



Confederation of Indian Industry

Vision 2047

India – Building the innovation powerhouse of tomorrow

The pharmaceutical and life sciences perspective

September 2026



The better the question.
The better the answer.
The better the world works.

EY Parthenon
Shape the future with confidence



Fore word

India has built a formidable position as a trusted global supplier of high-quality, affordable medicines and vaccines. Our next ambition should be equally clear: to build on this strength and establish India as a global hub for pharmaceutical and biopharmaceutical innovation.

The world of healthcare is transforming. Precision medicine, genomics, biologics and advanced therapeutics, artificial intelligence and resilient supply chains are transforming how medicines are discovered, developed, manufactured and delivered.

India already possesses many of the building blocks: strong science, world-class manufacturing, entrepreneurial talent and a growing biotechnology ecosystem. Our opportunity now is to connect these strengths: to discover in India, develop in India, manufacture in India and take Indian innovation to patients around the world.

But innovation alone is not the destination. Scientific progress has meaning only when it improves patients' lives. Innovation should therefore be accompanied by quality, affordability, accessibility and equity—from research priorities and representative clinical trials to regulatory pathways, financing and last-mile delivery.

Achieving this transformation may require deeper collaboration among government, industry, academia, research institutions, healthcare professionals, investors and patients, supported by trusted quality systems, future-ready talent, responsible use of AI and data, advanced manufacturing and resilient supply networks.

The opportunity before us is not simply to produce more; it is to create more value through science, translate that science into meaningful innovation, and help bring that innovation to the people who need it.

This report provides a timely framework for the journey. I hope this leads to more than just discussions. I hope it results in collaboration, investment and measurable action.

India's next chapter should combine our strengths in scale, quality and affordability with innovation, positioning India as one of the world's most trusted partners for pharmaceutical and biopharmaceutical innovation.

Patient-centric in design. Equity driven in delivery. Innovation led in growth.



Dr. Rajesh Jain

Chairman,
CII National Biotechnology Committee
Chairman & Managing Director,
Panacea Biotec

India's pharmaceutical industry has established a strong global presence by delivering quality medicines at scale and expanding access to healthcare worldwide. As India progresses towards the vision of Viksit Bharat 2047, the sector has an opportunity to build on this foundation and shape the next era of global healthcare through science, innovation and research.

The next phase of growth increasingly depends on India's ability to generate new knowledge, translate scientific discoveries into innovative therapies and bring them to patients with speed, quality and trust. Strengthening research and development, creating intellectual property, accelerating technology adoption and building globally competitive innovation ecosystems remain critical to realizing this ambition.

India is well-positioned for this journey. Our scientific talent, manufacturing capabilities, entrepreneurial ecosystem and expanding healthcare and digital infrastructure provide a strong foundation. The imperative now is to connect these strengths more effectively and foster deeper collaboration among industry, academia, government and healthcare institutions.

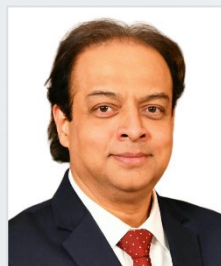
Talent is expected to be at the heart of this transformation. Scientists, researchers, clinicians, engineers and entrepreneurs have a critical role to play in driving discoveries and solutions that define the future of healthcare. Creating stronger pathways from research to commercialization, encouraging greater industry-academia collaborations and enabling sustained investment in innovation can help convert India's scientific capabilities into meaningful patient outcomes.

At the same time, innovation should remain closely aligned with the principles that have underpinned India's pharmaceutical success—quality, affordability, accessibility and trust.

The opportunity is not simply to develop new therapies, but to create solutions that are relevant, scalable and accessible to patients in India and across the world.

This report highlights key priorities and opportunities to strengthen India's pharmaceutical innovation ecosystem. It reflects the industry's shared aspiration to advance research, foster collaboration, harness emerging technologies and create an enabling environment for sustained innovation and investment.

As India moves towards Viksit Bharat 2047, the pharmaceutical sector can contribute far beyond economic growth. By combining scientific excellence with a steadfast focus on patient outcomes, India can strengthen its position as a global center for pharmaceutical innovation and continue to make a meaningful contribution to better health and wellbeing in India and around the world.



Shreehas Tambe

Chairman,
CII National Pharmaceutical Committee
on Pharmaceuticals and Chief Executive
Officer & Managing Director, Biocon

India's pharmaceutical industry has earned global recognition by delivering quality medicines at scale and expanding access to healthcare across the world. This foundation of manufacturing capability, scientific talent and entrepreneurship has established India as the "Pharmacy of the world." As the nation advances towards the vision of Viksit Bharat 2047, the sector now has an opportunity to build on this legacy and emerge as an innovation hub for the world.

The next phase of growth may require India to combine trusted manufacturing with differentiated science, intelligent technologies and equitable patient access. Competitiveness may increasingly be shaped by the ability to generate original knowledge, translate research into therapies, create intellectual property and bring innovation to patients with speed, quality and trust.

India enters this phase with considerable strengths. Its scientific talent, extensive manufacturing base, entrepreneurial ecosystem and expanding healthcare and digital infrastructure provide a strong platform for long-term growth. Realizing the full potential of these capabilities may require greater alignment among industry, government, academia, research institutions, healthcare providers, investors, technology companies and patient groups.

This report presents a four-pillar framework for India's pharmaceutical journey to 2047. It calls on the sector to defend trust through consistent quality and resilient manufacturing; differentiate through innovation and advanced therapeutics; leapfrog through responsible AI, data and digital infrastructure; and democratize access by embedding affordability, financing and patient outcomes into the innovation lifecycle.

These priorities are closely interconnected. Strong quality systems and resilient supply chains enable innovation to scale; scientific

and translational capabilities create differentiated therapies and platforms, while trusted data and responsible AI can accelerate discovery, manufacturing, regulatory processes and evidence generation. Equitable access helps translate scientific progress into better health outcomes for people across geographies and income groups.

Building specialist capabilities in areas such as biologics, genomics, cell and gene therapies, artificial intelligence, regulatory science and clinical research remains essential. Equally important may be stronger pathways for collaboration, technology transfer and the translation of academic research into commercially and clinically relevant solutions.

India's long-term success depends on combining trusted scale with original innovation, responsible technology and a steadfast focus on patient outcomes. This approach can further strengthen India's role in global healthcare and help shape the future of medicine.



Suresh Subramanian

Partner and National Life Sciences Leader
EY-Parthenon



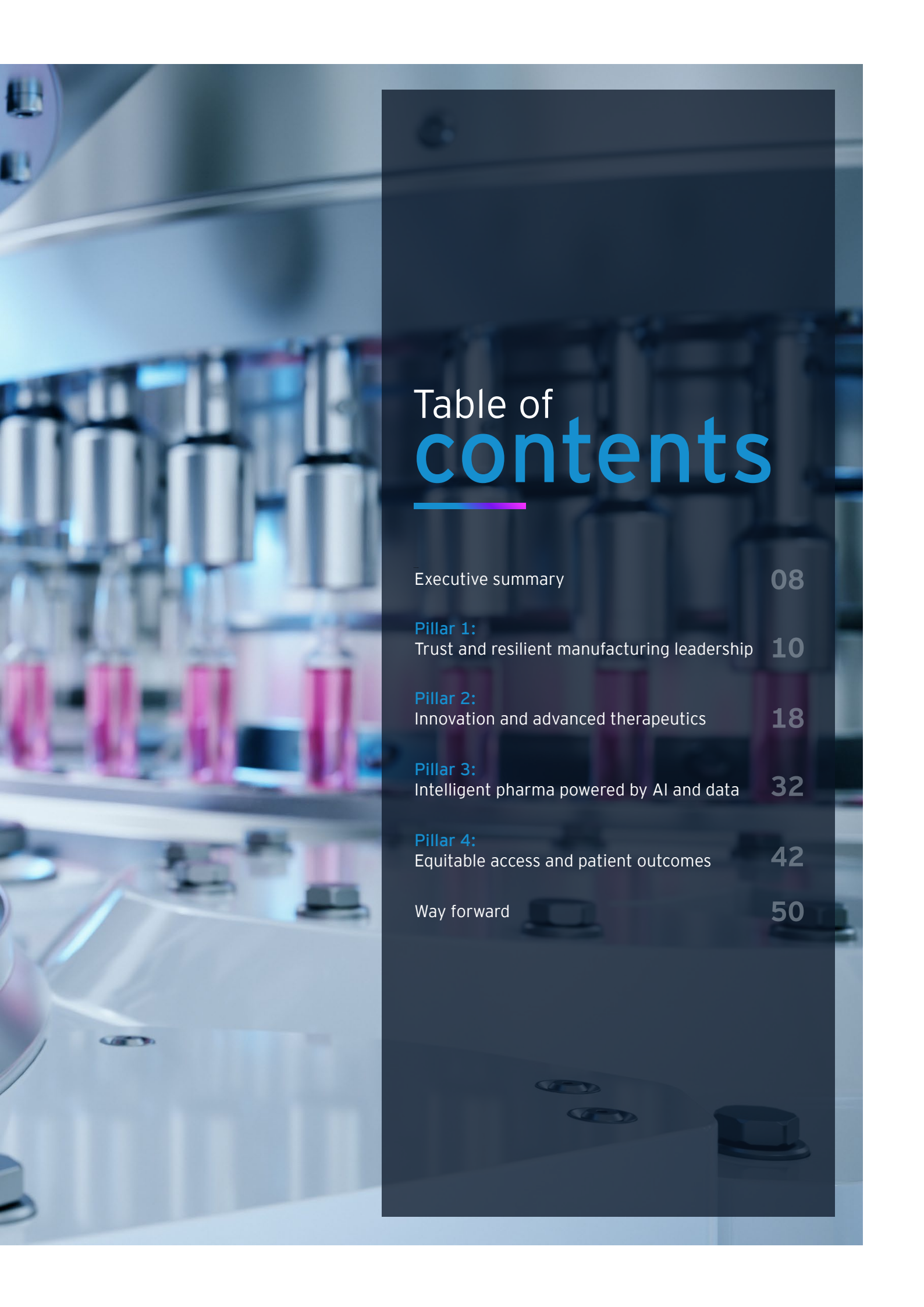


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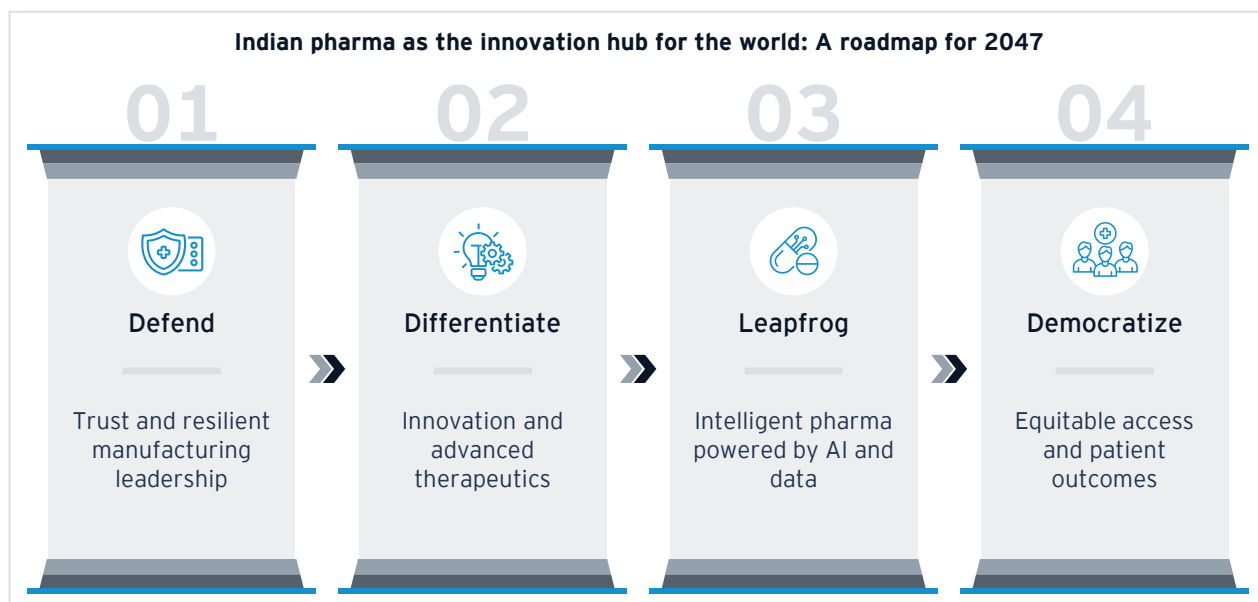


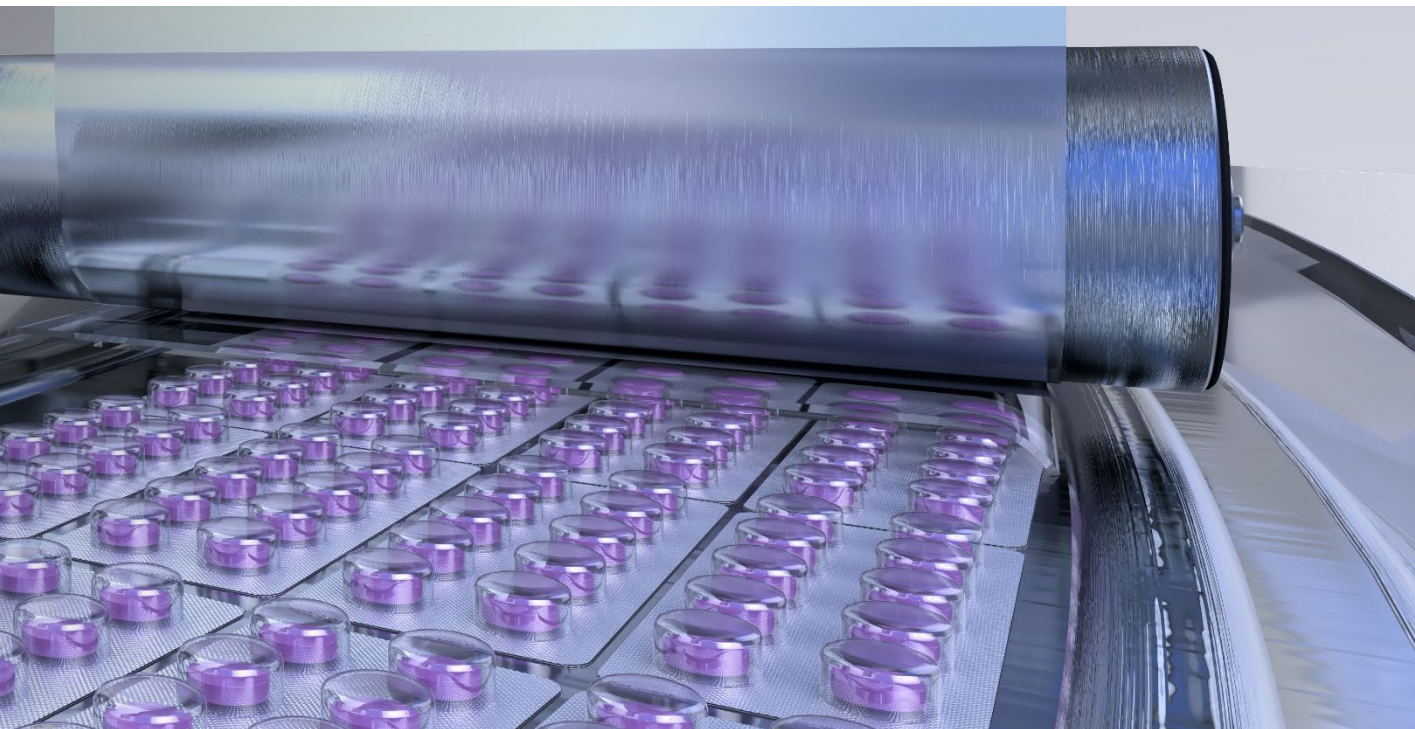
Executive summary

A four-pillar framework for India's pharma journey to 2047

India has earned global relevance through affordable medicines, manufacturing scale, scientific talent and entrepreneurship. The next ambition is larger: to evolve from the 'Pharmacy of the world' into an innovation hub that combines dependable supply, differentiated science, intelligent operations and equitable patient outcomes.

Four mutually reinforcing shifts can anchor this journey. India must defend trust through consistent quality and resilient supply; differentiate through science, platforms and advanced modalities; leapfrog through responsible AI and interoperable data; and democratize access by embedding affordability, financing and patient outcomes into innovation.





First, India must defend trust. Rising regulatory expectations and product complexity require lifecycle quality systems, faster Schedule M adoption, stronger data integrity and traceability, resilient critical inputs and climate-ready supply chains. Trust must be engineered deliberately, not assumed from scale.

Second, India must differentiate through innovation. Its scientific talent and research infrastructure can support a shift from volume-led manufacturing to value-led discovery across biologics, biosimilars, CGTs, precision medicine and platform-based R&D. Success is likely to depend on industry-academia-startup-investor collaboration and a clinical research ecosystem that converts science into therapies reaching patients.

Third, India can leapfrog through AI and digital infrastructure. Value may come from redesigning operating models around trusted data, validated models, digital workflows, human oversight and regulatory evidence, rather than adding isolated tools to existing processes.

Fourth, India must democratize access. Innovation creates value only when it reaches patients. Access must therefore be designed into R&D, manufacturing, diagnostics, financing, clinical capacity and delivery, with success measured through patient outcomes and financial protection.

The four pillars are interdependent. Trusted manufacturing enables innovation to scale; digital infrastructure increases its speed and reliability; equitable access converts scientific progress into health impact; and patient outcomes build the evidence required for sustained investment.

The chapters that follow explore these themes in greater detail:

- **Chapter 1** examines trust and resilient manufacturing leadership.
- **Chapter 2** explores the innovation and advanced therapeutics that can help India achieve value-led innovation.
- **Chapter 3** outlines ways in which AI, digital technologies and ecosystem collaboration can transform the pharmaceutical value chain.
- **Chapter 4** highlights how equitable access and improved patient outcomes can translate innovation into broader societal impact.
- The strategic test is execution. Government, regulators, industry, academia, healthcare providers, investors, technology companies and patient groups need defined ownership, transparent milestones and a national scorecard extending from 2030 to 2047.

