60 YEARS POWER OF PARTNERSHIP

OPPI

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Organisation of Pharmaceutical Producers of India

OPPI NEWSLETTER

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Foreword

Anil Matai
Director General, OPPI

Welcome to the eighth edition of the OPPI Newsletter!

With the last issue of this newsletter, the Organization of Pharmaceutical Producers of India (OPPI) entered its seventh decade of engagement with India's healthcare ecosystem. At the OPPI Annual Day, we celebrated this milestone while looking ahead to India's next chapter of moving beyond being the world's generic pharmacy to becoming a global leader in value-driven pharmaceutical innovation.

Nitin Paranjpe, Non-Executive Chairman of Hindustan Unilever Ltd., delivered the Chief Guest Address at the OPPI Annual Day 2026. This was followed by a leadership dialogue between Mr. Paranjpe and Bhushan Akshikar, President OPPI. The fireside chat on "AI in Healthcare" was moderated by Sampath Srinivasan, Senior Director, Commercial Data & AI Excellence, Novo Nordisk, and featured Prashant Tandon, Co-Founder and CEO, Tata 1mg, and Prashant Warier, Co-Founder & CEO at Qure.ai as the panelists. The evening concluded with the OPPI Annual Awards.

The 'Power of Partnerships' is perhaps more essential in healthcare than any other industry. OPPI's commitment to partnership has been further exemplified by a new strategic collaboration with the National Institute of Pharmaceutical Education and Research (NIPER), Rae Bareli.

With respect to regulation and policy, this newsletter explores the findings of a parliamentary panel on the drugs regulator's risk-based inspection program for strengthening compliance, and on India's patent opposition framework. Both are working well, broadly speaking, but the authors also highlight some key issues: significant manpower gaps in the regulatory workforce in the former and the way pre-grant opposition proceedings continue to lead to delays and uncertainty in the latter.

We are living at a time of great geopolitical uncertainty. At the time of publication, a fragile ceasefire was still in place in the Persian Gulf. This issue of the newsletter takes a look at what the results of the war have been for the Indian pharmaceutical industry and what to expect if the current state of play holds.

We hope this edition offers useful context and encourages continued engagement on the issues shaping India's healthcare future.

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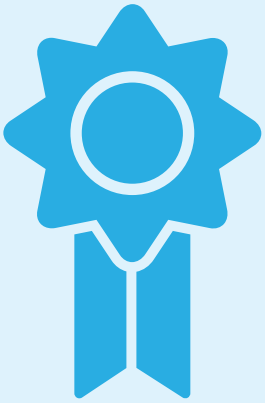

OPPI Annual Day 2026

Key Highlights:

- India needs to move up the value chain and become more of a pharmaceutical innovator
- Artificial Intelligence is moving beyond pilot projects and is increasingly being deployed across research, diagnostics, clinical operations, and commercial functions
- Partnerships, innovation, and shared responsibility will be key drivers in shaping the future of healthcare in India

The OPPI Annual Day is a formal evening where OPPI members gather to celebrate their achievements and acknowledge the work done in various business fields including Marketing, Sales, HR, Communications, Sustainability, Medical Regulatory and others.

Anil Matai, Director General OPPI, welcomed everyone to the event and highlighted the significance of the occasion as OPPI marked 60 years of contribution to India's healthcare and pharmaceutical ecosystem.

Reflecting on the event theme, "Power of Partnerships," he emphasised that progress in healthcare is driven through collaboration and collective action. He underlined the importance of partnerships between industry and government, industry and academia, between industry associations, and with key stakeholders in building a stronger and more resilient healthcare ecosystem.

Mr. Matai called for the pharmaceutical industry to move beyond its identity as the 'Pharmacy of the World' towards becoming a global innovation-led hub and encouraged stakeholders to work with a shared sense of purpose towards the vision of a healthier India and a future-ready pharmaceutical sector.

For more details about the OPPI Annual Day 2026, scan the QR code

Bhushan Akshikar, President OPPI, set the context for the evening by reiterating OPPI's core commitment to patient welfare throughout its 60-year journey. He highlighted how OPPI and its members have significantly shaped the pharmaceutical landscape by keeping patients at the core of all decisions and ensuring access to innovative medicines.

Mr. Akshikar further highlighted the growing opportunity for India to emerge as a global biologics hub and stressed the need for long-term investments in research, clinical trial infrastructure, and regulatory alignment to support this ambition. Emphasising the need to build a robust innovation ecosystem, he noted that strengthened research, collaboration, and scientific advancement in India will enable the country to move from Pharmacy of the World to the 'Research Powerhouse'.

He called for greater industry participation in shaping the future of healthcare innovation. He also established the tone for the discussions by reinforcing the need for partnerships, innovation, and shared responsibility in shaping the future of healthcare in India.

Nitin Paranjpe, Non-Executive Chairman of Hindustan Unilever Ltd., delivered the Chief Guest Address, drawing on over four decades of professional experience and the century-long journey of Unilever in India to share insights on building resilient and successful businesses in complex and evolving markets.

Nitin Paranjpe
Non-Executive Chairman, Hindustan Unilever Ltd.

Citing examples from Unilever's India journey, including the launch of low-cost shampoo sachets and the Wheel detergent business model, he demonstrated how innovation tailored to local market needs enabled large-scale growth and strong business outcomes.

