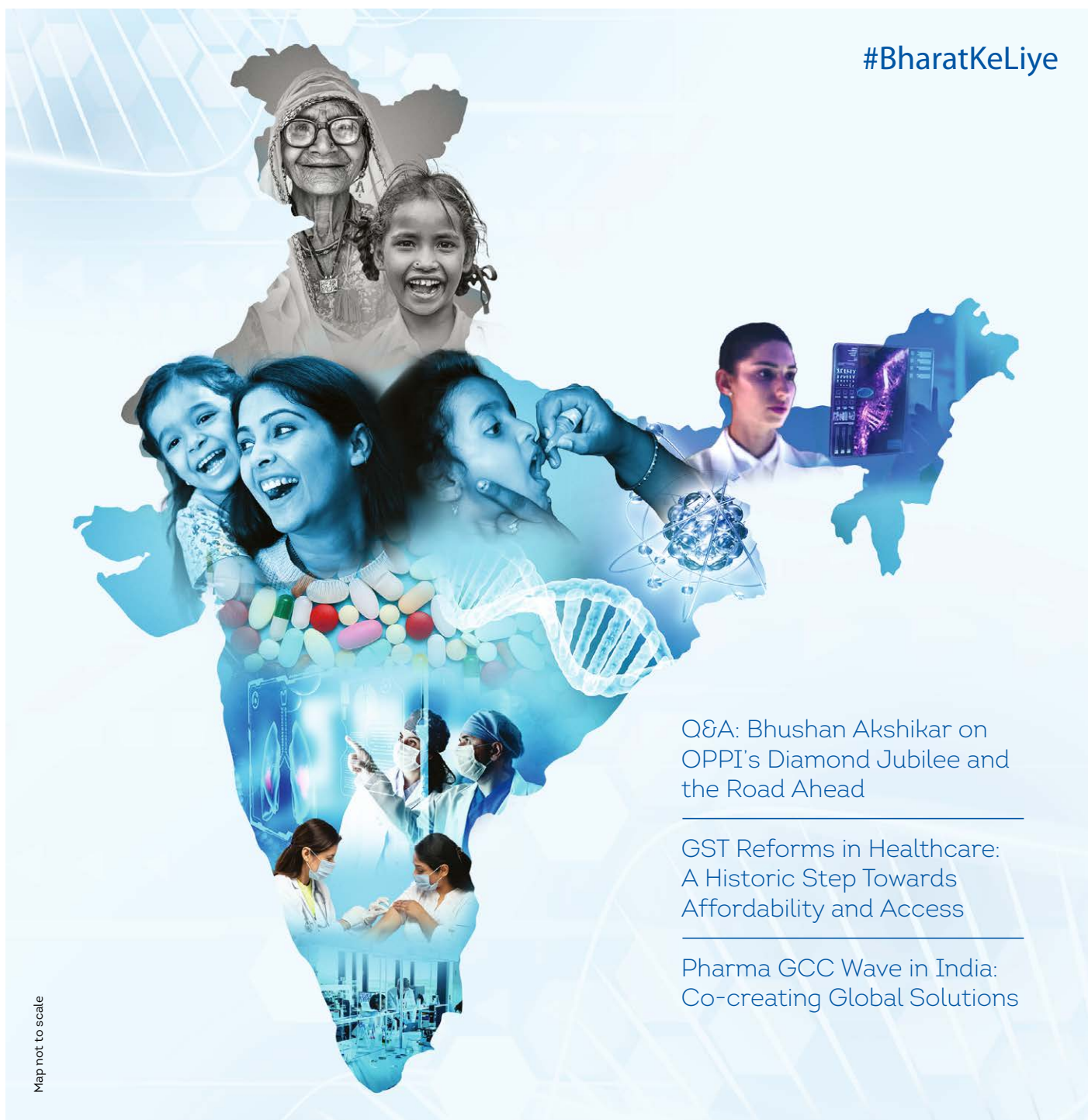


OPPI NEWSLETTER

Volume 2, Issue 1 | July - September 2025

#BharatKeLiye



Map not to scale

Q&A: Bhushan Akshikar on
OPPI's Diamond Jubilee and
the Road Ahead

GST Reforms in Healthcare:
A Historic Step Towards
Affordability and Access

Pharma GCC Wave in India:
Co-creating Global Solutions



Anil Matai
Director General, OPPI

Welcome to the second year of the OPPI Newsletter!

This quarter holds special significance as OPPI celebrates its Diamond Jubilee – 60 years of shaping India's healthcare journey through innovation, advocacy, and partnerships. Since our inception in 1965, OPPI has been the collective voice of research-based global pharmaceutical companies in India, championing policies that foster innovation, uphold ethics, and ensure that patients remain at the centre of every decision.

Over the decades, OPPI's journey has been defined by the power of partnerships – with policymakers to drive regulatory clarity, with academia to nurture innovation, with the media to promote understanding, and with our member companies to maintain the highest standards of ethics and compliance. This milestone is a reaffirmation of our values of innovation, access, and ease of doing business, and of our enduring commitment to support India's aspiration of becoming a global leader in healthcare.

This edition of the OPPI Newsletter reflects our legacy and future priorities, drawing together perspectives that underline how India's pharmaceutical sector is evolving through collaboration, policy reform, and scientific excellence.

Highlights from this edition include:

- A Q&A with OPPI President Bhushan Akshikar on OPPI's Diamond Jubilee and the future of partnerships, licensing, and innovation
- A comprehensive look at the recent milestone GST reforms
- A commentary on the power of partnerships as the foundation of India's healthcare transformation
- An editorial on the role of Regulatory Data Protection (RDP) in advancing innovation and global trust
- A feature on the rise of pharma GCCs in India, showcasing how they are delivering global healthcare solutions
- An article on the rising tide of NCDs and why it calls for a new era of pharmaceutical innovation

As we celebrate 60 years of OPPI, this edition reflects how our industry's evolution has been grounded in evidence, ethics, and partnerships – and how these values will continue to guide the next phase of India's healthcare journey.

We hope this edition provides useful perspectives and encourages continued discussion on the issues shaping India's healthcare future.

As always, we appreciate your engagement and partnership.