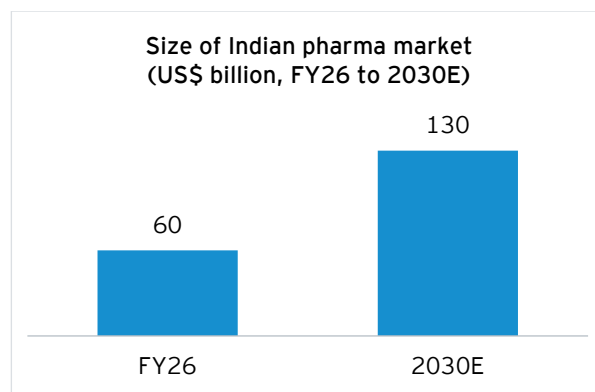


Pillar 1:

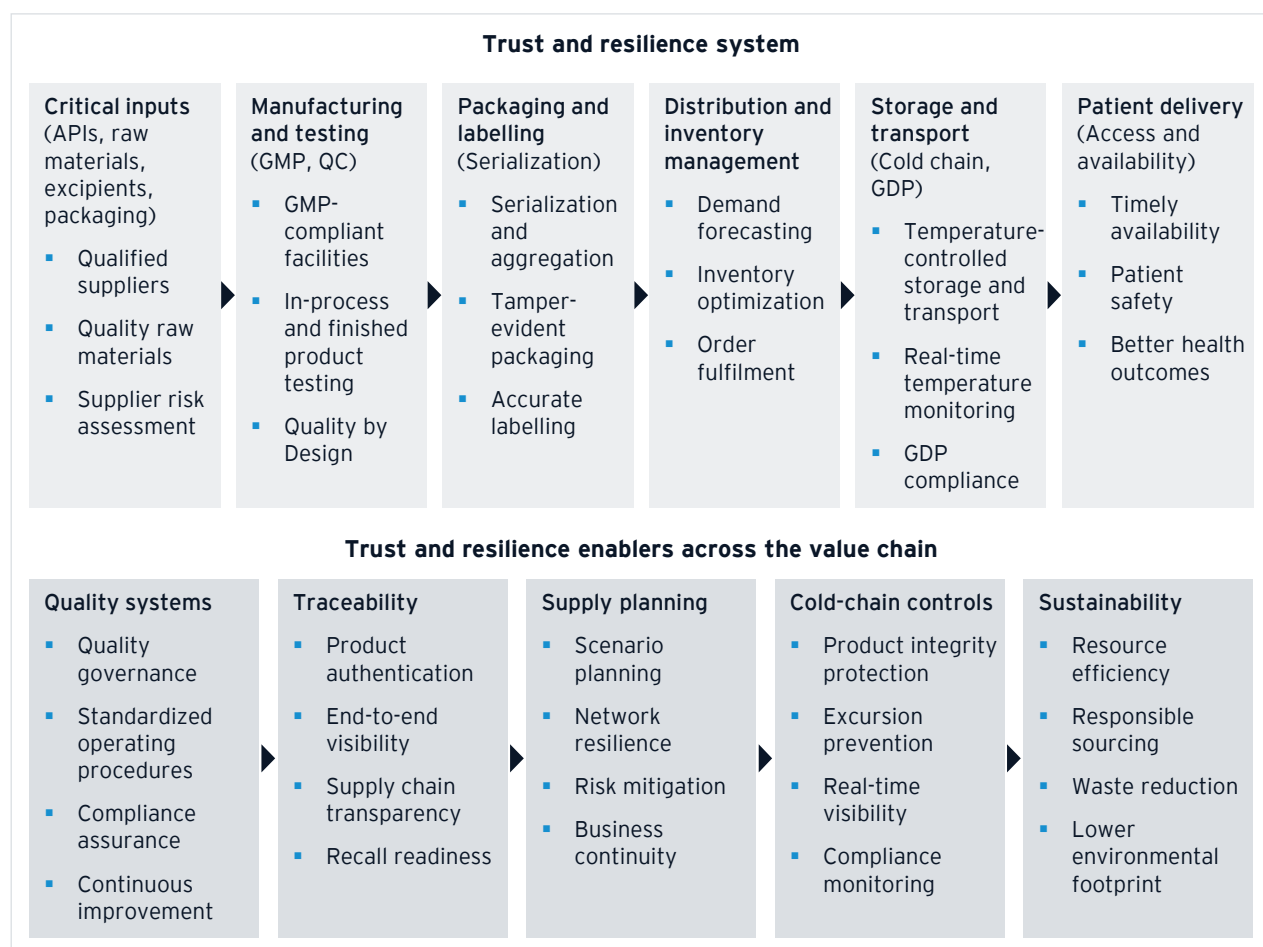
Trust and resilient
manufacturing leadership

India's manufacturing scale established its global role; future leadership may depend on consistent quality and reliability. Quality-led manufacturing is therefore central to protecting the 'Pharmacy of the world' position and enabling innovation-led growth.

Every medicine supplied in India and overseas must reinforce that trust.



Source: <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2243248®=48&lang=2>



1.1 Global quality and compliance leadership

For a manufacturing-led industry, patient centricity begins with a simple requirement: every batch must be safe.

India supplies around 20% of global generic medicine demand and exported pharmaceuticals to 191 countries in FY24-25. More than half of these exports went to regulated markets, including the US and Europe, linking international market access with manufacturing quality, reliable data and inspection readiness¹.

In December 2023, India notified the revised Schedule M requirements under the Drugs and Cosmetics Rules, 1945, strengthening Good Manufacturing Practice (GMP) standards under the Drugs and Cosmetics Act, 1940.

The revision incorporates a Pharmaceutical Quality System, Quality Risk Management, Product Quality Review, qualification and validation requirements, computerized-system controls and data integrity aligned with ALCOA principles² supporting records that are attributable, legible, contemporaneous,

original, accurate, complete, consistent, enduring and readily available for review. The requirements move quality control beyond finished-product testing and towards risk management across the manufacturing lifecycle. Regulatory attention is on compliance verification, and many manufacturers have sought additional time to complete upgrades.

For smaller manufacturers, financial support is helping bridge the investment gap. Under RPTUAS, eligible firms can receive incentives covering 10% to 20% of approved technology and facility-upgrade investments, capped at INR2 crore, thereby reducing the cost of compliance with revised Schedule M requirements³. Grant support worth INR248.20 crore had been sanctioned for 255 companies, with disbursement of INR18.25 crore approved for 19 companies as of December 2025⁴.

The challenge is to raise standards without disrupting supply. Stronger controls protect patients and market confidence, while smaller manufacturers need finance, technical support and practical transition plans to avoid capacity loss or shortages.

Consistent quality across products, sites and markets can turn compliance into competitive credibility and reinforce India as a dependable medicine supplier.

From India to the world

Third

largest production volume, 11th by value

~40%

of US generics, >50% of Africa, ~25% of UK medicines

70%

of WHO essential vaccine demand; 40%-70% of DPT/BCG

670-800+

sites form the highest number of USFDA-approved plants outside the US

500

active pharmaceutical ingredient (API) manufacturers; nearly 8% of the global API industry

Sources: <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2243248®=48&lang=2>; <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2243248®=48&lang=2>; https://www.business-standard.com/india-news/indian-pharma-sites-outpace-global-standards-in-usfda-inspections-for-2023-124062700386_1.html; <https://www.investindia.gov.in/team-india-blogs/harnessing-indias-api-potential>

¹ Press Release Page | Press Information Bureau

² <https://www.pib.gov.in/PressReleaseDetail.aspx?PRID=2224373®=48&lang=2>

³ <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2224373®=3&lang=1>

⁴ <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2224373®=3&lang=1>

1.2 Schedule M and QbD adoption

The revised Schedule M establishes the compliance framework for strengthening pharmaceutical quality systems and Quality by Design (QbD) provides a scientific approach for applying risk-based controls during product development and manufacturing, translating intended clinical performance into a Quality Target Product Profile. The process knowledge generated through this approach supports consistent technology transfer, faster deviation investigations and controlled lifecycle changes, particularly for complex generics and injectables.

Across regulated markets, QbD (guided by the International Council for Harmonisation or ICH) covers pharmaceutical development, quality risk management and pharmaceutical quality systems⁵. For example, the European Medicines Agency accepts QbD elements in marketing authorization applications, scientific advice and post-approval variations, allowing product and process knowledge to inform regulatory decisions throughout the lifecycle⁶.

India is moving towards the same lifecycle-based model through revised Schedule M, which has introduced quality risk management, validation and product quality reviews. To intensify regulatory vigilance, CDSCO and state authorities inspected more than 960 manufacturing premises since December 2022 and initiated over 860 regulatory actions⁷. The figures reflect wider GMP enforcement rather than direct QbD adoption, but also show the consequences of weak process knowledge and quality controls. Wider adoption requires manufacturers to build skills in risk assessment, experimental design, process analytics and lifecycle management, supported by regulatory guidance and industry-academia training.

Embedding these practices across development, technology transfer and commercial production can reduce batch variability and support acceptance across regulated markets.

1.3 Digital traceability and inventory control

Digital traceability records a medicine's identity and movement, while inventory-control systems determine

its release, availability and withdrawal status. Together, these capabilities support FEFO allocation, targeted recalls, counterfeit prevention and end-to-end visibility across the pharmaceutical supply chain. As Indian pharmaceutical companies expand exports to highly regulated markets such as the United States, European Union, GCC and other jurisdictions, serialization and track-and-trace capabilities have become critical infrastructure for regulatory compliance, product authentication and supply-chain integrity. India's pharmaceutical export ecosystem would benefit from adopting GS1-based serialization, aggregation and traceability frameworks to meet global requirements, while leading manufacturers can integrate packaging-line serialization, warehouse visibility and supply-chain monitoring into broader digital operations. Industry-wide adoption of serialization and traceability can increase recall readiness, reducing diversion risk and enhancing confidence among regulators, distributors and patients.

Dr. Reddy's Laboratories has publicly highlighted the use of advanced analytics, demand forecasting and integrated supply-chain planning to improve inventory management and responsiveness.

Sun Pharma, Cipla, Zydus Lifesciences and other export-oriented manufacturers operate extensive serialization and traceability infrastructure to support compliance across major regulated markets. The strategic importance lies not in serialization alone but in integrating packaging, warehousing, distribution and regulatory reporting into a connected supply-chain ecosystem.

Connected inventory planning extends the same control to medicine availability. Mankind Pharma, for example, reports linking demand forecasting, production, inventory and distribution across 30 plants and more than 50 distribution centers. The program reduced stockouts by 75% and inventory by up to 20% in 2026⁸.

Common data standards and shared investigation protocols can connect manufacturers, warehouses, distributors, pharmacies and regulators, supporting targeted recalls, stock accuracy and confidence in medicine quality.

⁵ ICH Q8, Q9 and Q10 - questions and answers - Scientific guideline | European Medicines Agency (EMA)

⁶ Quality by design | European Medicines Agency (EMA)

⁷ <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2244523®=48&lang=2>

⁸ <https://www.mankindpharma.com/media/press-release/mankind-pharma-reinvents-global-supply-chain-and-procurement-with-accenture/>

Digital traceability across the medicine journey

Establish product identity

Serialization, QR codes and DataMatrix assign a unique identity to each pack.

Connect packaging levels

Aggregation links individual packs with cases, pallets and shipments.

Record product movement

RFID, GPS and digital scanning capture location, custody and hand-offs.

Monitor product condition

IoT sensors track temperature, humidity, light exposure and shock.

Exchange trusted data

EPCIS-based records share product, location, time and transaction events across partners.

Detect compliance risks

AI identifies duplicate codes, route anomalies, missing records and suspicious transactions.

Support faster action

Regulators and companies can authenticate products, isolate affected batches and conduct targeted recalls.

Enable patient verification

Patients and pharmacists can scan packs to verify manufacturer, batch and expiry details.

1.4 Continuous manufacturing

Digital traceability maintains oversight after release; continuous manufacturing embeds real-time quality control within production. Guided by QbD parameters, connected stages detect deviations early and divert affected material, reducing rejects, investigations and supply interruptions.

For instance, Sai Life Sciences applied commercial-scale photo-flow chemistry at its Bidar API manufacturing site for a late-phase drug program. Its three-liter reactor supports kilogram-scale processing with tighter thermal control and greater reaction consistency than conventional batch production⁹.

Along with private-sector adoption, the government is building technical capability through NIPER Kolkata, an institute under the Department of Pharmaceuticals. Its Centre of Excellence in Flow Chemistry and Continuous Manufacturing is recruiting formulation scientists and leadership with product development and industry experience¹⁰. Coordination among manufacturers, academia such as NIPERs, equipment providers and regulators can generate local validation evidence, develop specialist skills, support regulatory submissions and help extend adoption beyond large manufacturers.

1.5 API self-reliance and security

Digital visibility can manage disruption, but it cannot compensate for unavailable critical inputs. India must therefore build competitive domestic capacity in APIs, drug intermediates and key starting materials.

China supplied at least 70% of India's imports for several identified pharmaceutical inputs in FY2024-25. Dependence reached 100% for selected products, including rifamycin sodium, methyl dopa and cysteamine hydrochloride¹¹. Such concentration can constrain formulation production for domestic and export markets during external disruptions. Government incentives and industry investment are increasingly converging around domestic API and key-starting-material manufacturing. Dedicated bulk-drug parks, common infrastructure and targeted incentives are helping improve the economics of domestic production, particularly for strategically important molecules where import dependence remains high.

⁹ Commercial-scale Photo Flow Chemistry successfully executed in Bidar - Contract Research, Development & Manufacturing Org | Sai Life | niperkolkata.edu.in/niperadmin/Upload/10.8.2026-AdvertisementforCOE.pdf

¹⁰ <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2237414®=48&lang=2>

¹¹ <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2237414®=48&lang=2>

Building API capacity

Bulk drugs PLI scheme

- **INR40,890 crore** cumulative PLI-driven pharma investment (Sep 2025)
- **INR5,070 crore** attracted across 48 approved projects
- **5,220-plus** jobs created
- **38 projects** covering 28 critical products commissioned
- **56,800 MT** of annual capacity created
- Imports worth **INR2,192 crore** avoided (December 2025)

Some state-led PPPs

- **INR3,000 crore** facility being built by Ramky Infrastructure's subsidiary and MIDC under a 95-year concession, in 2026.
- **INR1,560 crore** Lalitpur Bulk Drug Pharma Park has been initiated by UPSIDA and MoUs signed with private developers to establish common infrastructure and manufacturing facilities

Sources:

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2197944®=48&lang=2> | Press Information Bureau

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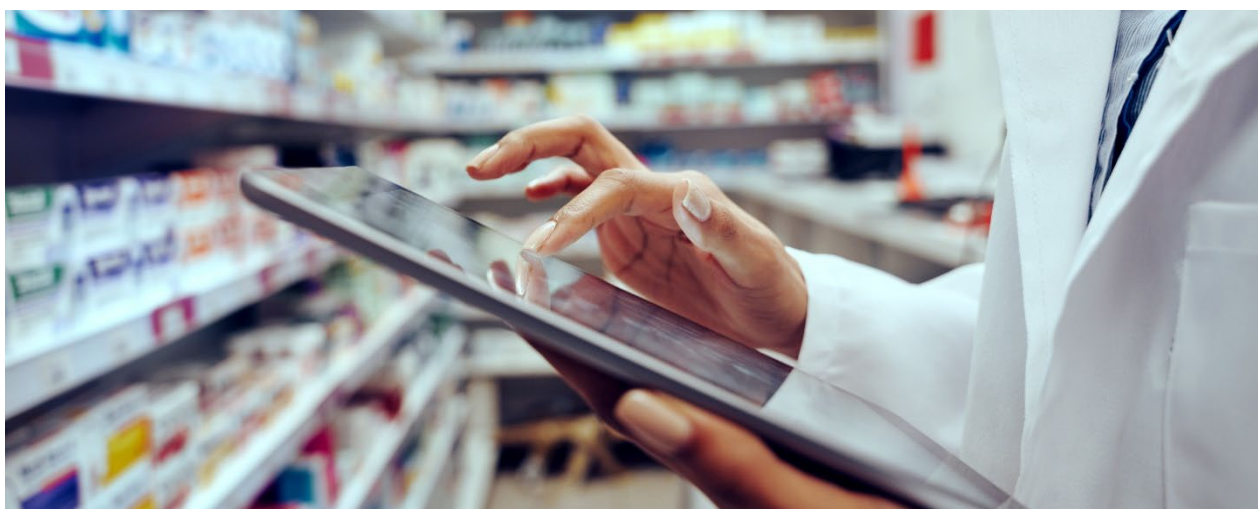
ramkyinfrastructure.com/docs/pdf/investordesk/announcements/Midcaggrement13.03.2026.pdf

<https://pharmabiz.com/NewsDetails.aspx?aid=184095&sid=1>

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Government incentives are supporting capacity creation on a wider scale. Along with central incentives such as the PLI scheme, state-led PPPs can provide the shared infrastructure needed to translate private investment into production. Such projects are underway in Maharashtra, Uttar Pradesh and Andhra Pradesh, among others. Shared utilities, effluent treatment and industrial infrastructure can lower capital and operating costs for participating manufacturers¹².

Sustained API security may depend on competitive operating costs, assured procurement, consistent quality and effective use of the new capacity.



¹² ramkyinfrastructure.com/docs/pdf/investordesk/announcements/Midcaggrement13.03.2026.pdf

1.6 Supply chain resilience and last-mile connectivity

API security protects production inputs; end-to-end resilience also requires medicines to move reliably from plants to patients. Shared visibility across production, inventory, orders and consumption can help redirect supply before shortages interrupt treatment.¹³

Technology can turn network visibility into early action. Across global markets, supply-chain teams are moving from periodic risk reviews to continuous monitoring. AI-based demand sensing can track changes in medicine consumption, digital twins can test route or distribution failures and control towers can connect production, inventory and transport data. IoT sensors provide live information on shipment movement and status. Together, these technologies can identify risks, compare alternative routes and support recovery planning before disruptions affect medicine availability.

For example, Dr Reddy's Laboratories uses AI and machine learning for demand forecasting and inventory planning, supported by real-time analytics and supplier coordination. The integrated approach helps anticipate demand, reduce back orders and respond faster to supply changes¹⁴. Such planning can lower excess inventory and emergency freight costs for manufacturers, with fewer stockouts and treatment interruptions for patients.

1.7 Cold chain infrastructure

Resilient networks maintain availability, but temperature-sensitive products require validated storage, transport and handling at every transfer point. As vaccines, biologics, specialty injectables and cell and gene therapies (CGTs) grow, cold chain becomes a product-quality and patient-safety capability and not merely a logistics function.

Most vaccines require storage between 2°C and 8°C, and selected advanced therapies require frozen or ultra-cold conditions. Temperature excursions can reduce potency without visible signs, leading to

rejected shipments, recalls or ineffective treatment. Continuous temperature records and auditable hand-offs help manufacturers meet regulatory requirements and protect high-value consignments during transit.

Reflecting private-sector investment in export logistics, Jeena & Company partnered with Envirotainer to provide Indian pharmaceutical exporters with specialized temperature-controlled containers, compliant handling and access to global distribution networks, in 2026¹⁵. Within the Government of India's immunization system, the cold-chain network covers around 28,000 vaccine-storage facilities. NCCVMRC supports supply-chain planning, equipment specifications, training and policy development¹⁶. Backup power, calibrated data loggers, IoT-based alerts, predictive maintenance, solar refrigeration and contingency routes can reduce temperature-excursion risks at vulnerable locations. Such controls protect product potency, reduce avoidable losses and support reliable access to sensitive therapies across regions.

a. Sustainable and climate-resilient manufacturing

Long-term trust also depends on responsible production. Water efficiency, solvent recovery, green chemistry, emissions, waste management and climate-resilient logistics should be integrated into quality, cluster planning and investment decisions. Sustainability metrics should form part of the national manufacturing scorecard, particularly for water-stressed clusters and temperature-sensitive supply chains.

b. A segmented MSME quality-transition pathway

Smaller manufacturers need a segmented transition model combining upgrade finance, technical assistance, shared validation services, specialist training and clear milestones. Public support should be tied to sustained quality performance rather than one-time certification. Where independent investment is not viable, shared infrastructure, contract-manufacturing collaborations or consolidation may provide more credible routes to compliance.

¹³ [Enhancing resilience and sustainable healthcare supply chains: integrating circular economy and dynamic barrier management | Discover Sustainability | Springer Nature Link](#)

¹⁴ [The Importance of Supply Chain Management and Dr. Reddy's Excellence | API](#)

¹⁵ [Jeena & Company inks MoU with Envirotainer to strengthen pharmaceutical cold chain logistics](#)

¹⁶ [National Cold Chain Management Information System](#)

1.8 India's position as a trusted global source

Reliability converts manufacturing capability into confidence among patients, regulators and buyers. It requires consistent quality, verifiable records, stable supply and timely action across the product lifecycle.

A connected assurance system combines QbD, digital traceability, API security, supply planning and cold-chain controls to prevent failures, trace causes and limit patient impact.

