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Organisation of Pharmaceutical Producers of India

From volume to value: Partnerships shaping the future of Indian pharmaceuticals

November 2026



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Foreword

India's pharmaceutical industry has long played an important role in expanding access to quality and affordable medicines, both in India and across the world. The opportunity now is to build on this foundation by moving further up the value chain, strengthening innovation while continuing to deliver affordable medicines at scale.

Realizing this opportunity may depend on how effectively stakeholders across the ecosystem work together. Industry, government, academia, technology, investors and healthcare providers each bring distinct capabilities. Bringing these strengths together can help accelerate research, strengthen manufacturing and digital capabilities and create more effective pathways for innovation to reach patients.

This report highlights the potential of partnerships across the pharmaceutical ecosystem and identifies areas where greater collaboration can help India strengthen its position in global healthcare. At its heart is a simple idea: partnerships create the greatest value when they translate collective capability into meaningful outcomes.

As OPPI marks 60 years of representing the research-driven pharmaceutical industry in India, this is also a moment to reflect on how far the ecosystem has come and, importantly, the opportunity that lies ahead. This milestone reinforces our commitment to fostering collaboration and advancing healthcare in India.

As we look towards 2047, India has the opportunity to emerge not only as a trusted global supplier of medicines, but as an increasingly important contributor to pharmaceutical innovation. Achieving this ambition may require shared commitment, sustained collaboration and, above all, a continued focus on improving health outcomes for patients.



Anil Matai,
Director General
OPPI

EY
Foreword

India's pharmaceutical industry has emerged as a significant force in global healthcare, earning recognition for its scale, reach as well as its contribution to affordable medicines. From supplying nearly half of all generic prescriptions in the United States to strengthening access to essential medicines at home and keeping them affordable for hundreds of people, India's pharmaceutical industry today contributes about 1.7% to the country's GDP and accounts for nearly 6% of merchandise exports.*

The success has been built on entrepreneurship, as founders took on the world's most demanding markets; on sustained investment in process science and quality, which has given India more US FDA-approved plants than any country outside the US; and on supportive policies, from the patent regime that allowed a generics industry to grow to export promotion and production-linked incentives.

But what brought India here may not, on its own, keep it ahead. The small-molecule generics space is crowded and prices keep falling. Global pipelines are shifting to new modalities, such as biologics, antibody-drug conjugates and cell and gene therapies, where India's presence is still small. AI and technology are changing how medicines are discovered, developed and made. And many of the diseases that weigh most heavily on India still see too little new drug discovery.

It is therefore imperative for India to embark on a journey from volume to value: earning its growth from innovation, complex products and the outcomes its medicines deliver, not just the volumes it supplies. This journey is central to India's ambition of becoming a developed nation by 2047.

To understand what it may take, we studied countries that have made this journey, including the United States, Ireland and China. None of them made the shift through companies acting alone. In each case, six partnerships drove success: **Industry and Government; India and World**; **Industry and Investors**; **Industry and Academia/Research institutions; Industry and Technology providers; and Industry and Health ecosystem**.

Together, these engines take ideas from research to market and, ultimately, to patients.

India already has many of the building blocks: a strong manufacturing base, deep scientific and technology talent, established research institutions, a growing start-up ecosystem and one of the world's largest digital health backbones. This report sets out how stronger partnerships can bring these together.

Success should be measured not by the number of partnerships created, but by what they deliver and how they feed each other. Predictable regulation and patient capital draw in investment; academic science becomes products; global partners bring Indian innovation to the world; and health systems that pay for value reward the next round of discovery. Together, they can create a virtuous cycle that turns India's scale and capabilities into greater innovation, value and health impact, helping the country achieve its 2047 vision.



Anirudh Roy Popli,
Partner & Leader, Life Sciences,
EY India

* IMD and CII, India Future Readiness Indicator 2025, via The Tribune, December 2025. https://www.tribuneindia.com/news/business/indias-pharma-sector-emerging-as-global-generics-powerhouse-need-to-scale-ai-usage-beyond-rd-report

Preface

For the last 60 years, the Organisation of Pharmaceutical Producers of India (OPPI) has been a partner in India's pharmaceutical journey, playing an important role in its growth and evolution. Since 1965, it has brought industry, government, academia, scientists, healthcare stakeholders and global institutions to the same table, helping turn dialogue into policy, knowledge into action and collective ambition into progress.

This has been anchored in three interconnected pillars: Innovation, Access and Ease of Doing Business. OPPI has supported innovation by promoting research-driven ecosystem, stronger scientific capabilities and policies that enable new therapies and technologies. It has advanced access by keeping equitable healthcare and patients at the centre of industry and policy dialogue. And it has advocated Ease of Doing Business by promoting regulatory clarity, predictable policy and an enabling environment for sustainable growth. All these have played an important role in shaping India's healthcare ecosystem.

Over six decades, this approach has translated into action. Early engagement on patent and pricing frameworks evolved into evidence-led advocacy on intellectual property, affordability, research and regulatory reform. OPPI supported global standards and good practices, strengthened public understanding through initiatives such as OPPI Medical Hour and Know Your Pill, encouraged scientific excellence through awards, and created platforms for industry, academia and government to exchange ideas. Through sustained global partnerships, OPPI has helped connect India's pharmaceutical ecosystem with international standards and practices.

The Power of Partnerships therefore reflects how OPPI has operated for six decades and a bridge between its proven legacy and the next partnership agenda. As India moves from scale towards greater value and innovation, the six partnership engines explored in this report connect industry with government, global partners, investors, academia and research institutions, technology providers, and the wider health ecosystem. They provide a practical architecture to carry the three pillars forward: accelerating Innovation, widening Access, and strengthening Ease of Doing Business.

As India looks towards Viksit Bharat 2047, the opportunity is to translate OPPI's six decades of partnership-led progress into the collaborations needed for the future. By connecting science, policy, technology, manufacturing, capital, health systems and patients, a new partnership economy can convert India's scale into better outcomes, stronger resilience and shared prosperity for Viksit Bharat. This report brings together perspectives from across this ecosystem to build a shared view of where Indian pharma can aspire to be in the years ahead, and how the power of partnerships can help turn that ambition into progress. In doing so, it seeks to provide a collective direction for the journey ahead, shaped by the stakeholders who will ultimately make it possible.





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60 YEARS POWER OF PARTNERSHIP

Bharat Ke Liye: 60 years of conviction, collaboration and continuity

For 60 years, OPPI has championed the principles of a shared vision for healthcare, bringing together voices that enrich understanding: policymakers and scientists, industry leaders and academia, global perspectives and local priorities. It has helped shape policy and contemporary reforms while recognizing scientific excellence and innovation to advance affordability and access. Some of its key successes through the decades include:

1967-1975

- Contributed to the Patents Act and Pricing Policy through the Hathi Committee, aligning industry growth with public health priorities.
- Joined the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) to align Indian research with global standards.
- Contributed to the 5th Five-Year Plan, balancing industrial advancement with healthcare accessibility.

1976-1985

- Initiated industry engagements to address challenges in drug pricing and the rationalization of import duties on bulk drugs and intermediates.
- Represented industry perspectives before key government committees, including the Dagli Committee on Drug Policy, helping shape approaches to pricing, technology transfer and industrial participation.
- Advanced professional and postgraduate medical education in collaboration with the Indian Academy of Paediatrics and other specialist associations.

1986-1995

- Expanded focus on quality assurance and international credibility as Good Manufacturing Practices (GMP) were introduced in the mid-1980s.
- Made evidence-led recommendations on Drugs (Prices Control) Order, 1987 (DPCO); joined other leading organizations in Joint Council to form a unified policy voice.

1996-2005

- Strengthened policy advocacy through submissions on the Patents (Second Amendment) Bill.
- Collaborated with other industry organizations to develop a Consensus Document on the New Drug Policy, creating the first unified industry representation in India's history.

2006-2015

- Launched the Health Index of States, offering a comprehensive view of regional performance.
- Expanded quality frameworks to include Cold Chain Guidelines, Good Laboratory Practices (GLP) and Anti-Counterfeiting Guidelines.
- Recognized excellence in science and healthcare through the Young Scientist Award (2012), OPPI Healthcare Access Award (2014), Women Scientist Award and Lifetime Achievement Award (2014-15).

2016-2025

- Advocated on key policy issues, including the implementation of Rule 101 of India's New Drugs and Clinical Trials Rules, 2019, the Rare Disease Policy and over-the-counter (OTC) medicines.
- Supported India's COVID-19 response by improving access to essential medicines and strengthening hospital readiness, diagnostic systems and health infrastructure.
- Launched the Bharat Ke Liye campaign, reinforcing a collective commitment to align science, policy and public good with the Viksit Bharat 2047 vision.

Looking toward India@2047, OPPI envisions resilient and inclusive healthcare, harnessing research, policy, industry expertise, advanced technologies and robust supply chains to enable equitable care nationwide.


27TH ANNUAL GENERAL MEETING
SEPTEMBER 29, 1993
Chief Guest: Shri Eduardo Faleiro
Hon'ble Minister of State for Chemicals & Fertilizers


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Chapter 1

Volume built the industry; value is likely to shape its future

1.1 How India became the pharmacy of the world

Over the last five decades, India has built the world's third-largest pharmaceutical industry by volume. It supplies about 20% of global generic medicines and about 60% of UNICEF's vaccines, and exports to 191 countries.[1]

