Vision 2025
Unlocking India’s potential for leadership in pharmaceutical innovation

October 2016
Executive summary

1. Introduction

India is a global leader in the production of quality generic pharmaceutical medicines, but has not yet realized its potential to develop a strong, research-based pharmaceutical industry that can produce innovative medicines. This report presents a vision for an innovative pharmaceutical industry in India, showing how developing a robust, innovative ecosystem can improve the health and productivity of patients in India and around the world, while also generating economic benefits by making India an attractive place and destination for investment in R&D, thus creating more value-added jobs and driving a higher research output of global significance.

We base our approach on research that examines the current landscape of the Indian innovative pharmaceutical industry and identify areas that need to be strengthened, offering an analysis of ways to bring India into the forefront of leading countries in pharmaceutical innovation. While much work lies ahead, the report provides an achievable policy road map to guide policymakers and industry.

The study also involved interacting with central and state government officials, industry leaders, start-ups, academia, and research centers, among others, to understand their perspective on the current state of the Indian innovative ecosystem.

The recommendations from this study address four areas in need of attention—infrastructure, financing, human resources, and legal and regulatory—to enable the growth of a domestic innovative pharmaceutical industry with global significance. It is important to foster better cooperation and collaboration among the many stakeholders that contribute to building a vibrant, innovation-driven pharmaceutical industry in India—government, industry, academia, financial, and the medical professional communities. Ultimately, the innovations produced will contribute to improving the health and well-being of patients across India.

2. Indian pharmaceutical industry

India is a leader in global generic pharmaceuticals manufacturing. It supplies 20% of global generic drugs and is a preferred location for generic drug production.\(^1\) The size of the Indian pharmaceutical market in the financial year 2014–15 was estimated to be approximately 20 billion USD, making India the 3\(^{rd}\) largest pharmaceutical market in terms of volume and 14\(^{th}\) largest by value.\(^2,3\) The Indian pharmaceutical sector has attracted substantial FDI (foreign direct investment)—a total of 11.4 billion USD of foreign investment was received between April 2000 and September 2013.\(^3\) However, the FDI in 2015–16 was almost halved as compared to 2014–15, from 1.6 billion USD to 0.8 billion USD.\(^4\) Export of generics is a key growth area and almost half of the market size by value.

India has an opportunity to build on its strengths in generics and move up the value chain by enabling innovations and new drug discovery. However, the Indian pharmaceutical industry does not have a strong track record of innovation. A comparison of India with established pharmaceutical innovation leaders—the US, UK, and Japan—and with countries that have recently moved up the innovation ladder—South Korea, China, and Singapore—shows that there are multiple gaps in the Indian ecosystem. India invests just 0.9% of its GDP (Gross Domestic Product) towards overall research and development compared to an investment of 1.6% in the UK, 1.9% in China, 2.8% in the US, and 3.3% and 4% in Japan and South Korea respectively.\(^5\) Specifically, India’s spend on pharmaceutical R&D at 0.08% of the GDP is just 1/8\(^{th}\) of the amount the US spends (0.62% of GDP) towards overall research and development compared to an investment of 1.6% in the UK, 1.9% in China, 2.8% in the US, and 3.3% and 4% in Japan and South Korea respectively.\(^5\) Specifically, India’s spend on pharmaceutical R&D at 0.08% of the GDP is just 1/8\(^{th}\) of the amount the US spends (0.62% of GDP) and 1/4\(^{th}\) the spend of the UK (0.3% of GDP).\(^6,7\) Availability of funding and overall investment are key concerns that were highlighted by almost all stakeholders contacted for this study.

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India is not short of intention and has started to recognize the need to develop an enabling ecosystem that supports investment, technology transfer and growth in innovative areas such as biosciences. The current central government in India led by Prime Minister Narendra Modi has reinforced the intent in public discussions. The government’s flagship Make in India program has also seen active involvement from the Indian pharmaceutical companies. Some of this intention has started to reflect in actual progress. There are examples of collaborations between Indian and foreign companies on early stage compounds. However, India needs to undertake multiple initiatives across infrastructure, financing, human resources, and the legal and regulatory framework to find a place as a preferred destination for pharmaceutical innovation.

3. Study results in brief

This report seeks to articulate a vision and roadmap for India to focus on innovation, outlining the required policy interventions to encourage local research and development as well as to attract more foreign investment.

Figure 1: Vision for the innovative pharmaceutical industry of India

- Health benefits:
  - Improve health outcomes through new treatment
  - Strengthen R&D centres and biotech clusters
  - Sustainable clinical trial infrastructure
  - Improve availability of data for research

- Economic benefits:
  - Become an attractive destination for investment in R&D
  - Higher value-added jobs
  - Higher research output

- Strengthening of ecosystem
  - Increase the variety of R&D financing resources to encourage and support an increase in life sciences R&D
  - Adopt healthcare financing policies to increase availability and usage of pharmaceutical innovation
  - Improving the education level of the workforces based on industry needs
  - Incentives to attract talent

- Access to quality infrastructure
- Availability of financing for research and purchase of medicine
- Cultivating high-quality, well-trained human resources
- Sound and effective IP, legal and regulatory framework

The vision is in line with various government initiatives such as Make in India, Start-up India, the National Education Policy, the National Health Policy and Digital India. The report also discusses the likely benefits to India.

Creating an innovative ecosystem to foster growth and development in the pharmaceutical research sector requires four key pillars: infrastructure, financing, human resources, and a legal, IPR (Intellectual property rights) and regulatory framework (Figure 1). There are multiple stakeholders involved across these pillars, who are all important for promoting pharmaceutical innovation in India. India can unlock its innovation potential by taking steps across the four key pillars to strengthen its ecosystem and address the roadblocks faced by all the stakeholders—pharmaceutical companies, universities, research labs, financial institutions, hospitals, etc.
Vision for the pharmaceutical innovation ecosystem of India and the four key pillars

Pillar 1: Infrastructure

- Strengthen R&D (research and development) centers and biotech clusters by establishing a single body accountable for performance of public R&D centers and facilitate better tech transfer infrastructure and collaboration among academia, research centers, and industry.
- Bolster clinical trial infrastructure by developing specific courses in clinical trials, improved infrastructure in hospitals and increased public investment.
- Improve availability of data for research enabled through implementation of EHR (electronic health records) standards and certification of EHR products.

Pillar 2: Financing

- Increase the variety of R&D financing resources to encourage and support an increase in pharmaceutical R&D. This can be achieved through various financing schemes such as subsidies for start-ups focusing on R&D, increased limits for grants/loans, and tax incentives, among others.
- Adopt health care financing policies that improve coverage for primary health care and increase penetration of health care insurance programs, which will enable growth, access to, and use of pharmaceutical innovation.

Pillar 3: Human resources

- Improve the education and skills level of the workforce to meet the needs of the domestic and global pharmaceutical industry by introducing new national training programs with expanded access to grants and scholarships.
- Enhance incentives to attract and retain scientific talent, both from foreign institutes and individual scientists, researchers etc.

Pillar 4: Legal and regulatory framework

- Develop effective and adequate IPR laws and policies by establishing specialized IP (intellectual property) courts, streamlining administrative processes to file patents and removing barriers to patentability.
- Develop guidelines to facilitate knowledge and technology transfer to bridge the gaps between the discovery, development and commercialization of innovative drug products.
- Strengthen the regulatory framework to streamline and expedite the development and launch of new products that are benchmarked with internationally available practices, and increase resources for the regulatory agencies.

While steps have been taken, the recommendations in this report offer a roadmap for policy implementation. The potential benefits, which are highlighted below, are significant.

Employment opportunities could be increased fourfold from the current level of 0.9 individuals per every thousand employed in R&D.9,11
- An enabling ecosystem will attract more FDI in R&D. Assuming India’s innovation evolution is similar to China, India has the potential to attract 300–400 million USD worth of FDI in R&D in five years.9,10
- Also, India would be able to increase its research output both in quantity and quality. There could be a threefold increase in life sciences Patent Cooperation Treaty (PCT) applications from the current 1.5% to 4.5%.11
- Improvement in the clinical trial regulatory environment and adoption of practices aligned to global standards could enable India to increase its share of global clinical trials from the current 1.3% to 5%.12
- A greater focus on innovation will enable the development and commercialization of 3–4 new molecular entities (NMEs) from India every year from 2020–2025, with a potential to generate 1.5–2 billion USD in revenues from 15–20 NMEs by 2025.9
- An innovation-oriented industry will lead to the generation and commercialization of home-grown IP and help position India globally as a strong knowledge-driven economy with advanced capacities in science and medicine. However, time-bound implementation of policy interventions is a prerequisite for India to realize its innovation potential and vision.
Introduction

India has many attributes necessary to support greater levels of clinical research and drug development; however, a strong domestic innovative pharmaceutical industry has not yet developed. Achieving this potential is well-aligned with Prime Minister Modi’s goals of bringing growth to India through innovation in research and manufacturing.

We are once again turning to the country’s scientists and innovators to realize the goals of human welfare and economic development.

- Narendra Modi, Prime Minister, Government of India

The Indian pharmaceutical industry has witnessed significant growth in sales, both domestic and overseas. During the financial year 2014–15, the Indian pharmaceutical market clocked total sales of approximately 20 billion USD, 50% of which are exports. The country is also a leader in the manufacturing of low-cost generic medicines and vaccines. Steady growth in the Indian pharmaceutical industry has helped improve key health indicators and outcomes, both at a local and global level.

I am certain that India has the potential of becoming a global pharmaceutical powerhouse and is in the process of putting some key enablers in place. These include giving the right incentives for R&D, forging alliances with the private sector and keeping an open mind on suggestions for fiscal relief to the private sector so that its role in R&D is enhanced… Strengthening of the R&D ecosystem is the priority.

- Dr. Harsh Vardhan, Minister, Ministry of Science & Technology, Government of India

With India’s considerable pharmaceutical industry size, there is substantial potential to attract investments in this sector. Additionally, India’s leaders have repeatedly expressed their intention to promote a culture of innovation in the country, and increase self-reliance to provide quality as well as affordable medicines to the population and, above all, pave the way to make the country a significant player in drug discovery. This aspiration has become more pronounced in the last few years under the Modi government. Indian government and its ministries have repeatedly emphasized the strategic importance of the pharmaceutical sector in promoting economic growth through focus on innovation and scientific research.

The Indian government has also recently rolled out several initiatives such as Make in India, Start-up India, the Draft National Health Policy and the National IPR policy, which are expected to contribute positively to building an environment that encourages the development of local R&D and in attracting global investment for innovation.

AIM (Atal Innovation Mission) will be an innovation promotion platform involving academics, entrepreneurs and researchers and draws upon national and international experiences to foster a culture of innovation, R&D and scientific research in India.

- Arun Jaitley, Union Finance Minister of India

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**Make in India** (launched in 2014)

- Aims at encouraging multinational and domestic companies to invest and manufacture in India, as well as promoting job creation and skill enhancement.  
- Biotechnology and pharmaceutical industries highlighted as key sectors.

**Start-up India** (launched in 2016)

- Aims at promoting bank financing for start-up ventures to boost entrepreneurship and job creation.  
- The Ministry of Human Resources and Development (MHRD) and the Department of Science and Technology (DST) have agreed to partner in an initiative to set up over 75 start-ups in leading educational institutes—National Institutes of Technology (NITs), Indian Institute of Technology (IITs) and National Institute of Pharmaceutical Education and Research (NIPERs).

**Draft National Health Policy** (released in 2015)

- Aims to improve population health through the expansion of health coverage, for primary care and essential medicines in particular, reduce out-of-pocket health care expenditures, and ensure improved access to secondary and tertiary services.  
- Sets out the objectives of IP awareness and promotion and initiates measures to encourage IP generation, establish a strong legal and legislative framework, strengthen IP administration and management, foster commercialization of IP, strengthen enforcement and adjudication mechanisms, and promote human capital development to generate IP.

**IPR policy** (released in 2014)

- Aimed at transforming India into a digitally empowered society and knowledge economy.  
- The Digital India program is centered on three key vision areas: digital infrastructure as a core utility to every citizen, governance and service on demand, digital empowerment of citizens.

**Digital India** (launched in 2015)

- Aims to make India a knowledge superpower by equipping its students with the necessary skills and knowledge and by eliminating the shortage of manpower in science, technology, academics and industry.  
- Aims to address the changing dynamics with regards to quality education, innovation and research.