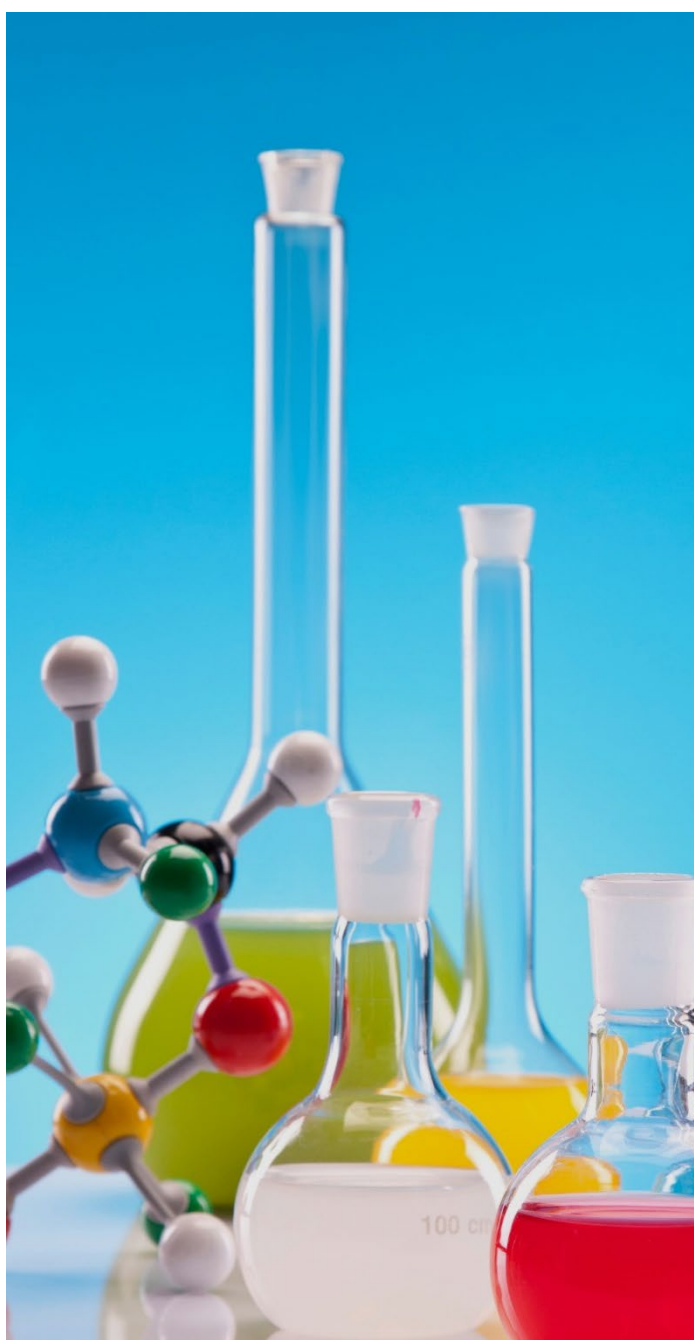
Regulatory oversight provides accountability and industry collaboration adds a capability-building layer. The Indian Pharmaceutical Alliance (IPA) Quality Forum, for instance, supports peer learning, performance benchmarking, global connection and dialogue with regulators¹⁷.

India can strengthen global trust by applying common quality expectations across large companies, smaller manufacturers and supply partners. A shared quality culture would support dependable products in every market.



Pillar 1: **2030 action agenda**

Define a national quality-maturity baseline; create an MSME transition program; prioritize critical inputs by clinical importance and supply concentration; accelerate interoperable traceability; and include resource intensity and climate resilience in manufacturing incentives



¹⁷<https://www.ipa-india.org/quality>



Pillar 2:

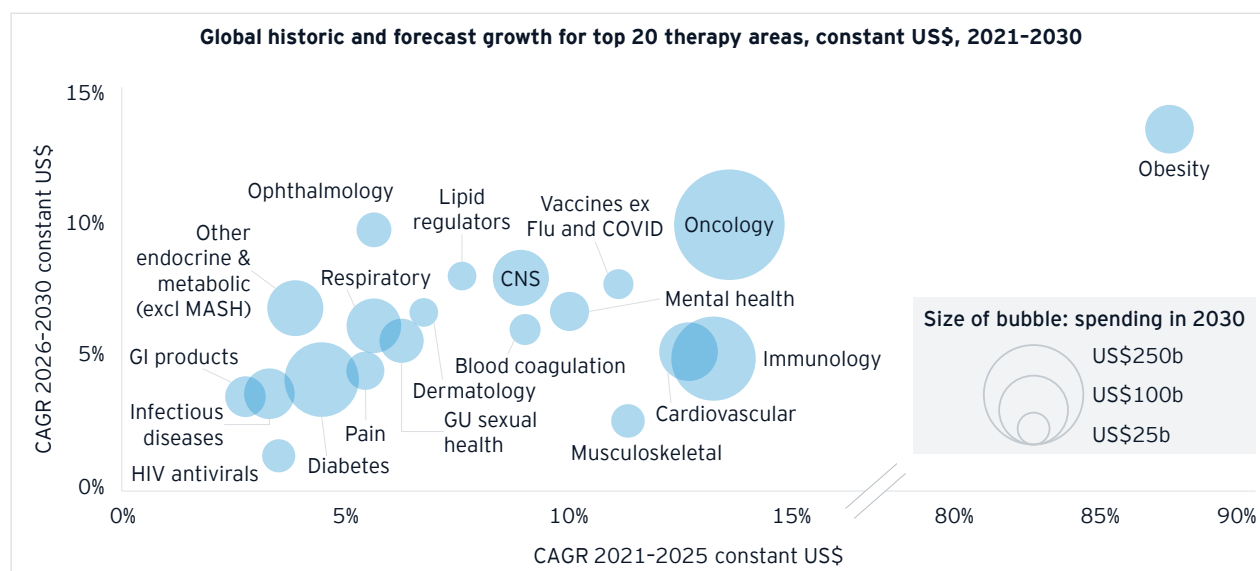
Innovation

and advanced therapeutics

Global developments are creating new opportunities for Indian pharma to build on its manufacturing strength and move towards innovation-led, high-value growth.

While major patent-expiry cycles have traditionally slowed industry growth, the global pharmaceutical

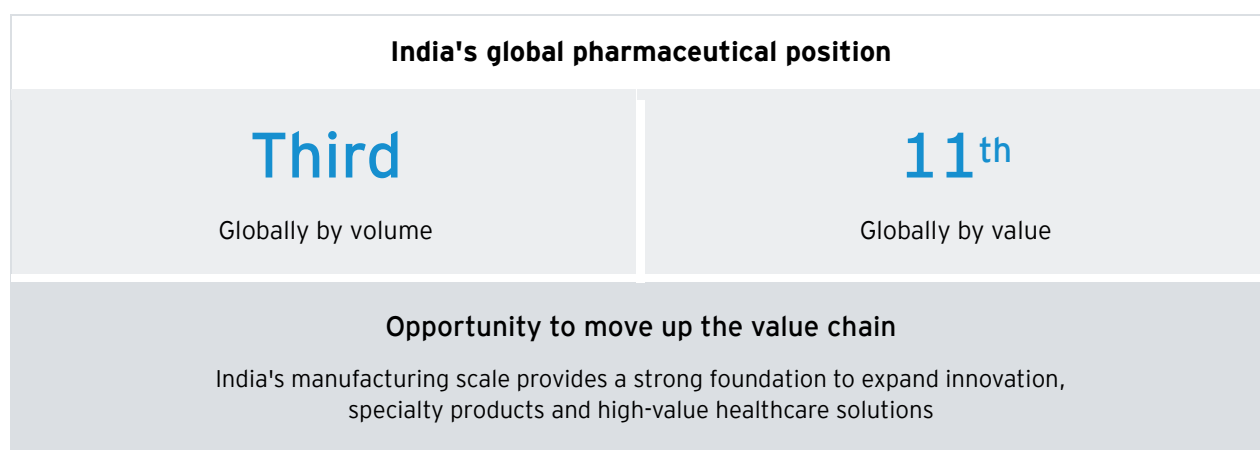
market is expected to grow 5% to 8% annually through 2030 and exceed US\$2.6 trillion¹⁸, even as products representing nearly US\$200 billion in branded sales lose exclusivity. The therapeutic areas driving most of the growth continue to be oncology, immunology and endocrinology, particularly diabetes and obesity.¹⁹



Source: <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-medicine-use-trends-2026>

India's pharmaceutical market is also expected to grow from INR5.30 lakh crore (US\$60 billion) in FY26 to INR12.47 lakh crore (US\$130 billion) by 2030, supported by strong manufacturing capabilities, growing exports, policy support and continued leadership in generic medicines and vaccines.²⁰

Recent performance reflects continued momentum. Pharmaceutical exports grew 6.8% year-on-year in Q1 FY27, with June growth reaching 7.3% despite disruptions in the Middle East.²¹ However, FY26 export growth moderated to around 2.1%, while continued price erosion in the US generics market is putting pressure on margins.



¹⁸ <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-medicine-use-trends-2026>

¹⁹ <https://www.iqvia.com/blogs/2026/03/iqvia-institutes-2026-forecast-global-medicine-use-stays-strong-despite-headwinds>

²⁰ https://www.ibef.org/download/1787908200_Pharmaceuticals-May-2026.pdf

²¹ <https://www.aninews.in/news/business/pharma-exports-have-grown-68-in-q1-fy27-june-growth-hits-73-despite-global-disruptions-pharmexcil-chairperson20260902202258/>

2.1 Emerging hubs of innovation

Pharmaceutical innovation is becoming more geographically distributed, reducing its historic concentration in the US and Europe.

China illustrates this shift. Out-licensing from mainland China accounted for 32% of global biopharma transactions in the first half of 2025, up from 5% in 2020.²² Total licensing activity between Greater China biopharma companies and global drugmakers reached US\$137.7 billion in 2025, compared with US\$13.9 billion in 2021.²³ Much of this activity has been concentrated in advanced modalities such as antibody-drug conjugates (ADCs), bispecific antibodies and cell therapies, primarily targeting oncology indications.²⁴ Major agreements involving Bristol Myers Squibb, Pfizer and Chinese biopharma companies highlight growing global demand for innovation assets originating from emerging innovation hubs.²⁵

Many of the country's top 10 companies developing novel drugs are also focusing on generics industry. Type 2 diabetes, autoimmune/inflammatory diseases, rheumatoid arthritis, ulcerative colitis, and chronic obstructive pulmonary disease are priority.

Source:

<https://www.thefinancialworld.com/decoding-fy26-rd-expenditure-of->

India is also beginning to participate in this shift. In May 2026, Wockhardt received US FDA approval for Zaynich (a novel antibiotic discovered and developed in-house), for adults with complicated urinary tract infections, including pyelonephritis, caused by

susceptible Gram-negative organisms.²⁶ At the same time, Sun Pharma expanded its innovation portfolio through the acquisition of Checkpoint Therapeutics, gaining access to Unloxcyt, the first FDA-approved anti-PD-L1 therapy for advanced cutaneous squamous cell carcinoma.²⁷

As global companies face higher R&D costs, productivity pressure and patent expiries, they are using licensing, partnerships and targeted acquisitions to replenish pipelines. India can contribute innovative assets, development capabilities and specialized manufacturing across precision medicine, biosimilars, cell and gene therapy, ADCs, peptides and oligonucleotides.

Advanced-modality capabilities

Modality	Discovery	Development	Clinical	Manufacturing	Commercial access
Peptides	Strong	Strong	Moderate	Strong	Moderate
Oligonucleotides (incl. RNAi)	Moderate	Strong	Nascent	Moderate	Nascent
Antibody-drug conjugates	Moderate	Moderate	Nascent	Moderate	Nascent
Monoclonal antibodies	Moderate	Strong	Strong	Strong	Strong
Cell and gene therapies	Moderate	Moderate	Nascent	Nascent	Moderate
Targeted protein degradation	Strong	Moderate	Nascent	Moderate	Nascent

■ Strong - commercial-scale capability demonstrated
■ Moderate - capability established, scale still building
■ Nascent - little or no present capability

²² <https://pharmasource.global/content/chart/china-now-sources-32-of-global-biopharma-out-licensing-deals-up-from-5-in-2020/>

²³ <https://pharmasource.global/content/china-biopharma-out-licensing-surges-to-record-137-7b-in-2025-2026-on-pace-to-break-it-again/>

²⁴ <https://www.pharmaceutical-technology.com/features/china-pharma-licensing-deals-oncology-innovative-drugs/>

²⁵ <https://pharmasource.global/content/chart/china-now-sources-32-of-global-biopharma-out-licensing-deals-up-from-5-in-2020/>

²⁶ <https://www.wockhardt.com/wp-content/uploads/2026/05/wockhardt-zaynich-fda-approval-press-release.pdf>

²⁷ <https://www.fortressbiotech.com/news-media/press-releases/detail/692/sun-pharma-to-acquire-checkpoint-therapeutics>

2.2 Precision medicine

The shift towards value-based healthcare is accelerating the adoption of precision medicine, which tailors treatment to individual patient characteristics and expected response to therapy. Enabled by genomics, multi-omics, AI and real-world health data, it moves healthcare beyond the traditional one-size-fits-all approach towards more targeted and personalized care.²⁸

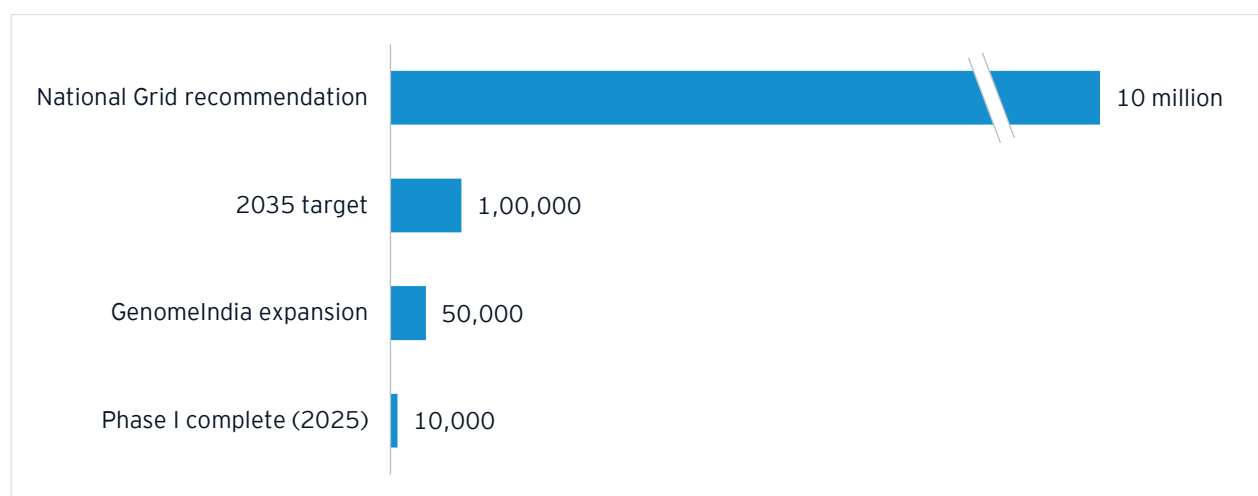
Advancements in genomics, AI-powered diagnostics and targeted therapies are driving rapid growth in the global precision medicine market, which is projected to grow from US\$138.67 billion in 2026 to US\$537.17 billion by 2035, at a CAGR of 16.26%. Asia Pacific is expected to be one of the fastest-growing regions, supported by expanding genomics infrastructure and healthcare investments, while North America continues to lead due to higher clinical adoption and R&D spending²⁹. India can participate more actively in this growing market by strengthening the genomic infrastructure needed to translate patient data into targeted clinical insights.

2.2.1 Genomics inputs in drug discovery

With over 4,000 to 5,000 distinct communities and one of the world's largest genetic pools, India offers unique opportunities for genomic research. The Genome India initiative has completed sequencing of 10,000 Indian genomes. The long-term national goal is sequencing 10 million genomes to strengthen disease prediction, precision diagnostics and personalized treatment approaches.³⁰

Sequencing roadmap in India: Building the genomic foundation for precision medicine

Genome India and related initiatives are creating population-scale genomic datasets that can support disease prediction, precision diagnostics and the development of therapies tailored to Indian populations.



Sources: <https://www.niti.gov.in/sites/default/files/2026-07/Roadmap-for-Building-India-as-a-Leading-Bioeconomy-Powerhouse.pdf>; <https://www.healthcareitnews.com/news/asia/india-targets-sequence-10-million-genomes>

Next-generation sequencing (NGS) is accelerating the adoption of genomics in India as sequencing costs continue to decline. Sequencing capabilities are expanding across research institutions, hospitals, molecular diagnostics companies, biobanks and specialized genomics providers.³¹ However, linked

clinico-genomic datasets remain limited to select institutions and disease areas. Addressing gaps in sequencing access, data integration and analytics can strengthen targeted drug discovery and enable precision healthcare at scale.

²⁸ <https://pmc.ncbi.nlm.nih.gov/articles/PMC8282508/>

²⁹ <https://www.precedenceresearch.com/precision-medicine-market>

³⁰

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2239775®=48&lang=2>

³¹ [India Next-generation Sequencing Market Size, Share, Trends, Growth Analysis Report, 2031](#)

Stakeholders in India that generate genomic data using third-generation sequencing



Clinical diagnostics



Research and Academia

Public

- Government diagnostic laboratories and hospitals (some are public-private partnerships)

- Public research and academic institutions; some are PPPs
- Bio-incubators and Biobanks

Private

- Pathology and molecular pathology diagnostic labs
- Molecular pathology diagnostic companies (wet and/or dry lab)/MSMEs
- Large corporate, multi-specialty hospitals
- Specialty hospitals, e.g., Oncology
- DTC genomic testing companies
- Biobanks, e.g., Cord blood banking

- Companies support research by providing wet and/or dry lab capabilities
- Multispecialty/specialty hospitals that conduct research

Source: <https://www.iqvia.com/locations/india/blogs/2025/10/advancing-genomics-and-precision-medicine-in-india#ii>

The Ayushman Bharat Digital Mission (ABDM) is establishing an interoperable digital health ecosystem that can support the use of longitudinal health data in clinical decision-making. Complementing these efforts, the BioE3 Policy identifies precision biotherapeutics as a priority area, with a focus on advanced modalities, research infrastructure and collaboration across government, academia and industry to support the development of indigenous precision therapies, including cell and gene therapies.³²

2.2.2 Companion diagnostics and targeted therapies

Companion diagnostics are becoming integral to modern oncology, helping match patients to targeted therapies based on their molecular profile. The field continued to expand in 2025, with the US FDA approving or clearing new or expanded indications for 16 companion diagnostic testing systems.³³ In India, companies such as United Biotech are aligning targeted oncology therapies with companion diagnostic strategies, while the CDSCO's proposed guidance is creating a clearer regulatory pathway for their approval.³⁴

2.2.3 Precision oncology

Precision oncology is expanding access to genomic testing, helping identify actionable mutations and guiding targeted treatment decisions. One example is the LuNGS Alliance, led by the Cancer Research and Statistics Foundation, with support from AstraZeneca, Pfizer and Roche, and with 4baseCare as a laboratory partner. Since its launch in March 2025, the alliance has supported genomic profiling of lung cancer patients through a free NGS biomarker testing program. Using the India-developed 72-gene TARGET First Solid panel, the initiative aims to expand access to precision oncology in Tier 2 and Tier 3 cities.³⁵

2.2.4 Indian precision medicine capabilities

Indian companies are building capabilities across multi-omics, AI-enabled diagnostics, genomic testing and clinico-genomic decision support. Recent developments highlight their growing clinical application.