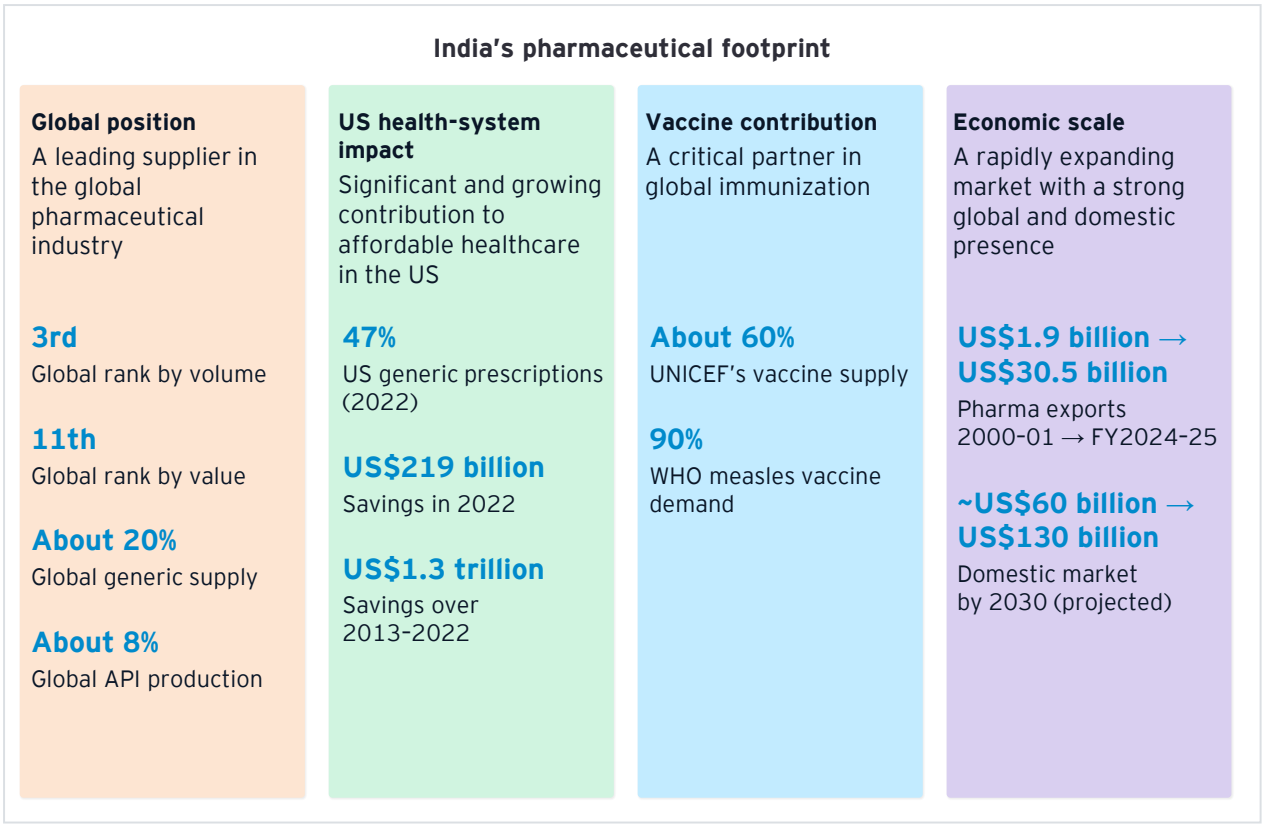
India's place in global health rests on three things: **breadth, affordability and reliability**.

- **Breadth:** India makes about 60,000 generic brands across 60 therapeutic categories and has about 500 active API makers, so it can supply almost any essential medicine.[2]
- **Affordability**: Indian generics have brought down the cost of treatment for patients and health systems in rich and poor countries alike. In the US, medicines from Indian companies saved an estimated US$219 billion in 2022 alone.[3] In developing countries, Indian supply underpins childhood immunization and HIV treatment.
- **Reliability:** India hosts more US FDA-approved plants than any country outside the US, and half its pharma exports go to highly regulated markets such as the US and Europe. During the COVID-19 pandemic, the world relied on India for both medicines and vaccines.

In short, a large share of the world's patients depends on India for the medicines they need.

[1] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2243248&reg=48&lang=2
[2] https://static.pib.gov.in/WriteReadData/specificdocs/documents/2026/mar/doc2026321831401.pdf
[3] https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/us-india-medicine-partnership

The figure below shows the scale of that role:



Sources: PIB, March 2026 (industry turnover; Economic Survey 2025–26); IQVIA Institute (US prescriptions and savings).

1.2 India's pharma journey: What got us here and what comes next?

The journey to become the "Pharmacy of the world" was shaped by deliberate policy choices and the entrepreneurship they unlocked:

- **The Patents Act, 1970**: Abolished product patents on medicines so that drugs would be available at reasonable prices.[4] Indian companies learned to develop new, lower-cost ways of making medicines already sold abroad. This built deep skills in chemistry and process engineering, and a domestic industry that came to lead its home market.
- **The global generics opportunity**: The US Hatch-Waxman Act of 1984 created the regulatory and commercial pathway for generic medicines through abbreviated approvals and bioequivalence. India's 1991 economic reforms opened the industry further to global markets, enabling Indian companies to build regulatory capabilities and compete in the expanding US generics market.
- **Strength in chemistry and manufacturing**: India built deep capabilities in chemistry, APIs, process engineering and scale-up, supported by a large US FDA-approved manufacturing base and growing expertise in complex generics and biologics.
- **Entrepreneurship and risk-taking**: Founder-led companies, built on India's strengths in chemistry and manufacturing, invested ahead of demand, challenged patents to be first to market with generics in the US, and expanded boldly overseas, turning policy opportunities into a globally competitive industry.

[4] https://www.undp.org/india/publications/five-years-product-patent-regime-indias-response

The model that built India's pharmaceutical industry—making proven medicines at lower cost and greater scale—is reaching its limits. Three shifts underscore the need to move beyond volume-led growth:

Pressures on India's pharmaceutical industry



Health spending is rising worldwide. With governments and payers prioritizing medicine affordability, there is pressure on generic margins.

Competition is intensifying both in India's crowded domestic market and from abroad. For example, Bangladesh and Southeast Asian countries are building generics capability.

R&D is moving towards biologics, ADCs, peptides, and cell and gene therapies, which make up about 35% of oncology trials. Many of the largest drugs losing patents this decade are biologics. These opportunities need capabilities beyond those that built India's generics leadership.

India's next ambition

In line with the Government of India's ambition[5] to move from the "Pharmacy of the world" to a "hub of innovation", and from "volume" to "value" leadership, India's next phase can build on its existing strengths around three ambitions:

- **Maintain leadership in affordable medicines**, extending scale and affordability into complex generics, biologics, and new modalities.
- **Capture a greater share of global value** through R&D, CRDMO services, advanced manufacturing and development partnerships.
- **Develop innovative medicines for India and the world**, building deeper scientific capabilities and translating them into next-generation therapies and better health outcomes.

> "The opportunity now is not to move away from scale, but to build on this foundation and move up the innovation curve.
>
> *– Senior leader, global pharmaceutical MNC*

> "India has considerable capability in traditional small molecules. But when you start looking at areas such as peptides, oligonucleotides, biologics or ADCs, the manufacturing footprint available in India at scale is much more limited.
>
> *– CXO and Leader, Indian CDMO*

[5] https://www.pmindia.gov.in/en/news_updates/pm-shares-an-article-on-indias-growing-strength-in-the-pharma-sector/

The value gap in numbers

Volume vs. value

47%
Of US generic prescriptions supplied by Indian companies

15%
Of total US medicine spending accounted for by all generics

A small slice of world trade

~20%
India's share of global generic supply

~2.5%
India's share of world pharmaceutical export value

Low reinvestment

5%–8%
Leading Indian firms: research as a share of revenue

≈20%
Research as a share of sales (approximate) for large global innovators

Sources: IQVIA Institute (2022 data); WITS; ITC Trade Map; IMD and CII, December 2025.

1.3 How the leading countries create value and what can we learn?

The countries that lead on value earn more from each unit they make. They do it in one of three ways: by owning the innovation, providing high-value services or hosting high-value production.

1. Owning the innovation	2. Providing high-value services	3. Hosting high-value production
Most value comes from new drugs (NCEs and NBEs) discovered and developed by their own companies, which keep the returns from IP. E.g., US, Switzerland, Germany, UK, Japan	Global companies choose these hubs to make their patented medicines and biologics. They invent little of what they make, but capture value through high-end manufacturing, attracted by stable policy, tax, talent and infrastructure. E.g., China (small molecules and new modalities), South Korea (biologics)	Global companies choose these hubs to make their patented medicines and biologics. They invent little of what they make, but capture value through high-end manufacturing, attracted by stable policy, tax, talent and infrastructure. E.g., Ireland, Singapore



Success stories: Partnerships as one of the most important enablers behind the value

Route 1: Owning the innovation

The US: An ecosystem that keeps renewing itself

The US remains the world's largest source and market for pharmaceutical innovation. US companies accounted for 46% of the 634 novel drugs approved globally over the past decade—twice the output of European-headquartered companies. US-headquartered companies also sponsored 35% of global clinical trial starts in 2024—the largest national share.[6]

This leadership is sustained by partnerships that move science from public research through start-ups and clinical development to global markets:

- **Universities pass discoveries to companies**: Federal funding through the National Institutes of Health supports basic biomedical research, while the Bayh-Dole Act of 1980 lets universities own and license inventions made with federal funding.
- **Capital and large companies scale the best ideas:** Venture capital funds start-ups, and large companies license or acquire their drugs. US biotech start-ups raised US$37.2 billion[7] of venture capital between January 2025 and September 2026, about two-thirds of the global total. Emerging biopharma companies originated 65% of new medicines launched during the 2020–2024 period.[8] Large companies then pay for and scale the best of them.
- **A regulator supports innovation:** Many regulators see the FDA as the global gold standard, and it has built tools that speed innovations to patients. For new medicines that treat serious conditions with unmet needs, including new chemical entities (NCEs) and new biological entities (NBEs), the FDA offers expedited programs: fast track, breakthrough, accelerated approval and priority review programs that give earlier and more intensive FDA support. Innovators use them widely. In 2025, half of the 46 novel approvals used expedited routes.[9]
- **Partnerships at work:** Government with academia (NIH funding, Bayh-Dole), academia/start-ups with capital providers and large companies (licensing and acquisition), and industry with a trusted regulator.

Route 2: Providing high-value services

China: From contract services to a source of new medicines

China has built the world's leading base for innovative contract research, development and manufacturing (CRDMO) work, joining global companies' molecules early and staying with them through to commercial supply. China's CRDMO market reached about US$25 billion in 2023, or 12.7% of the global market, more than three times India's US$7 billion (3.6%).[10] Chinese CRDMOs are involved in about half of all clinical-stage drugs worldwide.[11]

What helped China win the lion's share of innovative CRDMO work:

- **One partner from discovery to commercial supply**: Chinese CRDMOs built integrated platforms that cover every stage, so a molecule that enters at discovery can stay with the same partner through trials and into commercial manufacturing.
- **Betting early on new modalities**: Chinese CRDMOs invested in biologics, bispecifics, ADCs, peptides and oligonucleotides before demand peaked.[12]
- **Bringing home experienced talent**: CRDMOs recruited senior scientists back from global pharma companies to lead their platforms,[13] supported by a deep pool of engineers that enables fast design-test-learn cycles.

Partnerships at work: Government reform of the regulator, global deals that share long-term returns, and capital for biotech.