**New Education Policy** (inputs to be submitted by 2016)

- Indian companies in the health services sector made global pharmaceutical investment a priority in the 1990s and were able to become net pharmaceutical exporters through strategic governmental planning and economic liberalization. In order to keep pace with its competitors in the long run, focus and investment in the innovative pharmaceutical sector becomes a key priority for India, as is evident from the Make in India initiative for both the biotechnology and pharmaceuticals sectors. The ‘smart city’ concept introduced by the Ministry of Urban Development has ‘health’ as one of the core infrastructure elements necessary for the development of a smart city.

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Other efforts have set out ambitious yet achievable goals for India. For example, in 2010, India’s Vision 2020 aimed to make India one of the world’s five leading producers of affordable pharmaceutical drugs by 2020. Vision 2030 aims to expand India’s global leadership and relevance in life sciences, while driving domestic access by becoming the world’s largest and most reliable drug supplier; providing access to affordable, quality medicines to every Indian; and establishing a globally recognized presence for the Indian industry in pharmaceutical innovation.

Overall, the Indian pharmaceutical sector currently has a strong presence in manufacturing low-cost generic medicines, but needs to foster an environment conducive to innovation. Countries with strong innovation capabilities in the pharmaceutical sector have moved ahead by discovering and manufacturing medicines more suited to their own problems. India has a high burden of both communicable diseases and non-communicable diseases and is vulnerable to pandemics. To improve health outcomes, India would need to focus on developing new and cost-effective therapies that address this disease burden. Many generics manufactured in India are at the end of their respective product life cycles, with limited new research and development taking place on those drugs. India needs to create a conducive policy environment, increase its spending on research and development, introduce a stable regulatory regime, and institute a strong IP framework in order to foster innovation within the domestic industry. This will also encourage foreign multinationals to invest in the innovative ecosystem to develop new medicines not just for India but also for the world. In turn, such reforms would also generate economic benefits by creating more value-added jobs and driving a higher research output of global significance.

**Report methodology**

This report seeks to articulate a vision for India’s innovative pharmaceutical sector, outline the necessary policy elements required to encourage local R&D and attract investment from the global innovative industry, and make policy recommendations to achieve the desired vision. In order to advance these objectives, the report’s methodology involved numerous steps:

- Reviewed the existing innovation landscape to understand the current state of the Indian pharmaceutical industry
- Identified international best practices for the promotion of an innovative pharmaceutical sector
- Described policy elements necessary to encourage local R&D and attract foreign investment
- Incorporated insights from interviews conducted with stakeholders from the government (6), pharmaceutical companies (5) and biotech companies (6), funding institutions (4), universities and research centers (3), associations (4), and biotech parks (1) to understand where key stakeholders see gaps and areas for improvement in India’s innovation ecosystem. Interview insights from experts of identified model countries (the US, UK, Japan, Singapore, South Korea and China) were also carried out.
- Analyzed gaps in India’s policy environment in comparison with international best practices
- Recommended policies to address gaps and achieve the vision
- Prioritized the policy recommendations with respect to impact in advancing the vision
- Analyzed potential benefits to India from the implementation of the policy recommendations

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Current state of the Indian pharmaceutical industry

India is the 14th largest pharmaceutical market in the world by value and 3rd largest by volume. The country manufactures 20% of all generic drugs manufactured globally and exports to 200 countries. With over 10,000 manufacturing units and the largest number of US FDA-approved facilities outside the US, India has emerged as a leader in generics manufacturing. During the financial year 2014–15, the Indian pharmaceutical market clocked a total sales of −20 billion USD, 50% of which are exports. With an expected year-on-year growth of 12–15%, the Indian pharmaceutical market is expected to reach 40–45 billion USD by 2020. Indian pharmaceutical companies have 3,411 US drug master file (DMF) filings for generic drugs—the highest from any country in the world. This strong performance and the strategic importance given to the sector offers significant growth opportunities. The industry has ushered in economic benefits and has attracted approximately 12 billion USD in FDI between April 2000 and September 2013. Simultaneously, this growth has contributed positively to improving domestic health outcomes. The infectious disease burden, life expectancy, maternal mortality, and infant mortality rates in India have improved substantially in the last two decades.

On the back of this growth, the Indian pharmaceutical industry has also significantly contributed to global health care needs. It has made drugs available at a lower cost across the world as a leading exporter of generic products.

Improvements in health outcomes in India

- Life expectancy at birth has improved by 12% from approximately 60 years in 1995 to 67 years in 2013.
- Age-standardized DALY has dropped from 60,447 in 2000 to 47,950 in 2012 for all causes; from 24,726 to 15,840 for communicable and other group 1 diseases; and from 29,039 to 26,503 for non-communicable diseases.
- The maternal mortality rate has less than halved between 1995 and 2013, and has reduced below the world average.
- Infant mortality rate has reduced significantly by 44% between 1995 and 2013, and is now closer to the world average.

India is also the largest manufacturer of anti-HIV medicines globally, with about a 30% market share. Several Indian companies supply AIDS drugs to global agencies like the Global Fund and the governments of various African countries. India is also the leading manufacturer and supplier of vaccines, providing vaccines to global agencies such as GAVI and the WHO.

Given the capabilities and established position of the Indian pharmaceutical industry, it has the necessary attributes to support an increase in research and development activity to move up the value chain with its own innovative drugs. However, investment in research and development as well as in health financing in the country is low, compared to other countries that are high on pharmaceutical innovation, such as the US, UK, Japan or countries that have moved up the innovation value chain such as Singapore and South Korea. There has been some progress in early-stage drug development, particularly through the recent collaborations between Indian and foreign companies on early-stage compounds. However, success in the commercialization of new medicines developed in India is yet to materialize at the desired levels.

Despite its size and potential, India currently lags behind other countries in aspects such as innovation capacity and research output. The country lags behind smaller nations such as Switzerland, Singapore and Ireland when it comes to attracting significant new capital investment into the pharmaceutical sector (e.g. plants, equipment, and facilities). Regulatory issues in the recent past have led to a fall in the number of clinical trials conducted in the country between 2010 and 2014. On the other hand, the IPR system in the country needs strengthening. Between 2002 and 2012, the number of patent filings from India was almost negligible, as compared to more than 5,00,000 in the US, and more than 2.3 million across the world.

Comparison of current investment in R&D

The inflow of adequate funds into R&D is currently a critical issue faced by the country. In general, India spends less than other countries in these areas, including pharmaceutical R&D. The country’s overall average R&D spend as a percentage of GDP between 2012 and 2014 was at a mere 0.9%—lower than Brazil’s (1.3%), Russia’s (1.5%), China’s (1.9%) and South Korea’s (4%). The total expenditure on pharmaceutical R&D in India is 0.08% of GDP, as shown in Figure 2.

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Comparison of current state of cluster development

India ranks 27th in terms of cluster development, and scores a low rating on the World Biotechnology Innovation Scorecard due to low enterprise support environment.\(^\text{28},\text{29}\) Even while the life science clusters in India are developing at a rapid pace, it lags behind countries high on innovation due to the business and regulatory environment.

- Clusters and the New Economics of Competition, Michael Porter, 1998

Clusters are geographic concentrations of interconnected companies and institutions in a particular field. Clusters encompass an array of linked industries and other entities important for competition. They include, for example, suppliers of specialized inputs such as components, machinery, and services, and providers of specialized infrastructure. Clusters often extend downstream to channels and customers and laterally to manufacturers of complementary products and to companies in industries related by skills, technologies, or common inputs. Finally, many clusters include governmental and other institutions – such as universities, standards-setting agencies, think tanks, vocational training providers, and trade associations – that provide specialized training, education, information, research, and technical support.

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Figure 3 draws a relation between the ranks of cluster development, as provided by the World Economic Forum, and the score assigned for biotechnology innovation.\textsuperscript{25,26} The state of cluster development concerns two elements that are intricately linked: the quality of a country’s overall business network and the quality of individual firms’ operations and strategies. Within a cluster, interconnected sectors reside in geographically proximate groups; thus, efficiency is increased and there are greater opportunities for innovation in processes and products. This helps in reducing barriers for the entry of new firms targeting innovative products. The World Biotechnology Innovation Scorecard reflects the country’s biotechnology innovation potential. India is a “follower”, along with other nations such as China, Brazil and Turkey. The same study classifies several other countries as “leaders”, due to factors such as a positive business environment for the pharmaceutical sector in terms of intellectual property, drug approval process and clinical trials. This segment includes nations such as South Korea, Japan, Israel, France, Germany, and the UK, with the US leading the pack.

Comparison of current ability to retain talent

India ranks low in terms of ability to retain talent within the country, resulting in the continued trend of “brain drain”. It is well established that countries high on innovation also have a strong academic ecosystem. As indicated in Figure 4, the best and the brightest talent from the US stay in the US to pursue further work and study opportunities, while those in India, Brazil and Russia pursue opportunities in countries other than those in their home country.

It is not just about establishing academic institutes and developing talent but also about creating an environment that is conducive to performing, protecting and commercializing research, as this is necessary to attract and retain talent capable of innovating.

India would also benefit from improvement in areas such as skill development, quality education and basic research. India ranks below the OECD (Organization for Economic Cooperation and Development) average in three crucial areas: tertiary education expenditure as a proportion of the GDP, top 500 universities and publications in top journals.

Comparison of current clinical trial activity

Clinical trial activity in India is low, with the country contributing only 1.3% of the total global clinical trials. In comparison, South Korea, China, and the UK have a 3.3, 3.5 and 5.5% share respectively of the total global clinical trials. The US has the bulk of the share, commanding a 43.6% share of the total global clinical trials.\textsuperscript{12}

Moreover, the clinical trial activity in India is concentrated mostly in phase III trials, due to in-licensing deals from other developers. The initial stage—phase I—is limited only to a few firms, indicating low technological innovation and low clinical research capacity at the early stages of clinical drug development.\textsuperscript{12}


Currently the Indian pharmaceutical innovation ecosystem needs improvement in many areas. Given the position of India vis-à-vis other economies in terms of innovation output, it is imperative that India take timely interventions on multiple dimensions. To achieve these improvements, a vision to meet the objective and policies across the ecosystem would be necessary. To become an innovative pharmaceutical industry of both domestic and global relevance, India would need to develop new medicines and contribute to innovation on a sizeable and sustainable basis.

6.42 on a scale of 30 points, well behind nations such the US (28.6), UK (27.5), Japan (23.3), Singapore (25.6), South Korea (23.3) and China (12.6).21

The low number of Life Sciences PCT applications also suggests a need to further improve the IP environment.27

The PCT assists applicants in seeking protection for their patents internationally. The treaty lays out guidelines to assist patent offices with their patent-granting decisions. The PCT also grants access to technical information relating to those inventions.

Strengthening of clinical trial regulatory capacity and recognition in India's National IP Policy of the importance of IP as a foundation for an innovation ecosystem are steps in the right direction. Still, IP policies need to be strengthened to accelerate the reforms needed to foster medical innovation and enhance India's global competitiveness. India has a strong starting position, and augmenting the key components of the ecosystem to create an enabling environment can unlock India's potential to be a leader in pharmaceutical innovation.

Comparison of current intellectual property environment

India lags behind both developing as well as developed countries on intellectual property rights environment. In the GIPC Index 2016, which ranked countries based on 30 indicators spread across six categories—patents, copyrights, trademarks, trade secrets, enforcement and international treaties. An overall score approaching 30 on this index is indicative of a highly robust IP system. Among the 38 economies surveyed, India was ranked 37th, scoring only 6.42 on a scale of 30 points, well behind nations such the US (28.6), UK (27.5), Japan (23.3), Singapore (25.6), South Korea (23.3) and China (12.6).21

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Figure 5: Comparison of phase-wise clinical trials and % share of global clinical trials in the US, UK, South Korea, China, Japan and India12

Figure 6: Number of life sciences PCT/% of total life sciences PCT

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A vision for India

Vision 2025 aims to provide a roadmap to strengthen the overall innovation ecosystem of India, which will help the country emerge as a leader in the global pharmaceutical space. The bright promise of an innovative pharmaceutical industry in India will require all stakeholders to work together to build, sustain, and grow a scientific, economic, and policy ecosystem that promotes and rewards medical innovation.

Figure 7 outlines the various stages of the R&D cycle, along with the timelines and cost for each of the stages. The process of developing a new molecule can easily take 10 to 15 years of research.