He also highlighted the importance of resilience, patience, and integrity in operating within dynamic markets like India and called upon the pharmaceutical industry to help reshape global perceptions of India by highlighting the country's potential as a centre for innovation and growth. He expressed optimism about India's future and the pharmaceutical industry's ability to play a transformative role in advancing healthcare and innovation globally.

Nitin Paranjpe and **Bhushan Akshikar**

The Leadership Dialogue between Nitin Paranjpe and Bhushan Akshikar focused on leadership, resilience, organisational culture, innovation, and the evolving role of technology in business and healthcare.

Mr. Paranjpe reflected on the importance of adaptability, long-term commitment, and continuous learning in navigating changing business environments. The discussion also explored the importance of continuous learning and self-improvement. The discussion also addressed the growing impact of technology on organisations and customer engagement. The conversation reinforced the need for adaptive leadership, innovation-led growth, and strong organisational cultures to navigate an increasingly dynamic and technology-driven environment.

Nitin Paranjpe (Left) and **Bhushan Akshikar** (right) in an engaging discussion

The fireside chat on "AI in Healthcare" was moderated by Sampath Srinivasan, Senior Director, Commercial Data & AI Excellence, Novo Nordisk, and featured Prashant Tandon, Co-Founder and CEO, Tata 1mg, and Prashant Warier, Co-Founder & CEO at Qure.ai as the panelists. The discussion explored the rapidly evolving role of Artificial Intelligence across healthcare, pharmaceuticals, and life sciences, beyond experimentation to real-world applications across research, diagnostics, clinical operations, and commercial functions.

The discussion also underscored the importance of trust in building and scaling AI-driven healthcare businesses. The speakers further explored India's growing position within the global healthcare AI ecosystem. The speakers envisioned a more integrated and personalised healthcare ecosystem enabled by AI, where real-time data sharing and coordinated care models can support better long-term patient outcomes.

An engaging conversation between **Prashant Warier** (Left), **Prashant Tandon** (Centre) and **Sampath Srinivasan** (Right)

The evening concluded with one of the most anticipated segments of the event: the OPPI Annual Awards. These awards recognize excellence and outstanding achievements across among OPPI members. This year, a total of 22 winners were recognised pacross the following 9 categories:

1. Ranjit Shahani Memorial OPPI Award for Excellence in Patient Centricity 2025-26

Winner:
Roche Products (India) Pvt. Ltd.

Runner Up:
Novo Nordisk India Pvt. Ltd.

2. Dr. H. R. Nanji Memorial OPPI Marketing Excellence Award 2025-26 - Existing Pharma Product

Winner:
Johnson & Johnson Private Limited for existing pharma product – Darzalex

Runner Up:
Novartis Healthcare Private Limited for existing pharma product – Kryxana

3. Dr. H. R. Nanji Memorial, OPPI Marketing Excellence Award 2025-26 - New Pharma Product

Winner:
Eli Lilly & Company (India) Pvt. Ltd. For new pharma product – Mounjaro

Runner Up:
AstraZeneca Pharma India Ltd. For new pharma product – Lokelma

4. OPPI Healthcare Communications Award 2025-26

Winner:
Novo Nordisk India Pvt. Ltd.

Runner Up:
Johnson & Johnson Private Limited

Runner Up:
Roche Products (India) Pvt. Ltd.

5. OPPI Diversity & Inclusion Award 2025-26

Winner:
Novartis Healthcare Private Limited

Runner Up:
Eli Lilly & Company (India) Pvt. Ltd.

6. OPPI HR Excellence Award 2025-26

Winner:
Eli Lilly & Company (India) Pvt. Ltd.

Runner Up:
MSD Pharmaceuticals Pvt. Ltd.

Runner Up:
Novo Nordisk India Pvt. Ltd.

7. OPPI Medical Excellence Award 2025-26

Winner:
AstraZeneca Pharma India Ltd.

Runner Up:
Pfizer Limited

8. OPPI Sales Force Excellence Award 2025-26

Winner:
Novartis Healthcare Private Limited

Runner Up:
Bayer Pharmaceuticals Private Limited

Runner Up:
Novo Nordisk India Pvt. Ltd.

9. OPPI Sustainability Excellence Award 2025-26

Winner:
Sanofi India Ltd.

Runner Up:
ACG

Runner Up:
Pharmapoint (India) Pvt. Ltd.

Parliamentary Panel Backs Risk-Based Inspections, AI-Powered Pharmacovigilance

Anju Ghangurde, Executive Editor of APAC, Citeline

Key Highlights:

- Indian Parliamentary panel endorses risk-based inspections, cites "remarkable efficacy", and pushes for a permanently institutionalized framework.
- Time-bound recruitment and training targets for states recommended as a prerequisite for future fund disbursements.
- Regular pharmacovigilance inspections of marketing authorization holders among key measures proposed to strengthen oversight.

A parliamentary panel in India has commended the drugs regulator's risk-based inspection (RBI) program for strengthening compliance but warned that significant manpower gaps in the regulatory workforce could undermine the efficiency and quality of surveillance and enforcement.

The panel, headed by Member of Parliament Ram Gopal Yadav, called for the RBI framework to be "permanently institutionalized, standardized, and fully digitized" across all state drug control offices. This will ensure that crackdowns on non-compliant manufacturing practices remain "consistent, transparent, and data-driven" nationwide, so as to avoid public health crisis such as the contaminated cough syrup incident that occurred in the state of Madhya Pradesh, the panel stated as part of its wider 300-plus page report.