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[6] https://www.pmindia.gov.in/en/news_updates/pm-shares-an-article-on-indias-growing-strength-in-the-pharma-sector/

[7] US biotechs take lion's share of $54.5B VC money raised since 2025 - BioSpace

[8] Expanding Options for Emerging Biopharma in the U.S.: A Decade of Change | IQVIA

[9] CDER approved 46 novel drugs in 2025, half for rare diseases | RAPS

[10] India becoming an attractive option for global pharmaceutical supply chain: Macquarie Report and https://www.sailife.com/wp-content/uploads/2025/10/frost-sullivan-industry-report.pdf

[11] ValueQuest, Decrypting the DNA of CRDMOs, January 2025 (Frost & Sullivan data, 2023). https://www.valuequest.in/wp-content/uploads/2025/01/VQ-Deep-Dive-Decrypting-the-DNA-of-CRDMOs.pdf

[12] PR Newswire Asia, "WuXi Biologics reports record 2025 annual results", March 2026. https://en.prnasia.com/releases/global/wuxi-biologics-reports-record-2025-annual-results-526507.shtml

[13] PharmaBoardroom, "The WuXi alumni: how China's top CDMO fosters the next generation of biotech leaders", April 2026. https://pharmaboardroom.com/articles/the-wuxi-alumni-how-chinas-top-cdmo-fosters-the-next-generation-of-biotech-leaders/

Route 3: Hosting high-value production

Ireland: A long partnership between government and global companies

Ireland has built one of the world's leading pharmaceutical manufacturing hubs without relying on a large home-grown pharma industry. **Ireland exported about €139 billion of pharmaceuticals in 2025 (partly reflecting stockpiling ahead of US tariffs) with most of it coming from the newest kinds of medicines such as GLP-1 peptide ingredients, mAbs and vaccines.**[14] That is about five times India's pharma exports in FY25. Its innovation lies in manufacturing; it has kept moving up to the newest and most complex kinds of medicines. Five factors have contributed to this, namely:

- **A long partnership with global companies**: Its development agency, IDA Ireland, has courted global companies since the 1960s. Pfizer opened at Ringaskiddy in 1969 and MSD at Ballydine in 1976. Today, the top 15 global pharma companies operate in Ireland.[15]
- **A stable tax and incentive regime**: Predictable policy over decades, including an R&D tax credit raised to 35%[16] in Budget 2026, has drawn more than €15 billion of biopharma investments over the last decade.[17]
- **Making the world's newest medicines at scale**: Over five decades, Ireland has moved from small-molecule manufacturing into biologics and advanced therapies. Today, about a third of Ireland's 75 major pharma plants are large scale biologics manufacturing and aseptic fill and finishing facilities.[18] Ireland is also building capabilities in gene therapies, viral vectors and ADCs.
- **Skills built through partnerships**: The National Institute for Bioprocessing Research and Training (NIBRT) brings government, academia and industry together to build skills in biologics, cell and gene therapies and mRNA. It trained 4,900 people in 2025[19].



[14] https://www.irishexaminer.com/business/economy/arid-41804225.html
[15] Goodbody_Pharma-in-Ireland.pdf
[16] Goodbody_Pharma-in-Ireland.pdf
[17] Ireland's Biopharma Manufacturing Future | IDA Ireland
[18] https://www.idaireland.com/latest-news/insights/the-future-of-biopharma-in-ireland
[19] NIBRT Publish Annual Report 2025 - National Institute for Bioprocessing Research

Different countries have taken different routes to value, but no one has made the shift through industry alone. The US connected public science, academia, capital and industry to sustain innovation; Ireland paired long-term government support with global investment and specialist skills; and China combined regulatory reform, capital and global partnerships to move from scale to innovation.

For India, the lesson is not to replicate any one model, but to build the partnerships its own transition requires. Its existing strengths in scale, chemistry, manufacturing and talent provide the base; moving further into innovation and higher-value activities may depend on how effectively these strengths are connected with government, global partners, technology, academia, capital and health systems.

In India, however, industry and academia tend to work in isolation.

> Most of the innovation or technology that is there within the academic institutions remains unavailable to the industry, while industrial technology stays enclosed within the industry. The two systems largely work in isolation.
>
> *– Academic leader, pharmaceutical research institution*

> It is all about confidence and courage. Courage gets an outcome, the outcome then creates confidence, and the wheel of innovation starts to move faster.
>
> *– Healthcare investor and industry leader*

> When companies see the potential in the market, they will invest. What they need is an ecosystem that supports and rewards innovation.
>
> *– Industry leader, global pharmaceutical company*

1.4 Partnerships: The common thread

Different countries such as the US, Ireland and China have adopted various partnership routes to value. In each case, partnerships supplied what companies could not build on their own: regulation that rewards innovation, access to global science and markets, patient capital, skills and research, data at scale, and health systems that adopt and pay for new medicines.

These partnerships fall into six engines. Together, they turn manufacturing scale into innovation, higher-value products and durable returns. They also form the framework for the rest of this report: Chapter 2 assesses where India stands on each engine, and Chapter 3 sets out the actions needed to accelerate the shift.

Partnership engines that accelerate the shift from volume to value

1.	**Industry and government** *Industry and Government come together to create predictable regulations, pricing and incentives that reward innovation.*
2.	**India and world** *Indian companies and global pharma come together as long-term partners, sharing science, markets and returns.*
3.	**Industry and investors** *Pharma companies, start-ups and investors come together to provide patient capital that carries innovation from the lab to market.*
4.	**Industry and academia/research institutions** *Industry and academic institutions come together to turn research and talent into products and companies*
5.	**Industry and technology providers** *Pharma, technology firms and health-data platforms come together to accelerate medicine discovery, development and clinical trials.*
6.	**Industry and health ecosystem** *Pharma, payers, providers and patients come together to bring innovative medicines to patients and support payment based on value.*

“

Partnerships that build capabilities in advanced manufacturing, biologics and complex drug development can help India move higher up the pharmaceutical value chain.

– Senior leader, global pharmaceutical MNC





Chapter 2

The partnership imperative: Progress so far and the gaps to close

India's move from volume to value may not come from companies acting alone. In every country that has made the shift, partnerships supplied what companies could not build on their own: trusted regulation, access to science and markets, capital, talent, data and health systems that pay for value. This chapter defines six partnerships, or engines, that can do the same for India. Together, these partnerships, supported by greater ease of doing business, should deliver two outcomes: a more innovative, globally competitive industry, and equitable access to quality medicines for patients across India.

> "India does not lack the ingredients for innovation. It lacks the connections between them. Talent in our laboratories, insight from our hospitals, ideas in our start-ups and capability in our factories often coexist rather than connect.
>
> *– Industry association leader*

For each partnership engine, we identify the enablers of value: the conditions that may accelerate the shift towards value. For each enabler, we set out:

- Target state: where India should aim to be
- Current state: what has been achieved so far, and what is holding progress back

2.1 Industry and government

Government shapes almost every condition in which pharmaceutical companies operate. It regulates and approves products, determines pricing, supports ease of doing business by providing policy support, incentives and building shared infrastructure and purchases medicines. Industry brings scientific and technical expertise, investment, manufacturing capabilities and experience from global markets. Government and industry can act as joint owners of India's shift from volume to value, making India a globally trusted hub for developing, making and launching high-value medicines, with shared goals, two-way commitments and joint accountability for results, and equitable access to quality medicines for patients.

A strong government–industry partnership can establish the following key enablers to accelerate the shift from volume to value:

a) Predictable, science-based and time-bound regulatory pathways

Target state:

- New drug review timelines benchmarked to international practices, such as 10 months for standard review and 6 months for priority review under the US FDA framework.[20]
- The delay between US approval and Indian approval of a new medicine reduced to 12 months, against a median of about 43 months today[21] thereby getting earlier access to the treatments.

[20]Perspectives in Clinical Research (KEM Hospital, Mumbai), "An evaluation of drug lag for new drugs approved by the Indian regulator", 2021 (median lag vs US FDA, 2004–2018). https://www.kem.edu/wp-content/uploads/2021/07/Drug-lag_PICR_2021.pdf

[21]Perspectives in Clinical Research (KEM Hospital, Mumbai), "An evaluation of drug lag for new drugs approved by the Indian regulator", 2021 (median lag vs US FDA, 2004–2018). https://www.kem.edu/wp-content/uploads/2021/07/Drug-lag_PICR_2021.pdf

Current state:

- Reforms are moving in the right direction. The 2019 NDCT Rules set statutory timelines, and the 2026 amendments replaced most test licenses with online intimation, cut the statutory time for the remaining test licenses from 90 to 45 days and waived permission for low-risk BA/BE studies.[22]
- CDSCO is building a 1,500-member scientific cadre over five years.[23]
- India has no breakthrough or fast-track route for innovative drugs and no published data on how long reviews actually take, so timelines remain unpredictable.

> Innovative CDMO programs can encounter regulatory requirements designed around generics, including requests for information that the manufacturer may not possess at that development stage.
>
> *– CXO and CDMO industry leader*

> Government is doing good work when it comes to funding early-stage science, but after that the start-up is largely left to fend for itself, both for money and for the market.
>
> *– Healthcare investor and industry leader*

b) Policies and incentives that reward innovation and advanced capabilities

Target state:

- Industry R&D spending rising from about 5%–8% of revenue today[24] to 10%–12%, supported by incentives linked to novel drugs, biosimilars, new modalities and patents, rather than to manufacturing capacity alone and kept stable.
- Companies can set up, expand and operate through a single, digital, time-bound process for licenses and clearances, under rules that are clear, stable and consistently applied.

Current state:

- The PLI schemes drew investment well above target and built domestic capacity for critical APIs.[25]
- PRIP, Biopharma SHAKTI and the RDI scheme are steps in the right direction for innovation-focused support.[26]
- However, incentives so far have mostly rewarded capacity and sales rather than innovation: PLI payouts are linked to incremental sales, not to R&D or new products. Meanwhile, tax support for in-house R&D has been scaled back over the years.[27]
- Innovation-focused support remains nascent, relatively small in scale and fragmented across the innovation value chain and has yet to produce a novel drug.
- Recent reforms, such as moving several approvals online, have made compliance simpler. There is scope to go further by streamlining the many compliance requirements companies manage and by better aligning central and state processes.

As a result, industry R&D spending remains well below that of global innovators. Schemes that run for only a few years give little certainty for R&D cycles that take a decade or more

[22]India Briefing, "India fast-tracks new drug and clinical trial approvals with 2026 NDCT amendments", February 2026. https://www.india-briefing.com/news/india-new-drug-clinical-trials-rules-2026-42721.html

[23]BioSpectrum India, "Indian regulator's revamped approval route looks to clear biosimilar bottleneck", August 2026. https://biospectrumindia.com/news/109/28302/indian-regulators-revamped-approval-route-looks-to-clear-biosimilar-bottleneck.html

[24]IMD and CII, India Future Readiness Indicator 2025, via The Tribune, December 2025. https://www.tribuneindia.com/news/business/indias-pharma-sector-emerging-as-global-generics-powerhouse-need-to-scale-ai-usage-beyond-rd-report

[25]Press Information Bureau, Government of India, factsheet on India's pharmaceutical industry, March 2026. https://static.pib.gov.in/WriteReadData/specificdocs/documents/2026/mar/doc2026321831401.pdf

[26]Press Information Bureau, Government of India, factsheet on India's pharmaceutical industry, March 2026. https://static.pib.gov.in/WriteReadData/specificdocs/documents/2026/mar/doc2026321831401.pdf

[27]Takshashila Institution, "Capital for Innovation in Indian BioEconomy". https://takshashila.org.in/content/blogs/innovation-capital-india-bioeconomy.html

c) Predictable pricing that rewards innovation and supports an enabling business environment while ensuring access to quality medicines

Target state:

- Essential medicines stay affordable and available to patients across income groups and regions, while innovative and complex products earn predictable, fair returns under a transparent, multi-year framework agreed by both sides.

