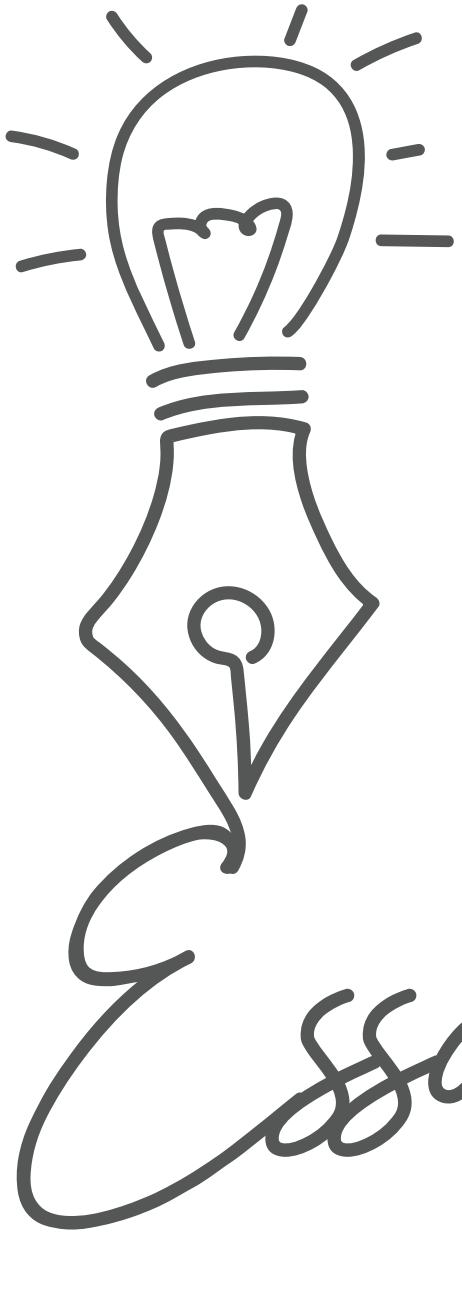

OPPI

भारत के लिए

Organisation of Pharmaceutical Producers of India

Essays on Innovation

The India growth story gains traction

Curated By

Asawari Sathaye
Director, Communications and Patient Advocacy, OPPI

Innovation has always been at the heart of progress – the bridge between imagination and impact. It drives economic growth, transforms societies, and ultimately, shapes a better future for all. At OPPI, we have always believed that India's true potential lies in its ability to innovate, to think beyond the conventional, to create solutions that address unmet needs, and to ensure equitable access to those solutions for all.

The idea for Essays on Innovation was born out of this conviction. We wanted to capture how different voices across India's healthcare and life sciences ecosystem view innovation – what it means to them, and what it will take for India to emerge as a true global powerhouse. This publication brings together the independent thoughts of 39 distinguished authors representing public sector, industry, academia, policy, think tanks, media, patient groups, and other key stakeholders, each sharing their perspective on how innovation can drive our nation's growth story.

This has been a long journey from inception to execution. From a wide array of ideas, we carefully cherry-picked those that we believe India must focus on to accelerate its innovation journey and achieve its vision of Viksit Bharat @2047. These essays are not just reflections; they are a roadmap — one that highlights both our achievements and the areas where collective effort is the key.

We are immensely grateful to our authors for their time, insights, and candor. Their perspectives enrich the conversation on innovation and reaffirm that with determination, collaboration, and vision, India can truly lead the world in pharmaceutical and medical innovation.

A special note of gratitude to Mr Anil Matai, Director General, OPPI, for being the guiding force and inspiration behind this initiative. This publication would not have been possible without his encouragement and commitment to advancing the dialogue on innovation. I would also like to extend my heartfelt thanks to my team, Clara Rodricks and Cheshta Shetty, whose tireless efforts and creative energy have been instrumental in bringing this publication to life.

We hope you find Essays on Innovation as engaging and thought-provoking as we did while curating it. May these essays spark new ideas, inspire collaboration, and strengthen our shared resolve to make India not just the Pharmacy of the World, but the Pharma Powerhouse of Innovation for the world.

Preface

Anil Matai
Director General, OPPI

Innovation - The fundamental engine of progress; driving economic growth and fostering societal transformation. Indeed, there can be no true progress without innovation…Just as there can be no true innovation, without determination.

As India strides towards its goal of ***Viksit Bharat @2047***, we are witnessing the doubling of this determination, especially in the Pharma sector! India is now aiming at breaking the shackles of being known as 'Pharmacy of the World' to evolve as a global powerhouse in pharma and the nucleus of medical innovation. This becomes all the more vital in a country with an increasingly aging population facing a substantial rise in Non-Communicable Diseases (NCDs).

This goal can be achieved by developing indigenous capabilities in APIs, enhancing drug manufacturing quality, embracing AI technology for improved outcomes and strengthening supply chains.

At OPPI, we have always striven to give impetus to innovation, working with the nation, and working for the nation. And as we celebrate the Diamond Jubilee year of our inception, we renew our pledge towards building value of innovation, and access to more equitable healthcare while we focus more on unmet medical needs and rewrite India's growth story.

We believe concerted efforts bring concrete results. Towards this end, we have invited some of the best minds in industry, academia and the media to put forth their views and suggestions on how to ignite India's innovation journey. The result is this book, 'Essays on Innovation'.

As you peruse these 39 articles, you will understand the potential waiting to be tapped in this sector. Already the leading supplier of vaccines to the world, the near future foresees MedTech picking up the mantle of transforming healthcare in India. AI, Machine Learning, IoT and allied digital processes are projected to take the market to USD 50 billion by 2030, at an impressive CAGR of 20%. Adding its weight are the various start-ups with their patient-centric diagnostic

solutions. Similarly, gene therapy, botanicals, biologics and emerging disciplines are gaining tremendous traction, too.

Though India is going from strength to strength in the pharma sector, these essays will also throw light on the areas that have scope for improvement. Two areas that stand out here are poor R&D funding and weak academic-industry collaboration. The former can be tackled with increased public spending on healthcare (at present less than 2% of GDP) and mobilizing private sector investment through venture capitalists, coercing them away from the safer option of backing biosimilars and incremental innovation. Eliminating bureaucratic hurdles and delays in grant of disbursements will also boost an innovation-inclined industry, as will creating a strong IP ecosystem and speedier judicial redressal. The industry also needs to stem the very real problem of brain-drain and attract a talent-rich workforce.

But these essays also show that there is hope on the horizon. In recent years, the government has developed multiple schemes and programs that aim to give major thrust to this sector. Such as the PLIS (Production Linked Incentive Scheme) with its outlay of Rs 15000 crore, that has helped develop 55 APIs and over 20000 jobs. PRIP (Promotion of Research and Innovation in Pharma) scheme and Innovation in Pharma-MedTech Sector' in India are two initiatives that upgrade CoEs within existing NIPERs, spurring deeper innovation in the sector. Other initiatives include Atal Innovation Mission (AIM) with its various programs, BioE3 (Biotechnology for Economy, Environment & Employment) and ANRF Act 2023 – Anusandhan National Research Foundation, which coordinates public-private R&D. Startup India aims to foster both innovation and entrepreneurship.

CRDMOs (Contract Research, Development and Manufacturing Organizations) that are working towards creating new molecular entities, development of Pharma Parks, GCCs and the setting up of NIPERs pan India also aim to revolutionize India's innovation ecosystem.

On the regulatory side, changes in the clinical trial requirements, revised biosimilar guidelines by CDSCO and India's signing of important trade agreements such as EFTA, TEPA, India-UK CETA, will bring forth further growth in the sector.

In conclusion, all the articles make it evident that Viksit Bharat is a very achievable goal. Indeed, it is a laudable mission - a call to action. One that OPPI and its member companies have taken up with all sincerity!

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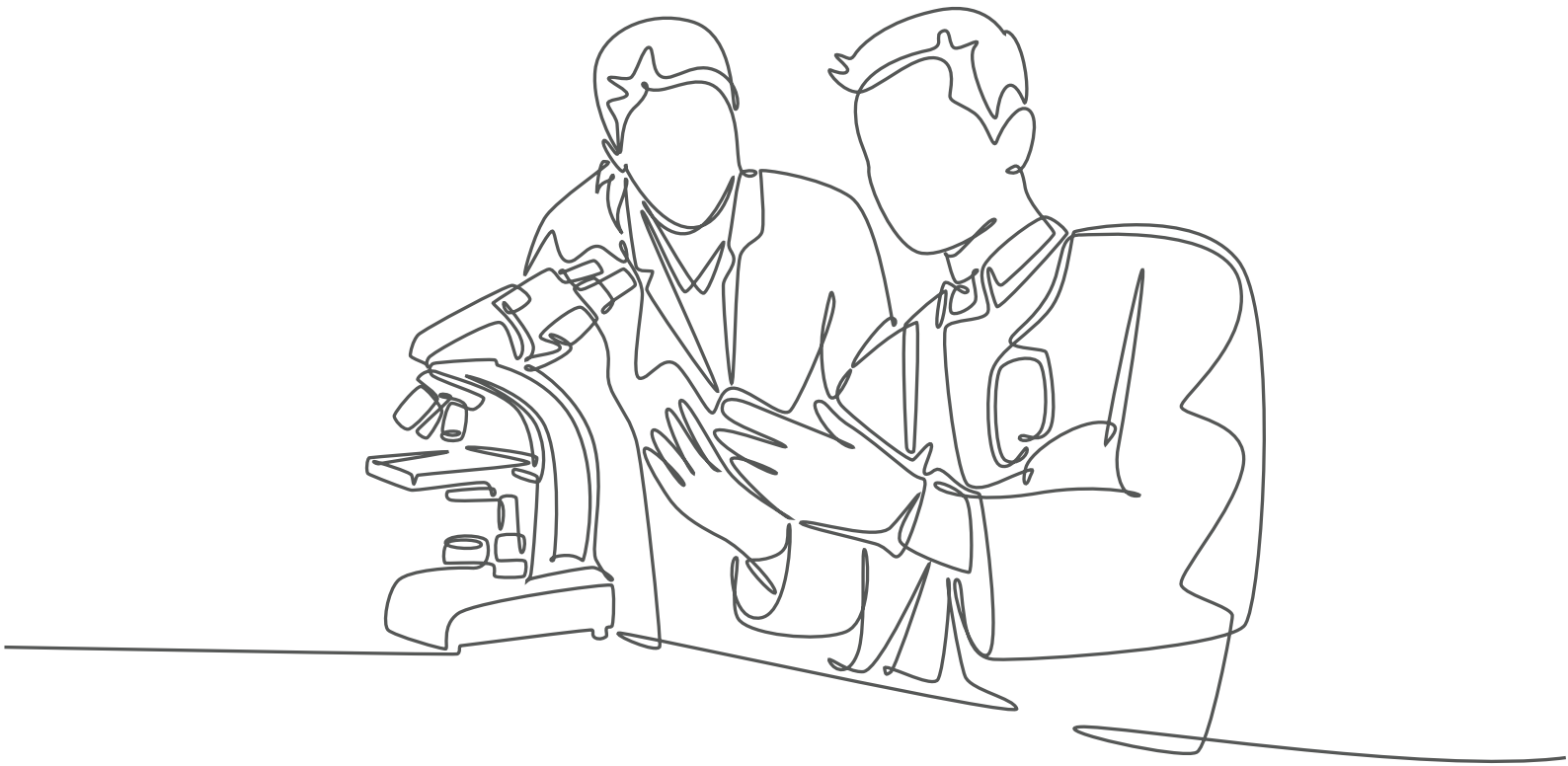


Securing the Future: Innovation, IP, and India's Road to a Knowledge Economy

Bhushan Akshikar

President, OPPI and Vice President & Managing Director, GlaxoSmithKline Pharmaceuticals Limited

The Prime Minister Shri Narendra Modi, in his address to the nation on the 79th Independence Day, once again delineated his vision for a Viksit Bharat @2047 by underscoring innovation as one of the key pillars of India's economic progress.

The Government of India's vision to shift from a volume to a value-based pharmaceutical industry reflects its commitment to delivering high-quality, innovative healthcare solutions that meet the evolving needs of patients and healthcare providers. Healthcare systems are able to thrive because of continuous research & innovation in the fields of science and technology that results in finding new treatment outcomes to address unmet medical needs.

It is encouraging that India witnessed a significant surge in IP filings between 2020–21 to 2024–25 with 180% increase in patent filings alone. Also encouraging for the research based pharmaceutical industry is the recognition by the Prime Minister during his Independence Day address, on the need to enable researchers and entrepreneurs to secure patents for new drugs and medical technologies.

Several schemes launched by the Government of India such as the Promotion of Research and Innovation in Pharma-MedTech Sector (PRIP) scheme and the National R&D Policy are indeed steps in the right direction.

However, one pillar that stands out as foundational to India's ambition to becoming a global innovation hub is a robust pharmaceutical research and development (R&D) ecosystem, underpinned by a strong, predictable intellectual property (IP) particularly, patent regime.

A robust IP framework along with a streamlined, fair and transparent regulatory mechanism not only incentivizes innovation but also facilitates the development, protection, and commercialization of novel healthcare solutions that meet the evolving needs of patients and healthcare providers.

India's signing of the trade agreements such as EFTA TEPA, India-UK CETA has been contributing to shaping up of its legal framework, including IP laws. Several positive measures have been undertaken by the Government of India to augment its IP framework such as streamlining of the pre-grant opposition process, simplification and reduced frequency to file working statement in Form 27, simplification of the requirements to file information in respect of corresponding patent applications, modernization of IP Offices including increase in the sanctioned strength and working manpower of the Indian Patent Office etc. OPPI member companies look forward to further shaping up of India's patent law as agreed to between India and UK under India-UK CETA such as non-disclosure of confidential information contained in the disclosure (Form 27) in the public domain other than in exceptional circumstances.

On August 13, 2025, the Commerce Minister, Shri Piyush Goyal rightly recognized data exclusivity (also termed as regulatory data protection) as the last missing link before India witnesses an inflow of foreign investment leading to millions of jobs.

For research based pharmaceutical industry, generation of regulatory data generated in the course of developing a drug product (required for making regulatory submissions) is cost and time intensive and also involves significant risks. Since RDP merely provides protection of the data package required to be submitted before a drug regulatory authority from its unfair commercial use by third parties without the originator's concurrence. In this way, RDP systems balance and advance both the development and testing of new medicines and enabling availability of lower-cost alternatives.

RDP does not extend the patent term nor does it create "evergreening". It, in fact, typically overlaps with the patent term without preventing generics from entering the market through independent effort. Therefore, the apprehension that RDP will slacken growth of generic market is ill-founded.

Indian companies aggressively seek opportunities for generics even in regulated markets mainly the EU, UK and other well-regulated countries. RDP incentivises innovators to invest in R&D, particularly for biologics, which involve greater complexity and cost, and for AYUSH/phyto-products, which may not be patentable but require large investments in generating clinical data.

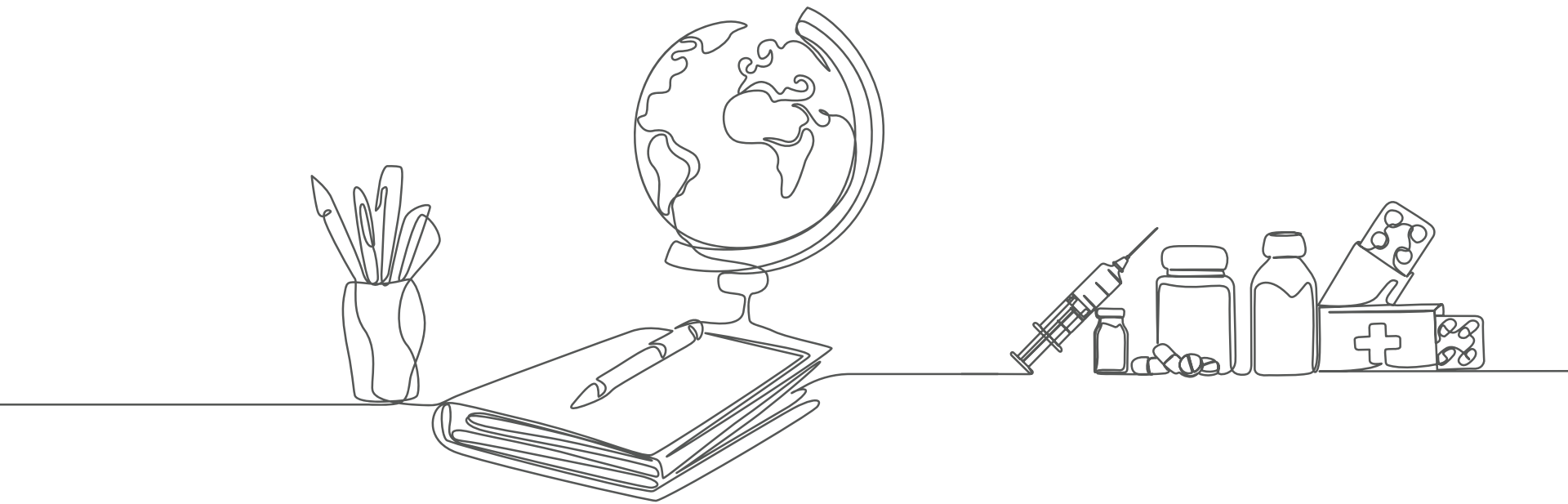
As an industry association representing R&D based innovative pharma companies, Organisation of Pharmaceutical Producers of India (OPPI) looks forward to discussions on RDP including the deliberations envisaged under the India-EFTA TEPA.

India has the potential to be a global leader in research and development-based industries. Indian scientists have demonstrated their critical research talent in the biotech

and pharmaceutical spheres. The country is poised to make important contributions to public health through innovation, not only within India, but globally. To become fully integrated into the larger family of scientists around the world working to bring new therapies and cures to patients, a conducive innovation ecosystem is critical. Also critical is an effective IP enforcement mechanism that enables enforcement of IP rights in a timely and consistent manner instils confidence in the rule of law and provides a fillip to innovation-led investments.

Fostering innovation, enhancing ease of doing business and establishing a clear, strategic framework for a robust IP regime can empower India to realize its full potential as a global centre for innovation. Further, as global IP laws evolve, India's alignment with emerging global IP norms will be crucial for India's competitive growth in the knowledge economy.

With these pillars in place, the country is well-positioned to lead in the 21st-century knowledge economy, driving sustainable growth and achieving our prime Minister's vision of making India a global hub of medical self-reliance and innovation.



Viksit Bharat and the Innovation Imperative

Amitabh Dube

President Elect, OPPI and Country President and Managing Director, Novartis India

"There's no single formula for breakthrough innovation – but when passionate people unite for a cause, guided by purpose and not just process, transformation follows."

India today stands at a powerful inflection point. With a growing economy, a youthful population, burgeoning entrepreneurial mindset, a digital backbone that is the envy of many nations, and a clear national vision through Viksit Bharat@2047, the country is poised to lead – not just in size, but in ideas.

But to truly become a developed nation by 2047, India needs something more fundamental than infrastructure, education, digital transformation, or sustainability. It needs a healthy, productive population – one that can actively participate in and shape the country's growth story.

The essence of Viksit Bharat lies in creating an India that is prosperous, equitable, healthy, and future-ready. This vision cannot be achieved without fostering an innovation-first mindset – one that is consistent across industry, policy, academia, and society.

The Innovation imperative

As we move toward a Viksit Bhart with intention, India must make innovation its central engine toward progress. Not innovation for its own sake, but purposeful innovation – one that meets the needs of our people, addresses systemic gaps, and ensures that growth is inclusive.

Innovation is rarely about "Eureka!" moments. It is about persistent problem-solving, bold collaboration and the courage to rethink what's possible. It must be defined not only by technological breakthroughs or research milestones, but also by re-imaging systems, processes, and delivery models.

Take healthcare for instance – an industry close to my heart. Healthcare offers perhaps the most compelling canvas for innovation to thrive. A rising burden of non-communicable diseases, a growing aging population, and infrastructure strained by both scale and complexity.

Innovation in this space must encompass how we design systems, deliver care, reach patients and measure outcomes. And for such innovation to succeed, it must be enabled by partnerships – between government, industry, academia, patient communities, start-ups, healthcare providers, diagnostics labs, and more.

Building on a decade of progress

The last decade has already given us a blueprint for what works.

- **Ayushman Bharat**, the world's largest government-funded healthcare program, has issued over 354 million health cards, established 1.17 lakh Health and Wellness Centres, and enabled 78 million hospitalisations worth ₹10 trillion – reducing out-of-pocket expenditure by an estimated 21%.[iii]

- The **Ayushman Bharat Digital Mission** has created over 670 million digital health IDs, laying the foundation for truly portable and patient-centric care.[iii]

- The **Production Linked Incentive Scheme for pharmaceuticals** – with an outlay of ₹15,000 crore – has helped develop 55 critical APIs domestically, reducing import dependency and generating 23,000 jobs.[iv]

- **Health-tech** emerged as the second most funded vertical after fintech in the first half of this year attracting USD828 million.[v]

These are not isolated wins. They demonstrate what happens when **policy, investment, and innovation align**. The next step is to move beyond fragmented efforts and embed **partnership as a national innovation strategy** with shared infrastructure, streamlined regulation, and co-owned outcomes.

Priorities for an innovation-driven Viksit Bharat

1. **Investing boldly in R&D**
   While India's Gross Expenditure on R&D (GERD) has grown over the years, it remains at just 0.64% of GDP[vi]. In the pharmaceutical industry, R&D spend is about 0.7%[vii], mirroring the national average – compared to 1.6% in the United States of America[viii]. As Viksit Bharat, we need to shift the narrative to **innovating in India for the world!**

Closing this gap requires more than increased funding. We need targeted Public–Private Partnerships (PPPs), innovation-linked incentives, and streamlined clinical trial processes.

A stronger R&D pipeline will enable India to lead in biologics, advanced therapies, and AI-driven diagnostics – moving beyond being a manufacturing hub to becoming a true innovation hub.

2. **Harness talent and strengthen Industry-Academia collaboration**
   By 2030, India will have the largest working-age population in the world – **our demographic dividend!** Yet, in life sciences, only 46% of pharma graduates are directly employable[ix]. In healthcare particularly, the gap between academic curricula and industry needs must be bridged through structured partnerships with institutions such as NIPER, IISc, and AIIMS, focusing on regulatory science, advanced clinical research, and biostatistics.

   Nearly 25 years ago, Novartis recognized India's talent potential and committed to nurturing the broader life sciences ecosystem. Today, this vision has translated into a robust presence across Research, Drug Development, Commercial, and Operations – anchored in world-class facilities that drive innovation and enable our purpose of *reimagining medicine* for the world, from India.

   Our highly skilled workforce has also fuelled the growth of Global Capability Centers across the country. Initiatives like NEST – our real-world, case-based student competition – further cultivate the next generation of innovators and strengthen academia-industry bridge.

3. **Ensuring Equitable Access to Innovation**
   In the Viksit Bharat we envision and work towards, **access is not a privilege – it is a right!** Innovation has no meaning unless it reaches the patient who needs it. To pave the way for equitable access, we must:

   - Create **fast-tracked regulatory pathways** for breakthrough therapies, linked to improved patient outcomes.

   - Provide **customs duty exemptions** on critical medicines, such as recent measures for certain cancer drugs.

   - Strengthen **IP protection** – India ranks 42nd of 55 countries in the International IP Index since 2022 and improving this will be vital for attracting high-value investment in innovation.

   - **Increase India's public spending on healthcare** – currently at 1.9% of GDP[x]. While this marks a significant improvement, it still falls short of the recommended benchmarks for developing nations. Raising this further will be essential to ensure that innovation translates into accessible and affordable care for all.

The Time is NOW

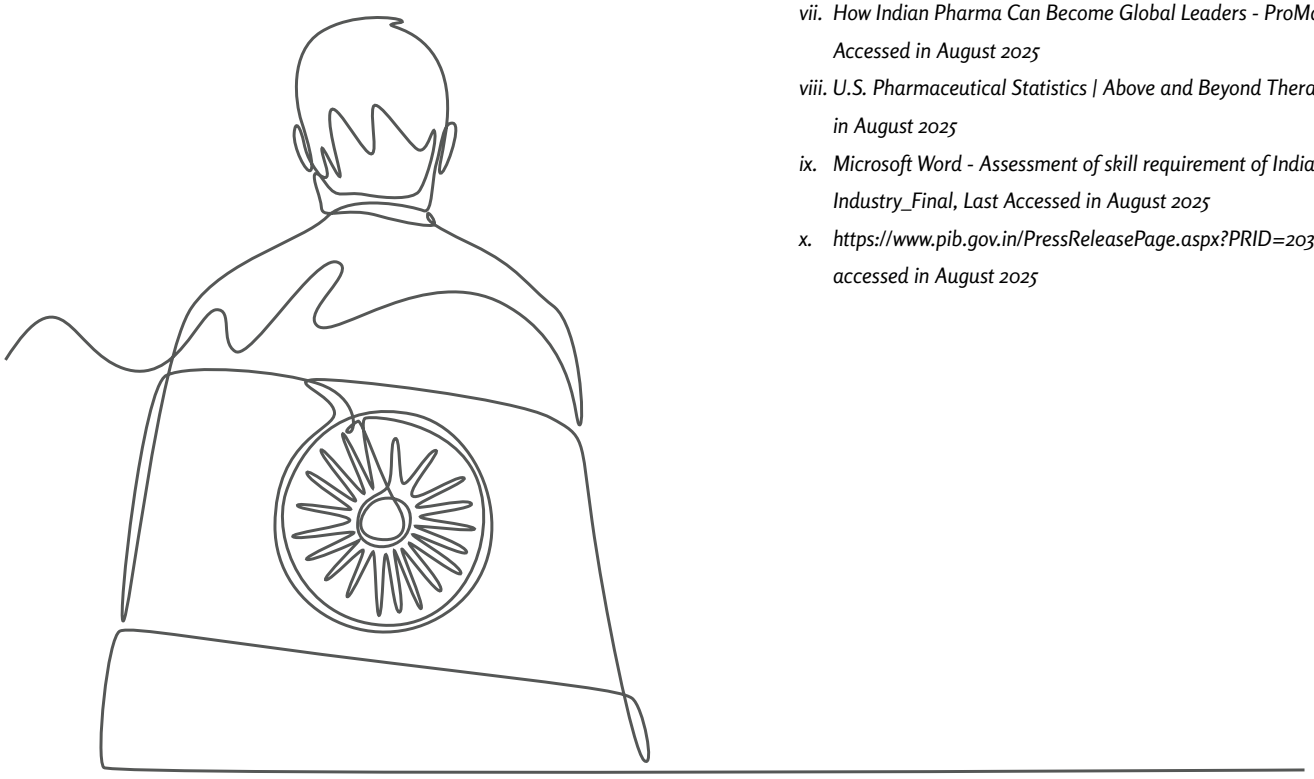
India has never lacked talent or tenacity. What we need now is **trust** – in our potential, in our people, and in the power of innovation to transform lives.

If we align on these priorities, the Indian pharmaceutical industry – currently a $50 billion market – can align on these priorities, we have the potential to reach $130 billion

by 2030 and $450 billion by 2047. This will require both global integration and local commitment – innovating in India, for India, and for the world.

Viksit Bharat will not be a dream on paper, but a lived reality for 1.4 billion Indians – where innovation not only creates economic value but enhances human dignity, well-being, and opportunity.

We have already begun our journey to 2047. The innovation imperative is not just an opportunity – it is our responsibility. Let us have the courage to imagine differently, collaborate deeply, and to act boldly.



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Navigating India's Evolving Healthcare Needs Through Innovation - Need for a Roadmap

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Harsh Bedi

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Abstract

India faces an unprecedented demographic shift over the next 25 years, with its elderly population projected to double by 2050. This transition coincides with a sharp escalation in the burden of non-communicable diseases (NCDs) and associated adverse impact on the economy. This essay will examine the pressing need to devise a roadmap that allows the Indian pharmaceutical sector to pivot to an innovation-led growth model. Only the latter will be fit to develop the next-generation technologies, moving from chemically synthesized products to biologically produced products, capable of addressing the complex therapeutic needs of

an aging population burdened with chronic NCDs. The success of India in its Amrit Kaal, and upon reaching Viksit Bharat @2047, will depend on whether the demographic and epidemiological transition are handled with a parallel transition from volume to value focused growth in the pharmaceutical sector. This will have implications extending well beyond healthcare, on the economic sustainability and social welfare the world's most populous nation.

I. Introduction – Contextualising India's Evolving Healthcare Needs

India celebrates its title of being 'Pharmacy of the World,' a commendable position reflecting the fact that 20% of the world's generics and ~60% of its vaccines are supplied by it. The domestic and foreign investments have built significant capacity and expertise which can help cement India's global position in the long-run, should the advantages be strategically harnessed to meet key future challenges and the forecasted evolution towards to biologically produced products. The Indian economy is on the ascendant; the country's demographic profile represents the most significant comparative advantage fuelling its impressive economic growth. With a median age of ~28, and more than 65% of its population under the age of 35 years, India presently has one of the youngest populations in the world. However, ageing will progress rapidly and unavoidably; analyses consistent with UN population data project that the median age by 2050 will be ~39.[1] This demographic shift over the next 25 years will have staggering economic implications.

Compounding the risks of the demographic transition is the currently unfolding epidemiological shift. We are witnessing an alarming escalation in the global burden of Non-Communicable Diseases (NCDs); in India, the figures are starker, as deaths attributable to NCDs have increased from 36% to 65% from 1990 to 2019.[2] It is important to keep in mind that NCDs typically start showing up at 35+ years of age. As the older cohort swells, the economic drag will also rise. This happens as NCDs cause productivity losses due to increase in absenteeism, early retirement, and care costs. Each 10% increase in NCD mortality correlates with a 0.5% decrease in annual economic growth, creating a vicious cycle that threatens long-term prosperity.[3]

Lancet Global Health studies reveal that cardiovascular diseases alone account for 45% of all NCD deaths, followed by chronic respiratory diseases (22%), cancers (12%), and diabetes (3%).[4] Conservative estimates project that India will lose $4.58 trillion before 2030 due to NCDs and mental health conditions, with cardiovascular diseases accounting for $2.17 trillion of this loss.[5] Seen thus, failure to aggressively control NCDs will have significant ramifications. The Union Ministry of Health and Family Welfare is sentient to this has been responding to increasing NCD risks with commendable efforts, yet these symptomatic interventions cannot address the fundamental challenge: the need to invest in innovative pharmaceutical interventions capable of preventing and treating complex disease patterns of an ageing population.

II. Enter biologics: our chance to move become to 'lab to the world'

The pharmaceutical industry is undergoing a paradigmatic transition from small molecule chemicals to biologics. This represents one of the most significant advancements in modern medicine, one which reflects an evolving understanding of disease mechanisms and the limitations of traditional chemical approaches in addressing complex diseases.[6] Biologics have revolutionised NCD treatment through multiple mechanisms, whether observed in the therapeutic advantages of monoclonal antibodies which can precisely target cancer cells, or the superior glycaemic

control offered by biological insulin and GLP-1 receptor antagonists in diabetes control.[7] Biosimilars extend these benefits through cost reductions, performing a role analogous to generics for innovative drugs.

Biologics would hold the key, amongst other items, on how we move from IP recipients to IP generators while meeting the complex needs of an older nation. Fall behind the innovation bandwagon, and we would again be focused on battling market access and affordability issues with foreign rights holders. Unless there are an impetus and clear roadmap for these established the goal to move from "pharmacy of the world" to the "lab to the world" remains unclear.

III. Effectively Leveraging India' Pharmaceutical Strengths

India's pharmaceutical sector is positioned quite favourably for the biologics and biosimilars transition. India has already established itself as a global biosimilar powerhouse - the market has grown from $6 billion in 2022 to a projected $12 billion by 2025 at an impressive 22% CAGR.[8] For starters, the cost advantage is substantial – in the EU or US it takes ~8 years and approximately $100-200 million to develop a biosimilar while it in India it takes 3-5 years and approximately $10-20 million, which is nearly 10 times lower.

India is well positioned to lead in biologics: strong players like Biocon have global proof points, and India already supplies over half the world's vaccines. Government pushes for API self-reliance and biotech innovation, combined with looming patent expiries on blockbuster biologics, create a major market opening. With biosimilars at ~$30B and growing ~17% CAGR to 2030, India can shift from generics to higher-value therapies—especially for cancer, autoimmune and cardiovascular diseases that will dominate the nation's health burden.

IV. Incentivizing Research and Development

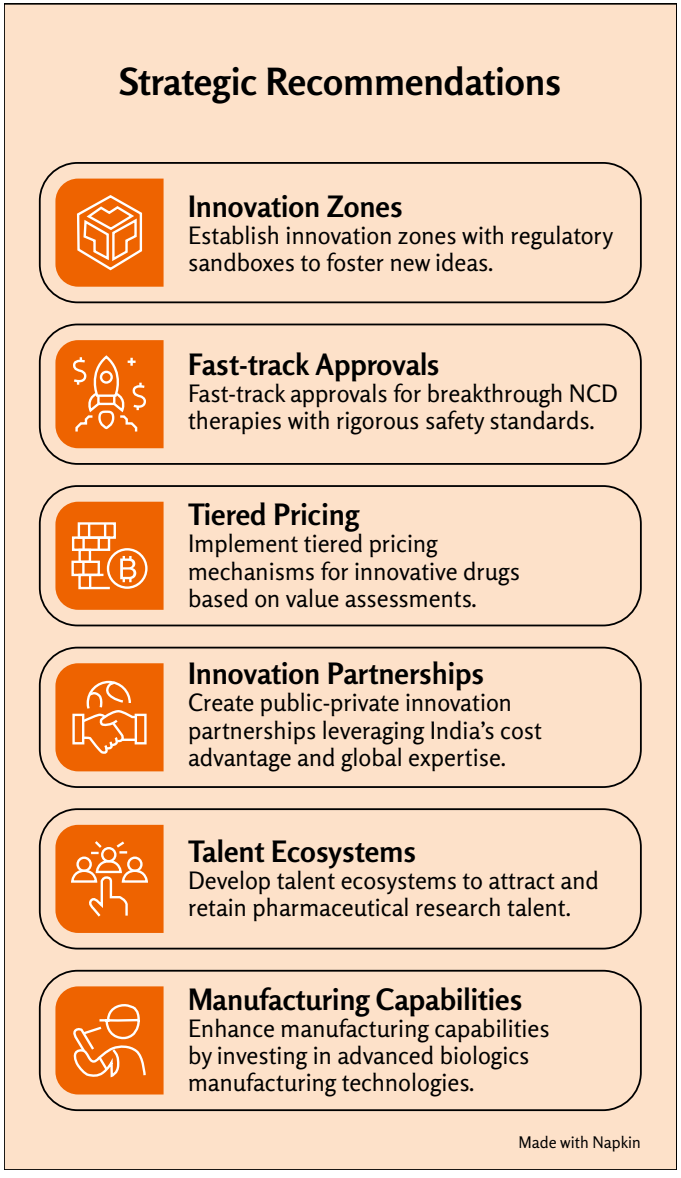
Despite recent measures, R&D investment in India sits at a paltry ~0.64% of GDP, significantly below global standards where average spending is slightly above 2% of GDP. This underscores the need for a better strategy to enhance private sector participation. The government's Anusandhan Research Foundation, with a budget of 50,000 crores across 4 years is a good step towards strengthening public-private collaboration, but more needs to be done. Transitioning from a volume-focused to an innovation-driven pharmaceutical sector requires comprehensive and along with policy restructuring and innovation.