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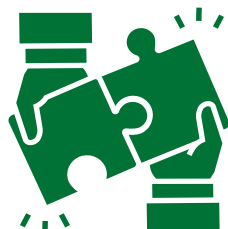
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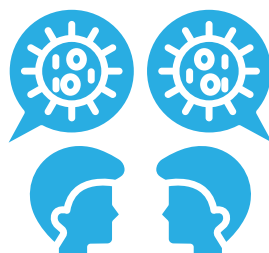
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Q&A: Bhushan Akshikar on OPPI's Diamond Jubilee and the Road Ahead

By Izabela Chmielewska, Managing Editor,
Custom Content at Citeline

Interviewee:
Bhushan Akshikar, President, OPPI

Key Highlights:

- Marking OPPI's Diamond Jubilee and reflecting on its 60-year legacy in shaping India's healthcare ecosystem
- Strengthening partnerships with government, academia, and industry to advance patient outcomes
- Showcasing the role of Global Capability Centers (GCCs) in driving global innovation and excellence from India
- Promoting responsible licensing models that balance innovation with equitable access
- Aligning OPPI's strategy with national priorities such as *Atmanirbhar Bharat* and *Jai Anusandhan*
- Calling for greater collaboration, integrity, and innovation as OPPI enters its next chapter

In this Q&A, Bhushan Akshikar, President of the Organisation of Pharmaceutical Producers of India (OPPI), shares his reflections on OPPI's Diamond Jubilee and its evolving role as the collective voice of the global research-based pharmaceutical industry in India. He discusses how OPPI strengthens partnerships across government, academia, and industry, advancing equitable access, and shaping an innovation-driven future aligned with India's national priorities.

Leadership & Legacy

As OPPI marks its Diamond Jubilee, what does this 60-year milestone mean to you as President? How does it reflect OPPI's evolution as a voice for the research-based pharmaceutical industry in India?

Celebrating 60 years of OPPI is a profound moment, not just for our members, but also for the Indian healthcare ecosystem. This milestone reflects our enduring commitment to shaping a healthier, more self-reliant India through science, innovation, and patient-centric care.

Through the years, OPPI has evolved from an industry body into a trusted partner in nation-building, advocating for policies encouraging innovation, ensuring ethical practices, and enabling global-standard healthcare for millions of Indians. It represents decades of resilience, advocacy, and purposeful collaboration with government, regulators, academia, and patients.

More importantly, as President of this esteemed organization, this milestone is a powerful reminder of our legacy and the responsibility we uphold as the collective voice of the research-based pharmaceutical industry. This is the clarion call to lead the next era of transformative healthcare,

where India is not just the 'Pharmacy of the World,' but a true Powerhouse of Research, Discovery, and Equitable Access.

Over the decades, OPPI has worked with a range of partners, including government, academia, and industry. How have these partnerships evolved in practice, and what lessons from the past are most relevant today?

OPPI's partnerships with government, academia, and industry have evolved from basic dialogue to robust, evidence-led strategic collaborations focused on improving patient outcomes and supporting the growth of the pharmaceutical sector.

In today's rapidly advancing healthcare landscape, such partnerships have become dynamic, multi-stakeholder focused. Whether it's working with policymakers to streamline regulatory pathways, collaborating with academic institutions to nurture scientific talent, or co-creating solutions with the industry to improve access and affordability, OPPI has consistently served as a unifying force. As we look ahead, OPPI will continue strengthening sustained dialogue, trust, and collaborations to support India's ambition of becoming a global leader in research-led, patient-centric healthcare.



Enabling Innovation & Global Integration

India has emerged as a hub for Global Capability Centers (GCCs) that support everything from R&D to patient safety. How is OPPI highlighting the role of pharma GCCs in delivering global value from India?

India's emergence as a strategic hub for Global Capability Centers (GCCs) marks a transformative shift in the global pharmaceutical value chain. It is a strong testament to the talent, innovation, and scientific depth present in the country.

With leading global pharma organisations increasingly leveraging India for high-end capabilities ranging from early-stage R&D and clinical development to pharmacovigilance, digital health, and patient safety, GCCs are becoming pivotal drivers of innovation, efficiency, and compliance on a global scale. OPPI is actively championing this evolution by showcasing the impact of pharma GCCs through industry reports, policy dialogues, and member-led success stories that underline India's role in delivering high-quality, knowledge-driven services to the world.

Our recently launched publication, *Global Capabilities Centres 2025: Enabling an environment for Innovation and Excellence - Bharat Ke Liye*, showcases the pivotal role our member companies are playing in shaping India's pharmaceutical landscape. The report offers a comprehensive perspective on how the GCCs of our member companies are driving innovation, excellence, and delivering significant global value across the healthcare ecosystem.

Through collaborations with knowledge partners and stakeholders, OPPI continues to spotlight how India's GCC ecosystem is helping global organizations achieve scale, speed, and scientific excellence. These centers are building deep domain expertise and accelerating the adoption of cutting-edge technologies such as AI, real-world evidence, and data analytics in drug development and patient outcomes. OPPI has also been engaging with policymakers to create an enabling environment that nurtures these centers through improved IP frameworks, digital infrastructure, and a skilled talent pipeline aligned with global regulatory and innovation standards.

OPPI sees pharma GCCs as integral to India's aspiration of becoming a true "Pharma Powerhouse

to the World." By amplifying their contributions on global platforms and advocating for supportive reforms, OPPI reinforces the narrative that India is no longer just a manufacturing base—it is a center for integrated, end-to-end pharmaceutical innovation shaping the future of global healthcare.

Academia-industry collaboration is a crucial driver of long-term innovation. How is OPPI working to strengthen partnerships with academic and research institutions to build capacity and accelerate translation of science into solutions?

OPPI is deeply committed to strengthening academia-industry collaboration to drive meaningful scientific breakthroughs and address India's and the world's evolving healthcare needs. We are actively fostering partnerships with leading academic and research institutions to bridge the gap between discovery and deployment, enabling faster translation of science into real-world solutions. OPPI supports the establishment of innovation hubs and incubators that encourage startups and academic researchers to collaborate with industry leaders.

We also advocate for a robust ecosystem that includes streamlined regulatory pathways, strong IP protection, and incentives for R&D-led collaboration. Our focus is on ensuring that research leads to meaningful outcomes for patients. By nurturing a culture of open innovation and aligning academic research with industry needs, OPPI aims to build long-term capacity that positions India as a global hub for cutting-edge, patient-centric healthcare innovation.