Current state:

- Price controls have kept essential medicines affordable, and Jan Aushadhi has widened access to low-cost generics.[28]
- Patented new drugs are exempt from price control for their first five years, which is an important signal for innovation.[29]
- However, ceiling prices apply in much the same way, whether a product is simple or complex, so they give little reward for better products. Annual revisions linked to wholesale inflation do not always keep pace with rising input costs.
- In practice, though, exemptions for patented drugs are decided case by case, and the regulator itself has sought clarity on how to apply them, leaving companies uncertain at launch.[30]
- There is no multi-year, agreed framework for pricing. Additions to the essential medicines list and other pricing decisions can change the economics of a product with little notice, which makes it hard for companies to plan long-term investment in innovative and complex products.

d) Shared infrastructure for advanced manufacturing, testing and clinical research

Target state:

- Every major pharma cluster has shared world-class infrastructure (pilot plants for biologics and new modalities, advanced testing labs and accredited clinical trial sites) that companies of all sizes, including MSMEs and start-ups, can access affordably.
- Infrastructure is co-designed with industry and delivered on time, so no company has to build costly scale-up facilities alone.

Current state:

- Government has launched several infrastructure schemes: three bulk drug parks and medical device parks have been approved, seven centers of excellence run at NIPERs under PRIP,[31] Biopharma SHAKTI plans more than 1,000 accredited clinical trial sites[32] and a network of 21 biomanufacturing facilities has been announced under the BioE3 policy.[33]
- Existing infrastructure is also focused on APIs and conventional manufacturing rather than new modalities. India has more than 70 bio-incubators, but few offer end-to-end GMP or pilot-scale facilities, so start-ups often travel between Hyderabad, Pune and Bengaluru to complete one product cycle.34 Integrated clusters elsewhere, such as Boston and Seoul, are reported to have cut scale-up costs by about 25%.[35]

[28]Press Information Bureau, Government of India, factsheet on India's pharmaceutical industry, March 2026. https://static.pib.gov.in/WriteReadData/specificdocs/documents/2026/mar/doc2026321831401.pdf

[29]Mondaq, "New drugs patented under the Indian Patent Act 1970 are outside the price control for the first 5 years from their commercial marketing". https://www.mondaq.com/Article/782384

[30]Medical Dialogues, "NPPA turns to Patent Office for clarity on drug price exemptions". https://medicaldialogues.in/amp/news/industry/pharma/nppa-turns-to-patent-office-for-clarity-on-drug-price-exemptions-defers-intas-biological-es-applications-140187

[31]Press Information Bureau, Government of India, factsheet on India's pharmaceutical industry, March 2026. https://static.pib.gov.in/WriteReadData/specificdocs/documents/2026/mar/doc2026321831401.pdf

[32]Press Information Bureau, Government of India, factsheet on India's pharmaceutical industry, March 2026. https://static.pib.gov.in/WriteReadData/specificdocs/documents/2026/mar/doc2026321831401.pdf

[33]BioSpectrum India, "DBT-BIRAC unveils high performance biomanufacturing platforms", September 2025. https://biospectrumindia.com/news/16/26624/dbt-birac-unveils-high-performance-biomanufacturing-platforms.html

[34]InsightsIAS, "India's biotech surge and its scaling challenges" (citing The Hindu), October 2025. https://www.insightsonindia.com/2025/10/16/indias-biotech-surge-and-its-scaling-challenges/

[35]InsightsIAS, "India's biotech surge and its scaling challenges" (citing The Hindu), October 2025. https://www.insightsonindia.com/2025/10/16/indias-biotech-surge-and-its-scaling-challenges/

2.2 India and world

India's pharmaceutical sector is already closely connected to global markets through exports, contract research and manufacturing, licensing and investment. India brings scientific talent, manufacturing scale and development capabilities, while global partners bring access to new science, technologies, capital and markets. The partnership should help India move from being largely a reliable, cost-efficient supplier to becoming a global partner in drug discovery, development, advanced manufacturing and commercialization, capturing more value from innovation. Indian companies become long-term innovation partners to global pharma, trusted with early-stage, high-value work and paid for the value they create, not at "India rates."

A strong partnership between India and the world can establish the following key enablers to accelerate the shift from volume to value:

a) Early, integrated CRDMO partnerships

Target state:

- Indian CRDMOs move from mainly commercial manufacturing into early discovery and development, staying with molecules through to commercial supply.
- The sector grows substantially faster than the global CRDMO market over the next 10 years to become a market leader,[36] with a much larger share of work in new modalities, including biologics, ADCs, peptides and oligonucleotides.

Current state:

- India has a strong base to build on. Its CRDMO sector is the fastest-growing in the world and is expected to double by 2028.[37] That growth rests on deep process chemistry skills, cost-competitive scale and more US FDA-approved plants than any country outside the US.[38]
- Leading CRDMOs are now investing in biologics, peptides and ADC capacity, and global companies diversifying their supply chains are bringing them new opportunities.
- But most partnerships with global pharma are still transactional: project-by-project, fee-for-service and concentrated in late-stage and commercial manufacturing of small molecules. India holds about 3.6% of the global market, against China's 12.7%,[39] and is barely present in early-stage and new-modality work, where the market is growing fastest.[40]
- This reflects the industry's roots in generics, where it competed on cost rather than science. Few Indian players offer an integrated platform from discovery to commercial supply, and few scientists and leaders have discovery and new-modality experience.
- India also lacks a domestic biotech base on which to build early-stage skills and incentives to bring Indian scientists working in global companies back to India. An academic leader at a pharmaceutical research institution stressed that returning scientists need sustainable research environments, not only short-term support.

> "India and the world, and pharma and manufacturing services, are the two partnership areas that are working the best today.
>
> *– Healthcare investor and industry leader*

b) Licensing and co-development of Indian innovation

Target state:

- Indian companies become regular partners in global innovation. They bring global medicines to India and emerging markets faster, license their own molecules to global pharma on strong terms and co-develop the best of them as equal partners.
- India's pipeline of novel, partner-ready molecules grow steadily, fed by start-ups and research institutes as well as large companies.

Current state:

- India has shown that its science can command global value. Glenmark's licensing of ISB 2001 to AbbVie in 2025 brought US$700 million upfront, in a deal worth up to US$1.925

[36]BioPharm International, "India's CRDMO sector could grow to $25 billion by 2035" (BCG and IPSO), 2025. https://www.biopharminternational.com/view/india-crdmo-sector-could-grow-25-billion-2035-report

[37]Frost & Sullivan, Industry Report on the Global CRDMO Market (prepared for Sai Life Sciences), July 2024. https://sailife.com/files/investors/frost-sullivan-industry-report.pdf

[38]Press Information Bureau, Government of India, factsheet on India's pharmaceutical industry, March 2026. https://static.pib.gov.in/WriteReadData/specificdocs/documents/2026/mar/doc2026321831401.pdf

[39]ValueQuest, Decrypting the DNA of CRDMOs, January 2025 (Frost & Sullivan data, 2023). https://www.valuequest.in/wp-content/uploads/2025/01/VQ-Deep-Dive-Decrypting-the-DNA-of-CRDMOs.pdf

[40]Frost & Sullivan, Industry Report on the Global CRDMO Market (prepared for Sai Life Sciences), July 2024. https://sailife.com/files/investors/frost-sullivan-industry-report.pdf

billion.[41] A few large companies now run genuine novel pipelines and some Indian companies already in-license global medicines for the Indian market.

- But such deals are rare. Part of the reason is a thin pipeline: India has relatively few novel molecules, mostly small molecules in crowded target classes.
- Promising existing assets may also face hurdles when Indian companies try to out-license them:
- **Lack of trust in data**: Early studies are often designed for Indian rather than global regulators, with small patient numbers and concerns about data integrity lingering.
- **Weak IP and differentiation**: Patents may be filed late or narrowly, freedom-to-operate is not always established and many molecules are fast followers rather than first-in-class or best-in-class.
- **Gaps in development readiness**: Manufacturing and quality (CMC) packages and early dialogue with the US FDA or EMA are often missing, which adds risk for buyers.
- **Limited deal-making capability**: Few companies have experienced business-development teams, networks with global buyers or realistic valuation benchmarks, and Indian assets are less visible than Chinese ones at global partnering events.

2.3 Industry and investors

Pharmaceutical innovation needs patient capital because development takes time, carries high risk and often generates returns only after several years.

Government funds early research and de-risks projects; venture and private equity investors back start-ups; public markets fund growth; and large companies share risk through licensing, spin-outs and co-investment. In a partnership, capital providers bring money and expertise; pharma companies and start-ups bring science, assets and governance that investors can trust. Each stage depends on the next: early investors back start-ups only if they can see a route to later funding and an exit.

A strong partnership between pharma and capital providers can establish the following key enablers to accelerate the shift from volume to value:

a) Public funding that draws in private capital

The role of public funding in attracting private investment is discussed earlier, in the section on industry–government partnerships (2.1).

b) Specialist venture capital for life sciences

Target state:

- India has a strong base of specialist life-sciences investors who back start-ups at every stage, from first funding to late development.
- Investors bring scientific and company-building expertise as well as money.

Current state:

- India's biotech start-up ecosystem is expanding, with more than 11,800 start-ups and a BIRAC-supported network of 94 incubation and pre-incubation centers.[42] Specialist healthcare funds and broader investors are backing health and life-sciences businesses.
- But funding is small and shallow. Between 2020 and 2024, Indian life-sciences start-ups raised only about US$1.9 billion, with an average deal of under US$5 million.[43]
- For research-led medicine developers, the challenge is to build a continuous funding pathway from early science through clinical development and commercialization. There were only 13 Series C and D deals in 2020–24, so most start-ups lack follow-on capital for the costly later stages.[44] Interview evidence highlights gaps in funding continuity, market access and credible investor exits.[45]

c) Public markets for science-led companies

Target state:

- Science-led companies can raise capital on Indian stock exchanges before they earn revenue, under robust disclosure rules.
- A deep base of investors and analysts understand and values science-led companies.