Government of India has taken major steps to initiate the transformation viz. the Production Linked Incentive (PLI) Scheme for pharmaceuticals, the Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) scheme, etc. These measures must play to the strengths of the Indian pharmaceuticals sector while simultaneously developing high-value, complex segments like biologics and biosimilars. As a step in this direction, the Government may consider putting together an Essential Biologics Input List (EBIL) which would allow for expedited customs and fiscal perks for notified items. This can be offered until domestic capacity stands on its own legs, which can be followed by local-content bonuses, similar to offsets in the defence procurement playbook.

V. The Way Ahead: Strategic Recommendations

As we look to usher in the next phase of development for the Indian pharmaceuticals sector, the industry will require predictable frameworks that encourage genuine innovation while ensuring access during health crises. Price

control mechanisms must be reimagined to accommodate innovation incentives, such as value-based pricing models which consider therapeutic innovation, clinical outcomes, and holistic economic benefit. Other recommendations are provided in the figure below:



VI. Conclusion

The writing is on the wall as India stands at a critical inflection point, one demanding a fundamental transformation wherein the pharmaceutical sector must pivot to innovation and value-driven growth. Aggressive control of NCDs is the need of the hour, and lack of policy foresight on this front can cloud the vision for Viksit Bharat @2047. The economic stakes are enormous; failure to address the NCD crisis could cost India ~$5 trillion before 2030, while success in developing innovative therapeutic solutions could position the country as a $130 billion pharmaceutical market by 2030. Should we set in motion measures that can enable us to seize the opportunity, the innovation dividend in pharmaceuticals offers a pathway to sustainable prosperity. The health of 1.4 billion Indians - and India's economic future - depends on getting this balance right.

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India's Dual Leadership in Global Healthcare

Anand Prasad

Assistant Vice President, Invest India

Introduction

India occupies an unparalleled position in the global healthcare ecosystem by seamlessly integrating large-scale, cost-effective pharmaceutical manufacturing with rapidly advancing research and development capabilities. Often referred to as the world's "pharmacy," India produces one in every five generic medicines consumed globally and dominates the vaccine segment, delivering close to 60% of the global demand. Yet this impressive manufacturing prowess tells only half the story. Over the past decade, India has transformed its life sciences landscape into a dynamic innovation hub, demonstrating that affordability and breakthrough research can reinforce—rather than undermine—each other. With the domestic pharmaceutical industry valued at roughly $55 billion and forecast to exceed $120 billion by 2030, India is charting a path where accessible healthcare and cutting-edge innovation drive sustainable growth.

This dual leadership arises from a constellation of factors: a vast network of manufacturing facilities that adhere to rigorous global quality standards; government policies that incentivize both production and research; a surge in

biotechnology startups tackling complex medical challenges; and an influx of strategic investments from global private equity, venture capital, and public funding. Taken together, these forces have positioned India not merely as an affordable medicine supplier but as a comprehensive partner in global health, capable of delivering quality medicines, pioneering novel therapies, and responding nimbly to emerging health crises.

Manufacturing Excellence and Global Accessibility

At the core of India's global healthcare role lies its expansive and highly diversified manufacturing ecosystem. Home to over 3,000 pharmaceutical companies, India operates more than 10,500 manufacturing facilities, including more than 750 plants approved by the U.S. Food and Drug Administration—the highest number for any single country. This scale allows India to meet domestic requirements for essential medicines while simultaneously fulfilling significant portions of the global generic drug and vaccine supply chain.

During the COVID-19 pandemic, India's manufacturing infrastructure proved critical: local producers rapidly ramped up production of both indigenous vaccines such as Covaxin and licensed formulations like Covishield. Within months, Indian firms supplied hundreds of millions of vaccine doses to low- and middle-income countries, exemplifying the country's capacity to address urgent global health emergencies at affordable costs.

India's biotechnology sector has undergone similarly dramatic expansion. Between 2014 and 2024, its value surged from around $10 billion to nearly $166 billion, driven by increasing domestic demand, export growth, and strategic government support. Ambitious targets aim to elevate this figure to $300 billion by 2030. These targets recognize that manufacturing scale must be complemented by robust quality assurance, supply chain resilience, and continual capacity enhancement to sustain both domestic public health objectives and international commitments.

Crucially, affordability in India is achieved not by lowering quality standards but through innovative process engineering, optimized supply chains, and economies of scale. Drug manufacturing costs are kept low by integrating end-to-end operations—from active pharmaceutical ingredient (API) synthesis to formulation and packaging—within the same industrial clusters. Shared infrastructure in emerging drug parks reduces capital expenditure for individual firms and fosters collaborative networks that enhance efficiency. This cost competitiveness underpins India's reputation as a global provider of reliable, high-quality generics and vaccines.

Transformation of the Innovation Ecosystem

While manufacturing remains a foundational pillar, India's life sciences sector has shifted toward a vibrant research-driven model. Nearly 9000 biotechnology startups now operate across a network of 95 bio-incubation centres, collectively addressing complex health challenges such as precision oncology, rare diseases, and advanced drug delivery systems. This entrepreneurial pulse is fuelled by targeted government initiatives—from the Department of Biotechnology's BioNEST program, which provides incubation space and mentorship, to BIRAC's Biotechnology Ignition Grant (BIG) and SEED fund, which support proof-of-concept and early-stage development.

The growing prominence of contract research, development, and manufacturing organizations (CRDMOs) further illustrates India's evolution. Leveraging a skilled scientific

workforce and cost advantages, Indian CRDMOs entered into at least 32 strategic alliances for new molecular entities (NMEs) between 2019 and early 2024. These collaborations integrate India's manufacturing strides with global pharmaceutical innovation pipelines, accelerating timelines for drug discovery and development while maintaining stringent regulatory compliance.

Vaccine innovation remains a standout strength. Beyond COVID-19, Indian manufacturers have historically delivered large-scale immunization solutions such as the recombinant hepatitis B vaccine (Shanvac-B), priced at under $1 per dose compared to over $20 in high-income markets. Similarly, Biocon's recombinant Human Insulin disrupted global pricing dynamics while maintaining quality standards, supplying over 2 billion doses to nearly 40 countries since 2004. This track record underscores India's ability to harness indigenous research for global health impact.

Emerging disciplines like cell and gene therapy are gaining traction at breakneck speed. Collaborative projects—such as the Letter of Intent signed between BIRAC and Germany's Miltenyi Biotec, at the Bio International Convention 2025 in Boston, to advance India's capabilities in Cell and Gene Therapy through capacity building, advancing clinical research and solving unmet medical needs by local manufacturing of cell therapies—demonstrate India's foray into advanced therapeutic modalities. Meanwhile, precision medicine ventures are leveraging genomic insights to tailor treatments for complex conditions, signalling India's readiness to tackle the frontiers of personalized healthcare.

India also continues to attract a growing share of clinical trials, currently ranked third globally with around 71000 registered trials, buoyed by its large, diverse patient population, established clinical infrastructure, cost-efficient research protocols and growing international confidence. This positioning not only provides international sponsors with accelerated enrolment and diverse data sets but also affords Indian institutions greater exposure to novel therapies, bolstering local R&D capabilities.

Strategic Investments and Financial Ecosystem

The narrative of India's healthcare ascendancy is incomplete without examining the **financial ecosystem** that fuels both manufacturing and innovation. Between 2020 and 2024, India's life sciences startups secured over $1.9 billion in funding from venture capital, private equity, and strategic corporate investors. This influx reflects growing confidence in the sector's potential to generate high-value products while sustaining cost advantages.

Significant **mergers and acquisitions** have reshaped the industry. Advent International's creation of Cohance Lifesciences by consolidating RA Chem Pharma, ZCL Chemicals, and Avra Laboratories—and its subsequent majority acquisition of Suven Pharma for about $1.15 billion—demonstrate how strategic consolidation unlocks value through integrated supply chains and operational synergies. Torrent Pharma's acquisition of J.B. Chemicals for over $2.2 billion in mid-2025 further highlights investor belief in scaling domestic players to compete on a global stage.

Foreign direct investment (FDI) inflows corroborate this trend: in fiscal year 2024–25, FDI into pharmaceuticals and medical devices totalled ₹19,134 crores, including ₹11,888 crores in greenfield projects approved automatically and ₹7,246 crores for brownfield expansions. Policy frameworks facilitating 100% automatic FDI for greenfield manufacturing and up to 74% for existing facilities have streamlined capital infusion while retaining oversight on strategic acquisitions.

The rise of the **contract development and manufacturing organization (CDMO)** model has attracted particular investor interest as it enables participation in higher-margin services—such as complex biologics and specialized APIs—while leveraging India's scale and cost structure. The CDMO sector's growth trajectory is expected to outpace general manufacturing, further diversifying the country's export profile.

Enabling Policy and Regulatory Ecosystem

India's success in marrying accessibility with innovation is spruced up by comprehensive policy frameworks that align incentives across manufacturing, research, and investment. The **Production Linked Incentive (PLI)** scheme for pharmaceuticals (₹15,000 crores) and bulk drugs (₹6,940 crores) has already catalysed over ₹33,500 crores in commitments—nearly double initial projections—by supporting capacity expansion, technology adoption, and value addition.

To bolster research intensity, a new ₹1 lakh crore **RDI scheme** complements the **PRIP program's** ₹5,000 crore allocation for academia-industry collaboration in priority areas. These initiatives aim to address India's R&D expenditure gap, currently at around 0.64% of GDP compared to higher rates in leading economies. By de-risking early-stage research and promoting translational science, policymakers seek to elevate India into the top tier of global innovation.

Regulatory reforms by the Central Drugs Standard Control Organisation (CDSCO) have streamlined processes through digital licensing portals, simplified inspection protocols, and expedited export clearances. These measures reduce time-to-market for new products without compromising safety or efficacy, thereby enhancing India's competitiveness, making it attractive for both domestic and international stakeholders.

Intellectual property frameworks balance innovation incentives with public health objectives. TRIPS-compliant flexibilities—such as pre-grant oppositions, compulsory licensing options, and a rigorous patent examination regime—safeguard generics producers' ability to supply affordable medicines while encouraging domestic R&D through robust patent protection for truly novel inventions.

Conclusion

India's pharmaceutical and biotechnology sectors defy the traditional dichotomy between cheap manufacturing and high-end innovation. Through a synergistic blend of enabling policy frameworks, strategic investment flows, vibrant startup energy and manufacturing excellence, India has crafted a sustainable model that simultaneously advances global public health and fosters cutting-edge research. As looming patent expiries offer opportunities for biosimilars and novel generics, and as new health challenges demand rapid innovation, India's dual leadership will be tested. Maintaining this balance will require continual policy refinement, sustained investment in R&D infrastructure, and a commitment to global collaborative networks. In doing so, India will not only uphold its role as the world's "pharmacy" but will also cement its place as an innovation leader delivering affordable, life-saving solutions to patients worldwide.

Global Innovation Sweepstakes: India's Quest to Win

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China's rise in just over a decade on the global stage for biopharma innovation, with an increasing dominance in areas like antibody-drug conjugates (ADCs), is striking.

While a copy-paste of the China template, that is buttressed by a top-down ecosystem isn't always replicable or feasible, countries like India can draw from the playbook as they shape their own innovation trajectory, investing in next generation therapies and new modalities.

Besides a vibrant ecosystem, certain broad related themes from the approach used by China and other Asian nations around market creation and reinforcing the talent funnel remain relevant in the Indian context, though it will probably require some desi tadka for these to deliver sustained long-term gains.

A robust domestic market and an effective reimbursement mechanism especially for home-grown cutting-edge innovation will not just catalyse frontline Indian firms to bet big but also attract investors to the discovery model. China has, over the years, decisively backed local innovation by reimbursing selected higher cost, patent-protected products via the basic medical insurance system and by implementing supportive regulations and policies.

"There has to be some reimbursement system for India-developed innovative products, which can be compared to 'world benchmarks' and be at a premium to generic or branded generic drugs in the country," the head of one Indian firm earlier suggested at an industry event.

Current private and government health insurance schemes and pricing benefits in India don't go far enough, per industry, though Health Technology Assessment in India (HTAIn) is seen bolstering reimbursement efforts.

A report by Bain & Company in collaboration with the Indian Pharmaceutical Alliance, Pharmexcil, and the Indian Drugs Manufacturers Association, similarly quoted the CEO of an Indian company as saying that the government needs to establish a fund to partially finance patients treated with innovative drugs, driving affordability, and "limiting downside" for companies. "This will dramatically spur innovation and encourage firms to take more risks," the CEO said.

Government initiatives like the National Biopharma Mission, the Scheme for Promotion of Research and Innovation in Pharma MedTech Sector (PRIP), support from BIRAC and funding efforts for rare disease drugs suggest that things are headed in the right direction, though a wider enabling environment could add momentum.

Innovation Niches

Innovation is a high-stakes game, fraught with risks, high failure rates and fierce competition. Experts have underlined the value of identifying high-priority areas where "you can win" drawing parallels with South Korea's rise in biotechnology or China's vault to the forefront of ADC innovation.

Impressively, the 2025 American Association for Cancer Research meeting saw data presented from almost 100 investigational ADCs under development by Chinese biotechs.

Citeline's Pharma R&D Annual Review 2024 also highlighted how R&D is experiencing an "easterly airflow", with the US losing its majority as the favoured place for pharma R&D. While 49.1% of all drugs in development have some US R&D activity, the review showed that 26.7% of industry's pipeline was being developed in China, with South Korea edging out the UK to move up to third place, accounting for 14.2% of pharma's R&D pipeline. The trend holds in our 2025 review and India should aspire to be part of this altered airflow.

Initiatives like PRIP set the broader framework for the biopharma and medtech industry to transform from cost-based to value-and innovation-based growth, but staying the course will be critical.

PRIP, which covers a range of proposals, specifies six "moon-shot" areas including NCEs/NBEs, complex generics, biosimilars, precision medicine, orphan drugs and antimicrobial resistance wherein financial assistance will be provided to industry, MSMEs and startups working with government institutes and for both in- house and academic research. A dash of space-based research in some of the areas could also perhaps alter the orbit of India pharma's R&D push.

PRIP also expects to strengthen research infrastructure by establishing Centres of Excellence at India's National Institutes of Pharmaceutical Education & Research. "PRIP is a good starting point, and the government has also announced the Anusandhan National Research Foundation - these should build momentum for pharma going forward," an industry head told *Citeline*.

Recent strides in the cell and gene therapy space, where a young Indian firm, ImmunoACT, could deliver a CAR-T cell therapy at a fraction of the cost of globally available products, augurs well (there are now several others in the CAR-T fray), while Glenmark arm IGI's large deal for its trispecific antibody with AbbVie marks a huge milestone for Indian discovery R&D. IGI, though, runs R&D activities in India, the US and Switzerland.

Talent War

Nurturing India's talent ecosystem and attracting top tech personnel back home will be pivotal as big data and computational techniques transform drug R&D and uncover new biological insights and help develop reproducible disease models and scalable therapies. The number of AI-discovered molecules, for instance, has surged by 40% per annum between 2018 and 2021.

China's "Thousand Talents" program and efforts by Singapore's National Science and Technology Board (since renamed A*STAR) to recruit experienced foreign researchers and then provide part of the funding needed for relocation and for salaries for post-doctorates/master's fellowships are long-cited references to draw from. Tax breaks and other tailored incentives may be enticing amid the current geopolitical turmoil.

While numerous efforts, including by the government and industry-academia linkages, to close the talent gap or hone skills are being considered or underway, recent deals by Microsoft and Google that bring with them star AI experts and Meta's astronomical pay packages to lure AI top guns from OpenAI, Apple and Anthropic suggest that the talent war is shifting gears.

India should also build on the emerging talent base at big pharma's local global capability centres (GCCs), which are evolving beyond being cost efficiency outposts to driving innovation across operations.

McKinsey & Company senior partner, Sathya Prathipati, earlier told Citeline that it's critical to "manage and retain the talent that these GCCs are grooming to help build the muscle in local firms".

There's clearly a lot at stake as India seeks to emerge as a global innovation hub -- it will require bold steps, with all hands on deck.

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The Role of R&D and Patents in Nation Building: The Indian Context

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Introduction

Research and Development (R&D) and a robust intellectual property regime are among the strongest economic transformation and nation-building engines. Countries that have risen from developing to developed status—such as South Korea, Israel, Germany, the United States, and, more recently, China—share a consistent strategy. They invested heavily in R&D, built strong institutions to transfer technology into markets, and developed patent systems that protected innovators and diffused knowledge across industries. For India, which aspires to achieve developed nation status by 2047, strengthening its R&D and intellectual property ecosystem is fundamental. Not only can it unlock productivity growth and create high-value jobs, but it can also enhance strategic autonomy in critical technologies ranging from defence and health to clean energy and artificial intelligence.

R&D as a Driver of Nation Building

R&D, especially for converting scientific discoveries into commercial value, social progress, and global competitiveness, plays a transformative role in upgrading

economies from resource-dependent to innovation-driven. R&D is creating the foundation for higher productivity across agriculture, industry, and services while diversifying into new knowledge-intensive sectors. Moreover, enhanced R&D efforts can help us achieve strategic autonomy by enabling domestic capabilities in sensitive areas such as vaccines, semiconductors, AI, Quantum, and defence equipment and finally, improving the quality of employment by creating demand for scientists, engineers, and designers, thereby supporting a highly skilled workforce.

India has demonstrated the power of mission-driven R&D in specific cases. The Mars Orbiter Mission, Chandrayaan-3's successful lunar landing, and the development of indigenous COVID-19 vaccines highlight what can be achieved when research is supported with clear policy direction and institutional alignment. Similarly, India's digital public goods, such as Aadhaar and the Unified Payments Interface (UPI), are global case studies of innovation at scale. However, India's gross expenditure on R&D (GERD) remains at around 0.7 per cent of GDP, well below the global leaders. In contrast, South Korea spends nearly 4.8 per cent, Israel spends 5.4 per cent, and the United States spends about 3.4 per cent of GDP on R&D. This gap is one of the clearest indicators of the challenge India must overcome if it is to sustain growth and build a globally competitive innovation ecosystem.

R&D driving Intellectual Property creation

Legal protection that secures returns on risky investments is essential for innovators, industries, and startups who are putting huge efforts into research. For startups and industry, the intellectual property also signals credibility to investors and opens doors to global markets through licensing, technology transfer, and participation in standard-setting. For the broader economy, patents serve as a public record of knowledge that enables cumulative innovation. Therefore, a country's patent strength is a key indicator of its innovation ecosystem.

India has made progress in this area. Ministry of Commerce and Industries data shows IP filings have increased from 4,77,533 in 2020–21 to 6,89,991 in 2024–25, a 44% surge. Geographical Indications (GI) had a 380% increase, followed by Designs (266%), Patents (180%), Copyright (83%), Trademarks (28%), and Semiconductor Integrated Circuits Layout-Designs (SICLD) with a 20% rise. For the first time in more than a decade, domestic patent filings by Indian residents surpassed those by foreign applicants, indicating a maturing ecosystem. Yet the overall share of India in global patent filings remains modest at about two per cent. WIPO's Global Innovation Index (GII) 2024 ranked India 39th among 133 countries, making it the leading middle-income innovator in South Asia, but well behind advanced innovation economies. India's strengths in ICT services exports and venture capital inflows must now be complemented with more vigorous patent intensity and commercialisation capacity.

Lessons from Global Leaders

The experience of other countries provides valuable lessons for India. South Korea transformed itself in less than four decades by steadily raising its R&D spending, embedding research in corporate conglomerates, and building strong patent portfolios in semiconductors, consumer electronics, and automotive technologies. Israel offers another model, where defence-driven R&D and university tech transfer offices created one of the world's densest deep-tech startup ecosystems. The United States highlights the power of institutions such as DARPA,

NIH, and the Bayh–Dole Act, which enabled universities to patent federally funded inventions and translate them into companies and licensing revenue. Germany demonstrates how applied research institutes such as the Fraunhofer Society directly feed patented solutions into industry. At the same time, China's strategy of large-scale R&D investment and aggressive patent filing has already made it the world's largest source of patents.

A comparative look underscores the scale of India's challenge. Apart from the earlier-mentioned comparison of the cent of GDP spent on R&D, the patent filings tell a similar story: China filed more than 1.6 million patents in 2023, the United States 594,340, South Korea 237,633, Israel around 10,073, and India 77,000. On the Global Innovation Index, India ranked 39th, compared to sixth for South Korea, 15th for Israel, 11th for China, and third for the United States. These numbers show both the gap and the opportunity: India's trajectory is positive, but scaling is essential.

These examples show that nations that prioritised R&D and intellectual property not only grew richer but also secured global influence in critical technologies.

India's Emerging Steps toward an R&D-Driven Economy

India is beginning to implement structural reforms that mirror these global best practices. A centrepiece is the Anusandhan National Research Foundation (ANRF), launched in 2023, designed to increase private sector participation in R&D funding, strengthen university-industry collaborations, and provide predictable long-term financing for large-scale research missions. If implemented effectively, the ANRF could raise India's GERD closer to global benchmarks and rebalance the heavy reliance on government spending.

Alongside ANRF, several industry-oriented programs are steering R&D investment. Production-Linked Incentive (PLI) schemes encourage electronics, EV batteries, and semiconductor firms to localise design and innovation, thereby building indigenous patent portfolios. The Biotechnology Industry Research Assistance Council (BIRAC) supports biotech startups & industry with grants, R&D facility creation, incubation, and IP assistance. During the COVID-19 crisis, BIRAC-backed ventures were critical in vaccine and diagnostic development. The iDEX and Technology Development Fund under DRDO promotes indigenous defence technologies through partnerships with startups and MSMEs. Digital India and AI Missions are seeding applied research in AI, 5G, and IoT, with strong potential for patent generation.

India has also reformed its patent ecosystem in recent years. Expedited examinations for startups and MSMEs, reduced filing fees, and the creation of specialised IP benches in courts have improved the process. Patent filings have increased significantly, and there is growing awareness among universities and entrepreneurs about the strategic value of intellectual property. IITs and leading universities have set up Technology Transfer Offices to professionalise research licensing. For example, IIT Delhi's Foundation for Innovation and Technology Transfer has facilitated close to 2000 IP filings and numerous technology licenses and supported startups across defence, life sciences, cleantech, and mobility.

At the same time, India's startup ecosystem has grown into the world's third-largest, with nearly two hundred thousand registered startups. Increasingly, these ventures are moving into deep-tech areas such as semiconductors, quantum technologies, and clean energy, where R&D and patents are central to competitiveness.

Gaps and Challenges

Despite this progress, India must address several challenges. Business expenditure on R&D is only about 37 per cent of GERD, compared with over 70 per cent in developed economies. Patent enforcement remains slow, reducing investor confidence. Universities need stronger institutional mechanisms for commercialisation and clear revenue-sharing frameworks to incentivise researchers. Financing for deep-tech ventures is limited, particularly in capital-intensive domains such as medical devices, advanced manufacturing, and energy storage. Finally, India's presence in global standards-setting bodies remains limited, reducing its influence in shaping future technologies.

A Policy Roadmap for India

To bridge these gaps, India should raise its GERD to at least two per cent of GDP by 2030, with half of the funding coming from private industry. Long-term support to the thematic missions like India AI mission, Semiconductors Mission, National Quantum Mission, Hydrogen mission, etc, will play a crucial role. Applied research networks similar to Germany's Fraunhofer Institutes should be established in partnership with industry consortia. Bayh–Dole style mechanisms should be strengthened to ensure publicly funded inventions are patented and commercialised. Public procurement should be a powerful tool to provide early markets for indigenous innovations, particularly in defence, healthcare, and renewable energy. International patent filings by Indian startups should be supported with subsidies, and IP strategy should be deeply integrated into higher education curricula to prepare future innovators. Strengthening standards development organisations should be prioritised, particularly in emerging sectors such as 6G, EV charging, and medical devices.

Conclusion

India's ambition to become a developed economy by 2047 depends on strengthening its R&D and patent ecosystem. Global experience makes it clear that sustained investment in research, coupled with a strong intellectual property regime, is the foundation for national prosperity and technological leadership. India has begun to move in this direction with multiple government initiatives; however, the challenge now lies in accelerating these efforts, mobilising private sector investment, enforcing IP rigorously, and ensuring that public research translates into market-ready products. Done well, this strategy will drive GDP growth and create high-quality employment, secure India's technological sovereignty, and position Indian firms as global leaders. R&D and patents are not abstract measures but the architecture of a modern economy, and they will be central to India's journey of nation-building in the coming decades.

Viksit Bharat and the Innovation Imperative in MedTech

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Introduction

As India approaches the centenary of its independence in 2047, the vision of Viksit Bharat a fully developed and globally competitive nation stands as both a guiding framework and a national aspiration. This vision extends beyond economic prosperity or a higher gross domestic product (GDP). It embraces equitable healthcare access,

social well-being, and global leadership in science and technology. At the heart of this transformation lies innovation, a force that will determine whether India can realize its promise of becoming a developed nation.

Sectors like pharmaceuticals, medical technology (MedTech), and in vitro diagnostics (IVDs) are poised to drive this innovation. Together, they represent India's strengths and potential to evolve into a global hub of healthcare solutions. The COVID-19 pandemic, although a crisis, served as a wake-up call. It revealed the vulnerabilities of global supply chains and underscored the urgency of building resilient domestic innovation ecosystems, particularly in the health sector. It is in this context that innovation becomes inseparable from the *Viksit Bharat* agenda.

The Innovation Imperative in Viksit Bharat

For a nation of 1.4 billion people, innovation is not optional; it is essential. India continues to shoulder the double burden of disease. Infectious diseases, such as tuberculosis, sepsis, urinary tract infections, malaria, dengue, and typhoid, on one hand, and lifestyle-related conditions, such as diabetes, cardiovascular ailments, obesity, and cancer, on the other. This challenge is further compounded by the rapid rise of antimicrobial resistance (AMR), which threatens to roll back decades of progress in modern medicine and push society toward a dangerous pre-antibiotic era.

Recognizing these challenges, the Government of India has launched a series of initiatives to foster innovation. Flagship programs such as Startup India, Atal Innovation Mission, the National Research Foundation, and the Production Linked Incentive (PLI) schemes have built momentum. More recently, the Promotion of Research and Innovation in Pharma-MedTech (PRIP) scheme has been designed specifically to nurture research-led growth. Yet, the central challenge remains: how to ensure that science travels the journey from lab to land and from research to revenue. Only then can India's innovations generate both economic value and societal impact.

Pharmaceuticals: From the "Pharmacy of the World" to a Global Innovation Hub

The Indian pharmaceutical industry has established itself as the "Pharmacy of the World." India supplies nearly 20% of the global generics market and more than 60% of the world's vaccines, ensuring affordable access to lifesaving medicines in both developed and developing countries. While this legacy is impressive, the next phase of growth necessitates a transition from a volume-driven industry to an innovation-led ecosystem centered on drug discovery, biotechnology, and precision medicine.

Currently, India's pharmaceutical R&D spending accounts for less than 1% of its GDP, which is significantly lower than that of global innovation leaders, such as the United States and China. To bridge this gap, India must invest heavily in translational research clusters, biopharma parks, and public–private partnerships that can reduce the "valley of death" between academic discoveries and market-ready therapies.

Emerging technologies, including artificial intelligence (AI), machine learning (ML), and big data, are already reshaping drug discovery, biomarker identification, and clinical trials. Indian start-ups are carving a niche in AI-driven healthcare, competing globally in algorithmic drug development. On the regulatory front, the proposed New Drugs, Medical Devices, and Cosmetics Bill (2023), coupled with digital approval systems, is fostering transparency and efficiency. Schemes

such as PLI and PRIP are also reducing reliance on imported active pharmaceutical ingredients (APIs), thereby improving supply chain resilience.

By 2047, India's pharmaceutical industry is projected to grow to USD 400–450 billion, with expanded roles in advanced therapies, biologics, and next-generation vaccines. At that milestone, India will not only be the trusted supplier of affordable generics but also a recognized global powerhouse of original drug discovery and healthcare innovation.

MedTech: The Catalyst of Healthcare Transformation

Parallel to pharmaceuticals, MedTech is rapidly becoming a catalyst for healthcare transformation in India. Valued at USD 12–14 billion in 2023, the MedTech market is projected to reach USD 50 billion by 2030, representing an impressive compound annual growth rate of nearly 20%.

This surge is fuelled by digital technologies such as AI, ML, the Internet of Things (IoT), and cloud computing, which are revolutionizing remote monitoring, minimally invasive surgery, and personalized care. Nearly 70 percent of MedTech innovations in India today are rooted in these advanced technologies. Policy measures ranging from 100 percent foreign direct investment to reduced import duties and the "Make in India" initiative have significantly boosted domestic manufacturing. Already, India's MedTech exports exceed USD 4 billion annually, with ambitions to capture 10–12 percent of the global market by 2047.

Importantly, start-ups are leading the way in developing patient-centric solutions, including wearable devices, home-based diagnostic kits, and portable imaging tools. These innovations are not merely about convenience; they are essential for extending quality healthcare to rural and underserved regions, where access remains limited.

In Vitro Diagnostics: The Cornerstone of Preventive Healthcare

If pharmaceuticals and MedTech are the twin pillars of healthcare innovation, IVDs form the foundation. Diagnostics are the entry point to healthcare. They guide treatment decisions, support disease surveillance, enable national health programs, and play a critical role in pandemic control. The COVID-19 crisis provided a vivid demonstration of the power of diagnostic innovation, as indigenous test kits and rapid assays became frontline tools in India's containment strategy.

Currently valued at USD 5.3 billion (2024), India's IVD market is expected to double to USD 10 billion by 2033. Yet, ~70% of the diagnostic kits, reagents, and instruments are imported, exposing vulnerabilities in affordability and supply chains. To address this, national institutes and innovation hubs must work closely with start-ups and industry to strengthen domestic manufacturing capacity.

The future of diagnostics lies in digital and decentralized solutions: point-of-care devices, biosensor- and aptamer-based assays, portable microfluidic platforms, and AI-enabled analytics. Such innovations can dramatically improve access to reliable testing in both tertiary hospitals and rural health centers, ensuring timely and accurate care across the spectrum of infectious and non-communicable diseases.

Policy and Regulatory Catalysts

India has made significant progress in creating an enabling policy ecosystem for healthcare innovation. The Medical Device Rules (2017) introduced risk-based classification for safety and quality. The PLI Scheme for Medical Devices (2020) provided incentives for domestic production and R&D. The adoption of Health Technology Assessment (HTA) mechanisms ensures that cost-effectiveness becomes a core consideration, safeguarding affordability and sustainability.

The government's investments in MedTech parks, incubation centers, and National Institutes of Pharmaceutical Education and Research (NIPERs) reflect a strong commitment to nurturing talent, research, and entrepreneurship. The next leap must involve scaling up innovation hubs within pharmaceutical and biomedical institutes to fast-track the translation of discoveries into market-ready solutions.

Challenges on the Path to 2047

Despite the momentum, challenges remain formidable. India's gross expenditure on R&D is still less than 1.0 percent of GDP, well below the global average. Weak technology transfer systems and limited academia–industry linkages hinder commercialization. Public procurement policies often prioritize the lowest cost over innovation, discouraging risk-taking by entrepreneurs. Moreover, shortages of skilled professionals in regulatory science, biomedical engineering, and quality systems constrain sectoral growth. Addressing these gaps is critical for India to fully realize its potential in healthcare innovations.

Roadmap to Viksit Bharat 2047

The journey to Viksit Bharat will hinge on sustained innovation-led growth in healthcare. Key priorities include:

- **Increased investment in R&D**, particularly in high-priority areas such as AMR, rare diseases, and maternal health.
- **Stronger industry–academia partnerships,** enabling smooth translation from lab to market.
- **Simplified regulatory and licensing processes**, reducing barriers to commercialization.
- **Expansion of domestic diagnostics manufacturing,** reducing import dependence.
- **Integration of digital health technologies**, leveraging AI, IoT, and mobile platforms for predictive and connected care.
- **Global collaborations**, including WHO prequalification and cross-border partnerships, to expand India's global footprint.

India possesses unique advantages including a young tech-savvy workforce, a vast consumer base, and a high disease burden, making it an ideal testbed for scalable innovations. National initiatives such as the *National Digital Health Mission and IndiGen* are building powerful datasets to drive personalized, AI-enabled medicine. Achieving the goals of *Viksit Bharat 2047* requires sustained health innovation across pharmaceuticals, MedTech, and *in vitro* diagnostics. These sectors form the backbone of resilient healthcare systems

by enabling timely detection, precision treatment, and proactive disease management. Ultimately, true development is not measured by GDP alone, but by health, dignity, and well-being. Innovation in MedTech and diagnostics is both a technical and moral imperative. By 2047, India must not only safeguard lives and empower communities but also establish itself as a global leader in healthcare innovation, transitioning from the "Pharmacy of the World" into the "*Innovation Hub of the World*".

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India's Regulatory Policy Landscape for Innovative Pharmaceutical Products: Opportunities, Gaps

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India's pharmaceutical industry is at a turning point as the global healthcare landscape pivots toward innovation-driven therapies like cell and gene therapies, drug-medical device combination products and personalized medicine.

India's CDSCO has optimized its regulatory framework by streamlining drug approvals with defined timelines (e.g., New Drugs and Clinical Trials Rules, 2019), introducing risk-based oversight, and digitizing processes via the SUGAM Portal. India introduced changes for expediting the approval process for innovative drugs, particularly those addressing unmet medical needs. Furthermore, CDSCO has also announced its first-ever Subject Expert Committees (SECs) Guidance Document in July 2025, which provides formal structure and clarity to the evaluation process for new drugs, biologicals, and investigational medical devices.

While India's regulatory landscape has evolved with the New Drugs and Clinical Trials (NDCT) Rules, 2019, significant challenges persist, particularly in local clinical data requirements, accelerated regulatory pathways, intellectual property (IP) and regulatory data protection/exclusivity (RDP). Addressing these issues in a cohesive manner is crucial to foster innovation and position India as the key market expediting access to life-saving therapies.

The Role of IP and RDP in Fostering Innovation

Current Challenges

Currently, Section 3(d) of the Indian Patent Act discourages patents for incremental advancements like improved formulations or delivery mechanisms—areas critical for innovation in biologics and complex generics. Delays and unpredictability in patent disputes further deter global companies from investing in cutting-edge research in India due to this IP challenge.

Moreover, India does not formally provide RDP against the unfair commercial use of undisclosed data. This discourages the development and introduction of innovative medicines in India and in the long-term will also lead to less generic medicines in the market, since there will be no new innovative therapies. These effects can exacerbate the already big drug lag in India, where the population has less timely access to innovative drugs than other developed countries (https://pmc.ncbi.nlm.nih.gov/articles/PMC8323564/)

Reform Opportunities

- Enhanced IP protections: Expedite the patent approval process and amend Section 3(d) to make it TRIPS compliant and remove or amend Section 3(i) to clearly allow for medical use claims.

- RDP: Established formal protection of regulatory data and to comply with the Article 39(3) of the TRIPS Agreement, aligning with international best practices.

Local Clinical Data Requirements:

Current Challenges

India's NDCT Rules require local phase 3 clinical trials for most new drugs, even when robust global clinical data exist. Although waivers are permitted under Rules 75(7) and 101—such as in cases of rare diseases or when no existing therapies are available for products approved and marketed by the reference countries—these provisions are inconsistently applied. Even products with global

data meeting International Council for Harmonisation (ICH) guidelines often face additional local phase 3 or 4 trial requirements, adding unnecessary delays. In some instances, even with global Phase 3 trials including a significant Indian patient base, Indian HA still requires post-approval commitment studies. For new indications of a product already marketed in India (same dose, route of administration), local clinical studies are commonly required, despite relevant safety data derived from the existing approved indication.