Access & Equity

Voluntary licensing has enabled broader access to essential medicines, especially in low- and middle-income settings. What role does OPPI play in advancing responsible licensing models that balance innovation with equitable access?

OPPI advocates for collaborative frameworks enabling partnerships between innovator companies, manufacturers, and global health organizations to scale access sustainably. Our focus is on promoting transparent, time-bound models aligned with public health goals, particularly in areas like infectious diseases, oncology, and rare diseases.



By facilitating dialogue between stakeholders and highlighting global best practices, OPPI continues to support a balanced ecosystem where innovation and access can coexist, delivering equitable health outcomes while sustaining the momentum of scientific progress.

What more can be done to ensure that innovation—whether developed locally or globally—has a real-world impact on Indian patients, particularly those in underserved communities?

To ensure that innovation, whether developed locally or globally, translates into real-world impact for Indian patients, especially in underserved communities, we must focus on building a more inclusive and innovation-friendly ecosystem. This means accelerating regulatory reforms that enable faster access to cutting-edge therapies, strengthening public-private partnerships to expand last-mile delivery, and investing in digital health infrastructure that can bridge the urban-rural care divide. True innovation is not just about discovery; it is also about its ability to reach every patient.

Along with innovation, we must also focus on strengthening healthcare infrastructure, particularly in rural areas. Enhancing primary healthcare facilities, improving diagnostic capabilities, and ensuring that healthcare reaches the last mile are critical steps in ensuring that innovation benefits all patients. OPPI remains committed to shaping policies and partnerships that make this vision a reality across India.

Looking Forward

As India moves toward its healthcare and innovation goals for 2047, how is OPPI aligning its strategy to support national priorities such as Atmanirbhar Bharat and Jai Anusandhan?

By fostering an ecosystem that champions self-reliance through science, innovation, and global collaboration, OPPI is well-poised to make meaningful contributions to India's national priorities. We are focused on strengthening R&D capabilities and supporting policies that enable faster adoption and parallel launch of breakthrough therapies in India. At the same time, OPPI is working closely with stakeholders to enhance regulatory agility, protect intellectual property, incentivize innovators, and invest in future-ready talent. These key pillars empower India to emerge as an innovation-led, end-to-end drug development hub.

Finally, what message would you like to share with OPPI's member companies and partners as the association enters its next chapter?

On this momentous occasion, I want to express my deep gratitude to our member companies and partners for their unwavering commitment and contribution to advancing India's pharmaceutical and healthcare landscape. We have made significant strides in improving patient access to quality medicines, fostering innovation, and driving the industry's growth. The future is full of exciting opportunities; the next chapter demands even greater collaboration and commitment. The healthcare landscape is evolving rapidly, with India poised to lead in global drug discovery, digital health, and equitable access.

As we align with national visions like Atmanirbhar Bharat and Jai Anusandhan, let us continue to be torchbearers of trust, scientific excellence, ethics, integrity, valuing innovation, and policy advocacy. OPPI will remain a strong enabler of this mission, bringing together government, academia, and industry to drive breakthroughs that transform lives in India and set new standards globally. The future of healthcare is being written now, and together, we have the responsibility and the opportunity to shape it meaningfully.



GST Reforms in Healthcare: A Historic Step Towards Affordability and Access

By: Anil Matai, Director General, OPPI

Key Highlights:

- India's new milestone GST reforms advance the government's vision of affordable and accessible healthcare for all
- GST reduced from 12% to nil for 33 lifesaving medicines, from 5% to nil for three critical drugs and from 12% to 5% on all other medicines
- GST reforms extended to medical apparatus, diagnostic kits, surgical devices, and a range of healthcare supplies.
- Lower GST to apply on job-work invoices for contract manufacturing and packaging
- Realigned GST structure reinforces government's effort to keep patient well-being at the core of India's healthcare policy

The Government of India's recent announcement on GST reforms marks a significant turning point for the healthcare and pharmaceutical sectors under the leadership of Hon'ble Prime Minister Shri Narendra Modi ji. The reforms, which focus on reducing the GST burden on medicines, medical devices, and healthcare supplies, are a bold and compassionate step towards making healthcare more affordable and accessible for all Indians.

One of the most transformative aspects of this reform is the decision to reduce GST on lifesaving medicines. In a historic move, 33 essential drugs have been brought down from a 12% GST rate to NIL. Additionally, three critical drugs used in the treatment of cancer, rare diseases, and other severe chronic conditions will also move from a 5% GST rate to NIL. This reduction is far more than a fiscal measure – it is an act of compassion that directly addresses the financial burden faced by patients and their families. For households that often struggle with the cost of prolonged treatment, this measure brings much-needed relief and hope.

GST REFORMS

A STEP TOWARDS AFFORDABLE, INNOVATIVE, AND INCLUSIVE HEALTHCARE

OPPI thanks Hon'ble Prime Minister Shri Narendra Modi Ji and applauds the government's visionary and far-reaching GST reforms that put patients and innovation at the heart of healthcare.

Key Highlights



GST on essential medicines reduced from **12% to 5% or Nil**, easing financial burden on patients.



Greater affordability for long-term treatment of chronic illnesses such as diabetes, hypertension, and cancer.



Job-work in pharmaceutical manufacturing reduced from **12% to 5%**, **lowering production costs** and addressing inverted duty structures.



OPPI | Advancing India's pharma innovation for a healthier tomorrow, bringing patient-centric solutions for unmet medical needs.

हम कल भी थे, हम आज भी हैं, हम कल भी रहेंगे
Bharat Ke Liye



Organisation of Pharmaceutical Producers of India

Besides the above, the job-work in pharmaceutical manufacturing has been reduced from 12% to 5%, lowering production costs and addressing inverted duty structures.

Equally significant is the broader reduction in GST on all other medicines to 5%. This decision will not only lower the overall cost of treatments but also ensure that access to medicines is not restricted by affordability. This will provide greater affordability for long-term treatment of chronic illnesses such as diabetes, hypertension, and cancer. At a time when healthcare demand is rapidly increasing due to rising lifestyle diseases, ageing populations, and the need for preventive care, such a reform can create a more inclusive ecosystem where no patient is left behind.