"The committee commends the remarkable efficacy of the RBI initiative, noting that out of 1,230 inspected units, a staggering 1,140 required stringent regulatory actions, such as stop production orders (SPOs) and license suspensions," the panel said in its report on India's Department of Health and Family Welfare (DHFW)'s Demands for Grants for 2026-27.

The Central Drugs Standard Control Organization (CDSCO), working with state regulators, had launched RBIs of drug manufacturers and testing firms in December 2022, prioritizing targets based on risk indicators including non-standard-quality (NSQ) drug records, compliance history, complaints, and product criticality.

Drugs Controller General of India (DCGI) Rajeev Raghuvanshi had noted at an industry summit earlier this year that RBIs had been completed at over 1,200 domestic sites, triggering actions ranging from SPOs to warning letters based on the severity of violations. RBIs were continuing with "the same rigor, motivation and purpose", he added. The regulator had also issued around 850 corrective and preventive action (CAPA) notices over roughly 10 months, alongside administrative actions against manufacturers flagged for producing NSQ drugs.

The parliamentary committee in its report maintained that the RBI initiative had provided valuable insights into the "ground reality" of manufacturing practices and had led to relevant corrective actions, resulting in noticeable improvements in the regulatory framework.

India is also deliberating enabling greater transparency in RBIs including public disclosure of certain specifics. A proposal to display the "brief details" of firms inspected under RBI, along with the recommendations of the inspection team, had been put forth before the country's Drugs Consultative Committee (DCC) for its perusal. The DCC, which reviewed the matter, recommended that a subcommittee be constituted to deliberate on the feasibility and legal implications of displaying such details on the CDSCO website.

Human Resources Framework

The panel also spotlighted workforce gaps as a critical vulnerability, underlining that even state-of-the-art testing infrastructure becomes "futile" without "sufficient trained analysts and uncompromising enforcement mechanisms". It recommended that the Strengthening of State Drug Regulatory System (SSDRS) 2.0 scheme make future funding contingent on states meeting specific, time-bound targets for recruiting and upskilling regulatory and technical personnel.

On vacancies, the panel pointed out that, out of the sanctioned strength of 613 posts under the drugs vertical, 257 were vacant, including 186 vacancies for drugs inspectors. While the delays in recruitment were partly due to litigation and the pending revision of recruitment rules, and proposals for filling several posts had been forwarded to the Union Public Service Commission (UPSC), the large number of vacancies could weaken regulatory efficiency, quality surveillance, and enforcement activities.

The panel urged the DHFW to expeditiously fill vacant posts in coordination with the UPSC and overhaul the regulator's human resources framework–encompassing specialized recruitment, structured training, and clear career progression–to keep pace with the rapid growth and technological evolution of the pharma and medical devices sectors.

Some capacity-building efforts are already underway. At the aforementioned industry summit, DCGI Raghuvanshi said the CDSCO expects to add around 1,500 personnel focused on "internal review of scientific matters, mainly the clinical side". This comes on the back of India's Union Budget 2026-27, in which Finance Minister Nirmala Sitharaman specifically proposed strengthening the CDSCO to meet global standards and approval timelines through a dedicated scientific review cadre and specialists.

Institutionalising Pharmacovigilance Inspections

The parliamentary committee also acknowledged India's progress under the National Pharmacovigilance Programme but flagged underutilised funds and patchy resource deployment as risks to expanding the Adverse Drug Reaction Monitoring Centre (AMC) network beyond its current strength of 1,150 and adopting advanced data-mining technologies for signal detection.

It recommended "institutionalising" regular pharmacovigilance inspections of marketing authorization holders, faster expansion of AMCs to underserved regions, and stronger awareness and training programs for healthcare professionals and consumers to ensure timely reporting of ADRs. Besides drugs, India has bolstered monitoring of adverse events related to medical devices via its materiovigilance program.

A June 3 circular has since urged all stakeholders to ensure a robust pharmacovigilance system is established and maintained in accordance with the provisions of the Drugs & Cosmetics Act, 1940, its associated Rules, and the NDCT Rules, 2019. Additionally, officials from the CDSCO/state licensing authorities/union territories may assess compliance with these requirements during routine inspections and other regulatory activities, the circular said.

The parliamentary panel also called on the department to harness AI and advanced data analytics for signal detection and risk assessment, arguing this would strengthen patient safety and consolidate India's standing in global pharmacovigilance.

India's growing contribution to the field is already evident. As of February 10, 2026, India had uploaded 1,079,698 Individual Case Safety Reports (ICSRs) to VigiBase—the World Health Organisation (WHO)'s global adverse event database—ranking it eighth among global contributors and reflecting the maturing sophistication of its pharmacovigilance system. India has also been designated a WHO collaborating centre for pharmacovigilance in public health programmes.