In addition, delays in clinical trial approvals may further lengthen the pharmaceutical product approval process and may increase additional costs, undermining affordability goals.

Reform Opportunities

- Expedite and streamline the review time and process for global MRCT application.
- Consistently apply the criteria for clinical trial exemption.
- Replace cumbersome phase 4 trials with real-world safety and efficacy monitoring programs, such as post-marketing observational studies or data from patient registries.

Expediting Drug Approval

Current Challenges

Despite NDCT provisions for expedited approvals for orphan drugs and rare diseases for prevalent diseases where existing treatments are inadequate, industry reports highlight limited benefits due to unclear procedures and lengthy, sequential processes.

Steps such as site registration, marketing authorization, and import licensing are time-consuming, adding up to nine to ten months after drug approval, delaying therapy availability.

Reform Opportunities

- Adopt reliance principles to recognize approvals from stringent regulatory agencies to expedite approval.
- Combine new drug approvals and site registration into a single, integrated application process.

Orphan Drugs and Rare Diseases

Current Challenges

India recognizes rare diseases as a public health challenge, yet regulatory hurdles persist for orphan drugs due to the lack of a formal designation process and specific incentives for their development. In addition, for an Orphan Drug with high unmet medical need, though there are provisions for a Phase 3 trial waiver under rule 101, request for Phase IV for orphan disease may still be required and has been challenging. Manufacturers also face barriers in producing country-specific packaging for low-volume supply, delaying availability.

Reform Opportunities:

- Introduce a clear dedicated pathway for orphan designation to consistently waive clinical trial requirements for rare diseases.
- Adopt flexible packaging policies, allowing English-neutral labels with country-specific stickers. Consider e-labelling to reduce logistical challenges.

Industry-Regulator Collaboration

Current Challenges

There is limited scope for structured interaction between regulatory authorities and the pharmaceutical industry in India. The absence of such dialogue restricts companies' ability to clarify ambiguities and incorporate regulatory feedback during the product development lifecycle, as well as providing a conducive environment for private-public partnerships.

Reform Opportunities

- Create formal platforms for periodic consultations between industry players, academia, and regulators to address evolving needs and share global best practices.

International Collaboration with other countries

Supplementing the government's National Pharmaceuticals Policy (2023), we believe that elevating CDSCO's status from observer status in ICH and joining PIC/S membership, implementing all internationally harmonised technical guidelines for pharmaceuticals, will enable India's growth as a competitive market for R&D investments. This will bring several strategic benefits to the country, strengthening its pharmaceutical regulatory framework, boosting exports, and enhancing global credibility.

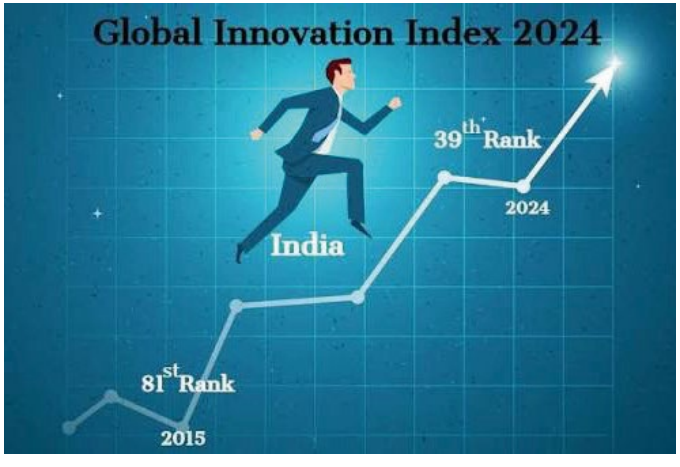
Conclusion

India's regulatory landscape for innovative pharmaceuticals is improving, with reforms such as clearer approval timelines, risk-based regulatory oversight, and greater digitization. However, gaps remain in key areas: IP protection, burdensome local clinical data requirements, and slow regulatory pathways. Strategic reforms are needed.

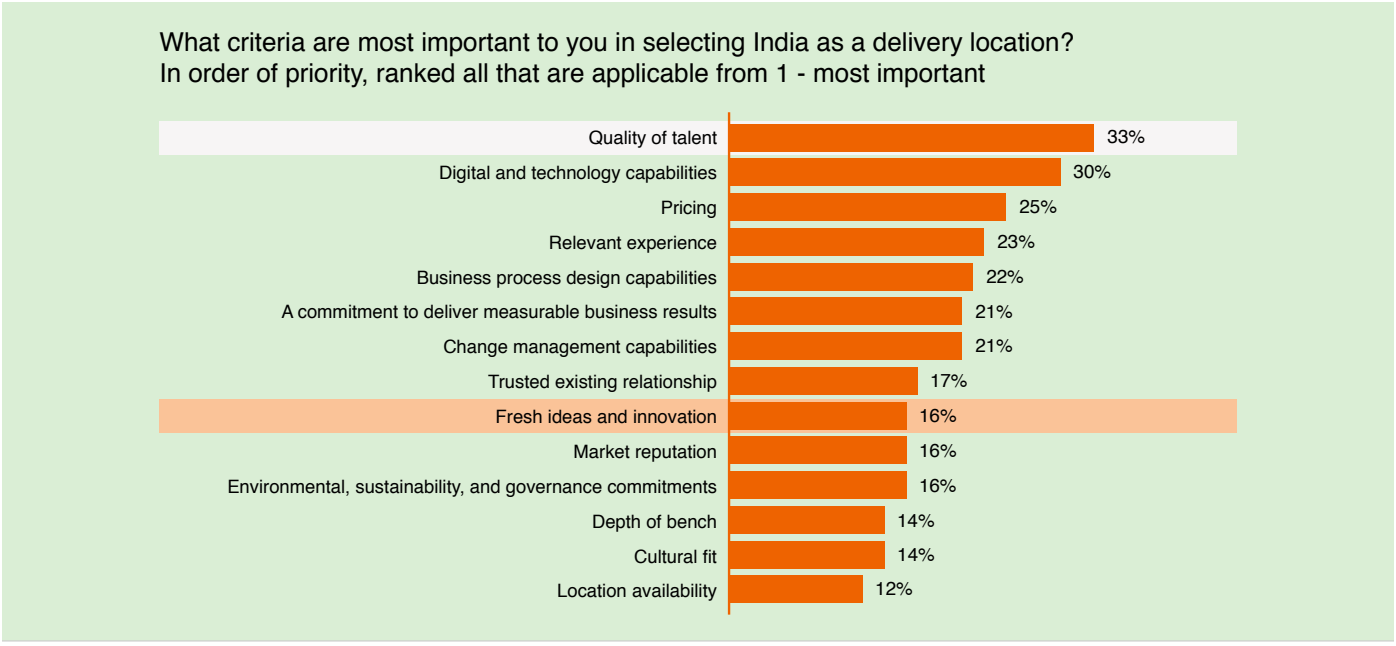
India's Innovation Policy Landscape: Opportunities and Gaps

Goutam Bhattacharya

CEO, Life Sciences Sector Skill Development Council (LSSSDC)



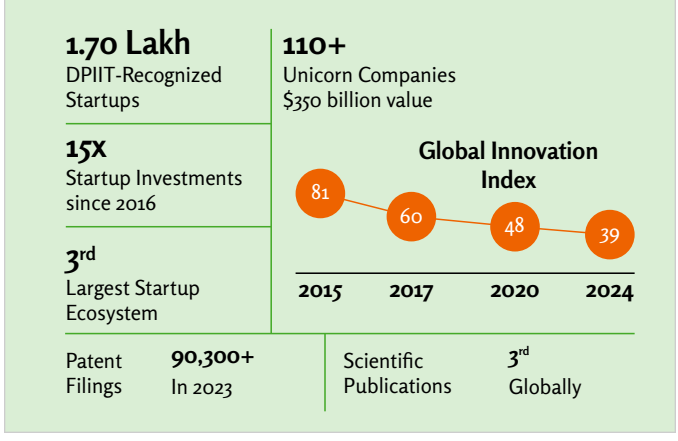
We have a good reason to applaud ourselves about India climbing the ranks of Global Innovation Index (GII) rapidly to reach 39th rank in 2024, but should rather reflect on a critical note. The reason is simple. We are in a VUCA world situation today and are fiercely competing with peer companies / countries for securing major business opportunities. Additionally, with AI and technological interventions providing better RoI, businesses are naturally aligning themselves towards securing their bottom line through early adoption of technology. So, even with such good results, we are yet to see that kind of innovation in the country. Are we then really doing very well in terms of innovation? Please look at this picture.



Although, India's innovation policy landscape has undergone significant transformation, aiming to cultivate a strong ecosystem for startups and R&D, we are still waiting for that 'multi-billion-dollar innovative products that can take world by storm'. We are still waiting for those innovations which is fetching large licensing fees. Our focus is still at incremental innovation and frugal innovation. While that may not be entirely wrong, I fear that we may miss the bigger picture. This leads us to another big question of 'who and 'where' are the innovators'. Are we creating enough number of innovators in the country?

Global innovation index (GII)

- India has made significant progress in the GII, rising to the 39th position in 2024 from 81st in 2015. India also leads among lower-middle-income economies and in the Central and Southern Asia region.
- India performs better in innovation outputs than inputs, according to WIPO. Key strengths include ICT services exports (rank 1), venture capital received (rank 6), intangible asset intensity (rank 7), and unicorn companies (rank 8).
- Countries like Switzerland, Sweden, and the US consistently occupy the top GII ranks, showcasing strong innovation



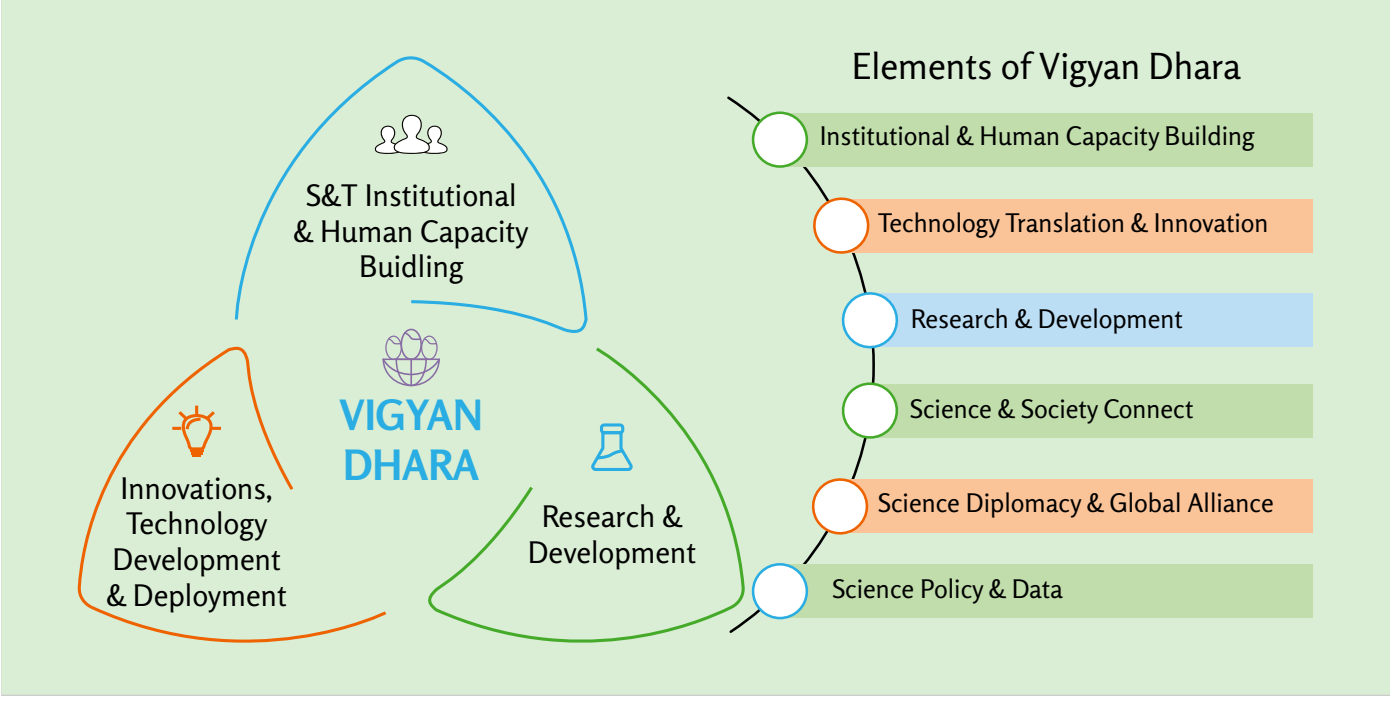
ecosystems driven by high R&D investment, skilled talent pools, and effective intellectual property protection.

Researchers with requisite skills for innovation

- India produces a large number of STEM graduates, ranking 2nd globally after China. **However, only 260 researchers per million people are engaged in R&D**, considerably lower than countries like South Korea (8,614) and China (1,601). This highlights a significant gap in human resources dedicated to research and innovation.
- Developed economies typically have a higher density of researchers involved in R&D, especially in the business sector. Their strong R&D funding and infrastructure foster a research culture that attracts and retains top talent.

The Indian government has launched various initiatives to promote innovation at multiple levels. The Startup India initiative, a flagship program, aims to build a strong ecosystem for nurturing innovation and startups, and drive sustainable economic growth and create large scale employment opportunities. Other key policies focused at the Life Sciences sector include:

- **Startup India:** Aims to foster a culture of innovation and entrepreneurship, provide financial support, ease regulatory burdens, and create a supportive environment for startups. The program has seen a significant increase in the number of DPIIT-recognised startups, from around 500 in 2016 to 1,59,157 as of January 15, 2025.
- **Atal Innovation Mission (AIM):** A flagship initiative launched under the NITI Aayog to foster innovation and entrepreneurship across the country, covering schools,



universities, research institutions, MSMEs, and industry levels. Key programs under AIM include Atal Tinkering Labs (ATLs), Atal Incubation Centers (AICs), Atal Community Innovation Centres (ACICs), and Atal New India Challenges (ANICs).

- **BioE3 (Biotechnology for Economy, Environment & Employment) Policy:** Approved in August 2024, this landmark policy aims to accelerate innovation-driven research and entrepreneurship in high-performance biomanufacturing. The policy seeks to achieve these goals by establishing Biomanufacturing & Bio-AI hubs and Biofoundries to accelerate technology development and commercialization. It aligns with India's "Green Growth" vision and the "Lifestyle for Environment (LiFE)" initiative, promoting a circular bioeconomy and aiming for a "Net Zero" carbon economy. It focuses on six strategic thematic sectors:

    - High-value bio-based chemicals, biopolymers & enzymes.
    - Smart proteins & functional foods.
    - Precision biotherapeutics.
    - Climate-resilient agriculture.
    - Carbon capture & its utilization.
    - Marine and space research.

I would specially like to mention "The PRIP scheme (Promotion of Research and Innovation in Pharma MedTech sector)" National policy on Research and Development and Innovation in Pharma-MedTech sector. Government launched the 'National Policy on Research and Development and Innovation in Pharma-MedTech Sector' in India and 'Scheme for promotion of Research and Innovation in Pharma MedTech Sector (PRIP). The policy aims to create an ecosystem of skills and capacities including the academia and the private sectors and give impetus to new talent among the youth through start-ups. It will also build synergies between various government institutions and agencies such as Pharma Department, Indian Council of Medical Research (ICMR), Department of Science and Technology (DST), Department of Biotechnology (DBT), National Institute of Pharmaceutical Education and Research (NIPER), etc.

The PRIP scheme encourages innovation through much needed funding and support, like:

- Financial Assistance: The scheme provides financial support to companies and projects involved in pharmaceutical and MedTech research and development.
- Strengthening Research Infrastructure: The scheme establishes and upgrades Centres of Excellence (CoEs) within existing National Institutes of Pharmaceutical Education and Research (NIPERs) to build specific research capacities and promote industry-academia collaboration.
- Industry-Academia Linkage: The PRIP scheme emphasizes fostering collaboration between the private sector and government institutions for R&D in priority areas.
- Focus Areas: The scheme targets six priority areas for research and development: New Chemical Entities, New Biological Entities, Phytopharmaceuticals, Complex Generics, Biosimilars, Precision Medicine, Medical Devices, Orphan Drugs, and Drug Development for Antimicrobial Resistance (AMR).

In essence, the PRIP scheme acts as a catalyst for innovation in the Indian pharmaceutical and MedTech sector by providing financial assistance, strengthening research infrastructure, promoting collaboration, and focusing on key areas that are crucial for both domestic needs and global competitiveness.

Challenges: Even after the plethora of schemes and support provided by Government and other institutions, we find **glaring gaps**, which can be attributed to:

- **Mismatch Between Skills and Industry Demand:** India's skilling programs often do not align with industry

requirements, leading to a significant employability gap. Traditional trades are often prioritized, while the demand for emerging skills like automation, AI, and green jobs is growing. Outdated curricula and limited real-world exposure further exacerbate the gap.

- **Low R&D Investment:** India's R&D expenditure as a percentage of GDP is significantly lower compared to developed countries. This underinvestment is particularly evident in the private sector, hindering the development of cutting-edge technologies and limiting India's global competitiveness.
- **Educational Bottlenecks:** India's education system faces challenges including a culture of rote learning, a lack of strong research culture in most universities, and insufficient infrastructure and funding for research.
- **Limited Industry-Academia Collaboration:** India ranks low in university-industry R&D collaboration. This disconnect prevents academic research from translating into market-ready innovations and contributes to skill gaps.
- **Brain Drain:** Highly skilled scientists and engineers migrate to countries offering better opportunities, funding, and quality of life, further depleting the domestic talent pool.
- **Governance and Institutional Inertia:** Bureaucratic hurdles, rigid funding rules, long delays in grant disbursement, and hierarchical cultures within public R&D organizations hinder innovation and research efforts.
- **Risk-Averse Private Sector:** Indian businesses often show a preference for incremental innovations or technology imports over deep tech R&D, impacting private sector investment in research and development.
- **Inadequate IP Commercialization:** Despite an increase in patent filings, many granted patents remain unutilized, highlighting a gap in commercialization strategies and support for converting research into marketable products.
- **Lack of Commercialization of Grassroots Innovations:** Efforts are needed to commercialize grassroots innovations on a larger scale.

Life Sciences Sector Skill Development Council

We at Life Sciences Sector Skill Council are doing enormous skill development activities for the human resources to augment the growth of the Life Sciences sector. Council is helping the Academic institutions connect with the industry and vice-versa through well thought of programs thus balancing the demand – supply of skill gaps. One of the leading sector skill councils of Ministry of Skill Development and Entrepreneurship (MSDE), LSSSDC has become the flagbearer for skill development in Pharma, Bio-tech & MedTech sectors.

The Life Sciences Sector Skill Development Council (LSSSDC) is an awarding body recognized by the National Council of Vocational Education and Training (NCVET) and works under the aegis of **Ministry of Skill Development & Entrepreneurship (MSDE)**. Established in 2014 by the National Skill Development Corporation (NSDC) with industry representatives, LSSSDC is mandated to create a robust and vibrant skilling eco-system for development of a skilled workforce matching globally recognized standards for Life Sciences sectors. LSSSDC's endeavour is to ensure a sustained supply of skilled workforce, across functional areas and levels that provide meaningful livelihood opportunities to a multitude of aspirants. Also, it is imperative to keep an eye on the evolution of the Life Sciences sector and integrate new age futuristic skilling into the courses that LSSSDC is creating.

LSSSDC eagerly invite industry to closely collaborate with the Council for development of Skilling infrastructure in the country through establishment of Skill Development Centres (SDCs); jointly develop industry required skill courses & programs; bring world class programs through their international parent organization.

Innovation: Prospects for Indian Pharmaceutical Industry

Harish K. Jain

Director, Embiotic Laboratories (P) LTD, Bangalore & National President,
Federation of Pharma Entrepreneurs (FOPE)

Indian pharmaceutical manufacturers have been working in a challenging Indian market characterized by price controls, limited insurance levels and low patient incomes. Since 1984, through the Drug Price Competition and Patent Term Restoration Act (also known as Hatch-Waxman Amendment), pharmaceutical manufacturers have been able to introduce generic drugs in the United States (US) market by submitting the Abbreviated New Drug Application (ANDA). This act has given the Indian firms an opportunity to market and sell their generic products in the US and their experience within the Indian market has allowed them to introduce products at competitive rates, giving them an edge in the generic pharmaceuticals' rat race. Consequently, India is now the world's largest exporter of generic drugs, with a net-worth of $30.47 billion sold during 2024-25. But is this unique position sustainable?

Years 2012-2017 have been called the "patent cliff" when many "blockbuster" drugs lost or will lose their patent protection[1]. After encashing patent expiries, post-2017, as fewer products lose their patent protection due to a fall in new chemical entity (NCE) fillings with the US Food and Drug Administration (FDA) over the last few years and as the competition in the generic pharma space becomes stiffer,

dramatic price drops (upto 99% of the branded product) is inevitable and growth, unsustainable. It then becomes imperative for the Indian firms to shift their business models from traditional and conservative to innovative and disruptive. Development of NCEs or value-added generics essentially constitutes the 'innovative' model. However, NCE discovery and development is a multi-billion dollar project, spanning from 10-20 years, a prospect majority of Indian firms are not in a position to pursue. A value-added generic or 'supergeneric', an improved version of an original drug which has lost its product patent protection, on the other hand, is a viable option to pursue from an Indian manufacturer's standpoint.[2] The improvements can be in terms of expanding therapeutic classes, improving bioavailability and stability, reducing side effects, reducing manufacturing costs, development of new dosage form, delivery mechanism or a never-attempted-before combination of known medicines. 1-Abraxane is a well known example of a supergeneric form of Taxol which uses albumin instead of Cremophor to deliver paclitaxel, thereby making the chemotherapy more efficacious, reducing paclitaxel's side effects as well as allowing it's administration without steroids.[2]

Supergenerics are filed under 505(b)(2) of the US Food and Drug Administration, a New Drug Application (NDA) and not ANDA, that contains full safety and effectiveness reports but allows some of the information required to complete the application to be referred from the application for the original product. Applications are reviewed based on the limited clinical trials of the drug unlike the exorbitantly expensive clinical trials for an NCE in the US and hence, are relatively less expensive ($20 to $30 million) and less time consuming (5-6 years). Suri et al. have outlined and compared the development processes of NCE, supergenerics and generics.[4] Moreover, probability of success of supergenerics has been reported to be about 60% which is significantly higher than NCE (0.01%). Although the development process of supergenerics is more expensive, time consuming and has lower success probability compared to generics, supergenerics can afford higher profit margins (~ 65% vs 10-20%, respectively). This can be attributed to a patent protection of 3 – 5 years of a supergeneric which can be more lucrative than the 180 days market exclusivity provided under Para IV filing for a generic. This distinction from the generics' competitors, and more-often-than-not patient-centric incremental innovation, is set to give the supergenerics' manufacturers, a leverage in the market place.

Considering the strength of Indian firms in reverse engineering innovator products, many of them have naturally developed the ability to add value to the original drugs through incremental innovation. Some of the supergenerics developed by Indian firms include Absorica (Ranbaxy), Fondaparinux (Dr Reddy's), Suprax (Lupin), Docefrez (Sun Pharma), Dymista (Cipla), Crofelemer (Glenmark) and Alzumab (Biocon). These companies, through their supergenerics, are vying for an annual revenue of $100-$200 million. Moreover, Sun (Ranbaxy) and Lupin have launched their supergenerics in the US market. However, marketing to the health care providers requires a field force and establishing a marketing team for just one supergeneric is not feasible. A portfolio of supergenerics is needed to justify the costs of marketing. To date, Indian firms have been striving to gain access to the distribution networks in the US market to sell their generic products. But with a rapidly evolving pharmaceutical industry and patent landscape, it is important to start promoting their own branded products on a much larger scale. Incremental innovation is an opportunity to help R&D personnel graduate to developing a new drug rather than developing pure generics from their R&D centers.

To reduce the risk of product failure as well as respond to the demands of FDA, quality-by-design (QbD) approach should be adopted. This approach has been reviewed in good detail

recently by Pramod et al.[5] Design of experiments (DoE), risk assessment and process analytical technology are tools of such a science and risk-based product development strategy which allows better management of changes in product or process. For example, renovation of original candesartan cilexetal led to the development of a tablet dosage form containing its nanoparticles to improve the drug's solubility and bioavailability as well as reduce its dose and toxicity. Use of DoE for process optimization resulted in robust, scalable manufacturing processes of this formulation by recognizing the critical process parameters that affect the critical product attributes thereby establishing a design space for non-linear, quadratic or interaction effects. The robustness of the model was validated based on confirmatory trials that indicated statistically no difference between predicted and experimental values of product performance.[6]

Generic drug manufacturers are especially seeing high price erosion in part due to increased competition from other countries like China, Taiwan, South Korea, Bangladesh, Vietnam, New Zealand and Japan as well as changing market needs from vanilla drugs to complex generics to address substantial unmet needs in the US, UK and Europe. The Indian pharmaceutical industry is at a very exciting, but challenging crossroad today. Innovation and technology are key to sustained growth in the future. The required investments can be recouped because innovative products have long life cycles and more importantly, allows product differentiation in a crowded market, providing potentially higher returns.

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Innovation in Pharma GCCs: Technology as a Catalyst, People as the Purpose

John Dauber

Corporate Vice President & Managing Director, Novo Nordisk Global Business Services (GBS)

Not too long ago, Global Capability Centers (GCCs) in the pharmaceutical industry was seen as the quiet backrooms of the industry - efficient, reliable, but far from the action. I have watched that perception change dramatically. Today, they've moved from the sidelines to the driver's seat.

What fuels this progress? Certainly, digitalisation, AI, and automation play their part, but equally important is a shift in mindset. GCCs across the globe today are no longer content to simply support. They are leading. They are influencing how drugs are discovered, how trials are run, and how patients are supported.

With all the technology at our disposal, we are making great strides to ensure that innovation truly serves the people at the heart of healthcare. In the pharmaceutical industry, the "end user" is not just a customer - it is a patient whose life depends on our work.

From Efficiency to Real-World Impact

In the early days, GCCs were about scale and cost efficiency: process more data, handle more documents and do it faster. That was valuable, but it was also limited.

Now, the tools are different. AI platforms can scan billions of data points from past clinical trials and give you a clear answer in hours, not weeks. Automation can take the pain out of regulatory submissions, cutting manual work by up to 70% and reducing the risk of human error. Generative AI can sift through medical records to match patients to trials they might never have known about.

But speed and efficiency are only part of the story. The real measure of success is whether these capabilities can lead to better patient outcomes, faster access to treatments, and more equitable healthcare.

And as these capabilities mature, the question becomes: where will GCCs make the most meaningful difference next?

The Next Frontier

If I look at where GCCs can truly move the needle in the years ahead, three areas stand out:

- Personalised Medicine - AI is helping us design therapies tailored to a person's genetic profile.

- AI-Driven Drug Discovery - We're seeing foundation models identify new molecules and repurpose existing drugs in months instead of years.

- Real-World Evidence - Data from wearables, patient surveys, and electronic health records is being used to improve regulatory submissions and spot safety issues earlier.

One example close to home is Novo Nordisk's patient support program for one of our diabetes medications. On the surface, it's a digital app available in India for people with diabetes. But the real value is in the personalised coaching, the human health coaches behind the screens, and the sense of community it builds. That's technology enabling care, not replacing it.

But as with any breakthrough, the pace of change must be matched with the wisdom to use it well.

GenAI: Exciting, But Handle with Care

Generative AI has rapidly moved to the forefront of industry conversations, carrying both extraordinary potential and important questions about how we use it. But in my experience, the smartest approach is to start small, run a Proof of Concept, see if it works in your context, and then scale.

Too many projects falter when they rush into enterprise-wide rollouts without first proving the concept. GCCs have the talent and infrastructure to lead in this space, but that leadership must be exercised with responsibility.

And while technology may be the enabler, the heart of transformation still lies elsewhere.

It Still Comes Down to People

It is tempting to see GCC transformation as a technology story. But the real differentiator has always been people.

Success depends on talent that can bridge worlds: those fluent in AI and data science, and those deeply grounded in the science of medicine, regulation, and ethics. It also depends on building ecosystems - partnerships with regulators, universities, technology providers, and patient groups; so that innovation is trusted and relevant.

In our industry, how we create is every bit as important as what we create.

Innovation Within the Rules

In the pharmaceutical industry, compliance is far more than a tick-in-the-box exercise. It is the foundation of trust. The FDA, EMA, and other regulators are already shaping guidelines for AI in drug development. GCCs that get ahead of these changes will avoid costly delays and, more importantly, protect patients.

I have always believed that regulations aren't there to slow us down; they are there to make sure we are doing the right thing. If your AI tools are GxP-compliant, with proper audit trails and safety checks, you are safeguarding lives.

A Call to Action

The rise of innovation-driven GCCs is one of the most exciting shifts I have seen in the pharmaceutical industry. Beyond faster processes and smarter algorithms, it is about reimagining how we bring life-changing treatments to the people who need them most.

If you are leading in this space, my advice is simple:

- Scale your digital capabilities but keep them human-focused.
- Break down silos and encourage collaboration across functions.
- Make regulatory alignment part of your innovation strategy, not an afterthought.

Technology will keep evolving. The real question is - will we use it simply to move faster, or to move faster towards what matters most? Because in the end, GCCs don't just have the tools to accelerate science, they have the opportunity and the responsibility to accelerate hope, improve access, and transform health outcomes for people everywhere.

Viksit Bharat @2047: Fostering and Enabling the Innovation Ecosystem in India

Krishna Sarma

Managing Partner, Corporate Law Group

India stands at a pivotal juncture in its ambition to transform into a global, innovation-led economy by 2047. With world-class talent, proven manufacturing scale, and a reputation as the "pharmacy of the world" – supplying over 50% of global vaccines and 40% of generic drugs consumed in the US[1] – India has undeniable strengths. Yet, its innovation output in pharmaceuticals, biotechnology, as well as in semiconductors and deep technologies, remains modest compared to global leaders. Structural constraints – weak intellectual property (IP) enforcement, underinvestment in R&D, limited risk capital and regulatory bottlenecks – continue to limit progress.

In this article, we examine three critical pillars for creating a cutting-edge innovation ecosystem: (1) the role of intellectual property rights (IPR) in incentivizing innovation, (2) the availability of venture and risk capital for pharma and deeptech, and (3) policy reforms required to position India as a global innovation leader by 2047.

India's world-class talent and scale can compete globally, but only if supply-side gaps in risk capital, commercialization, and IP are bridged. By contrast, China's coordinated national strategy delivers funding, talent, and IP protection for frontier technology sectors.

Current State of Innovation in Critical Sectors

India's Gross Expenditure on Research and Development (GERD) remains at a modest 0.64% of GDP, significantly lower than China (2.4%), the United States (3.5%), and Israel (5.4%). South Korea, Japan, and Taiwan - house global leaders in semiconductors, electronics, and material sciences - each outspend India on R&D and have built dense supply chain linkages and research commercialization pipelines through sustained public-private efforts.

Country	R&D Spend % GDP	Researchers /million	Strengths
US	~3.5	~4,300	Advanced tech, IP commercialization
China	~2.4	~1,200	Manufacturing, scale, policy focus
Israel	~5.4	~8,200	Startups, applied sciences
S. Korea	~4.8	~7,600	Chips, electronics, collaboration
India	~0.7	~260	Generic pharma, scale, process

More concerning for pharmaceutical innovation is the composition of this spending – private sector contributions account for only 36.4% of total R&D expenditure, contrasting sharply with developed economies, where business enterprises typically contribute over 70%.

While India's pharmaceutical companies, especially its top 10 players, maintain robust pipelines with over 40 New Chemical Entities (NCEs) and New Biological Entities (NBEs), breakthrough innovation remains limited, with most research focused on generics, biosimilars, and incremental improvements.

Policies and Actions to Unlock Innovation Potential

India's innovation ecosystem is talent-rich but short on risk capital, deep-tech funding, IP systems, and advanced lab infrastructure.

Academic-industry collaboration is weak — India ranks a low 86th globally on this metric. The bulk of Indian R&D is publicly funded (~55% government), unlike advanced economies, where private industry dominates R&D investment and drives commercialization.

India's IPR landscape creates specific challenges

Empirical evidence shows that stronger IP protection correlates with higher foreign investment and domestic R&D[2]. Strong IPR frameworks incentivize companies to invest in high-risk, long-gestation drug development by providing reasonable exclusivity periods to recover substantial research investments.

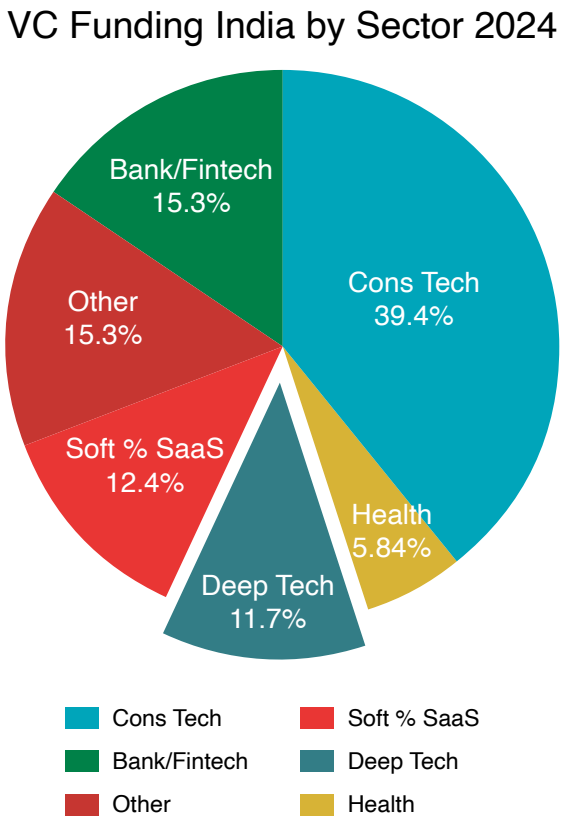
India's IPR landscape - with its limitations on the scope of patentability, an indifferent patent enforcement ecosystem, lack of Regulatory Data Protection, procedural delays, and extant compulsory licensing provisions - hinders effective and meaningful protections and incentives for robust innovation.

VC & Risk Capital and the Role of Venture Investment

Globally, venture capital (VC) has powered biotech clusters in Boston, AI platforms in Silicon Valley, and semiconductor giants in Taiwan. In India, however, most VC funding has

flowed to consumer-tech sectors such as e-commerce and fintech. Deeptech startups, by contrast, attract less than 1% of total VC investment[3]. As Henny Sender observed, raising money in India remains far harder, pushing entrepreneurs to ecosystems, such as in the US and Singapore, where deep tech is better supported[4].

Recent government efforts – the Startup India Seed Fund, a ₹10,000 crore Fund of Funds, and the draft National Deep Tech Startup Policy – are steps in the right direction[5]. Yet systemic change is needed:



Strategic Reforms

For India to become an innovation leader by 2047, some broad reform tracks are essential.