The reforms also extend to medical apparatus, diagnostic kits, surgical devices, and a wide range of healthcare supplies. These are critical elements of the healthcare delivery chain, both in hospitals and in households. By lowering GST on these items from 12% to 5%, the Government has ensured that affordability is not limited to medicines alone but extends to the entire continuum of care. Patients undergoing diagnostics, surgeries, or home-based treatments will now benefit from lower costs, which can encourage timely interventions and reduce the out-of-pocket expenditure that has long been a concern in India. This move will also encourage wider adoption of modern diagnostic tools and make medicines even more affordable, particularly in Tier-2 and Tier-3 cities.

By realigning the GST structure, the Government has sent out a strong and clear message: patient well-being is at the heart of India's healthcare policy. These reforms are not just about taxation; they reflect a commitment to strengthen India's journey towards universal health coverage. Reducing the financial strain on patients will not only help improve access but will also create greater demand for quality healthcare services, thereby driving further investment and innovation in the sector.

The cascading benefits of this move cannot be overstated. With reduced GST, hospitals and healthcare providers will be in a stronger position to offer affordable care without compromising on quality. Patients will experience reduced treatment costs, families will face fewer financial shocks due to medical expenses, and the overall healthcare

system will become more patient-centric and resilient. At the same time, pharmaceutical companies, diagnostic players, and medical device manufacturers will be encouraged to innovate and expand their offerings, knowing that affordability will not be a barrier to adoption.

This is, therefore, a decisive stride towards building an equitable healthcare system where affordability, access, and quality are seamlessly integrated. It aligns with India's long-term vision of strengthening public health infrastructure and ensuring that economic growth translates into better health outcomes for every citizen.

As an industry body, we wholeheartedly welcome this reform and acknowledge the government's intent to place patient welfare at the center of healthcare policy. It is now incumbent upon all stakeholders including pharmaceutical companies, hospitals, policymakers, and civil society to ensure that the benefits of these reforms reach those who need them most. Collaboration will be key in translating this policy decision into meaningful health outcomes.

The recent GST reforms are a historic milestone in India's healthcare journey. They reflect compassion, foresight, and a deep commitment to the people of India. These reforms complement Ayushman Bharat and PMJAY by expanding private coverage, reducing out-of-pocket expenditure, and driving the mission of Health for All. These reforms are also a progressive step towards achieving the vision of Aatmanirbhar Bharat. The reduction in GST rates will provide a tremendous and unprecedented boost to consumption demand. It is imperative that the industry ensures every rupee saved through the GST reduction is passed on to consumers, thereby maximizing the impact of this reform. We, as part of the healthcare and pharmaceutical ecosystem, remain committed to partnering with the Government and other stakeholders to build a patient-centric, equitable, and resilient healthcare system one where affordability and access are no longer barriers to good health.



Power of Partnerships: Building A Robust Healthcare Ecosystem for India

By: Anil Matai, Director General, OPPI

Key Highlights:

- Partnerships are essential: Collaboration between industry, government, academia, and civil society is critical to drive innovation, expand access, and build resilience in healthcare
- Innovation transforming care: Advances in science and precision therapies are shifting healthcare from reactive to proactive, improving survival and quality of life, especially in NCDs
- Policy as an enabler: Bold government initiatives and regulatory reforms are fostering innovation, strengthening public health, and creating a supportive environment for R&D and manufacturing
- Future priorities: Building a strong IP ecosystem will be vital to balance access and innovation, incentivize discovery, and secure India's global leadership in healthcare
- Shared vision for 2047: OPPI emphasizes that India's healthcare future will be defined by deeper partnerships, sustainable policies, and a patient-centric approach

Partnerships have always been at the heart of progress. Whether it is the collaboration between automobile companies and technology providers to drive the future of electric mobility, or the alliances between fintech innovators and traditional banks to expand financial inclusion, partnerships have shown us the transformative power of working together. In healthcare, too, partnerships are not just desirable; they are essential. From joint research efforts that accelerate drug discovery to public-private initiatives that expand access to care, collaborations are shaping a more resilient, inclusive, and patient-centric healthcare ecosystem.



As OPPI marks 60 years of its journey, it reflects on how far we have come and, more importantly, how we shape the future of healthcare in India. At the heart of this transformation lies one undeniable truth—healthcare cannot evolve in silos. The power of partnerships fuels innovation, drives access, and strengthens the foundation of a robust, patient-centric ecosystem.

Innovation Transforming Care

The past decades have shown how science and research can transform lives. Treatments today are faster, more targeted, and more effective—particularly in tackling non-communicable diseases such as cardiovascular conditions, diabetes, oncology, and obesity. What were once considered chronic and difficult-to-manage diseases are now being addressed with precision therapies that improve survival and quality of life.

This shift from reactive to proactive healthcare is the true value of research. It empowers individuals and communities with better disease management, enabling a more equitable and resilient system.

Why Partnerships Matter

A single stakeholder cannot drive this transformation alone. Partnerships between industry, government, academia, and civil society are critical to bridge innovation, access, and awareness gaps. Collaboration ensures that innovation does not stop at the laboratory but reaches the last mile, touching lives where it matters most. We have seen how partnerships, whether in advancing clinical research, strengthening supply chains, or fostering patient awareness, create collective impact. These alliances enable us to align shared goals: building resilience, ensuring equitable access, and addressing unmet medical needs.

Enabling Policy and Bold Government Initiatives

India's healthcare transformation has been strengthened by bold, visionary policies introduced in recent years. Initiatives such as the Pradhan Mantri TB Mukta Bharat Abhiyaan reflect a strong public health commitment to eliminating infectious diseases. Similarly, the Promotion of Research and Innovation in

Pharma MedTech Scheme is a landmark step towards positioning India as a global hub for innovation. At the same time, regulatory reforms to promote Ease of Doing Business have made the environment more conducive to research and manufacturing.

These initiatives exemplify how government and industry can work hand in hand to achieve shared health goals. We welcome and support such efforts, as they encourage innovation, nurture scientific talent and expand patient access to advanced treatments.

As India aspires towards Viksit Bharat @2047, one of the most critical priorities will be building a robust intellectual property (IP) ecosystem. Strong IP protection incentivizes innovators and ensures that patients continue to benefit from new, life-saving therapies. It is through this balance of access and innovation that India can emerge as a true leader in global healthcare.

Defining The Future Together

The next chapter of India's healthcare story will be defined by our ability to collaborate, innovate,

and adapt. With a strong policy framework, a growing pool of scientific talent, and rising public awareness of health issues, the potential for transformation is immense. However, realizing this potential will require deeper partnerships across sectors.