Reforming India's Patent Opposition Framework: A Case for Speed, Transparency, and Predictability

Dr. Malathi Lakshmikumaran, Executive Director and Practice Head, IPR division, and Anurag Pandey, Principal Associate, Lakshmikumaran and Sridharan Attorney

Key Highlights:

- India's pre- and post-grant patent opposition system is vital for screening patents for validity
- Opposition proceedings have led to delays and uncertainty, hindering innovation
- Despite recent reforms, repeated pre-grant opposition continues to cause problems
- Clear, time bound windows for pre grant opposition are an essential reform to the system

India's patent opposition system plays a crucial role in maintaining patent quality and protecting public interest. The Patents Act, 1970 allows challenges to patent applications at two stages. Under Section 25(1) of the Act, any person may file a pre grant opposition after publication but before grant. Under Section 25(2), a post grant opposition can only be filed by a "person interested" (as defined under Section 2(1)(t) of the Act) within one year from the publication of grant. This dual model of pre-grant and post-grant opposition gives India a robust validity-screening mechanism.

At its core, the opposition system serves two legitimate purposes. First, it allows third parties to bring relevant prior art and technical objections to the attention of the Indian Patent Office (IPO), thereby improving patent quality. Second, it protects competition and access by preventing weak or overbroad patents from becoming enforceable. However, opposition proceedings in India are now often associated with prolonged delays, repetitive filings, and procedural uncertainty. This has led to growing concern among innovator companies, competitors, and policymakers alike.

Why Reform Is Necessary

The urgency of reform is clear from official data. The annual report 2024-25 published by the IPO shows that pre grant and post grant oppositions are no longer rare events. According to the said report, IPO received 239 pre-grant oppositions and disposed of 711 pre-grant oppositions during the year 2024-25. Further, a total of 101 post-grant oppositions were filed in the year 2024-25 and 44 post-grant oppositions were disposed during the year. In commercially important areas, such as pharmaceuticals and chemicals, opposition has become part of routine patent strategy.

The Patents (Amendment) Rules, 2024 introduce measures to reduce delays in opposition proceedings. For instance, in pre grant oppositions, Rule 55(3) now requires a prima facie assessment by the Controller to filter out frivolous oppositions, and the applicant's reply period has been cut from three months to two under Rule 55(4). For post grant oppositions, timelines for constituting the Opposition Board have been shortened. However, procedural changes alone may not be enough to address deeper, systemic delays.

Judicial Assessment of Abuse in Pre Grant Oppositions

In practice, Controllers have often continued to issue notices in pre grant oppositions mechanically, without recording clear reasons for satisfaction of the prima facie standard, undermining the intent of the 2024 reforms. Courts have begun criticising this approach.

In Merck v. Controller of Patents, concerning Merck's Acalabrutinib application (408/CHENP/2014), the Madras High Court (12 February 2026) criticized the Patent Office for issuing notices in successive pre grant oppositions without meaningful scrutiny, allowing the patent term to be eroded through procedural delay. The Court stated that all pending oppositions be heard together within a fixed timeline and any new pre grant opposition shall only be entertained if it genuinely raises new grounds and satisfy the prima facie test. The ruling reinforces that opposition must be a disciplined process, not a tool for obstruction. This application has remained pending for nearly 12 years due to the filing of repeated and frivolous pre grant oppositions.

In another case, application No. 201717025098 was opposed through multiple pre grant oppositions; although all opposition proceedings, including hearings, were concluded in 2024, the matter continues to remain pending before the IPO, despite nearly nine years having elapsed since filing. These instances collectively highlight systemic delays caused by repetitive pre grant oppositions.

Another overlooked issue is misuse of the fee structure. Lower fees for natural persons incentivize proxy or *benami* pre grant oppositions by individuals lacking any real stake in the invention. Such fee arbitrage not only distorts the process but also results in revenue loss to the government and wastes limited administrative resources of the Patent Office.

Conclusion

Opposition proceedings profoundly shape innovation outcomes. In sectors like pharmaceuticals, prolonged pre grant and post grant oppositions can erode the effective patent term, rendering grants commercially meaningless.

India need not dilute its robust opposition framework, which is justified by public interest considerations. What is required is clear and time bound windows for pre grant opposition, meaningful prima facie screening through reasoned orders, filtering of repetitive filings, and strict timelines. The real choice is not between robust opposition and innovation, but between a system that allows uncertainty and delay to undermine patent rights and one that functions as a transparent, predictable, and time bound mechanism, capable of protecting both genuine innovation and the public interest.

India's Biopharma Moment - If We Get The Ecosystem Right

Krishna Sarma, Managing Partner, Corporate Law Group

Key Highlights:

- The Government of India is seeking to position India as a global biomanufacturing hub
- India currently lags behind in innovation, research institutions, and R&D intensity
- India must take the cost discipline it has applied in generics manufacturing to developing novel drugs
- Five "Pancha Bhutas" are outlined that can help India make this advance

Over the past five years, the Government of India has increasingly framed economic growth around innovation. Initiatives such as the Anusandhan National Research Foundation aim to steer research across domains, including healthcare. Programmes such as Atal Innovation Mission, Startup India, and the IndiaAI Mission similarly seek to strengthen entrepreneurship, research capacity, and adoption of emerging technologies.

The Biopharmaceutical Sector: Challenges and Initiatives

Biopharmaceuticals is among the most innovation-intensive sectors. Moving a new drug from discovery to market is high-risk, slow, and capital-intensive–requiring long time horizons, specialised talent, and strong translational capabilities.

