

Indian Pharmaceutical Industry 2021: future is now

February 2021



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FOREWORD

The role of the Indian pharmaceutical sector has been fortified during the pandemic when global and Indian companies stepped forward and enhanced their efforts in service of the country. India is often referred to as 'the pharmacy of the world.' This has been proven completely true during the ongoing COVID-19 pandemic when India continued to produce and export critical life-saving medicines to the rest of the world. Indian pharma industry has potential to emerge as global manufacturing hub and become self-reliant. This can be achieved by producing world class quality products and further strengthening our position by meeting the global quality requirements in our manufacturing facilities.

(D. V. Sadananda Gowda)

February 22, 2021



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Government of India

Dt. 22-02-2021



FOREWORD

It is imperative that India needs an independent and unique Healthcare Model for the growth of Pharmaceutical Sector. The developments in this sector have always been industry driven and should continue in this way to maintain our unique leadership position. India exhibited strength in Pharma Sector globally during the COVID-19 crisis by making available essential drugs across countries. What lies next is to be independent and to leverage resources to the maximum potential. Developing expertise in API production, collaboration with states and private sector to enhance the infrastructure, focus on R&D, accessibility and affordability are the goals to be achieved by us in the near future. The Pharmaceutical Industry should feel confident, look towards future goals while government supports the Industry.

(Mansukh Mandaviya)



सुश्री एस. अपर्णा
सचिव

Ms. S. Aparna
Secretary



भारत सरकार
रसायन और उर्वरक मंत्रालय
औषध विभाग
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

Dated 23rd February, 2021

FOREWORD

The pharmaceutical industry in India has contributed in a large way during the pandemic in the areas on preventive healthcare, sanitation, providing quarantine facilities, medicines, etc. The industry provided cooperation to the national cause with complete attention to societal and national needs during these unprecedented times making sure of uninterrupted supply of affordable and quality medicines. Despite several constraints, Indian pharma industry has helped to fulfil the healthcare needs of India and over 120 countries. The government has also launched schemes to focus on medical devices, manufacturing and innovation. The focus is also on attracting greater investments from global players not just in manufacturing but in research and development as well. This report will help explore the evolution of best practices that can guide policy.


(S. Aparna)

Foreword



Pankaj Patel

FICCI Pharmaceuticals
Committee Mentor
and Chairman, Zydus
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The Indian Pharma Industry is poised for a big leap forward in this decade. Health, Science and Innovation have come into sharp focus as never before. The developments over the past year have underlined the importance of an innovation ecosystem, a robust infrastructure for production of drugs and pharmaceuticals and the need to constantly build a huge talent pool of scientists, researchers and technologists who can be the arrowheads for the future. India has emerged as a pharmacy to the world, supplying critical drugs and vaccines in the course of this pandemic. To be able to do this more consistently, we will need to have a greater thrust on innovation, investments in new technologies, take a futuristic view in our approaches and look at new possibilities that can capitalise on our strengths. Building on the theme of Aatmanirbhar Bharat we need to create visibility on 'Brand India' centred on manufacturing and innovation. We will also need to look at global benchmarks of quality and supply reliability to increase pharma exports. As we build capabilities for producing innovative drugs and complex to manufacture generics, we will be able to access newer global markets. As we do this we will need to focus on streamlining our regulatory environment and also look at how we can sustain our cost competitiveness. Above all, India must look at building next-gen capabilities that will be a differentiator in the decade ahead. This is a time for the Indian Pharma Industry to move ahead full throttle, invest for the future and catapult itself into a new horizon of growth and opportunities.



Gagan Singh Bedi

FICCI Pharmaceuticals
Committee Chair and
Country President &
MD, Astra Zeneca India
Limited

Innovations from the pharma industry in India and globally are driving better health outcomes. The current focus needs to be on novel and targeted therapies. Scientific advancements along with industry – academia collaborations will benefit the pharma industry and facilitate its growth. Apart from this, technology can be a huge enabler across the value chain starting from diagnostics to treatment and drug delivery. It can help reduce costs, enhance quality of treatment as well as its access. The government has taken initiatives to reduce regulatory approval time and Ayushman Bharat to make drugs accessible to the massive population of India. This report gives a preview of advancements that are leading to changes in global healthcare.