³² <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2239776®=48&lang=2>

³³ <https://www.globenewswire.com/news-release/2026/05/14/3294895/0/en/new-pmc-report-shows-fda-advancing-a-new-era-of-personalized-patient-centered-care.html>

³⁴ <https://unitedbiotechindia.com/health/understanding-the-role-of-companion-diagnostics-in-cancer-treatment/>

³⁵ <https://www.bwhealthcareworld.com/article/lungs-alliance-launches-free-ngs-biomarker-testing-for-lung-cancer-patients-in-india-552207>

Capability area	Application
Multi-omics and precision medicine	MedGenome: Launched MetaSeq, a sequencing-based test capable of detecting 1,400+ pathogens from a single blood sample.
Genomics, AI and biomarker-driven diagnostics	Strand Life Sciences: Developed a blood-based early cancer detection platform combining genome sequencing, methylation analysis, fragmentomics and machine learning.
Precision oncology and clinico-genomic decision support	4baseCare: Established a Precision Oncology Centre of Excellence in Maharashtra and expanded OncoTwin, an AI-enabled clinico-genomic platform for personalized cancer treatment.

Sources: [MedGenome Launches MetaSeq: Revolutionary Blood Test for Rapid Pathogen Detection, ETHealthworld](#); [Reliance's Strand Life Sciences secures Indian patent for blood-based early cancer detection technology, ETHealthworld](#); <https://www.expresshealthcare.in/news/4basecare-signs-mou-with-government-of-maharashtra-to-set-up-precision-oncology-centre/453211/>

2.3 The modality shift: Biologics, biosimilars and beyond

As biologics lose patent protection, biosimilars can expand access to these therapies by providing clinically comparable treatment options at lower cost.³⁶ Indian pharmaceutical companies are among the global leaders in biosimilars. However, a significant gap remains between manufacturing scale and value capture. Moving up the value chain may require greater focus on complex biologics, differentiated biosimilars and innovation-led portfolios.

Updated regulatory frameworks are expected to support future biosimilar growth. In 2025, CDSCO and DBT released draft revised Similar Biologics Guidelines to reflect advances in scientific knowledge and align India's regulatory requirements more closely with evolving international standards, including those of the EMA, FDA and MHRA.³⁷ The revisions aim to reduce duplication and streamline approval pathways for biosimilars.

The biosimilar opportunity

20%-21%

projected CAGR of India biosimilar market, which is to grow to US\$5.95-6.44 billion by 2033

3.2%

India's share in global biosimilars revenue

Sources: [India Biosimilars Market Size, Trends, Growth & Demand 2032](#); <https://www.grandviewresearch.com/horizon/outlook/biosimilars-market/india>

³⁶ <https://pmc.ncbi.nlm.nih.gov/articles/PMC6394151/>

³⁷ <https://knowledge-healthcare.events/2025/06/01/similar-biologics-guidelines/>

Recent biosimilar milestones by some leading Indian companies

Company	Biosimilar milestone
Zydus Lifesciences	Launched Tishtha, the world's first nivolumab biosimilar and Anyra, India's first indigenous aflibercept biosimilar
Biocon Biologics	Received US FDA approval for Bosaya and Aukelso in September 2025 (biosimilar to Prolia and Xgeva, respectively. FDA also approved interchangeability); and launched Yesafili, an aflibercept biosimilar
Lupin	Received US FDA approvals for Armlupeg (pegfilgrastim) and Ranluspec (ranibizumab)
Alkem Laboratories / Enzene Biosciences	Launched Pertuza, a pertuzumab biosimilar and Cetuxa, the world's first cetuximab biosimilar (with Lupin)

Sources: <https://www.zyduslife.com/investor/admin/uploads/21/83/Zydus-launches-the-world-s-first-biosimilar-of-Nivolumab---Tishtha---in-India-to-treat-multiple-cancers.pdf>, Biocon Announces U.S. Commercial Launch of Bosaya™ and Aukelso™, Denosumab Biosimilars - Biocon; Lupin Receives Approval from U.S. FDA for Biosimilar Armlupeg™ (Pegfilgrastim-unne) - Lupin | Press Release; Alkem launches breast cancer biosimilar in India - The Economic Times; https://www.alkemlabs.com/pdf/press-release/2023/Press%20release_Cetuxa.pdf

2.3.1 New modalities landscape: Peptides and oligonucleotides, ADCs and cell and gene therapy (CGT)

Emerging modalities are projected to become major growth engines for the biopharmaceutical industry over the next five years. Cell and gene therapies, peptides and ADCs are expected to record high growth, reflecting higher investment in precision medicine and targeted therapeutics.

Emerging therapies to see strong growth over next few years

Technology	Market size (US\$b): 2024	Market size (US\$b): 2029E	CAGR 2024-29
Antibody Drug Conjugate (ADC)	13.3	45	27.6%
Peptides	3.5	14	32.4%
GLP-1	52.9	126	19.0%
Oligonucleotides including RNAi	5.3	12	18.1%
Lipids	1.04	2	13.8%
Recombinant Monoclonal Antibodies (mAbs)	237.4	328	6.7%
Cell and gene therapies	8.7	46	39.5%

Source: <https://www.hdfcsec.com/hsl.docs/Pharma%20-%20CRDMO%20-%20Sector%20Thematic%20-%20HSIE-202601061115425680440.pdf>

To capture these growth opportunities, Indian companies are increasingly leveraging their biologics expertise to expand into peptides and

oligonucleotides, cell and gene therapies, antibody-drug conjugates (ADCs) and other advanced biologics.

Indian companies advance next-generation therapeutic modalities

Modality	Recent milestones
Multi-specific antibodies	▪ Ichnos Glenmark Innovation (IGI): Licensed trispecific antibody ISB 2001 to AbbVie and advanced next-generation multispecific candidate ISB 2301 to preclinical development.
ADCs	▪ SPARC: Advanced SBO-154, an MUC1-targeting ADC for solid tumors, to the US FDA IND stage. ▪ Laurus Labs: Entered ADC development partnerships with Aarvik Therapeutics. ▪ Syngene: Added a GMP bioconjugation suite, enabling end-to-end ADC development and manufacturing services. ▪ Piramal Pharma: Expanded ADC development and manufacturing capabilities through Yapan Bio and a partnership with Ajinomoto Bio-Pharma Services. ▪ Anthem Biosciences: Expanded capabilities in ADCs and mAbs, supported by ADC conjugation, HPAPI and peptide manufacturing platforms.
RNA therapeutics and oligonucleotides	▪ Nucleon Therapeutics: Partnered with Quantoom Biosciences to establish RNA and oligonucleotide manufacturing capability in India. ▪ Cohance Lifesciences: Acquired Sapala Organics, the world's only supplier of tricyclo-DNA amidites, a specialized oligonucleotide building block.
Monoclonal antibodies, bispecifics, fusion proteins, complex protein therapeutics	▪ Aragen Life Sciences: New biologics manufacturing plant expanded with a new 2,000-liter scale bioreactor in Bengaluru.
Novel and biosimilar ADC innovation	▪ Emcure (Aurigene): Advanced a portfolio of novel and biosimilar ADCs supported by proprietary linker-payload technologies.

Source: <https://immunoact.com/press-release/pm-modi-unveils-nexcar19-at-estic/>; https://sparc.life/wp-content/uploads/2025/03/SBO-154-IND-press-release_31.03.2025.pdf; <https://quantoom.com/quantoom-and-nucleon/>; <https://www.ajibio-pharma.com/news-post/piramal-pharma-solutions-and-ajinomoto-bio-pharma-services-collaborate-to-support-adc-development-and-manufacturing/>; <https://pharma.economictimes.indiatimes.com/news/mergers-and-acquisitions/piramal-acquires-majority-stake-in-cdmo-yapan-bio-for-76-cr/133335451>; <https://www.aragen.com/webinar/on-demand-webinar-advancing-biologics-development-at-aragen/therapeutics-to-expand-rna-capacity-in-india/>; <https://www.lauruslabs.com/Investors/PDF/PressReleases/PressRelease-23.10.2025.pdf>; <https://www.sapalaorganics.com/about-us/>; <https://www.expresspharma.in/syngene-international-adds-gmp-bioconjugation-suite-at-bengaluru-facility-to-expand-adc-capabilities/>; <https://www.aurigeneservices.com/adc>

CGT: As of August 2026, the US FDA had approved ~50 cell and gene therapy products, reflecting the growing clinical and commercial maturity of these therapies across oncology, rare diseases and genetic disorders.³⁸ India is also strengthening the ecosystem required for cell and gene therapies. Proposed initiatives such as the GeneIndia Mission aim to build on existing programs, including Genome India, the

National Policy for Rare Diseases, UMMID and ICMR-DBT gene therapy guidelines, create a more coordinated pathway spanning research, clinical development, manufacturing and patient access. The objective is to accelerate the development of affordable, indigenous cell and gene therapies tailored to Indian healthcare needs.³⁹

³⁸ <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>

³⁹ <https://www.niti.gov.in/sites/default/files/2026-07/Roadmap-for-Building-India-as-a-Leading-Bioeconomy-Powerhouse.pdf>

India's emerging cell and gene therapy ecosystem: Key performance indicators

~1/10th the cost of imported CAR-T therapies in India	US\$9 billion Projected global CAR-T therapy market by 2031 (vs. US\$4.2 billion in 2025)	2026 CDSCO brings cell and gene therapies (CGTs) under the Clinical Trial Application Assessment (CTAA/CLAA) regulatory framework
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Source: <https://www.panaceamedcare.com/blog/car-t-cell-therapy-cost-in-india/>; <https://www.mordorintelligence.com/industry-reports/car-t-cell-therapy>; <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2280408®=48&lang=2>

Indian companies building capabilities in cell and gene therapy

Modality	Status	Recent milestones
Cell and gene therapy (CAR-T)	Approved	ImmunoACT: Received CDSCO approval and commercialized NexCAR19, India's first indigenous CAR-T therapy; partnered with Cipla for select international markets.
Cell and gene therapy (CAR-T)	Launched	Immuneel Therapeutics: Launched Qartemi, a CAR-T therapy for relapsed/refractory B-cell non-Hodgkin lymphoma, with encouraging Phase 2 outcomes.
Cell and gene therapy (CAR-T)	Phase 2	Aurigene/Dr. Reddy's: Advanced DRL-1801, a BCMA-directed CAR-T therapy for multiple myeloma, into Phase 2 development.
Cell and gene therapy (CAR-T)	Capability building/R&D	Meril-MicroCRISPR: Developing CAR-T and cell therapy programs and building hospital access/commercial infrastructure

Sources: <https://www.biospectrumindia.com/news/96/23709/immunoact-announces-cdsko-approval-of-indias-first-car-t-cell-therapy-nexcar19.html>; <https://www.expresspharma.in/immuneel-therapeutics-launches-qartemi-a-car-t-cell-therapy-for-non-hodgkins-lymphoma/>; <https://immunoact.com/press-release/immunoact-partners-with-cipla/>; <https://www.aurigene.com/aurigene-oncology-limited-announces-promising-results-of-phase-1-study-for-indias-first-trial-for-novel-autologous-car-t-cell-therapy-for-multiple-myeloma/>; <https://www.linkedin.com/posts/meril-moretolife-technologyandinnovation-share-7410273281083289601-MqfE/>

India's cell and gene therapy ecosystem is also attracting global investment. In 2024, Miltenyi Biotec established its India presence and announced a Cell and Gene Therapy Centre of Excellence in Hyderabad to support CAR-T development, translational research, manufacturing training and commercialization capabilities.⁴⁰

2.3.2 Scaling up innovation

India's pharma manufacturing is benefiting from a convergence of factors that are positioning it as a preferred destination for outsourced research, development and manufacturing services.

- China+1 and supply-chain diversification:** Globally, the outsourcing model is shifting. While China-based companies continue to anchor a significant share of the global drug development pipeline, the proposed US BIOSECURE Act and China+1 strategies are creating new opportunities

for Indian CRDMOs. By one estimate, this transition could generate approximately US\$700 million in annual incremental revenue and US\$2.4 billion in additional sales over the next four years for Indian CRDMOs.⁴¹

- Cost, speed and talent advantage:** One of India's competitive advantages is cost effectiveness. Drug development and manufacturing costs are approximately 30% to 40% lower than in the US or Europe. China's labor costs increased by 120%, while India's grew by 80% between 2010 and 2020, incentivizing global companies to partner with Indian CRDMOs⁴². In addition, supported by a large scientific workforce, 650+ US FDA-compliant facilities, and growing capabilities in flow chemistry, fermentation, HPAPIs, ADCs, RNA therapeutics and GLP-1s, India is strengthening its position as a preferred outsourcing destination⁴³.

⁴⁰ <https://www.miltenyibiotec.com/IN-en/about-us/newsroom/press-releases/miltenyi-biotec-opens-its-first-office-in-hyderabad-india-and-plans-invest-in-first-of-its-kind-cgt-coe-for-indian-academia-and-industry.html>

⁴¹ <https://www.aninews.in/news/business/indias-crdmo-sector-could-gain-usd-700-million-annually-from-china1-shift-jefferies20260611155312/>

⁴² <https://anthembio.com/wp-content/uploads/2026/06/Annual-Report-FY-2025-2026.pdf>

⁴³ <https://www.pharmabiz.com/NewsDetails.aspx?aid=185830&sid=2>

3. **Strength in complex development and formulations:** While China continues to dominate large-scale raw materials and intermediates manufacturing, India is increasingly differentiating itself in complex custom synthesis, formulations, biologics and integrated development and manufacturing services.⁴⁴
4. **Government policy is underwriting the pivot:** The INR6,940 crore bulk-drug PLI, three bulk drug parks, the National Biopharma Mission via BIRAC, the BioE3 policy and the Biopharma SHAKTI initiative are providing the policy impetus.⁴⁵

2.3.3 Scaling to commercial manufacturing in new modalities

Capability at development scale also depends on commercial supply. For emerging modalities, companies have to progress through multiple stages, from laboratory development to validated GMP manufacturing. Indian companies are increasingly investing in infrastructure, process development and manufacturing capabilities to move up the value chain.

1. **Peptides and oligonucleotides:** The explosion of GLP-1 receptor agonists and RNA therapeutics requires complex solid-phase peptide synthesis (SPPS) and liquid-phase chemistry at multi-hundred-kilogram scale. For example, Sai Life Sciences is building a peptide Centre of Excellence (end-to-end peptide capability spanning discovery, development and manufacturing), Aragen Life Sciences' PeptARx platform supports peptide discovery-to-scale-up, and Divi's Laboratories has deployed multiple 500-L SPPS reactors for GLP-1 peptide production.^{46 47 48}
2. **ADCs, CGT and complex biologics:** ADCs demand a convergence of high-potency cytotoxic payload synthesis, bespoke linker chemistry, monoclonal antibody (mAb) expression and sterile conjugation fill-finish. For example, Piramal Pharma Solutions' ADCelerate™ platform and Syngene's integrated ADC platform combine payload-linkers, bioconjugation and GMP manufacturing under one roof.^{49 50}
3. **Process innovation via continuous biomanufacturing:** While large-scale stainless-steel bioreactors infrastructure has been an important part of China's growth, Indian biotechs are pioneering modular, continuous bioprocessing. For example, Enzene Biosciences' EnzeneX continuous manufacturing platform delivers higher productivity and lower production costs than conventional fed-batch systems.⁵¹
4. **PROTACs and molecular glues:** These approaches in Targeted Protein Degradation offer the potential to target proteins that are difficult to address using conventional small-molecule drugs. Syngene has built end-to-end PROTAC capabilities from target identification to commercial manufacturing and is expanding into molecular glues⁵², while Aragen Life Sciences and Aurigene Pharmaceutical Services offer specialized targeted protein degradation, PROTAC synthesis and screening capabilities^{53 54}.

⁴⁴ <https://cdmoworld.com/india-vs-china-cdmo-outsourcing-cost-quality-regulatory/>

⁴⁵ <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2197944®=48&lang=2>

⁴⁶ <https://inve.money/concalls/DIVISLAB/q2-2025>

⁴⁷ <https://www.aragen.com/brochure/aragens-integrated-peptide-platform/>

⁴⁸ <https://sailife.com/our-capabilities/new-modalities/peptides/>

⁴⁹ <https://business.piramalpharmasolutions.com/ADCelerate>

⁵⁰ <https://www.syngeneintl.com/solutions/other-drug-modalities/antibody-drug-conjugates/>

⁵¹ <https://www.bioprocessintl.com/continuous-bioprocessing/opportunities-and-challenges-in-developing-a-fully-connected-continuous-manufacturing-process-for-biologics>

⁵² <https://www.syngeneintl.com/solutions/protacs/>

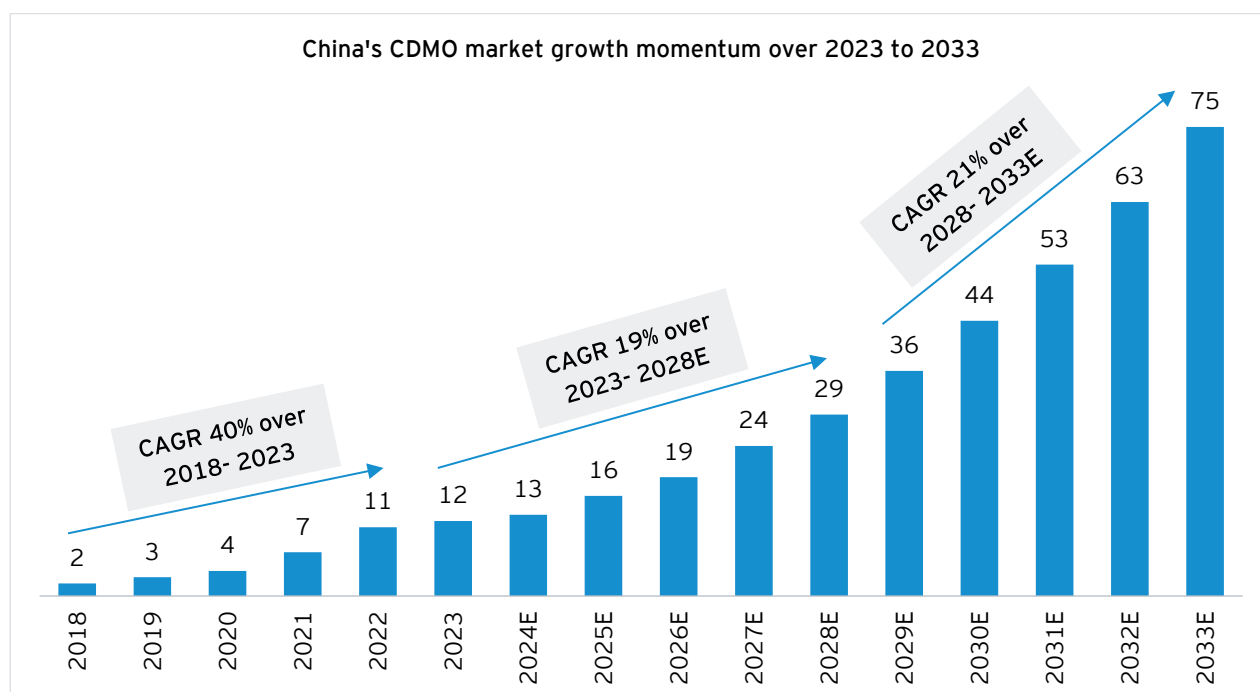
⁵³ <https://www.aragen.com/brochure/targeted-protein-degradation-solutions/>

⁵⁴ <https://www.aurigeneservices.com/services/discovery/protac-synthesis-and-screening>

2.4 CRDMOs/CDMOs moving up the value chain

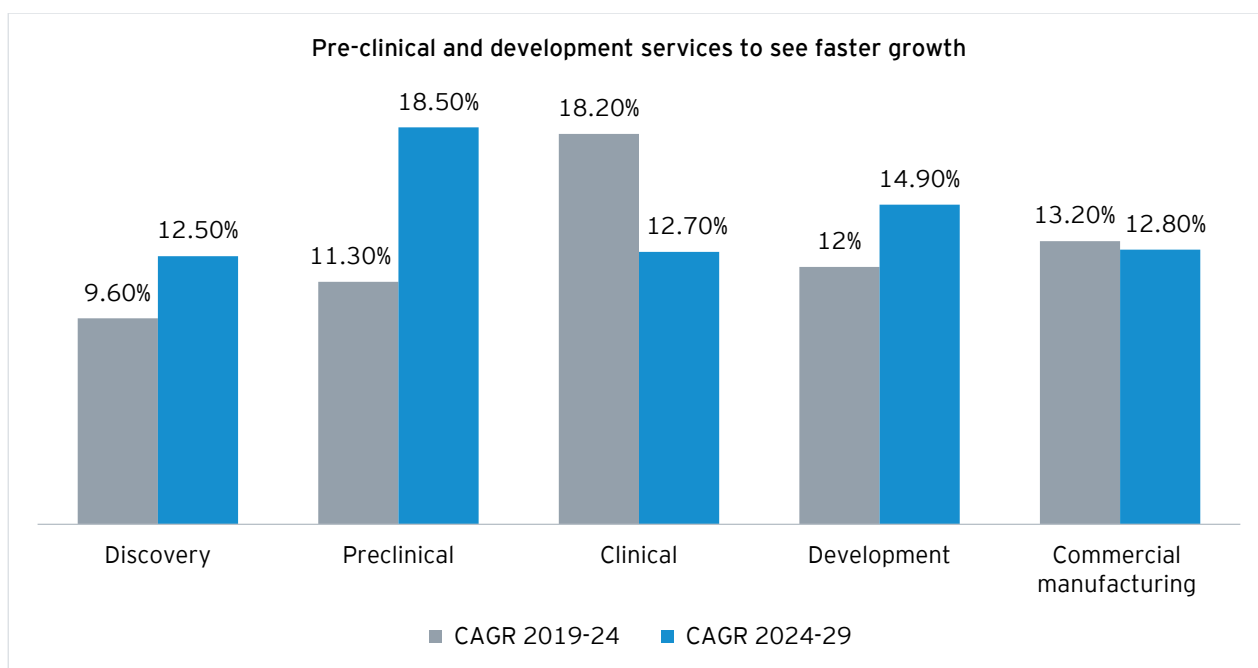
China remains the benchmark in the global CDMO industry, supported by a complete pharmaceutical ecosystem spanning discovery, development and commercial manufacturing across both small molecules and biologics. China's CDMO industry is expected to maintain strong growth momentum, reaching approximately US\$75 billion by 2033, up from approximately US\$12 billion in 2023. This implies a CAGR of approximately 19% during 2023-28 and approximately 21% during 2028-33. The value of Chinese biopharma licensing deals also increased by ~66% in 2024, reflecting continued innovation activity⁵⁵.

