, as well as advanced treatment modalities such as Continuous Renal Replacement Therapy (CRRT) and dialysis. His additional training in pulmonary and sleep medicine further augments his multi-disciplinary approach to patient care.

PAG-led Sekhmet Pharma announces appointment of Santosh Mahil as MD & CEO

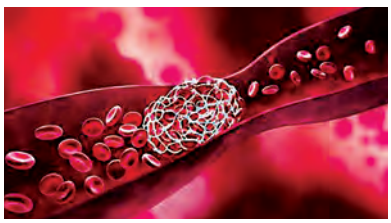
A private equity consortium led by PAG, a leading Asia-focused investment firm, has announced the appointment of Santosh Kumar Mahil as the Managing Director (MD) and Chief Executive Officer (CEO) of Sekhmet Pharmaventures, an investment platform established to nurture and grow India's next generation of active pharmaceutical ingredient (API) companies. Mahil brings with him nearly three decades of experience in the pharmaceutical industry, having held leadership roles at organisations including Lupin, USV, Unichem, and Shilpa Medicare. Most recently, he served as the CEO of Shilpa Pharma Life Sciences, an R&D and manufacturing subsidiary of Shilpa Medicare. His expertise spans the entire pharmaceutical value chain, including APIs, formulations, intermediates, and CDMO services. In each of his roles, he has focused on the development and growth of the business, including strategic expansion, operational excellence, consumer satisfaction and M&A.

Marengo Asia Hospitals strengthens orthopaedic leadership

Marengo Asia Hospitals' flagship unit, Marengo CIMS Hospital in Ahmedabad, has announced the strengthening of their orthopaedic leadership with the onboarding of world-renowned orthopaedic surgeon Dr K. C. Mehta as Director – Orthopaedics and Joint Replacement, Marengo CIMS Hospital, Ahmedabad. Dr Mehta is internationally acclaimed for designing his proprietary knee joint and holds ten global patents across countries including the USA, UK, Australia, New Zealand, Singapore, China, India, Indonesia, and Malaysia. With 35+ years of experience, Dr Mehta has done over 40,000 orthopaedic procedures. Setting a rare benchmark in clinical outcomes, Dr Mehta has performed thousands of successful knee replacement surgeries without patients requiring postoperative physiotherapy. This distinctive approach significantly reduces patient discomfort, shortens recovery time, and lowers overall healthcare costs.

IISc develops novel nanozyme to prevent excess blood clotting

Researchers at the Indian Institute of Science (IISc), Bengaluru have developed an artificial metal-based nanozyme that can potentially be used to clamp down on abnormal blood clotting caused by conditions like pulmonary thromboembolism (PTE). These "nanozymes" work by controlling toxic Reactive Oxygen Species (ROS) levels, thereby preventing the over-activation of platelets that leads to excess clot formation or thrombosis. The team injected the nanozyme in a mouse model of



PTE and found that it significantly reduced thrombosis and increased the animals' survival rates. They also observed the weight, behaviour, and blood parameters of the animal for up to five days after injecting the nanozyme, and did not find any toxic effects. Anti-platelet drugs that target thrombosis sometimes have side effects such as increased bleeding. Unlike conventional anti-platelet drugs that interfere with physiological haemostasis, the nanozymes modulate the redox signalling and do not interfere with normal blood clotting. The team now plans to explore the efficacy of the nanozyme in preventing ischemic stroke, which is also caused by clogging of blood vessels.

NIT Rourkela designs label-free biosensor for affordable breast cancer diagnosis

Researchers at the National Institute of Technology (NIT) Rourkela, Odisha have investigated a novel semiconductor device-based biosensor that can identify breast cancer cells without the need for complicated or expensive laboratory procedures. The research team has designed a novel approach that uses the physical properties of cancer cells to detect them. Cancerous breast tissues, which hold more water and are denser than healthy tissues, interact differently with microwave radiation. These differences, known as dielectric properties, make it possible to distinguish between healthy and cancerous cells. To take advantage of this, the research team has proposed an electronic device, 'TFET' (Tunnel Field Effect Transistor), based on TCAD simulation results, that can effectively detect breast cancer cells. FETs are commonly used in electronics, but here they have been adapted to function as a sensitive detector of biological materials. Unlike many traditional tests, this biosensor does not need any added chemicals or labels to work.

IIT Madras and US researchers study viruses with potential to kill disease-causing bacteria

Researchers at the Indian Institute of Technology Madras (IIT Madras) and US are studying viruses in freshwater lakes. Such research is critical to understanding viruses in nature as it has enormous applications that can benefit society and the environment. The findings of this research reveal the vital roles viruses play in ecosystems, not just by influencing the environment but also by supporting other organisms. This work highlights how viruses are beneficial to the health and stability of natural systems. This International Team of researchers developed and applied cutting-edge Machine Learning-based tools to uncover the hidden world of viruses in microbiomes. Using these methods, they studied 465 freshwater lake samples from the same location in Madison, Wisconsin, US, collected over a period of more than 20 years. This research represents the longest DNA-based monitoring of a natural environment on Earth. Viruses can be used to prevent harmful algal blooms or bacterial outbreaks (like the green slime seen in polluted lakes), ensuring safer drinking water and healthier recreational lakes.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VFL Sciences partners with Cytosurge AG to bring FluidFM OMNIUM platform to India

Chennai-based VFL Sciences has entered a partnership with Cytosurge AG to offer the FluidFM OMNIUM platform, a semi-automated single-cell manipulation system for non-destructive injection and extraction, compatible with single-cell RNA analysis and advanced gene editing techniques. With the blend of its products and partnered products, VFL Sciences has positioned itself as a complete solution provider for several workflows in life science laboratories. With their experienced team, VFL Sciences will be the go-to partner for FluidFM OMNIUM expertise, support, and solutions, especially within Pharma, Biopharma, and Cell and Gene Therapy laboratories across India.

