Reshaping India into a life sciences innovation hub

March 2020

FICCI

EY
Building a better working world

Message from

Hon'ble Minister D. V. Sadananda Gowda

Minister of Chemicals & Fertilizers

Government of India

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D.V. Sadananda Gowda
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सत्यमेव जयते

रसायन एवं उर्वरक मंत्री
भारत सरकार
Minister of Chemicals & Fertilizers
GOVERNMENT OF INDIA

MESSAGE

It is a matter of great pleasure for me to write this message for "INDIA PHARMA & INDIA MEDICAL DEVICE - 2020" an international exhibition and conference on Pharmaceuticals & Medical Device Industry schedule from March 5 – 7, 2020 at Mahatma Mandir, Gandhi Nagar, Gujarat, India.

With the theme "Meeting Challenges for Affordable and Quality Healthcare" & "Promoting Affordable, responsible, quality medical devices for Universal Healthcare", I am sure the event would be a positive step towards the development of the Pharmaceutical & Medical Device sector in India and also would be a platform wherein the Indian Pharmaceutical & Medical Device Industry will showcase its strength to the Indian and International audiences.

I am sure the 5th edition of this event will be beneficial for all the stakeholders. Parallel activities like the CEOs' Roundtable, Thematic Sessions, Vendor Development Program, State & International Drug Regulators' Meet and interactive sessions will create the right atmosphere for the exchange of ideas and doing serious business.

I am sure the participants will be benefited from this event. I wish the event a great success.

(D. V. Sadananda Gowda)

24th February, 2020

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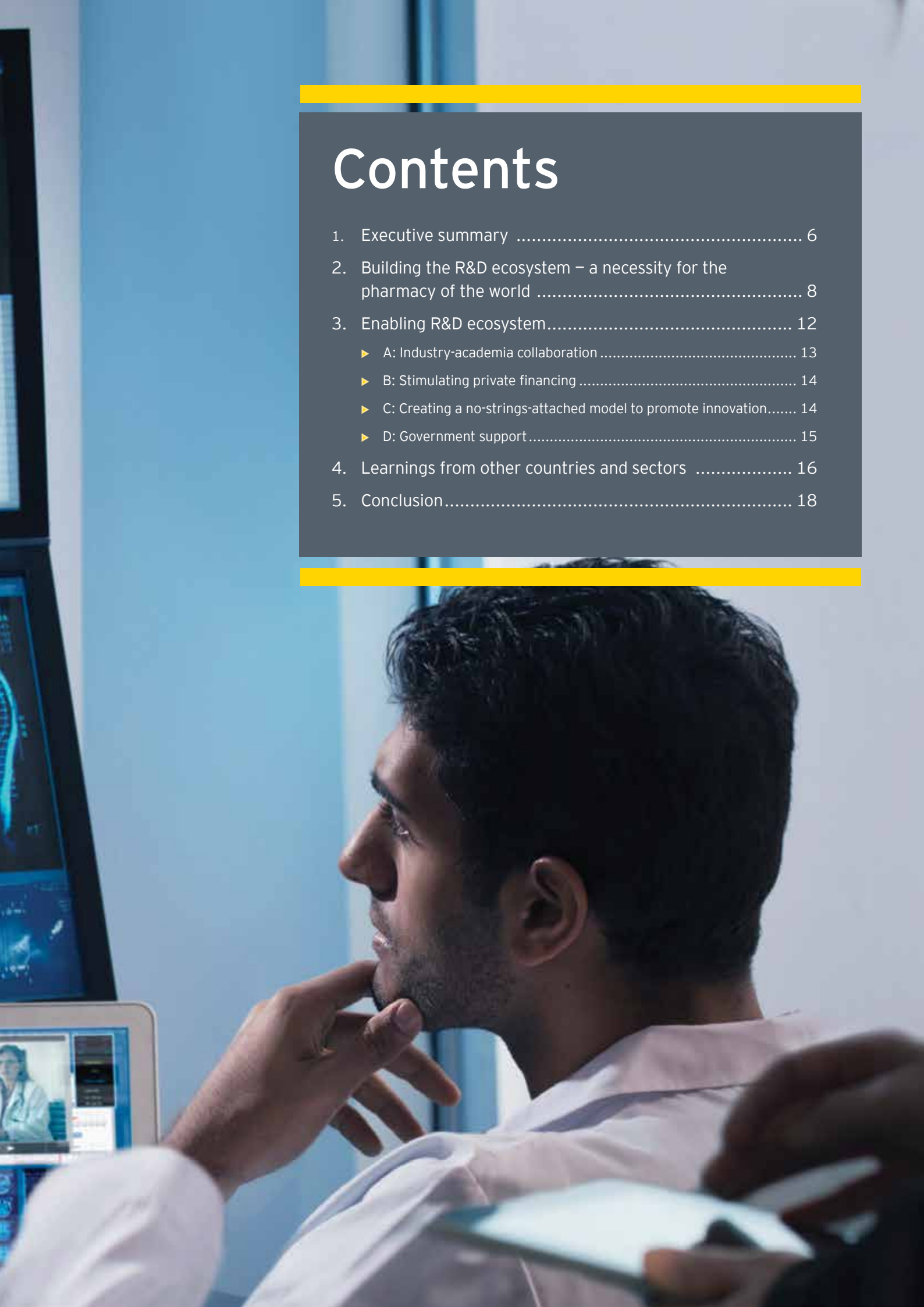