India, meanwhile, is emerging as one of the fastest-growing CRDMO markets globally. The Indian CRDMO market is expected to grow at a CAGR of ~13.4% between 2024 and 2029, reaching ~US\$15 billion by 2029. India's share of the global CRDMO market is projected to increase from ~3.8% in 2024 to ~4.7% by 2029, supported by broader service offerings, efficient supply chains, strong process and technology capabilities, cost competitiveness and a skilled scientific workforce. While China continues to lead in scale and value-chain integration, India is increasingly benefiting from China+1 diversification and rising outsourcing demand from global pharmaceutical companies.



Source: <https://www.hdfcsec.com/hsl.docs/Pharma%20-%20CRDMO%20-%20Sector%20Thematic%20-%20HSIE-202601061115425680440.pdf>

⁵⁵ <https://www.hdfcsec.com/hsl.docs/Pharma%20-%20CRDMO%20-%20Sector%20Thematic%20-%20HSIE-202601061115425680440.pdf>



Source: <https://www.hdfcsec.com/hsl.docs/Pharma%20-%20CRDMO%20-%20Sector%20Thematic%20-%20HSIE-202601061115425680440.pdf>

Within the value chain functions of the Indian CRDMO market, development and commercial manufacturing contributed 76.8% of the Indian CRDMO market in

2024 and are expected to grow at 14.9% and 12.8% between 2024 and 2029, respectively.

Indian CRDMOs expand into advanced modalities and integrated services

Area of focus	Recent milestone
Biologics and advanced therapeutics CDMO services	Piramal Pharma: Expanded biologics, gene therapy and ADC capabilities; integrated ADC manufacturing partnership Zydus Lifesciences: Launched Zylidac Bio LLC for CDMO services; secured rights to the botensilimab-balstilimab combination in India and Sri Lanka.
Multi-modality CDMO/CRDMO platforms	OneSource Specialty Pharma: Secured a manufacturing agreement with Formycon, expanding capabilities across biologics, sterile injectables and drug-device combinations. Aragen Life Sciences: Secured a US\$100 million private equity investment to strengthen multi-modality CRDMO platform.
ADC development and manufacturing capabilities	Anthem Biosciences: Expanded capabilities in ADCs and mAbs, supported by ADC conjugation, HPAPI and peptide manufacturing platforms. Syngene: Added a GMP bioconjugation suite, enabling integrated ADC services.

Source: <https://pharma.economictimes.indiatimes.com/news/mergers-and-acquisitions/piramal-acquires-majority-stake-in-cdmo-yapan-bio-for-76-cr/133335451>; <https://www.prnewswire.com/news-releases/zydus-lifesciences-limited-completes-the-acquisition-of-agenus-incs-biologics-manufacturing-facilities-launches-zylidac-bio-llc-in-the-us-302662438.html>; <https://economictimes.indiatimes.com/industry/healthcare/biotech/onesource-specialty-pharma-partners-with-formycon-ag-to-manufacture-biosimilars/articleshow/132385862.cms?from=mdr>; <https://anthembio.com/small-molecules/gmp-manufacturing/>; <https://www.expresspharma.in/syngene-international-adds-gmp-bioconjugation-suite-at-bengaluru-facility-to-expand-adc-capabilities/>; <https://www.bioprocessintl.com/facilities-capacity/aragen-100m-pe-boost-to-bolster-cdmo-ambition-in-india-and-beyond>; <https://www.prnewswire.com/in/news-releases/piramal-pharma-solutions-and-ajinomoto-bio-pharma-services-collaborate-to-support-adc-development-and-manufacturing-302744446.html>

2.5 From products to platforms: Redefining pharmaceutical innovation

As therapies become more complex, competitive advantage is increasingly derived not from a single product, but from the underlying platform that enables the development of multiple therapies. This shift is becoming an important strategic differentiator for Indian companies. The proposed acquisition of Avidity Biosciences by Novartis for approximately US\$12 billion illustrates this trend. The value lies not only in individual therapeutic assets but also in the antibody-oligonucleotide conjugate platform that can generate multiple future pipeline candidates.⁵⁶

Indian companies are also adopting platform-based innovation models. Ichnos Glenmark Innovation's BEAT® multispecific-antibody platform illustrates how reusable scientific architecture can create a pipeline of differentiated assets. Platform value should be assessed through repeatability, development productivity, licensing potential and downstream value capture, rather than through a single product alone.

a. Intellectual property and technology transfer

India needs stronger technology-transfer offices, transparent licensing frameworks, shared-IP models and milestone-based translational funding to move discoveries from laboratories into clinical and commercial development. Success should be measured through technologies licensed, assets entering development, follow-on investment and patient-relevant outcomes.

b. Specialist talent as national infrastructure

Advanced modalities require depth in bioprocess engineering, computational biology, bioinformatics, regulatory science, clinical operations and quality. Joint curricula, industry residencies, regulatory fellowships, shared faculty and cluster-based training can convert India's broad science base into specialist capability.

Capital and startups fueling innovation

- **Specialized growth-stage funding:** Global healthcare investors are backing companies to accelerate product development and expansion. For instance, Novo Holdings and Maj Invest co-led MedGenome's Series E round.
- **Expanding biotech startup ecosystem:** 11,855 active biotech startups in 2026, including 1,780 new startups founded in 2025.
- **Bio-incubation centers:** 95 BIRAC-supported centers are helping nurture early-stage innovation.

Source:

https://www.chittorgarh.net/reports/ipo_notes/DevenChokseyResearch_IpoNote.pdf;

<https://novoholdings.dk/news/medgenome-raises-series-e-funding-co-led-by-maj-invest-and-novo-holdings-to-expand-access-to-its-genomics-offerings-in-india>;

<https://www.birac.nic.in/mii/Map.php>.



⁵⁶<https://www.novartis.com/news/media-releases/novartis-agrees-acquire-avidity-biosciences-innovator-rna-therapeutics-strengthening-its-late-stage-neuroscience-pipeline>

2.6 Improving the clinical research ecosystem

A strong clinical research ecosystem requires regulatory-grade evidence, globally acceptable quality and efficient trial infrastructure. India has begun modernizing this ecosystem through policy, networks and digital capabilities.

While programs like GenomelIndia are enabling genetically informed and biomarker-driven studies that support pharmacogenomics, patient stratification and precision medicine research, National Biopharma Mission has expanded clinical research capacity. It has created a 36-site Good Clinical Practice (GCP)-compliant clinical trial network, established 21 disease registries covering around 90,000 patients and supported 100+ clinical trials across therapeutic areas. It enabled successful collaborations between industry, academia and government in high-impact

health innovations. For example, it supported Zydus Cadila's ZyCoV-D, the world's first DNA-based COVID-19 vaccine, in preclinical studies, immunogenicity testing and clinical trials. Mission-supported National Immunogenicity & Biologics Evaluation Center (NIBEC) in Pune has enabled trials for more than 30 antiviral studies⁵⁷.

Similarly, ABDM's interoperable digital health systems through ABHA identifiers, digital health records, facility registries and standardized data-sharing frameworks are key enablers of large-scale real-world evidence, longitudinal patient tracking and AI-enabled clinical studies.

Progress in precision medicine, advanced modalities, platforms, CRDMOs and clinical research signal an innovation-led ecosystem. Global impact may depend on translating research into evidence, scalable manufacturing and patient outcomes. Intelligent pharma can connect these capabilities.



Pillar 2: **2030 action agenda**

Prioritize innovation domains using unmet need, capability, affordability and global relevance; strengthen technology transfer and translational funding; expand trial-ready networks, build specialist talent pathways; and track original assets, licensing income and high-value exports.

⁵⁷ <https://blogs.worldbank.org/en/endpovertyinsouthasia/how-industry-academia-government-partnerships-are-driving-afford>

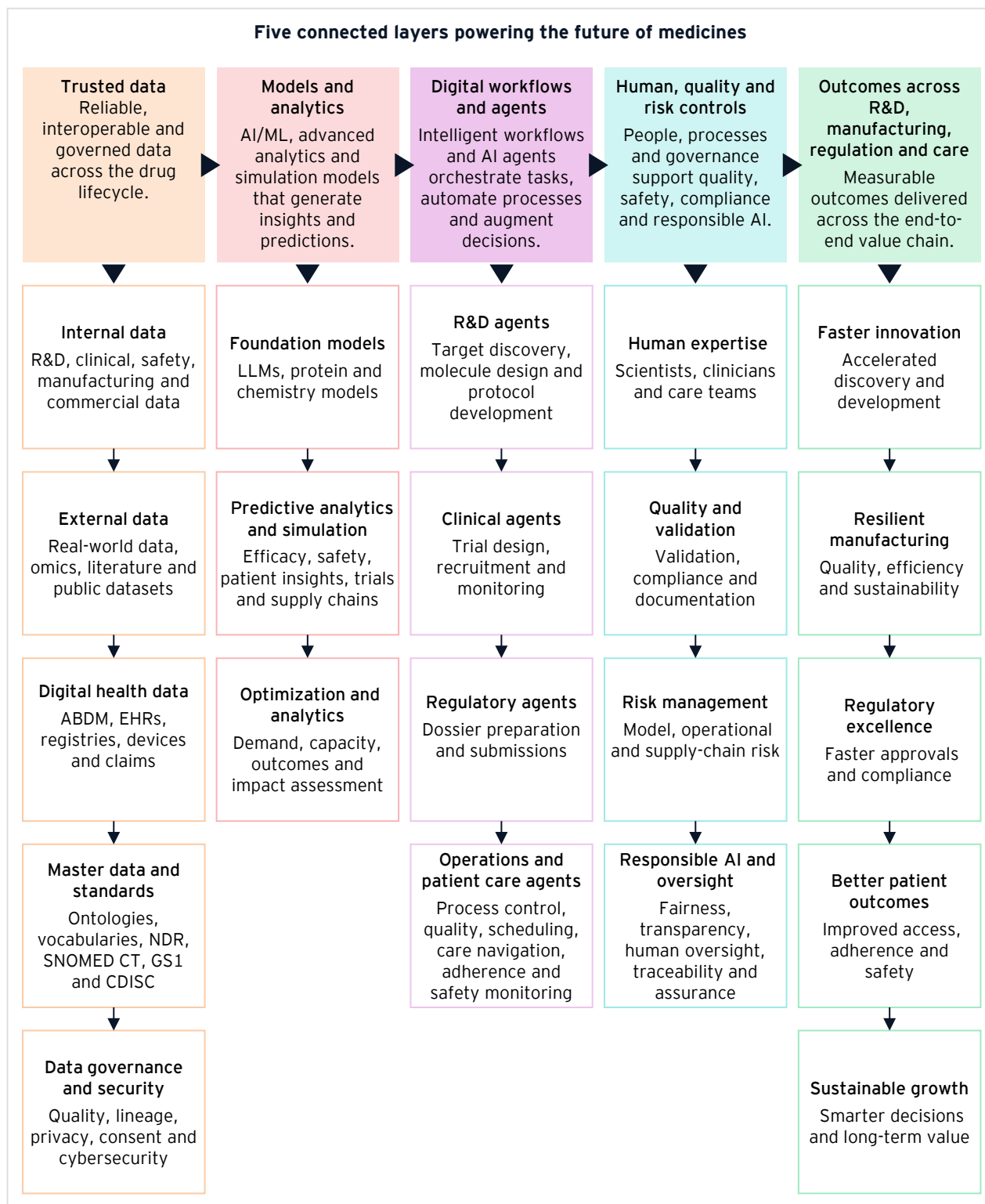


Pillar 3:

Intelligent pharma
powered by AI and data

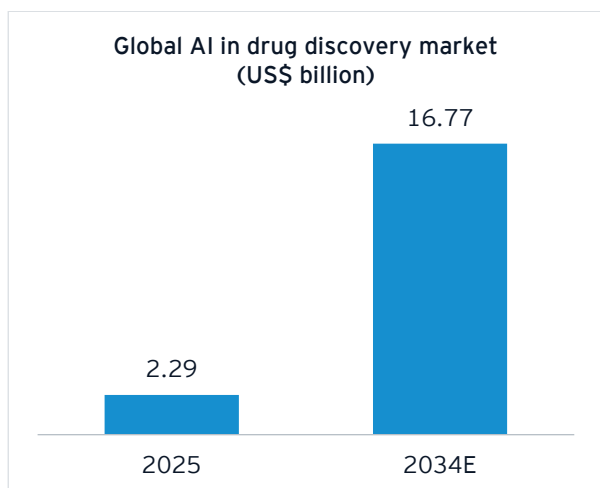
India's pharmaceutical ambition depends on connecting scientific innovation, manufacturing excellence and access through intelligent, data-driven ecosystems. GenAI, advanced analytics, interoperable platforms and digital infrastructure can accelerate discovery, development, manufacturing, regulation, evidence generation and patient access.

Globally, advances in GenAI and Agentic AI, digital twins, automation and intelligent manufacturing technologies are transforming how medicines are discovered, developed, manufactured, regulated and monitored. Global AI-in-drug-discovery market is expected to reach ~US\$16.7 billion by 2034 from US\$2.29 billion in 2025⁵⁸.



⁵⁸ <https://www.polarismarketresearch.com/industry-analysis/ai-in-drug-discovery-market>

Advances in foundation models, multimodal datasets and the computational study of complex biological molecules such as DNA and proteins are expanding what researchers can analyze and design. AI agents are used to scan biomedical datasets, assess biological targets and screen large numbers of molecules to predict efficacy and toxicity. As these capabilities mature, the drug lifecycle is becoming more connected, data-driven and responsive.



Source: <https://www.polarismarketresearch.com/industry-analysis/ai-in-drug-discovery-market>

Industry 5.0 is now set to reshape how medicines are developed, manufactured and distributed by bringing together automation, connected systems and human expertise.

- Synthetic or computational patient representations are being explored for trial simulation and treatment-response modeling.
- In manufacturing, the Internet of Things (IoT) is generating large volumes of operational data, while machine learning can predict equipment failures, identify process improvements and support formulation development.
- Digital twins are strengthening Good Manufacturing Practice (GMP) compliance by modeling process behavior, predicting variations and helping define tighter control specifications, reducing deviations and out-of-specification events.

Policymakers are also placing AI and digital capabilities at the center of their technology agenda with the government announcing AI and digital transformation as national priorities, with greater investment in interoperable platforms, data

governance and AI-enabled capabilities for real-time analytics in the last Union Budget.

For Indian biopharma, the opportunity is to move beyond isolated tools and build an integrated data and technology ecosystem connecting research, development, manufacturing and outcomes. India's scientific talent, digital public infrastructure and healthcare data assets provide a platform to leapfrog traditional models.

3.1 AI-enabled drug discovery and molecule design

Generative chemistry is accelerating molecule design and optimization, while domain-specific large language models (LLMs) are now able to identify patterns across complex biological and chemical data.

These capabilities are particularly valuable in early discovery, where large numbers of potential compounds must be assessed before laboratory testing. Quantitative Structure-Activity Relationship (QSAR) models, molecular docking and other computational methods can predict molecule behavior before they are synthesized. AI models can generate structures against desired properties such as binding affinity, selectivity and stability, while ADMET models can help filter out compounds with unfavorable characteristics earlier.

Globally, industry examples have already demonstrated the potential to compress development timelines. Insilico Medicine's AI-discovered fibrosis drug entered Phase II trials within approximately 12 to 18 months, and in July 2026, a global Phase III trial was initiated⁵⁹. Protein language models (pLMs) apply language-modeling techniques to amino acid sequences to infer aspects of protein structure, function and interactions, which can support protein engineering and candidate identification while reducing dependence on sequential trial-and-error experimentation. For instance, an AI firm, OpenProtein.AI⁶⁰, is helping scientists with a no-code platform with foundation models and tools for protein design, predicting protein structure and function and training models. Deep learning and generative models can explore chemical space more broadly and generate candidates against specific biological and developability criteria.

The shift extends across the development range, from lead identification and preclinical research to clinical development and regulatory review.

⁵⁹ <https://insilico.com/news/xmjsn4l091-insilico-initiates-phase-iii-clinical-tr>

⁶⁰ <https://news.mit.edu/2026/bringing-ai-driven-protein-design-tools-everywhere-0417>

In India, AI is shifting from a tool to an integrated R&D infrastructure layer, potentially cutting drug discovery and clinical trial validation cycles. AI-enabled

platforms like **Peptris Technologies' pepAI**⁶¹ have produced India's first AI-discovered molecule to be licensed out.