[41] Latham & Watkins, "Latham & Watkins advises AbbVie on US$1.925 billion licensing agreement with Ichnos Glenmark Innovation", July 2025. https://www.lw.com/en/news/2025/07/latham-watkins-advises-abbvie-on-us1-925-billion-licensing-agreement-with-ichnos-glenmark-innovation

[42] NewKerala, "BIRAC fuels innovation: ₹4,200 crore funding", 2026. https://www.newkerala.com/news/a/birac-fuels-innovation-rs-4200-crore-funding-across-114.htm

[43] Omnivore and Nucleate, India's Life Sciences Startup Investing Report: A 5-year review (2020–2024), 2025 (industry report). https://omnivore.vc/uploads/Bio_Wave_report_final_2_6513a9b872.pdf

[44] Omnivore and Nucleate, India's Life Sciences Startup Investing Report: A 5-year review (2020–2024), 2025 (industry report). https://omnivore.vc/uploads/Bio_Wave_report_final_2_6513a9b872.pdf

[45] CXO and expert interview conducted for this report, 2026.

Current state:

- India's public markets provide established funding and exit channels for pharma and CRDMO companies, with recent IPOs demonstrating strong investor demand.
- For pre-revenue biotechs, the gap is a dedicated listing framework, not a complete regulatory barrier. India permits IPOs without meeting profitability criteria through an institutional-investor-led route.

> "At the end of the day, science needs to convert into commerce at scale.
>
> – *Healthcare investor and industry leader*

2.4 Industry and academia/ research institutions

Much of the world's new medical science starts in universities, research institutes and national laboratories. Academia discovers new targets, molecules and platforms, trains scientists and solves hard technical problems; industry turns that science into products and takes them to patients.

In a partnership, academia brings scientific depth, facilities and talent; industry brings an understanding of patient and market needs, development skills and funding. India has strong science in its academic institutions, but too little of it translates into commercial products. Sustained academia–industry partnerships that share risk, reward and talent from discovery to market can make the translation of Indian research into Indian products the norm.

This can be achieved through the following enablers:

a) Turning academic research into products through licensing, partnerships in development and spin-outs

Target state:

- Indian institutes regularly license their inventions to industry or spin them out as start-ups, under clear, standard terms, with fair returns for institutes and inventors.
- Academic labs and spin-outs become a regular source of novel molecules and platforms for Indian companies.

Current state:

- Indian academia is generating more intellectual property than ever: universities now account for about 42% of patent filings in India.[46] Leading institutes have set up technology-transfer offices, and BIRAC has funded more than INR4,200 crore of projects and supports about 100 bio-incubators, many based at academic institutes.[47]
- But few of these patents become products. India ranked 86th in the Global Innovation Index 2025 on university–industry R&D collaboration, its lowest ever,[48] down from 23rd in 2017 and 2019.[49]
- Patents are often filed to meet ranking and funding metrics rather than market needs, and few start-ups emerge from academic labs with novel drug assets. IP and revenue-sharing rules vary between institutes, few have skilled technology-transfer staff, and rules for researchers who want to found companies are unclear.

b) Talent and mobility between academia and industry

Target state:

- Scientists move freely between labs and companies over their careers.
- India builds a pool of industry-ready scientists in discovery, new modalities and translational research.

[46]Takshashila Institution, "WIPO Global Innovation Index 2025: India's performance hides more than it reveals", October 2025. https://takshashila.org.in/content/blogs/20251010-WIPO-Global-Innovation-Index-2025-India.html

[47]NewKerala, "BIRAC fuels innovation: ₹4,200 crore funding", 2026. https://www.newkerala.com/news/a/birac-fuels-innovation-rs-4200-crore-funding-across-114.htm

[48]Takshashila Institution, "WIPO Global Innovation Index 2025: India's performance hides more than it reveals", October 2025. https://takshashila.org.in/content/blogs/20251010-WIPO-Global-Innovation-Index-2025-India.html

[49]The Captable, "Low industry–university collaboration in India", March 2025 (Global Innovation Index ranks, 2017–2024). https://cwv.the-captable.com/2025/03/low-industry-university-collab-india

Current state:

- India produces large numbers of science graduates, and initiatives such as NIPERs and the skilling programs under Biopharma SHAKTI aim to build industry-ready talent.[50]
- But academic and industry careers rarely cross. Training is often theory-heavy, with little hands-on experience on industry-grade equipment, and few PhDs are trained in industry problems.
- Academic rules make it hard for faculty to spend time in industry, and industry scientists rarely teach or research in academia. Ireland's NIBRT shows the alternative: a training institute run with industry, which trained 4,900 people in biopharma manufacturing in 2025.[51]

2.5 Industry and technology providers

India has strong capabilities in pharmaceuticals, technology and digital infrastructure. Bringing these together, in addition to enabling ease of doing business, can help India leapfrog across the pharma value chain, improving the competitiveness of generics, accelerating innovation and creating technology products for global markets.

For generics, technology can help Indian manufacturers reach or surpass global benchmarks on cost, productivity and quality. In innovation, AI and data can help India build capabilities faster and with lower investment than larger ecosystems such as China and Korea. India's technology companies can also move beyond IT services to build proprietary pharma and healthcare products for the world. Pharma and technology partners can combine India's science, IT strength and national health data to make medicine discovery, development and clinical trials faster and better than competitors.

A strong partnership between pharma, technology and data partners can establish the following key enablers:

a) AI-led discovery and development

Target state:

- AI and data tools are used at scale across Indian R&D, cutting the time and cost of discovering and developing new medicines.

Current state:

- India has the ingredients: deep chemistry skills, world-class IT companies, a growing AI start-up base and global capability centers doing advanced data science.
- But AI adoption in Indian pharma is still at the pilot stage, while global pharma is integrating AI across the value chain.[52]
- Partnerships with technology firms are mostly short-term, fee-based projects. Few companies have the high-quality, well-organized R&D data that AI needs, or mixed teams of scientists and data scientists who can turn AI outputs into molecules.

b) Integrated digital health solutions and real-world evidence

Target state:

- Trusted, research-ready health data enables robust evidence on medicines' effectiveness, safety and value for regulators, payers and clinicians.
- India becomes a leading contributor to real-world evidence through high-quality, longitudinal datasets reflecting its population's scale and diversity.

Current state:

- India has built one of the world's largest digital health backbones: the Ayushman Bharat Digital Mission has issued 93+ crore ABHA health IDs and linked 104+ crore health records (July 2026).53 The National Biobank, launched in July 2025,[54] and the DPDP Act and Rules, notified in November 2025,[55] add further building blocks.

[50]Press Information Bureau, Government of India, factsheet on India's pharmaceutical industry, March 2026. https://static.pib.gov.in/WriteReadData/specificdocs/documents/2026/mar/doc2026321831401.pdf

[51]NIBRT, Annual Report 2025. https://www.nibrt.ie/nibrt-publish-annual-report-2025/

[52]IMD and CII, India Future Readiness Indicator 2025, via The Tribune, December 2025. https://www.tribuneindia.com/news/business/indias-pharma-sector-emerging-as-global-generics-powerhouse-need-to-scale-ai-usage-beyond-rd-report

[53]News On AIR, "Over 104 crore health records linked to over 93 crore ABHA accounts", July 2026. https://newsonair.gov.in/over-104-crore-health-records-linked-to-over-93-crore-abha-accounts-says-govt/

[54]BioSpectrum India, "Can DPDPA's research exemption power private sector breakthroughs?", October 2025. https://www.biospectrumindia.com/public/views/17/26746/can-dpdpas-research-exemption-power-private-sector-breakthroughs-.html

[55]Hogan Lovells, "India's Digital Personal Data Protection Act, 2023 brought into force", November 2025. https://ca.hoganlovells.com/en/publications/indias-digital-personal-data-protection-act-2023-brought-into-force-

- But little of this data is usable for research. Headline enrolment and record-linkage figures do not establish research readiness: retrieving records across facilities remains extremely low.[56]
- There is no clear framework for how pharma companies can access health data for research, and how the DPDP Act's research exemption applies to commercial research remains uncertain.57 By contrast, UK Biobank was co-funded by pharma companies with government and Wellcome and has become a global resource for drug discovery.[58]
- Indian companies also remain largely product-led, while global companies are moving to integrated care that links medicines with diagnostics, devices, apps and data services.[59]

2.6 Industry and health ecosystem

Pharmaceutical innovation creates value when the right treatment reaches the right patient and improves outcomes. Patients bring insight into unmet needs; providers bring clinical expertise and care; payers determine coverage; and pharma brings medicines, evidence and support. The partnership should connect patient needs, care and financing, from research and diagnosis to treatment and follow-up, balancing access and affordability with treatment value. This would enable better medicines to reach Indian patients faster and be paid for based on the value they create. This engine is central to ensuring that the shift to value translates into equitable access to patients.

A strong partnership between pharma, patients and health systems can establish the following key enablers to accelerate the shift from volume to value:

a) Payment models that reward value

Target state:

- Payers, both public schemes and private insurers, have clear, evidence-based routes to cover innovative medicines, so that patients across income groups can access them.
- A growing share of medicines is paid for through models linked to outcomes, so that patients gain access and innovation is rewarded.

Current state:

- India has expanded public health coverage rapidly: PM-JAY has issued 43.5 crore Ayushman cards,[60] and government health spending has risen sharply over the past decade. HTAIn, under the Department of Health Research, provides a base for assessing the value of health technologies.[61]
- But patients still pay for much of their care themselves: out-of-pocket spending was 43.4% of total health expenditure in 2022–23,[62] and only about 2% of outpatient spending, where most medicines are bought, is covered by insurance.[63] This keeps the domestic market for innovative medicines small. It also means that access to newer medicines often depends on patient's ability to pay and varies widely across income groups and regions.
- Public schemes mainly cover hospital care and buy on price, and there is no established route for innovative medicines to be assessed and covered based on value.