1 Executive summary

India has come a long way in becoming a hub for manufacturing and supply of generic drugs since the patent reforms in 1970 and is today touted as the pharmacy of the world.

While India is lauded for its drive and efforts in becoming the pharmacy of the world, the country is still at a nascent stage in terms of its activities in commercially oriented R&D and innovation. Despite being the third largest seller of medicines in the world, India has been able to produce only a handful of novel commercially viable drug molecules.

This paper examines what will it take to replicate this success to novel products and medical devices.

Drawing upon the experiences in other countries and sectors, we recommend the following:

- **Establishing top-down governance structure**:
  - Creating a Centre of Excellence (CoE), where stakeholders are able to provide thought leadership and direction to innovators to create commercially viable projects
- **Enabling access to quality infrastructure and talent**:
  - Geographical proximity between universities supplying high skilled talent and R&D hubs of industries
  - Enhancing industry-academia collaboration
  - Improving the education level of the workforces based on industry needs Building sustainable clinical trial infrastructure
  - Constructing dedicated zones or mega drug parks
- **Creating sound and effective IP, legal and regulatory framework**:
  - Establish transparent and predictable IP laws and policies
  - Facilitate knowledge transfer
  - Strengthen the regulatory framework
- **Ensuring availability of financing for research and purchase of medicine**:
  - Adopt healthcare financing policies to increase availability and usage of pharmaceutical innovation
  - Risk sharing models are needed to incentivize PE/VC funds for making investments in high-risk life sciences R&D for long-term
  - Innovative financing models (e.g., debt-type instruments) need to be institutionalized by partnering with central banking organizations in the country
- **Streamline and fast-track regulatory approval process**: To boost the innovation in emerging areas such biosimilars and biologics, initiatives such as decreasing the number of authorities involved or specifying a maximum time-limit for approvals and simplifying the documentation and submission requirement, can help facilitate growth.

2

Building the R&D ecosystem – a necessity for the pharmacy of the world

2.1 How did India become the pharmacy of the world?

Over the last few decades, Indian pharma industry grew its expertise significantly in manufacturing and supplying quality generic drugs to address the growing need for affordable health care around the world. This helped the country earn the title of the pharmacy of the world. But, as the global innovator companies strive to change the treatment landscape with personalized medicines, the pressure is mounting on generics manufacturers in India to find a niche of their own with novel medicines in the tomorrow of therapeutics.

This section provides an overview of the catalysts that accelerated India's transformation into the pharmacy of the world. It also details about the status of novel drug R&D in India and how the country fares in comparison to other life sciences hubs on this aspect. Finally, it examines the factors impeding India's progress in novel drug development.

The above statistics are testament to India's significant contribution in improving health outcomes of millions of patients across the world with affordable and high-quality therapies.

The Indian pharma industry supplies ~40% of generic demand in the US and ~25% of all medicines in the UK

Over 50% of the global demand for vaccines is addressed by Indian pharmaceutical companies

India provided affordable HIV drugs at 96% price cut compared to western companies in response to the African HIV crisis in 1999

The journey of the Indian pharmaceutical industry to annual exports of ~US$19.1 billion and the top 20 Indian companies earning ~US$11 billion in revenues in India in FY19 can be attributed to various demand and supply-side factors.