INR128 crore

Raised by 4baseCare to scale AI-enabled precision oncology and genomics capabilities in India

Source:

<https://www.biospectrumindia.com/news/104/27941/4base-care-announces-close-of-series-b-round-at-rs-128-cr.htmlround-at-rs-128-cr.html>

25%

Lower costs from AI intelligence reshaping pharma R&D by potentially reducing 10-15-year drug development cycle by 60%-70%

Source: <https://trendlyne.com/posts/5811049/ai-driven-drug-discovery-reshaping-pharma-r-d-economics-and-pipeline-productivity>

Key Indian players in AI drug discovery

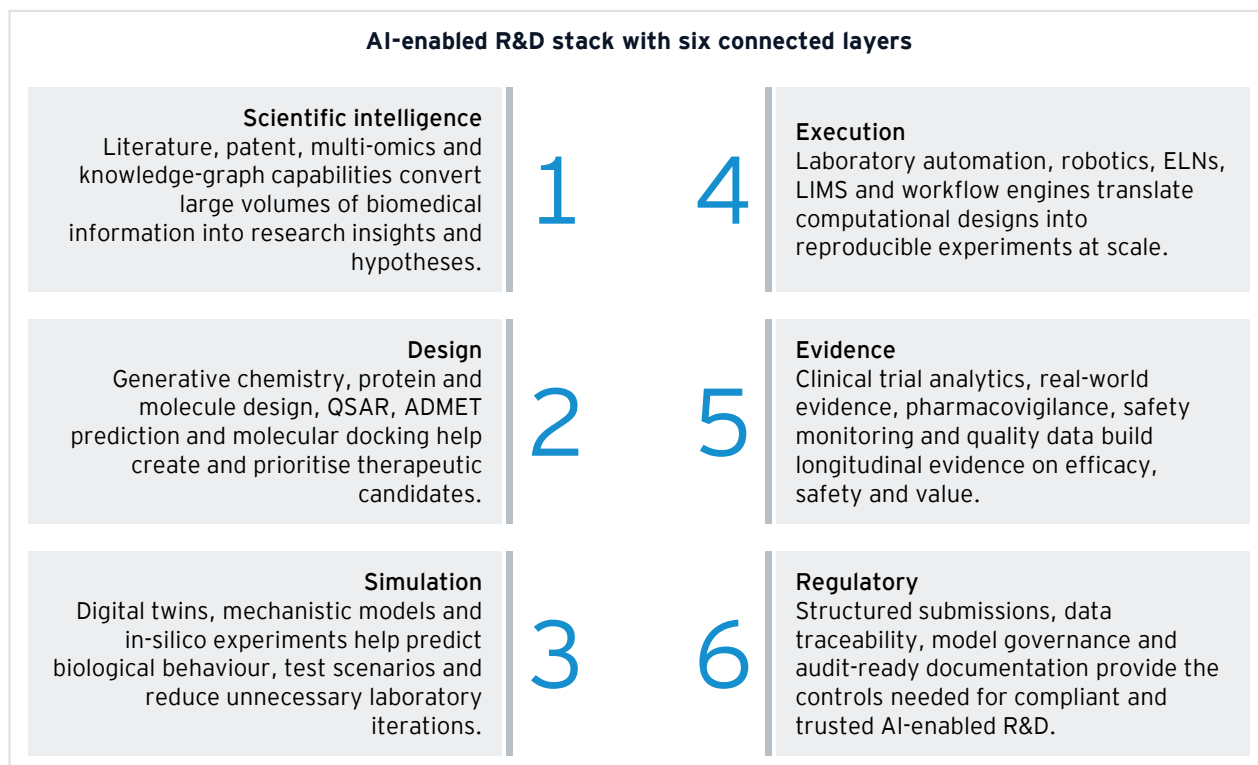
Innoplexus	Aurigene.AI (Dr Reddy's)	Syngene SynVent	Anthem, Aragen
Unified Biosystem on NVIDIA H100 GPU clusters and NIM microservices screens 5.8 million molecules in 5-8 hours	proprietary discovery platform with GenAI applied to synthetic-route generation in API development	integrated discovery platform advancing programs from target validation through pre-clinical development	AI-enabled discovery platforms for advanced modalities (oligonucleotides, PROTACs, ADCs); Aragen embeds AI across chemical synthesis and ADME workflows

Sources: <https://developer.nvidia.com/blog/high-throughput-ai-driven-drug-discovery-pipeline/>; <https://www.businesswire.com/news/home/20240403946999/en/Aurigene-Pharmaceutical-Services-Ltd.-introduces-Aurigene.AI-an-artificial-intelligence-AI-and-machine-learning-ML-assisted-drug-discovery-platform>; <https://www.syngeneintl.com/solutions/discovery/integrated-drug-discovery-solutions/>; <https://www.aragen.com/solutions/small-molecules/discovery/aragen-integrated-drug-discovery-idd/computational-and-data-science/data-science-ai/>

⁶¹ <https://trial.medpath.com/news/peptris-technologies-licenses-india-s-first-ai-discovered-drug-candidate-for-duchenne-muscular-dystrophy>

In a recent report, EY proposed an AI-enabled R&D stack with six connected layers that can help organizations extract higher value from AI. This

framework provides a foundation for the next stage of innovation and real value emerges from the connections between these layers.



Source: EY BioAsia 2026 report, “Pharma’s new architecture: Where novel science meets AI and manufacturing power” February 2026

The priority is to connect data, models, experimentation and evidence so that each continuously improves decisions across the drug lifecycle.

The shift has implications well beyond discovery. As AI capabilities mature, the same connected architecture can extend into preclinical development, clinical trials, manufacturing and regulatory processes.

Computational predictions can guide experiments, experimental results can improve models and clinical, manufacturing and real-world data can feed back into subsequent development decisions.

3.2 Digital twins and intelligent manufacturing

Digital twins combine sensor and machine data with process models to simulate batches, predict quality and optimize parameters. During production, real-time monitoring can flag deviations for earlier intervention.

Combined with AI, these capabilities can shorten cycles, reduce waste and enable more autonomous manufacturing.

Digital twins for pharmaceutical manufacturing are growing fast and are expanding from 1.3 billion in 2025 to a projected US\$8.5 billion by 2032 at a 30.2% CAGR⁶².

In India, digital twins are entering pharmaceutical manufacturing to transform it from reactive operations to intelligent, self-optimizing systems. Combined with AI, they enable real-time process monitoring, predictive optimization and automated decision-making, creating more agile, efficient and self-correcting production environments. Many pharmaceutical companies are adopting digital twins to optimize yield and cycle times, improve energy and waste efficiency, and enable real-time bioprocess monitoring, driving higher productivity, sustainability and operational excellence.

⁶² <https://www.industryarc.com/research/digital-twins-for-pharmaceutical-manufacturing-market-900002>

3.3 AI in regulatory affairs and pharmacovigilance

AI is extending into regulatory operations, including document processing, regulatory intelligence, submission automation and compliance monitoring.

It can help teams track changing requirements across major agencies and streamline evidence-intensive workflows.

Pharmacovigilance, compliance and RWE

Safety-in-a-box: AI platform monitors adverse events and drug safety signals, replacing fragmented manual pharmacovigilance processes.

AI is increasingly being applied across regulatory affairs, pharmacovigilance and quality operations. Regulatory teams are using AI to monitor changing requirements, support dossier authoring, improve traceability and strengthen inspection readiness. In pharmacovigilance, AI can assist with case intake, literature screening, signal detection and prioritization. Within quality operations, machine-learning tools can analyze audit trails, identify anomalous patterns and strengthen data-integrity monitoring. Together, these capabilities are helping organizations shift from reactive compliance towards continuous surveillance and risk-based decision making.

Beyond industry applications, AI-enabled clinical decision-support platforms are also being deployed in public-health programs. For example, the BODH/TB initiative has reported improved disease detection rates and reductions in adverse tuberculosis outcomes, illustrating how data-driven surveillance can support earlier intervention and better patient outcomes.

Sources: <https://venusremedies.com/blog/quality-assurance-in-pharmaceutical-industry/>;
<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2113683®=48&lang=2>

Regulatory affairs are consequently shifting from document management to a data-driven capability. AI can support intelligence, authoring, dossier management, traceability and inspection readiness, while links to clinical, safety and manufacturing data can improve consistency and transparency.

Indian pharma is embedding AI across regulatory dossiers, MLR review, pharmacovigilance, and compliance, anchored by the FDA's January 2025 draft guidance on AI in regulatory decision-making.

Pharmacovigilance (PV) is another area where AI is becoming embedded across the value chain. Large pharmaceutical companies and contract research organizations are using AI in areas such as case intake, triage, literature screening and signal detection, helping teams process growing volumes of safety information more efficiently.

Machine learning can analyze large and diverse datasets to identify potential adverse drug reactions (ADRs) and emerging safety signals, while multimodal

~97% reduction in time to first draft and 60% overall timeline compression as Weave Bio (with Takeda) uses GenAI to standardize regulatory dossiers.

Source: <https://www.weave.bio/resources/human-ai-collaboration-increases-efficiency-in-regulatory-writing-a-joint-study-with-takeda/>

approaches can combine different sources of evidence to improve detection. At later stages of the PV lifecycle, AI-supported signal analysis can help assess potential risks and prioritize those requiring further investigation.

The opportunity is to move pharmacovigilance from reactive processing to continuous surveillance. AI does not replace expert judgement; it helps safety teams identify, prioritize and investigate signals earlier across trials, real-world data and literature.

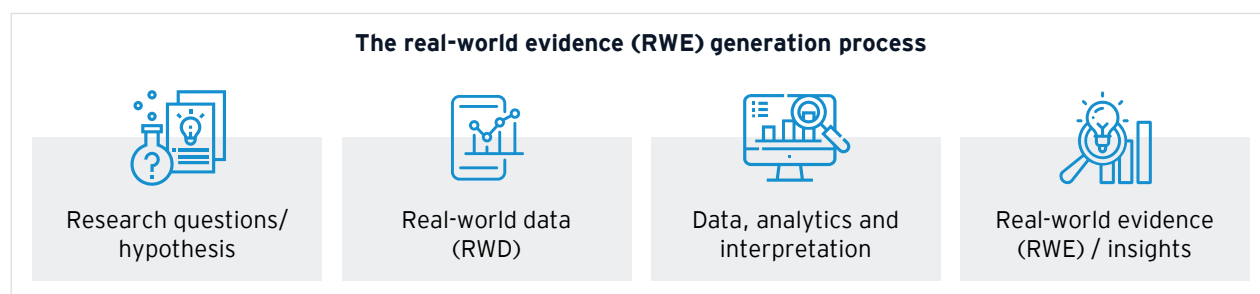
3.4 Real-world evidence

AI's impact now extends from discovery into clinical development, where patient data, reported outcomes, economics and access increasingly shape trial design and medicine evaluation.

Real-world evidence (RWE) is emerging as a powerful complement to traditional clinical trials, enabling pharmaceutical companies, regulators and healthcare providers to understand how therapies perform in routine clinical practice across diverse patient populations. Derived from real-world data (RWD) sources such as electronic health records (EHRs), insurance claims, disease registries, pharmacy databases, patient-reported outcomes, wearable devices, and digital health applications, RWE provides insights into treatment effectiveness, safety,

adherence, and long-term outcomes beyond the controlled environment of clinical studies.

Global regulators are increasingly incorporating RWE into decision-making frameworks. The US FDA has established a formal RWE program to support regulatory decisions, emphasizing high-quality data, rigorous methodologies and transparent study designs, while the European Medicines Agency (EMA) is expanding the use of real-world data to strengthen evidence generation across the product lifecycle. Advances in AI, machine learning, natural language processing and big data analytics are further enhancing the ability to capture, structure, and analyze vast volumes of healthcare data. The experience of monitoring COVID-19 vaccines demonstrated the value of RWE in generating rapid, population-scale insights into safety and effectiveness.



For India, RWE represents a strategic opportunity to accelerate clinical development, strengthen pharmacovigilance, enable outcome-based healthcare and support precision medicine.

ABDM, with its unique health IDs and growing digital health infrastructure, is laying the foundation for longitudinal patient records and interoperable health data at a national scale. While challenges remain, including fragmented data sources, inconsistent coding standards, and incomplete patient journeys, emerging approaches such as algorithmic phenotyping, AI-enabled data harmonization and NLP-based extraction of information from unstructured records are helping address these limitations.

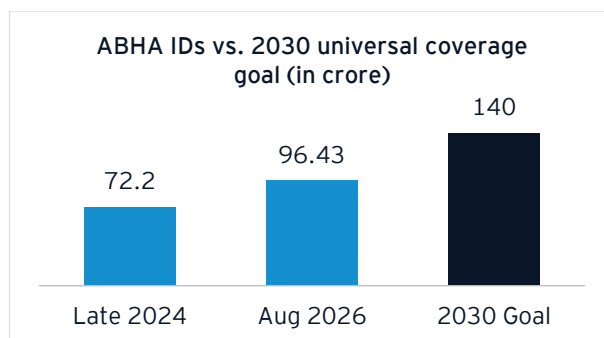
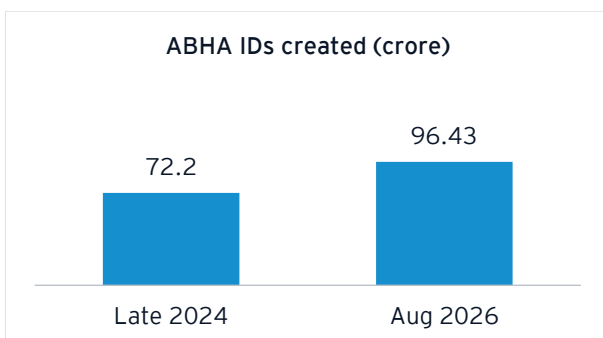
A robust RWE ecosystem can improve domestic decision-making and position India as a global evidence-generation hub, supporting faster innovation, smarter regulation, efficient research and better outcomes.

Over time, integrating RWE with clinical-trial data could support more informed decisions on trial design, treatment response, safety and value, while bringing development closer to how medicines perform in routine care.

3.5 Data-driven care: ABDM and the National Drug Registry

Healthcare is transitioning from reactive care to data-driven, personalized, and preventive models powered by genomics, molecular diagnostics, bioinformatics, AI and digital health platforms. As health data becomes a critical asset, integrated digital ecosystems are emerging to connect patients, providers, researchers and payers, enabling more informed clinical decisions and accelerating innovation.

ABDM is laying the foundation by creating a unified national digital health infrastructure. Complementing this effort, the National Medical Commission mandated ABDM-compliant Health Management Information Systems across medical colleges and teaching hospitals by 2027. This rapidly expanding digital infrastructure could create one of the world's largest longitudinal health datasets, enabling deeper disease understanding, supporting the development of more targeted therapies, strengthening real-world evidence generation, and opening new opportunities for domestic research, innovation, and AI-led healthcare solutions.

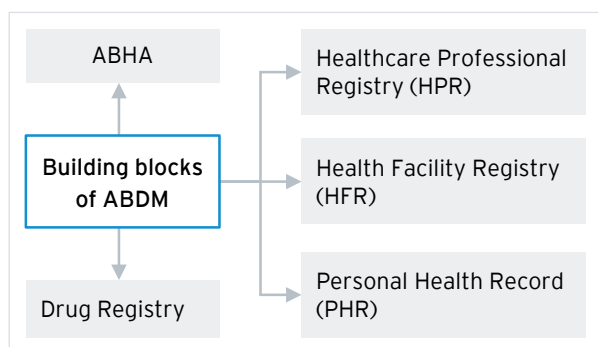


Sources: <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2266979®=3&lang=1;>

To further strengthen India's pharmaceutical ecosystem, the Indian government launched the Drug Registry in June 2026. Developed in collaboration with CDSCO and the National Resource Centre for EHR Standards (NRCeS), the Registry has been built using international standards such as SNOMED CT and serves as a single source of truth for medicines in India, enabling consistent identification, storage and exchange and usage of drug data across healthcare systems. It includes⁶³:

- 123,000-plus branded drugs
- 10,000-plus generic drugs
- 29,000-plus substances

Integrated with HMIS, e-prescription platforms and ABDM-compliant applications through open APIs, it enables accurate, interoperable and transparent drug information exchange, strengthening clinical decision-making, continuity of care and the broader digital healthcare ecosystem.



The ABDM network also includes several private sector companies:

1. **Health-tech companies:** Online healthcare platform Practo (for Health Management Information System), doctor-focused EMR platform HealthPlix (for EMR and provider workflows), technology-led, oncology-focused healthcare platform Karkinos Healthcare (for digital-health application suite)
2. **Digital pharmacy and healthcare software companies⁶⁴:** 1mg, C-Square Info Solutions, Marg ERP, Drucare, Dataman, Softworld India and more

Going forward, there is potential for patient records, prescriptions and follow-up monitoring to be integrated, which could improve tracking adherence and measuring outcomes. Subject to patient consent, purpose-specific data-sharing arrangements, and compliance with applicable data-protection and ABDM governance requirements, interoperable health records and digitally connected care journeys could support healthcare research, real-world evidence generation, precision medicine, disease management and more patient-centric models of care.

3.5.1 Responsible AI, cybersecurity and data governance

AI in regulated life sciences requires a defined purpose, trusted data, validated models, human review, change control, audit trails and named accountability. Cybersecurity, consent, data rights, third-party risk and model monitoring should be embedded from the outset. The objective is not automation alone, but auditable improvement in decision quality, cycle time, productivity and patient impact.

⁶³ <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2278991®=48&lang=2>

⁶⁴ <https://abdm.gov.in/our-partners>

3.6 GCCs as centers of innovation

GCCs are becoming strategic nodes in India's life sciences ecosystem. Their mandates are expanding from clinical operations, pharmacovigilance and regulatory support into discovery, digital therapeutics, analytics and AI-led innovation.

AI-enabled molecule design, predictive diagnostics, virtual clinical trials, digital twins and immersive technologies are being explored across the value chain. Increasingly, GCCs are assuming shared accountability for innovation and business outcomes rather than operating solely as execution centers.

Their role is also expanding into patient-centric innovation. By bringing together clinical, technology and patient data, GCCs can support patient engagement and help incorporate patient perspectives across the development lifecycle. Eye care company Alcon⁶⁵, for example, has established a dedicated Digital Health vertical focused on the verification and validation of medical devices using real-world evidence.

As GCCs take on more strategic mandates, they can also help bridge capability gaps in areas such as novel modalities, digital health and advanced discovery programs. This evolution, however, raises the importance of IP protection, data security, model governance and quality compliance. These capabilities may be essential if India is to move from being a delivery base to becoming a co-creator of global life sciences innovation.

India, a leading AI-enabled pharma ecosystem

By 2047, the convergence of AI, data, digital infrastructure and science could position India as a leading AI-enabled pharmaceutical ecosystem. Platformization may connect data, workflows and decision-making across research, development, manufacturing, regulation and patient access. By replacing fragmented systems with interoperable, AI-enabled platforms, it may reduce duplication, accelerate execution, improve asset utilization, driving productivity, efficiency and resilience across India's integrated pharmaceutical value chain at scale.



Pillar 3: 2030 action agenda

Publish responsible-AI and GxP validation principles; prioritize auditable use cases; build interoperable data foundations; strengthen AI, quality and domain-product roles; and measure validated adoption, decision quality and patient impact.



⁶⁵ <https://www.ey.com/content/dam/ey-unified-site/ey-com/en-in/pdf/2025/ey-reimagining-life-science-s-global-capability-centers.pdf>



Pillar 4:

Equitable access
and patient outcomes

Healthcare increasingly depends on innovative therapies for cancer, diabetes, rare diseases and other complex conditions. Generics are likely to remain essential, but scientific breakthroughs must also reach patients.

Affordable innovation embeds access into R&D, manufacturing and delivery so that new medicines reach patients at a viable price and scale. For India, this is the pathway from becoming a manufacturing hub to a champion of affordable innovation.

4.1 Affordability and access to innovative therapies

India is uniquely positioned to lead this transition. Its strengths in scientific talent, regulated quality systems, manufacturing scale and cost efficiency create a distinctive advantage in developing and delivering innovative therapies more affordably than many global peers.