1. **Scale up R&D investment:** Raise gross expenditure on R&D to at least 2% of GDP within a decade through expanded government budgets and private-sector incentives. Reinstate weighted tax deductions for R&D and launch mission-mode programmes targeting breakthroughs in tuberculosis vaccines, semiconductor design, and AI-driven healthcare.

2. **Strengthen IPR and lab-to-market technology transfer:** Introduce regulatory data protection aligned with TRIPS, restore patent notification, and modernize patent offices to cut pendency. Establish university technology transfer offices modelled on US and EU systems, and create innovation clusters co-located with IITs, IISc, and NIPERs to bridge academia and industry.

3. **Brain Drain and Talent Challenges:** Launch prestigious industry-linked PhD fellowships, revamp curricula to embed innovation and entrepreneurship, and offer returnee incentives and long-term visas to attract global Indian-origin scientists. Encourage academia-industry labs with shared IP frameworks.

4. **Streamline regulation and infrastructure:** Establish single-window clearances and regulatory sandboxes for biotech and AI products. Invest in shared infrastructure such as semiconductor prototyping centres and biotech labs accessible to startups.

5. **Anchor demand through procurement:** Commit a share of government health and defence budgets to Indian-developed products, expanding programmes like iDEX to pharmaceuticals and MedTech.

6. **Deepen and Diversify R&D Investment:** Raise GERD to at least 1.5-2% of GDP over the next decade as a mix of public and incentivized private R&D.

7. **Establish "Patient Capital" for Deeptech:** Investigate outcome-based grants for moonshot science (like novel drug development, advanced chip design, aerospace components), modelled on the US/EU Chips Acts. Consider a National Deeptech Fund (sovereign or PPP) with a 15–20-year horizon to underwrite risk in semiconductors, drug discovery, clean energy, and aerospace propulsion.

8. **Support long-gestation tech:** Strategically refocus on the Startup India Seed Fund, Fund of Funds for Startups, and PLI to support long-gestation projects. China's "Big Fund" exemplifies how government can create momentum via "patient Capital" for long gestation technologies.

Conclusion

India requires systemic reforms to fulfil its ambition to create the next generation of pharma, biotech, and deeptech leaders. Strengthening IPR, expanding patient capital, and implementing enabling policies are critical. With decisive action, India can evolve from being the "pharmacy of the world" for generics into a global hub for novel, cutting-edge innovation by 2047.

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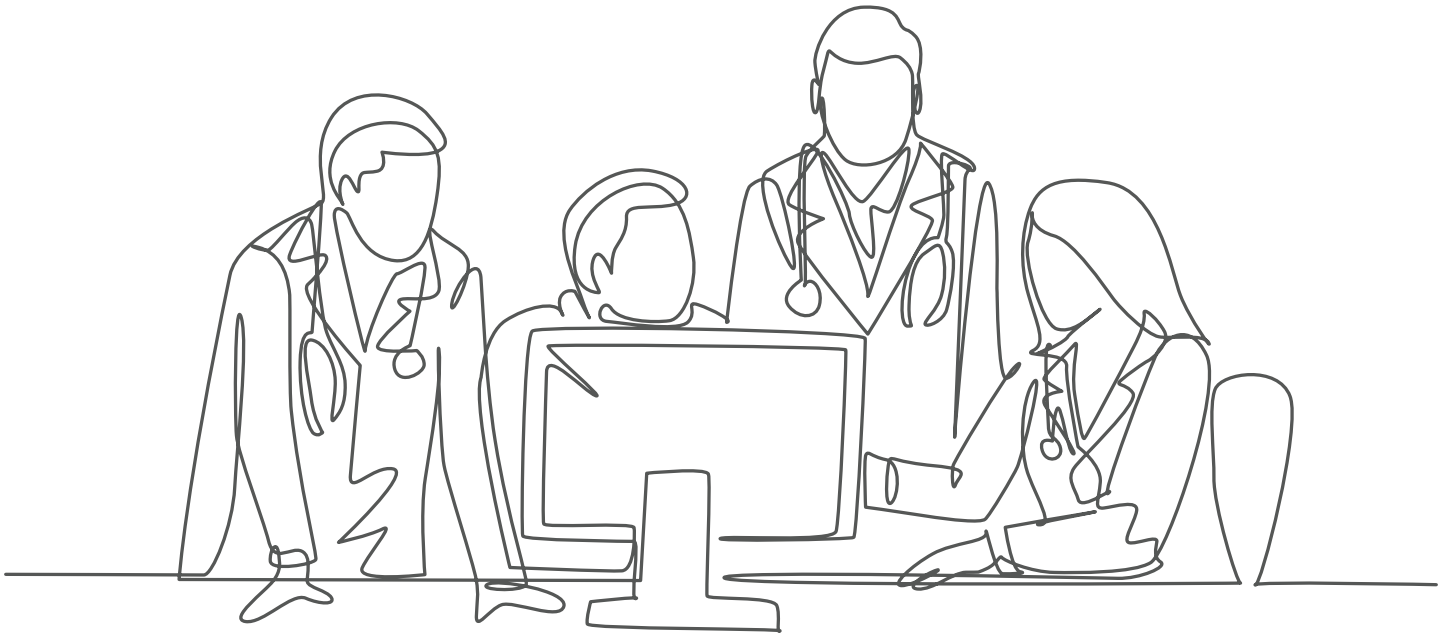

Patent Litigation and Interim Relief in India

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Introduction

Patent litigation in India represents a unique and somewhat challenging terrain of commercial disputes. The complexity of patent technologies, the intricacy of legal claims and the applicable laws, renders patent disputes as a dynamic and perhaps challenging class of commercial litigation. That said, the implications of decisions in patent disputes are

far-reaching and have an impact on the business of not only the parties involved, but other competitors in that field of technology. Therefore, in a transitioning economy like India, patent protection and enforcement are crucial. Undue jeopardy of patent rights constitutes a major challenge to innovation and causes irreparable harm. Therefore, interim injunction decisions in patent disputes as part of enforcement proceedings, are of considerable importance.

Interim Relief in India

In India, interim relief in general is not a matter of right, but rather a discretionary remedy provided to claimants who satisfy the judicial tests. In matters of patent infringement, interim relief usually takes shape in the form of interim injunctions, i.e., restraining the use of a product that infringes a granted patent. For the grant of interim relief, the Supreme Court has held that a party must establish a prima facie case, demonstrate the irreparable harm intended to be abated by the injunction and how the balance of convenience lies in the Plaintiff's/Patentee's favour.[1]

This serves two purposes: [1.] maintains status quo throughout the course of trial; and [2.] protects the rights of the litigants made vulnerable on account of infringement. The first point here is of considerable importance, since trials in India can be tedious. From 2005 – 2015, a mere 5 judgements were delivered from a total of 143 patent infringement suits filed before the High Courts at Delhi, Bombay, Madras & Calcutta. Interim relief, therefore, takes on greater importance.[2]

However, a recent challenge that has been observed in India is that patentees are experiencing a *mini trial* at the interim stage itself. A *mini trial* here implies determination of a *prima facie* case itself becomes an over-magnified exercise which takes on the characteristics of an actual trial. In this regard, the Supreme Court has sounded caution against conducting "*mini trials*" at the interim stage.[3] The Apex Court has also emphasized that judgements in IPR disputes should be pronounced within 4 months of institution of the suit.[4]

Approaches in Other Jurisdictions

Several major jurisdictions, including the IP-5 countries have evolved different methods to deter such mini trials at the interim stage proceedings.

United Kingdom

In the UK, final decisions in patent litigations usually come about in 2-3 years. However, to ensure expediency at the interim stage and in the overall trial, the House of Lords, in a patent dispute, held that interim injunctions can be given if the claimant demonstrates a serious question to be tried, that damages would not be an adequate remedy, and that the balance of convenience favours granting the injunction.[5] Building on this, in *Series 5 Software*,[6] it was further held that there are several cannons that need to be appreciated while adjudicating interim injunctions along with the classical triple test mentioned hereinabove. These include [1.] interim relief must be flexible; [2.] interim relief is dependent on the facts of the case; and [3.] judges should avoid complicated questions of fact and law.

In an innovative effort, the UK has also adopted an expedited trial scheme.[7] Under it, parties may jointly request a docketed judge to set tightly controlled case management directions and deadlines with limited evidence and disclosure. Effectively, these trials act as an alternative to interim injunctions.[8] The England & Wales Court of Appeals laid down a four-factor test to determine the legitimacy of requests for expedited trials.[9] They require justified reasons for expedition, balancing expedition with good administration and prejudice to the parties and consideration of special circumstances.

United States of America

The USA also faces considerable time in disposing patent litigations. It is estimated that patent infringement disputes go on for about 3-5 years. The USA follows a four-factor test to determine whether a case of interim injunction has been made out,[10] *viz*., [1.] likely success on merits; [2.] suffering irreparable harm; [3.] balance of equities; and [4.] whether injunction is in public interest. Statistics suggest that grant of preliminary injunction has been primarily contingent on the presence of irreparable harm.

The USA also conducts *Markman* hearings, after the Supreme Court's decision in 1996,[11] wherein technical terms utilized in the disputed patents are interpreted. This is also known as claim construction. Litigants in the USA also search for district courts which are recognized for quicker disposal of patent infringement suits. These are known as *rocket dockets*. The fastest Rocket Docket was in the district of Montana with 18.3 months from start to finish. Texas and Arkansas follow with 18.8 months.

Italy

In Italy, preliminary assessment for grant of interim injunction happens for assessing the likelihood of a finding of validity and infringement. In cases of challenge to validity, Italian Courts usually appoint a *Court Technical Advisor* (CTA), which is a peculiar aspect of Italian jurisdiction, when compared to India, UK and USA.[12]

The Way Ahead in India

Stakeholders in India have taken note of developments in these jurisdictions and have introduced similar means for expedition. The Commercial Courts Act, 2015 introduced case management hearings[13] and pre-institution mediation.[14] Litigants are expected to attempt settlement before litigation and are now also bound by timelines fixed by Courts. Recently, the Delhi High Court mandated that Plaintiffs provide claim mapping with the infringing products in the lawsuit itself.[15] This reduces the hearings needed to understand the technicality of the claims. In 2022, the Delhi High Court also released specific rules governing patent suits.[16] The Court also, relying on *Terrel's Law of Patent*, ruled that claim construction is a necessary exercise in patents suits and helps shape the foundation to determine infringement and validity.[17]

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Biosciences to Bioeconomy: Shaping the Next Industrial Revolution

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The 21st century has begun the unfolding of the exponential power of interdisciplinary strength of biosciences and bioengineering coupled with AI. Novel environment friendly bio-based products and technologies are now visible around us addressing some of the most pressing global challenges i.e., climate change, food security and healthcare. Countries have started following bioeconomy as a measure of the economic growth. Global bioeconomy is expanding rapidly, projected to grow from about $5 trillion to $30 trillion by 2050, driven by biotechnology, renewable bio-based materials, and sustainable bio-manufacturing. Leading regions like North America, EU and China have invested heavily in biotech R&D, infrastructure and supportive policies, integrating bioeconomy principles into their national strategies. India is top 12th global biotech destination and the third largest in the Asia-Pacific bioeconomy. India's Bioeconomy has also improved from $44.5 Billion USD in 2017 to $167.2 in 2024 at a double digit CAGR. The current contribution to GDP is 4.25% which is at par with US and China but behind Europe.

At the heart of the bioeconomy lies the principle of sustainability. Traditional economic models have often prioritized short-term profits over long-term ecological health. The bioeconomy challenges this paradigm by emphasizing

the importance of bioresources and renewable resources. For example, the substitution of non-renewables like fossil fuel with bio-fuel. The process of biofuel production also reduces carbon load from the environment as it uses waste, underutilized abundant bioresource and converts into high value product by microbial fermentation technology.

Advancement in bioengineering technologies like synthetic biology has empowered the manipulation of biological systems by scientists to create new products and processes that were previously unimaginable. This outcome of laboratory research can now be seen in clinics, agriculture fields and all around us. For example, insulin is commonly available worldwide for blood glucose management in diabetic patients. Likewise, humanized antibodies are synthetically produced in large scale by biopharma companies; scavenger bacteria is used to clear accidental oil spills in ocean; in vitro fertilization has given millions of childless couples new hope to bear child; leukaemia patients' immune cells get training on how to fight cancer cells, outside the body in test tubes and then CAR-T cells are injected back to cure the disease; lab grown synthetic meat, animal free milk, etc. These are just a few of the applications that have been successfully deployed yet. The future with Biosciences applications is even more fascinating.

Another perspective that favours bioeconomy is that it extends beyond just the production of goods; it encompasses a holistic approach to societal challenges. The global population is expected to reach nearly 10 billion by 2050, posing food security challenge, necessitating a radical transformation in how we produce and consume food. Through bioengineering, we have the ability to reduce crop cycle period, develop crops that use less water, are more resilient to climate changes and infection by pests, higher yields with reduced reliance on harmful chemical fertilizers, insecticides and pesticides, semi-synthetic sugar alternatives such as fructo-oligosaccharide, brazzein would cover the additional requirements supplementing shortfall or alleviate dependence on sugarcane.

Look at healthcare, the biotechnology has revolutionized how we diagnose and treat diseases. The integration of genomic data and personalized medicine has enabled healthcare providers to offer tailored treatments for patients, significantly improving outcomes. In India, CAR-T cells based affordable solutions have offered new life to leukaemia patients. Indigenous Covid vaccines using mRNA, DNA, nasal route for delivery as platform technology have added new arsenal into healthcare delivery to fight future pandemics.

However, transitioning to bio-based bioeconomy is not without its challenges. It is resource intensive in terms of capex and operational costs, and talent centric. Centre, State Governments and private sector should prioritize funding for R&D, creating incentives for collaboration between academia and industry. Establishing international partnerships can facilitate knowledge sharing and technology transfer, allowing for a more collective approach to addressing global challenges. The clarity of regulatory pathways and predictability is critical. The economy of cost in the beginning may not be in favour of bio-based alternatives to compete with conventional alternatives. Such circumstances would require government's strategic incentives support.

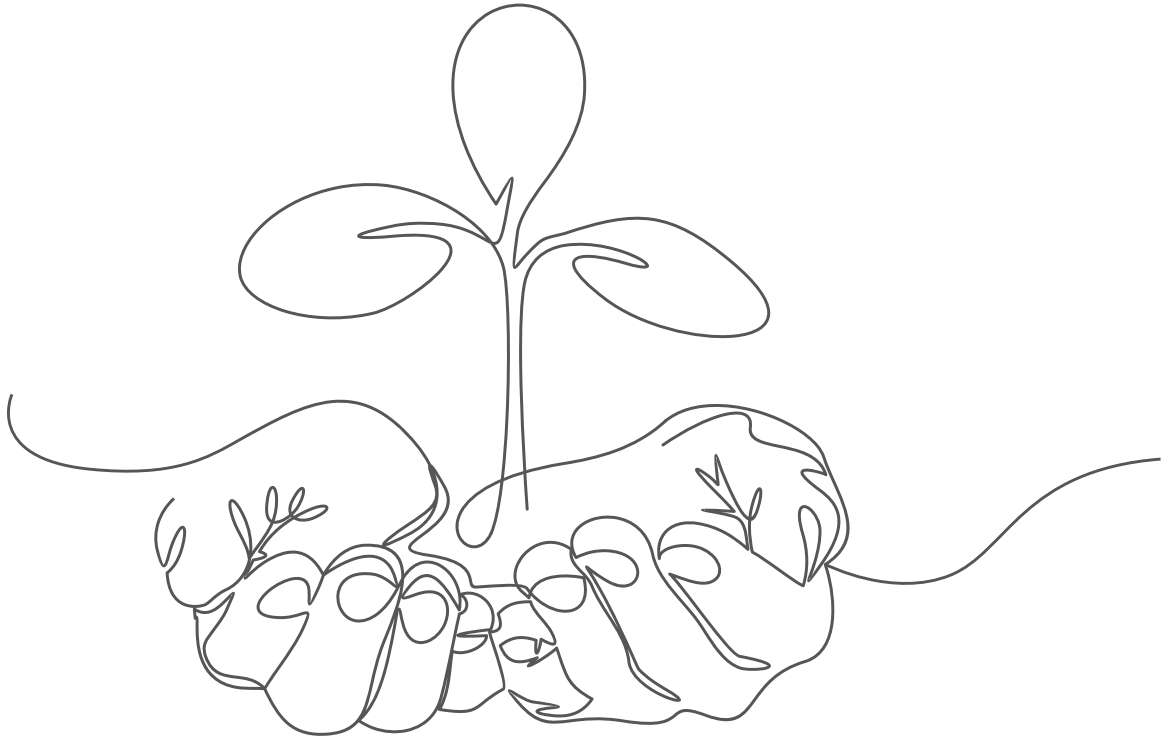
Strategic imperatives include:

- Launching supportive policies and incentives, spanning central and state governments, fostering public-private partnerships, and attracting talent.
- Allocating higher budgets for biosciences and biomanufacturing, integrating with national priorities.
- Building bioclusters and expanding networks of incubation

centres to spur startup growth, unicorn emergence, and increased investment flows.
- Capacity building through initial investments in pilot and validation infrastructure facilities.

Human resource development would play a pivotal role in this transition. Equipping the future workforce with knowledge in biosciences and bioengineering will empower the next generation to innovate and lead in this promising field. Integrating bioscience education into school curriculums, students exposure to Startups, Incubation centres, Atal Tinkering Labs coupled with public awareness campaigns like BioE3 policy stakeholder workshops, can cultivate a more scientifically literate society that embraces the principles of sustainability.

We can see that the ascent of the bioeconomy signifies a new industrial revolution that has the potential to redefine our relationship with nature and technology. By harnessing the tools of biosciences, we can create a sustainable future that prioritizes not only economic growth but also the health of our planet and its people. Viksit Bharat by 2047 aims to achieve sustainable growth with bioeconomy contribution to GDP improving to 10%. With announcement of INR 1 lakh crore (~$12 billion USD) for Deep Tech innovations, BioE3 policy, ANRF formulation, actions of national enabler bodies like DBT-BIRAC, it is expected to see a boost in bio-innovation and bio-manufacturing to shape a resilient and prosperous future for all.



Viksit Bharat and Pharmaceutical Innovation

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Pharmaceutical Innovation in India

- The pharmaceutical industry has made a significant contribution to the Indian economy, and India is known as the pharmacy hub of the world. India is the largest supplier of generic drugs in the global market.
- The pharmaceutical industry plays a crucial role in India's economy, contributing significantly to domestic healthcare and as a major supplier of medicines globally. Over the years, India has gained recognition as the "Pharmacy of the

World" because of its leading position in the production of generic medicines and vaccines(*Pharma, n.d.*). The economic contribution of the pharmaceutical sector constitutes approximately **1.72%** of India's Gross Domestic Product (GDP). In terms of exports, pharmaceuticals have represented approximately 6% of India's merchandise exports by value in recent years, with total exports ranging between USD **25 billion** and USD **27.8 billion**. Globally, India ranks third in pharmaceutical production by volume and fourteenth by value. Furthermore, India supplies over 50% of the world's vaccine demand, approximately **40%** of generic medicines in the United States, and **25%** of all medicines in the United Kingdom.

- The pharmaceutical industry plays a tremendous role in the economic growth of a country. Currently, the country requires a shift from generic to branded/innovative drugs for further growth.

- The country must shift its focus from the quantity to the quality of generic and branded drugs. To achieve this objective, the Indian Government has implemented a range of programs to foster innovation in pharmaceutical research and development. Given India's robust standing in the generics and vaccines sectors, along with government efforts such as the Production Linked Incentive (PLI) scheme, patent innovations, academic research orientation, academic industry collaborations, syllabus revision, new education policy, and large-scale projects such as Hyderabad Pharma City, Himachal Pradesh.

- India's Production-Linked Incentive (PLI) scheme has become a pivotal element in the nation's strategy to transition from being a global supplier of generic pharmaceuticals to a centre of pharmaceutical innovation and research. The initiative commenced with PLI 1.0, launched in early 2021, with a financial allocation of ₹6,940 crore, aimed at bolstering the domestic production of essential Active Pharmaceutical Ingredients (APIs), Key Starting Materials (KSMs), and Drug Intermediates (DIs). This scheme incentivized the local manufacturing of 41 critical bulk drugs, offering up to 20% support for fermentation-based products and 10% for chemical synthesis variants (Invest, 2021). Subsequently, the government introduced PLI 2.0, broadening the scope to encompass high-value pharmaceutical products such as biopharmaceuticals, complex generics, gene and cell therapies, orphan drugs, and in vitro diagnostics. With an allocation of ₹15,000 crore, PLI 2.0 provided 10% incentives on incremental sales between FY 2022–23 and FY 2025–26, decreasing to 8% in FY 2026–27 and 6% in FY 2027–28 (Health Economic Times, 2021; Professional Utilities, 2023).

- Production-linked incentive (PLI) schemes have established India as a prominent "pharmacy of the world" and a burgeoning centre for innovation. Although this transition is ongoing, the direction of the policy suggests a strategic shift: it began with a focus on achieving self-sufficiency in the production of bulk drugs, moved towards boosting export capabilities, and is now encouraging domestic pharmaceutical innovation (Lakshmi Tulasi DY, nd.).

- Patents have functioned as crucial conduits between academic research and practical innovation. Within academic institutions, obtaining patents enhances the potential for commercialization, thereby enabling these institutions to license their inventions and attract partnerships with industrial stakeholders. Over the past ten years, the Indian pharmaceutical industry has made remarkable progress in research and patenting activities. From 2010 to 2020, the average R&D intensity among top companies increased from 4.29% to 5.50%, while the number of patents more than doubled, increasing from 350 to 963. This highlights the increasing importance of

intellectual property in fostering innovation (Joseph A. DiMasi a, n.d.).

- Collaboration between universities and corporations is pivotal for discovering new pharmaceuticals. Universities excel at conducting fundamental research and generating novel scientific concepts. In contrast, companies possess the financial resources, technological infrastructure, and expertise necessary to transform these concepts into viable drugs. Such partnerships are instrumental in addressing significant health challenges (Perkmann et al., 2013). For instance, during the COVID-19 pandemic, they facilitated the accelerated development of a vaccine. As the pharmaceutical industry increasingly adopts advanced technologies such as precision medicine, artificial intelligence, and gene therapy, these collaborations will become even more crucial.

- The government has streamlined regulatory processes for pharmacy enterprises by integrating pharmacy sector clearances with the state's Single Window Portal (Invest Haryana). This ensures that approvals and renewals are conducted online within specified timelines, typically 30-45 days. The policy introduces auto/deemed renewal of drug manufacturing licenses, allowing entrepreneurs to retain licenses by paying an online retention fee, thus eliminating cumbersome renewal procedures unless a license is suspended or canceled. Pharma parks are industrial clusters designed to foster pharmaceutical manufacturing and innovation through shared infrastructure, incentives, and regulatory support.

- The act supports the establishment of a Pharma Park in Karnal, aiming to attract an investment of ₹2000 crores and create 25,000 jobs, fostering industry-academia collaboration and infrastructural growth in the sector. Pharma parks play a pivotal role in promoting large-scale pharmaceutical production, enhancing regulatory compliance, and stimulating research and development. By bringing together manufacturers, ancillary industries, and research organizations, these parks facilitate collaboration, reduce operational costs, and accelerate sectoral growth. The **Karnal Pharma Park** is set to be developed on approximately 100 acres in Karnal, Haryana, with the goal of becoming a key pharmaceutical centre in Northern India. This park will accommodate both bulk drug (API) and formulation units, offering amenities such as a centralized drug testing laboratory and an effluent treatment facility to assist companies in meeting regulatory requirements. **Hyderabad Pharma City** in Telangana is recognized as the world's largest integrated pharmaceutical cluster, providing cutting-edge infrastructure for manufacturing, research and development, and training. Meanwhile, the **Baddi Pharma Park** in Himachal Pradesh is a well-established hub for pharmaceutical manufacturing, hosting numerous large and small enterprises.

- The approval process is conducted online, and some timelines are set. These timelines are also fixed by various state governments under the Right to Services Act. In 2019, the Haryana state government implemented the Right to Service (RTS) Act, introducing substantial initiatives to improve transparency, efficiency, and accountability in the provision of public services in the pharmacy sector in India. Drug Inspectors in Haryana are tasked with ensuring compliance, maintaining records, and overseeing the enforcement of prescription drug regulations, including those related to Schedule H and H1 antibiotics. Despite advancements in knowledge and regulatory awareness, studies have identified challenges in implementation and enforcement, mainly due to relatively weak penalties and limited monitoring in retail pharmacies.

- In the case of any delay in the approval/registration, the government has made the deemed approval. The government has also notified the New Drug Clinical Trials

Rules, 2019. The Government of India promulgated the New Drugs and Clinical Trials (NDCT) Rules, 2019, under the Drugs and Cosmetics Act, 1940, to streamline the regulatory framework for the approval of new drugs and clinical trials. These rules represent a significant advancement in promoting ethical research, ensuring patient safety, and positioning India as a global hub for clinical studies.

1. Reduced Approval Timeline: The approval period for clinical trials of new drugs in India has been shortened to 30 days for domestically developed drugs. Drugs already approved in countries such as the US, UK, EU, and Japan receive approval within 90 days.
2. Ethics Committee Approval: Every clinical trial must undergo a review and approval by a registered ethics committee, ensuring the protection of the participants' rights, safety, and well-being.
3. Patient Safety and Compensation: It Medical management for trial participants is mandatory in the event of any injury during the study. Compensation must be provided for trial-related injuries or deaths, with clear timelines established.
4. Waiver of Local Clinical Trials: If drug is already approved in certain developed countries and addresses unmet medical needs, a waiver for local clinical trials in India may be granted, facilitating quicker access to innovative therapies.
5. Promotion of Innovation: Special provisions exist for the approval of orphan drugs (for rare diseases) with reduced requirements. Academic researchers are permitted to conduct non-commercial clinical trials under simplified regulations.
6. Transparency and Accountability: All clinical trials must be registered with the Clinical Trials Registry of India (CTRI), ensuring public access to information and ethical conduct.
7. Regulatory Strengthening: The Central Licensing Authority (CLA) is empowered to grant approvals, with stringent monitoring of trials through periodic safety reports and inspections.

- The 2019 New Drugs and Clinical Trials Rules achieved a balance between fostering innovation and patient protection. By shortening approval processes, enhancing ethical oversight, and ensuring participant compensation, these rules promote research while safeguarding the participants. This reform is anticipated to boost India's position in global clinical development and expedite the availability of modern treatments for patients.

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India's Innovation Policy Landscape: Opportunities and Gaps with the Pharmaceutical Sector in Focus

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India's pharmaceutical sector, long known as the "Pharmacy of the World," is at a pivotal point and has earned this honour by being the leading supplier of affordable generics and vaccines. The future of the pharmaceutical and healthcare sector in India and worldwide will be defined by its ability to move towards value-driven innovation. This transformation is being shaped by global trends that are rapidly changing healthcare.

The major innovation trends shaping the healthcare system include:

- **Adoption of Artificial Intelligence and other technologies**

Artificial intelligence is a booming industry driver across pharma, healthcare and life sciences sectors. The application of AI can already be seen in drug discovery, predictive diagnostics, and clinical trial design, helping reduce timelines and costs.

- **Predictive, Precision and Personalised Medicine**

The push for patient specific treatments through personalised medicine which tailor treatments to an individual's genetic profile and lifestyle factors is one of the key factors of innovation in pharma. It promises higher efficacy and fewer side effects compared to traditional "one-size-fits-all" therapies.

- **Digital Health**

India has seen significant growth in the development and demand of digital health in the form of electronic health records, wearables, telemedicine, and connected devices to create real-time data flows, enabling more informed decision-making and continuous care.

Alongside these global R&D shifts, India's policy environment provides a supportive base for innovation in the pharma and healthcare sector. The liberal foreign direct investment norms in India allow 100% FDI in greenfield and 74% FDI in brownfield projects through automatic mode, with SEBI regulations further facilitate financing for innovation-led ventures.

The National Policy on Research & Development and Innovation in the Pharma-MedTech Sector, notified in 2023, provides the strategic framework for promoting digitization and innovation in pharma. Implemented through the Promotion of Research and Innovation in Pharma-MedTech Sector (PRIP) scheme with an allocation of INR 5,000 crore budget over five years, it focuses on strengthening research infrastructure and funding innovation at multiple levels.

Under the PRIP scheme, INR 700 crores has been allotted to establish Centers of Excellence (CoEs) at seven National Institutes of Pharmaceutical Education and Research (NIPER) with the aim to provide academic and technical capacity. The objective of the scheme is to encourage industries to invest in R&D in designated priority areas.

The policy identifies six priority areas for building a strong innovation pipeline: new chemical and biological entities, complex generics and biosimilars, precision medicine, medical devices, orphan drugs, and capacity building for institutions and researchers.

By promoting strong linkages between industry and academia, the PRIP scheme seeks to create a sustained global competitive advantage and contribute to high-quality employment generation nationwide. This scheme which promotes R&D in pharmaceutical sector will also benefit animal health care market, thus, aligning with the vision of "ONE HEALTH".

Additionally, in the digital health sector, the Ayushman Bharat Digital Mission (ABDM) is building a countrywide digital health ecosystem by creating interoperable electronic health records and digital health IDs. This infrastructure not only improves service delivery but also provides data that can fuel AI-driven research, personalised treatment pathways, and more efficient clinical trials. In this way, the digitization of healthcare complements and strengthens the innovation push in pharma and med-tech.

Opportunities

Public-private partnerships (PPP) are particularly relevant in the Indian context enabling incentivization of early-stage R&D

through government funding. Private firms have the capacity to contribute to execution capacity, capital, and global distribution networks which can be worked in synergy with public players to form co-investment models that employ shared infrastructure and joint research programs. PPPs also help bridge capability gaps in costly areas such as biologics manufacturing and clinical trials where scaling and expertise are critical.

Challenges and Gaps

While ample focus is being places on adoption of innovative means in the pharmaceutical and healthcare sector in the country, challenges to the implementation of the innovation schemes and policies remain significant. The total funding pool is modest compared to global benchmarks, where developing a single drug can exceed USD 2 billion. Pharma companies continue to invest only a small fraction of their revenues in R&D relative to their global counterparts.

Additionally, the financial support earmarked for start-ups is often insufficient given the capital intensity of drug development. Moreover, ambiguity in funding selection criteria raises the risk of misallocation. The intellectual property framework also requires stronger public interest safeguards and innovation-oriented protections, to ensure affordability and equitable access.

Global View

The United States exemplifies the positive impact of substantial public investment in basic science through institutions like the National Institutes of Health (NIH). This is complemented by a supportive commercialization environment and effective public-private partnerships which have proven their ability to deliver rapid and large-scale breakthrough This was notably demonstrated during the pandemic with the swift development of vaccines.

Similarly, China demonstrates transformation of the innovation and consumer protection ecosystem with regulatory streamlining, large-scale R&D investment, and the development of innovation clusters integrating pharma, biotech, and digital health.

India's pharmaceutical industry has the chance to redefine its role in the global value chain. The country's generics strength provides a stable base, but it must now build a parallel engine of innovation. With enabling FDI norms, SEBI support, a national R&D policy targeting six strategic areas in pharma, the Indian pharma policy landscape is growing stronger.

To realize its full potential, India must significantly increase investment in research and development, strengthen public-private partnership models, and ensure precise and effective execution of policies. These measures are critical for transitioning from India being a predominantly generic drug supplier to a globally recognized innovator in pharmaceuticals and medical technologies. With a strategic focus on innovation, regulatory clarity, and collaborative ecosystems, India can position itself at the forefront of the next generation of healthcare solutions.

Strengthening the US–India Pharmaceutical Innovation Corridor: Policy Pathways for Discovery-Led Growth

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The United States and India have a longstanding relationship in pharmaceuticals. India, often called the "pharmacy of the world," supplies nearly 47 percent of America's generic drugs. The U.S. is also India's biggest export market for Indian-manufactured pharmaceuticals, accounting for more than 31 percent of India's total pharma exports. Earlier this year, President Trump and Prime Minister Modi set an ambitious goal of more than doubling bilateral trade to $500 billion by 2030. But to achieve this vision, the relationship must evolve from a transactional buyer-supplier dynamic to building a U.S.–India pharmaceutical innovation corridor in which the two countries collaborate not merely on low-cost medicines, but on cutting-edge drug discovery, clinical trials, and manufacturing of novel therapeutics.

India already possesses the foundations for such a transformation. It operates more than 650 FDA-compliant drug manufacturing plants - the largest number outside the United States - and has become globally recognized for its capacity to produce high-quality generics at scale. But this success has also limited the country's growth prospects - Indian pharmaceutical firms have historically invested just 6 percent of revenues in research and development, compared to roughly 17 percent for global industry leaders. As a result of which India's pharmaceutical success has been primarily in producing low-cost generics rather than pioneering new molecules or platforms.

That is now changing. Since India strengthened its patent regime in 2005 to comply with WTO-TRIPS obligations, the innovation ecosystem has steadily matured. Pharmaceutical R&D spending is rising, domestic patent filings have reached record highs, and India's ranking on the Global Innovation Index has jumped from 81st in 2015 to 39th this year. The country's $55 billion pharmaceutical market is expected to double by 2030, and early examples of homegrown vaccines and drugs are emerging. However, a leap from generic production to discovery-led growth will require sustained support from allies such as the US.

One priority is deepening trade cooperation. Pharmaceutical products are exempt from current tariffs, yet proposed tariff-rate quotas and potential 200–300 percent duties under Section 232 reviews would significantly harm India's export-based generics industry. Towards this end, it would be crucial to prioritizes life sciences in the on-going bilateral trade negotiations and lock in tariff exemptions, ease import procedures for drugs and ingredients, and create incentives for technology transfer. It could also include fast-track mechanisms for regulatory approvals and specific investment protections for companies engaged in joint research or co-production. Such provisions would send a strong signal of long-term strategic commitment and encourage companies on both sides to invest in higher-value collaboration instead of maintaining the status quo.

Investment and co-production are equally essential. Much of India's pharma innovation is currently driven by small biotech startups and contract research organizations that do not have access to requisite capital or global market experiences. U.S. companies can help by investing in these emerging players, forming research partnerships, and sharing best practices through co-development agreements. Conversely, Indian pharmaceutical firms should be encouraged to expand manufacturing footprints in the United States, particularly for critical medicines and biologics. These cross-investments not only build trust but also embed shared interests in long-term innovation.

At the heart of any discovery-led ecosystem lies intellectual property. Drug R&D is risky and capital intensive; companies invest billions of dollars and often face years of uncertainty. Strong IP frameworks that cover patents, data exclusivity and regulatory data protection provide the confidence firms need to invest at scale. While India has made significant improvements since adopting product patents in 2005, concerns remain regarding enforcement, the risk of arbitrary compulsory licensing, and weak protection for clinical data. This partly explains why Indian firms still spend only about 0.3 percent of GDP on R&D, far below the global average.

US and India should therefore establish a high-level bilateral task force to align patent examination procedures, improve enforcement mechanisms and address gaps in data protection. For instance, India could introduce limited data exclusivity for biologics and streamline its patent dispute resolution processes whereas US companies could commit to technology transfer and joint development. Such reciprocal steps would make it economically rational for Indian firms to

invest more aggressively in drug discovery and would equally reassure US innovators that collaborative research in India would be protected.