As the healthcare ecosystem evolves, organizations like OPPI continue to foster collaboration and support innovation. Marking six decades of its journey, OPPI reflects on the power of partnerships as the cornerstone of India's healthcare transformation. Whether addressing NCDs, expanding preventive healthcare, or ensuring access to the latest treatments, partnerships will help bridge gaps and deliver patient-focused solutions at scale.

Healthcare is not just about medicine; but about creating a sustainable ecosystem where science, policy, and compassion converge. Our efforts today, whether in research, policy advocacy, or patient engagement, will define the healthcare landscape of tomorrow. Together, we can ensure that India's healthcare system is stronger, more resilient, and truly equitable and inclusive.





OPPI: RDP Framework Pivotal in India's Innovation Journey

By Anju Ghangurde, Executive Editor, APAC for The Pink Sheet, Citeline

Key Highlights:

- OPPI Director General (DG) Anil Matai underscores the role of RDP in protecting innovators' data from unfair third-party use
- Effective RDP frameworks can stimulate local R&D and attract investments
- While India has made strides in supporting innovation, OPPI seeks dialogue on the protection of undisclosed regulatory data against unfair commercial use
- OPPI DG highlights a spurt in the establishment of India-based Global Capability Centers (GCCs), which are helping reshape the R&D ecosystem

India has made significant progress towards strengthening its intellectual property (IP) regime over the recent past. Still, foreign biopharma firms maintain that elements such as regulatory data protection (RDP) are 'foundational' as the country seeks to join leaders on the global innovation stage.

In a series of social media posts on IP and innovation, Anil Matai, Director General, Organisation of Pharmaceutical Producers of India (OPPI), underlined that RDP is designed to prevent third parties from unfairly using innovators' data for a limited period. This allows innovators to recoup their investments effectively and reinvest in future medical advances.

Such data, he emphasized, is generated through extensive clinical trials, preclinical studies, and rigorous evaluation. It requires years of effort, substantial investment, and "carries significant scientific and regulatory risks".

OPPI Director General pointed out that many countries have implemented effective RDP frameworks to stimulate local R&D and attract investments.

For instance, earlier this year, China put forth a draft version of Implementation Measures and Working Procedures for Drug Clinical Trial Data Protection, opening the proposal to public comment. US multinational law firm, Arnold & Porters, had, at the time, termed the measures as a significant development in China's regulatory data exclusivity protection trajectory, demonstrating the commitment of Chinese regulators' to "aligning with international regulatory norms".

Last year, the consulting company, Copenhagen Economics, estimated that introducing RDP could raise the availability of innovative medicines in China by up to 66%, making the Asian giant a more attractive place for companies to launch their innovative medicines. "As a result, China could also experience an increase in the number of clinical trials by up to 90%," the consultancy added in the study commissioned by PhRMA.

While India has outlined a range of initiatives to encourage R&D, Matai said the OPPI is keen to engage in discussions on protecting undisclosed regulatory data from unfair commercial use.

Patents, RDP Are 'Independent'

OPPI Director General also asserted that patents and RDP are "independent and separate" forms of protection for the biotech and pharmaceutical industries, and both are "required" of WTO members under the TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement.

"There are two essential elements for incentivizing and bringing innovative drugs to the market. Both steps are necessary. Neither is sufficient by itself," he declared in one video blog on social media.

However, data exclusivity (DE) has been a prickly issue in India, which essentially sees it as a TRIPS-plus measure (DE is not currently provided for in Indian regulations). Indian pharma industry experts and pro-health activist groups have long argued that the obligations under Art 39.3 of the TRIPS pertain to confidentiality and data protection, not exclusivity.

Art 39.3 essentially binds member states to protect undisclosed data required to be submitted for approval of pharmaceutical and agricultural chemical products against unfair commercial use, when such products are new chemical entities.

Matai also referred to a shift in the innovative index of the biopharma industry in India, with around 58





biotherapeutics, biosimilars, monoclonal antibody-based drugs, and mRNA vaccines reported to have been greenlighted by the Indian regulator in the last couple of years.

"It is timely to recognize that drug discovery is a long, expensive, and risky path. It is estimated that fewer than 14% of all drug candidates entering phase I clinical trials gain US FDA approval," he stated.

The probability of discovering a new drug that progresses to clinical trials is estimated to be about 35%, per experts, while the likelihood of advancing a drug candidate from Phase I trials to regulatory approval ranges between 9% and 14%. It is estimated that it will cost approximately \$2.5bn to bring a new drug to the market.

A balanced, predictable IP and regulatory framework encourages sustainable development of new therapies and will strengthen India's position as an innovation-driven and innovation-led economy, OPPI Director General added.

Call To Include GCCs in PRIP

Matai also referred to the surge in biopharma firms establishing Global Capability Centers (GCCs) in India, which are pivotal in driving innovation,

improving efficiencies, and contributing to the global competitiveness of the pharma sector.

These GCCs, positioned at the confluence of global expertise and local talent, are emerging across sectors as "de facto second headquarters, with a growing cadre of functional leaders and senior executives based locally who influence and shape global strategic priorities," per ANSR, which helps organizations build, manage, and scale teams through GCCs.

In the pharma space, some of these GCCs in India are emerging as centers of excellence (CoEs), unlocking new technological advancements and leveraging data insights, contributing to the global research ecosystem.

Matai, while reiterating the role of IPR in fostering innovation and scientific research also suggested that GCCs could potentially be included in India's Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) scheme.

Launched with an outlay of INR5,000 crore, PRIP aims to transform India's pharma and MedTech industry by shifting from cost-driven to innovation-focused growth with research at the fulcrum. It aims to promote industry-academia linkages for R&D in priority areas in drug discovery and development and medical devices.



Pharma GCC Wave in India: Co-creating Global Solutions

By: Anju Ghangurde, Executive Editor, APAC for The Pink Sheet, Citeline

Key Highlights:

- The Global Capability Centers (GCC) model is thriving in India, with pharma expanding the scale and scope of operations at these units, signaling a deep integration into global value chains across multiple activities
- Several pharma GCCs are evolving to prioritize innovation and new technologies, tapping into India's extensive talent pool
- 15 pharma GCCs spotlighted in this report are engaged in a range of activities that include integrating data science and technologies like AI, ML, and immersive digital tools as they seek to reimagine the future of healthcare

As the Global Capability Centers (GCC) model gains traction in India, pharma continues to tap into talent in the data analytics, artificial intelligence (AI), and IT segments to help deliver impact across various business and other high-value activities.