Globally, rising burden of chronic diseases, emphasis on mitigating communicable diseases and increase in spending on health care have been the key factors driving the demand for better treatments over the years. Indian life sciences industry with its significant formulations expertise and focus on building manufacturing and regulatory capabilities amid a favorable patent regime has successfully seized the opportunity in catering to this need

Type of driver	Factors	Key trends over the years
Demand-side	Rising incidence of chronic diseases	▸ Noncommunicable diseases (NCDs) are responsible for ~71% of deaths worldwide. Cardiovascular diseases, cancer, diabetes and chronic lung diseases account for most of these deaths.[1] ▸ India has the second-largest pool of diabetics in the world (>77 million people), that is projected to reach 134 million by 2045
	Emphasis on mitigating communicable diseases (CDs)	▸ Several initiatives by public and private organizations around the world focusing on reducing the CD burden have resulted in significant success: ▸ Polio cases have decreased by over 99% from an estimated more than 350,000 cases in 1988 to 33 reported cases in 2018 because of the Global Polio Eradication Initiative, 1988[2] ▸ Between 2000 and 2018, new HIV infections fell by 37% and HIV-related deaths fell by 45% because of efforts by national HIV programs supported by civil society and international development partners[3]
	Rising expenditure on health	▸ Spending on health care (as a % of GDP) increased globally from 8.6% in 2000 to 10.0% in 2016[4]

1 "Non-communicable diseases – key facts," WHO, 1 June 2018
2 "Poliomyelitis – key facts," WHO, 22 July 2019
3 "HIV/AIDS – key facts," WHO, 15 November 2019
4 "Current health expenditure (% of GDP)," World Bank, 2016

Type of driver	Factors	Evolution timeline		
		Pre-1970	1970-2004	2005 onwards
Supply-side	Favourable patent regime	▸ Patent Act of 1911 allowed for product-based patents for every new medicine ▸ This enabled foreign MNCs to enjoy monopoly and have ~99% share in the Indian market	▸ Indian Patent Act 1970 granted patents based on the process of manufacturing ▸ Market share of foreign MNCs, thereafter, dropped to ~50%	▸ Indian Patent (Amendment) Act 2005 led to the adoption of product patents in India, while at the same time, preventing evergreening
	Focus on R&D expertise	▸ There was limited focus on drug development	▸ Domestic players strengthened process chemistry skills by re-engineering patented drugs ▸ Expertise also grew in developing low-cost generic drugs	▸ Research in chemical entities and novel drug delivery started receiving endorsements ▸ India improved its system of higher and technical pharmaceutical education ▸ Few Indian pharma companies spun off their R&D divisions into separate units to scale up resources and to attract focused investments
	Manufacturing and supply chain expertise and focus on compliance	▸ India used to meet ~80% of its needs for pharmaceuticals through imports	▸ Domestic bulk drug production and finished formulation units were developed	▸ Stricter quality compliance in manufacturing was put into effect under a revised Schedule M – enabled harmonization of existing cGMP protocols along the lines of WHO and US-FDA protocols ▸ This led to the growth of contract manufacturing in India

2.2 Time is ripe to transition into an innovation hub

Indian pharma companies are now fighting battles on multiple fronts. Companies have witnessed significant price erosion of their generic drugs due to increased competition and channel consolidation in the US.