Since the 1980s, India has been called the "Pharmacy of the World" for its scale and quality in generics and vaccines. Yet novel drug and vaccine discovery has lagged. In August 2023, the government launched a scheme to promote research and innovation in the Pharma MedTech sector to accelerate investment across the R&D ecosystem.

In the Union Budget 2026–27, the government announced Bio-Pharma SHAKTI (Strategy for Healthcare Advancement through Knowledge, Technology & Innovation), a five-year programme with an allocation of ₹10,000 crore. It aims to strengthen the biologics and biosimilars ecosystem, reduce import dependence, and catalyse a private sector-led innovation environment–supporting the ambition of positioning India as a global biomanufacturing hub. Notably, the recent India Pharma Summit centred around the theme "Discover in India: Leapfrogging Life Sciences Innovation," reflecting a renewed focus on indigenous drug discovery.

Global Trends and India's Position

India ranks 39th in the World Intellectual Property Organization's (WIPO) Global Innovation Index 2024, which benchmarks countries across inputs (investment and institutions) and outputs (technology and impact).

The Nature Index 2025, a proxy for research quality and collaboration, highlights the scale of leading ecosystems: eight Chinese universities feature in the global top ten. India's premier research institution, IISc Bengaluru, is ranked 175th–underscoring India's opportunity to expand research depth, output, and global influence.

The Nature Index 2025 also places six biopharma companies (Roche, AstraZeneca, Merck, Johnson & Johnson, Pfizer, and Lilly) among the top corporate research leaders. IQVIA's 2026 reporting notes that ~73 novel active substances (NASs) were launched worldwide in 2025 and projects 65–75 NASs annually during 2025–2029. While leading Indian pharma companies report sizeable pipelines, much R&D remains concentrated in generics, biosimilars, and incremental improvements.

India's R&D intensity–gross expenditure on R&D (GERD) of roughly 0.66% of GDP–remains low relative to leading innovation economies. South Korea, with GERD above 4% in recent years, illustrates what sustained R&D investment can enable over time.

How can India realise its potential for discovering in India and leapfrogging life science innovation?

To "Discover in India" at scale, the country must pair an India-first innovation agenda with globally benchmarked quality, predictable and world class regulations, meaningful IP, and faster development

cycles. India can also apply the cost discipline honed in generics manufacturing to novel drugs and biologics–driving affordability without compromising ambition.

China is a useful reference point for ecosystem-building. In the last decade it has combined regulatory reform, higher clinical-trial activity, larger R&D outlays, and deeper pools of risk capital with stronger patenting and global licensing partnerships, helping companies move up the value chain in areas such as oncology and metabolic disease.

Five "Pancha Bhutas" can help India make this leap:

1. **Reset scientific temper:** Strengthen the spirit of inquiry (Article 51A(h)) across education and public discourse and reinforce evidence-based policy and decision-making.
2. **Build job-ready biopharma talent:** Modernise curricula for discovery-to-development, regulatory science, quality, and IP, while building specialised skills in platforms such as cell and gene therapy, RNA, radioligands, and AI/ML-enabled drug discovery.
3. **Make academia–industry collaboration the default:** Expand industry-linked doctoral pathways, strengthen technology transfer, and build clusters around IITs, IISc, and NIPERs with clear, workable IP frameworks that support translation.
4. **Catalyse private risk capital for translation:** Complement public programmes with conditions that attract venture capital–credible IP, predictable regulation, and strong proof-of-concept–especially in platform areas such as AI/ML, gene editing, mRNA, and synthetic biology.
5. **Strengthen IP and strengthening regulatory ecosystem:** Bring patent laws in line with international best practices, improve patent quality and timely granting of them, strengthen enforcement predictability, and consider providing regulatory data protection mechanisms that support innovation. Align India's pharmaceutical regulations with global standards and establish single-window clearances and regulatory sandboxes for biotech and AI products.

If these fundamentals are built with urgency and consistency, India can complement its manufacturing leadership with credible discovery, faster translation, and globally competitive biopharma innovation.

Public Health

India's Innovation Ambition: Building a Value-Driven Pharma Ecosystem

Regulatory Data Protection - the missing link in India's Innovation Journey to Viksit Bharat

By Anil Matai, Director General, OPPI

Key Highlights:

- India needs to move up the pharmaceutical value chain, from generics to next-generation therapies
- The PRIP scheme and the Biopharma SHAKTI initiative have laid the basis for this move
- Regulatory data protection is still lacking and there is no level playing field between first and subsequent new drug applications
- China and South Korea provide examples worthy of study

For decades, India has rightfully worn the mantle of the 'Pharmacy of the World'. By mastering the complexities of generic manufacturing and supply chain resilience, our pharmaceutical industry has become a cornerstone of global healthcare, supplying 40-50% of generic demand in the US and 25-30% in the UK.

As we celebrate World IP Day 2026, I take this opportunity to call out our Hon'ble Prime Minister's vision of Viksit Bharat @ 2047 and his clarion call of 'Jai Anusandhan' (Hail Research). OPPI believes that to realize the ambition of reaching a $350 billion pharmaceutical export target by 2047–a vision central to the Viksit Bharat roadmap, it is important that India transitions to inventing next-generation therapies that are innovation-led, high-value products. Moving up the value chain will not only enable higher economic returns and global competitiveness but also position India as a key player in cutting-edge biopharmaceutical innovation.