As outlined in Figure 8, the government provides R&D infrastructure, funding (direct or indirect), human resources, and a legal and regulatory framework for research and commercialization; clinical hospitals provide infrastructure and skilled human resources in order to conduct clinical research activities; biotech parks and incubators provide the much-needed R&D infrastructure for research and commercialization activities; while research centers and universities involved in research activities within the infrastructure provided by government universities or labs and biotech parks or incubators provide skilled human resources.

The first stage of research and development involves screening of chemical and biological compounds that may exhibit the potential for treating a new condition. The screening of thousands of compounds provides a promising candidate after several years of research. However, not all early phase compounds may make it to the market. Only once the preclinical and clinical trials demonstrate the efficacy, quality and safety of the drug can it be commercialized.

Various stakeholders, such as the government, pharmaceutical companies, funding institutions, universities and research centers, clinical hospitals, associations, biotech companies and biotech parks or incubators need to work in collaboration to provide an enabling environment for innovation.
Creating an innovative ecosystem to foster growth and development in the pharmaceutical research sector requires four key building blocks:

- **Infrastructure:** A robust network that enables innovation. This includes requisite facilities to conduct research, such as in-house pharma R&D, clinical infrastructure, biotech cluster, parks or incubators, start-ups, and IT infrastructure.

- **Legal, IPR, and regulatory framework:** A sound and effective policy environment that enables, protects and supports innovation.

- **Human resource:** A thriving and cooperative private and public scientific and research community. This entails making available highly skilled and technically trained human resources to conduct research, which includes skilled and trained scientists, researchers and technicians.

- **Financing:** A business environment that embraces innovation and a health care system that recognizes and rewards the value of medicine. The former deals with a public and private, direct and indirect R&D financing mechanism, while the latter concerns the overall public investment, insurance coverage, pricing and reimbursement.

Each of the building blocks consists of multiple components that need to be optimized to provide an enabling environment for innovation. The report identifies various sub-parameters within each building block that would provide a basis for evaluating our current position and the efforts that need to be taken to strengthen the building block.
Infrastructure sub-parameters

- **R&D centers and support infrastructure:** They serve as centers for start-ups or entrepreneurs in order to facilitate early-phase drug discovery through the provision of lab facilities, lab equipment, power, and basic IT infrastructure.

- **Biotech clusters:** They help accelerate innovation by providing a platform for collaboration between industry, academia and start-ups, thereby increasing the transfer of knowledge and facilitating sufficient funding to commercialize research ideas.

- **Clinical trial infrastructure:** For the purpose of registration, it is necessary to show the efficacy of a drug in the patient population. To evaluate the pharmacological, clinical, and health effects and side effects, a study may be carried out with a certain number of patients. Considering the complexities and sensitivities around this area, it is necessary to have trained personnel to perform clinical trials.

- **Availability of electronic health records (EHR):** Access to reliable, well-linked data is one of the biggest challenges facing pharmaceutical R&D. EHR can provide real-time observational data from the hospitals and diagnostics centers. Data thus obtained can be used by pharmaceutical companies to identify new potential drug candidates.

Financing sub-parameters

- **R&D financing:** Since the pharmaceutical R&D life cycle (for a medicine to complete the journey from initial discovery to the market place) is approximately ten years, significant funding is required at each stage of the life cycle. Public funding plays an important role in advancing basic scientific research, but it can only complement and can never replace private pharmaceutical R&D financing.

Research indicates that several innovation-driven countries have in place government policies that support the R&D value chain for start-ups and entrepreneurs, with academic laboratories playing a contributing role. The role of private funding becomes important when companies can further harness their R&D capabilities in order to deliver innovations and at the same time be risk averse. In this context, private equity—venture capital (PE-VC) funding plays a crucial role in ensuring continuity of R&D, especially for small and emerging pharma companies. Government incentives such as tax credits, soft loans (with minimal interest rate) and super deductions encourage start-ups, MSMEs (Micro Small and Medium Enterprises), and larger companies to invest more into R&D activities.

- **Health care financing:** A strong health care financing model provides greater accessibility to current and new treatments.

It covers health care and OOP expenditure, besides comprehensive health insurance. Total expenditure on health care measures the final consumption of health goods and services plus capital investment in health care infrastructure. It includes spending by both public as well as private sources. Comprehensive health insurance needs to include coverage for both generic and innovative medicines.

- **Pricing and reimbursement:** Simple and transparent government pricing and reimbursement mechanisms, including measures to increase transparency and accountability in national decision-making processes and to ensure the quality of medicines, are essential to creating an environment that provides access to medicines, rewards innovation and encourages continued investment into unmet medical needs.

Human resource (HR) ecosystem

- **Expenditure on education:** To meet the needs of an innovative pharmaceutical industry in India, the expenditure on education should be directed towards skill development at every level (primary, secondary, higher and tertiary), with a special focus on science, technology, engineering and mathematics.

- **Availability of research talent:** A strong HR ecosystem that provides world-class research talent improves the quantity and quality of research conducted in India.

- **Incentives to attract talent:** An HR ecosystem should provide incentives to attract talent to the biomedical and pharmaceutical research fields and to encourage those experts from India working in other countries to return to their home country.

Legal, IPR and regulatory mechanism

- **Patents:** Patent protection provides an innovator and incentive for research and development. Patent protection requires innovators to fully disclose their inventions in a manner sufficient to enable others to use the invention. In return, inventors receive exclusive rights relating to that invention for a set period. At the expiration of patent term, anyone can practice the invention as originally described. It is thus imperative that the rules governing patentability be predictable and applied in a consistent manner to provide innovators the necessary confidence to invest in and conduct high-risk R&D.

- **Data exclusivity:** Regulatory data proving the safety, efficacy and quality of new pharmaceutical compounds, formulations and indications are submitted to health regulatory authorities throughout all phases of pharmaceutical R&D.
The generation of these data accounts for the majority of R&D expenditures. It is important to protect the data generated by pharmaceutical innovators from disclosure because third parties would receive a significant competitive advantage by relying on innovator-created regulatory data for their market approval.

• **Patent enforcement and resolution mechanism:** Effective patent enforcement mechanisms provide innovators the ability to deter and resolve possible patent infringement. Once an infringing pharmaceutical is improperly introduced to the market, innovators often cannot regain lost market share. The availability of judicial and administrative enforcement mechanisms is critical to protecting intellectual property rights. Early resolution mechanisms, for example, enable innovators to resolve any patent disputes arising before generic marketing approval.

• **Patent term extension:** Patent term extension compensates the innovator for time lost during drug development and regulatory review, due in many times to review and approval delays.

• **Voluntary technology transfer:** The availability of patents and an effective patent enforcement mechanism is critical to foster an environment conducive to technology transfer. Voluntary transfer of technology helps in making patented medicine, biologic or diagnostic inventions available to other partners who can collaborate on further developing, manufacturing or selling the patented-protected invention.

• **Clinical trial regulations:** New medicines require extensive clinical trials to demonstrate their safety and efficacy in human use. Enabling regulatory capacity and requirements to conduct clinical trial is required to attract investment.33

• **Regulatory framework:** The pharmaceutical industry is influenced by several regulatory aspects, including drug procurement by government agencies, service providers, safety policies, drug regulation, drug promotion regulation, etc. Hence, strong, transparent and predictable regulatory frameworks are essential to protecting consumers as well as to promoting globally competitive innovative and generic pharmaceutical industries. Well-defined regulatory frameworks help navigation through the diverse sets of laws, policies and regulations governing the pharmaceutical sector.

In order to achieve the Vision 2025, efforts should thus focus on addressing the needs of the various stakeholders and issues across the building blocks to develop a vibrant innovative pharmaceutical sector in India. The objective of this vision has to be twofold: one, improve health and productivity for people in India and around the world; and two, generate economic benefits by making India an attractive place and destination for investment in R&D, thus creating higher value-added jobs and driving a higher research output of global significance.

![Figure 9: Vision 2025: Unlock the potential to be a leader in pharmaceutical innovation](image-url)

Recommendations to unlock India’s pharmaceutical potential

Recommendations to unlock India’s innovation potential (figure 9) should be based on benchmarking the current innovation ecosystem in India against that of countries who have historically been strong on pharmaceutical innovation (e.g. the US, UK, Japan) and of those who have moved up the value chain in recent times (China, Singapore, South Korea). Such analysis will offer insights into international practices in developing competitive policies to attract investment for R&D and help identify gaps in India that can be addressed with the implementation of innovation-enabling policies.

Infrastructure

Summary of key infrastructure gaps

For developing a strong innovation ecosystem, the following key infrastructure gaps in India need to be addressed:

• Absence of a single authority and mechanism to oversee the establishment of pharma R&D centers and monitor performance

• Non-availability of large animal-breeding facilities, GLP (Good laboratory practices)-certified animal and protein characterization labs, and trained technical personnel at GLP labs

• Limited collaboration between academia, research centers and industry to utilize public R&D centers

• Absence of specific guidelines for establishment of biotech parks around centers of excellence

• Limited availability of qualified personnel to carry out clinical trials

• Lack of a robust training curriculum in clinical trials, bioethics and regulatory science

• Inadequate infrastructure to perform clinical trials

• Absence of a clear roadmap for the implementation of EHR standards and data protections laws

• No mechanism to share EHR data from public health institutions with industry for research

• Absence of a certification body to approve EHR products

R&D centers and support infrastructure

Currently, there is no single mechanism or authority in India to oversee the establishment of public pharma R&D centers and monitor their performance. Additionally, India faces challenges with access to and availability of core and supporting infrastructure on the desired scale needed for innovative research. For instance, NIPERs and other pharma public sector undertaking (PSUs) are under the Department of Pharmaceuticals (DoP)\(^{34}\), and biotech parks are currently established by the Department of Biotechnology (DBT).\(^ {35}\) Over 20 centers come under the purview of the Council of Scientific and Industrial Research (CSIR) and 32 research centers under the Indian Council of Medical Research (ICMR).\(^ {36,37}\) Also critical is the utilization of developed infrastructure and accessibility to researchers.

In Singapore, the Agency for Science, Technology and Research (A*Star) is the lead public sector agency that spearheads economic-oriented research in order to advance scientific discovery and develop innovative technologies. The Biomedical Research Council (BMRC) oversees the development of core capabilities in R&D. As a result, the country has a complete gamut of offerings in research—basic, translational, as well as clinical research to support the pharmaceutical industry. Since the launch of the Biomedical Sciences (BMS) initiative in June 2000, approximately 2,016 primary patents have been filed to date, and there has been an increase in the number of industry collaborations.\(^ {38}\)

The important issue is accessibility to animal research in biotech pharma services.

- Central Government Institute

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\(^{37}\) Indian Council of Medical Research institutes. Retrieved from http://icmr.nic.in/institute.htm

Currently, India has limited availability of support infrastructure such as adequate animal-breeding facilities, GLP labs, and trained personnel to manage, maintain, and interpret results from instruments within these labs. There are only 71 registered animal breeders and suppliers and only 36 GLP-certified test facilities under the National GLP Program, and only one GLP-certified protein characterization lab at the National Centre for Biological Sciences (NCBS).

India also lags in terms of technology transfer offices at research and academic centers. Only a few Indian universities such as IITs have advanced and developed technology transfer capabilities.

Biotech clusters

While the central and state governments, in collaboration with private players, continue to develop new infrastructure facilities at biotech parks, currently, these clusters are concentrated in the states of Uttar Pradesh, Andhra Pradesh, Karnataka, Maharashtra, Gujarat and Delhi NCR (National Capital Region). Bengaluru is home to the biggest bio-cluster in India, with 137 biotechnology companies (40% of the 340 units in the country). In 2014, several state governments as well as central institutes had submitted proposals for setting up parks in states such as Assam, Karnataka, Kerala, Odisha, Madhya Pradesh, Jammu and Kashmir, West Bengal, Gujarat and Chhatisgarh.

As shown in Table 1, Indian biotech parks are also extremely small compared to those in leading countries, with limited proximity to centers of excellence. Innovation-driven economies have larger sized clusters that support a significantly higher number of companies and employees/researchers. On the innovation scorecard, India ranks much below countries such as the US, UK, Korea, Japan and Singapore.