Regulatory alignment is another crucial pillar of the innovation corridor. The FDA and India's CDSCO have a long history of informal collaboration, including joint inspections and training programs. But to truly accelerate innovation, the two regulators should move toward a mutual recognition framework. This would allow each country to accept quality inspections and clinical trial data conducted by the other, significantly reducing duplicative reviews and shortening the time-to-market for innovative drugs. Regular bilateral regulatory dialogues should also be institutionalized to harmonize guidelines for emerging therapies such as cell and gene technologies where regulatory uncertainty is often a bigger hurdle than scientific challenge.

At the same time, both countries should leverage public-private partnerships to jointly build resilient manufacturing capacity for critical pharmaceutical inputs, such as active pharmaceutical ingredients (APIs) and vaccines. The pandemic exposed the risks of over-dependence on a handful of production hubs, and a more distributed supply chain would allow the US and India not only to respond faster to shocks but to scale up newly discovered therapies more efficiently. Co-investment in API parks or vaccine manufacturing hubs in India combined with Indian investment in essential drug production in the United States would ensure that the benefits of innovation can reach patients in both countries without bottlenecks.

Taken together, these steps would transform the U.S.–India pharmaceutical into a truly strategic partnership where we could see co-developed drug candidates, shared clinical data, and simultaneous approvals in both markets. American scientific capital paired with Indian frugal innovation capabilities could generate game-changing therapeutic breakthroughs. But this future will not materialize on its own. It will require enlightened policy, sustained collaboration and a willingness to modernize outdated frameworks to match the pace of scientific progress.

At a time when the world urgently needs affordable and innovative healthcare solutions, US and India have an opportunity and arguably a responsibility to lead. By aligning trade rules, strengthening IP frameworks, harmonizing regulatory standards and investing together in resilient supply chains, both countries can catalyze a new era of discovery-led growth. The journey from generics to genuine innovation is neither easy nor automatic. But if they choose to walk it together, the United States and India can build a pharmaceutical corridor that not only strengthens their own societies but delivers life-saving medicines to patients around the world.

The role of R&D and patents in nation building

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Relevance of R&D in Nation building:

In a technological era, a genuine Research & Development ecosystem fosters innovation and subsequently drives industrial growth and nation building. The R&D encompasses series of methodical experimentation and investigation culminating into creation of novel concepts & new knowledge. Now the question is, why and how to encourage innovation so that substantial societal issues can be addressed on a wider scale. Firstly, it is required because innovation protects economic & technological base while it also facilitates sustainability and overall national security.

Innovation can be encouraged by creating a culture where novel ideas could emerge, be tested that could turn into a new products or processes. The researchers should be encouraged to carry out experiments without the fear of failure and celebrate successes and also well thought failures. This strong R&D ecosystem cannot be built in-silos but requires interdisciplinary team work at the national level wherein different perspectives from academia, industry and government could be combined.

In India R&D has already taken a leap in the area especially Pharmaceuticals, renewable energy and IT sectors. If we

focus on strengthening R&D in these areas, then it will ensure transforming from being a service driven economy to innovation driven economy that will culminate into self-reliant power center. R&D is no restricted to laboratory itself, but it has direct impact on social well-being. Needless to mention that India's green revolution in 1960's driven by agricultural research made the country self-sufficient while Indigenous vaccine development during COVID-19 pandemic strengthened India to be reckoned as "Pharmacy of the world". It is noteworthy to mention that India's progress in defense research and space technology highlight as to how R&D could make significant impact to position India as a global leader in these cutting-edge areas,

Overall, R&D serves as a vital component that transforms new knowledge into key solutions for the unmet societal and industrial needs and the future R& D can uplift millions of lives. It can It also enhances community well-being and creates ample of employment opportunities.

Role of Patents:

There are certain strategic sectors like Agriculture, healthcare & Pharma, Defense & Space and energy sectors which may play a big role in nation building. The nation building strongly demands link between R&D and patents. It is unique in the sense that unless we protect or incentivize the innovation we cannot ensure return on investment that is required to fuel further research. A patented invention doesn't just benefit its innovator; it also becomes a national asset. This modality creates a competitive environment where we can ensure efficiency, quality and safety of new indigenous products or processes that suits local market needs at affordable prices. Effective patent portfolios can augment collaboration, attract investors and may open the doors for commercialization.

Currently, "Make in India" initiative have undoubtedly emphasized the importance of indigenous innovation. If this innovation is paired with strong R&D investment and a more rationalized patent process, we can allow our country to produce world-class technologies along with capacity building. Intellectual property becomes not just a legal concept, but a stepping stone towards global recognition and influence. It is onus on our shoulders to create an environment and ecosystem where the innovators get the confidence that their efforts will be dealt fairly and the risk will be rewarded. Moreover, we need to build a culture for the continued incentive linked support for the innovation.

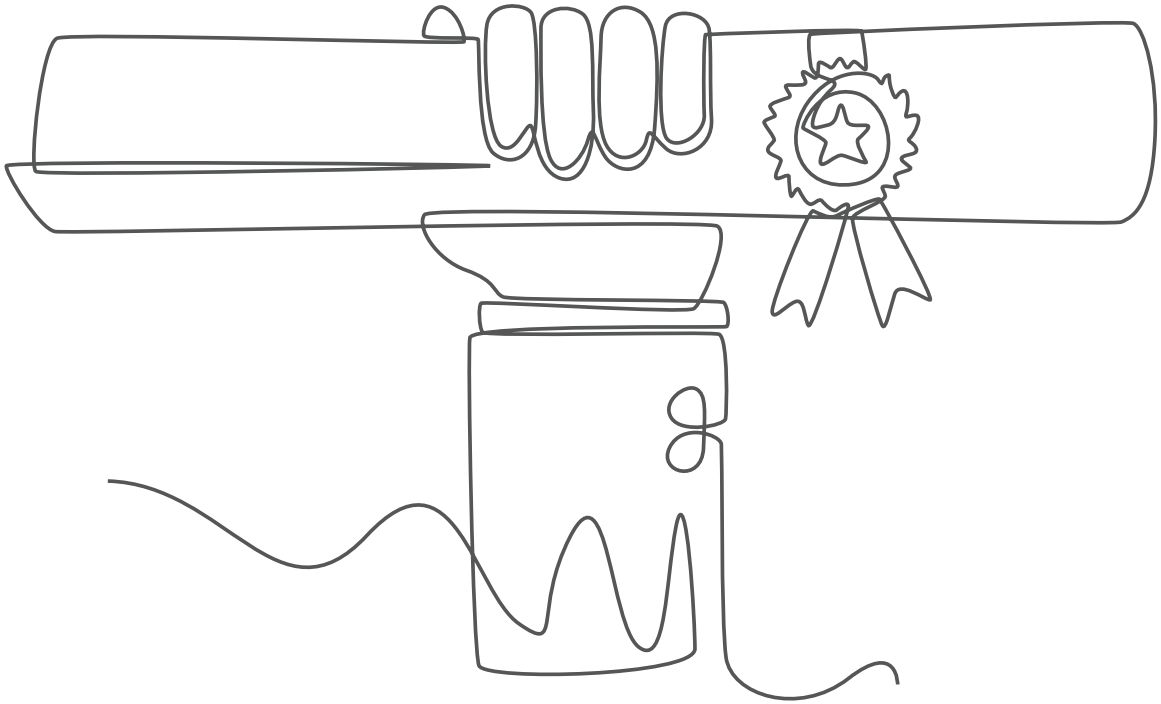
We can prioritize patenting in critical sectors like pharmaceuticals, space, semiconductors, artificial intelligence etc. to acquire global leadership and independence. We should also encourage to train researchers, startups, and MSMEs about patents and simplifying procedural complexities to enhance domestic filing. If we look towards few developed nations, they consistently take leap forward in technological innovation and economic resilience. In this line we can also create an environment by adapting frameworks where the society respects ideas and reward them in a consistent manner. Nation building is all about empowering people to envisage, create and expand in the context of innovation. In this scenario R&D opens up avenues which encourages young minds to be like a problem solvers and innovators.

Challenges and way forward:

Although there are challenges especially for developing nations, investment in R&D is irregular and patent awareness is low. The complexity of processes and cost involved are highly deterrent in patenting by MSMEs and startups. However, it is to be noted that several solutions are emerging

like government is offering tax benefits, simplifying patent laws and encouraging public-private partnership. Over a period of time when these processes are evolved, it would become clear that innovation is everyone's cup of tea and not just for scientists in the lab but also for the farmers, teachers, engineers and entrepreneurs.

Eventually, the role of R&D and patents in nation building cannot be measured just in terms of statistics or GDP graph but it lies in the ability of a nation to harness its own potential. It is actually all about as to how the lives of people has improved or jobs created and ideas born that were once considered impossible. R&D facilitates nation to dream big, imagine the future while patents secure the future Insafe and capable hands. The CSIR-CDRI Communication Number Allotted to this paper is 11047.



The Patent Amendment Rules 2024...Paving A New Pathway For Speedy Processing Of Pre-Grant Patent Oppositions

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Pregrant Opposition Proceedings in India has been in practice for over one hundred years. Section 9 of the Indian Patents and Designs Act 1911 (II of 1911) provided for pre-grant patent opposition proceedings, wherein *any person with the payment of a prescribed fee at any time within 3 months of the date of advertisement of the acceptance of a patent application could give notice at the Patent Office to oppose the grant of a patent on specified grounds.* The Controller was empowered in such cases to give notice of opposition to the applicant, and on expiration of those three months, after hearing the applicant and the opponent, if desirous of being heard, decide on the case. The decision of the Controller was subject of appeal to the Governor General in Council".

In 1948, a "*Patents Enquiry Committee*" appointed by the Government of India was commissioned to review the Indian Patents and Designs Act 1911. The Committee submitted an interim report and the Indian Patents and Designs (Amendment) Act, 1950 was enacted to give effect to the main recommendations in that report. The final report of the "*Patents Enquiry Committee*" was submitted in 1950. A *Bill No. 59 of 1953, was introduced in the Lok Sabha, proposed the elimination of opposition proceedings and the same be*

replaced (Clause 21 of the Bill) *by a procedure by which after the acceptance of a specification, and its being thrown open to public inspection by advertisement, there should clapse an interval of four months within which any person might inform the Controller specified grounds upon which the grant of the patent might be withheld by him, and if after considering the points set out, he came to the conclusion that the objection was well-founded, he could refuse the patent. This recommendation of the Review Committee was based on their observation that opposition proceedings in the past have proved frivolous and obstructive, further causing serious delays and substantial loss to the effective term of a patent* The Bill, however, was not proceeded with, and it lapsed.

In April 1957, the Government of India requested Justice N. Rajagopala Ayyangar to advise on the revision of the law relating to Patents and Designs. Justice Ayyangar's report titled "*Report on the Revision of the Patents Law*" submitted in September 1959 formed the basis of the Indian Patents Act 1970. He stated that the proposed step of eliminating opposition proceedings is retrograde, and that it is neither in the interests of the patentees themselves nor calculated to further the progress of research or industry in India. His study concluded that oppositions during the period 1950 to1957, were not entered with malafide view to blackmail poor inventors. He recommended retention of the Opposition Proceedings in the public interest by inviting the cooperation of those who are interested in the invention by entering an opposition and pointing out to the Controller the deficiencies of the invention which would render it unpatentable. This was the genesis of Sections 25 (Opposition to grant of patent) and Section 27 (Refusal of patent without opposition) of the Indian Patents Act 1970.

The Patent Act 1970 as amended in 2005 split the Section 25 into Sections 25(1) [pre-grant opposition] and 25(2) [Post Grant Opposition] with Rule 55 of the Patent Rules 2023 governing the procedures for patent oppositions. Section 27 was dropped.

The pregrant opposition under Section 25(1) could be *filed without a fee*, by any person after the publication of the patent application until the grant of the patent, citing specified grounds. No patent would be granted before the expiry of a period of 6 months from the date of publication of the patent application (Rule 55). Further, if the Controller was of the opinion that the patent application is be refused or the complete specification requires amendment, he had to give a notice to the applicant to that effect along with a copy of the representation. The applicant was entitled to respond with their own statement and evidence. After due consideration of both parties' submissions and a hearing, the Controller could either reject the opposition, refuse the patent, or direct amendments before granting the patent by issuing a reasoned order, ordinarily, within one month from the completion of the proceedings.

Of the 1,500 oppositions during the period 2019-2022, only 102 were disposed of. The average time to dispose of a patent application was between 5 and 10 years. Thes inordinate delays were because of oppositions filed by individuals without proper credentials, filing of serial oppositions, delay by Controller to initiate opposition proceedings, adjournment of proceedings, delayed hearings and issuance of decision by the Controller.

The Amendment to the Patent Rules 2003 was notified on 15 March 2024. Rule 55 was amended to address the identified issues thereby facilitating speedy and transparent pregrant opposition proceedings.

For pre-grant opposition,

- a filing fee of Rs 4000 (for natural persons) and 20000 (other than natural person) has been introduced.

- The Controller is required to make an assessment on whether a prima facie case is made out in the pregrant representation before notifying the applicant of the pre-grant opposition.

- If according to the Controller, a prima facie a case is not made out and the opponent has not requested to be heard in the matter, the Controller must notify the opponent and pass an order recording the grounds for refusal of the representation within one month from the date of such notification.

- If a prima facie case is not made out and the opponent has requested an opportunity for a hearing, the Controller shall provide an opportunity of hearing, and pass an order within one month from the date of hearing, recording reasons for refusal or prima facie acceptance of the representation and notifying the applicant accordingly.

- If a prima facie case is made out in the representation, the Controller shall, within one month of receiving the representation, pass an order recording his reasons and notify the applicant accordingly.

- If a prima facie case is made out, the examination will be conducted as per the procedure for expedited examination.

- If either party desires to be heard in a pre-grant opposition, the parties must give notice to the controller along with the payment of the requisite fee (INR 7500 for large entities and INR 1500 for others).

During the period from 01.04.2014 to 29.07.2025, the patent office received 3351 unique pre-grant oppositions in different technological fields/subjects of which 2444 have been disposed with the following breakup: Granted – 1038, Refused – 804, Deemed to be abandoned U/S 21(1) of the Act – 459, Withdrawn – 131 and Others – 12. As of 31.07.2025 a total of 907 pregrant applications are pending.

Substantial enhancement of the infrastructure and human resource implemented in the patent office have boosted the disposal of the patent applications and patent oppositions.

As of 30.06.2025, total strength of Controllers and Examiners in the Patent Office is 1294. Since the amendment of Rule 55, several pregrant oppositions have been received. As per the amended Rule 55, the Controllers have done the mandated due diligence and disposed of many cases in which a prima facie a case is not made out in the pregrant representation. For 411 cases, hearing has been fixed. Further, for 262 cases, hearing has been fixed since the new amended Rules came into effect. In July 2025, 15 pre-grant oppositions have been received. During July 2025, 48 pre-grant oppositions were disposed of.

The Patent Amendment Rules 2024 supported by enhanced human resource has now paved a new pathway for speedy processing of pre-grant patent oppositions.

Balancing Access and Innovation under the Indian Patent Act

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India's pharmaceutical industry is one of the great success stories of independent India.

India is among the world's leading producers of cost-effective generic medicines and vaccines. The landmark Indian Patents Act of 1970 (often associated with later TRIPS-related reforms in the 1990s) enabled the industry to focus on process patents rather than product patents, which in turn fostered innovation in reverse engineering, built robust capabilities in Active Pharmaceutical Ingredients (APIs) and formulations, and strengthened the domestic manufacturing ecosystem. This shift allowed India to become self-sufficient in meeting domestic demand and positioned it as the "Pharmacy of the World."

Today, India supplies around 20% of the total global demand for generic medicines by volume and contributes ~60% of global vaccine demand. It is a key supplier to international health initiatives such as Gavi, the Vaccine Alliance, the Global Fund, and UNICEF, and plays a critical role in ensuring affordable access to essential medicines and vaccines in both developed and developing countries.

While India's pharma industry was growing well and creating

strong manufacturing and process innovation foundation, in line with its WTO commitments, India undertook a major overhaul of its intellectual property framework in January 2005 to align with the TRIPS Agreement. The amendments to the Indian Patents Act reintroduced product patents for pharmaceuticals, established a uniform 20-year patent term, and modernized procedures for patent examination and enforcement to meet international standards. At the same time, the revised law incorporated key public health safeguards, such as Section 3(d) to prevent evergreening of patents and provisions for compulsory licensing, ensuring that the shift toward stronger IP protection did not come at the cost of affordable access to essential medicines.

Section 3(d) is unique in blocking "evergreening," denying patents for minor tweaks to known drugs unless they deliver significantly improved therapeutic efficacy. In Novartis v. Union of India (2013), the Supreme Court ruled that imatinib mesylate (Gleevec) failed this test — higher bioavailability alone wasn't enough. Alongside 3(d), compulsory licensing serves as a public health safeguard, used sparingly but decisively, as in Bayer's Nexavar case, to ensure access during health emergencies. Together, these tools embody India's ongoing balancing act between affordable access and pharmaceutical innovation.

Further, India has implemented supportive policies to boost local innovation. The Production-Linked Incentive (PLI) Scheme for Pharmaceuticals allocates ₹15,000 crore (≈USD 2 billion) through 2028–29 to boost domestic manufacturing in high-value segments: biopharmaceuticals, complex generics, patented drugs, cell/gene therapies, and orphan drugs, key starting materials (KSMs) and critical APIs and also in-vitro diagnostics (IVDs) with an objective to reduce import dependence, and strengthen India's position in global value chain. The ₹5,000 crore Promotion of Research and Innovation in Pharma-MedTech (PRIP) scheme, expected to begin disbursals by end of 2025, aims to mobilize an additional ₹17,000 crore in R&D investment—signaling a strategic shift from generics to innovation. The Anusandhan National Research Foundation (ANRF) Act, 2023, enacted in August 2023 and effective from December, strengthens India's research backbone by coordinating public-private R&D in health tech and allied disciplines.

These programs not only build critical manufacturing and research infrastructure but also de-risk investments and provide direct financial incentives for innovation-led pharmaceuticals — addressing one of India's most persistent gaps: limited local R&D capacity for novel, high-value products.

Over the past decade, India's annual R&D spend by pharma firms has risen to around 7–8 percent of sales (albeit still behind global levels of 15–20 percent), and notable homegrown innovations such as the antibiotic Nafithromycin and novel vaccine platforms (e.g., ZyCoVID) demonstrate a maturing innovation ecosystem.

The real test, however, is whether these interventions have truly set in motion a self-sustaining "flywheel of innovation" or if they remain isolated boosts requiring further policy and ecosystem support. Despite the progress, several structural and operational challenges continue to constrain India's ability to translate incentives into globally competitive, innovation-driven outcomes. Even twenty years after TRIPS implementation, the value of patented products in Indian pharma market is still <10% - although growing quickly off a small base.

New therapies that are launched in India, have a significant time lag over those in global markets. A 15-year analysis of drug approvals/launches in US, Europe & Japan revealed that the relative lag in drug approvals by the CDSCO vs. the US FDA was 43.2 months, 25.6 months vs. European Medicines Agency was 25.6 months and vs. PMDA (Japan) was 30.3

months. vs. PMDA (Japan). The absence of Regulatory Data Protection (RDP) and the unpredictability of pricing and IP enforcement hampers commercial viability. Thus MNCs are still shy of bringing their newest launches to India in time.

Global pharmaceutical R&D investment surpasses USD 200 billion annually, while for Indian companies spend only ~7% of their sales on R&D ($2-4 billion annually). Consequently, there haven't been a lot of New Chemical Entity (NCE) launches from Indian companies yet , <10 novel drugs vs. >200 each in the US and EU in last 5 years!

Thus, several imperatives are needed to ensure that India can scale from a generics leader to a true hub of pharmaceutical innovation.

Strengthen and Clarify the Regulatory Framework.

The government should uphold strong and predictable patent norms while enhancing transparency in decision-making. This includes clarifying interpretations of Section 3(d) to reduce uncertainty, limiting the scope for arbitrary compulsory licensing, and bolstering the capacity and technical expertise of the patent authorities. Industry stakeholders have also called for the phased introduction of Regulatory Data Protection (RDP) to responsibly attract innovation while balancing affordability and alignment with global norms.

Expand Healthcare Financing for High-Value Therapies.

Scaling up healthcare financing is critical to support patient access to advanced, high-cost treatments must be supported by scaling up healthcare financing. This can be achieved through expanded public and private insurance coverage, outcome-linked reimbursement models, and procurement frameworks tailored for advanced therapies such as cell and gene treatments.

Build Robust R&D Infrastructure and Ecosystems.

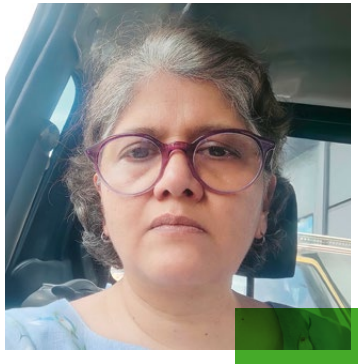
India must invest in upgrading its research infrastructure and creating innovation hubs with integrated capabilities — from discovery to commercialization. Public–private partnerships in priority disease areas can help share R&D risks, align innovation with public health needs, and fast-track solutions for high-burden conditions.

Industry-Led Actions:

Innovation inherently involves risk — the cost of technology, capability building, long gestation periods, and even failure. To address this, industry players should seek patient capital and adopt models that align profitability with accessibility. MNCs can bring patented drugs faster to Indian market, implement tiered pricing, and invest in patient access programs – to improve uptake of innovative therapies. They can also expand voluntary licensing and co-marketing arrangements to leverage India's manufacturing strengths while keeping prices in check.

By combining predictable regulation, sustainable financing, upgraded R&D capacity, and collaborative industry leadership, India can create a virtuous cycle — where innovation and access reinforce each other, securing the country's position not just as the "Pharmacy of the World" for generics, but as a source of groundbreaking, affordable therapies for the future.

A Pharmaceutical Journey that Tests and Toughens



PT Jyothi Datta

Deputy Editor, The Hindu-businessline

The last thirty years have been nothing short of dramatic for pharmaceutical companies in India, when it comes to the slew of changes on the patents front, the nudge up the innovation curve, and Covid-19 - a pandemic not seen in a 100-years.

No matter which side of the aisle one stands – multinational company (MNC) or domestic drugmaker – the pharmaceutical industry has been kept on its toes, thanks to the everchanging regulatory and geo-political landscape. And as a journalist, it's been more than just a ring-side view of these historic changes – it has been a journey of non-stop learning as well.

The tide turned (again, one may say) on product patents, in January 1995, when India became a member of the World Trade Organization. But the energy and excitement of understanding, and writing on global discussions on patents and public health, happened for me, with the Doha ministerial conference (2001). Representatives involved with these meetings shared with some of us in India, the historic decisions taken on public health – flexibilities that were drawn up, so countries could protect the health of its citizens.

That being the backdrop, the stage was set for intense discussions and legal battles back home. Domestic

drugmakers braced for the time when product patents were to honoured. And multinational drugmakers readied to bring in innovative medicines, using the law to keep possible generics at arms-length. Meanwhile, another stake-holder's voice began to get heard in this battle - that of public health advocacy groups who red-flagged high prices on innovative medicines. And although innovative drugmakers were at pains to put distance between patents and pricing, there was no escaping the discussion, in a country where people fork out money from their own pockets for medicines and healthcare services.

While concerns that medicines were getting priced beyond the reach of ordinary citizens, gained momentum – two benchmark patent-related cases were fought in Indian courts – on technicalities. Novartis's blood cancer drug Glivec was at the centre of a high-profile and high-decibel legal battle. The case at the Supreme Court reinforced Section 3 (d), of the amended Patents Act (2005), and the idea that an incremental innovation needed to establish enhanced efficacy as well. The idea of curbing "ever-greening" (tweaking a known product and seeking patent protection) is not out of sync with global regulatory yardsticks and technical assessments, where companies are required to establish that their product is more effective than the existing standard of care.

The other critical case under the amended Patent regime involved Bayer's advanced kidney cancer drug Nexavar – and the decision by the Indian Patent Office (IPO) to allow a compulsory license (CL) on it. The CL allowed domestic drugmaker Natco to make its version of the drug, at a reduced price and on payment of royalty to the innovator.

Besides the CL and Section 3(d), other features like pre / post-grant oppositions are also points that come up during global discussions and trade talks between countries.

Some of these legal provisions and Court decisions split the pharmaceutical industry wide open - on access and affordability of medicines; the fine print involving the cost of innovation, working of patents etc. As a media representative who watched some of these arguments play out at the IPO (Mumbai) – it became crystal clear, such debates were indeed necessary. Because what emerges in the end, is a legal framework that's tested, and a verdict that was well-argued and anchored in law. And that's something that pharmaceutical industry representatives agree on, even if they disagree with the precise verdicts.

Learning on your feet

When it comes to medicines and health, there is the worry that emotions will rule and innovative efforts will not get the recognition it deserves. But that does not seem to be the case, as till date, companies and health advocacy groups battle it out on patents and medicine prices, in the interest of the patient. In fact, these discussions also paved the way for initiatives like the Patient Assistance Programme, to support those who cannot afford expensive medicine. And while that in itself can be a point of discussion, the fact remains that all of this has tumbled out into the open in the last three decades. And that's a lot of learning on your feet, so to speak.

Covid-19 put governments and healthcare providers on the mat like none other. But as agencies worked with information that was publically shared by global regulators – drugmakers too started collaborating on vaccines and medicines – through technology transfers and voluntary licenses. Industry-watchers may have different views on how the pandemic should have been approached in terms of policy decisions and so on. But the silver lining is that terms like "equitable distribution" and "access planning" have

been introduced into the conversation. And hopefully, they become a permanent part of it.

Testing times

As 2025 draws to a close, there are too many moving parts – strife in multiple regions and the shadow of tariffs over medicines imported into the United States. While there's much at stake for corporates – years down the line, this too will be a learning. Is it wise to import critical products from other countries, and be caught on the wrong foot in the face of a health emergency – as Covid-19 illustrated to the world? Or does it make sense to produce medicines on home turf? But then again, how would making products locally impact prices?

Looking outwards from India, drug companies will need to navigate these turbulent times, even as it caters to a large and receptive home market. Newer physical and digital technologies looking to cut short research timelines or do away with regressive animal studies, for example, are available in the tool-kit. The journey is poised to take on a fresh trajectory with AI, 3D and so on, but in times that will test the mettle of pharmaceutical companies, young and old.

(The writer is Deputy Editor, The Hindu-businessline. Views are personal.)

India's Ongoing Innovation journey Toward Viksit Bharat

Dr. Rajeev Ranjan

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Introduction

India today stands at the crossroads of transformation. As the country aspires toward the vision of Viksit Bharat by 2047, it must embrace innovation as the primary driver of growth, competitiveness, and healthcare access. In this journey, Intellectual Property Rights (IPR) play a pivotal role not merely as legal safeguards, but as strategic enablers that turn ideas into therapies, patents into products, and knowledge into national wealth.

For the pharmaceutical sector, IPR serves as the bridge between scientific discovery and patient benefit. It ensures that India continues to be the "Pharmacy of the World" while also emerging as a global leader in novel therapies and cutting-edge drug discovery.

India's Innovation Performance: Rising but Room to Grow

India's steady rise in the Global Innovation Index from 81st place in 2015 to 39th in 2024, signals growing recognition of its innovation ecosystem. The country leads in ICT services

exports, venture capital flows, and the creation of unicorns. Importantly, India produces more innovation outputs than inputs, demonstrating high efficiency in converting resources into tangible results.

Yet, a closer look at R&D investment reveals a challenge. India spends less than 0.7% of its GDP on research, far below the global average of 1.8% and significantly lower than innovation leaders such as South Korea and Israel. To achieve the vision of Viksit Bharat, India must aim for at least 1.5–2% of GDP in R&D expenditure, with stronger private sector participation alongside public investment.

Pharmaceuticals: From Generics to Innovation

India's pharmaceutical industry is valued at nearly US$50 billion and is projected to grow to US$130 billion by 2030. For decades, India's strength has been its unrivaled capability in producing affordable generics, exporting to over 200 countries, and supplying more than 60% of global vaccine demand.

The future opportunity lies in innovation-led growth. The Production Linked Incentive (PLI) scheme and policies to boost indigenous API manufacturing are important steps. However, to move up the value chain from being a cost-competitive manufacturer to becoming a global innovator India must prioritize new drug discovery, biologics, and precision medicine.

A robust IPR ecosystem assures innovators that their investments will be rewarded. It also enables partnerships, licensing, and technology transfers that expand patient access. However, investments in high-risk, long-cycle R&D may falter without strong and predictable IP protections. Therefore, IPR becomes the crucial enabler of this transformation.

AI and the Future of Drug Discovery

Artificial Intelligence is rewriting the rules of drug discovery. Algorithms can now identify promising molecules in months rather than years. Indian startups and academic labs are beginning to integrate AI with clinical and chemical datasets, accelerating the path from lab to patient.

This revolution raises several critical IPR questions:

- **Inventorship:** Can an AI system be credited as an inventor, or must all IP remain tied to natural persons?
- **Data Rights:** Who owns discoveries generated from training datasets shared by hospitals, research institutions, or companies?
- **Premature Patenting:** With AI generating thousands of molecules, how can we avoid cluttering the system with weak and unvalidated patents?

India has an opportunity to become a thought leader by shaping policies that balance innovation with accessibility. Such policies should ensure AI-driven discoveries are protected without creating barriers to genuine medical progress.

The Patent Cliff: Risk and Opportunity

Globally, the pharmaceutical industry faces a patent cliff by 2027–2028, with over US$180 billion in drug revenues at risk as patents expire on blockbuster therapies. For India, this presents two possible scenarios:

1. **Opportunity:** Indian companies can step up as suppliers of affordable generics and biosimilars, reinforcing their global leadership in access.
2. **Challenge:** Domestic innovators must protect their IP while scaling up R&D pipelines to remain competitive in novel therapies.

Managing this duality will require strategic IP management, effective patent enforcement, and policies that encourage both affordability and innovation.

Research and Human Capital: The Missing Link

India produces one of the world's highest numbers of PhDs in science and engineering annually, but the density of researchers per million people remains low compared to global peers. To harness its demographic dividend, India must:

- Increase researcher density from the current 140 per million to at least 500 per million by 2040.
- Strengthen academia-industry collaborations to translate research into commercially viable products.
- Expand fellowships and global exchange programs to nurture talent in frontier fields such as genomics, biologics, and AI.

Public institutions like CSIR already hold more than 14,000 patents, but commercialization remains limited. Bridging this gap between knowledge creation and market application is central to India's innovation ambitions.

Policy Priorities for Viksit Bharat through IPR

To align the IPR ecosystem with the national development agenda, India must:

- **Increase R&D Intensity:** Double R&D spending to 1.5–2% of GDP, with tax incentives and venture capital support for pharmaceutical innovation.
- **Strengthen IP Enforcement:** Streamline patent processes, reduce litigation timelines, and clamp down on piracy and counterfeiting.
- **Balance Innovation and Access:** Protect high-risk innovation while ensuring patient access to essential medicines.
- **Leverage AI Responsibly:** Frame policies on AI inventorship, data rights, and prior art to encourage innovation without creating legal uncertainty.
- **Promote Collaboration:** Encourage global research partnerships and cross-licensing agreements to accelerate breakthroughs.
- **Skill India's Talent:** Expand STEM education and create career pathways for researchers to build a deeper innovation workforce.

Conclusion

The path to Viksit Bharat runs through science, innovation, and intellectual property. India has already proven itself as a trusted partner in global healthcare through its role as the "Pharmacy of the World." The next frontier is to emerge as a hub of original innovation producing not just affordable medicines, but also first-in-class therapies that change the course of disease worldwide.

In this journey, IPR is not merely a legal safeguard but the foundation of a sustainable innovation ecosystem. It reassures inventors, attracts investments, and builds confidence in India as a global innovation partner. With the right policies, investments, and a sharper focus on R&D, India can transform its intellectual capital into tangible outcomes making innovation the true engine of its march toward Viksit Bharat 2047.

Viksit Bharat:
Let's Lead with Innovation

Rajwinder (Raji) Mehdwan

MD and CEO, Roche Pharma India

As India approaches 2047—the centennial year of its independence—Viksit Bharat stands as a bold vision for inclusive, sustainable development. Economic growth grabs the headlines, but true progress lies in the health of our people. A healthier population means thriving and happy families, fewer missed school days, stronger workforces, vibrant communities and reduced strain on health systems. At its core, healthcare is not just about treating illness, it is about enabling a nation to thrive.

India has made encouraging progress toward this vision. Over the years, India's health expenditure has seen a significant shift towards public funding with Government spending as a share of total health expenditure rising from 29% in 2014–15 to 48% in 2021–22, reducing the financial burden on citizens. Government initiatives such as Ayushman Bharat have modernized primary care and brought millions under the umbrella of public insurance. At the same time, the private sector has expanded access to high-quality healthcare, leveraging cutting-edge technology and innovative delivery models. Together, these public and private efforts have strengthened the foundation for a more resilient healthcare system.

But the journey to Viksit Bharat has just started. The growing burden of non-communicable diseases, compounded by an ageing population, threatens to outpace these advancements. To fulfill this vision, we need transformative solutions—powered by bold innovation across the healthcare ecosystem.

Innovation: The Healthcare imperative

Innovation is the spark that drives breakthroughs in healthcare. It has the power to transform what once seemed impossible into reality—to turn a terminal diagnosis into a treatable condition, to make the inevitable into something preventable.

Think of breast cancer. Decades ago, it was a devastating diagnosis for many women. Today, thanks to relentless advances in diagnostics and targeted therapies, millions are living longer, healthier lives. This transformation didn't happen by chance—it happened because deeply committed scientists, physicians and pharmaceutical companies invested, nurtured, supported, and brought innovation to market.

But innovation isn't just about breakthrough treatments. True transformation lies in reimagining every step of the patient journey. It's about driving awareness to prevent illness before it takes hold. It's about leveraging AI-powered diagnostics for early, more accurate detection. It's about improving access to cutting-edge therapies and using digital technology to connect care seamlessly—from the remotest villages to the busiest urban hubs.

The future of healthcare innovation in India calls for investment not just in treatments, but in prevention, early detection, and holistic care. Decentralized care delivery, value-based reimbursement models, and data-driven public health interventions must all be part of this transformation. Achieving the vision of Viksit Bharat will require sustained investment to build a health system driven by innovation and technology, adopt an outcome and impact based approach and make evidence-informed investments that serve both patients as well as national priorities. Most importantly, we have to join hands - it is not going to be a single entity effort. The common agenda must be to put Indian patients at the centre.

Putting Primary Care First

If healthcare is the foundation of Viksit Bharat, then primary care is its bedrock. When our primary health system is strong, families are healthier, diseases are caught earlier, and the entire healthcare ecosystem runs more efficiently.

Imagine a patient in rural India suffering from a retinal disease like diabetic retinopathy. Without early intervention, they face irreversible blindness, robbing them of their ability to work, support their families, fulfill their passion and live independently. But with innovative tools like AI-powered fundus cameras in primary health centers, early diagnosis becomes possible—saving vision, livelihoods, and dignity.

India's ongoing digital revolution, led by Ayushman Bharat Health Accounts (ABHA), offers the chance to connect patients seamlessly with the care they need. Real-time referrals, disease registries, and continuity of care are no longer distant possibilities; they are within our grasp. This will ensure patients get access to treatment they need and not get lost after screening and diagnosis. The first step toward Viksit Bharat is ensuring primary care that is preventive, digitally enabled, and innovation-driven.