The Government of India has already laid a fertile ground with the Promotion of Research and Innovation in Pharma MedTech (PRIP) scheme, which carries a financial outlay of 5,000 crores. This, alongside the proposed Biopharma SHAKTI initiative, signals a clear intent towards becoming a Vishwa guru in pharmaceutical innovation. These schemes are designed to de-risk R&D, but they cannot function in a vacuum – it would require advanced R&D capabilities, strong intellectual property (IP) frameworks, and globally harmonized regulatory systems.

India introduced a product patent regime in 2005 to comply with its obligations under the World Trade Organization Agreement on TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights). This marked a significant shift from its earlier process patent system and laid the foundation for increased investment in research and development, encouraged multinational participation, and signaled India's intent to integrate more deeply into the global innovation ecosystem. However, the actual enforcement of IP remains a complex challenge, particularly regarding the protection of the massive data investments required for modern medicine. Herein lies the "missing link": regulatory data protection (RDP). Without a robust framework to safeguard clinical trial data, our journey to becoming a global innovation leader remains fundamentally incomplete.

Under the current New Drugs and Clinical Trials Rules, 2019, a subsequent applicant can often gain market entry for a "new drug" by merely demonstrating bioequivalence to an innovator's product. This creates an environment where the innovator–who has committed to a development lifecycle often costing between $1 billion and $3 billion–sees their investment effectively relied upon the moment they receive marketing approval. Clinical trials and other regulatory data generation represent the most capital-intensive and risky components of this lifecycle.

OPPI welcomes the recent CDSCO recognition that there is lack of level playing field between first and the subsequent new drug applicants. Providing a predictable window of RDP (10 years for small molecule drugs and 12 years for biologics that require the generation of regulatory data to demonstrate safety and efficacy for marketing authorization) from the date of marketing approval in India against disclosure and unfair commercial use is one of the ways of ensuring level playing field in the drug approval process and provide economic incentives to inventors and investors to invest risk capital in inventive activity.

The MSME pharma sector in India has also started recognizing that without protection of the regulatory data, initiatives to encourage research and innovation in India may not fully achieve their intended impact. Recently, Entod Pharmaceuticals, which is a known name in the MSME pharma sector too, echoed the same opinion when it stated that many significant pharmaceutical innovations, such as repurposed medicines, new drug delivery systems, improved formulations, and new therapeutic uses that cannot be patented or protected in practice may remain exposed to rapid imitation despite substantial clinical research investments.

An "India-first" innovation push–built on high quality, faster development cycles, and cost discipline honed in our generics ecosystem–can help India leapfrog

into leadership in novel biologics while keeping cutting-edge treatments affordable.

China has moved from low-cost generics manufacturing to the front ranks of pharmaceutical innovation, with a growing share of drugs in global testing now originating in its labs. This shift has been powered by regulatory reforms, AI-enabled discovery, sustained R&D investment, expanded clinical-trial capacity, global licensing partnerships, stronger IP regime and rapid growth in patent filings (including first-in-class drugs).

China is also signaling a further strengthening of its IP and regulatory framework. Although China was obligated upon WTO accession to provide six years of regulatory data protection, implementation has been uneven. More recently, China's National Medical Products Administration (NMPA) issued draft implementing guidelines proposing six years of data protection for innovative drugs. Alongside other reforms, this points to closer alignment with international regulatory norms.

South Korea is another case study worth emulating. It leveraged sustained R&D investment to build technological competitiveness and industrial capability, moving from relatively low-income levels in the 1960s to joining the ranks of trillion-dollar economies by 2004. South Korea provides six-plus years of regulatory data protection for new-drug clinical trial data–covering both new chemical entities and biologics–and prevents competitors from relying on the originator's data to obtain marketing authorization.

If India aims to match–or surpass–this trajectory, our approach to IP and regulatory data protection must become explicitly strategic, not merely reactive. Predictable, credible safeguards will give domestic and global researchers the confidence to invest, collaborate, and innovate, supporting a healthier, more prosperous, and truly innovative Viksit Bharat.

Public Health

OPPI Collaborates with NIPER Rae Bareli to Advance Research Excellence

Key Highlights:

- OPPI has formed a strategic collaboration with NIPER-R to support pharmaceutical research, including scholarships
- Partnership strengthens industry-academia collaboration to drive translational research and innovation
- OPPI members will deliver knowledge sessions, workshops, and mentorship engagements
- Initiative aligns with Government focus on strengthening pharmaceutical education and research

The Organisation of Pharmaceutical Producers of India (OPPI) has announced a strategic collaboration with the National Institute of Pharmaceutical Education and Research, Rae Bareli (NIPER-R), to support and promote outcome-oriented pharmaceutical research in India.

As part of this initiative, OPPI will award gold and silver scholarships to two meritorious research scholars currently in their third or fourth year at NIPER-R. These scholarships will be extended as research grants to support ongoing projects that demonstrate strong potential to address real-world healthcare challenges.

The selection of scholars will be undertaken by an expert panel, which will evaluate applications based on the quality, relevance, and translational impact of the research work. The collaboration aims to incentivize scientific excellence while encouraging research that can meaningfully contribute to advancing patient care and healthcare innovation in India.