[56]Health Management, Policy and Innovation, "From infrastructure to impact: operationalizing India's Ayushman Bharat Digital Mission", July 2026. https://hmpi.org/2026/07/09/from-infrastructure-to-impact-operationalizing-indias-ayushman-bharat-digital-mission/?pdf=6336

[57]BioSpectrum India, "Can DPDPA's research exemption power private sector breakthroughs?", October 2025. https://www.biospectrumindia.com/public/views/17/26746/can-dpdpas-research-exemption-power-private-sector-breakthroughs-.html

[58]UK Biobank, "World's largest genetic project opens the door to new era for treatments and cures". https://www.ukbiobank.ac.uk/news/worlds-largest-genetic-project-opens-the-door-to-new-era-for-treatments-and-cures-uk-biobanks-major-milestone/

[59]IMD and CII, India Future Readiness Indicator 2025, via The Tribune, December 2025. https://www.tribuneindia.com/news/business/indias-pharma-sector-emerging-as-global-generics-powerhouse-need-to-scale-ai-usage-beyond-rd-report

[60]Medical Dialogues, "43.5 crore cards issued under AB-PMJAY". https://medicaldialogues.in/amp/news/health/hospital-diagnostics/36229-hospitals-empanelled-435-crore-cards-issued-under-ab-pmjay-166744

[61]Center for Global Development, "Building a better evidence base: health technology assessment lessons from India". https://www.cgdev.org/blog/building-better-evidence-base-health-technology-assessment-lessons-india

[62]ThePrint, "As govt cut health spends post-Covid, Indians paid more out of pocket in 2022–23" (National Health Accounts 2022–23), May 2026. https://theprint.in/health/as-govt-cut-health-spends-post-covid-indians-paid-more-out-of-pocket-in-2022-23-reversing-10-yr-trend/2943692/

[63]Business Today, "Just 2% of everyday healthcare is insured in India" (Praxis Global Alliance and NATHEALTH), April 2026. https://www.businesstoday.in/industry/pharma/story/just-2-of-everyday-healthcare-is-insured-in-india-heres-why-528300-2026-04-30

b) Diagnosis-to-treatment partnerships with providers and patients

Target state:

- Pharma, hospitals, doctors, diagnostic labs and patient groups work together so more patients are diagnosed early, receive the right treatment and stay on it, therefore providing equitable access to patients.
- Genuine partnerships are allowed, trusted and clearly separated from promotion.

Current state:

- India has large hospital groups and diagnostic chains, a fast-growing digital health sector, and active patient groups in areas such as cancer and rare diseases. Some companies run patient-support and disease-management programs.
- But these efforts are mostly small and stand-alone, and collaboration between pharma and providers is largely limited to marketing. Diagnosis rates are low in many diseases, and many patients stop treatment early, especially in chronic conditions, so medicines deliver less than their full value.
- The marketing code Uniform Code of Pharmaceutical Marketing Practices (UCPMP 2024) has rightly tightened rules on engagement with doctors, but leaves grey areas for genuine collaboration, such as undefined "bona fide research".[64]

> "Access and innovation are mutually reinforcing priorities.
>
> – *Industry leader, global pharmaceutical company*



[64]Majmudar & Partners, "The Uniform Code for Pharmaceutical Marketing Practices, 2024 – impact on India's pharma industry", June 2024. https://www.majmudarindia.com/uniform-code-pharma-marketing-impact/

2.7 Summary

India has built strong foundations for the shift to value: regulatory reform is under way, policy initiatives support ease of doing business, new public funding for innovation is in place, its CRDMO sector is the fastest growing in the world, its start-up base and digital health backbone are among the largest anywhere, and its science has begun to command global value.

However, many partnerships remain transactional rather than long-term and strategic. They are focused on cost and volume rather than shared value and fragmented rather than continuous from discovery to market. The table below summarizes the main gaps across all six engines

The gaps holding back the shift to value

Industry and government	India and world	Industry and investors
a) Approval timelines are unpredictable, with no fast-track route for innovative drugs b) Incentives reward capacity and sales rather than innovation c) No multi-year, predictable pricing framework	d) Partnerships are transactional and concentrated in late-stage manufacturing e) Limited presence in early-stage and new-modality work f) Out licensing existing assets remains limited	g) Funding is small and early-stage, with little follow-on capital h) Few specialist life-sciences investors and few exits i) No listing framework tailored to pre-revenue biotech
Industry and academia/research institutions	**Industry and technology providers**	**Industry and health ecosystem**
j) Weak collaboration between universities and industry k) Few academic patents become products l) Little movement of talent between academia and industry	m) AI use is largely limited to pilots n) Health data is not yet research-ready o) Unclear rules for research use of health data	p) Most medicines are paid for out of pocket, with little outpatient cover q) No value-based route to coverage; public schemes buy on price r) Care programs are small and stand-alone



Chapter 3

Recommendations to accelerate partnerships

3.1 Summary of recommendations

The table below summarizes the recommendations for each engine. Section 3.2 discusses them in detail.

Industry and government	India and world	Industry and investors	Industry and academia/ research institutions	Industry and technology providers	Industry and health ecosystem
Explore the creation of a Regulatory Performance Compact with published review timelines	Pursuing opportunities to build long-term, strategic CRDMO partnerships Identify priority areas or modalities where investment barriers can be addressed and capabilities developed	Assess the potential to establish specialist life sciences funds that provide patient capital across the innovation cycle	Looking to establish national rules for academic IP and spin-outs	Seeking to move from AI pilots to multi-year, shared-value collaborations that deliver transformational outcomes	Consider creating a value-based route to coverage and piloting outcome-based payment agreements
Look at ways to make innovation schemes faster, larger and outcome-focused Consider providing enhanced R&D tax deductions including restoring of earlier deductions Consider enhancing single window and digitally enabled clearances for setting up and running business	Look to build a value chain less dependent on China	Encourage pharma companies to pursue co-investment opportunities with specialist funds	Pursue the development of shared technology-transfer hubs	Examine the potential for creating a national evidence consortium with clear data-use rules	Look to develop diagnosis-to-treatment care programs that support access to innovative medicines

Industry and government	India and world	Industry and investors	Industry and academia/ research institutions	Industry and technology providers	Industry and health ecosystem
Examine opportunities to add more clusters or shared infrastructure	Ensure out licensing readiness of existing pipeline	Look at creating attractive exit pathways that can attract and recycle innovation capital	Evaluate approaches to rewarding licensing rather than patent filing	Seek to develop innovative digital products in India, for India and the world	
Evaluate the potential for introducing a five-year pricing and access framework	Seek to expand India's role beyond GCCs to include global discovery and manufacturing for the sponsoring companies	Examine the potential for developing a dedicated biotech listing framework	Explore opportunities for two-way secondments		

3.2 Recommendations to harness the power of partnerships

The recommendations below are organized by engine and enabler, following the structure of Chapter 2.

3.2.1 Industry and government

a) Explore ways to make regulatory pathways predictable, science-based and time-bound

Consider the creation of a Regulatory Performance Compact between CDSCO and the Health Ministry, in collaboration with industry associations and modeled on the US PDUFA,[65] that could:

- Set up specialist review units for biologics, cell and gene therapies and ADCs, staffed partly through secondments and joint training.
- Pilot an India breakthrough designation with early scientific advice and a 30-day trial-approval pathway for innovative drugs developed in India, similar to China's pilot.[66]
- Set published review timelines and SOPs by product type and strengthen specialist review capacity, supported by an appropriate industry fee framework.
- Improve the quality of filings. CDSCO could publish clear guidelines, SOPs and checklists for each type of application, while industry could commit to complete, high-quality submissions, with performance tracked through a joint annual scorecard covering timelines and filing quality.

b) Explore opportunities to reward innovation and advanced capabilities through policy and incentives

Examine the potential for creating an Innovation Incentive Partnership between the Department of Pharmaceuticals, the Finance Ministry and industry that could:

- **Look at ways to make PRIP, Biopharma SHAKTI and the RDI scheme faster and easier to access**: Publish timelines for decisions and disbursements, introduce a simple application and review process across the schemes and include industry professionals on selection panels.
- **Focus the schemes more closely on outcomes**: Concentrate support on fewer, larger projects in priority areas such as novel drugs, biosimilars and new modalities. Funding could be linked to milestones so that it follows progress rather than paperwork.

> "There is a need to concentrate support, rather than spread relatively small incentives across many participants, by prioritizing companies with the technical capabilities, scientific orientation and track record to successfully build these platforms, as this would provide a big safety net.
>
> — CDMO industry leader

[65] ITIF, "Preserving PDUFA is critical for US biopharmaceutical innovation", July 2025. https://itif.org/publications/2025/07/01/preserving-pdufa-is-critical-for-us-biopharmaceutical-innovation/

[66] Covington, "China implementing pilot work program for expedited clinical trial review and approval", September 2024. https://www.covingtonblogs.com/2024/09/20/china-implementing-pilot-work-program-for-expedited-clinical-trial-review-and-approval/

- **Extend support across proof of concept, validation and development rather than focusing on early-stage science alone**: An academic leader at pharmaceutical research institution supports exploratory funding followed by milestone-based support, recognizing that responsible scientific risk-taking may not always result in a commercial product.
- **Consider restoring enhanced tax deductions for innovative R&D**: Incentives could remain stable for a period long enough to cover a full R&D cycle.
- **Consider setting up a single digital platform for licenses and compliance filings**: These could be shared by central and state authorities, together with a joint review to simplify overlapping requirements, would make it easier to do business.

c) Look at ways to make pricing predictable and reward innovation

Assess the potential to jointly develop a Multi-year Pricing and Access Agreement between the Department of Pharmaceuticals and NPPA, in collaboration with industry, that could:

- Establish a five-year pricing framework with clear, predictable rules for exemptions and the pricing of innovative and complex products.
- Examine mechanisms to protect patient affordability through targeted subsidies or other access mechanisms where required.
- Link pricing predictability to reciprocal industry commitments on assured supply of essential medicines and reinvestment in R&D.
- Review outcomes annually against defined measures for patient access, supply reliability and innovation investment.
- Connect innovation support with evidence-based routes to adoption. An industry association leader advocates recognizing clinical outcomes and total healthcare value rather than medicine acquisition costs alone. This complements the observation of a healthcare investor and industry leader that start-ups face gaps in both funding and market access.

d) Assess opportunities to build shared infrastructure for new modalities and innovation

Explore the potential to increase and enhance Cluster Infrastructure Partnerships between the Department of Pharmaceuticals, DBT, state governments, anchor companies and MSMEs in each major cluster, structured as public–private partnerships that could:

- **Prioritize new modalities**. Build shared pilot plants and GMP scale-up facilities for biologics, ADCs, peptides, oligonucleotides and cell and gene therapies, alongside advanced testing labs and accredited trial sites.
- **Co-design and anchor demand**. Involve industry in designing each facility and secure anchor-user commitments before construction, supporting asset utilization from the outset.
- **Facilitate affordable access**. Reserve capacity and introduce pay-per-use pricing for MSMEs, start-ups and academic spin-outs.
- **Deliver on time**. Fast-track environmental and other clearances through a single-window mechanism, publish milestones for every project and link central funding to progress.
- **Integrate clusters end to end**. Co-locate pilot plants, labs, trial sites and incubators, allowing a product to move from proof of concept to clinical supply within a single cluster.