There are renowned educational and research institutes across India, which can be leveraged to develop biotech clusters. For instance, NIPER, Post-Graduate Institute of Medical Education and Research (PGIMER) in Chandigarh; Institute of Microbial Technology (IMTECH) and Indian Institutes of Science Education and Research (IISER) in Punjab and Haryana; NIPER in Gandhinagar, Pharmaceutical Education & Research Development (PERD) in Ahmedabad and MS University in Baroda, Gujarat; Tata Institute of Fundamental Research and IIT in Mumbai; National Chemical Laboratory, Pune, and National Centre for Cell Science and IISER in Maharashtra; Indian Institute of Chemical Technology, Centre for Cellular and Molecular Biology (CCMB), National Biotechnology Research Institute, Osmania University, IIT Hyderabad and Birla Institute of Technology and Science (BITS) Pilani in Telangana; Indian Institute of Science, National Centre for Biological Sciences, JNCASR, and Rajiv Gandhi University of Health Sciences in Karnataka; ICMR, Indian Council of Agricultural Research (ICAR), IIT Delhi, Translational Health Sciences National Institute of Immunology (THSTI), Faridabad; International Centre for Genetic Engineering and Biotechnology (ICGEB) and Institute of Genomics and Integrative Biology in Delhi; and Central Drug Research Institute, Lucknow, IIT Roorkee, and the National Biotechnology Research Institute and Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS) in Uttar Pradesh.

A lot of these biotech parks should have been in a cluster of institutions rather than in isolation. Today, an academician in one part of the city may not go to the other part of the city where the biotech park is located. So, that park will be used by large companies who can operate in isolation as well. These biotech parks need to look for a mechanism to connect with these institutions and research centers. It has been rolled out in at some places. However, this needs to happen nationally.

- Head, biotech company

### Table 1: Indian biotech parks as compared those of with other countries (State of cluster development is defined as how widespread are well-developed and deep clusters—geographic concentrations of firms, suppliers, producers of related products and services, and specialized institutions in a particular field.)44,45,46,47,48,49,50

<table>
<thead>
<tr>
<th>Country</th>
<th>Innovation Scorecard Rank</th>
<th>State of cluster development</th>
<th>No. of employees</th>
<th>Total companies</th>
<th>Academic institutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>1</td>
<td>5</td>
<td>20,000 to 50000</td>
<td>Minimum 100 companies to more than 1000 companies (including major multinationals)</td>
<td>Development of clusters around major universities and research centres for e.g. Harvard, University of Massachusetts, Boston University and MIT in the Boston cluster, University of California around San Diego, University of San Francisco around San Francisco Cluster</td>
</tr>
<tr>
<td>UK</td>
<td>9</td>
<td>10</td>
<td>1500 to 7700</td>
<td>Approx. 100</td>
<td>built around major universities like Oxford, Cambridge while the cluster in London has collaboration with 28 Universities</td>
</tr>
<tr>
<td>Singapore</td>
<td>5</td>
<td>12</td>
<td>~ 4000</td>
<td>40 Corporate Research labs</td>
<td></td>
</tr>
<tr>
<td>South Korea</td>
<td>23</td>
<td>31</td>
<td>-</td>
<td>30 to 300</td>
<td>~10</td>
</tr>
<tr>
<td>Japan</td>
<td>16</td>
<td>8</td>
<td>1500 to 7000</td>
<td>~300</td>
<td>Kobe Biomedical cluster built around RIKEN which is Japan’s largest research institution</td>
</tr>
<tr>
<td>India</td>
<td>51</td>
<td>27</td>
<td>~500 to 1500</td>
<td>Less than 20 in most cases</td>
<td>No Specific Guidance to develop around centres of academic excellence</td>
</tr>
</tbody>
</table>

49 Biotech clusters. Liftstream. Retrieved from V_XFdP97IU
Clinical trial infrastructure

Limited availability of infrastructure and qualified personnel to carry out clinical trials and lack of a robust curriculum for clinical trials, bioethics education and training pose significant challenges to advancing a robust clinical research environment. Other factors include low availability of hospital beds and limited practical exposure of personnel to clinical trials. India is low on both hospital beds as well as doctors, the ratio being 0.7 per 1,000 population for each. Against this, the ratio of doctors in the UK, US and Japan are much higher at 2.8, 2.5 and 2.3 per 1,000 population respectively. 

Furthermore, in India, there are only 1.7 nurses per 1,000 population, much below 11.5, 9.8 and 9.5 in Japan, the US, and UK respectively. India also loses a considerable number of qualified doctors as well as nurses to other countries due to better living conditions and remuneration.

An example of a country with good clinical trial infrastructure is Korea. The Korea National Enterprise for Clinical Trials (KONECT) is concentrated across three divisions: (1) the clinical trial centers manage the 15 regional clinical trial centers, (2) the clinical trial training academy trains and educates professionals involved in clinical trials, and (3) the clinical trial technology development funds are provided by the Korean Ministry of Health and Welfare for facilitating innovations within clinical trials. Substantial alliances between KONECT and various private contract research organizations (CROs) have created an ecosystem for conducting high-quality clinical trial by devising trainings and workshops.

India needs to facilitate the availability of quality public health infrastructure for clinical research, and public centers need to train clinicians to conduct clinical trials with the help of a curriculum that includes relevant courses in pharmacology, principles and practice of clinical research, as well as bioethics and drug regulatory science.

- Head, biotech company

**Availability of EHR**

India currently lacks a clear roadmap for the implementation of EHR standards and data protection laws. The benefits of EHR are many. EHR makes health information easily available to authorized health care providers for informed decision-making. It also helps in drug safety surveillance by adverse event follow-up and epidemiology studies or disease prevalence data. Building clinical trial capacity is dependent on reliability and secure EHR systems to support data-driven patient identification, recruitment and clinical trial protocol design. Standardization in EHR, including data capture, retrieval and reporting, improves the efficiency of clinical research.

In 2013, EHR standards were finalized and approved by the Ministry of Health and Family Welfare in India (MoHFW)\(^5\), with limited focus on developing an implementation roadmap. Although data protection guidelines are mentioned in the approved EHR guidelines, issues related to security requirements and technology for data protection are left to the discretion of individual organizations. Moreover, only a few hospitals maintain digitized versions of patient records. Model practices from other countries show how to augment the availability and utilization of EHR. Learnings can be drawn from data protection acts similar to the Health Insurance Portability and Accountability Act (HIPAA) of 1996 in the US, which governs EHR data privacy and security.\(^5\) The Clinical Practice Research Data link (CPRD) in the UK provides availability of real-time data and is considered as a gold standard for its observational data and interventional research. There is also a need for central bodies to certify EHR products. The structure of these bodies can be similar to that of organizations such as the Certification Commission for Health Information Technology (CCHIT) in the US to approve EHR products.\(^5\)

**Recommendations to strengthen infrastructure for innovation**

1. **Strengthen R&D centers and biotech clusters**
   a. Establish a single body to oversee public pharma R&D centers and monitor their performance.
   b. Allocate funds to establish large public animal breeding facilities and GLP-certified public labs.
   c. Incentivize pre-clinical service providers to establish GLP-certified facilities/animal breeding facilities through subsidized land and soft loans.
   d. Establish a body to facilitate collaboration between academia, research centers and industry in order to improve the utilization of R&D centers.
   e. Establish technology transfer offices to link the outputs from academic research to the development and commercialization by companies.
   f. Define policies that would enable the development and refinement of biotech parks around centers of academic excellence.
   g. Create a policy roadmap for accelerating technology transfer from lab to market as suggested in the National Biotechnology Development Strategy (NBDB) 2015-2020 released by the Department of Biotechnology.

2. **Bolster clinical trial infrastructure**
   a. Increase the number of enrolments into public medical schools and simplify regulations to establish private medical colleges, with the goal of achieving a ratio of at least 1 physician per 1,000 population by 2025, as recommended by the Health Level Expert Group for Universal Health Coverage appointed by the Planning Commission.\(^5\)
   b. Establish curricula for developing expertise and experience in conducting clinical trials, including clinical pharmacology, clinical research, bioethics and regulatory science in collaboration with the pharmaceutical industry.
   c. Develop infrastructure to improve the quality and impact of research at universities and hospitals to achieve integration of India-based drug discovery, clinical, and other pharmaceutical research within global R&D networks.
   d. Increase public investment in hospitals and encourage private companies to establish research-quality hospitals through appropriate incentives such as tax breaks and public private partnerships. The goal should be at least two hospital beds per 1,000 population and three nurses per 1,000 population by 2025, as per the recommendations given by the Health Level Expert Group for Universal Health Coverage.\(^5\)

3. **Improve availability of data for research**
   a. Define a clear roadmap for the implementation of EHR standards and data protections laws.
   b. Integrate guidelines for sharing EHR data from public health institutions for research purposes.
   c. Establish a central body to certify EHR products.

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Potential impact

The policy recommendations are aimed towards enhancing the capacity, availability and utilization of infrastructure across the research cycle. A robust network of technology transfer offices at universities would enable the scale-up of basic research and early drug discovery, and further development and commercialization of research conducted by academic institutions. This would assist research personnel/academia to transfer their patents to a company who can invest in R&D and lead to a path of commercialization. This, along with a dedicated collaboration mechanism, would ensure research is in sync with the health needs of the country, while also addressing issues with R&D for the industry. Strengthening of pre-clinical infrastructure would lead to higher levels of pre-clinical research in India and reduce outsourcing of pre-clinical research to other countries, resulting in lower costs for companies. A robust EHR infrastructure would substantially improve the depth and quality of clinical research. A well-developed EHR framework will also help in pharmacovigilance as well as the monitoring of patients undergoing clinical trials. The enhancement of clinical trial infrastructure both in terms of quantity and quality would encourage more placement of clinical trials in India. The proximity of biotech parks and academic institutes will enhance the utilization of such infrastructure by research companies. Finally, the creation of a nodal body to monitor public R&D centers would reduce the administrative burden on individual institutions and researchers receiving financial support.

Financing

Summary of key financing gaps

For adequate financing of innovation in India, the following key gaps need to be addressed:

- Low public pharma R&D spend as a percentage of the total GDP
- Low spend on R&D by pharmaceutical business enterprises on NMEs
- Absence of a single body to oversee public fund allocation and monitor performance
- Limited fund availability for scale-up of projects
- Lower level of super deductions on R&D capital expenditure incurred by the Department of Scientific and Industrial Research (DSIR) recognized centers at external vendors in India
- Absence of differential incentives provided to SMEs for carrying out R&D
- Low level of public and private health care expenditure
- High burden of OOP expenditure in India
- Limited health coverage of the population
- Lack of coverage of drugs for outpatient services in the existing health coverage schemes
**R&D expenditure for pharmaceuticals**

India currently has a low public pharmaceutical R&D spend as a percentage of the total GDP. There is also low spending on R&D by pharmaceutical business enterprises on NMEs. While in India, the total pharmaceutical R&D spend is 0.08% of the GDP, countries high on innovation, such as the US, spend approximately 0.6% of their GDP on pharmaceutical R&D (private and public expenditure on R&D as a percentage of GDP is 0.42 and 0.20% respectively). Currently, R&D efforts in India are mainly targeted towards a new drug delivery system (NDDS), reverse engineering and the development of alternate manufacturing processes for existing drugs.

The research-based pharmaceutical industry in the US has consistently invested the most among innovation-driven economies in R&D, comprising 0.4% of the total US GDP. In the US, R&D investments of pharmaceutical companies have grown consistently over the past 15 years, and more than doubled the publicly funded NIH (National Institute of Health) expenditures in 2014 to reach $30.1 billion USD. Expenditure on R&D by the research-based pharmaceutical industry amounts to 11% of total sales in Japan, 21% in the US and 17% in the European Union, while in India it is about 8%.

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**Direct public funding of research**

In India, currently, there is no single-window mechanism to oversee the flow of public fund allocation and monitor its performance. Instead, funding is routed through multiple bodies such as DBT, DST, MoHFW and DoP (figure 10). The model practice suggests that pharmaceutical funding should be channelized through one organization, and there is consistent performance monitoring through regular reviews and priorities by external expert review groups.

In Japan, the Japan Agency for Medical Research and Development (AMED) consolidates budgets for research for the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labor and Welfare, and the Ministry of Economy, Trade and Industry (previously allocated from different sources), thereby providing an integrated approach to research funding, establishing and maintaining conducive research environments, and unifying points of contact.

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At least for the public funding, we should identify five to six priority areas required for the country and ask institutes to collaborate on the same. That kind of program should be funded with adequate money. Due to scarcity of resources a top-down approach is necessary.

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In the US, for instance, the NIH invests nearly 30.1 billion USD annually in medical research, of which more than 80% is allocated to approximately 2,500 universities, medical schools, and other research institutions in every state in the country and around the world. The NIH performance framework includes regular review of performance and priorities by external expert review groups, including peer review groups, advisory councils, and ad hoc working groups.