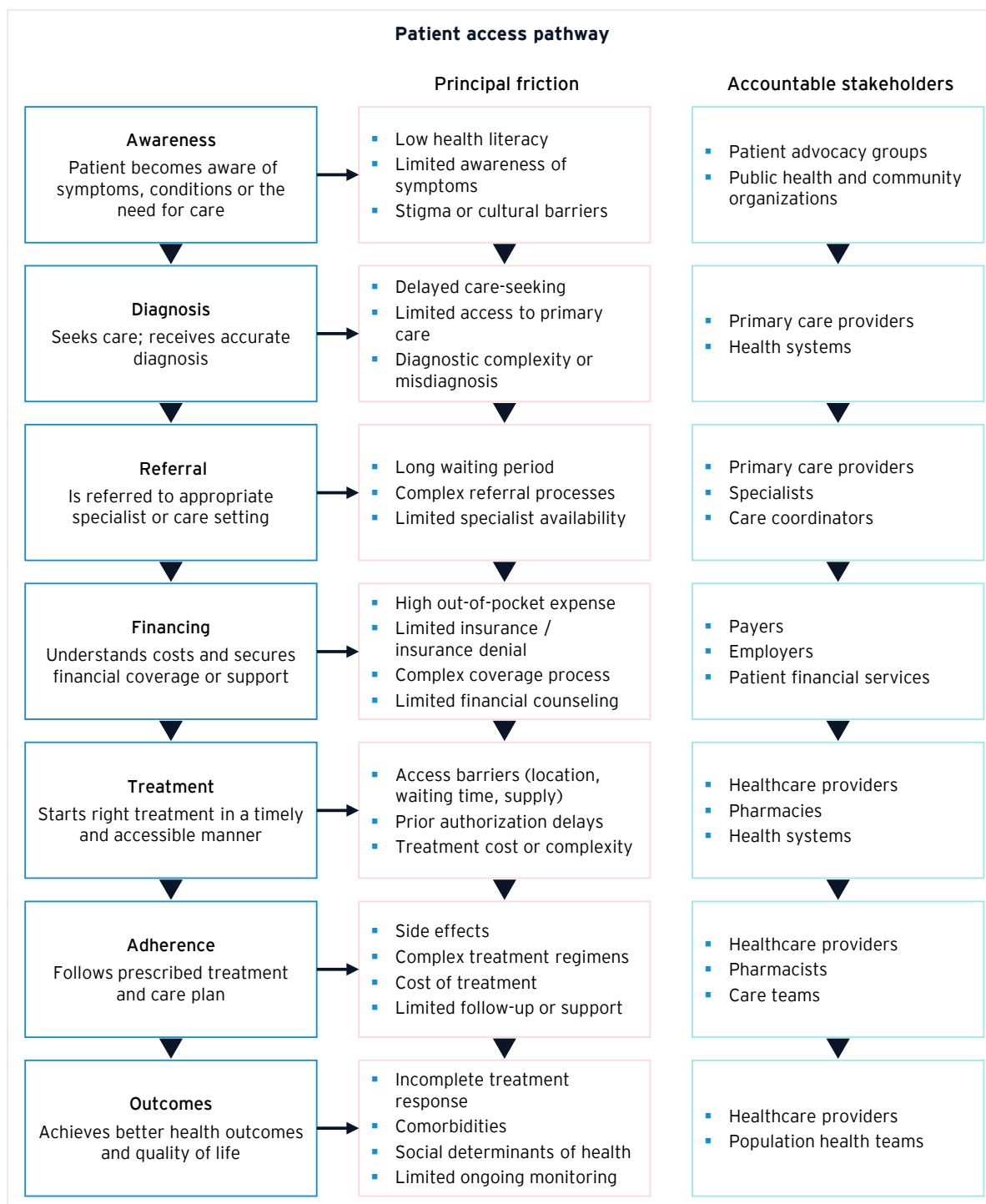
The impact could be transformative. Advanced therapies are expanding treatment options for cancer, rare diseases and chronic conditions, yet high costs, limited insurance coverage, delayed diagnosis and uneven specialist capacity continue to restrict access. Affordable innovation can help narrow this gap by reducing the cost of treatment while expanding availability.

India is already demonstrating this potential. Biosimilars are making established biologic therapies more affordable through increased competition. For example, Zydus Lifesciences launched Tishtha⁶⁶, a domestically developed nivolumab biosimilar for multiple cancers, at approximately one-fourth the price of the reference medicine.

Public financing can complement such market-led efforts by reducing the cost of hospital-based care.



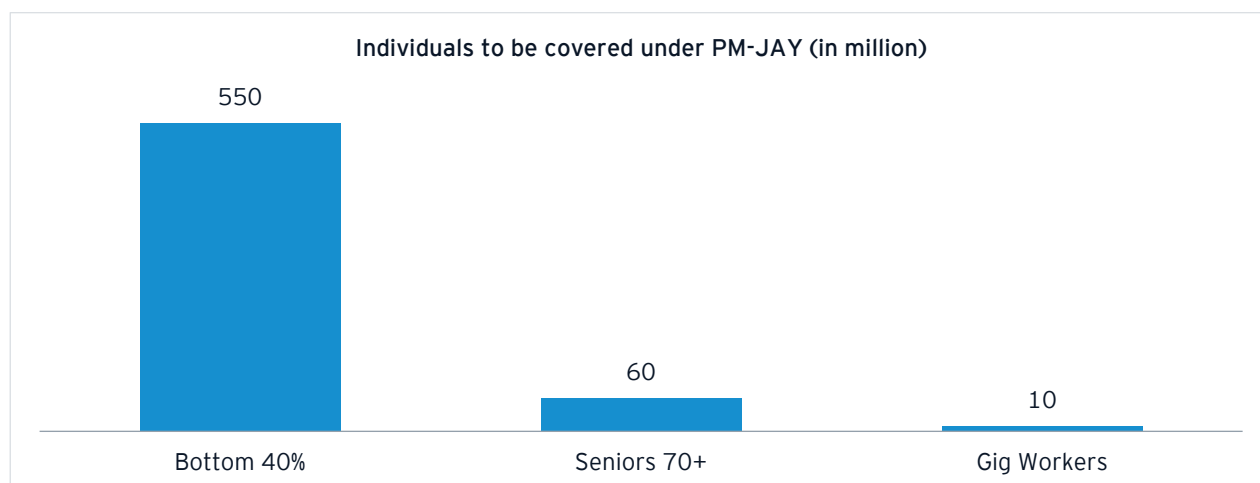
⁶⁶ [Zydus launches the world's first biosimilar of Nivolumab, 'Tishtha', in India to treat multiple cancers - Express Pharma](#)



4.1.1 Pradhan Mantri Jan Arogya Yojana (PM-JAY)

Innovation reaches patients only when financing, local manufacturing and delivery systems reduce access

barriers. PM-JAY, one of the world's largest publicly funded health assurance schemes, addresses hospital-care affordability, while PMBJP reduces medicine prices through Jan Aushadhi Kendras.⁶⁷



Key figures

45.5 crore Ayushman cards issued (Aug 2026)	12.69 crore Cumulative admissions	INR1.2 lakh crore Cumulative treatment	38,466 Empanelled hospitals (14,194 private)	40,000 Claims processed per day
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Sources: <https://www.pib.gov.in/PressNoteDetails.aspx?NoteId=153181&ModuleId=3®=3&lang=1>;
<https://www.pib.gov.in/PressReleaseFramePage.aspx?PRID=2179940®=48&lang=2>;
<https://www.pib.gov.in/FactsheetDetails.aspx?id=150834&ModuleId=16®=48&lang=2>;
<https://www.labour.gov.in/static/uploads/2025/07/59f33509a43b87977c1e28045d8544ae.pdf>

4.1.2 Jan Aushadhi Kendras

As of June 2026, more than 20,140 Jan Aushadhi Kendras were operating, covering 776 of India's 784 districts.⁶⁸ A portfolio of 2,110 medicines and 315 surgical items, medical consumables and devices is offered, while quality is maintained through procurement from WHO-GMP-compliant manufacturers and mandatory batch testing at NABL-accredited laboratories before distribution⁶⁹. Its data-driven approach further strengthens availability, with Kendra operators incentivized to maintain stocks of high-demand medicines based on real-world consumption patterns.

Quality assurance is built in. Medicines are procured only from manufacturers compliant with WHO GMP, and each batch is tested at laboratories accredited by the National Accreditation Board for Testing and Calibration Laboratories before distribution.⁷⁰

Affordability alone does not guarantee access; financial protection and delivery capacity are equally important. On the supply side, Biopharma SHAKTI commits INR10,000 crore over five years to expand domestic biologics and biosimilars capacity⁷¹. Together, affordable product development, financial protection, local production, suitable reimbursement and specialist care can widen access across regions and income groups.

⁶⁷ Ayushman Bharat Digital Mission, Health Facility Registry and Healthcare Professionals Registry. <https://abdm.gov.in/>

⁶⁸ <https://www.newsonair.gov.in/govt-aims-to-open-25k-jan-aushadhi-kendras-by-march-2027-minister-anupriya-patel>

⁶⁹ <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2297568®=3&lang=1>

⁷⁰ <https://www.pib.gov.in/PressNoteDetails.aspx?NoteId=157711&ModuleId=3>

⁷¹ <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2221492®=3&lang=1>

4.2 Digital infrastructure for equitable access and clinical capacity

As India expands affordable medicines and advanced therapies, digital infrastructure can connect innovation with patients across geographies. Linking providers, records, diagnostics and pathways can make care timelier and more equitable.

India's digital public infrastructure reflects a patient-centric approach that connects patient records, verified providers and healthcare services across fragmented care settings. Under ABDM, consent-based exchange of ABHA-linked EHRs supports record portability, while HFR and HPR connect patients with registered facilities and professionals. UHI links these components with service discovery, appointments and teleconsultations across compatible apps. Together, they provide the digital foundation for extending clinical capacity to regions where doctors and specialists remain unevenly distributed.

This capability is increasingly important because access gaps are often driven not by medicine availability alone, but by limitations in clinical capacity. Government estimates place India's doctor-population ratio at 1:778 in 2026, yet the national figure masks regional gaps in specialist care⁷². Telemedicine, teleradiology, remote intensive care, digital triage and referral networks allow primary care teams to access specialist input without requiring physical presence. India's public telemedicine system had delivered over 47 crore consultations as of June 2026⁷³.

Public-private partnerships can extend such services through government facilities supported by private technology, diagnostics and specialist networks. For instance, a Bayer-supported program implemented by Telerad Foundation across 15 government primary health centers delivered 90,034 teleconsultations and 1.88 lakh screenings, reaching 10.59 lakh people across 463 villages in FY25-26⁷⁴. Reliable connectivity, trained frontline workers and defined referral pathways remain necessary for digital consultations to lead to diagnosis, treatment and follow-up care.

4.3 Rare diseases

Rare diseases are among the clearest tests of affordable and accessible innovation. Scientific advances are creating new possibilities for diagnosis and treatment, but their impact depends on how effectively health systems connect patients to care. Currently:

- **400 million** people around the world are living with a rare disease.
- **7 years** is the average time needed to diagnose a rare disease.
- **Less than 6%** of rare diseases in India have available treatments⁷⁵.

In India, the diagnostic journey remains challenging. Limited awareness of rare diseases, uneven access to genetic testing, concentration of specialist services in major cities and fragmented referral pathways can all delay diagnosis. The absence of universal newborn screening further means many conditions may only be identified after symptoms become severe.⁷⁶

India has also institutionalized its response through the National Policy for Rare Diseases (NPRD), 2021, which positions India among countries with a comprehensive national framework for rare diseases.⁷⁷

⁷² <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2288843®=3&lang=1>

⁷³ <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2269699®=3&lang=1>

⁷⁴ <https://thewire.in/ptiprnews/bayer-supported-phygital-telemedicine-programme-implemented-by-telerad-foundation-wins-fkcci-global-csr-and-sustainability-award-2026>

⁷⁵ <https://www.astrazeneca.in/TherapyAreas/raredisease.html>

⁷⁶ <https://medicaldialogues.in/news/industry/pharma/cdsc-dop-told-to-find-workable-solution-on-revised-schedule-m-gmp-concerns-162969>

⁷⁷ <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2257977®=3&lang=1>

The National Policy for Rare Diseases (NPRD) 2021 expands to 15 CoEs; However, funding gaps persist

Theme	Strengths	Risks and considerations
Infrastructure	15+ Centres of Excellence nationwide, up from eight	Only ~1,118 patients treated under NPRD as of May 2026 – coverage remains a fraction of the addressable base
Funding	Financial assistance ceiling enhanced to INR50 lakh per patient for identified rare diseases	Ceiling frequently exhausted by patients requiring lifelong therapy
Regulatory and duties	Customs duty exemptions on life-saving rare-disease drugs; CGT products brought under CLAA framework via 2026 Drugs Rules amendment	Indigenous CGT/CAR-T approvals still nascent; accelerated pathways for orphan drugs remain a policy ask
Patient access	Three-group disease categorization structures eligibility and prioritization	Crowdfunding portal avenues have achieved limited success; estimated ~INR9,100 crore annual requirement for verified cases
Sustainability	PRIP Scheme (INR5,000 crore) prioritizes orphan drugs and precision medicine	Advocacy groups flag rollout delays in proposed funding programs; need outcome-linked orphan drug procurement

Sources: <https://www.medgatetoday.com/indias-national-policy-for-rare-diseases-to-encompass-rare-dermatological-conditions/>; <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2043516®=48&lang=2>; <https://www.rarediseases.in/india-15-centres-of-excellence-rare-diseases-nprd-2021/>; <https://www.insideprecisionmedicine.com/news-and-features/tackling-rare-disease-in-india/>; <https://www.orfonline.org/expert-speak/rare-diseases-justice-delayed-treatment-denied>

The policy is implemented through Centres of Excellence, which are premier tertiary hospitals. The number expanded from eight to 15 across multiple states and Union Territories, including two in North-East India. The three additions during 2025 were the Regional Institute of Medical Sciences Imphal, AIIMS Patna, and Assam Medical College and Hospital Dibrugarh.⁷⁸

In 2026, Assam Medical College and Hospital administered enzyme replacement therapy to a child with a rare disease. This is reported to be the first such treatment delivered in North-East India, demonstrating how rare disease capabilities are extending to previously underserved regions.⁷⁹

The overall direction is toward indigenous capability with the aim to develop context-specific models for diagnosis, treatment and prevention while reducing dependence on imported therapies. Supporting this objective, ICMR is advancing the indigenization of affordable therapies through industry collaborations

and Centres of Excellence, with six repurposed drugs currently being evaluated for rare diseases.

Digital innovation is helping close the diagnosis gap. A recent private-sector initiative comes from Sanofi India, which launched AccelRare, a free digital pre-diagnosis tool covering 310 rare diseases and connecting suspected cases with government-recognized Centres of Excellence⁸⁰.

Government support for domestic production is widening treatment availability. Five domestically manufactured medicines covering seven rare conditions are available, with four more therapies under development⁸¹. Customs duty relief on therapies for seven rare diseases, including Alnylam's lumasiran for Primary Hyperoxaluria Type 1, can lower import costs and support patient access⁸². Earlier identification, domestic availability and specialist referral need to operate as one pathway to reduce delays between symptoms, diagnosis and treatment.

⁷⁸ <https://www.rarediseases.in/india-15-centres-of-excellence-rare-diseases-nprd-2021/>

⁷⁹ <https://timesofindia.indiatimes.com/city/quwahati/amch-administers-enzyme-replacement-therapy-to-child-with-rare-disease-1st-in-ne/articleshow/133812036.cms>

⁸⁰ [Fighting against rare diseases together - Sanofi India](#)

⁸¹ [Four new drugs for rare diseases on anvil; five medications for 7 ailments in market: VK Paul - The Economic Times](#)

⁸² [Budget 2026: Customs duty relief to make cancer, rare disease drugs cheaper | Budget 2026 News - Business Standard](#)

4.4 Patient-centric trials

Affordable, accessible innovation also requires research designed around patients. Patient-centric trials involve patients and caregivers early to shape questions, endpoints, visit schedules and consent materials, revealing barriers such as travel, lost wages, language, accessibility and caregiver responsibilities.

Sponsors can respond through decentralized visits, remote monitoring, home-based sample collection, flexible scheduling and reimbursement for participation costs. These approaches can widen recruitment beyond major cities, improve retention and include patients from different regions and socioeconomic groups. Patient experience data can also capture changes in symptoms, daily functioning and quality of life that conventional clinical measures may miss. Strong scientific methods, informed consent and data privacy remain essential. For rare disease patients, a more accessible trial model can shorten participation journeys, strengthen evidence and support the development of therapies that reflect real patient needs.

4.4.1 Patient voice in research and access

Patient voice should become a core element of pharmaceutical innovation and access. Patients and caregivers can provide valuable insights into unmet needs, treatment burden, trial participation barriers and meaningful outcomes. Integrating these perspectives into research, development and access pathways can improve study design, strengthen evidence generation and increase the likelihood that innovative therapies deliver measurable value in real-world settings.

4.5 Outcome-based care: Redefining how value is measured

Outcome-based care pays for what treatment achieves, not how much is delivered. Moving from volume to value requires robust evidence and financing mechanisms that reward measurable outcomes.

The Health Technology Assessment in India (HTAI) mechanism was set up under the Department of Health Research to analyze medicines, devices and health programs for cost-effectiveness, clinical effectiveness and equity, with the objectives of maximizing population health, reducing out-of-pocket expenditure and reducing inequity.⁸³ To address the critical gap in reliable cost data, HTAI funded PGIMER Chandigarh to conduct the Cost of Health Services in India study, to sample public and private hospitals across 13 states, with the published hospital-cost analysis covering 38 public and 16 private hospitals.⁸⁴

⁸⁵

The National Health Authority also established a Health Financing and Technology Assessment unit to prioritize assessment topics, selecting from stakeholder nominations and horizon scanning against criteria including disease burden, budget and economic impact, feasibility, clinical impact, evidence quality, policy relevance and social value judgments.⁸⁶

In January 2023, it announced a shift under Ayushman Bharat PM-JAY from measuring the volume of services to measuring their value. Empaneled hospitals are to be paid and graded against five performance indicators: beneficiary satisfaction, hospital readmission rate, extent of out-of-pocket expenditure, confirmed grievances and improvement in patients' health-related quality of life. Performance grades are to be made available on public dashboards so that beneficiaries can make informed choices.

PM-JAY itself covers more than 500 million Indians among the economically weakest 40% of the population. It has also been extended to six crore senior citizens aged 70 and above under Ayushman Vay Vandana.⁸⁷

Measuring outcomes changes what is worth developing. If payment follows results, a marginal product in a crowded category has little value, while a

⁸³ <https://htain.dhr.gov.in/about-htain.php>

⁸⁴ <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0232873>

⁸⁵ <https://link.springer.com/doi/10.1186/s12913-022-08707-7>

⁸⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC12355834/>

⁸⁷ <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2241085®=3&lang=1>

therapy that produces a durable result in a defined group of patients has a great deal. The commercial logic can then favor patient-defined needs.

4.5.1 Healthcare financing

Healthcare financing should focus on:

- Public financing
- Insurance expansion
- Rare-disease financing
- Outcome-based reimbursement
- Sustainable access to advanced therapies

Access depends on how healthcare costs are shared across public financing, insurance, employers and private payment throughout the patient journey. While many health-insurance models provide protection for acute hospital-based care, diagnostics, outpatient medicines, monitoring and long-term disease management often remain outside traditional benefit packages.

As advanced therapies, biologics and precision medicines become more common, financing models may need to evolve beyond episodic reimbursement towards continuous-care frameworks. Public investment remains the foundation of financial protection, supporting insurance coverage, primary care, healthcare infrastructure and public-health programs. At the same time, broader insurance coverage, innovative risk-sharing arrangements and

outcome-linked reimbursement models can help improve access to high-cost therapies while maintaining system sustainability.

Emerging patient-financing initiatives further illustrate how innovative therapies can be made more accessible. For example, Immuneel Therapeutics and Arogya Finance introduced a financing model for eligible CAR-T therapy patients, demonstrating how private financing mechanisms can complement conventional reimbursement pathways for treatments with high upfront costs. However, such approaches should be viewed as supplements rather than substitutes for broader health-system financing solutions.

Health Technology Assessment (HTA), real-world evidence and outcome-based care can support more efficient allocation of healthcare resources by linking payment to measurable clinical and patient outcomes. Over time, wider risk pools, broader benefit packages and performance-based reimbursement mechanisms can strengthen affordability while encouraging innovation that delivers tangible health impact.