More global pharma companies are setting up or expanding their GCCs in India as these centers evolve beyond driving cost efficiencies, focusing on innovation, "agile experimentation", as one expert put it, and new technology, with some sites positioned as Centres of Excellence (COEs).

"With rapid adoption of frontier technologies like Generative AI, immersive digital tools, and connected health systems, these centers are helping reimagine the future of healthcare delivery, research, and patient engagement," said Anil Matai, Director General, OPPI.

The scale and pace of growth of GCCs in India across sectors is striking, with India's finance minister, Smt Nirmala Sitharaman, earlier noting that at least one GCC was set up each week on average in 2024. As of June 30, 2025, 174 Fortune Global 500 companies had GCCs in India employing 950K-plus professionals, per an ANSR report.

The Indian government has assured all requisite support to bolster the GCC ecosystem, urging companies to take these centers to tier 2 and 3 cities and engage talent there.

Here's a snapshot of key activities at pharma GCCs in India:

Amgen has established a technology and innovation hub in Hyderabad, joining a growing list of peers tapping into the Indian talent pool for a range of capabilities and solutions across the pharma value chain. The hub, Amgen India, is expected to accelerate digital capabilities through AI and data science to further advance the US group's pipeline of medicines. Amgen recently announced plans to invest \$200 million through 2025 in Amgen India, with additional sustained investments planned over the coming years.

AstraZeneca's Global Innovation & Technology Centre (GITC) in Chennai has evolved from an IT support center to a major engine propelling the group's digital transformation and technological innovation. Last year, AstraZeneca announced plans to invest INR250 crore to expand its GITC. More than 50% of the company's global IT workforce is based in GITC, which is pivotal in integrating technologies like AI, machine learning, hyper automation, cloud, and cybersecurity into the group's global operations. More widely, the center houses a diverse team across IT Global Business Services, and global operations like supply chain and external supply manufacturing. The group's Bangalore hub contributes to global medicine development across a range of activities.

Bayer's Centre of Excellence in Hyderabad helps ensure faster Phase III and IV clinical trials while contributing to cutting-edge advancements in AI for drug discovery. Its thrust includes enhancing existing products and expediting new introductions in oncology and cardiology. The team also provides real-time analysis of market conditions and insights to global sales representatives. With plans to expand the workforce in the future, Bayer expects

the center to provide meaningful job opportunities that foster healthcare innovation. The German group also has a center in Bengaluru that is part of the Global Business Services (GBS) network, which provides multi-lingual support for a range of capabilities, including intelligent automation, operational excellence, and project management for Bayer across countries in North and South America, Europe, Africa, and APAC. GBS India also partners with global and country programs to provide a scalable pool of on-demand capabilities under the 'As-A-Service' program.

Bristol Myers Squibb's GCC, which was set up in July 2023 with an investment of \$100 million, has rapidly evolved into a fully functioning center with over 2,000 employees and is growing. In the past year, the drug development team established a suite of capabilities spanning clinical development, operations, regulatory, biometrics, and safety, which is already delivering results. In business insights and technology, the teams integrate the power of applications, platforms, AI, data, and analytics to drive value and innovation for patients. BMS also has an R&D site in Bangalore, in partnership with Syngene International, which supports target identification, lead discovery, and optimization, among other activities. Close to 1,000 people are engaged in activities at the R&D center.

The **Lilly Capability Centre India (LCCI)**, now in its tenth year, engages about 3,500 professionals. It continues to play a key role in driving progress in drug development, marketing and sales, digital and technology, operational excellence, and improved patient outcomes worldwide for the US multinational. LCCI Bengaluru drives operations across three key business functions: Lilly Research Laboratories, the Commercial function, and Tech@Lilly. By integrating expertise across these areas, the center enables seamless collaboration with Lilly global teams, driving operational efficiency, scientific innovation, and digital transformation. Lilly is also setting up a new GCC in Hyderabad, which is expected to leverage advanced technologies such as automation, AI, software product engineering, and cloud computing, to deliver cutting-edge solutions to enhance its global operations.

GSK's Global Capability Centre in Bengaluru was established in 2021, and its integrated technology teams support R&D, global supply chain, commercial and medical, and global functions, driving advancements in healthcare, improving patient



Global Capabilities Centres 2025

Enabling an environment for
Innovation and Excellence - Bharat Ke Liye

outcomes, and optimizing operational efficiencies. The GCC leverages technologies like AI, data analytics, and digital twins, making vital contributions across GSK's value chain. The R&D team at the GCC, with satellite units in Hyderabad and Mumbai, has been in India since 1996 and is active across key functions, including safety science, regulatory, biostatistics, clinical operations, and clinical trial transparency.

Headquartered in Hyderabad, with offices in Mumbai and Bangalore, **Johnson & Johnson's** Global Capability Centers provides support and solutions for various functions, including clinical trials, analytical development, data sciences, and technology. For instance, the Discovery Product Development & Supply (DPDS) site in Mumbai is a cornerstone of the group's global R&D center, propelling late-stage product development and plays a key role in areas like addressing health authority queries and sustaining product life cycles management. Similarly, the global development

team focuses on clinical studies, assisting with patient recruitment and submission of health data for pre- and post-market Phase IV studies.

Merck's three GCCs in India - Merck Healthcare R&D, Merck IT Centre, and the newly established Merck's Global Enterprise Services - bring a range of capabilities. The Merck Healthcare R&D India hub supports the global team across disease areas, including oncology, fertility, neurology, and immunology. It enables and supports Global Regulatory Functions, Global Patient Safety, and Clinical Measurement Science among other critical activities across R&D. The Merck IT Centre is a key global technology hub for the German group and delivers cutting-edge tools, services, and digital platforms that enhance research processes from drug discovery to automotive coatings, among other niche capabilities. Global Enterprise Solutions provides innovative, high-quality, and scalable solutions, with a portfolio of services across areas ranging from procurement, innovation and data to strategy and transformation.