Looking across the various stages of research, the Indian government makes funding available to encourage early-stage and development phase research with grants of approximately 5 million INR per project.

The funding by the Government (in India) in R&D is broken. The money is being distributed to many research institutions. The outcome is none of them get adequate money.

- Head, biotech company

Figure 10: Public funding across various stages of research in India

<table>
<thead>
<tr>
<th>Student/researcher/academic institute</th>
<th>Development phase</th>
<th>Advanced stage of development</th>
<th>Commercialization</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIG, PRISM Phase I-Category I, AIM, SBIRI</td>
<td>PRSIM Phase I – Category II,</td>
<td>PRSIM Phase II, TDB#, CRS#</td>
<td>TDB#</td>
</tr>
<tr>
<td>BIG, PRISM Phase I-Category I, SBIRI, BISS, SSS, TBI</td>
<td>PRSIM Phase I – Category II, NMITLI, SBIRI, PACE</td>
<td>PRSIM Phase II, BIPP#, NMITLI, TDB#, DPRP#</td>
<td>BIPP#, NMITLI, TDB#, SRIJAN**</td>
</tr>
<tr>
<td>BIG, PRISM Phase I-Category I, SBIRI, BISS</td>
<td>PRSIM Phase I – Category II, DPRP, NMITLI, SBIRI, PACE, MVIF</td>
<td>PRSIM Phase II, BIPP#, NMITLI, TDB#, DPRP#, MVIF</td>
<td>BIPP#, NMITLI, TDB#, SRIJAN**</td>
</tr>
<tr>
<td>SBIRI</td>
<td>SBIRI Phase I &amp; II, DPRP, NMITLI, PACE</td>
<td>Prism Phase II, BIPP#, NMITLI, TDB#, DPRP#, SRIJAN**</td>
<td>BIPP#, NMITLI, TDB#, SRIJAN**</td>
</tr>
</tbody>
</table>


* Sole Entrepreneur sole proprietary concerns are not eligible for TDB. ** SRIJAN is restricted to start ups and MSME, # Can be claimed in collaboration with other academia/research centre/industry
Investment needs to be done substantially in R&D and once the research outcomes are there what is required is to convert the ideas into ventures. The kind of investments that we are making now is very thinly distributed. There are so many Indian entrepreneurs who need adequate resources to convert their ideas into products, then into a venture and from there to a company.

- Head, central government institute

Small companies do have challenge in terms of funding. The issue is not in terms of money not being available. But those with money do not know what specifically to invest in in the biotech and pharma sector. What VCs therefore need is a way in which they can judge the relative quality of projects which will survive over the long haul and which are likely to fail.

- Central government institute

However, funding for scale-up projects from the proof of concept stage is still very low, with approximately 10 million INR available as soft loan.

Even venture capital (VC) funding is low in India, unlike model practices such as those in the US, where the PE/VC funding showed accelerated growth for both early and late stage. In 2014, the total life sciences VC funding in the US, including biotechnology and medical devices, was 8.6 billion USD; early-stage funding rose by 35% to $3.7Bn, while late-stage funding increased by 21% to 2.3 billion USD.⁶⁰

Funding is more of a challenge for small companies. After initial funding there is a concern about who would do the next round of funding. The first stage of funding is available and government is doing a great job by making the fund available. The problem is the next stage.

- Head, funding institute

R&D expenditure incentives

Government incentives such as tax credits and super deductions encourage start-ups, MSMEs and larger companies to invest more into R&D activities. In India, there is limited incentive in terms of tax benefits on R&D expenditure, as against those provided in the countries such as Singapore and China (Table 2).

Countries such as Japan and the UK have differential incentive structures for SMEs as well as a patent box regime which reduces the corporate tax rate for income arising from IP exploitation.⁶¹ The Indian Union Budget 2016 does provide for a special patent regime, with a 10% rate of tax on royalty income from worldwide exploitation of patents developed and registered in India.

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Table 2: Tax deductions and other benefits available in countries for R&D expenditure

<table>
<thead>
<tr>
<th>Country</th>
<th>Tax incentives/relief</th>
</tr>
</thead>
</table>
| India   | • Uniform super deductions of 100% on R&D capital expenditure across industries  
         | • 200% “super deduction” weighted deduction for capital and revenue expenditure (other than cost of land or building) for approved “in-house” R&D expenditure for units recognized by the Department of Scientific and Industrial Research (DSIR)  
         | • 125% deduction for sum paid to approved R&D institutions or companies for R&D use; 175% deduction for sum paid to university/colleges for R&D use  
         | • Benefit of deductions for research would be limited to 150% from 1.4.2017 and 100% from 1.4.2020 as per the Union Budget 2016 |
| China   | • 150% “super deduction”  
         | • 15% reduced Corporate Income Tax (“CIT”) rate for High and New Technology Enterprise (“HNTE”) (Standard CIT rate is 25%)  
         | • Zero-rated Value-added Tax (VAT)/VAT exemption for export of R&D services  
         | • VAT exemption on certain technology-related offshore outsourcing services in pilot cities  
         | • CIT exemption/reduction on technology transfer income  
         | • VAT exemption on income arising from technology transfer, technology development and associated consulting/services  
         | • Duty/VAT/Consumption Tax free importation of certain R&D equipment imported by qualified foreign-invested R&D center  
         | • VAT refund for purchasing certain R&D equipment by qualified domestic and foreign-invested R&D centers |
| Singapore | • 150% super deduction on qualifying R&D expenditure (essentially staff costs and consumables)  
         | • Productivity and Innovation Credit - PIC (YA 2011 to YA 2018): Deductions/allowances of 400% (instead of 150%) on up to 4,00,000 of total qualifying expenditure per year across six qualifying activities, including R&D  
         | • With effect from YA 2012, the scope of R&D activities under PIC is expanded to include R&D cost sharing agreement.  
         | • PIC+ scheme for qualifying small and medium size enterprises introduced with effect from 2015 to 2018. The expenditure cap under the PIC+ scheme will be 6,00,000 SGD for each of the six qualifying activity per YA.  
         | • The Research Incentive Scheme for Companies (RISC) awards government grants to develop research and development capabilities in strategic areas of technology.  
         | • The Initiatives in New Technology (INTECH) Scheme awards government training grants to encourage capability development in applying new technologies, industrial R&D and professional know-how. |
Health care expenditure

India has a low level of total health care expenditure at 4% of GDP, much below the global average of 9% of GDP, and 17%, 10%, and 9% in the US, Japan, and the UK respectively. China and South Korea spend 6% and 7% respectively of their GDP on health care (figure 11). This percentage of health care expenditure in India has stagnated since 2005, while in model countries, it has increased by at least 1% over the past five years. Further, in India, almost 60% of health care expenditure is OOP as against the global average of 30% and less than 40% in most of the model countries (figure 12).

Potential reasons for low health care spend in the country include factors such as a nascent health insurance market and low government expenditure, which leads to people having to spend money out of their own pocket.

OOP expenditure as a percentage of the total spend on health care is high in India—at 58%, it is much higher than 34% and 37% in China and South Korea respectively. In more mature economies, such as the UK and the US, the OOP expenditure percentage is 9 and 12 respectively of the total expenditure on health care.

High OOP expenditure increases the burden on the patients and, in a few cases, may cause non-adherence to recommended therapies and adversely affect the patient’s health, particularly in the case of management of many chronic diseases. The link between OOP pocket expenditure and poverty is validated in India’s draft National Health Policy 2015, which claims that “55 million Indians fell into a serious poverty-trap because of their health care spending during [the] 2011-12 period.”
Since there is a sizable percentage of the population not covered under any insurance scheme in India, high OOP expenditure exposes patients to financial hardship and discourages them from seeking necessary health services.

**Population insurance coverage**

There is a significant opportunity to expand the availability of health insurance in India, as only 17% of the total population is currently covered by health insurance. Predominantly, the growth of private insurance companies has been restricted to Tier II cities. Some of the steps taken by the government with regards to increasing insurance penetration are mentioned in the latter part of the report. There is a slow penetration of private health care providers and reimbursement does not include outpatient drugs.

Five states—Maharashtra, Tamil Nadu, Karnataka, Delhi UT and Gujarat—contribute around 71% of the total health insurance premium collected in the country, while the remaining 31 states and UTs contribute the balance 29%. The government-funded insurance schemes, like the Central Government Health Scheme (CGHS), Employment State Insurance Scheme (ESIS) and Rashtriya Swasthya Bima Yojana (RSBY), cover an estimated population of 181 million. Many state governments have also started health insurance schemes for specific sections of the population. For example, the Rajiv Gandhi Jeevandayee Arogya Yojana by the Government of Maharashtra covers 971 procedures and 121 follow-up procedures in all districts of Maharashtra. Stand-alone health insurance providers have a presence in Tier I (255 offices) and Tier II (203 offices), but have no presence in Tier III or VI. Similarly, other private sector health insurance providers have a presence in Tier I cities. However, their penetration in Tier II and Tier III cities is low, with no presence in Tier IV to VI.

The government has proposed some positive steps in Union Budget 2016:

- A health insurance scheme which protects one-third of India’s population against hospitalization expenditure was announced.
- The Government will launch a new health protection scheme for families below the poverty line which will provide a health cover up to 1 lakh INR per family. For senior citizens of age 60 years and above belonging to this category, an additional top-up package up to 30,000/- INR will be provided.
- The FDI policy in the insurance sector can be relaxed to attract more overseas investments. Foreign Investment Promotion Board (FIPB) approval shall not be required for foreign investment in insurance.
- Exemption on service tax on general insurance services has been provided under the “Nirmanaya” Health Insurance Scheme launched by the National Trust for the Welfare of Persons with Autism, Cerebral Palsy, Mental Retardation and Multiple Disability.

The model practice involves universal health coverage, including drug reimbursement and a mix of public and private health insurance coverage options, to meet diverse patient needs. Most insurance plans have a patient co-payment system, which may be used to decrease overall health care payments and select the nature of treatment (i.e. the patient can opt for higher co-payment to avail of higher cost services). The private sector can relieve the pressure on the public system. Private coverage can also substitute or supplement public coverage depending on income and other factors. Private health insurance can expand the choice of hospitals, private beds and full coverage of services beyond basic services, including newer treatments with appropriate but reasonable adjustments in costs. In India, a segmented approach utilizing both public and private health insurance is the most likely answer to the challenges of risk pooling and health care financing.

In the US, 86.6% of the population had health insurance for all or part of 2013, of which private insurance covered 64.2% of the population and employment-based health insurance covered 53.9% of the population. Government health insurance covers 34.3% of the population. A co-payment system exists through the use of tiered formularies. The number of tiers included in a drug benefit package varies by plan, with those with fewer tiers and restrictions usually being more expensive.

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Japan’s public health insurance system provides universal primary health coverage. The base cover for all insurance costs is capped and a majority of the adult population has private health insurance to cover episodes that cost more than the cap. Patients can receive necessary medical services, including drugs covered on the reimbursement list by making certain co-payments (10% for the elderly, 30% for the general public and 0–10% for children).66

China expanded its health coverage from less than 50% in 2005 to over 95% by 2011 through two newly established public health insurance schemes—new cooperative medical scheme (NCMS) for the rural population and urban resident basic health insurance (URBMI)—thereby increasing public healthcare expenditure from 1.8% in 2006 to 3.1% in 2013.67

India’s draft National Health Policy 2015 accepts and endorses the understanding that a full achievement of the goals and principles as defined will require an increased health expenditure to 4–5% of the GDP. For this, it has proposed a target of raising public health expenditure to 2.5% of the GDP by 2020. An increased FDI cap of 49% in the sector is likely to attract a number of players offering a range of health insurance solutions.

**Pricing and reimbursement**

Predictable and transparent government pricing policies foster patient access to new, safe and effective treatments, allow planning for long-term supply of medicines, and encourage investment in R&D. Government pricing policies should recognize medicines as an economic investment in health rather than a cost, as they can provide the means to treat or cure disease, improve quality of life, and build a healthier and more productive population. Simple and transparent government pricing mechanisms are essential for creating an environment that rewards innovation and encourages continued investment into unmet medical needs. Further, decisions about pricing mechanisms should recognize that innovation in medicine and health system research is incentivized through intellectual property protection.