This partnership underscores the growing importance of industry-academia collaboration in building a robust and future-ready pharmaceutical ecosystem. As part of this engagement, OPPI will actively support the development of a 'Professor of Practice' framework, enabling experienced industry professionals from its member companies to engage directly with students and researchers at NIPER-R.

Through this initiative, subject-matter experts from OPPI member companies will deliver curated knowledge sessions, workshops, and mentorship engagements for students. These interactions will provide valuable real-world insights, bridge the gap between academic research and industry expectations, and equip students with the practical understanding needed to translate scientific discoveries into impactful healthcare solutions.

Anil Matai, Director General, OPPI, said, "India stands at a pivotal moment in its journey to become a global hub for pharmaceutical innovation. To realize this ambition, we must invest not just in infrastructure, but in ideas–and the young minds that power them. Our collaboration with NIPER Rae Bareli is rooted in the belief that research must go beyond academic pursuit to deliver tangible health outcomes. Through these scholarships, we aim to empower promising researchers to push the boundaries of science, accelerate innovation, and develop solutions that can transform patient lives not just in India but globally. This initiative is also aligned with the Government's continued focus on strengthening pharmaceutical education and research, including the recent push to establish three new NIPERs and upgrade seven existing institutions, as highlighted by the Department of Pharmaceuticals. This collaboration further builds on OPPI's longstanding commitment to advancing research and development in India, with several member companies already partnering with NIPER institutions across the country to foster innovation and talent development.

Shubhini Saraf, Director NIPER-R, said, "At NIPER Raebareli, we are committed to nurturing scientific talent that can drive meaningful innovation in healthcare. This collaboration with OPPI marks an important step in strengthening the bridge between academia and industry. By supporting meritorious scholars and enabling direct engagement with industry experts, this initiative will enhance the quality, relevance, and impact of research undertaken at our institute. We believe such partnerships are critical to preparing the next generation of researchers to address evolving healthcare challenges in India and beyond."

About OPPI

The Organisation of Pharmaceutical Producers of India (OPPI) established in 1965, represents the research-based global pharmaceutical companies in India and proudly marks 60 years of its contribution to the country's healthcare ecosystem. 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

External

West Asia Crisis: Indian Pharma Navigates A Perfect Storm

Anju Ghangurde, Executive Editor of APAC, Citeline

Key Highlights:

- US-Iran MoU to end the war bodes well for the world and pharma but requires a lasting solution around the Strait of Hormuz to fully restore supply chain buoyancy.
- Pharma firms are absorbing the pressure for now, but supply chain uncertainties and fluctuations in input prices have led to some contract-related stress.
- Indian government steps in with duty relief on critical petrochemicals.

With a framework to end the Iran war in place, pharma hopes that supply chain strain and fluctuations in input costs–particularly in markets like India – will ease though much will depend on how reliably shipping lanes through the Strait of Hormuz remain open and operational.

The Hormuz bottleneck had choked energy supply lines critical to India's active pharmaceutical ingredients (API) sector, setting off what some experts earlier termed a 'systemic supply shock'. Shipping disruptions around the Strait of Hormuz had triggered massive freight diversions, with carriers rerouting cargo. That in turn had a cascading effect on logistics costs across global supply chains.

While the US-Iran Memorandum of Understanding (MoU) to end all hostilities has raised optimism of restoring normalcy around the Strait of Hormuz, experts have warned that any further disruptions could slow the recovery of stretched supply chains with ripple effects threatening key export markets. For now, most drug makers in India appear to be absorbing the pressure, while some raw material prices have tapered from the initial highs in April, even as overall trends remain somewhat mixed.

The US-Iran MoU sets the base for a 60-day window to negotiate a final deal aimed at ending the war.

Solvent Prices, Government Intervention

Prices of solvents such as isopropyl alcohol (IPA), acetone, methanol, acetonitrile, THF, and toluene had seen significant increases ranging from 15% to 40% around March-April with factors such as energy inflation, refinery shutdowns, petrochemical feedstock costs, and liquefied natural gas (LNG) scarcity contributing to the surge, though prices had generally declined from that level by June. An industry expert told Citeline that June prices of acetone, for instance, are in the region of INR160 per kg, lower than INR190 per kg in April, but still way higher than the INR88 per kg price line of January 2026. In the case of acetic acid, which can be used to make acetic anhydride, a key ingredient for paracetamol that has significant import dependence, trends were different. Prices rose from INR40 per kg in January to INR56 in April but have since held somewhat steady at that level. Industry is monitoring the situation closely.

On June 8, *Business Standard* reported a senior Indian government official as saying that concerns around solvent and API supply constraints had been addressed.

Notably, the Indian government, apprised of the developing situation, had intervened in April, extending a customs duty exemption on critical petrochemical products–including acetic acid and methanol–until June 30 in response to the supply chain strain.

Anil Matai, director general of the OPPI, termed the government's decision as a "highly timely and strategic intervention" amid ongoing geopolitical uncertainties and supply chain disruptions. "This targeted relief will help mitigate volatility, support operational continuity, and enable companies to sustain their focus on patient-centric innovation and access," Matai stated.

The April duty exemption was aimed at assisting a range of sectors dependent on petrochemical feedstock and intermediates, including textiles, pharmaceuticals, and automotive components, and at containing cost pressures on downstream sectors, ensuring supply stability. A review is underway for a possible extension of the duty exemption, per media reports.