Access to Innovation: A cornerstone of Equity

Universal access to advanced therapies is critical to realizing Viksit Bharat. Innovation holds no value if it cannot reach those who need it most. Yet, for many Indians, healthcare access remains a significant barrier. Access to innovation is not just a privilege — It is the foundation of equity.

If we want innovation to be accessible and affordable, we must first recognize its true value.

Value for the patient, who gains better outcomes and hope. Value for society, where innovation strengthens and uplifts the healthcare system. And value for the innovator, who takes on the risk, the challenges, and the long journey to bring that breakthrough to life.

Take for example targeted treatments for lung and breast cancer. These therapies have revolutionized outcomes, extending survival by many years and improving quality of life. Many of these treatments, often requiring lengthy hospital stays, can now be administered as quick subcutaneous injections—saving patients time, money, and emotional toll. Healthcare system capacity (time, resources, money and physical capacity) is also freed up. Decentralised care is possible due to such advances. These are critical aspects of 'value' that must be considered.

Without placing value at the core, we cannot create an environment that fuels research, development, and the courage to keep pushing boundaries. Rewarding innovation means recognizing the real value it creates - improving lives, strengthening society, and inspiring future breakthroughs. Without such support, we risk losing the chance to solve today's challenges with the healthcare solutions of tomorrow. That must remain a cornerstone of Viksit Bharat.

That is why we must act together- as governments, innovators, providers, and insurers to rethink how care is delivered and how innovation is sustained. Models like managed entry agreements—linking payment to real-world outcomes can reduce financial risk while driving innovation. Countries such as South Korea and Taiwan tie conditional or phased reimbursement to real-world outcomes, ensuring that payment reflects actual clinical benefit. Closer home, In Kerala, the state Government's KARE (Kerala United Against Rare Diseases) program demonstrates what is possible when government support through funding is aligned with patient needs. Targeted interventions and alignment across stakeholders can break barriers to access and ensure no patient is left behind.

The Call to Action

Viksit Bharat is more than a vision—it is a commitment to securing healthier lives for all Indians by driving systemic change. It is a nation where no family fears the financial burden of treatment, where every child can stay in school, and where no patient is left behind because of geography or affordability.

To lead this transformation, we must embed innovation at every level of the healthcare system—rooted in evidence, equity, and measurable outcomes. Together, we can build a system that doesn't just deliver care but delivers hope, dignity, and opportunity for millions.

A healthier India is not just a possibility. It's our shared responsibility.

India's Innovation Policy Landscape in Healthcare: Opportunities and Gaps

Dr. Ratna Devi

CEO, DakshamA Health and Education

India, home to more than 1.4 billion people, is at a critical juncture in its healthcare transformation. Over the past two decades, the country has seen a surge in technological advances, digital health solutions, and public-private partnerships. Yet, the healthcare innovation policy landscape remains fragmented, with both immense potential and persistent gaps. Understanding this complex ecosystem is essential for leveraging innovation to address India's unique healthcare challenges—ranging from infrastructure deficits and health inequity to rising non-communicable diseases and the growing need for personalised care. India's healthcare system is undergoing rapid transformation, with innovation and digital technologies promising to bridge gaps in access, affordability, and quality of care. National policies and programs—from the Ayushman Bharat Digital Mission to Production Linked Incentives for medtech—are focused on driving healthcare innovation. However, from a **patient's perspective**, the impact of these innovations is mixed. While many advances have improved care delivery, others are yet to reach those who need them most. For innovation to be truly effective, it must be guided by the **lived experiences, expectations, and needs of patients**.

Opportunities in India's Healthcare Innovation Policy

India boasts the third-largest start-up ecosystem globally, with over 10,000 health-tech start-ups as of 2024. Policies such as the Startup India initiative (2016) and the National Bio Entrepreneurship Mission (NBEM) have catalyzed entrepreneurial ventures in medtech, diagnostics, AI-enabled platforms, and digital therapeutics. Government funding schemes like *Biotechnology Industry Research Assistance Council (BIRAC)'s* BIG grants and SIDBI's financial support have played a pivotal role in encouraging early-stage innovation. Incubators such as C-CAMP, IIT Madras HTIC, and AIIMS Innovation Facilities have provided technical and regulatory mentoring.

The launch of the Ayushman Bharat Digital Mission (ABDM) in 2021 marked a watershed moment. By creating digital health IDs, interoperable electronic health records (EHRs), and national registries for healthcare professionals and facilities, ABDM aims to establish a robust digital health backbone. India's push toward digital health, supported by the National Digital Health Blueprint (NDHB), has enabled telemedicine expansion, remote monitoring, and health data analytics—crucial for rural outreach and personalised care models.

The GATI (Gender Advancement for Transforming Institutions) and TIDE (Technology Incubation and Development of Entrepreneurs) schemes offer inclusive platforms for women and underrepresented innovators in health. The rise of health-tech start-ups has led to personalized solutions for diagnostics, chronic disease management, mental health support, and preventive care.

Gaps in the Policy Landscape

Despite these advances, significant challenges remain in aligning innovation with ground realities and ensuring equitable health outcomes.

1. Fragmentation Across Ministries and Regulations

India's healthcare innovation policies are scattered across multiple ministries—Health, Science & Technology, MSME, Education, and Commerce—with little integration or convergence. Innovators often face bureaucratic complexity in approvals, duplicative compliance requirements, and unclear accountability across agencies. Regulatory silos make it harder to bring multidisciplinary innovations (e.g., AI-based diagnostics or genomics) to market swiftly. The absence of a single-window innovation facilitation mechanism hinders time-to-scale.

2. Insufficient Focus on Health Systems Integration

While innovation thrives in pockets, there is weak linkage between innovation pilots and systemic health service delivery. Many technologies remain in pilot mode without adoption by public health systems due to:

- Lack of budgetary alignment;
- Absence of robust health technology assessment (HTA);
- Weak capacity of states to procure or implement new models.

This results in a low return on investment from public R&D and underutilization of scalable innovations in primary care, mental health, and chronic disease management.

3. Digital Divide and Data Governance Issues

Despite the promise of digital health, nearly 40% of rural populations lack internet access. The elderly, women, and

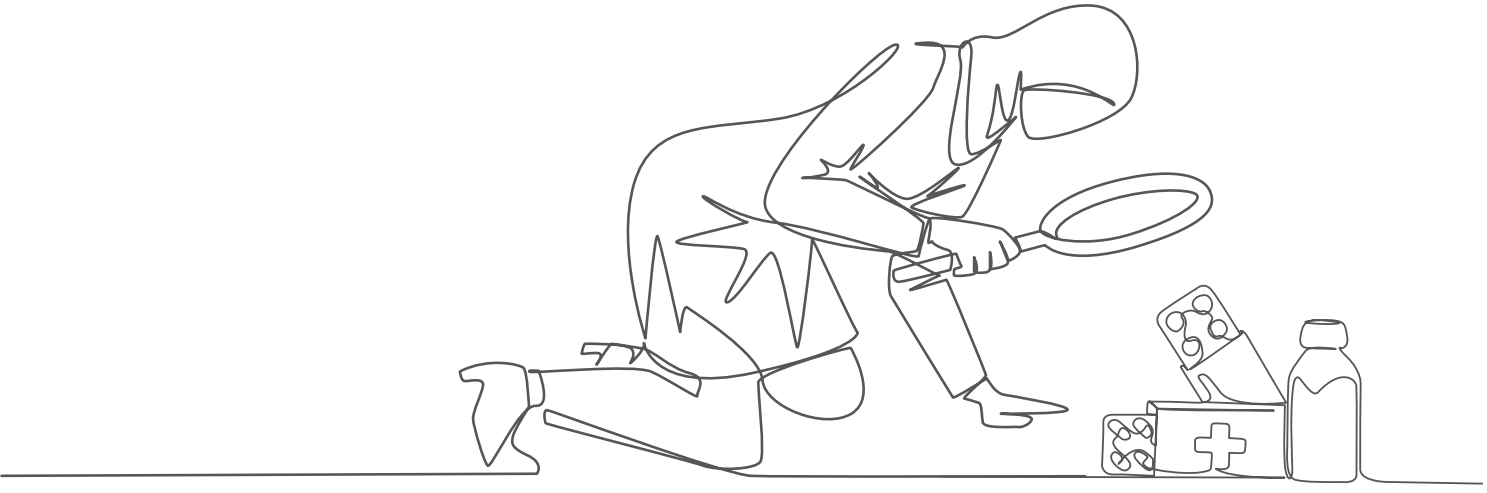
marginalized communities often remain excluded from digital health benefits. Moreover, India lacks comprehensive health data protection legislation. The Digital Personal Data Protection Act, 2023 is a step forward but does not fully address sector-specific concerns such as consent frameworks, anonymization standards, and ethical use of AI in healthcare. Without robust data stewardship, patient trust in innovation will erode, especially for sensitive areas like mental health, reproductive health, and genomics.

4. **Skewed Funding and Innovation Gaps in Public Health Needs**

Venture capital and grant mechanisms supporting health-tech start-ups remains skewed towards urban, high-income use-cases such as fitness, wellness, or tertiary care diagnostics. Many advanced technologies—such as robotic surgery, next-generation sequencing, or AI diagnostics—are concentrated in urban private hospitals and **remain unaffordable for the average patient**. Even basic diagnostic tools or wearable devices often fall outside the purchasing power of rural and low-income patients. Despite government incentives to manufacture affordable devices, **out-of-pocket expenses for patients remain high**. There is also inadequate coverage of these innovations under insurance schemes or reimbursement mechanisms. This market failure is exacerbated by insufficient investment in public health research, health systems science, and implementation innovation.

5. **Lack of Patient and Community Involvement**

Patients and communities are rarely co-creators in the innovation lifecycle. Few policies mandate or incentivize patient participation in design, testing, or deployment of technologies. Without community engagement, innovations risk being misaligned with cultural, behavioural, or local system realities—leading to poor uptake or abandonment. The absence of user-centered innovation also limits responsiveness to issues like trust, privacy, language diversity, and accessibility.



The Way Forward: Bridging Policy and Practice

To unlock the full potential of healthcare innovation, India must take a systems-oriented, equity-driven approach. Key recommendations include:

1. Create a National Healthcare Innovation Authority

A central coordinating body—similar to the US NIH or UK NICE—can bridge policy, funding, regulation, and public procurement. It can provide one-window support to innovators and ensure technology evaluation aligns with public health priorities. Patients are increasingly aware that their health data is being collected, stored, and used—often without clear consent or transparency. **The Digital Personal Data Protection Act (2023)** should ensure that sector-specific safeguards are built for health data, patients own and have access to their health records and there is protection from algorithmic bias or misuse by insurers and employers. Patients deserve a data governance framework that **builds trust**, respects autonomy, and enables them to make informed decisions.

2. Mainstream Health Technology Assessment (HTA)

Health Technology Assessment in India (HTAIn) needs to be strengthened by giving it statutory powers and embedding it into procurement and policy decisions at national and state levels. This will improve cost-effectiveness, transparency, and accountability. Including patients and users in the selection and evaluation at an early stage will further strengthen the process

3. Invest in Public Health Innovation

Government and philanthropy must increase funding for innovations targeting neglected diseases, primary care, mental health and rural health. Models like challenge grants, outcome-based funding, and sandboxing can promote mission-driven innovation. Patient organisations need to be given agency and recognition and included at all levels.

4. Build Capacity at the Last Mile

Training healthcare workers and administrators to adopt, adapt, and manage innovations. Investing in task shifting and alternate models moving away from clinician based curative models to preventive models and lifestyle modification. Recognising and upscaling grassroots innovation, especially those that preserve traditional knowledge and culture.

5. Incorporate Patients and Communities

Incentivizing patient organizations, caregivers, and civil society to participate in innovation design and policy discussions will ensure sustainability and uptake. Support participatory research and patient-led testing platforms to make innovations inclusive and context-sensitive.

India stands at the cusp of a healthcare innovation revolution. But from a patient's perspective, the success of this revolution will depend not on the number of apps or devices created—but on how effectively these innovations **solve real problems, reduce suffering,** and **empower patients** to take charge of their health. Healthcare innovation policy in India must move from being technology-driven to **people-driven**, ensuring that no **patient is left behind** in the quest for progress.

The Role of R&D and Patents in Nation Building

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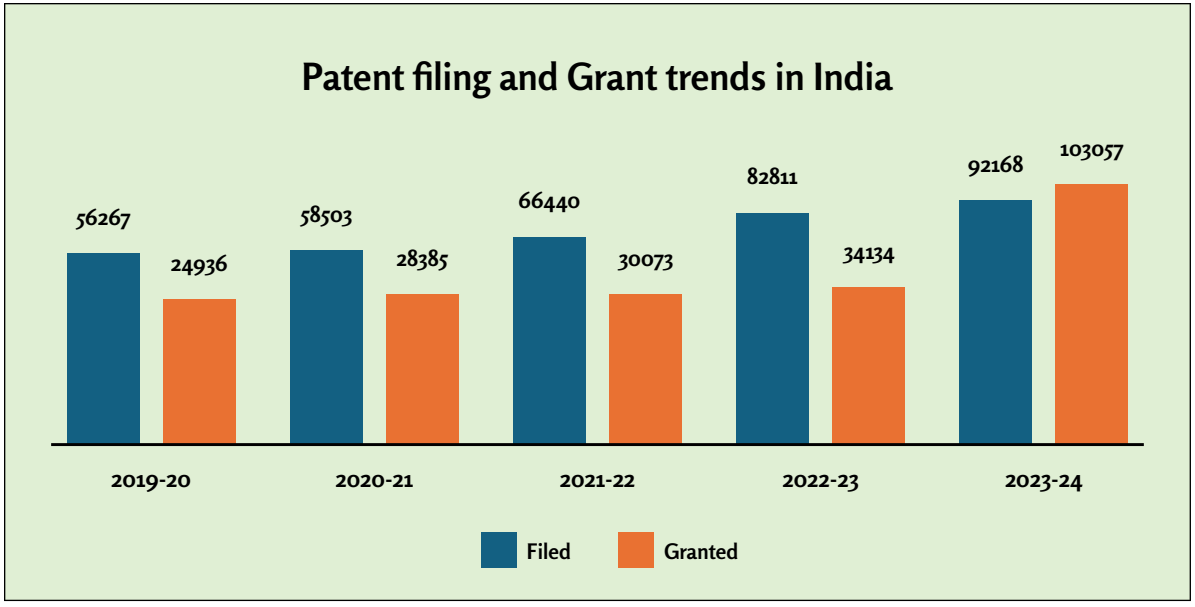
India is progressing from strength to strength on its way to achieving the ambitious goal of Viksit Bharat 2047. Viksit Bharat envisions transformational changes for our nation-building to become a developed country. To achieve this goal, given the changing global economy, innovation and self-reliance are one of the critical pillars. Research and Development (R&D) fosters innovation and reduces dependence, thus realising India's dream of becoming an innovation hub. Patents are the outcome of R&D for creating valuable inventions for the economic development of the nation. In fact, R&D spending of a country tends to directly improve the national patent applications, thus contributing to nation-building.[1]



Interestingly, since the year 2000, the share of R&D in total world GDP has increased from under 1.5% to nearly 2% by 2023[2] reflecting more focus towards an R&D-driven global economy. However, India's Gross Expenditure on R&D (GERD) has remained stagnant between 0.6% to 0.7% unlike other countries that spent more than 0.7% of their GDP on R&D, such as Brazil (1.3%), Russia (1.1%), China (2.4%), and the USA (3.5%)[3,4].

Recently, on July 01, 2025, the Union Cabinet approved Rs 1 Lakh crore (~11.5 billion USD) Research Development and Innovation (RDI) scheme for strategic areas of research[5]. This will offer long-term and low-cost capital to private enterprise working in sunrise domains, including deep tech, to spur private sector investment in R&D. Fortunately, India is well placed to leverage its demographic advantage of young population and skilled workforce having deep technical expertise and advanced degrees to drive the R&D for self-reliance and to become a global powerhouse of innovation. However, unlike developed nations where private industry invests over 75% of total R&D, only about 36.4% of India's R&D expenditure comes from the private sector[6]. The time has come now to strengthen our industry-academic collaboration for a fruitful result for the development of a robust R&D and innovation ecosystem in India.

While India is steadily moving forward in R&D investments, the patenting side is also catching up with the pace. India ranks sixth globally in patent filing, with resident filings accounting for over half of all patent filings (55.2%) in FY 2023-24 - a major milestone for the country in decades. In addition, the year-on-year rise of patent filing in India is proof of a resilient and innovative India leading to a new growth era to fulfil the global aspirations of the start-ups and innovators. In FY 2023-24, a complimentary record-breaking patent grant above 100K (1 lakh) in India,[7] is a testament to India's commitment to innovation, resonating with the slogan 'Jai Jawan, Jai Kisan, Jai Vigyan, Jai Anusandhan'.

However, comparatively, India's resident patent-to-GDP ratio, a measure of the economic impact of resident patent activity

per USD 100 billion GDP, was still low (381 in 2023) versus 4875 in China and 1,119 in the USA. A higher patent-to-GDP ratio is often seen as a sign of a knowledge-driven economy, where patents play a vital role in economic development[8]. India must take a further leap to enhance its capability to innovate to raise its global standards of competitiveness for the benefit of the nation. Recently, GCCs (Global capability centres) have been creating a significant impact in India and becoming a global magnet of R&D and innovation to move up the value chain and global integration.

Global disruptions like the COVID-19 pandemic have stressed the importance of self-reliance and created not only an opportunity to safeguard our autonomy and reduce dependence but also, from the perspective of national security, particularly in the areas of defence and the pharmaceutical sector. By bolstering our capabilities in these sectors, we can reduce import dependencies and ensure uninterrupted access to essential defence equipment, medicines, and key starting materials.

Indian Pharmaceutical industry offers a robust research ecosystem attracting global pharma giants for active collaboration in the complex areas of drug discovery and advanced drug delivery systems, leading to path-breaking success, for example, Novartis-Advinus collaboration led to the identification of a potential drug, Licogliflozin, which is currently under trials[9]. Global collaboration is a key to success to solve the challenges for humanity.

To fortify our pharmaceutical industry and safeguard against future disruptions, investments in R&D and eventually creating patent assets will transform India to the next level. To harness its full potential, legislative and policy reforms in the R&D sector and the Indian Patents Act will be a game-changer. A step-by-step transformation such as increasing R&D tax incentives, low-interest financing for R&D intensive industries, and revisiting Section 3(d) of the Patents Act for recognizing meaningful incremental inventions would have a noteworthy effect to incentivise R&D and the patent ecosystem in India for the benefit of our nation. India is on the right track to create a vibrant ecosystem for treating R&D and patents as a strategic asset to fulfil the vision of a developed nation and global aspirations.

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From Generics to Breakthroughs: India's Pharma Leap Toward a Viksit Bharat

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Introduction

India's pharmaceutical industry has long been recognized as the 'pharmacy of the world', supplying 20% of global generics and nearly 70% of vaccines[1]. This global position was built on scale, cost efficiency, and the ability to deliver high-quality, affordable medicines. But the global healthcare environment is shifting.

The next phase of growth is expected to depend not only on access and affordability, but also on science-driven innovation.

India's Innovation Deficit – A Historical Perspective

Despite its global scale, the Indian pharmaceutical industry has historically invested relatively little in research and development (R&D), averaging approximately 5.8% of revenues—significantly lower than the ~17% invested by global innovators[2]. Much of the investment has focused on improving existing molecules, delivery systems, and complex generics, while innovation in novel drugs and biologics has gained momentum in recent years.

However, to truly become a science-driven pharmaceutical leader and fulfill the vision of a Viksit Bharat by 2047, India must shift its focus from scale to innovation.

Early Signs of Momentum: India's Emerging Pathways

India's pharma sector is beginning to show early signs innovation-led growth. While India has historically focused on generics and affordability, recent developments suggest a shift toward science-driven breakthroughs.

- ***A novel antibiotic approval:*** The US FDA's clearance of an antibiotic discovered and developed in India marked it as one of the country's first such drugs to gain global recognition[3]. It shows India can address urgent challenges such as antimicrobial resistance.

- ***Oncology biologics innovation:*** A leading Indian pharmaceutical innovator recently entered into a $1.2 billion global licensing agreement for a next-generation multi-target biologics platform, underscoring how Indian research capabilities are being recognized and valued on the world stage.

- ***Biosimilars and vaccines leadership:*** India has developed more than sixty biosimilars in areas such as oncology, diabetes, and autoimmune disorders[4]. It also continues to lead the world in vaccines, building on its vital role during the COVID-19 pandemic.

Taken together, these developments show that India's pharma sector is no longer limited to generics. It is laying the foundation for an innovation-led ecosystem that is both credible globally and relevant to domestic healthcare priorities.

Global Lessons for India's Pharma Innovation

To accelerate this momentum, India can learn from global peers who have successfully transitioned to innovation-led growth:

- ***South Korea:*** Once investing less than 1% of GDP in life sciences R&D, South Korea now spends ~4.5%[5]. Targeted funding and biotech clusters have helped build a thriving biologics sector, especially in biosimilars

- ***China:*** Adopted a strategic approach by aligning regulatory reforms, venture funding, and commercialization. In 2024 alone, it recorded ninety-three drug approvals (42% domestic) and over $40 billion in out-licensing deals[6]. Today, nearly 28% of innovative assets in global pharma pipelines originate from Chinese firms—highlighting the impact of integrated policy, capital, and innovation[7]

- ***Singapore:*** By investing in strong regulatory systems, intellectual property frameworks, and translational research centers, Singapore has become a global hub for clinical trials and biotech innovation despite its small size[8]

- ***Israel:*** With government-backed venture funds and strong academic linkages, Israel has become a leader in oncology and advanced modalities such as cell therapy[9]

These global examples show that innovation thrives when policy, capital, and science move in sync. For India, the path forward lies in building a similarly cohesive ecosystem that nurtures discovery and accelerates translation from lab to market.

A Four-Pillar Framework for India's Innovation Journey

India's ambition to lead in pharmaceutical innovation demands more than policy intent—it calls for coordinated execution across four strategic pillars. These pillars must operate in synergy to drive science-led growth and build a globally competitive innovation ecosystem:

- ***Investment:*** Catalyze early-stage innovation through targeted PE/VC funding and milestone-based subsidies for clinical trials and regulatory filings of India-origin drugs, especially in high-impact areas such as antimicrobial resistance (AMR), oncology, and biologics. A PLI-style incentive model can be adapted to support these efforts.

- ***Talent:*** Strengthen India's scientific workforce by funding advanced training programs, including translational PhD tracks, postdoctoral fellowships, and academic–industry exchange initiatives. India currently has seven times fewer PhDs than leading innovator economies—closing this gap is critical.

- ***Infrastructure:*** Expand shared manufacturing and testing facilities under the Biotech R&D Innovation and Development Ecosystem (Bio-RIDE) scheme. Scale modular infrastructure in established innovation clusters across the country to foster dense ecosystems that support pharmaceutical research and development. Promote the use of AI/ML tools in drug discovery, modeling, and analytics to reduce costs and accelerate development timelines.

- ***Government–Private–Academic Partnerships:*** Foster deeper collaboration to translate research into scalable therapies and accelerate commercialization.

In light of shifting global geopolitical dynamics, India must also establish a resilient and future-ready growth framework—one that ensures sustainable development and protects the pharmaceutical sector from macroeconomic shocks through 2047.

Conclusion: From Generics to Breakthroughs

India has demonstrated its strength as the pharmacy of the world—delivering affordable, high-quality medicines at scale. The next frontier is clear: to become a global innovation powerhouse. Achieving this transformation is expected to require bold investments in R&D, agile policy frameworks, deep public–private–academic collaboration, and a regulatory environment that fosters trust and speed. Innovation must be embedded not just in strategy, but in execution.

Pharma innovation is no longer a choice—it is a national imperative. It holds the key to addressing India's evolving healthcare needs, enhancing global competitiveness, and ensuring equitable access to breakthrough therapies.

The journey from generics to breakthroughs marks a transformative shift—positioning India to lead the next wave of global pharma innovation.

Abbreviations

Abbreviation	*Full Form*
R&D	*Research and Development*
PLI	*Production-Linked Incentive*
PRIP	*Promotion of Research and Innovation Programme*
Bio-RIDE	*Biotech R&D Innovation and Development Ecosystem*
CAR-T	*Chimeric Antigen Receptor T-cell Therapy*
CDSCO	*Central Drugs Standard Control Organization*
ICMR	*Indian Council of Medical Research*

Innovation in Clinical Trial in India: Opportunities, Challenges and Solutions

Sanjay Vyas

President and Managing Director, Parexel India

India presents a compelling opportunity to reimagine clinical trials. With its vast and diverse population, expanding digital infrastructure and emerging technology, and an increasingly sophisticated healthcare ecosystem, India is positioned to emerge as a global leader in innovative trial design and execution.

With a report by the Lancet said that while India has 20% of the global population, it accounts for just 1.5% of the clinical trials. Through trial innovation, India has the opportunity to create an accessible, efficient and patient-centric clinical trial ecosystem.

How Innovation can create that difference

Among the key innovations reshaping clinical trials, three stand out for their ability to overturn the manual processes that have changed very little in decades. Each present opportunities to address fundamental barriers that have historically limited the speed, scale, and effectiveness of clinical research.

Decentralized clinical trials (DCTs) leverage technology and other service elements to move research from major urban centers closer to patients to reduce geographic limitations, boost trial efficiency and increase patient access and engagement.

India's push on digital infrastructure, through schemes like Digital India, which expands technology access nationwide, and the Ayushman Bharat Digital Mission (ABDM), which is creating a unified digital health ecosystem through Health IDs and digitized records, along with expanding smartphone penetration within India indicates that remote trial tools like e-consent, telehealth, and wearables can truly connect with patients across metros and villages. As these decentralized approaches continue to advance, it supports trials run faster and reach wider populations.

In addition, **real-world data & evidence (RWD/E)** provides insights that complements trials, supports trial design and informs regulatory decisions. India has access to a large trove of health data to support studies, from hospital records like Jehangir Hospital to large-scale registries, The Indian Society for Clinical Research (ISCR) builds awareness among policymakers and professionals about RWE/D.

Our industry has been successful at developing artificial intelligence-enabled solutions that speed clinical trial timelines, while also achieving superior first-time quality. Some examples include:

1. **Study planning and design:** GenAI can support optimizing protocol by leveraging relevant recent public domain trial designs and outcomes, anticipating and offering mitigations of expected study startup issues and selecting optimal investigative sites.
2. **Study conduct:** GenAI can help automating data capture, cleaning, transformation (e.g., into CDISC format) and reporting.
3. **Risk management:** GenAI can identify potential risks and challenges that are common in certain therapeutic areas, diseases or study types, allowing for proactive risk mitigation strategies.

The integration of AI into clinical trial design and delivery is a transformative moment. AI is more than a technological advancement but a shift in how we develop life-changing therapies.

The Other Side of the Coin: Challenges

Innovation such as decentralized clinical trials (DCTs), real-world data & evidence generation, and AI-powered analytics offer flexibility, minimize logistical challenges, and enable near-real-time data collection. However, these key challenges must be addressed collectively:

- **Data Overload:** With vast data influx from wearables and genomic sequencing, organizations must maintain data integrity and quality while benefiting from comprehensive insights. AI-driven platforms that efficiently process large datasets while adhering to regulatory standards can address this challenge.

- **Interoperability:** Effective collaboration across various systems remains challenging. Enhanced system integration through seamless data flow promotes efficient partnerships toward shared trial objectives.
- **Privacy/Security:** Protecting patient data is crucial as regulations evolve. Robust security systems, data governance practices, and adherence to Good Clinical Practices build trust and support ethical research.
- **Regulatory Gaps**: Despite India's comprehensive policy ecosystem on the digital front, clear guidance on DCT, RWD/E, and AI integration remains limited. For instance, while DCT pilots show promise for expanding trial access beyond urban centers, implementation faces significant regulatory barriers.

  The New Drugs and Clinical Trial Rules 2019 can be updated to support comprehensive DCT operations. Enhanced regulatory frameworks are essential to maximize their potential in transforming India's clinical research landscape.

- **Workforce Readiness:** The clinical research workforce faces significant adaptation challenges as traditional roles evolve. According to research from Parexel, 87% of biopharmaceutical leaders believe more innovative approaches and tools, such as AI and RWE, are needed to execute trials. However, both biopharmaceutical leaders and frontline workers agree that today's workforce has progress to make in order to fully develop these key skills. This skills gap demands comprehensive training in data interpretation, cross-functional collaboration, and technology adoption.

These challenges are best addressed together as part of the broader framework needed to make clinical research innovation both effective and trustworthy.

A Patient-First Future: What India Must Do Next

The ultimate measure of clinical trial innovation is better outcomes for patients. The convergence of DCT, RWD/E, and AI in India's context promises a research ecosystem that is more inclusive, representative, and effective at developing treatments for unmet needs.

To realize this vision, India must focus on two critical areas:

- Continue enhancing infrastructure and capabilities by strengthening digital connectivity across rural areas, building standardized health data systems, and developing expertise in innovative areas within clinical research organizations.
- Foster collaboration among key stakeholders such as pharmaceutical companies, technology providers, healthcare institutions, and regulatory bodies, to create unified standards and shared best practices.

Every patient waiting for a new treatment is counting on the clinical trials industry to move faster and think smarter. With innovation leading the way, India can help turn today's trials into tomorrow's cures.

Innovations in Pharmaceutical Sciences in India: Challenges and Opportunities

Dr. Shekhar C. Mande

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The act protecting individual and institutional innovators, known as the act VI of 1856, was the beginning of recognizing innovations in India. This act gave exclusive rights to manufacturers based on the now protected innovations, and interestingly, the first exclusive privilege was granted to DePenning, soon after the act came into being, for his invention of "*efficient punkah pulling*" machine in 1856. The patent act has since been modified multiple times, the last time in 1970, when the old patent acts were repealed and the new one was brought in force. The 1970 act enabled Indian pharmaceutical industry to significantly reduce import of bulk drugs and be self-reliant in manufacturing. A few amendments have been brought later, especially after India joined the World Trade Organization (WTO) and became signatory to the Trade Related Intellectual Property Rights (TRIPS). Among these amendments, the widely known one is the recognition of products,

especially in pharmaceutical and agricultural sectors, which were not allowed earlier. Thus, the patent act in India has undergone multiple changes, keeping up with the needs of the time, and allowing Indian manufacturing sector to prepare itself for a major role on the global stage.

While the regulatory systems were being put in place, Indian pharmaceutical industry had been growing from strength to strength. Simultaneously, academic institutions in India too had begun innovations in the pharma sector. Among the early institutions with a strong presence in the pharmaceutical sector was the Council of Scientific and Industrial Research (CSIR), with multiple laboratories focusing on different aspects of pharma and biotech-related research. CSIR also became the hub of innovations and maintained the pole positions of filing the highest number of patents every year, until recently, among all academic organizations in the country. Indeed, close collaborations among pharmaceutical industries and CSIR allowed organic growth of the industry in the country. Establishment of the National Institute of Pharmaceutical Education and Research (NIPER), Mohali, in the 1990's, and its multiplication at different locations in the country in subsequent years, also allowed training of manpower for pharmaceutical industries at a larger scale.

India's signing the TRIPS agreement was intended to integrate Indian industry at the global stage and was anticipated to stimulate the innovation movement in pharmaceutical research and discovery. Indeed, most Pharmaceutical and Biotechnology industries now have established a strong in-house presence in Research and Development (R&D). Moreover, many global pharmaceutical industries now have established R&D hubs in India, much like the software technology industries. One of the major motivations for doing so is the large English-speaking talented pool of young people, presence of some of the best educational Institutes, and a strong democratic governance backing. The new drug discovery value chain has therefore witnessed a paradigm shift in recent years in the country. In order to further promote R&D in this sector, the Government of India has recently come up with attractive schemes such as the Promotion of Research and Innovation in Pharma Medtech (PRIP), and has similarly outlined a fund of INR 1 lakh Crores for industrial R&D. Similarly, the BioE3 policy released by the Indian Government aims at enabling bio-manufacturing. With these developments, therefore, the outlook for pharma-biotech innovations in India appears to be very bright.

Despite the atmosphere of hope and optimism, the number of new chemical entities and new drugs that have been discovered in India has remained low. In many countries, the early discovery and breakthrough innovations have happened in either academia, or more recently in start-ups. In India, the start-up movement has just begun, but yet the number of start-ups in pharmaceutical sector has remained low. Two areas that need urgent attention are therefore strong policy to promote industry- academia collaborations, and removal of uncertainty from young minds in taking risks of floating start-ups. If industry- academia collaborations were to be aggressively promoted, publicly funded academia needs to be encouraged for collaborations with industry, keeping them insulated from government bureaucracy. The same also holds true for spin-offs from academic organizations and increasing the number of start-ups from these Universities/ Institutes.

India has also many other areas of strengths, which are yet to be explored to their true potential. One of them is in the area of Botanicals according to the US FDA definition, or what are known as phytopharmaceuticals in India. This class of drugs received recognition in the US FDA in 2004, but till date only 4 formulations have received the formal approval

for use. However, considering India's traditional knowledge in plant-based extracts for treating different diseases, a huge opportunity awaits Indian researchers to tap into this class of drugs. The bringing together of practitioners of traditional medicine, AYUSH, and those of modern medicine, indeed presents an unprecedented opportunity.

Human health and the treatment of different health-related disorders in humans has long been a subject of practice in ancient cultures such as India and China. Whereas China has taken the lead to explore uses of traditional Chinese herbal medicines from the modern perspectives, these are yet to take a formal central stage in India. It is critical that the uses of traditional formulations are tested with well-designed clinical trials. It is only then that one may expect global reach of Indian traditional knowledge. Whether these formulations have active ingredients as a mixture of compounds, or as pure components, is a question that needs to be examined in detail. Thus, the opening up of the possibility of uses of botanicals, or phytopharmaceuticals, a very large opportunity exists for researchers in India and China.

The innovation movement in Pharmaceutical and Biotechnology sectors is at a critical juncture in India currently. With its long traditional base in healthcare, presence of a large number of young people, many promotional schemes by the government, beginning of R&D by many pharmaceutical and biotech industries, Indian Pharma sector indeed appears to be at the crossroads of the renaissance moment. Only time will tell how well these opportunities have been used for the benefit of mankind.

Acknowledgements

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AI: Where Is the Technology Taking Us?

Dr. Shoibal Mukherjee

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Average life expectancy around the world was 46 years for a child born in 1950. In India it was 35. We have come a long way in the 75 years since then. Average human life expectancy at birth is over 73 years now, and India has caught up with the world average. Improvements in nutrition and sanitation have most certainly been very important factors. But improvements in healthcare have undoubtedly had the greatest direct impact, particularly in preventing childhood mortality and death from infections. Much of this is attributable to innovations led or taken forward by the pharmaceutical industry. Contributions of the Indian pharmaceutical industry in sustaining these improvements by enabling affordable childhood immunization programs within India and across the least developed and developing worlds cannot be overlooked.

What of the future? World Health Organization's median projections suggest an increase of 5 years in the global average life expectancy in the next 25 years to 2050 and another 4 years in the subsequent 50 years. That should take us to average life expectancy at birth of about 82 years by 2100. But projections are just that – a projection into the future, of trends from the recent past. By implication it means that the WHO does not take unexpected breakthroughs in medical science into consideration in putting out these numbers.