3.2.2 India and world

a) Pursue opportunities to build early, integrated CRDMO collaborations

Explore the creation of collaborations among Indian CRDMOs, global pharma and biotech companies that could:

- **Turn transactional contracts into strategic collaborations.**
  - Indian CRDMOs and their largest global clients could consolidate project-by-project work into multi-year portfolio agreements.
  - Contracts could combine a base fee with milestone payments and a right of first refusal on development and manufacturing, allowing CRDMOs to share in success and remain involved with a molecule through commercial supply.
  - Two-way secondments could help bridge local talent gaps through hands-on learning and knowledge exchange.
- **Assess opportunities to break the investment standoff in new modalities.** Global pharma companies, Indian CRDMOs and government could jointly build capacity in ADCs, peptides, oligonucleotides and biologics:
  - **Global pharma**: Explore commitments to multi-year contracts for dedicated capacity.
  - **Government**: Evaluate opportunities to link proposed co-funding through Biopharma

SHAKTI or a next-generation PLI scheme to signed anchor contracts.

- **CRDMOs**: Look to co-invest in and operate facilities, while reserving capacity at affordable rates for Indian biotech companies to strengthen the domestic innovation base and build early-stage development skills.

- **Seek to build a trusted value chain less dependent on China.**
  - Indian CRDMOs and global pharma companies could co-invest through JVs or alternative modes backed by long-term "China-plus-one" sourcing commitments. This could provide global clients with a reliable alternative to China while giving Indian CRDMOs greater demand visibility to support investment.

b) Explore opportunities to license and co-develop Indian innovation

- **Look to make existing assets ready for out-licensing.** Industry bodies and government could help companies address gaps identified by global buyers through:
  - Early scientific advice from CDSCO aligned with US FDA and EMA expectations and early trials designed to global standards.
  - Independent data-quality audits and IP and freedom-to-operate reviews before assets are taken to market.
  - Manufacturing and quality (CMC) packages prepared to standards expected by prospective buyers.
- **Seek to expand India's role beyond GCCs to include global discovery** and manufacturing for sponsoring companies.

These collaborations could help Indian companies deepen their contribution to global drug development and expand their commercial reach. The focus could be on building relationships around scientific capability, quality and shared value, supported by clear responsibilities and commercial terms.

3.2.3 Industry and investors

a) Examine opportunities to use public funding to draw in private capital

- Refer to Section 3.2.1(b) for recommendations on policies and incentives for industry and government.

b) Assess the potential to build specialist life sciences funds that provide patient capital across the innovation cycle

- **Look to scale publicly anchored specialist life sciences funds** that could crowd in private capital and provide funding across the drug-development cycle, with fund tenures and milestone-based follow-on investments aligned with the long timelines of pharmaceutical innovation.
- **Encourage pharma companies to pursue co-investment opportunities with specialist funds** and provide development, regulatory and manufacturing support, with narrowly defined, time-bound licensing options negotiated for specific assets.

c) Pursue credible exit pathways that attract and recycle innovation capital

- Explore opportunities to position large Indian companies as natural buyers of Indian innovation. Pharma companies could allocate part of their R&D budgets to licensing or acquiring Indian start-ups, including through option deals that provide the right to acquire an asset or company once key data become available.
- Assess the potential to develop a secondary market. Specialist funds could acquire stakes from early investors, allowing early capital to be recycled without forcing a premature sale or listing.

d) Examine ways to open public markets to science-led companies

- Explore developing a dedicated biotech listing framework. SEBI and exchanges, in consultation with industry and investors, could establish clear eligibility criteria for qualifying pre-revenue biotechs based on development milestones, IP rights, specialist-investor backing and adequate working capital. Independent scientific advice and continuing disclosures on trials, regulatory developments, cash runway and risks could support investor protection.

3.2.4 Industry and academia/research institutions

a) Seek to turn academic research into products through licensing, co-development and spin-outs

- **Look to establish clear national rules for academic IP and spin-outs**. Government, leading institutes and industry could develop a national framework that:
  - Gives institutes and individuals clear ownership of publicly funded inventions, with a defined share of income for inventors.

- Provides model license agreements with standard royalty ranges that could be signed in weeks rather than months.
- Allows researchers to hold equity and take leave to work on start-ups without losing their academic posts, with conflicts of interest managed transparently.

- **Pursue the development of shared, professional technology-transfer offices.** Institutes and industry could create regional technology-transfer hubs serving multiple institutes:
  - Staffed by professionals with scientific, legal and business experience, including some seconded from industry.
  - Tasked with scouting inventions, assessing their commercial potential and matching them with companies.
- **Evaluate approaches to reward licensing, not filing.** Funders and ranking bodies could place greater emphasis on licenses signed, income earned and products launched rather than the number of patents filed.

b) Look at ways to facilitate talent mobility between academia and industry

- **Assess opportunities to build industry-led training institutes for new modalities.** Industry, government and institutes could set up NIBRT-style centers that:
  - Provide hands-on training using industry-grade equipment in biologics, cell and gene therapies, ADCs and other new modalities.
  - Operate through joint funding, with curricula set by industry.
- **Explore opportunities to enable two-way secondments.** Companies and institutes could establish regular exchanges, with faculty spending time in industry labs and industry scientists contributing to teaching and research in academia.

3.2.5 Industry and technology providers

a) Explore ways to scale AI-led discovery and development

- **Look to move from pilots to multi-year AI partnerships.** Pharma companies and AI and IT firms could form long-term discovery and development collaborations that include:
  - Multi-year programs focused on specific targets or diseases, supported by joint teams of chemists, biologists and data scientists.
  - Shared value through milestones, royalties or co-ownership of molecules rather than a fee-for-service model.
- **Seek to make R&D data ready for AI.** Pharma companies could work with technology companies to organize their historical R&D, manufacturing and clinical data according to common standards, making the data suitable for training and running AI models.

b) Pursue opportunities to build innovative digital products in India, for India and the world

- **Look to support Indian digital products first.** Indian pharma companies could act as anchor customers for Indian AI, digital health and manufacturing-technology firms. They could pilot these firms' products across R&D, plants and patient programs, and then scale successful solutions, providing Indian technology companies with early references to support their expansion into global markets.
- **Assess ways to co-develop products with shared IP.** Pharma and technology companies could jointly build proprietary products, such as AI discovery platforms, digital quality systems and companion apps, with shared ownership and revenue rather than a fee-for-service model.

c) Examine opportunities to build integrated digital health solutions and real-world evidence

- **Evaluate the potential to create a national evidence consortium.** Pharma companies, hospitals, labs, the National Health Authority and research bodies could build research-ready datasets using the national digital backbone, supported by clear rules for the research use of health data.
- **Seek to improve hospital connectivity.** Technology firms and government could support hospitals in linking their systems to the national backbone through affordable software and incentives tied to data quality.

3.2.6 Industry and health ecosystem

a) Examine opportunities to introduce payment models that reward innovation and support equitable access to quality medicines

- **Assess the potential to create a value-based route to coverage.** The National Health Authority, HTAIn, insurers and industry could develop a clear process for assessing and covering innovative medicines, supported by:
  - Published criteria and timelines for HTAIn assessments, with a mechanism for industry to submit evidence.

- A pathway for medicines that complete assessment to receive coverage through PM-JAY and private insurers.

- **Explore opportunities to pilot outcome-based agreements.** Pharma companies, the National Health Authority, state health systems and insurers could pilot agreements across a few priority diseases, such as cancer, diabetes and heart disease, with:
  - Payments linked to agreed patient outcomes or volume commitments in return for lower prices.
  - Outcomes tracked through the national digital health backbone.

b) Look to build diagnosis-to-treatment partnerships with providers and patients. Pharma companies, hospitals, diagnostic labs, digital health firms and patient groups could jointly run programs in diseases such as diabetes, heart disease and cancer that:

- Improve screening and diagnosis and connect patients with appropriate treatment.
- Support patients in staying on treatment through digital tools and follow-up.

3.3 From here to value: Recommendations for next 10 years

Delivering these recommendations could help shift a focused set of metrics that indicate whether India is moving from volume to value. A proposed headline indicator of this transition is the registration of 10 or more India-origin new molecular entities (including NCE/NBEs) annually. The table below compares India's current position with proposed targets for 2037, 10 years from the start of implementation, for the lead indicators across these partnerships. The targets are proposed for discussion and could be agreed jointly by partners.

Engine	Metric	Today	FY37 target
Industry and government	Standard review time for new drugs	No published standard	Less than 12 months; ~6 months for priority products
	Industry R&D spend, % of revenue	5%–8% (leading firms, 2025)[67]	10%–12%
India and world	India's CRDMO market share	~4%	~8%- 10%
	India's share of world pharma export value	~2.5% (2024)[68]	10%+
	Major out-licensing deals by Indian innovators	Rare	5+ per year
Industry and investors	Life sciences venture funding per year	~US$268 million (2024)[69]	US$2 billion+
	Series C and later rounds	13 over five years (2020-24), averaging 2-3 per year[70]	15+ per year
Industry and academia/research institutions	Global Innovation Index rank for university–industry R&D collaboration	86th (2025)[70]	Top 25
Industry and technology providers	AI use in pharma R&D	Pilot stage (2025)[71]	~5% of EBITDA value unlocked through AI across the industry

[67] IMD and CII, India Future Readiness Indicator 2025, via The Tribune, December 2025. https://www.tribuneindia.com/news/business/indias-pharma-sector-emerging-as-global-generics-powerhouse-need-to-scale-ai-usage-beyond-rd-report

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Conclusion

India's next pharmaceutical chapter is set to reflect the changing needs of the country and the world. Real value will emerge where capabilities converge. Over the next 10–15 years, OPPI can strengthen the redefined connections between industry, government, academia, healthcare institutions and global partners, creating a shared impact in innovation, access and capabilities for the future. The years ahead build on what OPPI has stood for over the past 60 years: bringing the ecosystem together around a shared ambition and helping India move from pharmaceutical scale to greater value, innovation, access and global leadership. The power of these partnerships will be critical to sustaining this journey. OPPI remains committed to acting as a catalyst, enabling partnerships to connect ideas, capabilities and opportunities across the ecosystem. As these partnerships reinforce one another, they can create a virtuous cycle of innovation, investment, capability-building and access, helping India realize its larger pharmaceutical ambition.

Acknowledgements

Industry leaders

Dr. Abdelaziz Toumi
CEO, Lupin Manufacturing Solutions Ltd.