India does not have a pharmaceutical reimbursement system to match that seen in many other countries, with the majority of the population not benefiting from any form of broader public health insurance provision. Individuals with coverage obtain this through public sector employer schemes and voluntary public sector schemes, as well as private health care schemes. A number of public and private sector insurance schemes exist, but not many of these provide drug cover. Where drugs are covered, there is no established system of assessment and tenders to determine drug choice based on price. With a high level of out-of-pocket payment, the patient is therefore a key stakeholder in the funding of treatment, with input and guidance from health care professionals.

Hospital procurement is managed via tenders, usually on an annual, centralized basis, or sometimes as needed according to local demand. Many state governments and national health programs procure medicines directly from the manufacturer through an e-tendering process. Specialized procurement agencies like Tamil Nadu Medical Supplies Corporation purchase medicines on behalf of state governments. In some public hospitals, tendering is handled on a local basis by the individual hospital, with price often being the key criterion in the selection process. In many government hospitals, patients often leave with prescriptions for drugs that the facility does not possess and that must be paid for on an OOP basis.

Drug prices in India are amongst the lowest in the world, but the bulk of pharmaceutical spending falls on the shoulders of the patient population. The National Pharmaceutical Pricing Authority (NPPA) fixes the ceiling price of essential drugs. The prices of these drugs are allowed to be increased annually as per the Wholesale Price Index notified by the government. For other drugs, the price increase allowed is 10% annually. There is no separate pricing for patented drugs. Various state governments procure patented drugs based on negotiations with the manufacturer.

The intensive investment in the development of innovative medicines involves a high degree of uncertainty in the screening process for new compounds or molecules, the rigors of pre-clinical testing and clinical trials, and the fact that only a small number of marketed medicines match or exceed R&D costs. The investment in innovation and the development of new and important medicines is ultimately funded by economic return of past investments. As such, innovation must be supported by appropriate protections as well as policies that create a favorable business environment. A considerable body of evidence demonstrates that price controls contribute to lower investment in pharmaceutical research and development, ultimately harming patients who are in need of improved therapies. Thus, a lack of recognition of the innovation process through strict price controls or unviable price calculations has a direct effect on the ability of research-based pharmaceutical companies to bring new medicines to patients and stimulate future innovation.


Recommendations to strengthen financing

1. Increase the variety of R&D financing resources to encourage and support an increase in pharmaceutical R&D
   a. Increase availability of government grants for basic research projects.
   b. Increase weighted tax deductions on all R&D expenditure, both capital and revenue, incurred by DSIR recognized centers at external vendors in India to at least 200% (as per the model practices) under section 35 (2AB) of the Income-tax Act.
   c. Route public funding and monitoring of public pharmaceutical research through one organization (similar to NIH in the US).
   d. Increase monetary limits of funds/grants/soft loans for scale-up of projects; total public expenditure on pharma R&D should be at least 0.2% of the GDP as observed with the model practice.
   e. Identify focus disease areas based on the needs of India to provide Advance Market Commitments (AMC) to encourage research in those areas as suggested in the National Biotechnology Development Strategy 2015-2020 released by DBT.
   f. Provide patent filing subsidies for start-ups as per the Startup India Policy
   g. Exempt startups from capital gain tax as per the Startup India Policy.

2. Adopt health care financing policies that enable pharmaceutical innovation
   a. Increase public health expenditure to 2.5% of the GDP by 2020, which is in line with the National Health Policy.
   b. Improve coverage for primary health care, including outpatient services and medicines, by increasing the coverage in public and private schemes.
   c. Encourage growth of private health care insurance through enhanced tax benefits and awareness programs.
   d. Establish government reimbursement policies at the center and state level based on negotiations with manufacturers.
   e. Utilize both public and private health insurance to address the challenges of risk pooling and health care financing.

Potential impact

The policy recommendations aim towards the creation of an environment where adequate financing is available across the research stages. A single point of contact for various R&D funds may reduce the administrative burden and ensure proper evaluation of projects for fund allocation to institutes and researchers. There are few incentives for start-ups/researchers to invest in pharmaceutical R&D. Incentives provide a better opportunity for researchers/academia for basic research and scale-up projects. The expansion of the scope of super deduction would help companies tap into a more specialized pool of external vendors from where they can obtain R&D support. Additional incentives for companies to focus on commercially viable projects and projects related to India-specific diseases will help address country-specific health issues and expand India’s position as a ‘pharmacy to the world’, and from move up the chain from manufacturing generics to developing innovative medicines. Finally, the policies also aim towards robust health financing to improve health care access and demand generation for both innovative and generic products.
Human resources

Summary of key human resources gaps

In the human resources building block, the following are the key gaps that need to be addressed:

- Shortage of research personnel with doctoral qualifications
- Lack of research output in terms of publications and citations
- Inability to attract adequate graduate and post-graduate students towards the science, technology, engineering and mathematics (STEM) field
- Few mobility schemes for researchers
- Gap in skills between available talent and industry requirement
- Lack of incentives for foreign institutes to set up campuses in India which can attract a good talent pool
- Limited number of initiatives to attract and retain overseas scientists

Availability of research talent

India faces a shortage of research personnel with doctoral qualifications and an inability to attract adequate graduate and post-graduate students to the STEM field. India also ranks low in retaining talent with a high outflow of the talent pool to countries such as the US and the UK. The talent pool for science and technology is smaller in India than in China and the UK. In India, around 119 researchers are engaged in R&D per million people, while China has over 1,000 and the UK over 4,000. India produces three times as many post-graduates as the UK, but the UK produces 1.5 times more PhDs than India.46

In the US, the 2014 budget set a goal of increasing by a third (or by one million) the number of well-prepared college graduates with STEM degrees over the next decade. The federal budget invests an overall 3.1 billion USD in programs on STEM education.

There are capability gaps in a few critical areas. One is in the area of biology. Competency in discovery biology, understanding of diseases at molecular target levels and identifying novel targets and their characterization—there are resource-related issues. There is a gap both in terms of quantity as well as quality.

- Head, research center

There is an issue both in terms of the quality and quantity of available talent in India, which reflects in the research output. Compared to other countries, India lacks a quality research output both in terms of publications as well as citations. This also has a bearing on the employability of the talent because of the skill sets not being aligned to the industry needs.

Figure 13: Quantity and quality of scientific publications by country 2003–2011

![Figure 13: Quantity and quality of scientific publications by country 2003–2011](image-url)

The translation aspect is the biggest gap. You come up with a discovery followed by patenting and then publish it. After that, you require a partner to take it forward. The discovery role is played by academia and the industry then takes it forward. Unfortunately here, the connect between industry and academia is not strong.

- Head, research center

The Indian government has taken some effort to promote and develop the scientific talent pool. There are a few mobility schemes like the CSIR’s Scheme for Mobility of Scientists from CSIR to industry or R&D institutions and vice versa; and the Researcher Mobility Grant by DBT and the Academy of Finland for international mobility. The government has proposed a few steps in the Union Budget 2016 to improve the quality of higher education:

• Empower higher educational institutions to help them become world-class teaching and research institutions. An enabling regulatory architecture will be provided to ten public and ten private institutions to emerge as world-class teaching and research institutions. This will enhance affordable access to high-quality education for Indians at mid- and low-income levels.

• There is also a focus on setting up a Higher Education Financing Agency (HEFA) with an initial capital base of 10,000 million INR. HEFA will be a not-for-profit organization that will leverage funds from the market and supplement them with donations and corporate social responsibility (CSR) funds. These funds will be used to finance improvement in infrastructure in the top institutions in India and will be serviced through internal accruals.

These are steps in a positive direction. More efforts are required to make STEM more attractive and to develop talent with skill sets aligned to industry needs.

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The incentive and the freedom enjoyed is limited. One of the reasons the US system is successful is there is freedom to academicians, and there is a concept of academic entrepreneurs. Having the right incentive for the innovator is also important. Capability development outside the academic institutions is important. The training aspect outside of university is required. This bridging course is essential because as we go for scale, the employability of university output is limited.

- Head, research center

Incentives to attract talent

India ranks low in terms of its ability to retain talent, resulting in a high efflux of talent to countries like the US. Opportunities need to be created by a conducive environment and adequate compensation to attract and retain talent and also incentives to attract foreign talent (both Indian scientists settled abroad and foreign scientists).

A comparative analysis of compensation to scientists in India compared to that in the US and European countries on a purchasing power parity (PPP) basis reflects a huge differential in compensation (figure 14).

Foreign institutes are not allowed to repatriate surplus income to their home country and need to maintain a minimum corpus of 250 million INR. Model practices highlight the presence of incentives to foreign institutes to set up campuses, including tax breaks, repatriation of profits, easy visa norms, and single-window clearances.

There have been some steps taken to attract overseas scientists of Indian origin to take up research positions in India, like the Ramalingaswamy Fellowship and DBT-Wellcome Trust Fellowship; however, the number of initiatives and scientists benefitting annually are few.

- EVP/CMO, global bio-pharma

Great seeds but not in the right soil. India’s talent potential is immense, with people really driven to innovate... this should be recognized and people should be rewarded in order to retain the brightest talent.

- EVP/CMO, global bio-pharma

Figure 14: Comparison of average compensation of scientists across countries on a PPP basis

A comparison of the compensation (in USD) of scientists across countries on a PPP basis (2014).

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A sustainable pharmaceutical industry needs great academic research institutions. Explore reverse scouting and facilitate academia to be more quality driven.

- R&D head, global bio-pharma

Recommendations to strengthen human resources

1. Improving the education level of the work force based on industry needs
   a. Introduce a national program to increase funding support through grants, scholarships/fellowship programs and enhanced stipends for researchers.
   b. Increase schemes/grants for mobility of researchers from universities to industry/R&D labs and the broader global research education structure.
   c. Improve quality of training in National Institute of Pharmaceutical Education and Research (NIPERs) (pharmaceutical R&D sciences courses, etc.)
   d. Incentivize industry to conduct industrial training and internships for undergraduate/graduate programs to enhance R&D skills.
   e. Increase scholarships, fellowships, grants and training programs for graduates and post-graduates in the STEM field.

2. Incentives to attract talent
   a. Incentivize foreign institutes to set up campuses, including tax breaks, repatriation of profits, easy visa norms and single-window clearances.
   b. Provide income tax exemptions to visiting scientists and researchers of Indian origin.

Potential impact

The policy recommendations would improve the quality and quantity of research talent. There would be an expansion of the number of indigenous doctoral graduates and requisite skill development, leading to an increase in the quantum of research and improvement in the quality of research output. Industry-led training would result in better transfer of knowledge and technology between industry and academia. The establishment of reputed foreign institutes in India would strengthen research output by knowledge sharing, peer-reviewed journal publications, and making world-class infrastructure accessible to Indian students. An enabling environment would encourage both foreign scientists and scientists of Indian origin working internationally to contribute to research in India.

Legal, IPR, and regulatory

Summary of key legal, IPR and regulatory gaps

In the legal, IPR and regulatory building block, the following key gaps need to be addressed:

- Lack of transparency and consistency in patentability standards
- Absence of a data exclusivity law in the country
- Insufficient specialized mechanism for speedy hearing and resolution of patent infringement cases
- Absence of a specific formula for calculating loss to patent holder in case of an infringement
- Non-existence of a regulation under which patent term extension can be granted
- Absence of a framework or established guidelines to address the right of ownership of an invention by individuals or universities
- Limited availability of technology transfer capability
- Lengthy regulatory and patent approval timelines
- Unpredictable framework and timelines for clinical...
Patentability requirements

IP protection provides incentives to companies to make the long, costly investments that lead to medical advances and balances those with the desire for increased competition through the timely entry of generics and biosimilars. Strong IP protection, in the form of patents and exclusivity, provides companies with the opportunity to potentially recoup investments made to develop new medicines and to fund future research.

A number of studies have found that patents and other IP protection are significantly more important to biopharmaceutical firms in “appropriating the benefits from innovation compared with other high tech industries.”

Another major challenge that we are grappling with is uncertainty in policies with regard to patenting pricing, clinical trials, imports, etc. Hence, we cannot plan strategically ahead. The government should provide a complete clarification and definitive stance along with effective implementation to help us plan better.

- Head, India operations, pharma company

The Indian government should clarify the IP policy. Once an IP is granted, it has to be enforced. There is lack of clarity post granting IP. Either the agency granting IP is not qualified enough to grant an IP, or once IP granted, the enforcement agency is not able to enforce. The implementation is broken.