API Prices

The strain on solvent supplies and allied inputs had also translated into higher prices for APIs across a broad range of molecules. Prices of ibuprofen, diclofenac sodium and ciprofloxacin, had earlier risen by 18-30%, but have since stayed at those levels. For example, ibuprofen prices were in the region of INR680 per kg in January and shot up to INR800 per kg in April and has held steady at that level so far in June, the industry expert indicated. Some API prices are trending lower currently, though.

The price pressure is not confined to Asia. BASF Pharma Solutions, for instance, announced on March 30 that it would raise prices on excipients and selected APIs by up to 20%, with the increase taking effect immediately or as existing contracts permitted. On April 27, BASF said it would further increase prices for additives in plastic applications in response to the "substantial increases" in raw material, energy, and logistic costs due to the Middle East conflict.

Complicating matters for India is the reliance more widely on China for about 70% of API supplies. While policy efforts to reduce this reliance are underway, experts say a material impact from such measures was likely only in the medium term.

Containing rising input costs could be crucial, given that the ripple effects could be felt way beyond. India and the EU account for more than half of all APIs used in US prescription drugs. About 90% all US prescriptions filled by US residents are dispensed as generics and 47% of those are filled with products made by Indian companies.

Among other inputs, packaging materials were also under pressure with polyethylene prices estimated to have almost doubled over the recent past. PVC bottles, aluminium blister foil, glass vials, and rubber stoppers had all earlier seen price increases ranging from 20% to 45%, partly due to energy-intensive production and using crude-linked polymers. While the January-April period saw moderate-to-high price inflation, the primary market for packaging materials in the current period appears much more resilient, the aforementioned expert said.

Contract Stress

Supply chain uncertainties and volatility in input prices had also led to some contract-related stress, though for now pharma in India is absorbing the shocks.

An industry veteran pointed to how certain large Indian suppliers of antiretrovirals, faced with an 18-20% jump in input costs, had sought to renegotiate contracts, but couldn't make much headway. "For now, they have little option but to absorb the impact," he explained.

Others indicated that it was an "evolving scenario", reinforcing the fact that the initial response in such situations is typically to try and cushion the blow through inventories and existing purchase agreements on hand.

"Only if it prolongs beyond a certain point [are there] discussions with customers on whether the cost increases can be passed on to the pricing. We've seen a supportive environment six years back when the pandemic hit. We have not yet entered that kind of zone ... we are probably at the cusp of it," the CEO of the Indian firm said during its Q4 FY26 earnings call.

Key Interactions

Meeting with the Hon'ble Union Minister Shri Jagat Prakash Nadda ji

The OPPI team met with the Honb'le Union Minister for Health and Family Welfare and and the Minister of Chemicals and Fertilizers Shri Jagat Prakash Nadda ji along with the Secretary of Pharmaceuticals Shri Manoj Joshi to discuss key priorities for strengthening India's innovation-driven healthcare ecosystem, including fostering innovation, improving patient access, strengthening the policy environment, and enabling ease of doing business.

Meeting with the Hon'ble Union Minister Shri Piyush Goyal ji

The OPPI industry delegation met with Hon'ble Union Minister of Commerce and Industry Shri Piyush Goyal Ji at his office along with senior officials from Department for Promotion of Industry and Internal Trade. The deliberations focused on increasing collaborations and partnerships between Government and Industry on Innovation and Access.

Meeting with ICMR

The OPPI delegation met with the Indian Council of Medical Research (ICMR) team, led by Director General Dr. Rajiv Behl, to discuss opportunities to strengthen India's clinical trial ecosystem as part of the Biopharma Shakti Initiative

Acknowledgements

We would like to extend our sincere thanks to everyone who contributed to this edition of the OPPI Quarterly Newsletter. This issue reflects a collective effort to examine India's healthcare journey with depth, balance, and perspective.

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- **Dr. Malathi Lakshmikumaran,** Executive Director and Practice Head, IPR division, and **Anurag Pandey,** Principal Associate, Lakshmikumaran and Sridharan Attorney, for highlighting India's pre- and post-grant patent opposition system

To our readers, thank you for your continued engagement. We look forward to sharing further insights and perspectives in the next edition as India's healthcare landscape continues to evolve.

Warm regards,
Asawari Sathaye
Senior Director, Communications and Access, OPPI

60 YEARS POWER OF PARTNERSHIP

About Power of Partnership

2025-26 marks a defining chapter for the Organisation of Pharmaceutical Producers of India (OPPI) – our Diamond Jubilee. Since its inception in 1965, OPPI has been the voice of the research based global pharmaceutical companies in India, advocating policies that encourage scientific innovation while ensuring that the patients are always at the centre of all decisions.

For six decades, OPPI has been at the forefront of shaping the Indian pharmaceutical landscape, fostering a patient-centric ecosystem grounded in innovation, ethics, access, and collaboration.

OPPI's journey has been defined not only by scientific and industrial progress but by the Power of Partnership.

Our legacy is rooted in partnerships with multiple stakeholders, i.e., with policymakers to drive regulatory clarity, with academia to nurture innovation, with the media to promote public understanding, and with our member companies to maintain the highest standards of ethics and compliance. This landmark is a reaffirmation of our commitment to India's future in healthcare.

About OPPI

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#BharatKeLiye ***#PowerofPartnership***

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POWER OF PARTNERSHIP

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