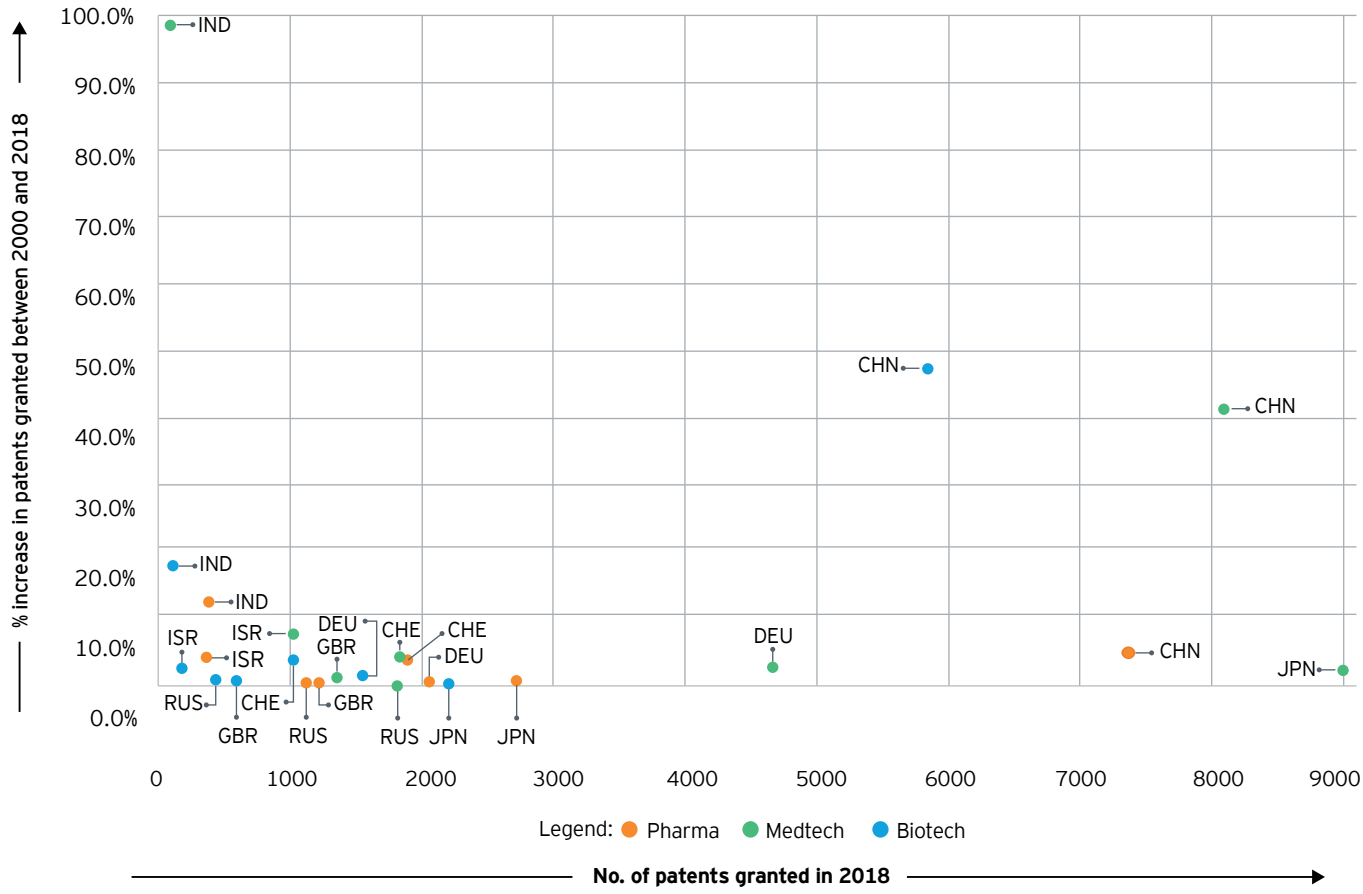
Moreover, with rising burden of diseases once considered intractable, the demand for precision medicine and other complex drugs have increased significantly, calling out the need for innovation in the Indian pharma industry. Biologics have thus become one of the fastest-growing classes of therapeutic compounds and are expected to account for more than a quarter of the global pharma market in 2020. These drugs have proven their potential to treat a wide range of conditions and have witnessed notable success rate in cancer and autoimmune diseases. While most the US and EU-based companies have been agile in speeding up the development of these drugs, Indian companies have relatively lagged behind.

Time is therefore ripe for Indian pharmaceuticals companies to look at novel drug development in a significant way.

While the country's R&D intensity (the amount it invests in R&D as a percentage of sales) has been rising for several years and now stands at 6%, it is well short of the 20% typical of western pharmaceutical companies. Furthermore, when viewed from a sector-agnostic perspective, India spends only ~1% of its GDP on R&D activities and, only ~20% of which comes from the private sector. In contrast, in developed nations, ~75% of the research funds come from the private sector.

This is also reflected in the low number of patents granted to it in biotech, pharma and MedTech in 2018, in comparison to some of the major suppliers of drugs and devices.