Qiagen expands portfolio for minimal residual disease testing in oncology

Netherlands-based holding company Qiagen N.V. has announced the expansion of its oncology diagnostics portfolio with two strategic partnerships to advance the use of minimal residual disease (MRD) testing in clinical trials to support pharma co-development projects for companion diagnostics. The new collaborations with Tracer Biotechnologies and Foresight Diagnostics expand Qiagen's reach in MRD testing and cover solid tumours and hematological cancers. Tracer Biotechnologies, a developer of blood-based molecular diagnostics for cancer, is working with Qiagen to create companion diagnostics for MRD testing in solid tumours. These assays, designed for use on Qiagen's QIAcuity digital PCR platform, are designed to enable the use of minimally invasive blood samples to monitor residual disease with high sensitivity. Foresight Diagnostics and Qiagen are creating a kit-based version of the Foresight CLARITY assay, a circulating tumour DNA (ctDNA)-based NGS test for certain types of lymphoma.

Thermo Fisher Scientific launches new Spectral Flow Cytometer

Thermo Fisher Scientific Inc. has launched the spectral-enabled Invitrogen Attune Xenith Flow Cytometer, allowing immunology and immuno-oncology researchers to automate and streamline workflows to obtain more detailed and accurate insights from critical cellular samples. By leveraging Thermo Fisher's legacy core acoustic focusing technology, this new solution offers improved time to results for scientists researching cellular behaviours and mechanisms and discovering targeted therapies. It enables both spectral unmixing and conventional flow cytometry, allowing researchers to tackle a broader range of applications with greater flexibility and sensitivity. As the field of flow cytometry grows and research needs become more complex, scientists require access to even more data from cells which can help provide insights into how diseases, including cancer, manifest and progress in the body.

Disruptive AI-Driven Innovations in Disease Diagnosis

For years, blood tests have been relied upon for detecting numerous conditions including diabetes, cancer, arthritis, HIV, cardiovascular diseases, genetic disorders, COVID-19 and much more. Joining this list is a first-of-its-kind blood test to detect early onset of Alzheimer's disease, recently approved by the US Food and Drug Administration.

Holding a value of $96.62 billion in 2024, the global blood testing market is now witnessing advancements in automation and point-of-care (POC) testing devices methods, especially with the use of artificial intelligence (AI), that are making blood tests more efficient, reducing turnaround times and enhancing patient outcomes.

On the contrary, studies have revealed that when AI models are used to analyse blood test results, these at times fail to identify medical conditions like high cholesterol and anaemia, without indicating further evaluation. Nonetheless, researchers across the world are exploring the use of AI to build new versions of blood tests for early disease detection.

A recent example is an AI-based test for detecting DNA fragments shed by tumours in a patient's blood, developed by US-based Johns Hopkins Kimmel Cancer Center investigators, that could help clinicians more quickly identify and determine if pancreatic cancer therapies are working. After testing the method, called ARTEMIS-DELFI, in blood samples from patients participating in two large clinical trials of pancreatic cancer treatments, researchers found that it could be efficiently used to identify therapeutic responses.

Citing another example, US-based company Circulogene has commercially launched LungLifeAI, a breakthrough AI-driven blood-based test designed to improve clinical decision-making in patients with indeterminate pulmonary nodules (IPNs) detected through CT scans. When a lung nodule is discovered on a CT scan, deciding whether to proceed with a biopsy, especially for nodules smaller than 2 cm, can be difficult. LungLifeAI helps close this gap by delivering high-performance molecular biomarker analysis to support informed biopsy decisions.

Further, the UK government, in collaboration with the National Institute for Health and Care Research (NIHR), has awarded £2.4 million to progress the development of an AI-driven blood test known as miONCO-Dx. Initial tests of the technology show that it is able to detect 12 of the most lethal and common cancers, including bowel cancer, at an early stage with over 99 per cent accuracy. The blood test has been developed on data from over 20,000 patients and will now be assessed in a clinical trial of 8,000 patients.

Also, researchers from University College London and University Medical Center Goettingen, Germany, have developed a simple AI-based blood test to predict Parkinson's disease up to seven years before symptom onset.

Looking at the Asia region, an interesting AI model has been developed by researchers at Osaka University, Japan that can determine the biological age by using a simple blood test to analyse hormone (steroid) metabolism pathways. Apparently, this innovative method requires just five drops of blood to analyse 22 crucial steroids and their interactions.

For India, a one-of-its-kind AI-based blood test has been developed by health-tech startup Quick Vitals, that uses advanced face-scanning technology to deliver blood test results in 20 to 60 seconds without needing a single drop of blood. Leveraging this opportunity, Niloufer Hospital in Hyderabad has become the first in India to adopt this artificial intelligence-based diagnostic tool that conducts non-invasive blood testing in less than a minute.

Adding to this, Chinese scientists from Fudan University have now developed a blood test that uses AI to predict the risk of developing diseases 15 years before the first symptoms appear.

While AI technology can bring a huge level of precision and speed to disease detection that was previously unattainable, the process comes with multiple challenges such as data quality, accessibility, affordability etc. For instance, AI-powered blood tests can only be made useful for rural settings if the need for expensive equipment and specialist expertise can be addressed. BS

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RNI TC No. MAHENG14628
Date of Publication - 30.6.2025

RNI NO. DELENG/2004/13061
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