- Head, India operations, pharma company

IP not only attracts innovative medicines to a market, but “it can also impact whether that nation’s scientists and physicians will play a role in global drug development, and if drugs will be developed for locally endemic conditions.” To generate these long-term benefits of patient health and economic growth, innovators must be able to secure patents, effectively enforce patents, and protect regulatory test data and other intellectual property. Through the National IPR Policy, the Indian government is committing additional resources to improving the patent application process.21 Still, clarity in the standards for patentability, as well as consistent application of such standards, is an area for improvement.

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The consistency and clarity of such a system provide the certainty needed to incentivize and sustain high-risk, resource-intensive investments in new products and technologies over many years.

**Data exclusivity**

Patents grant inventors the exclusive right with respect to their inventions without others being able to copy and sell them for a set period. Data exclusivity runs concurrently with patents and prohibits third parties for a set period from using or relying upon an innovator's valuable clinical data to obtain approval for their product.

The Indian IP environment does not provide for data exclusivity laws. The duration of data exclusivity needs to be long enough to compensate for the drug development costs of an innovator for NCEs, biologics and orphan drugs, and an effective mechanism needs to come in place in order to ensure protection of test data submitted to the regulatory body.

According to the US data Protection laws, there is data exclusivity of five years for NCEs. The Biologics Price Competition and Innovation Act of 2009 (BPCIA) provides 12 years of data protection to biologics and orphan drugs get seven years of drug exclusivity.78

The Government of India constituted an Inter-Ministerial Consultative Committee on 19 Feb 2004 to study the data protection provision. The committee had recommended five years of data protection for pharmaceutical products. The committee also suggested several safeguards with respect to data protection for drugs used for life-threatening diseases such as HIV/AIDS. The decision is still pending.

**Patent enforcement and resolution mechanism**

In India, there is a need for a specialized mechanism for speedy hearing and resolution of patent infringement cases. In addition, there is no formula for calculating loss to the patent holder in case of an infringement. Model countries, however, demonstrate effective patent enforcement and resolution mechanisms.79 In the US, there is a specialized court practice with an effective mechanism of preliminary injunctions to protect patentees against infringements. In case for patent infringement, according to the US Patent Law USC section 284, the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.80

**Patent term extension**

In India, the patent term is 20 years from the date of the application under Article 33 of the TRIPS agreement. There are no provisions in the country for obtaining an extension of term of a patent or for the protection of data submitted to a regulatory authority.81

According to the model practice, a maximum period of five years of patent term extension is granted in order to compensate for drug development and regulatory review periods. Such provisions are present in countries high on innovation such as the US, UK and Singapore.82,83,84

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Technology transfer

Basic science, which provides a foundation to discover and develop drugs, is often initiated in academia; thus, mechanisms to allow partnerships and technology transfer between industry and academia are critical. Revenue from technology transfer and academia patenting rates are relatively low in India. The Government of India has invested in efforts to improve the process of commercialization of technology. Few Indian universities, such as the Indian Institute of Technology, have advanced and developed technology transfer capabilities.9

Although the government has started a few initiatives to promote the commercialization of intellectual property from publicly funded research, no framework or established guidelines have come into place to address the right of ownership of an invention by individuals or universities.56

The US Bayh Dole Act, 1980, has led to increased patenting activities at US universities.55 The act created a uniform patent policy among the many federal agencies that fund research, enabling small businesses and non-profit organizations, including universities, to retain title to inventions made under federally funded research programs. For example, a 2012 survey of 82 institutions, conducted by the Association of University Technology Managers (AUTM) reported steady increases in licensing, start-ups and cumulative active licenses: 40,007 cumulative active licenses, 5,145 issued US patents, 6,372 new licenses and options executed, 705 new start-up companies formed, and 2.6 billion USD total income received.57 Prior to the Bayh-Dole Act, all federal sponsored research was owned by the federal government, and less than 5% of the 28,000 federally owned patents had been licensed to the industry. Since the passage of the law, commercialization of federally funded research has increased dramatically—between 1980 and 2002 alone, US universities generated a tenfold increase in patents. A similar act in South Korea, known as the Technology Transfer Promotion Act and the Technology Transfer and Commercialization Promotion Act, provides direct support, opportunities and incentives for universities and research institutions to engage in technology transfer and commercialization activities.88 Japan has a provision called the Industry Revitalization Law that aims to give ownership to universities and research institutions and promote transfer of their technology to industry for commercialization.89

Clinical trial regulation

A potential new medicine must go through extensive studies in humans and demonstrate that it is safe and effective before receiving regulatory approval. This process involves three phases of clinical trials, each with its own specific goals and requirements. Companies identify physician researchers to conduct the research and work with them to carry out the procedures of each trial according to a detailed plan or protocol. The clinical trials process is both expensive and time consuming, and ends more often in failure than success. Less than 12% of the candidate medicines that enter clinical testing make it to approval. From start to finish, the clinical development phase takes an average of six to seven years.56 There are many people involved in the process, including doctors, nurses, lab technicians, clinical trial support team members and clinical trial managers, among others. Clinical trials are a significant undertaking, requiring extensive infrastructure, investment, careful regulation, safety measures and coordinated planning across stakeholders, as well as regulators.

The increasing burden of non-communicable diseases (NCDs) and communicable diseases (CDs) in India, and the need for new innovative medicines for treatment has provided a vast array of opportunities for clinical trials. However the clinical trial activity in India is lower than that in other BRIC countries and several developing countries. Moreover, it is mostly concentrated towards phase III trials. Although clinical trial guidelines in India have evolved, there has been a steady decrease in trials due to an uncertain regulatory climate in the country and some firms deciding not to pursue trials in India. Furthermore, concerns about the ability to conduct clinical trials in India in accordance with global good clinical practices present a stumbling block for clinical trials in India.

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Clinical trials across the world: A comparative picture

Figure 16: Comparison of clinical trials in various countries as per the phase of clinical trial

- **Developed countries:**
  - Carry out the riskier, complex trials
  - Host more early stage trials (Phase I and II), which typically involve the newest technologies

- **Developing countries:**
  - Tend to be concentrated more towards Phase III trials; drug development technology is not involved here

Developing countries: India, Malaysia, Indonesia

![Comparison of phase-wise CTs in leaders vs laggards](image)
If we have to conduct an early clinical program, it is next to impossible to do it in India in a reasonable time frame. There are restrictions on animal research. So what it means that one needs to be financially strong and resourceful to carry out these programs because the only possible way to do this is going abroad. Many organizations will not have the capability to do so. So if you are a small Indian company with good assets, you are forced to exit early. The ability to attract the real value of the asset is limited.

- Head, research center

Initiatives have been taken by the government to restore the clinical trial environment, but approval delays persist. While DCGI wishes to reduce the approval time to conduct clinical trials to one month, current guidelines of six months deter the placement of clinical trials in India, and ultimately delay the introduction of new drugs.\(^{91}\)

![Figure 17: No. of clinical trials registered per year](image)

Practices such as the one observed in the US and the UK suggest that there needs to be a single regulatory body to review clinical trial application with approval timelines of 30 days. The availability of sufficient and well-qualified manpower in the Central Drugs Standard Control Organization (CDSCO) is a challenge. While it has increased from a total sanctioned strength of 111 posts (including 32 drug inspectors) in 2008 to 475 posts (including 279 drug inspectors), there is an additional need of manpower in different disciplines at various levels for effective functioning of CDSCO. Under the 12th Five Year Plan, CDSCO shall have a total manpower strength of 1,102 posts at various positions. With regard to biologics, the regulatory framework should accommodate sufficient guidelines on the approach of clinical trials for biologics that are life-saving in particular.

Approval processes and timelines are lengthy. For example, by the time I get a Phase II trial approval in India, I would have finished the study in the US.

- Head, biotech company

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\(^{90}\) Actions on the recommendations of Prof. Ranjit Roy Chaudhury Expert Committee to formulate policy and guidelines for approval of new drugs, clinical trials and banning of drugs (2013). Retrieved from http://www.sgpgi.ac.in/sop/Action_RR_Choudhury_Committee__06.11.2013.pdf

\(^{91}\) Clinical Trials and Human Subject Protection. FDA. Retrieved from http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/

\(^{92}\) Clinical trials for medicines: Apply for authorisation in the UK. Retrieved from https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk
Regulatory framework

The main regulatory body entrusted with the responsibility of ensuring the approval, production and marketing of quality drugs is CDSCO, which falls under the Ministry of Health. The standards for ensuring the quality, safety and efficacy of drugs are prescribed by CDSCO, which is presided over by the Drug Controller General of India. It is responsible for the license of drugs both at the state and central level.\(^{93}\) The process for drug approval entails the coordination of different departments, in addition to DCGI. It is also the onus of DCGI to ensure a good manufacturing practices (GMP), good clinical practices (GCP) and good laboratory practices (GLP) to ensure that safe and efficacious drugs are available to the patients. The regime of compliance is getting stronger by the day, with not just the Indian regulatory bodies enforcing stricter norms.

Strong, transparent and predictable regulatory frameworks are essential to protecting patients, as well as to promoting globally competitive innovative and generic pharmaceutical industries. India has many of the components of an effective regulatory system, such as institutional capacity across central and state regulators and a robust technical framework. India also has several components to support a broader ecosystem for clinical research and drug development, such as the presence of a highly skilled workforce of qualified scientists, hundreds of medical colleges, and a large and diverse patient pool. Recently, DCGI has announced work streams to look into amending India’s drug manufacturing laws to conform to the World Health Organization’s Good Manufacturing Practices (GMP) guidelines. The government had earlier taken another concrete step towards improvement by approving a substantial and much-needed increase in the funding allocation to improve government regulation of drugs at both the central and state level.

Still, there are opportunities to strengthen the regulatory system and improve delays in bringing new medicines to Indian patients.\(^{94}\) Currently, coordination between the central regulator, which approves new medicines, and state regulators, which grant manufacturing licenses and conduct inspections, leads to challenges. In Japan, the Pharmaceuticals and Medical Devices Agency (PMDA) was previously understaffed and under-resourced, leading to lengthy review times for drug applications. The Japanese government set out to reduce review times from over 20 months in 2008 to 12 months for standard review in 2012, which was accomplished by strengthening PMDA in both size and quality and through greater integration.\(^{95}\)

In India, the GMP guidelines followed by the manufacturers vary from Schedule M and WHO GMP to those of the United States Food and Drug Administration (USFDA), Medicines and Health care Products Regulatory Agency (MHRA) and several others. As per the norms laid down in the Drugs and Cosmetics Act, 1940, all Indian manufacturers have to comply with the GMP guidelines as per Schedule M. In addition, those who wish to export have to comply with international GMP guidelines, such as the WHO GMP or specific GMP requirements of the importing country (such as those of US FDA and MHRA). Generally, at the international level, the WHO GMP guidelines are considered the general and minimum technical requirements for quality assurance.

Several instances of non-compliance with international quality norms have arisen recently. Between 2008 to 2015, the US FDA issued around 50 warning letters to Indian companies. Out of these, around 40% were converted to import alerts. Only a third of the warning letters between 2008 to 2013 have been resolved, a majority of which involved large companies.\(^{96}\) GMP compliance is necessary to enhance the industry’s credibility within the domestic and international market and forms an important part of the innovative ecosystem for serving quality and safe medicines. Efforts should be made towards increasing quality standards in the larger interest of ensuring access to good quality and safe medicines to patients.

There is a major gap in the policies involving granting of patent, protection of patent, data protection, slow litigations with regards to patent dispute.

- Head, India operations, pharma company

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The Government needs to ensure faster approval of drugs. They should establish committees that aid an innovative ecosystem. The current committees do not have technical knowledge about innovation. Regulatory changes are required to improve processes and make them less cumbersome. We need to revamp the CT environment. There is a huge opportunity loss in this field. Closing of business is also difficult.

- Head, biotech company

Recommendations to strengthen the legal, IPR and regulatory system

1. Establish transparent and predictable IP laws and policies
   a. Establish clearly defined patentability criteria and uniform application across patent offices.
   b. Embed a data exclusivity status review into the drug registration process for the following: biologicals, orphan drugs, new indications.
   c. Increase the number of judicial personnel for speedy resolution of cases.
   d. Establish strong and early enforcement mechanisms, including a formula for calculating loss to the patent holder in case of infringement.
   e. Establish patent term extension guidelines.
   f. Streamline administrative procedures for patent applications to reduce delays.