MSD, which already has a dedicated Insights, Analytics & Data center in Pune, announced plans earlier this year to establish a Global Technology Centre in Hyderabad. The new center is expected to expand the company's capabilities to develop talent globally in areas such as AI, cloud, data and analytics, cybersecurity, software engineering, product management and SAP to support growing opportunities to leverage digital technology to drive the company's purpose of saving and improving lives. The Pune hub provides a range of near-shore capabilities, including strategic forecasting, application of digital and web analytics, optimizing investment, and providing market performance analysis to MSD's businesses in the Asia-Pacific, Europe, and Africa.

Novartis's GCC, now known as the Novartis Corporate Center (NOCC), in Hyderabad houses operations, the Development India Hub, and Biomedical Research teams. The capability center provides specialist support across multiple functions and competencies such as business services, data, digital and IT, manufacturing supply, finance, risk and compliance. The development hub supports all the global development functions including Global Clinical Operations, technical R&D, patient safety, and pharmacovigilance. Globally, the biomedical research division is a network of scientists, physicians, and business professionals working to propel the discovery of high-value, next-generation drugs, with the India unit supporting the vision.

Novo Nordisk's Global Business Services in India, which started as a transactional service center for finance, patents, and data management in 2007, now functions as an integrated extension to the group's headquarters in Denmark. The Bengaluru site has emerged as a strategic location for highly skilled talent, tech innovation, and a robust startup ecosystem. The center offers solutions in various areas, including finance, medical and regulatory affairs, safety operations, clinical reporting, biostatistics, drug development, and supply chain.

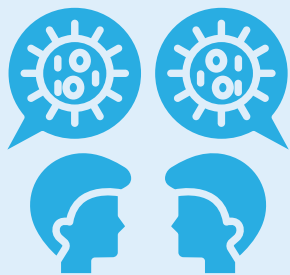
Pfizer's GCCs in India support the US company's operations worldwide and cover a range of critical global functions including worldwide drug safety, global drug development, regulatory, data management, and more recently, the commercial analytics and artificial intelligence center. For instance, the Global Drug Development Centre in Madras, an intrinsic part of Pfizer's global R&D, develops complex sterile injectable formulations and device combination products and is involved in research on small molecules, innovative formulations, and APIs for Pfizer's global markets. The small molecules R&D team supports Pfizer globally across 30 different capabilities and 10-plus products. The new dedicated commercial analytics center in Mumbai expects to serve all of Pfizer's international (ex-US) markets for analytics and insights, with its data analytics experts leveraging data science and AI solutions.

The **Roche** Digital Center of Excellence (CoE) India, which is spread across Pune, Hyderabad, and Chennai, has been playing a key role in integrating data across the patient healthcare journey. It

deploys advanced data analytics tools to help simplify decision-making for clinicians and patients, thereby supporting the larger objective of providing personalized healthcare and improved decision-making capabilities. The digital CoE is expected to emerge as Roche's largest footprint in India in the coming years. The Swiss group's Offshore Development Center (ODC) in Chennai, partnered with ZS Associates, consolidates the existing data and business operations services of all Roche Pharma affiliates at a single location. It brings together a range of capabilities including business data operations, data quality management and global analytical product support.

Sanofi's GCC in Hyderabad, launched in 2019, has evolved from a medical hub to a comprehensive center supporting multiple global functions. With over 2,200 professionals specializing in diverse areas, including R&D, medical, and manufacturing, it is now one of Sanofi's largest global talent amalgams and is projected to double in size. The Hyderabad Hub reintegrates high-value capabilities previously outsourced, strengthening Sanofi's operational backbone and fostering innovation in R&D, quality management, digital transformation, and intelligent automation. In addition, Sanofi's Manufacturing Sciences, Analytics & Technology (MSAT) center in Goa has developed expertise in various dosage forms, including capsules, suspensions, and nano formulations. R&D activities at the Goa site and ongoing research at this CoE cover areas such as new product development, lifecycle management of established products, troubleshooting for industrial sites, and product harmonization, among other functions.

Takeda's Innovation Capability Center (ICC) in Bengaluru, the first such center in Asia, is part of the Japanese group's global network of ICCs, aimed at strengthening its digital capabilities with internal talent to drive data and digital transformation across the company. The ICC team expects to understand and anticipate business needs and to shape strategies that improve patient experiences by leveraging data-driven insights. By the end of 2025, Takeda expects the ICC to have a diverse team of over 750 skilled employees, including software engineers and AI specialists. The ICC also hopes to create a robust ecosystem of partnerships with academia and the tech community, fostering innovation and driving global impact from India.



Rising Tide of NCDs: Why the Future Demands a New Era of Pharma Innovation

By: Anil Matai, Director General, OPPI

Key Highlights:

- NCDs as India's top health burden: Now the leading cause of illness and death, impacting both urban and rural populations
- Changing risks: Aging, urbanization, and lifestyle shifts drive early-onset, atypical NCDs and rising multi-morbidity
- Innovation in care: New therapies like SGLT2 inhibitors, Semaglutide, and Tirzepatide are transforming diabetes, obesity, and cancer management
- Future potential: Innovation promises earlier diagnosis, lower mortality, better quality of life, and more equitable access
- Call to action: Urgent need for cross-sector collaboration, stronger R&D, and adaptive regulation to drive India-specific solutions

Non-communicable diseases (NCDs) have now overtaken infectious diseases as the leading cause of illness and death in India. An estimated 5.8 million Indians die from NCDs each year; approximately one in four Indians faces the risk of dying from an NCD before reaching the age of 70¹. The most prevalent NCDs include cardiovascular diseases (CVDs), diabetes, cancers, obesity, and chronic respiratory conditions, each of which brings with it a significant burden of morbidity and long-term care. These conditions are no longer confined to urban or affluent populations; they are increasingly affecting rural areas and economically vulnerable groups, creating a widespread health crisis.

India's rapidly evolving demographic profile, characterized by an aging population, accelerated urbanization, and shifting lifestyle patterns, is reshaping the country's healthcare needs. Sedentary behaviors, unhealthy diets, rising stress levels, and pollution contribute to a growing burden of NCDs. This shift has expanded the number of people at risk and identified the types of NCDs being diagnosed across age groups and geographies.