How some life sciences hubs rank against each other in patent landscape, by type of technology



Source: WIPO statistics database. Last updated: October 2019.
Note: US has not been included in the graph above as it was skewing the dataset with significantly larger number of patent grants in each field Expanded forms of country name abbreviations: IND – India, ISR – Israel, CHE – Switzerland, CHN – China, DEU – Germany, GBR – United Kingdom, JPN – Japan, RUS – Russia

2.3 Key constrains to building an R&D ecosystem

> **The industry's potential is being curtailed by a host of constraints, including the absence of an enabling ecosystem and limited collaboration between industry, academic institutions, incubators and the government**

- **Limited talent pool with advanced skills**: 2,000 PhD students enrolled in Indian pharmacy institutes, compared to >15,000 students enrolled in the US pharmacy institutes, according to a report by Indian Pharmaceuticals Alliance (IPA)
- **Gap** between the academic curriculum and industry requirements
- **Clinical trial approval process** in India is subject to stringent and time-consuming regulations
- **Limited incentives from the government**: The weighted deduction on R&D expenses in income tax was reduced from 200% to 150% in 2016, and will be further reduced to 100% from 1 April 2020

To overcome these challenges, every stakeholder group directly or indirectly involved in life sciences R&D in India needs to be aligned on the same path. Course correction at every level will be needed, more so because the demand for personalized medicine by all customer groups will grow in the India as it catches up globally. Its high time pharma industry capitalizes on India's large skilled, yet cost-efficient workforce to foster innovation.

3 Enabling an R&D ecosystem of change, innovation and growth

India needs an ecosystem built on the foundations of its distinctive capabilities in key areas of the value chain, such as manufacturing, product development and process innovation. Both public and private organizations in the life sciences sector in India would need to invest in the development of the skills, infrastructure and culture to transform the country into a life sciences innovation hub of the world. Fostering an innovation ecosystem or hub will require interventions across following four dimensions:

A. Encouraging industry-academia collaboration
B. Stimulating private financing
C. Creating a no-strings-attached model for promoting innovation
D. Reinvigorating government support

A: Industry-academia collaboration is the need of the hour

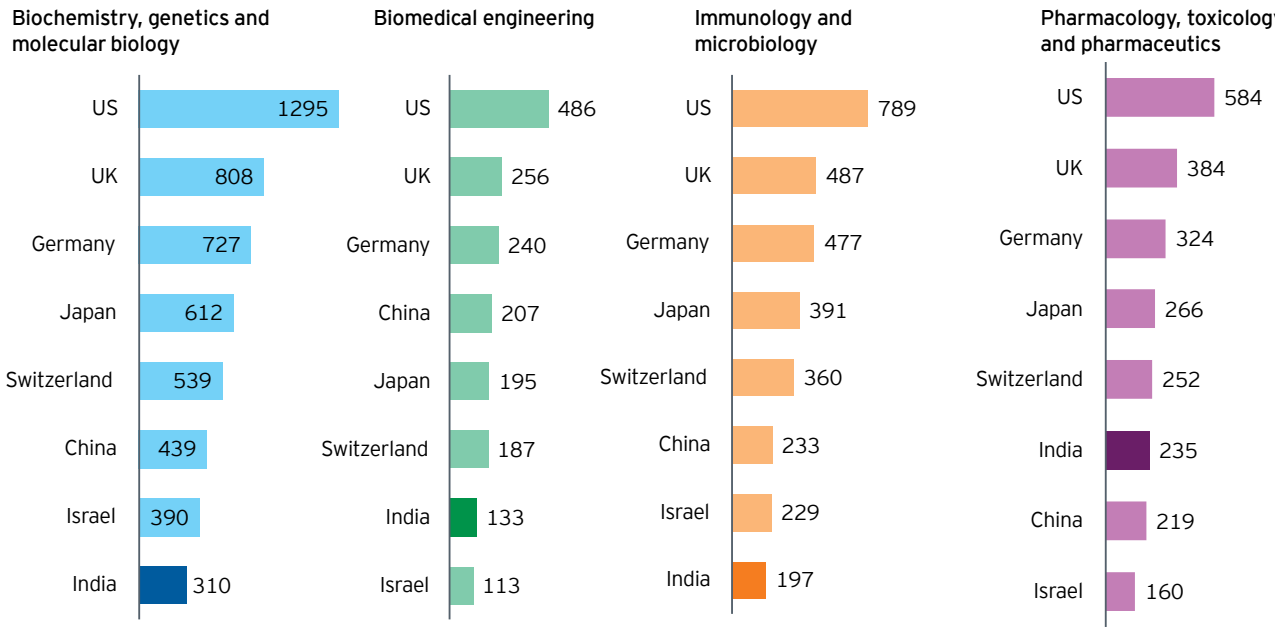
Academic institutions are generally considered as the research undertakings driving innovation at the most elementary level in a sector. Globally, companies that are looking to innovate in their fields of play, forge strategic collaborations with the academia to reinvent their value proposition and provide better solutions to the customer.