2. Facilitating knowledge transfer
   a. Set a policy framework to allow transfer of ownership of IP from government-funded university research institutes to the private sector for further development and commercialization
   b. Establish regional technology transfer office to promote commercialization of IP generated by respective zonal public universities.

3. Strengthen the regulatory framework
   a. Review the regulatory framework to ensure faster introduction of new and innovative products into the market.
   b. Strengthen the drug regulatory agency through increased resources and training.
   c. Encourage participation of regulatory agencies in international forums.
   d. Implement procedures and personnel to reduce delays in the clinical trial approval process.
   e. Establish simplified regulatory processes for start-ups, including an exit mechanism as per the Startup India Policy.

Potential impact

The policy recommendations aim to build more confidence among researchers and investors by encouraging, supporting and protecting research. They will help in removing ambiguity on patentability and providing stronger IP protection through data protection, stronger patent enforcement and resolution mechanisms. Patent term extensions and provision for transfer of research-based IP ownership would encourage researchers. The policies also aim to improve the regulatory approval timelines at all stages through capacity enhancement or capability enhancement which would help in the faster introduction of new and innovative products in the market.
Policy prioritization

The stakeholder discussions have led to prioritization of recommendations. Areas which need maximum correction or are required to be immediately addressed as per the stakeholders have been given relatively high urgency. Moreover, the policy recommendations would have varied complexity in terms of implementation. Policies which require adoption of new laws or amendment of existing laws, need consensus building among stakeholders or impact multiple stakeholders would be relatively complex to implement. The implementation complexity and urgency helps in policy prioritization. The owners of the policies have also been highlighted to drive effective implementation.

1. Quick wins: Policies with higher urgency and lower implementation complexity:
   - Increase public investment in hospitals and encourage private companies to establish research-quality hospitals through appropriate incentives such as tax breaks and public private partnerships. The goal should be at least 2 hospital beds per 1,000 population and 3 nurses per 1,000 population by 2025 as per the recommendations of the Health Level Expert Group for Universal Health Coverage – Ministry of Finance and state governments
   - Identify focus disease areas based on the needs of India to provide advance market commitments (AMC) to encourage research in those areas as suggested in the National Biotechnology Development Strategy 2015-2020 released by the DBT – Ministry of Health and Family Welfare
   - Allocate funds to establish large public animal breeding facilities and GLP certified public labs – Ministry of Health and Family Welfare
   - Incentivize pre-clinical service providers to establish GLP certified facilities/animal breeding facilities through subsidized land and soft loans – Department of Biotechnology along with State Governments

2. High priority: Policies with higher urgency and higher implementation complexity
   - Increase the number of enrollments into public medical schools and simplify regulations to establish private medical colleges, with the goal of achieving a ratio of at least 1 physician per 1,000 population by 2025 as recommended by the Health Level Expert Group for Universal Health Coverage appointed by the India Planning Commission – state governments (Public) and Medical Council of India

3. Policies with relatively lower urgency
   - Develop infrastructure to improve the quality and impact of research at universities and hospitals to achieve integration of India-based drug discovery, clinical, and other pharmaceutical research within global R&D networks – Ministry of Health and Family Welfare, respective state governments, Ministry of Human Resource Development
   - Define clear roadmap for the implementation of EHR standards and data protection laws – Ministry of Health and Family Welfare and Ministry of Information Technology
   - Integrate guidelines for sharing EHR data from public health institutions for research purposes – Ministry of Health and Family Welfare, Department of Electronic and Information Technology and state governments

Infrastructure:
2. **Financing:**

1. **Quick wins: Policies with higher urgency and lower implementation complexity:**
   - Increase public health expenditure to 2.5% of the GDP by 2020, which is in line with the National Health Policy - Ministry of Health and Family Welfare and respective state governments
   - Encourage growth of private health care insurance through enhanced tax benefits and awareness programs – Ministry of Health and Family Welfare and respective state governments
   - Increase availability of government grants for basic research projects – Department of Biotechnology
   - Increase monetary limits of funds/grants/soft loans for scale-up of projects; total public expenditure on pharma R&D should be at least 0.2% of the GDP as observed with the model practice – Department of Biotechnology
   - Restore weighted tax deductions on all R&D expenditure, both capital and revenue incurred by DSIR recognized centers at external vendors in India to at least 200% (as per model practices) under section 35 (2AB) of the Income-tax Act – Ministry of Finance

2. **High priority: Policies with higher urgency and higher implementation complexity**
   - Improve coverage for primary health care, including outpatient services and medicines, by increasing the coverage in public and private schemes – Ministry of Health and Family Welfare & respective state governments
   - Establish government reimbursement policies for medicines at the center and state level based on negotiations with manufacturers – Ministry of Health and Family Welfare and respective state governments
   - Route public funding and monitoring of public pharmaceutical research through one research organization – Ministry of Health and Family Welfare, Department of Pharmaceuticals and Department of Biotechnology

3. **Policies with relatively lower urgency:**
   - Provide patent filing subsidies for start-ups as per the Startup India Policy – Ministry of Finance
   - Exempt start-ups from capital gain tax as per the Startup India Policy – Ministry of Finance

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3. **Human resources:**

1. **Quick wins: Policies with higher urgency and lower implementation complexity**
   - Strengthen drug regulatory agency through increased resources and training – Central Drugs Standard Control Organization and Ministry of Finance
   - Incentivize industry to conduct industrial training and internships for undergraduate/graduate programs to enhance R&D skills – Ministry of Finance
   - Increase the number of appropriately trained judicial personnel for speedy resolution of cases – Department of Industrial Policy & Promotion (Appellate Tribunal) and Chief Justice of India (courts)

2. **Policies with relatively lower urgency:**
   - Improve quality of training in NIPERs (pharmaceutical R&D, sciences courses, etc.) – Ministry of Chemical & Fertilizers
   - Incentivize foreign institutes to set up campuses including tax breaks, repatriation of profits, easy visa norms, single window clearances, etc. - Ministry of Human Resource Development
   - Introduce a national program to increase funding support through grants, scholarships/fellowship programs and enhanced stipends for researchers – Ministry of Science and Technology and Ministry of Human Resource Development
   - Increase schemes/grants for mobility of researchers from universities to industry/R&D labs and to the broader global research education structure – Ministry of Science and Technology and Ministry of Human Resource Development
   - Increase scholarships, fellowships, grants and training programs for graduates and post-graduates in STEM field – Ministry of Human Resource Development
   - Income tax exemptions to visiting scientists and researchers of Indian origin – Ministry of Finance
1. Quick wins: Policies with higher urgency and lower implementation complexity
   - Create a policy roadmap for accelerating technology from lab to market as suggested in the National Biotechnology Development Strategy 2015-2020 released by DBT – Ministry of Science and Technology
   - Establish curricula for developing expertise and experience in conducting clinical trials, including clinical pharmacology, clinical research, bioethics and regulatory science in collaboration with the pharmaceutical industry – Department of Health Research (Ministry of Health and Family Welfare)
   - Implement procedures and personnel to reduce delays in the clinical trial approval process - Central Drugs Standard Control Organization
   - Establish technology transfer offices to link the outputs from academic research to development and commercialization by companies– Ministry of Human Resource Development

2. High priority: Policies with higher urgency and higher implementation complexity
   - Establish a body to facilitate collaboration between academia, research centers and industry in order to improve the utilization of R&D centers – Ministry of Health and Family Welfare
   - Define policies that would enable the development and refinement of biotech parks around centers of academic excellence – DBT
   - Establish clearly defined patentability criteria and uniform application across patent offices – Ministry of Commerce and Industry
   - Embed data exclusivity status review into the drug registration process for the following: biologicals, orphan drugs, new indication – Ministry of Commerce and Industry
   - Establish strong and early enforcement mechanisms, including a formula for calculating loss to patent holder in case of infringement – Ministry of Commerce and Industry
   - Establish patent term extension guidelines – Ministry of Commerce and Industry
   - Streamline administrative procedures for patent applications to reduce delays – Department of Industrial Policy & Promotion
   - Review the regulatory framework to ensure faster introduction of new and innovative products into the market – Central Drugs Standard Control Organization
   - Establish a single body to oversee public pharma R&D centers and monitor their performance – Ministry of Health and Family Welfare
   - Set policy framework to allow transfer of ownership of IP from government-funded university research institutes to the private sector for further development and commercialization – Ministry of Human Resource Development

3. Policies with relatively lower urgency
   - Establish a central body to certify EHR products – Ministry of Health and Family Welfare, Department of Electronics and Information Technology
   - Establish simplified regulatory processes for start-ups, including exit mechanisms as suggested in the Startup Policy – Department of Industrial Policy & Promotion
   - Encourage participation of regulatory agencies in international forums - Central Drugs Standard Control Organization
Potential impact

Countries that invest in R&D, develop technology and effectively convert this technology into products become more competitive. Innovative medicines create added value in the pharmaceutical industry and are key to a country’s economic and well-being advancement. Vision 2025 will provide economic and social benefits for India and increase competitiveness. The pharmaceutical industry is important for its potential to support the government’s public health and economic targets by increasing R&D, innovation, employment, production and exports.

Social benefits

Promoting innovation in the pharmaceutical industry is aligned with the government’s vision. It will complement the government’s headline programs like Make in India. Benefits such as access to early medicines, capacity building from clinical trials, knowledge of new treatments for doctors, and improved productivity and quality of life will help reduce the disease burden. A time-bound implementation would, however, be essential to achieve the vision by 2025.

Economic benefits

A stronger innovation ecosystem would attract investment. Economic research shows that improvements to India’s innovation ecosystem could attract FDI worth 300–400 million USD. This would also lead to the creation of more value-added jobs. Currently, R&D employment per 1,000 total employment is 0.9% in India, with China being at 3.6% and US at 9.4%. With a better environment for innovation, there would be more opportunities to develop, attract and retain talent. The evolution of model practices suggests the potential of a fourfold increase in R&D employment generation.

With improvement in the clinical trial environment, it is expected that India would have a larger share of global clinical trials, which is currently less than 1.3%. Given that the model practices have a share greater than 5%, a four times increase in clinical trial activity could lead to 400–500 trials being conducted in India against 100–150 in the recent years. Research shows that if India were to address outstanding concerns with clinical trials regulations, India could see an increase in the number of new clinical trials per year to above 800 and add over 600-million USD in economic gains.97

Competitiveness

Knowledge and IP is at the center of innovation. With improvements in multiple areas, India would be able to increase its research output both in quantity and quality. The percentage top cited publication of India is 7%, while for all the model practices it is greater than 10%. There is also a potential of a threefold increase in life sciences PCT application, given that it is 1.5% for India and greater than 4.5% for model practices.

A greater focus on innovation would lead to the development and commercialization of NMEs from India. With improvements in the ecosystem in the next five years, India can contribute to the global NME pipeline and emulate model countries by commercializing three to four new medicines every year. By 2025, this can lead to 15 to 20 new medicines from India, with a potential to generate 1.5–2 billion USD in revenue.

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Conclusion

The global health care industry has grown significantly over the past few decades and has led to improved health outcomes. The overall impact of this can be seen in the increased life expectancy, reduction in infant and maternal mortality rates, and improved health care coverage.

The Indian pharmaceutical industry has also played an essential role in the development of the health care industry by providing affordable medicines through strong research skills and manufacturing capabilities. Today, it is at the forefront of supplying drugs and vaccines to all countries.

While India has the foundation to support greater levels of clinical research and drug development, it has not been able to bring its pharmaceutical industry to a level that can be driven by innovation. This is largely due to modest funding, especially public funding, and low investment in R&D, in addition to regulatory hurdles.

In recent years, India has signaled its intention to become a more significant player in the innovative medicines sector and develop the necessary environment to support biomedical investment, technology transfer and growth.

To achieve the vision, India would need to strengthen its pharmaceutical innovation ecosystem across multiple dimensions. The creation of such an environment would require close collaboration between the government, academia and the pharmaceutical industry. Learning from economies strong on innovation and those who have moved up the value chain in recent times will help, along with a policy framework aimed at the holistic development of the ecosystem for innovation.

The recommendations offer a roadmap for policy implementation to unlock India’s potential as a leader in pharmaceutical innovation, bringing in benefits in the form of more job opportunities, increased local and foreign investment, and higher tax revenues and export revenues, apart from vastly improved health outcomes through access to newer medicines. An innovation-oriented industry will lead to the generation and commercialization of home-grown IP, which will help position India globally as a knowledge-driven economy, and will advance its capacity in science and medicine.
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