What unprecedented breakthroughs can we expect? The first thoughts that come to mind revolve around the possible discovery of new medicines, particularly those that target the most burdensome of diseases. In the past, vaccines and antimicrobial agents have had a major impact on life expectancy. While there have been many path breaking discoveries in other therapeutic areas, their impact on overall life expectancy of the human race as a whole has been marginal. Perhaps these areas will see impactful discoveries in the future – those that will make atherosclerotic cardiovascular disease a thing of the past, eradicate tuberculosis altogether, or render cancer largely curable. Yes, these can happen. But, more likely, the struggle with cancer will remain a difficult and arduous struggle with small wins that may be important for the individual patient but not enough to move the needle on average life expectancy. Tuberculosis may still continue to have more to do with poverty and access to healthcare than to the availability of curative therapies. Lifestyle changes, coronary interventions, and faster access to emergency care may continue to have a greater impact on atherosclerotic disease than medicines. Incremental improvements in treating disease have made a modest contribution to increasing life expectancy in the past and are therefore already built into future projections. Wild speculations of people regularly living beyond hundred can only come true if contributions to human longevity come from quarters other than the contributors of the past.

Can AI be that unprecedented factor? A session on AI is an invariable part of every conference one attends these days. In the pharmaceutical world the talk is generally about how AI can help with drug discovery or improve the process of clinical trials. Within hospitals the discussion is about how AI can help organize the patient database, improve workflows, and make it simpler to answer research questions from retrospective data. These are basic and preliminary uses that AI can certainly be put to. However, the bigger question may be whether AI can find connections within large bodies of data that the human mind is unable to comprehend, and thus lead to unprecedented breakthroughs that we find difficult to imagine at this time.

That brings us to the topic of probability and risk – the propensity to develop a particular disease and the likelihood of responding (or developing unacceptable side effects) to treatments. It is evident that each individual carries a different propensity for disease and cure. Some individuals may be more prone to cardiac disease while others are destined for cancer. Some individuals and populations are inexplicably protected from certain diseases. Some medicines work well for some patients while other patients need second-line therapies. The propensity for disease and cure may arise from multiple factors, broadly classifiable to genetics or the environment. Sometimes a single aberrant gene may be a factor of doom, as happens with, for example, familial hypercholesterolemia, a disease that runs in families and leads to severe and early cardiac disease due to high levels of cholesterol. It occurs in fewer than 1 in 300 persons and is clearly not the reason for the high frequency of cardiac disease seen in younger people these days.

A more common genetic reason for heart disease is thought to be polygenic risk. Discovered as a result of gene association studies, a large number of genes in the human genome have been found to be linked to heart attacks. Each

one of these genes has only a small influence, but when many of them come together in a single individual, a tendency to develop coronary disease manifests itself. The same can be said of all other multifactorial diseases.

Environmental factors that contribute to propensity for disease are, likewise, numerous. Heart disease is thus more common in smokers, people who get less exercise, those who consume an unhealthy diet, and perhaps even those who are exposed to environmental pollutants.

People are much more likely to come down with a disease if polygenic risk is compounded with environmental factors that contribute to risk. But the interplay between different risk and protective factors is not well characterized. Is a combination of some risk factors more predictive of disease than combinations of other risk factors? Is one medicine destined to work better for one patient than for another? The questions get more complicated as we learn more about diseases and what causes them, and as the number of treatments available to treat them multiplies: to the extent that, after a point, analysis becomes too complex, studies required to perform the analysis become too time-consuming and expensive, and everything becomes too intertwined to unwind with traditional tools, or comprehend with the human mind. Perhaps AI can begin to unravel this conundrum by learning from millions of cases and deep analysis of interrelationships between causes, treatments, and outcomes.

Eventually, a day may come when we will be able to pinpoint with 99% accuracy, whether, and under what circumstances, a teenager is likely, in her lifetime, to suffer from any of a range of diseases, and how that risk can be eliminated. Perhaps AI will provide us with a list of medicines that will work in an individual patient and another of those which will not. Perhaps we will be able to get AI to write us a prescription with the right combination of medicines and interventions in their right doses, to be taken for the right duration to eliminate the risk and cure the disease.

Medical scientists have continued to make breakthroughs in our understanding of disease. The pace of progress has been increasing relentlessly. Between 30 and 50 new medicines are discovered every year. With the advent of AI in drug discovery, this number is set to increase. More new medicines will be discovered in the next 25 years than have been in the last 50. This does not mean that the older medicines have stopped working – only that we have more choices now than we ever had before, and that doctors will have a tough time choosing medicines for their patients in the not-so-distant future. Decision support systems and AI-based prescription writing will then become unavoidable low-end necessities rather than the high-end novelties they are today. Eventually, it is highly likely that the medical profession will move to the full-time role of managing the patient: documenting signs and symptoms, ensuring compliance to treatment, performing or coordinating interventional procedures, and providing the human touch. All decisions will be made by AI algorithms. And this might just be the breakthrough that will push life expectancy to 100 and beyond.

Fostering Innovation and Collaboration to Elevate the Future of Pharma in India

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The vision for a Viksit Bharat by 2047 emphasises the critical role of innovation within the pharmaceutical sector. To achieve this, India must transition from a volume-based approach to a value-driven, innovation-focused model. With advancements in technology significantly reducing the cost and time associated with research and development, India's potential in indigenous innovation can be ramped up. Machines are now capable of analysing data at a level that often surpasses human capability, highlighting an opportunity for researchers to harness this data effectively. By leveraging these technological tools, we can foster the emergence of disruptive and innovative ideas for the pharmaceutical industry.

The foundation of this innovation lies in appropriate skilling and a robust collaboration between industry and academia. The key components for this collaboration are an Industry partner, willing to innovate and an academic partner with the capacity to engage. Both sectors need to establish dedicated points of contact to engage in dialogue about real-world challenges in drug discovery, development and regulatory frameworks. It is important to monitor the input (skilled manpower) to come up with the desired output (innovative products). Industry insights enable academic institutions to update their curricula, aligning them with current industry needs and ensuring that graduates are well-prepared for

the workforce. This collaborative approach is also crucial when students work on their theses and dissertations. Here, industry insights can guide them in developing practical and innovative solutions and skills through real-world problems. To foster this shift, pharmaceutical academia must integrate artificial intelligence (AI) and machine learning (ML) into its core scientific disciplines and research and be prepared to rapidly change curricula, as and when desired. A broad base is required where mentors could be made available from the medical, engineering, pharmaceutical industry, and policy domains for troubleshooting.

Innovation is often sparked by critical questions: Why? How? What next? It requires analytical thinking, which can be bolstered by technological advancements. It's important to recognise that connecting the dots in research, development, and innovation is a collective effort, drawing valuable perspectives from various stakeholders. Sometimes, the most profound insights come from simply observing with empathy and curiosity, driven by a genuine desire to find solutions.

However, fostering innovation also demands a certain risk appetite. Overcoming resistance from stakeholders, confronting the fear of the unknown, and cultivating a supportive environment where experimentation is encouraged are vital components for success. Negative results are also valuable because they give important inputs as to what not to do. Within an academic setting, the groundwork for proof-of-concept can be established, and industry can play a pivotal role in guiding projects toward a higher technology readiness level, ensuring a seamless transition to upscaling if the idea has merit.

Confidentiality agreements can pave the way for fruitful collaboration, creating a win-win situation for both academia and industry. It is important to recognise that this collaboration represents a low-risk opportunity; the fresh perspective of youth can unlock a wealth of new ideas. Students are naturally inclined to think outside the box, since their minds are not conditioned to think in a particular manner. Experienced professionals can then point out the problem areas, and the innovation can be refined into a workable solution. Not only is the gap between theoretical knowledge and practical applications bridged, but it also leads to effective skilling, improved pedagogy and a robust educational system.

The pharmaceutical industry is innovating in a host of areas, including biologics, API, smart excipients for better physical properties, automation, PAT, Digital twins in manufacturing, microfluidics and 3D printing, personalised medicine, modular systems for change management. All these areas need significantly different skill sets, which necessitate flexibility in curricula, constant revisions and updates, and suitable skilling. At the industry level, upskilling of manpower in niche areas is a necessity, which can be offered by academia. Another aspect which must be factored into innovation is sustainability. This has been neglected in the past, as when considering the benefit-to-risk ratio, sustainability took a back seat. When these principles are inbuilt in the foundation skills by academia, the sustainability drive would gain traction. Global capability centres are also closely monitoring data and coming up with area-specific, as well as global requirements, fuelling innovation in the required direction. Hyderabad is fast emerging as the Hub of Pharma GCCs in India. These organisations can also give insights regarding the required skills for an innovation-driven industry in Bharat.

Innovative solutions also lead to economic growth, solutions to societal challenges and a better quality of life and healthcare. Through innovation, significant strides can be made towards a vibrant and thriving pharmaceutical future for India, ensuring that we remain the Pharmacy of the World.

Viksit Bharat and the Innovation Imperative in Pharmaceuticals

Srikanth Mahadevan

Director, Deloitte India

India's "Viksit Bharat" vision by 2047 will demand universal access to medicines and propel the building of an innovation-led, self-reliant, globally competitive and affordable-for-all pharmaceutical industry. India already supplies about one-fifth of the world's generic drugs by volume[1]. It is among the largest vaccine producers globally, yet much of the value in global pharma accrues to innovators and platform owners. For India to transcend from the "pharmacy of the world" to the "lab of the world" will require bold investments in R&D, quality, talent and digital public goods.

While generics and biosimilars constitute the backbone of the country's pharmaceutical manufacturing and exports, sustainable growth in a highly competitive global landscape depends on innovation. Innovation in the pharmaceutical sector is more than just new drug discovery; it encompasses process innovations, formulation development, digital health integration and personalised medicine.

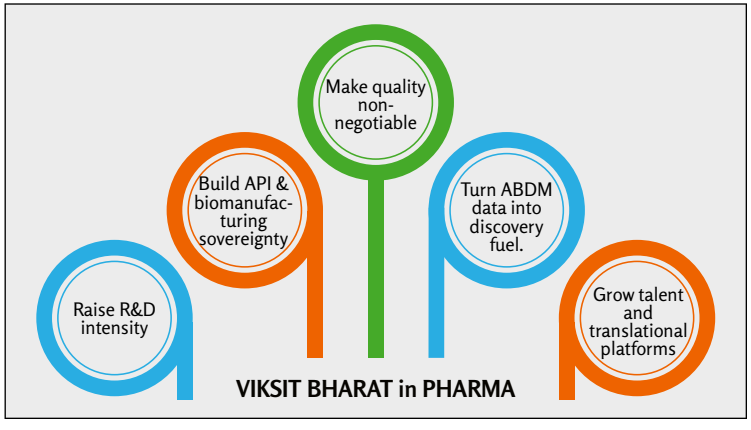
The global biopharmaceutical market is expected to grow at a CAGR of 7.6% during 2024-2030, to reach US$745 billion by 2030[2].To position itself competitively, India must shift from being a generic producer to an innovation-driven hub. This shift is essential for several reasons, some of which are mentioned below:

- **Increasing R&D costs and time:** Developing a new drug costs ~US$2.6 billion and takes around 10–15 years[3]. India's current R&D expenditure is about 0.7 percent of its GDP, significantly lower than the global average of 1.8 percent[4]. Enhanced innovation can streamline R&D processes and improve success rates.

- **Regulatory and market sustainability:** Regulatory agencies worldwide, including the United States Food and Drug Administration (USFDA) and the European Medicines Agency (EMA), are strengthening requirements for novel drugs, challenging India to innovate for compliance and market differentiation.

- **Addressing unmet medical needs:** Innovative solutions are crucial for tackling complex diseases such as cancer, Alzheimer's and rare genetic disorders, which account for a growing share of the global health burden.

- **Heavy import dependence for APIs:** About 70 percent of Active Pharmaceutical Ingredients (APIs) by value come from China; for dozens of critical molecules, dependence is 50–100 percent[5]. To become self-reliant and avoid potential supply-chain-related disruptions, India must focus on import substitution and domestic manufacturing of APIs.



To overcome these challenges and realise the Viksit Bharat "Pharma" vision, India needs to drive the innovation agenda through the following five concrete shifts:

1) **Raise R&D intensity.** A realistic near-term target is 10–12 percent of sales for the top 20 firms, concentrated on complex generics, biosimilars, differentiated formulations (e.g., long-acting injectables, inhalation), and selected New Chemical Entity (NCE)/New Biological Entity (NBE) bets where India has scientific depth (infectious diseases, oncology, metabolic disease). Global benchmarks show that sectors with the highest R&D-to-sales ratios also capture the greatest value in new launches.

2) **Build API and biomanufacturing sovereignty.** Use Production-Linked Incentive (PLI) and parks to reshore fermentation-based and chemo-intensive APIs (cephalosporins, statins, analgesics), secure KSMs and develop continuous-flow capabilities. Reducing China's concentration from ~70 percent[6] of import value to <40 percent by 2030 is an achievable national KPI if park commissioning, utilities reliability and environmental clearances are executed on time.

3) **Make quality non-negotiable.** The Schedule M upgrade must be paired with Good Manufacturing Practice (GMP) skilling, Quality by Design (QbD) adoption and digital plant systems (Manufacturing Execution System (MES) and Electronic Batch Manufacturing Record (eBMR)). Transparent, risk-based inspections and public dashboards would reward compliant facilities and speed global trust rebuilding.

4) **Turn ABDM data into discovery fuel.** With appropriate consent and anonymisation, Ayushman Bharat Digital Mission's (ABDM) longitudinal records plus e-Sanjeevani's scale can power Real World Evidence (RWE) studies and

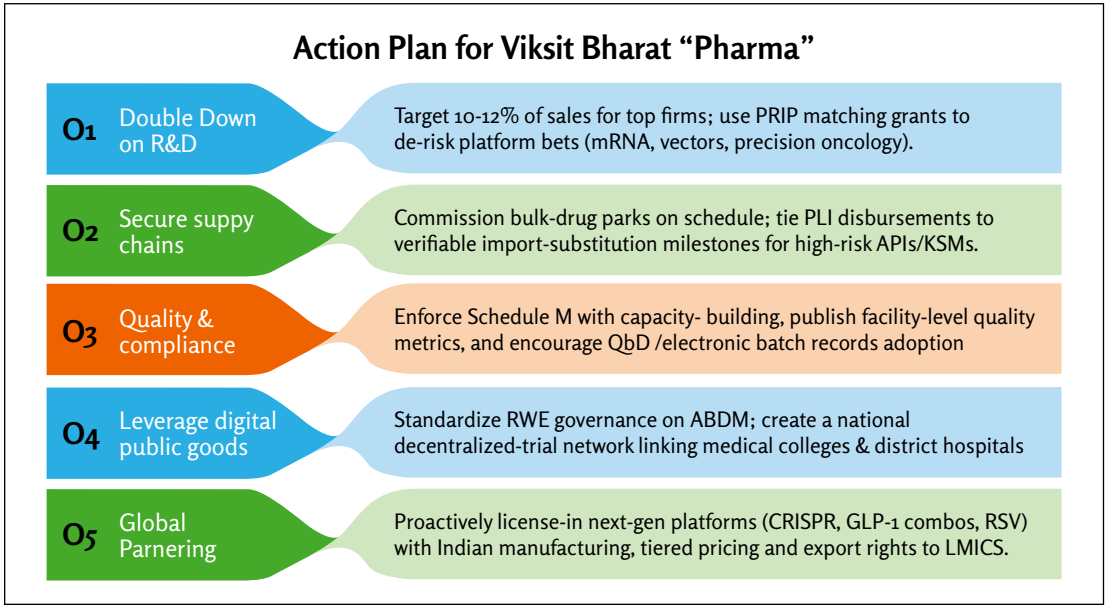
pragmatic trials at costs far below Western benchmarks. This is critical for demonstrating value in cardiometabolic, oncology and respiratory therapies that dominate India's burden (101 million with diabetes and 315 million with hypertension[7]).

5) **Grow talent and translational platforms.** Expand fellowships linking IITs/NIPERs with clinical centres; co-fund shared platforms for Messenger Ribonucleic Acid (mRNA)/Lipid Nanoparticle (LNPs), viral vectors and Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) editing; and create "trial-ready" hospital networks with unified contracts, ethics SOPs and data standards.

India can decisively move up the value chain if it executes these five steps. The payoff is more than market share. It is resilience in crises, better health outcomes for 1.4 billion citizens and a genuine claim to leadership in the next era of global pharma, precisely the kind of innovation-led growth a Viksit Bharat demands.

Some of the leading innovations happening around the world that India can capture to provide an impetus to its growth ambitions are as follows:

- **Gene editing and advanced therapies.** In December 2023, the FDA approved CASGEVY (exa-cel), the first CRISPR-based therapy for sickle cell disease[8]. Gene therapy is moving from promise to practice. India can benefit by adopting and localising manufacturing know-how over time and exporting affordable cell-gene therapy models, as shown by India's own NexCAR19, which was approved in 2023 and priced at ~US$30,000–50,000[9], a fraction of Western Chimeric Antigen Receptor T-cell therapy (CAR-T) prices. Building a domestic vector supply chain and specialised care centres could make India a global hub for affordable advanced therapies.



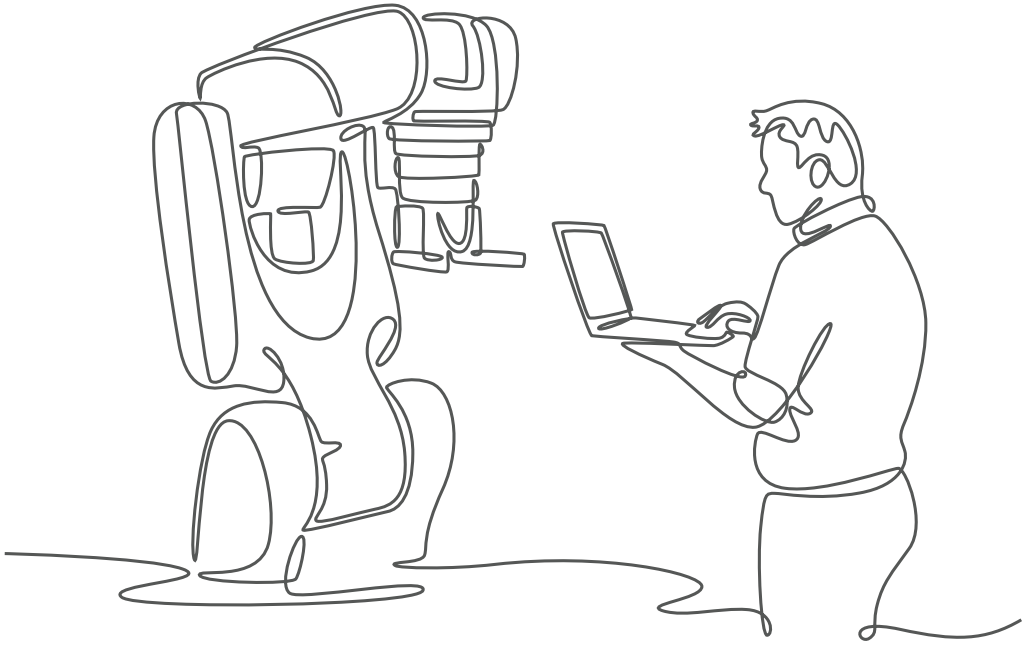
- **Metabolic breakthroughs (Glucagon-Like Peptide-1 (GLP-1)/Glucose-Dependent Insulinotropic Polypeptide (GIP)).** Tirzepatide reduced body weight by ~16–22.5 percent at 72 weeks in SURMOUNT-1; semaglutide 2.4 mg delivered ~15 percent reductions[10]. Given India's massive NCD load (101 million people with diabetes), collaborations for local manufacturing, value-based pricing pilots and patient-support programmes could bend morbidity and cost curves at scale.

- **Respiratory vaccines for seniors.** FDA's approval of the first Respiratory Syncytial Virus (RSV) vaccine (Arexvy) opens the door to healthy-ageing immunisation programmes[11]. With India's vaccine strengths, tech transfer or co-development for Low- and Middle-Income Countries (LMIC)-tailored RSV and pneumococcal vaccines could be a strategic export play.

- **AI-accelerated discovery.** Breakthroughs in protein and complex structure prediction and the advancement of the first AI-designed antifibrotic entering Phase 2 signal faster target-to-lead cycles. Anchoring national consortia that couple Indian chemistry and biology talent with AI models and train them on local disease datasets could compress timelines for TB, dengue and NCD targets.

- **Continuous manufacturing.** With improved harmonisation, companies adopting continuous processes can gain quality and cost advantages, which are ideal for APIs and complex oral solids India exports in volume. Fast-track regulatory pathways for CM conversions would reward early movers.

From the pharmacy of the world to the lab of the world, India's innovation-driven pharmaceutical journey will be the cornerstone of a truly Viksit Bharat by 2047.



India's Next Leap: From 'Pharmacy of the World' to Innovation Powerhouse

Sudarshan Jain

Secretary General, Indian Pharmaceutical Alliance

India's pharmaceutical industry has earned global recognition as the "pharmacy of the world," supplying affordable, high-quality generics and vaccines to more than 200 countries. From overcoming medicine shortages in the 1970s to becoming the world's third-largest drug producer by volume, the industry has played a vital role in advancing health equity and contributing to India's economic growth.

Today, India's pharmaceutical sector is valued at over USD 60 billion, with a trade surplus approaching USD 20 billion, underscoring its global competitiveness. However, the next phase of growth will not be driven solely by volume; it must be anchored in value creation. The industry aims to expand to USD 120–130 billion by 2030 and USD 400–450 billion by 2047. Realizing that vision depends on India's ability to lead in pharmaceutical innovation.

Why Innovation Matters Now

Globally, innovative therapies make up nearly two-thirds of the pharmaceutical market by value. India needs to

capture a larger share of this high-value segment. The goal is clear: develop 100 new drugs by 2047, India's centenary year. This is a bold ambition, but early signs are promising—from homegrown Glenmark's success in out-licensing with AbbVie on multiple myeloma and CAR-T therapies to Zydus' Saroglitazar (India's first NCE to be discovered and marketed domestically) and Wockhardt's new antibiotics.

To realise this vision, India must accelerate its transition from a manufacturing hub to an innovation engine, while staying true to its strengths in affordability, access, and quality.

Four Enablers of India's Innovation Leap

1. **Incentivising R&D**
   India is supporting innovation with strong policy measures. The ₹5,000 crore Promotion of Research & Innovation Programme (PRIP), ₹1 lakh crore Anusandhan National Research Foundation (ANRF), and the Research, Development and Innovation (RDI) Scheme are positive steps. The RDI scheme's model—long-term, low-interest financing for high-risk projects—has the potential to boost private sector R&D. To maximize impact, we need to encourage public-private partnerships and develop pricing models that recognize genuine innovation.

2. **A Modern and Agile Regulatory System**
   Timely regulatory approvals are essential for innovation. The Central Drugs Standard Control Organisation (CDSCO) is advancing through digital transformation, global harmonisation, and capacity building. Streamlining accelerated approval pathways, recognizing Indian clinical trial data globally, and providing regulatory clarity for novel therapies will reinforce India's reputation as an agile innovator.

3. **Industry-Academia Collaboration and Infrastructure for Skilled Talent**
   Innovation requires strong industry–academia collaboration to build future-ready talent for pharmaceutical operations. These partnerships help align academic training with industry needs and foster hands-on learning. Equally important is a strong foundation of infrastructure and people. India's expanding network of biotech parks, translational research hubs, and Global Capability Centres (GCCs) is promising.

4. **Leveraging Digital and Deep Tech**
   Advanced technologies are transforming every stage of the pharmaceutical value chain. AI, machine learning, and CRISPR are enabling faster drug discovery and more targeted therapies. India's genomic diversity gives it a unique edge in precision medicine. By partnering with tech startups, healthcare innovators, and space research institutions, India can lead in frontier science.

From 'Made in India' to 'Made and Discover in India'

India's pharmaceutical sector stands at an inflection point. India has the scale, talent, and scientific potential to shape the next era of global healthcare, not just as a manufacturer, but as a source of innovation. However, to get there, we must stay the course: sustained investment, regulatory simplification, and an ecosystem that supports long-term innovation.

Above all, we must prioritize patient centricity, scientific excellence, and equitable access. That is how India will redefine its place in the world—not just as the Pharmacy of the World, but as an innovation powerhouse for global good.

Viksit Bharat and the Innovation Imperative for the Pharmaceutical Sector

Suresh Pallathil

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Introduction

The vision of Viksit Bharat, a developed India by 2047, reflects the country's aspiration to become an economic powerhouse that thrives not only on scale but also on knowledge, technology, and innovation. For decades, India has been recognized as a hub for affordable manufacturing, particularly in the pharmaceutical sector. However, as the global economy shifts toward knowledge-driven growth, India's challenge lies in moving from being a cost-efficient manufacturer to becoming a leader in innovation. This transformation is not limited to pharmaceuticals but extends across biotechnology, medical technology, chemicals, and other industries. Innovation is therefore the central imperative for realizing the vision of Viksit Bharat.

Pharma at the Heart of Innovation

India is the world's third-largest producer of pharmaceutical products by volume and among the leading suppliers of generic medicines globally. The country contributes nearly half of the world's vaccines and a large share of generic drugs used in the United States and Europe. In 2022–23,

pharmaceutical exports touched over USD 25 billion, and the sector is projected to reach USD 120–130 billion by 2030.

Despite these achievements, the sector's growth has been largely dependent on generics and bulk drug production. The innovation pipeline: new molecules, breakthrough therapies, and advanced biologics remains limited. For India to sustain leadership, it must focus on original research, advanced drug delivery systems, and integration of digital technologies such as artificial intelligence (AI) in drug discovery and clinical trials.

The government has recognized this need and rolled out targeted initiatives. The Production Linked Incentive (PLI) scheme, worth over ₹15,000 crore, has boosted manufacturing capacity for active pharmaceutical ingredients and critical medical products. More recently, the Promotion of Research and Innovation in Pharma-MedTech (PRIP) scheme, with an outlay of ₹5,000 crore, is designed to encourage R&D and help the sector transition from copy to create. Industry leaders also stress the importance of ecosystem collaboration, bringing together academia, startups, and industry—and adopting technologies like AI and machine learning to shorten development timelines and improve efficiency.

The recent in-licensing of an early stage candidate for the treatment of cancer by the global Pharma major AbbVie from an Indian company Glenmark with a deal value of ~ 2 Billion USD (16000 crore INR) underlines the importance of consistent R&D investment and persistence which results in innovation.

Regulatory and Quality Imperatives

To become a true innovation hub, India must also strengthen its regulatory environment. Compared to developed markets, approval timelines remain longer, and harmonization with global quality standards are not optimal. Building transparent, agile, and science-driven regulatory frameworks will be critical for encouraging investment in innovation. This reform is particularly important as multinational companies increasingly view India as a base for clinical research and innovation centres.

Global capability centers of major global pharma companies are expanding rapidly in India, focusing on AI-driven drug development, clinical trial support, analytics and digital innovation. These developments indicate confidence in India's talent pool and its potential to move up the innovation value chain.

Beyond Pharma: Innovation Across Industries

While pharmaceuticals play a leading role, the broader innovation ecosystem in India is equally critical for realizing the vision of Viksit Bharat.

- **Biotechnology:** The Indian biotech sector, valued at around USD 80 billion in 2022, is expected to reach USD 300 billion by 2030. With initiatives like the Bio-RIDE scheme, which supports R&D and entrepreneurship, India is building capacity in bio-manufacturing, vaccines, and diagnostics. This complements the pharmaceutical industry and strengthens India's position in healthcare innovation.

- **Medical Technology:** MedTech is emerging as another key pillar. India's focus on diagnostic devices, implants, imaging solutions, and digital health platforms is expanding rapidly under government support. With foreign direct investment approvals crossing ₹11,000 crore in

2024, domestic manufacturing is scaling up, reducing import dependence and encouraging indigenous design and innovation.

- **Chemicals and Specialty Chemicals:** India's chemical industry contributes nearly 7% to the GDP and is one of the largest globally. It produces over 80,000 products, many of which are critical inputs for pharmaceuticals, agrochemicals, and industrial applications. Innovation in green chemistry, sustainable manufacturing, and high-value specialty chemicals is becoming a vital area of growth.

- **Digital and AI-driven industries:** Innovation in information technology and artificial intelligence is enabling efficiency across sectors. In pharma, AI is reducing drug discovery timelines. In manufacturing, digital twins and Industry 4.0 solutions are helping optimize production. In agriculture, data-driven solutions are enhancing yields and sustainability. Such cross-sector innovations reinforce India's march toward Viksit Bharat.

The Innovation Imperative for Viksit Bharat

For India to achieve the vision of Viksit Bharat, innovation must be treated as a national priority. The following areas are critical:

1. **Policy and Investment Support:** Sustained government support through funding, incentives, and infrastructure creation.
2. **Collaboration:** Stronger partnerships between academia, industry, and startups to drive original R&D.
3. **Talent Development:** Skilling the workforce in emerging technologies, biotechnology, data science, and regulatory science.
4. **Regulatory Reform:** Building agile, globally benchmarked frameworks to accelerate approvals and maintain high standards.
5. **Sustainability:** Promoting green manufacturing and circular economy practices across industries.

Conclusion

The journey toward Viksit Bharat is not only about economic growth but also about positioning India as a hub of knowledge and innovation. The pharmaceutical sector, already a pillar of India's global reputation, must now shift its focus from being the "Pharmacy of the World" to becoming the "Innovation Lab of the World." Alongside pharma, industries like biotechnology, medical technology, chemicals, and digital services must embrace innovation as their central growth driver. With the right policies, investments, and collaborative efforts, India can transition from a cost-competitive manufacturing hub to a global leader in cutting-edge innovation fulfilling its ambition of becoming a truly developed nation by 2047.

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Viksit Bharat and the Innovation Imperative

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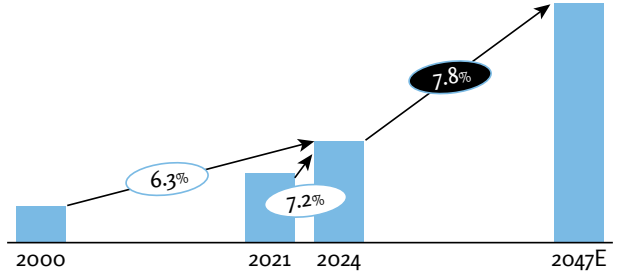
Viksit Bharat by 2047 – a national aspiration

India has set the ambitious goal of Viksit Bharat by 2047, marking a century of independence. According to a World Bank report released earlier this year, India will need to grow by 7.8% on average over the next 22 years to achieve its aspiration.[1]

Box/highlighted text: Achieving the Viksit Bharat goal by 2047 will require reforms and their implementation to be as ambitious as the target itself.

India's annual GDP growth rate (2000-2047E)



Source: India: Accelerated Reforms Needed to Speed up Growth, India GDP (World Bank data)

At the heart of this vision lies innovation. This is particularly crucial in the life sciences and healthcare sectors, where innovation will not only drive scientific progress but also promote social equity and bolster economic resilience.

India's pharmaceutical sector, globally recognized as the "pharmacy of the world," is uniquely positioned to catalyze this transformation. From vaccines and generics to complex biologics and digital therapeutics, the next phase of India's development narrative will hinge on its transition from a cost-efficient manufacturer to an innovation powerhouse. This shift will be pivotal in determining how India secures its healthcare future, fuels economic growth, and contributes to global health security.

The innovation imperative in Indian pharma

Innovation is no longer optional; it is critical for national health sovereignty and fulfilling the commitment to a healthy nation. The COVID-19 pandemic served as a defining moment, underscoring the necessity for a robust indigenous innovation pipeline amid the global race for vaccines and novel therapeutics.

India has a genuine opportunity to transcend its dominance in generics and emerge as a global leader in AI-driven drug discovery and development. This innovation landscape will encompass not only New Chemical Entities (NCEs) but also biosimilars, complex biologics, mRNA platforms, next-generation therapies like cell and gene therapies (C&GT), and novel drug delivery systems.

With over 60% of global vaccine demand met by Indian manufacturers and a growing share in biosimilars, India must leverage these foundational strengths to forge a more diversified, innovation-led strategy. Importantly, homegrown innovation can enable faster and more equitable access to life-saving treatments for Indians while also positioning India not just as a supplier to the world but as a problem-solver on the global stage.

To catalyze pharmaceutical innovation, the Government of India has launched a series of targeted interventions, including the Promotion of Research and Innovation in Pharma MedTech sector (PRIP) scheme and Pharma Innovation Fund, complemented by PLI schemes and initiatives such as Startup India. There is also focus on regulatory enhancements and reforms, including simplified licensing requirements, fast-track approvals for critical drugs, improvements in biosimilar and biologics approval guidelines, and recent advancements in C&GT guidelines. Collectively, while these initiatives are establishing the institutional, financial, and regulatory framework necessary for India's transition from generics to globally competitive innovation, they are still subscale. Much needs to be done to facilitate and fast track agency among government and stakeholders.

From generics to discovery: India's evolving pharma trajectory

India's pharmaceutical evolution has predominantly been characterized by its strength in generics; however, green shoots of innovation are beginning to emerge. Several domestic companies are now spearheading bold R&D agendas. For instance, Glenmark Pharma's licensing agreement with AbbVie for its investigational cancer drug ISB2001, a first-in-class trispecific antibody, signifies more than just a transaction; the platform and the pipeline mark a pivotal moment in the innovation landscape of Indian pharma and biotech. This partnership underscores the notion that innovations originating in India, despite being cash strapped, can compete on a global scale through alliances and partnerships.[2]

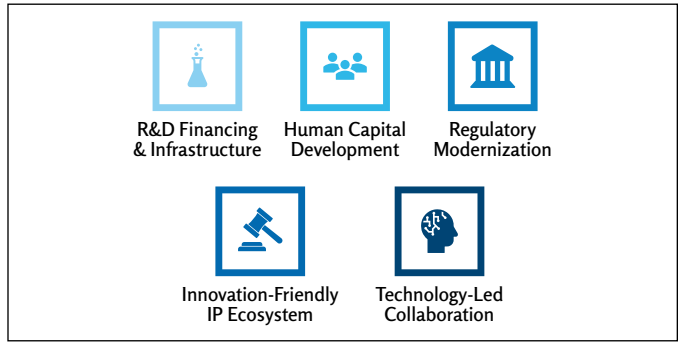
Wockhardt has developed a robust anti-infective pipeline. Miqnaf, created in collaboration with BIRAC, is the first indigenous macrolide antibiotic in over 30 years globally. Zaynich, currently in Phase 3 clinical trials, represents a new-generation beta-lactam antibiotic.[3]

With the launch of NexCAR19 in 2023 and Qartemi in 2025, India is establishing itself as a key player in the global immunotherapy arena.[4] Additionally, Cellogen Therapeutics has achieved a significant milestone with regulatory approval for the world's first indigenous Bi-Specific 3rd Generation Chimeric Antigen Receptor T (CAR T) cells. This breakthrough aligns with the Atmanirbhar Bharat initiative, showcasing India's capacity to lead in medical innovation. The research has garnered support from prominent institutions, including the Council of Scientific & Industrial Research (CSIR), the Regional Centre for Biotechnology, the Institute of Genomics and Integrative Biology, and NATCO Pharma. With this approval, India is poised to make significant advancements to cancer treatment, making CAR T therapy more effective, affordable, and accessible for patients both domestically and globally.[5]

Indian Contract Research, Development, and Manufacturing Organizations (CRDMOs) are also gaining prominence, supporting early-phase innovation for global clients and increasingly for Indian biotech startups. The formation of the Innovative Pharmaceutical Services Organization (IPSO) reflects the industry's commitment to transitioning towards next-generation therapies.