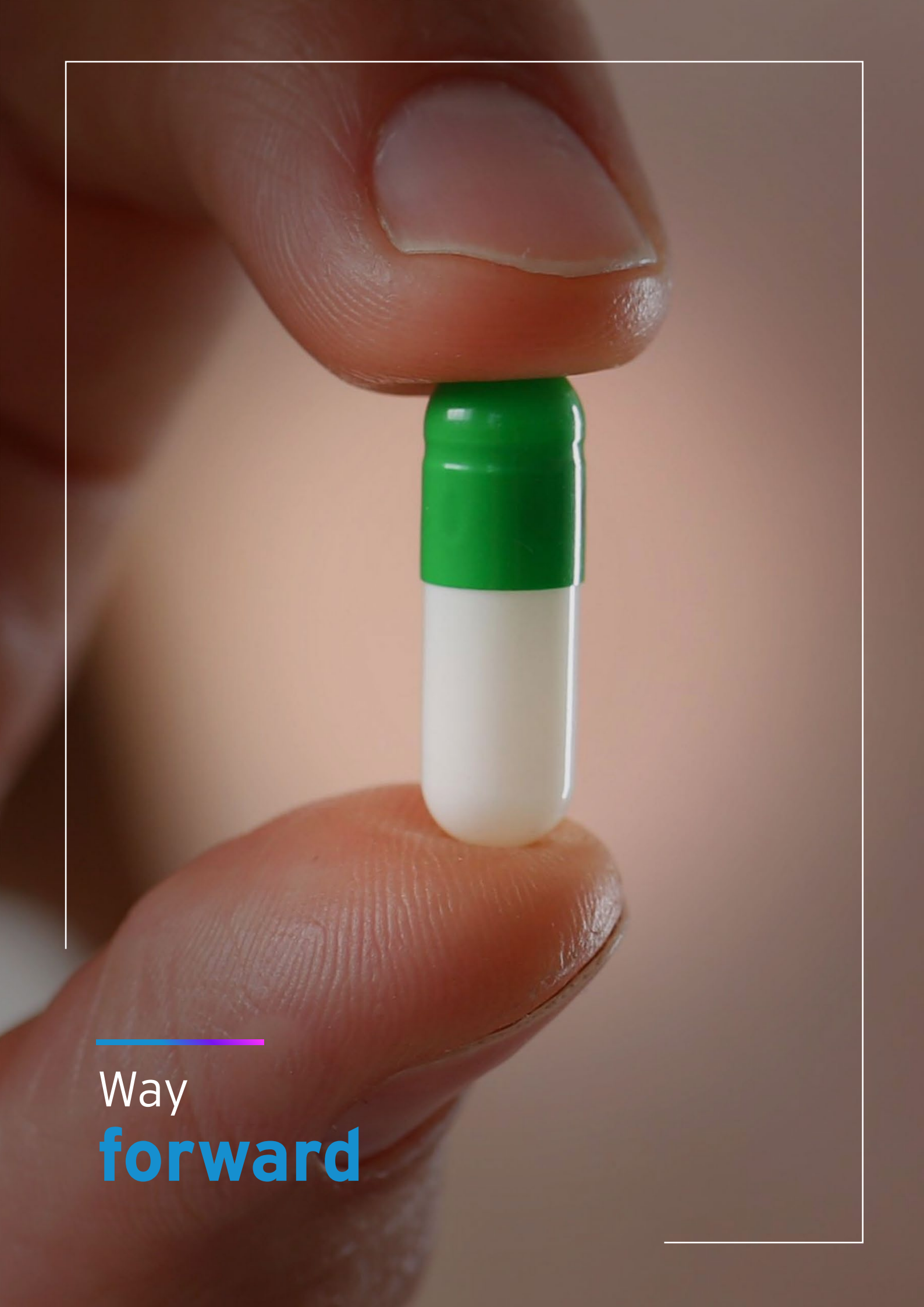
Ultimately, a sustainable financing ecosystem should ensure that scientific advances are accessible to patients irrespective of income or geography. Success should be measured not only by the availability of innovative therapies, but by the ability of healthcare financing systems to support timely diagnosis, equitable access, treatment adherence and improved patient outcomes.



Pillar 4: **2030 action agenda**

Map the full access pathway for selected conditions; expand diagnostic and referral capacity beyond major cities; pilot outcome-linked reimbursement; include patient organizations in policy and research design; and track time to diagnosis, treatment, adherence, financial protection and outcomes.





Way
forward

Accelerating towards 2047: A national blueprint for India's pharma ambition

India's pharmaceutical ambition for 2047 may require coordinated action across manufacturing, innovation, technology, talent and healthcare delivery. Success is likely to depend on aligning government, regulators, industry, academia, investors, healthcare providers and patient groups behind a shared national agenda with clear ownership, measurable milestones and transparent accountability.

The journey can be organized around four strategic priorities that mirror the report's core pillars:

Defend: Strengthen trust, quality and resilience

Manufacturing leadership must be engineered, not inherited. Revised Schedule M provides the regulatory foundation, but sustained competitiveness may require quality-by-design, digital traceability, risk-based inspections, resilient supply chains and commercially viable domestic capacity in APIs, drug intermediates and key starting materials.

Differentiate: Scale innovation and advanced therapeutics

Investment should focus on areas where unmet patient need intersects with India's scientific strengths, including biologics, biosimilars, precision medicine, peptides, oligonucleotides, ADCs and cell and gene therapies. Translational infrastructure, technology-transfer mechanisms, IP frameworks and trial-ready clinical networks may be critical to converting scientific research into globally relevant products.

Leapfrog: Create an AI-enabled pharmaceutical ecosystem

AI, digital infrastructure and interoperable health data can accelerate discovery, manufacturing, regulatory processes and evidence generation. Responsible AI governance, GxP-aligned controls, cybersecurity and trusted data foundations should be embedded from the outset to ensure innovation remains transparent, auditable and scalable.

Democratize: Expand access and patient outcomes

Affordability, financing and patient access should be integrated throughout the innovation lifecycle. Rare-disease care, decentralized trials, digital-health infrastructure and outcome-based healthcare models

can help ensure that scientific advances translate into measurable improvements in patient outcomes across India.

National enablers

Recommendations to accelerate execution:

- A National Pharma Innovation Council to align policy, funding and regulation
- Shared testing, validation and translational infrastructure
- Regulatory sandboxes for advanced therapies and AI-enabled innovations
- A national talent strategy covering biologics, genomics, AI and regulatory science
- Annual scorecards tracking quality, innovation, resilience, access and outcomes

Measuring success

By 2047, success should be measured not only through market size or export growth, but through India's ability to combine trusted manufacturing, original innovation, AI-enabled competitiveness and equitable patient outcomes at a global scale.

India pharma 2047 execution roadmap

2026-2030: Build the foundations

Strengthen quality systems, manufacturing resilience, translational research infrastructure, digital interoperability, responsible AI governance and specialist talent pipelines. Establish the regulatory, scientific and operational foundations required for innovation-led growth.

2030-2035: Scale innovation and competitive advantage

Accelerate advanced modalities, platform-based R&D, CRDMO value expansion, AI-enabled operations and commercial manufacturing capabilities. Expand global collaborations and pilot outcome-based access models to translate innovation into scalable economic and patient value.

2035-2047: Lead as a global innovation powerhouse

Position India as a trusted source of high-quality medicines, original intellectual property, advanced therapeutics, digital-health innovation and equitable patient outcomes. Drive global leadership through differentiated science, resilient supply chains, high-value exports and measurable healthcare impact.

Proposed national pharma 2047 scorecard

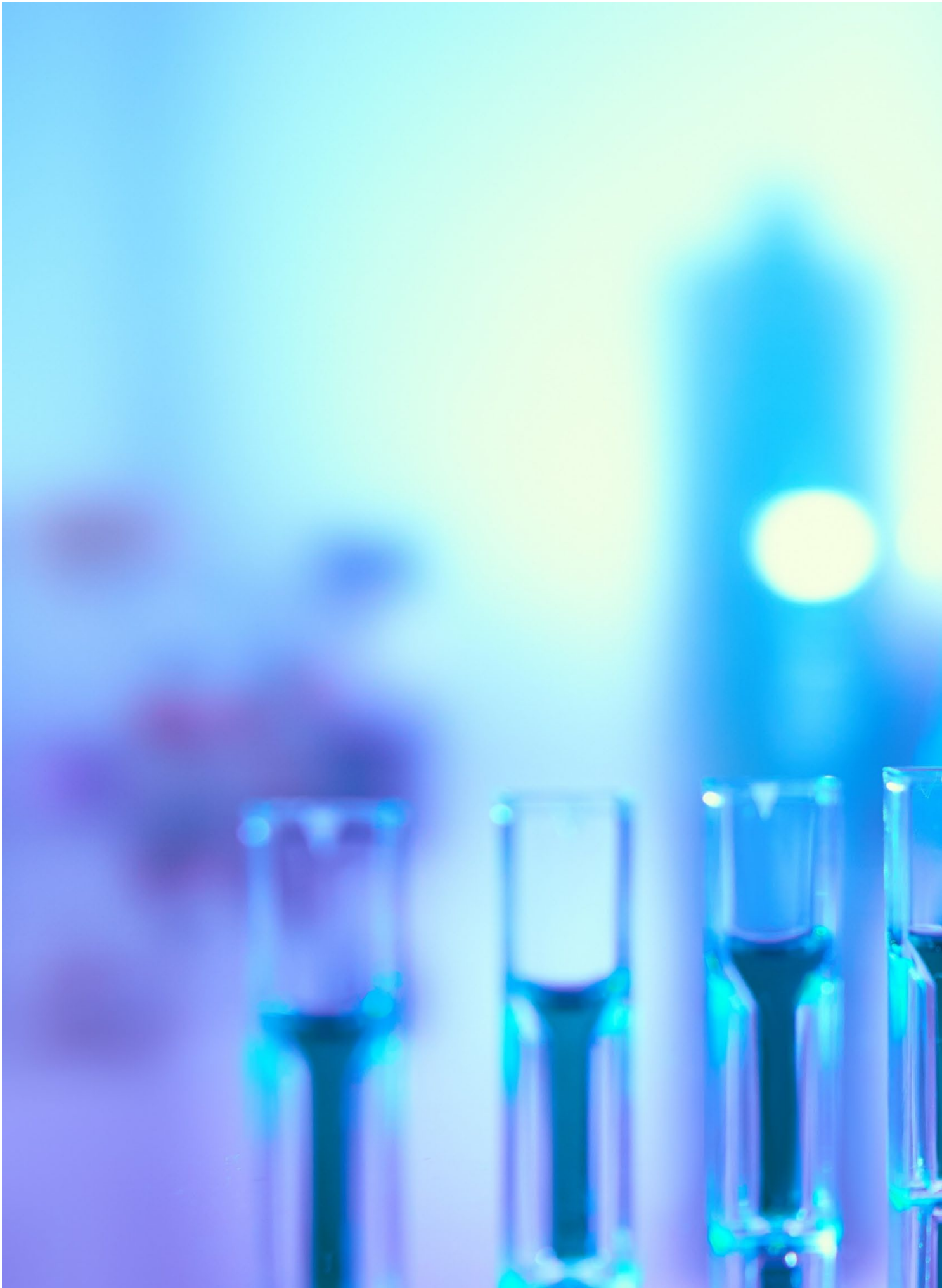
Progress towards India's pharmaceutical ambition should be measured through a balanced scorecard spanning trust, resilience, innovation, intelligence, access and sustainability.

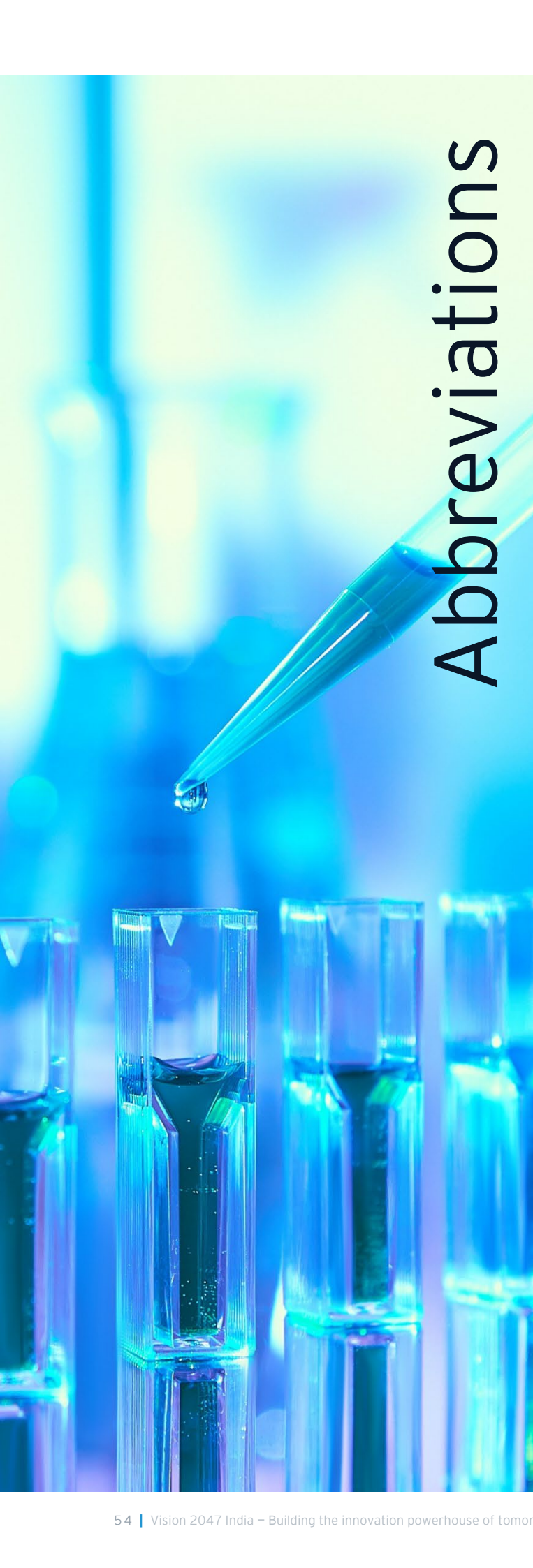
Each metric should have a defined baseline, a 2030 milestone, a 2047 ambition, an institutional custodian and a transparent annual reporting mechanism.

India may not secure long-term leadership by choosing affordability over innovation, or manufacturing scale over scientific discovery.

Countries that are strong in only one dimension may remain specialist suppliers. Those combining dependable manufacturing, differentiated research, responsible technology, skilled talent and equitable access may shape global healthcare. Guided by the four pillars, India can evolve by 2047 from the 'Pharmacy of the world' to an 'Innovation hub for the world'.

Strategic objectives	Indicators
Trust and quality	Quality maturity index, inspection outcomes and data-integrity compliance
Supply resilience	Critical-input dependency exposure, domestic API/KSM self-reliance and supply continuity
Innovation leadership	Indian-origin assets entering development, licensing deals, patent filings and royalty income
Clinical and research excellence	Trial capacity, enrollment diversity and translational research outputs
Intelligent pharma	Validated AI deployments, digital maturity and productivity gains from digital technologies
Talent and capability	Specialist workforce availability across biologics, CGT, AI, genomics and regulatory science
Patient access	Time to diagnosis, time to treatment, affordability and coverage metrics
Health outcomes	Real-world effectiveness, patient-reported outcomes and disease-specific outcomes
Sustainability	Water intensity, carbon emissions, waste reduction and circularity indicators





Abbreviations

ABHA - Ayushman Bharat Health Account

ADMET - Absorption, Distribution, Metabolism, Excretion and Toxicity

ALCOA - Attributable, Legible, Contemporaneous, Original and Accurate

API - Active Pharmaceutical Ingredient

BCG - Bacillus Calmette-Guérin

BCMA - B-cell Maturation Antigen

BIRAC - Biotechnology Industry Research Assistance Council

CAR-T - Chimeric Antigen Receptor T-cell

CDMO - Contract Development and Manufacturing Organization

CDSCO - Central Drugs Standard Control Organization

CLAA - Central Licensing Approving Authority

CoE - Centre of Excellence

CRO - Contract Research Organization

CTAA - Clinical Trial Application Assessment

DBT - Department of Biotechnology

DNA - Deoxyribonucleic Acid

DPT - Diphtheria, Pertussis and Tetanus

EHR - Electronic Health Record

EHRs - Electronic Health Records

EMA - European Medicines Agency

EMR - Electronic Medical Record

ERP - Enterprise Resource Planning

FDA - Food and Drug Administration

FEFO - First Expiry, First Out

GCP - Good Clinical Practice

GenAI - Generative Artificial Intelligence

GLP-1 - Glucagon-Like Peptide-1

GMP - Good Manufacturing Practice

GxP - Collective term for Good Practice quality guidelines and regulation

HFR - Health Facility Registry

HMIS - Health Management Information System

HPAPI - High-Potency Active Pharmaceutical Ingredient

HPR - Healthcare Professional Registry

HTA - Health Technology Assessment

HTAI_n - Health Technology Assessment in India

ICMR - Indian Council of Medical Research

ICH - International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

IND - Investigational New Drug

KSM - Key Starting Material

mAb - Monoclonal Antibody

MHRA - Medicines and Healthcare products Regulatory Agency

MLR - Medical, Legal and Regulatory

MoU - Memorandum of Understanding

MSME - Micro, Small and Medium Enterprise

MUC1 - Mucin 1

NABL - National Accreditation Board for Testing and Calibration Laboratories

NCCVMRC - National Cold Chain and Vaccine Management Resource Centre

NDR - National Drug Registry

NGS - Next-Generation Sequencing

NIBEC - National Immunogenicity and Biologics Evaluation Center

NIPER - National Institute of Pharmaceutical Education and Research

NPRD - National Policy for Rare Diseases

NRCeS - National Resource Centre for EHR Standards

OTC - Over the Counter

PD-L1 - Programmed Death-Ligand 1

PGIMER - Postgraduate Institute of Medical Education and Research

PHR - Personal Health Record

PLI - Production Linked Incentive

pLM - Protein Language Model

PMBJP - Pradhan Mantri Bhartiya Janaushadhi Pariyojana

PM-JAY - Pradhan Mantri Jan Arogya Yojana

PPP - Public-Private Partnership

PRIP - Promotion of Research and Innovation in Pharma

PROTAC - Proteolysis-Targeting Chimera

PV - Pharmacovigilance

QbD - Quality by Design

QMS - Quality Management System

QSAR - Quantitative Structure-Activity Relationship

RNA - Ribonucleic Acid

RPTUAS - Revised Pharmaceuticals Technology Upgradation Assistance Scheme

RWD - Real-World Data

RWE - Real-World Evidence

SNOMED CT - Systematized Nomenclature of Medicine Clinical Terms

SPPS - Solid-Phase Peptide Synthesis

UMMID - Unique Methods of Management and Treatment of Inherited Disorders

US FDA - United States Food and Drug Administration

WHO-GMP - World Health Organization Good Manufacturing Practices

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For more than 130 years, CII has been engaged in shaping India's development journey and works proactively on transforming Indian Industry's engagement in national development. CII charts change by working closely with the Government on policy issues, interfacing with thought leaders, and enhancing efficiency, competitiveness, and business opportunities for industry through a range of specialised services and strategic global linkages. It also provides a platform for consensus-building and networking on key issues.

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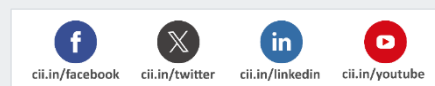
For 2026-27, CII has identified "Accelerating Competitiveness: Growth, Resilience, Inclusion, Sustainability, Trust" as its theme, prioritising five key pillars. During the year, CII will align its policy advocacy, institutional initiatives, partnerships, and outreach to support Indian industry in strengthening these five interconnected pillars of competitiveness.

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