As a result, numerous such collaborations exist between the life sciences industry and research institutions working on to improve health care through innovation in pharmaceuticals, biotechnology and medical devices. India, however, is yet to witness significant levels of synergy between the life sciences companies and academic institutions.

The H-Index defined by SCImago Journal Rank (SJR) provides a useful measure to quantify this impact. It measures the number of research articles in a scientific journal and number of citations of those articles by origin of research to assess a country's scientific productivity and impact. To this date, India ranks much lower on the H-Index compared to other life sciences hubs around the world, primarily in areas such as biochemistry, genetics, molecular biology, immunology and microbiology biomedical engineering.

Pharmacology, toxicology and pharmaceutics is one area where the country still holds a better position as a result of decades of focus on it – reason why India is now known as the pharmacy of the world. In the era of personalized medicine however, India needs to graduate to the level of a life sciences innovation hub. This could happen only when the country focuses on quality research aligned with the needs of the market in the first three areas and there are long-term partnerships based on trust between the industry and academia to commercialize the ensuing intellectual property.

H Index by country and specialty



Source: Scimago Journal and Country Rank

Geographical proximity can play a vital role in stimulating frequent exchange of ideas on commercially viable research between the academia and life sciences companies. This leads to the establishment of trust and cooperation between the stakeholder groups. It also creates a forward-looking economy in the region as highly skilled talent becomes a commonplace there and entrepreneurial spirit is promoted in all the echelons of the society. Boston and Cambridge in Massachusetts and San Francisco Bay Area in California, respectively, are couple of shining examples in this respect, ranking first and second respectively on the list of leading biopharma clusters in the US.

High density of highly skilled human capital has led to the growth of entrepreneurial culture in both regions as companies tend to create spinoffs and attract other companies, boosting the growth further around the clusters. In the Bay Area, presence of strong industry associations such as Biocom and California Life Sciences Association (CLSA) has also provided the right environment for start-ups to flourish through industry engagement and brand awareness.

B: Private financing is the booster fund to push innovation

Limited private financing continues to plague biotech R&D in India. Most biotech start-ups have been successful in receiving seed and early proof of concept funding via the public exchequer and international grants. However, they have struggled to survive thereafter. This is especially true in case of high-risk biotech ventures. Based on the current pipeline in India and continued venture creation, it is estimated that aggregate investment required for developing assets until stage of commercialization is US$6.2 billion.

India can look up to some of the global biotech leaders for lessons to attract private sector funds in high-risk life sciences ventures. Europe could be an interesting example to follow in this case where novel financing providers and mechanisms are emerging to stimulate private funding for life sciences ventures. Key trends in the evolving R&D financing space in European life sciences sector are as follows[5]:

- Increase in adoption of patient venture capital includes technology transfer funds and accounting for extended terms and increased flexibility for traditional equity investors. The UK already has several patient investors. The UK Treasury, in fact, launched the Patient Capital Review in 2017 to provide insights on applicability of such models on developing clusters.
- Increase in the variety of financing instruments. For instance, debt-based instruments are now more accessible, with investors willing to offer them to life sciences small and medium enterprises (SMEs) in combination with funding from equity providers. Key European financing institutions such as the European Investment Bank (EIB), are also getting actively involved in this space to offer innovative financing models and higher risk-taking venture debt-type instruments via European Fund for Strategic Investments (EFSI) and InnovFin programs for high-growth SMEs

Owing to such innovative financing measures among other factors, venture capital investment in Europe's biotech firms has more than doubled in the past five years compared with the previous five: from US$7.4 billion (2010 to 2014) to US$16.0 billion (2015 to 2019).[6]

EIB has also tabled proposals on risk-sharing models to further incentivize private sector participation by improving the risk-return profile of investing in areas with high unmet medical need, such as infectious diseases and dementia that typically fall out of the investment spectrum of private investors due to low expected yield.

The aforementioned measures are truly innovative in the world of financing life sciences R&D, which is generally high-risk and requires long-term commitment. By all means, these measures could help boost the confidence of private investors in innovation-focused life sciences companies in India.