The Emergence of New NCD Variants

As the population's genetic predispositions intersect with new environmental exposures and lifestyle risks, we are witnessing the emergence of atypical disease patterns. There is growing evidence of early-onset diabetes, unusual forms of cancer, and other evolving NCD presentations. For example, A pan-India registry found that over 25% of youth-onset diabetes cases were Type 2, despite patients being under 25; incidence among those <19 was ~0.5 per 100,000². T2DM prevalence in the 35-44 age group rose from 18.3% to 22.5% over a decade, prediabetes from 13.5% to 21.5%—signaling an atypical shift toward younger, lean populations.

Moreover, the healthcare system is increasingly encountering cases of multi-morbidity, where patients suffer from two or more chronic conditions simultaneously. This trend complicates diagnosis, treatment protocols, and long-term disease management, pushing for more nuanced and integrated approaches to care.

Advances In Pharmacological Treatments

The pharmaceutical sector has made significant strides. We have witnessed the development of powerful new classes of medications and innovative combination therapies, each targeting specific pathways and disease mechanisms. Take type 2 diabetes as a prime example: the introduction of SGLT2 inhibitors has transformed disease management—offering not just improved glycemic control but also meaningful reductions in cardiovascular risk³. These advancements are translating into longer, healthier lives for millions. Similarly, targeted therapies for drug-resistant cancers and emerging treatments for complex metabolic disorders signal that the pharmaceutical sector is actively responding to the evolving nature of NCDs.

Similarly, drugs like Semaglutide and Tirzepatide not only regulate blood sugar levels but also help with weight loss. These drugs, introduced in India by Novo Nordisk and Eli Lilly respectively, have gained momentum in India, especially to combat obesity, which is one of the major health crises we are facing currently.

Vision For the Future

As we look ahead, pharmaceutical innovation promises immense transformative potential for India's NCD landscape. Reduced mortality and disability, through earlier diagnosis and more effective treatment, will directly result from continued innovation.

We can also expect a significant improvement in quality of life with the help of minimally invasive therapies that allow patients to manage conditions without extensive hospital stays or adverse side effects. Perhaps most importantly, pharma innovation will help bridge the care gap between urban and rural populations, ensuring equitable access to advanced treatments across socio-economic groups.

A Strategic Call-To-Action

The rising tide of NCDs, combined with demographic change and urbanization, presents a healthcare challenge that demands nothing short of a new era in pharmaceutical innovation.





To usher in this new era, we must foster cross-sectoral collaboration—bringing together industry, academia, regulators, and healthcare providers. Research and development (R&D) investments must be scaled up, focusing on India-specific innovations. Simultaneously, regulatory frameworks must evolve to fast-track the development and approval of novel therapies without compromising safety and efficacy.

If we act with urgency and intention, the rising wave of NCDs can become a defining moment in our healthcare journey—not as a threat, but as a turning point that accelerates medical breakthroughs, reduces systemic inequities, and reinforces India's position as a global hub for life sciences innovation.

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To our readers, thank you for your continued engagement. We look forward to sharing more insights and industry updates in the next issue.

Warm regards,

Asawari Sathaye

Director Communications and Patient Advocacy, OPPI

About OPPI

The Organisation of Pharmaceutical Producers of India (OPPI) established in 1965, represents the research-based global pharmaceutical companies in India. OPPI has been an integral part of the healthcare journey of the country. We remain committed to supporting the nation's healthcare objectives, putting patients at the core of all decision making and collaborating with all stakeholders to find sustainable solutions to realize the collective vision of Health for All.

Our member companies have been serving the country's healthcare ecosystem since pre-independence and continue to remain committed to patient safety and providing quality care in the future as well. As an association, our advocacy decisions, patient commitment and work are always keeping the country first and we embody the spirit of working for 'Bharat Ke Liye'; driven with innovation to find solutions for unmet medical needs, collaboration with government stakeholders, and co-creation with partners coming together to address the nation's healthcare challenges. We are committed to the Hon'ble Prime Minister Shri Narendra Modi-ji's clarion call of 'Jai Vigyan and Jai Anusandhan'.

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EVERY PATIENT EVERY FAMILY BENEFITS FROM GST REFORMS IN HEALTHCARE

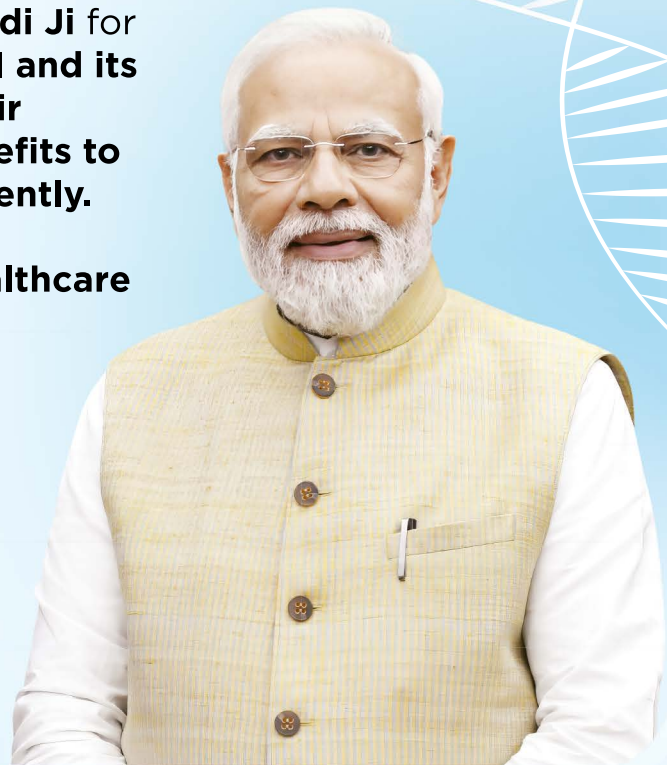


Organisation of Pharmaceutical Producers of India

The Organisation of Pharmaceutical Producers of India (OPPI), thanks **Hon'ble Prime Minister Shri Narendra Modi Ji** for this bold and timely reform. **OPPI and its member companies reaffirm their responsibility to deliver the benefits to patients efficiently and transparently.**

GST Reforms for Affordable Healthcare Effective September 22, 2025

- GST reduction on life-saving drugs (cancer, rare diseases, severe chronic diseases):
12% → 0%
- GST reduction on other essential medicines:
12% → 5%



OPPI | Advancing India's pharma innovation for a healthier tomorrow. Bringing patient-centric solutions for unmet medical needs.

**हम कल भी थे, हम आज भी हैं, हम कल भी रहेंगे
Bharat Ke Liye**