Academic research, once isolated from industrial needs, is now finding expression through incubators, translational research centers, and public–private partnerships. India is also witnessing an uptick in global licensing deals, venture investments, and M&A activity.

Key enablers to realise the innovation vision



To truly unlock the potential of India's pharma innovation ecosystem, five critical enablers must converge:

1. R&D Financing and Infrastructure bringing early commercial viability: Current R&D spending in Indian pharma hovers around 5%–8% of revenue, much below the global average. There is an urgent need to catalyze more investment, both public and private, into high-risk early-stage research. Structured models that combine public risk mitigation with private venture capital can be transformative. To bring in agency to the effort, some out-of-the-box initiatives may help. For example, encouraging early-stage funding and VC participation, government-led funding on a case-to-case basis, exploring possibilities of strategic partnerships and licensing deals at multiple stages of the discovery value chain, shared infrastructure and translational ecosystems, open source drug discovery and innovation models.

2. Human Capital Development: From clinical researchers to formulation scientists, and from regulatory experts to IP lawyers, India requires a next-generation workforce. Dedicated STEM training, exposure to translational science, and cross-sectoral mobility are vital.

3. Regulatory Modernization: Regulatory agencies must continue to evolve to strengthen the country's innovation foundation and transition into a robust ecosystem. Institutionalizing regulatory science and engaging with industry on emerging platforms (e.g., digital health, gene therapy) is critical to ensure India remains at the forefront of innovation trends.

4. Innovation-Friendly IP Ecosystem: Stronger IP protection, expedited dispute resolution, and global harmonization of patent norms will instill confidence in innovators to invest in India. Issues surrounding Section 3(d) and Form 27 in the Patents Act, and pre/post-grant opposition require careful balancing—topics that subsequent chapters of this compendium will explore in depth.

5. Technology-Led Collaboration: India must position itself as a key player in global innovation value chains. This entails embracing AI/ML, quantum computing in drug discovery, and leveraging cloud-based platforms for trial management and pharmacovigilance.

Conclusion: The time is now

The path to Viksit Bharat runs through the lab bench, the incubator, and the boardroom. If India is to secure its place as a global innovation leader, it must move with urgency and intent. The pharmaceutical sector — already a flagbearer of India's global competence — must now become the epicenter of bold, inclusive, and scalable innovation.

Government, industry, academia, and capital providers must come together in an unprecedented alliance to realize this vision.

The opportunity is real.
The capability exists.
The time is now.

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Pharmaceutical Innovations in India and Why North-East India Matters

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India's pharmaceutical sector is one of the country's most consequential science-led industries-by volume, among the largest producers of medicines worldwide, and by value, steadily ascending from a generics powerhouse to a broader innovation engine. Over the past decade production-linked incentives for bulk drugs, biopharmaceuticals and medical devices; demand-side anchors such as Ayushman Bharat and the Jan Aushadhi scheme, and a vibrant start-up/ entrepreneurship ecosystem supported by the Govt. of India have begun to reshape incentives from affordable to better, safer, and more patient-centric approaches. The national conversation now routinely includes cutting-edge modalities like AI/ML, biosimilars, RNA vaccines, long-acting therapeutics, phytopharmaceuticals/herbal

medicines, personalized & customized medicines, etc., alongside the traditional strengths of process chemistry and high-quality generics.

Yet the innovation arc must bend toward unmet public health needs and regional development. Nowhere is this more relevant than in India's North East, a region of extraordinary biodiversity and cultural knowledge. In this context, the National Institute of Pharmaceutical Education and Research (NIPER) Guwahati is strategically positioned to act as a catalyst-linking ethnopharmacology and modern drug discovery, talent and industry, laboratory know-how and enterprise/start-up creation. As an Institute of National Importance, NIPER Guwahati sits at the intersection of education, research, and enterprise. Its comparative advantages can be organized along five pillars:

Phytopharmaceuticals/Herbal Medicines: Move beyond crude extracts toward well-characterized, multi-marker products with defined mechanisms, robust stability data, and scalable processes. Establish a shared biobank of authenticated regional botanicals with barcoding and chemometric fingerprints to accelerate reproducibility.

Translational Research with Societal Relevance: NIPER Guwahati can prioritize discovery and development in areas where the region's needs and scientific assets align: anti-infectives, anti-malarial anti-inflammatories, metabolic disorders, cardiovascular, neurology and respiratory health. Natural-product chemistry, coupled with modern hyphenated analytical techniques (LC-MS/MS, GC-MS/MS) and computational docking/simulation, AI/ML techniques allows rapid triaging of lead molecules from regional botanicals into standardized extracts, characterized fractions, and eventually clinically testable phytopharmaceuticals.

Advanced Drug Delivery Engineering and Personalized Medicines: The institute can deepen strengths in formulation science: nano- and micro-particulate or emulsion carriers, topical drug delivery systems, solid-state pharmaceutics, long-acting injectables, and personalized 3D/4D printed dosage forms. Emerging technologies such as 3D/4D printing platform technologies for making personalized & customized medicines are especially relevant for treatment & patient centric approach adherence-sensitive conditions. A pilot-scale formulation & development facility at NIPERG enables scale-up studies, stability, and tech-transfer readiness.

Clinical Partnerships and Community-Embedded Practices: Collaborations with regional medical colleges and public-health programs can create pragmatic trial networks for device-drug combinations, OTC re-formulations, and pharmacy-based interventions. Pharmacovigilance and medication-use studies, conducted in local languages with patient-reported outcomes, can generate data that directly inform product design and labeling.

Innovation & Entrepreneurship Ecosystems: A tight loop from lab to market-IP support, rapid prototyping, seed funding, and industry mentorship can anchor a North East Biopharma Innovation Corridor. Short courses in tech-transfer, regulatory pathways, health-economics, and reimbursement prepare founders to build investor-ready ventures. Strategic co-development with MSMEs in Assam and neighbouring states can distribute manufacturing value chains-APIs, excipients, packaging-closer to raw-material sources.

In order to boost & build the capabilities & a holistic approach for innovation ecosystem creation following practical roadmap is the way forward:

People and Skills.
Attract and retain cross-disciplinary faculty-formulators, analytical chemists, biostatisticians, regulatory experts, while upskilling students in data science (DoE, PBPK modeling, AI/ML, etc).

Platforms over Projects.
Creation of Centre of Excellence (CoEs), National Centres with cutting edge facilities, high-resolution analytics, GMP-pilot-scale set-up, GLP Animal House Facility, Cell screening, and GLP-aligned preclinical unit. Platforms outlive projects and draw industry collaborations.

Partnerships with Purpose.
Structure collaborations with regional premium institute in NER like IITG, AIIMSG, IAAST, ISBD, CSIR-NEIST, etc. including universities like Guwahati, Tezpur, Cotton, etc, and Biotech/Innovation Hubs around milestone-based deliverables: a marker-based standard, or a stability-cleared formulation with a tech-transfer plan.

Data and Documentation.
Implement electronic lab notebooks, sample traceability, and a repository for characterization data that simplifies patent drafting and regulatory filings. Good documentation is a force multiplier in translational science.

Access Pathways.
Design for affordability from day one: optimize dose loads, use locally available excipients where possible, and explore public procurement routes for first market entry. Demonstrating health-economic value in North Eastern populations strengthens national scaling.

India's pharmaceutical innovation journey is shifting from low-cost replication to high-value differentiation. The North East can, and should, be a proving ground for solutions that are scientifically rigorous, context-appropriate, and globally competitive. NIPER Guwahati is uniquely placed to orchestrate this shift-bridging biodiversity and biodesign, public health and product development, students and start-ups. By focusing on translational platforms, regulatory readiness, and community-anchored clinical partnerships, the institute can help deliver the next generation of Indian pharmaceutical products: robust, affordable, and designed with the realities of the North East in mind-yet ready for the world.

Innovation Policy Landscape in India: Opportunities and Gaps

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India stands in a critical phase of transition, seeking to assert itself as a leading innovation economy. With its vast scientific base, dynamic startup ecosystem, and a rapidly digitizing economy, the country has both the ambition and capability to lead in frontier sectors such as life sciences, biotechnology, digital health, and clean energy. Yet, India's innovation journey is a work in progress—marked by flashes of promise and a tangle of persistent gaps. This essay reflects on recent policy shifts, particularly in life sciences and public R&D, and lays out the opportunities and bottlenecks shaping India's innovation future.

I. Recent Policy Developments: Signals of a New Direction

Over the past two years, India's innovation framework has begun to pivot. A major policy milestone is the 2025 draft of the Revised Biosimilar Guidelines issued by the CDSCO.[1] These introduce pragmatic reforms—waiver pathways for Phase III trials, acceptance of international reference biologics, and a stronger emphasis on analytical comparability. Such changes are not just regulatory tweaks; they reflect a broader move to align Indian standards with global science.

To complement regulatory clarity, the government launched the Research Development and Innovation (RDI) Scheme,[2] a bold step aimed at unlocking private R&D investment. With Rs 1 lakh crore (about USD 12 billion) committed through the ANRF,[3] and funds channeled via NBFCs, AIFs, and DFIs, the scheme aims to underwrite high-TRL ventures in sectors of strategic relevance. It's a rare example of patient capital in Indian R&D—and one that could tilt risk-reward calculations in favor of experimentation.

This policy momentum is echoed in the private sector. Indian pharma, for instance, is undergoing a quiet reinvention. According to the EY-BioAsia 2024 report,[4] firms are increasingly deploying GenAI for molecular modeling, trial design, and process optimization. This signals a shift from scale-led generics toward precision-led innovation.

Public research institutions are not far behind. Following recommendations from the Center for Global Development,[5] a new Public R&D Evaluation Framework was rolled out in 2025 across 244 institutions.[6] For the first time, impact is being measured not only by papers and patents but also by startup formation, inclusivity, and sustainability metrics.

Still, the optimism must be tempered with realism. The CTIER Handbook[7] highlights persistent fragmentation, regional imbalances, and chronic underinvestment by industry. Competitive, performance-based funding remains the exception, not the rule. This is where the real test lies: can good policy be matched by execution and scale?

II. Key Opportunities: Building on Momentum

India now stands at a promising juncture. Several levers, if strategically pulled, could accelerate progress:

Area	Opportunity
Regulatory Reform	Biosimilar and MedTech rules offering faster, adaptive approval pathways
AI & Digital Tools	Potential to reduce R&D costs by up to 50% through GenAI, digital twins, and diagnostics
Public Institutions	R&D Over 1,000 products and 1,700 services launched; strong push on startup incubation
Startup Integration	Labs enabling entrepreneurship through Section 8 spinouts and testbed access
Mission-Driven Programs	Coordination under AI, Bioeconomy, and One Health Missions linking public and private efforts
State-Led Innovation	Regional champions like Karnataka, Telangana, Gujarat driving policy and investment
Talent & Inclusivity	Women and youth engagement up, with targeted fellowships and infrastructure schemes

India's steady climb in the Global Innovation Index—from 81st in 2015 to 39th in 2024[8]—is not incidental. It reflects real, albeit uneven, reform.

III. Systemic Gaps: The Stubborn Middle

For all the traction, India's innovation system still wrestles with structural challenges. The most striking is the low private R&D intensity—less than 0.3% of GDP. As CTIER notes,[9] even India's top firms lag global peers in R&D-to-revenue ratios. Innovation remains a cost center, not a competitive differentiator.

Governance silos further dilute impact. Ministries and departments operate with overlapping mandates, and coordination is weak.[7] India needs an empowered, execution-oriented national innovation strategy.

Commercialization is another pain point. Over 1,100 patents sit idle in public labs,[10] a testament to the missing bridge

between invention and market. Unlike ecosystems in Israel or the US, India lacks well-resourced tech transfer offices and commercialization professionals.

Even in digital health—a sector ripe for global leadership—regulation is behind the curve. AI/ML-enabled devices are entering clinics faster than they can be evaluated.[11] While CDSCO and ICMR have begun capacity building, much more is needed to instil regulatory confidence.

Global linkages are underutilized. Less than 15% of public labs collaborate internationally,[12] limiting access to knowledge networks and downstream markets. Subnational inequity adds to the challenge: 90% of private R&D is concentrated in just five states[10]. That's not innovation at scale.

IV. Strategic Imperatives: From Reform to Realization

The road to becoming a globally relevant innovation economy will demand tough choices and bold reforms. Key imperatives include:

1. **Create a National Innovation Strategy** under ANRF to unify mandates and ensure outcome-oriented governance.[3]
2. **Expand Mission-Oriented Programs** in health, climate, and AI, backed by TRLlinked and milestone-based funding.
3. **Commercialize Public Research** through IPR cells, a national tech transfer office, and reactivation of dormant patents.[13]
4. **Digitize Regulatory Functions** with sandboxes for AI/ML in health and upgraded technical expertise at CDSCO and ICMR.[11]
5. **Use Market Levers**—such as tax credits and public procurement tied to R&D performance—to stimulate private investment.
6. **Decentralize Innovation Support** by funding district-level hubs and building regional STI indicators.[10]
7. **Reform Public R&D Funding** using third-party evaluations and competitive grant mechanisms to drive efficiency.[7]
8. **Strengthen IP protection and redressal mechanism** on the lines of the Delhi High Court Intellectual Property Division
9. **Invest in Talent and Data Infrastructure,** ensuring open-access research data and targeted support for women and early-career researchers.

Conclusion

India's innovation policy is evolving—from passive subsidy to strategic enablement. The foundation has been laid through reform, but it is the institutional agility and commercial translation that will define the next decade. As India aspires to "Viksit Bharat by 2047," it must align its science and technology system with national priorities and global markets.

The choice is not whether to innovate, but whether to lead or lag. With coordinated eiort, India can transition from incremental progress in science to becoming a catalyst for global impact.

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Viksit Bharat and the Innovation Imperative

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Viksit Bharat by 2047! For a nation trudging through unprecedented geopolitical disruptions and one that carries the weight of nearly a fifth of the world, this is not a transient catchphrase. It is a clarion call for an orbital shift as a developed nation. Viksit Bharat sets India on an expedition to earn its rightful place on a coveted pedestal occupied for long by the US, Europe, Japan, Korea and now increasingly China. Viksit Bharat, importantly, is the development of not just the country but a world that has been neglected for centuries.

Can India pivot to innovation?

With an enviable history for scientific temper that should not be an insurmountable task.

Scarce resources decades ago failed to hold Dr C V Raman as he spun miracles of light scattering in physics or Srinivasa Ramanujan from proving he was in the world's best minds in mathematics with nearly no formal training in the subject. Homi Bhabha, Har Gobind Khorana, APJ Abdul Kalam - the list is long. India has nurtured scientific brains and that reservoir keeps filling.

But hard facts bite. Over the last three decades, while India achieved major milestones across sectors and grew its economy manifold, in the field medical and pharmaceutical innovation, the country lost the steam and is outpaced by China.

Why? There is no easy answer to this puzzle.

Conducive policy framework and resources is a big missing link. Risk financing, a government policy that rewards innovation, and an industry that embraces failures in innovation has been lacking, barring a few exceptions. Playing safe helps but there are clear boundaries to growth.

Therefore, many illustrious and trained scientists came, tried their bets and left the Indian shores. They went and continued to lead, deeply engaged in their own fields of research – in start-ups or research labs of the exalted universities or at the helm of global pharmaceutical corporations. In India innovation had not halted, some of it simply moved out to places where scientific rigour was respected and found its true value.

Match that with China. The country welcomed their scientists, they built communities with their US counterparts, learnt the ropes and the growth of the Chinese biopharma industry over the last two decades is a testimony of that grand plan to spur an entire research-based industry. When the drugs were ready for clinical research, they were given accelerated approvals and tested for launch. Policies ensure that local innovations were rewarded and gained scale first within the country and then get ready for the global markets.

The results were stupendous – the biggest pharmaceutical companies are now licensing new products from their Chinese counterparts. They form at least 30% of all global deals in the pharma sector and that number is growing fast. Importantly, Chinese companies are now competing within themselves in new innovations. While clinical trials are expensive in US and Europe, take a longer time and regulatory approvals are stuck in queue, Chinese companies have realized their full potential with agility and careful planning.

As an exception, only one company, Glenmark clicked a licensing deal, after a long hiatus of over a decade, with AbbVie for its multiple myeloma drug for close to $2 billion. It's a fine example of perseverance.

Can innovation bounce back?

A large part of that lofty goal hinges on how India builds on its strategy in diverse fields of medicine, space technology, rural focus, digital integration, and industrial automation for global excellence.

For instance, in supplies of medicines, India has a proven track record of growth. The country supplies drugs worth billions of dollars to scores of low-and-middle-income countries. India saved millions of lives in smaller nations during the catastrophic Covid-19 pandemic. For the global south, India stood strong as a dependable supplier, providing medicines, diagnostics, and vaccines as part of its shared responsibility.

For the US healthcare system, Indian generic companies saved $219 billion alone in 2022. This came despite an increasingly tough regulatory environment.

But to rest on the laurels will keep India in a small loop. As much for itself as for the world, India needs to shift gears to innovative research. Indian companies are no longer the

dwarfs in the world of giants that they were three decades ago. They have deep pockets and are maturing. Bets must be taken to tread the path less travelled, risks must be seen as a strategy than mistake and failures must be celebrated as part of the journey, a step that gets closer to success.

Drugs are becoming complex but saving lives with low-cost options will remain as critical as ever. This is best illustrated through an example.

What does a life-saving drug mean to a patient and what if India does not have the capability to make it?

Trikafta is a life-saving medicine for patients with cystic fibrosis, a debilitating genetic disorder that affects the lungs and pancreas. From wheezing, cough, breathing distress and in severe cases pneumonia and bronchitis, the patient goes through insufferable pain. Vertex, Trikafta's Boston-based innovator, does not sell the drug in India. Recently, a kind-hearted doctor in Mumbai was reported to have secured supplies of Trikafta on compassionate grounds from Vertex.

Out of 80 patients that he had listed for eligibility, only half will probably get it for life. The drug costs a mind numbing Rs 1 crore and no Indian company has the rights to make it. Trikafta's India patent expires somewhere around 2037, records show.

Hence, the minuscule patients who receive the drug on compassionate grounds may live a full life of up to 80 years. Seen as a silver bullet, Trikafta improves lung function, cuts infections, and improves life expectancy. But those who may not get the drug tragically have their lives shrunk. Now think of the thousands who go uncounted and have no access to the drug.

Also think of the change it could have made to the patients if an Indian company had an innovative drug that worked in cystic fibrosis.

Is there hope?

A few green shoots of innovative research may change this dire situation, not just for patients of cystic fibrosis but thousands of other conditions where India can serve better.

For example, Infosys co-founder Kris Gopalakrishnan has pumped hundreds of crores in a human brain mapping project in IIT Madras and Indian Institute of Science, Bengaluru. This is a unique effort to find the root causes to several neurological issues in Indians.

C-CAMP (Center for Cellular and Molecular Platforms), a government incubation arm in Bengaluru, is working on many diverse leads, of which it is working on powerful drugs against super bugs or Anti-microbial Resistance, a silent threat that is killing thousands of people.

The Indian government has initiated bold and unprecedented measures to push innovation, one of which is a Rs 1 lakh crore fund for research and innovation in sunrise sectors. This single step is perhaps more transformative than the multiple small steps taken in the last two decades.

That apart, some big names in the pharma business have set a goal to develop 100 new chemical entities by 2047. The industry has never made such serious commitments in the past. Clearly it is time to shed the status quo of incremental profits from launching generic drugs.

A groundswell of Indian companies can change things fast. India has a vast demand for locally developed medicines. There are at least 6000 rare diseases in India, vector-borne

diseases like dengue and malaria are big killers, chikungunya is hard to treat. Besides, tuberculosis, cancers, autoimmune diseases are presenting new challenges of access as a new wave of innovative medicines spiral out of control. Cardiac and diabetes are getting deeper in the Indian populace.

The foundations of Viksit Bharat can be strengthened only when Indian pharmaceutical industry cranks up its innovation engine, not only for India, but for the world that looks up to it for help.

The path is difficult but not beyond limits.

As Robert Frost said in his golden lines:

The woods are lovely, dark, and deep, but

I have promises to keep and miles to go

before I sleep.

Patent Infringement and Enforcement Challenges in India

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1. Introduction

Patent infringement and its enforcement in India present a complex landscape shaped by a unique legal framework, an evolving judicial system, and the country's socio-economic priorities. While India's patent laws are largely harmonized with global standards, their application and enforcement face significant challenges, particularly in balancing innovation with public interest. This article delves into the intricacies of patent infringement, the key enforcement challenges, and the potential way forward in India.

2. Understanding patent infringement in India

2.1. A patent grants an inventor an exclusive right for a limited period (20 years in India) to prevent others from making, using, selling, or importing the patented invention without permission. Patent infringement occurs when a third party, without authorization, performs any of these acts. The Indian Patents Act, 1970, provides the foundational legal structure, and while it doesn't explicitly define infringement, Section 48 of The Patents Act, outlines the exclusive rights of a patent

holder, the violation of which constitutes infringement.

2.2. Indian courts recognize two primary types of infringement:

2.2.1. **Literal Infringement:** This occurs when the infringing product or process uses every element of the patent's claims, without any modification.

2.2.2. **Infringement by Equivalence:** This doctrine is invoked when the infringing product or process does not literally copy the patent claims but is substantially similar, performing the same function in the same way to achieve the same result as the patented invention. This is a crucial tool for patentees to combat minor design changes aimed at circumventing a patent.

2.3. Remedies for infringement are primarily civil in nature and include

2.3.1. injunctions (temporary or permanent orders to stop the infringing activity),

2.3.2. damages (to compensate for losses), or

2.3.3. an account of profits (to compel the infringer to turn over profits made from illegal activity).

Courts in India do grant interim or preliminary injunctions to halt infringement while a case is pending, a powerful tool for patentees.

3. Key Challenges in Patent Enforcement

Despite the legal framework, the enforcement of patent rights in India is fraught with several challenges.

3.1. **Protracted Litigation & Judicial Delays**
A significant hurdle is the time-consuming nature of patent litigation. Cases can drag on for many years, impacting the patent holder's ability to monetize their invention and discouraging foreign and domestic investment in R&D. While the Commercial Courts Act, 2015 including the High Court of respective State High Courts, aims to expedite commercial disputes, including IP cases, the sheer backlog of cases and a shortage of judicial officers continue to be a problem. This delay can render the patent's term meaningless, as a final verdict may only be delivered close to or after its expiry.

3.2. **Specialized IP Courts**
Unlike some other jurisdictions, India has limited dedicated, specialized IP courts. Patent infringement suits are heard by at high courts, which may not always have the necessary technical expertise to handle complex patent matters, particularly in fields like biotechnology or pharmaceuticals. While some high courts, such as the Delhi High Court, have developed expertise in IP matters, the overall lack of specialized benches can lead to inconsistent rulings and a reliance on external experts, which further prolongs the process.

3.3. **Public Interest vs. Patent Rights**
Indian patent law operates on a principle of balancing private rights with public interest, a stance most famously articulated in the landmark Novartis v. Union of India (2013) case. The Supreme Court's ruling, which denied a patent for a new form of a known cancer drug, highlighted the significance of Section 3(d) of the Patents Act. This provision prevents the "evergreening" of patents by requiring an invention to show "enhanced therapeutic efficacy" to be patentable. While this provision protects public health by ensuring access to affordable generic drugs, it can also create uncertainty for innovators, particularly in

the pharmaceutical sector, who may be hesitant to invest in research for incremental improvements.

3.4. **Compulsory Licensing**
The concept of compulsory licensing (CL), which allows the government to authorize a third party to manufacture a patented product without the patent holder's consent under specific circumstances (e.g., public health emergencies or when the patented invention is not reasonably available or affordable), is another unique challenge. The grant of India's first compulsory license to Natco Pharma for Bayer's cancer drug Nexavar in 2012 underscored the government's commitment to public health. Nevertheless, later IPO denied CL to BDR for BMS's Dasatinib (2013) and Lee Pharma for Astra Zeneca's Saxagliptin (2015). While a legitimate tool under the TRIPS Agreement, the specter of compulsory licensing can be a deterrent for global pharmaceutical companies, who view it as a weakening of their patent rights.

3.5. **Challenges with Expert Evidence & Discovery**
Patent litigation is highly technical, requiring expert testimony to explain the complexities of the invention and the alleged infringement. The process of gathering and presenting this evidence is cumbersome and costly. Further, obtaining discovery (the process of obtaining evidence from the opposing party) in India can be challenging, particularly for the patent holder who needs to prove that the defendant is using their patented process. While Section 104A of the Patents Act shifts the burden of proof in process patent cases onto the defendants/ infringers, its application in court can be difficult.

3.6. **Determining Damages**
Determination of damages is yet another key challenge in enforcing patent rights as there is no established methodology or guidelines to quantifying economic losses—including lose sales and profits; potential license revenues— can lead courts to award inadequate, low or no compensation. This weakens the effect of patent law and deters patentees from pursuing legal remedies.

4. The Way Forward

India has been taking steps to address these challenges, aiming to create a more robust and predictable patent enforcement regime.

4.1. **Judicial Activism and Specialized Benches**
Some high courts, most notably the Delhi High Court, have taken a proactive approach. The Delhi High Court has developed specific practices and benches for IP matters, showcasing a willingness to streamline litigation and deliver timely judgments. Recent judgments have also shown a greater willingness to grant interim injunctions and award substantial damages, sending a strong signal that infringement will not be tolerated.

4.2. **Policy Reforms**
4.2.1. **Expertise of IP Courts:** Creating dedicated IP courts with judges who have the necessary technical and legal expertise is crucial including mandatory training for judges on patent law, including technical aspects.

4.2.2. **Litigation Efficiency:**
4.2.2.1. Implement strict timelines and streamlined procedures for faster case resolution.
4.2.2.2. Standardize the process for granting interim injunctions to provide timely relief and prevent irreparable harm.

4.2.3. **Evidence:**
4.2.3.1. Establish clearer rules for evidence and damages to ensure fair compensation. Establish clearer rules for

admitting technical evidence and utilizing court-appointed scientific advisors to assist judges.

4.2.4. **Predictable damages:** Develop a predictable methodology for calculating damages, such as lost profits or a reasonable royalty, to ensure that patentees are adequately compensated and to deter future infringement.

4.2.5. **Alternative Dispute Resolution:** The use of mediation and arbitration is gaining traction as a faster, more cost-effective alternative to traditional litigation. Encouraging parties to resolve disputes out of court can significantly reduce the burden on the judiciary and provide a more flexible and confidential environment for resolution.

5. Conclusion

The landscape of patent infringement and enforcement in India is a dynamic one, reflecting the nation's dual identity as a developing economy and a rising global innovator. The legal framework, while strong on paper, is challenged by procedural delays and the delicate balance between protecting innovation and ensuring public access. While significant hurdles remain, recent judicial and policy developments indicate a positive shift towards a more robust and efficient enforcement regime. As India's innovation ecosystem continues to grow, a strong and predictable patent system will be vital to encourage R&D and secure the country's place on the global stage.

Innovating for a Healthier India: Pharma's Role in Viksit Bharat

Winselow Tucker

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Innovation is the lifeblood of progress. No nation can aspire to become truly developed without placing innovation at the very core of its growth agenda. For India, which has set its sights on becoming a developed nation by 2047[1] (its centenary year of independence) through the Viksit Bharat vision, innovation is not a choice but a necessity. From creating better infrastructure to delivering advanced healthcare, innovation will determine how fast India can move from aspiration to achievement. As a multinational pharmaceutical company with a growing presence in India, we have seen firsthand that India's progress in healthcare has always been tied to its ability to innovate—whether in digital health, clinical research, or expanding access to essential medicines. The next phase focused on reforms, especially the policy reforms under the banner of Viksit Bharat, promises to accelerate that journey.

Health at the heart of development

Viksit Bharat is a holistic vision for a society that is inclusive, prosperous, and resilient. Among its central pillars is the emphasis on healthcare. This matters deeply for patients and companies alike. For patients, it means more investment in

hospitals, public health, and digital systems that will ensure continuity of care. For pharmaceutical companies, it signals a clearer, more supportive environment to research, develop, and deliver new therapies at scale.

A nation cannot achieve its fullest potential if its citizens are not healthy. Chronic diseases like diabetes, obesity, fast-rising cancer incidence, and immune-related disorders already present immense challenges. Non communicable diseases – NCDs, such as heart disease and cancer, have immense pressure on any economy. The World Economic Forum[2] estimates that India will lose about US $4.58 trillion between 2012 and 2030, due to the combined effects of NCDs and mental health conditions, including reduced workforce output and premature mortality. As per the global burden of disease 2016 estimates[3], Non-communicable Diseases (NCDs), cause 62% of all deaths in India. Mitigating the impact of NCDs requires innovation not only in medicines but also in systems of care.

The digital revolution in health

Unlike many developed countries, where public health systems cover a majority of citizens, India remains a largely out-of-pocket market. Most households bear the cost of care directly, which often results in delayed treatment, financial strain, and in many cases, significantly high health expenditures. The Ayushman Bharat scheme has been a significant step in addressing this gap by providing insurance coverage for millions of low-income families and now for all elderly people more than 70 years of age, but it is still the beginning of a much longer journey towards universal health coverage.

Here, India can draw lessons from countries like Thailand, which successfully scaled its Universal Coverage Scheme to reduce household health expenses, and Japan, which built a strong foundation of public health and insurance systems decades ago. For India, the challenge is to combine such systemic reforms with its unique strength—digital innovation.

The Ayushman Bharat Digital Mission (ABDM) is a pioneering effort in this direction. By building a national health stack where citizens have digital health IDs, facilities and providers are registered, and records are interoperable, India is laying the groundwork for a more equitable system.

For patients, this means portability and reduced fragmentation. For researchers and pharmaceutical innovators, it opens the door to using anonymised, consent-based data to generate real-world evidence, design better trials, and track long-term outcomes. Chronic conditions such as diabetes can be monitored more effectively, while in oncology and immunology, digital records enable earlier diagnosis, timely referrals, and improved follow-ups.

Digitisation also reduces inefficiencies. Pilots of “scan and share” technology in hospitals have shown how paperless, instant registrations can cut waiting times. These may appear small improvements, but at scale, they represent a transformational shift. By combining current reimbursement programs like Ayushman Bharat with digital innovation, India can build a stronger, more inclusive health system that supports patient care and fosters innovation for decades ahead.

Regulatory reforms that accelerate innovation

Another critical enabler under Viksit Bharat will be regulatory reforms. It will show India’s determination to make its clinical research ecosystem faster, more responsive, and globally competitive.

1. **Innovation in clinical trials**[4]**:** Innovative medicines have the potential to help Indian patients with chronic diseases such as cancer, diabetes, and heart disease. However, the approval process for these treatments is longer than in the US and EU. India can accelerate access by using global clinical trials already including Indian patients, which provide high-quality evidence recognized internationally. The International Conference on Harmonization (ICH) offers guidance on multi-regional clinical trials (MRCTs), and accepting such trials could cut Indian approval timelines by at least 24 months.

   In 2025, India's drug authorities have proposed reduction of the timeline for granting permissions to manufacture new drugs for clinical trials from 90 working days to 45 for purpose of test license only. This is more than a bureaucratic change—it is a statement of intent. However, this will not be sufficient to attract global innovation and investments as it does not improve timelines of global clinical trials approvals. For this to happen, same amendment needs to happen in Rule 22 of NDCT Rules (2019).

   Establish Central ERBs (Ethics Review Boards): Many countries have central ERBs to streamline site approvals and reduce start-up times. A central ERB in India would minimize duplicative reviews, provide consistent oversight, and accelerate trial launches. India's regulatory approvals currently take 135–237 days, with ERB approval between 30–90 days, compared to 70–84 days for ERB in Australia and Argentina's new 60-day law.

2. **Unique regulatory requirements**[4] also slow down product submissions and launches. Harmonizing India's product testing and data submission processes with global, risk-based standards would further reduce launch times by 5 to 6 months. Currently, India's three-stage product approval process creates redundancies; moving to a single approval could shorten launch timelines, and pursuing full ICH membership would facilitate international convergence and enable Indian innovation to reach global markets faster.

3. **Intellectual Property and Innovation:** Robust IP protection is essential for pharmaceutical progress. India's recent Patent Rule amendments and acceptance of certain international trial data are promising steps that could speed patient access. Still, challenges remain, including restrictive patent criteria, lack of regulatory data protection, and weak deterrents against counterfeits. Addressing these issues and building on ongoing reforms are crucial for attracting investment, fostering innovation, and ensuring patients benefit from biopharmaceutical advances.

From innovation to patient delivery

Innovation matters only when it reaches patients quickly. Viksit Bharat's focus on logistics, infrastructure, and digital governance will be vital here. For complex therapies like oncology and biologics, stronger cold-chain systems and smarter warehousing can cut delays. Digital platforms can track inventories in real time, preventing shortages, while linked health records strengthen pharmacovigilance and ensure safer use of medicines.

Every day saved in approvals, logistics, or wait times brings hope closer to patients.

Investing in people and health

The government's 2025 vision rightly emphasizes investment in people—through healthcare, education, and skills. More funding for health programs, expanded medical education, and skilling in the sector create a healthier population and a

predictable demand environment. For patients, this means earlier diagnosis and treatment, and less risk of catastrophic health expenses.

As India grows toward a $30–40 trillion economy by 2047[5], healthcare will be both a driver and beneficiary of this growth. Innovation in health multiplies impact—it boosts productivity, reduces poverty, empowers women, and extends healthy lives, all of which are central to Viksit Bharat.

A shared opportunity

Viksit Bharat is not just a vision statement—it is a call to action. India has shown before that transformation is possible at scale, whether in financial inclusion, digital governance, or vaccination drives. The same spirit, applied to healthcare, can redefine patient care for a billion people and set a global benchmark.

As the centenary year approaches, optimism is well placed. With health at the heart of progress and innovation as the driver, India is poised to ensure faster access to therapies, more equitable care, and longer, healthier lives for all. It is a journey of confidence—one we are proud to share in.

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About OPPI

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

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

About Bharat Ke Liye

Bharat Ke Liye captures the essence of OPPI's commitment towards India, one that's backed by innovative solutions with a mission to improve the country's healthcare infrastructure. Along with our member companies, we have been a strong partner to the nation since pre-independence. With a strong Indian ethos and a deep understanding of the country's complex fabric, we have been investing in India to build a healthier and stronger country.

As we move towards India@100, we will continue to partner the with Government to advance its vision of Healthcare for All, investing in building India's capability to solve the health challenges of its people & the world at large. It's important now more than ever before to CONVERGE, COLLABORATE, and CO-CREATE with the Government and other stakeholders in India.

We are #BharatKeliye

We were there
Since pre-independence, we've partnered with India to eradicate many diseases, address many epidemics, and solve health problems; together.

We are there
We've been collaborating for critical support during the pandemic, co-creating with the government to strengthen our healthcare ecosystem, converging our knowledge, and leveraging technology to innovate for unmet medical needs, all in an effort to improve the quality of care & access to healthcare.

We will be there
As we work towards India@100, we pledge to keep investing in the future of the nation, pushing boundaries of innovation, research, and development, to make every Indian healthy, prosperous, and resilient.

Partnering India on its mission to progress, amplifying our Hon'ble PM Shri Narendra Modiji's clarion call of

Jai Vigyan, Jai Anusandhan!

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