C: Creating a no-strings-attached model for flourishing innovation

Unlike the software industry, where few developers or testers can build a new software or an app within months, the innovation in the healthcare industry is a different matter altogether. Innovation requires sophisticated lab equipment, chemical reagents, electronic microscopes and often access to live cultures that must be grown and stored under precise conditions. And if the idea works well in lab and on animal models, it goes through series of regulatory procedures and approvals to enter human trials and finally reach consumers. This demands huge amount of capital and research infrastructure and a trust-worthy development environment.

5 "Access-to-finance conditions for Life Sciences R&D," European Investment Bank, March 2018

6 EY analysis based on data from S&P Capital IQ and VentureSource

Building no-strings-attached business model for small and medium-sized companies working on complex science and creating an incubation environment by providing the expertise, mentoring, funding, services and facilities needed to flourish innovation. At the same time, it is critical to let these companies be strings-free by not asking them to share confidential information, their intellectual property or provide rights. The pharmaceutical industry must assist in navigating a tide of business, financial and operational obstacles and empower small healthcare companies to focus on key scientific discoveries.

Take the example of a top 10 global healthcare company. This company opened its first incubator in San Diego with the purpose of supporting young healthcare companies. The incubator has since worked to build a large ecosystem of 13 incubators across the globe. It supports entrepreneurs by helping them overcome common barriers to discovery and development, such as the large initial investment of time and money that is necessary to establish working labs and other business infrastructures.

Currently, the incubator is incubating more than 100 enterprises, and they are given access to a wealth of resources, including the multinational's compound library and a business services unit, which can help them in numerous ways, such as turning a university research project into a company and then scaling up the operation. This allows start-ups and entrepreneurs to focus all their attention on doing science. Some of the techniques used by the incubator to attract entrepreneurs is to throw crowdsourcing challenge inviting innovation ideas in areas where pharma hasn't historically been strong. These contests are cost-effective — they can be run inexpensively but potentially generate big leaps in entrepreneurial thinking or trigger product development around non-core pharma assets.

Over the past several years, the different incubator sites have nurtured more than 430 start-ups helping them to secure more than US$11.6 billion through financing and strategic relationships. Many of the incubator resident companies have moved beyond the discovery phase into human trials.

This model proved successful as it helped many companies find investors, navigate the approval process and launch their ideas. Its's high time life sciences in India emulate the globally successful models and methods to bring innovative solutions to patients. One of the leading domestic players in India is pioneering an innovation challenge to crowdsource and incubate disruptive ideas in healthcare, ranging from pharma, diagnostics, devices, digital, and services.

D: Government support is a strategic necessity

Government support is critical in building the start-up infrastructure, resource investment and other policy regulations to flourish innovation.

Several proactive measures have been taken by the government of India to support the vision of making India a hub for biotechnology-based innovation and research — from offering grants and tax incentives to implementing investment-friendly regulations, domestic or foreign. The Department of Biotechnology (DBT) established a Public-Sector Undertaking, Biotechnology Industry Research Assistance Council (BIRAC) to enable biotech enterprises to undertake strategic research and innovation. BIRAC along with DBT is playing an important role in the implementation and delivery of the flagship programs of the Indian Government especially Make in India and Start-up India and has a crucial role in transformation of the Indian Bioeconomy to US$ 100 billion by 2025. Until 2018, BIRAC has successfully created pan-India presence supporting over 700 biotech companies, research institutes, small and medium scale enterprises (SMEs). These includes 500 start-ups and entrepreneurs; generated about 155 Intellectual Property Rights (IPs); supported 30 Bio-incubators across India and around 100 products/technologies developed.