Ajay Nyamati
CEO & Co-Founder, Kitsa

Akhil Ravi
CEO, Aurigene Pharmaceutical Services

Amit Mookim
Board Director & CEO, Immuneel Therapeutics

Amitabh Dube
President, OPPI and Country President &
Managing Director, Novartis India

Aurélien Breton
Managing Director, Servier India

Brecht Vanneste
Managing Director, MSD India

Dr. T. S. Balganesh
President, GangaGen Biotechnologies;
Former Head of Research, AstraZeneca India

Kil To Chong
Professor, Jeonbuk National University,
South Korea

Narendra Chirmule
Co-Founder & CEO, SymphonyTech Biologics

Olga Kubassova
Founder & President, Image Analysis Group

Prof. K. Ruckmani
Director, NIPER, Hajipur

Rizwan Koita
Chairperson, NABH and Co-Founder, Koita
Foundation

Saharsh Davuluri
CEO & MD, Neuland Laboratories

Shweta Rai
President-Elect, OPPI and Managing Director, India
& Country Division Head, South Asia, Bayer India

Prof. Shubhini A. Saraf
Director, NIPER, Raebareli

Sunil Thakur
Partner, Quadria Capital and Founder, HealthQuad

EY Life Sciences contacts

Ashish Nanda
Managing Partner, Consumer and Health Service, EY India
ashish.nanda@in.ey.com

Anirudh Roy Popli
Partner & Leader, Life Sciences, EY India
Anirudh.Roy.Popli@parthenon.ey.com

Suresh Subramanian
Partner, National Life Sciences Lead, EY-Parthenon
Suresh.Subramanian@parthenon.ey.com

Sumeet Chandna
Partner, Strategy and Transformation, Life sciences, EY-Parthenon
Sumeet.Chandna@parthenon.ey.com

Phalgun Rudrapatna
Partner, R&D, Manufacturing and Quality, Life sciences,
EY-Parthenon
Phalgun.Rudrapatna@parthenon.ey.com

Saikat Ghosh
Partner, Supply Chain, Operations & Strategy, Life sciences, EY-Parthenon
Saikat.Ghosh1@parthenon.ey.com

Anand Darbhe
Partner, Supply Chain, Operations & Strategy, Life sciences, EY-Parthenon
Anand.Darbhe@parthenon.ey.com

Satyam Mehra
Partner, Transactions & Strategy, Life sciences, EY-Parthenon
Satyam.Mehra@parthenon.ey.com

Niladri Majumdar
Partner, Supply Chain, Operations & Strategy, Life sciences, EY-Parthenon
Niladri.Majumdar@parthenon.ey.com

Abhinav Johri
Partner, Digital engineering & AI, EY India
abhinav.johri@in.ey.com

Amit Gupta
Partner, Merger & Acquisitions, EY India
amit1.gupta@in.ey.com

Vikrant Doshi
Partner, Merger & Acquisitions, EY India
Vikrant.Doshi1@in.ey.com

Sunil Gangwal
Partner, Transaction Diligence, EY India
Vikrant.Doshi1@in.ey.com

Parag Gandhi
Partner, Post Merger Integration, EY-Parthenon
Parag.Gandhi1@parthenon.ey.com

Rajiv Joshi
Partner, Forensics & Quality, EY India
rajiv.joshi@in.ey.com

Divin Proothi
Partner, Technology Risk, EY India
Divin.Proothi@in.ey.com

Shahida Anware
Practice Coordinator, Life Sciences, EY India
Shahida.Anware@in.ey.com

Organisation of Pharmaceutical Producers of India (OPPI) Leadership and Team

Anil Matai
Director General, OPPI

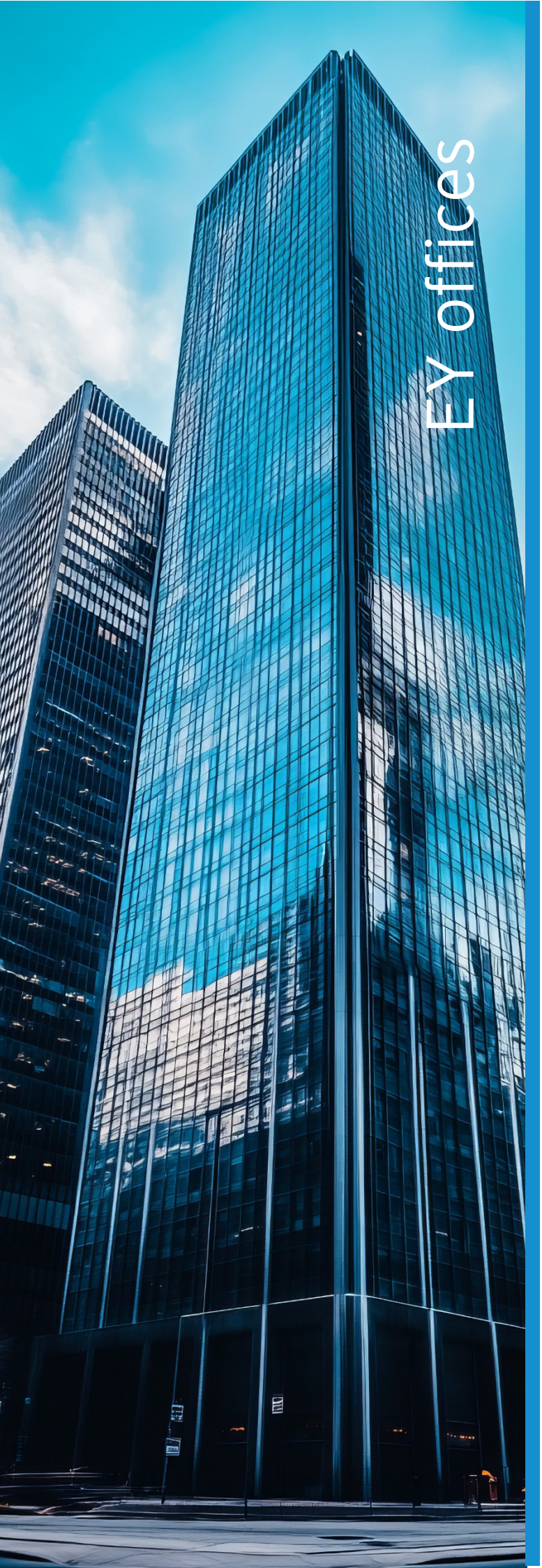
Asawari Sathaye
Senior Director Communications and Access, OPPI

Content, insights and editorial team

Tapan Mehta
Radhika KTP
Apurva Prasad
Kartik Verma
Mahima Puri
Shweta Sharma
Sushmita Yadav

Brand, Marketing & Communications

Bhavisha Jogi
Jayanta K Ghosh
Tarannum Khan
Shreya Narang



Ahmedabad

22nd Floor, B Wing, Privilon
Ambli BRT Road, Behind Iskcon Temple
Off SG Highway, Ahmedabad - 380 059
Tel: + 91 79 6608 3800

Gandhinagar

8th Floor, Building No. 14A
Block 14, Zone 1
Brigade International Financial Centre
GIFT City SEZ
Gandhinagar - 382 355, Gujarat
Tel: + 91 79 6608 3800

Bengaluru

12th & 13th Floor
"UB City", Canberra Block
No.24 Vittal Mallya Road
Bengaluru - 560 001
Tel: + 91 80 6727 5000

Ground & 1st Floor
11, 'A' wing, Divyasree Chambers
Langford Town
Bengaluru - 560 025
Tel: + 91 80 6727 5000

3rd & 4th Floor
MARKSQUARE
#61, St. Mark's Road
Shantala Nagar
Bengaluru - 560 001
Tel: + 91 80 6727 5000

1st & 8th Floor, Tower A
Prestige Shantiniketan
Mahadevapura Post
Whitefield,
Bengaluru - 560 048
Tel: + 91 80 6727 5000

Ecospace
1st Floor, Campus 1C
Ecospace Business Park
Outer Ring Road,
Bellandur - Sarjapura Area,
Varthur Hobli,
Bengaluru Urban - 560103

Bhubaneswar

8th Floor, O-Hub, Tower A
Chandaka SEZ, Bhubaneswar
Odisha – 751024
Tel: + 91 674 274 4490

Chandigarh

Elante offices, Unit No. B-613 & 614
6th Floor, Plot No- 178-178A
Industrial & Business Park, Phase-I
Chandigarh - 160 002
Tel: + 91 172 6717800

Chennai

6th & 7th Floor, A Block,
Tidel Park, No.4, Rajiv Gandhi Salai
Taramani, Chennai - 600 113
Tel: + 91 44 6654 8100

Delhi NCR

Aikyam
Ground Floor
67, Institutional Area
Sector 44, Gurugram - 122 003
Haryana
Tel: +91 124 443 4000

3rd & 6th Floor, Worldmark-1
IGI Airport Hospitality District
Aerocity, New Delhi - 110 037
Tel: + 91 11 4731 8000

4th & 5th Floor, Plot No 2B
Tower 2, Sector 126
Gautam Budh Nagar, U.P.
Noida - 201 304
Tel: + 91 120 671 7000

Hyderabad

THE SKYVIEW 10
18th Floor, "SOUTH LOBBY"
Survey No 83/1, Raidurgam
Hyderabad - 500 032
Tel: + 91 40 6736 2000

THE SKYVIEW 20
2nd Floor, 201 & 202
Right Wing, Survey No 83/1
Raidurgam, Hyderabad - 500 032
Tel: + 91 40 6736 2000

Jaipur

9th floor, Jewel of India
Horizon Tower, JLN Marg
Opp Jaipur Stock Exchange
Jaipur, Rajasthan - 302018

Kochi

9th Floor, ABAD Nucleus
NH-49, Maradu PO
Kochi - 682 304
Tel: + 91 484 433 4000

Kolkata

22 Camac Street
3rd Floor, Block 'C'
Kolkata - 700 016
Tel: + 91 33 6615 3400

6th floor, Sector V,
Building Omega, Bengal Intelligent Park,
Salt Lake Electronics Complex, Bidhan Nagar
Kolkata - 700 091
Tel: + 91 33 6615 3400

Mumbai

14th Floor, The Ruby
29 Senapati Bapat Marg
Dadar (W), Mumbai - 400 028
Tel: + 91 22 6192 0000

5th Floor, Block B-2
Nirlon Knowledge Park
Off. Western Express Highway
Goregaon (E)
Mumbai - 400 063
Tel: + 91 22 6192 0000

3rd Floor, Unit No 301
Building No. 1
Mindspace Airoli West (Gigaplex)
Located at Plot No. IT-5
MIDC Knowledge Corridor
Airoli (West)
Navi Mumbai - 400708
Tel: + 91 22 6192 0003

18th Floor, Altimus
Pandurang Budhkar Marg
Worli, Mumbai - 400 018
Tel: + 91 22 6192 0503

Pune

C-401, 4th Floor
Panchshil Tech Park, Yerwada
(Near Don Bosco School)
Pune - 411 006
Tel: + 91 20 4912 6000

10th Floor, Smartworks
M-Agile, Pan Card Club Road
Baner, Taluka Haveli
Pune - 411 045
Tel: + 91 20 4912 6800

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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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