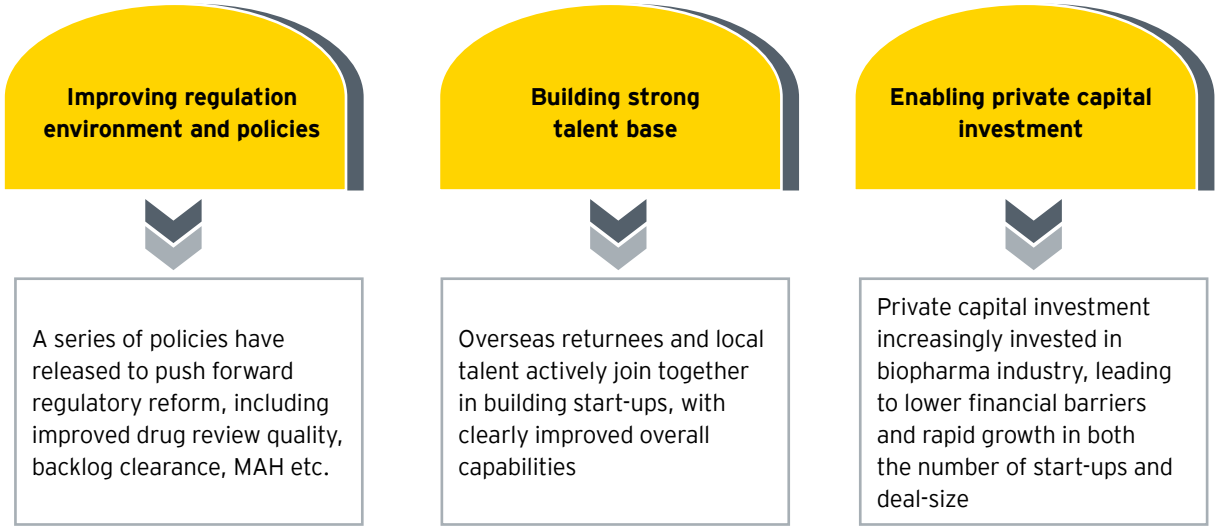
It's high time pharma and the med-tech sector, which are also heavily dependent on R&D, get risk funding support to position India as an innovation-based economy. Here is a case study of how China did it.

4 Learnings from other countries and sectors

How China created an R&D ecosystem

The Chinese Government initiated a new wave of regulatory and policy-level interventions to foster innovation locally. These The Chinese Government initiated a new wave of regulatory and policy-level interventions to foster innovation locally. These include changes in approval process, rationalizing clinical trial data and creating guidelines for fostering digital healthcare innovation. The China Food and Drug Association (CFDA) became a member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and integrated itself into the international pharma market. This indicates the government's drive to streamline its regulatory procedures and pace with rapid drug development occurring internationally in Europe and the US.

Three key elements in China's Pharma innovation ecosystem that have contributed to growth



Additionally, the government launched the Thousand Talents Plan in 2008 to attract foreign researchers and provide an incentive for Chinese scientists living abroad to return home. The returning talent helps support major alliances between multinational biotechnology firms and Chinese universities, cancer research partnerships and company-to-company deals. The pilot schemes are being rolled out to encourage the development of high-quality generics. This policy aims to eliminate low-cost, low-quality copycats from the market and prioritize high-quality generics in more direct, centralized hospital procurement processes. In 2018, a new reform package was also introduced to allow generics manufacturers receive tax breaks through designating themselves as high-tech enterprises.

Learnings from the automotive industry: Motion initiative

in India, Software Technology Parks of India (STPI), an autonomous association, along with the Union ministry of electronics and information technology, soft-launched a center of excellence Motion (mobility in action) in Pune. This is to facilitate innovation in emerging automotive technologies, primarily autonomous, connected, electric and shared (ACES) mobility. The center will create a holistic ecosystem for encouraging R&D, innovation, entrepreneurship in the mobility sector in India. It will host a physical laboratory, state-of-the-art incubation center along with training, mentoring, networking and marketing support, access to the financial resources and other support services for the benefit of the start-ups.

Conclusion

It is a well-known fact that the investment in R&D activities carries significant risk because the benefits only emerge over a long period of time and after considerable expense. But without injections of R&D investment, neither incremental nor breakthrough innovations will occur. The time is now to distribute the risk among several stakeholder groups in an ecosystem. A collaborative ecosystem comprising private enterprises, government, investors, academic and research institutions, and individuals can be the potential solution to the problems faced by pharma R&D.

The way forward requires concerted efforts by all stakeholders working together towards a common goal of creating an innovative ecosystem. The world of academia, clinical hospitals, industry, funding institutions (PE/VC funds, central banking organization) and the government needs to converge and collaborate to unlock India's capacity in science and innovation. Improving communication between industry stakeholders and Indian regulators would help to build a stronger platform for pharma while developing more certainty around drug costs, such as policies that provide a framework for pricing, would contribute to a steady regulatory environment. Establishing trust between industry and academia over ownership of intellectual property, creating no-strings-attached model are some critical elements to successful relationships.

It is important to note that this change will not happen in a short duration. Future success will require a lot of experimentation, as well as some failures. Setting reasonable expectations at the start, promoting frequent conversations within the ecosystem and providing competent training will facilitate the trust needed to achieve the vision of India being a preferred destination for pharmaceutical innovation.

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