S Sridhar

Immediate Past Chair,
FICCI Pharmaceuticals
Committee and MD,
Pfizer Limited

Access and Innovation have always been the two key driving factors for progress in healthcare, not just in India but across the world. The COVID-19 pandemic has further underscored the critical importance of these aspects to secure both the immediate and the long-term health and wellbeing of our citizens. This report provides a detailed view of the tremendous achievements of the pharmaceuticals sector in India, while also laying a template of what we must do, collectively as stakeholders, to accelerate this progress.

Important themes of accelerating research and innovation, achieving sustainable and equitable healthcare, strengthening manufacturing and supply chains are addressed as both success stories and future imperatives. We take up the need for supporting quality research institutions, upskilling a skilled workforce and enhancing collaboration between stakeholders and academia.

Innovation does not only pertain to bringing novel therapies to market, but to exploring new and sophisticated approaches on pricing and funding that take them to patients. We take up the need for India to explore innovative new solutions to sustainably enhance access while ensuring that we maintain a positive operating environment for R&D investments and risk-taking to thrive.

The renewed focus on leveraging digital technologies to increase awareness, prioritize the needs of the less economically privileged is heartening. Undoubtedly, global healthcare has taken a drastic turn with its focus on preventive healthcare and it is a step in the right direction towards a healthier tomorrow!

We hope that this report serves as a thought starter and a guiding document for all stakeholders to collaborate, envision India's healthcare future together and bring these goals to life.



Sriram Shrinivasan

National Health Sciences
Leader Leader - EY India

The Indian pharmaceutical industry has grown from strength to strength in the last few decades. The industry has shown tremendous resilience in its ability to serve people in India as well as across the globe, ensuring accessibility and most importantly affordability of quality medicines.

The pandemic has highlighted the growing complexity of challenges that lie ahead and the need to strengthen India's capabilities, over the next decade, to respond to them adequately. EY has collaborated with FICCI to put together this report, collated insights from a wide array of stakeholders - the Indian government, pharmaceutical and healthcare industry leaders, functional experts of the pharma industry and experts in the allied sectors - and complemented it with extensive secondary research, leveraging EY global research outreach, to give you a holistic view of the entire ecosystem.

The pandemic has also revealed the importance of Digital in all walks of life. This fits in well with two sectors that India is strong in - Technology and Pharmaceuticals and the convergence of both these strengths could make India a leader in the Healthcare of tomorrow.

The unique challenges and the way forward have been discussed under chapters dedicated to the objectives of accelerating research & innovation, achieving equitable and sustainable healthcare, strengthening manufacturing and supply chains and improving access to medicines. We must take upon ourselves a moon-shot target for the pharma industry in India, whereby all stakeholders come together on one platform and take a pledge of commercialising Indigenous new chemical entity and new biological entity OR novel drugs (both biological and chemical). This will take unprecedented effort and resources, however if there is anything positive that has emerged from the COVID-19 pandemic, it is that nothing is impossible if we bring in right stakeholders on one platform for the larger good of human-kind. Our very future depends on it.

We hope that this report acts as guiding document for the stakeholders, prompting policy as well as action, while we set out to bring the envisioned goals to life.

EY remains committed to support all stakeholder of Indian pharmaceutical industry on this journey of future excellence.



Executive Summary

The position paper, Indian Pharmaceutical Industry 2021: future is now, has been written with an objective to reassess the Indian pharmaceutical industry's positioning in the world order, define India's ambition by 2030 and identify a set of imperatives for all stakeholders to realize this ambition.

The pharmaceutical industry, along with the healthcare sector globally, has been impacted in an unseen way due to the outbreak of the COVID-19 pandemic leading to material impact around consumer requirements and preferences accompanied by macroeconomic, structural and microeconomic changes in the end-to-end value chain. In the midst of the pandemic and a changed world, the pharmaceutical industry across the world has responded with agility – from the sequencing of the novel coronavirus in January to vaccines being administered to the first recipient in the United Kingdom by December 2020, with efficacy levels over 90%, exceeding all expectations of governments and markets across the world. This innovation has been possible owing to the most extraordinary global efforts: collaboration like never seen before, redeployment of resources and sharing of data on a real time basis. Barring the pace, which is critical in a public health emergency (progressing Phase 3 clinical trials with limited adherence to traditionally established safety norms), the blueprint has been developed to fast-track innovation with a complete imperviousness to financial stakes. This includes collaboration around resources and data sharing, nimbleness and productivity through adaptation of newer technologies and most importantly balancing risks across stakeholders. Healthcare is likely to be on top of the strategic agenda across

geographies. The pharma industry will be closely monitored by governments in all countries in times to come.

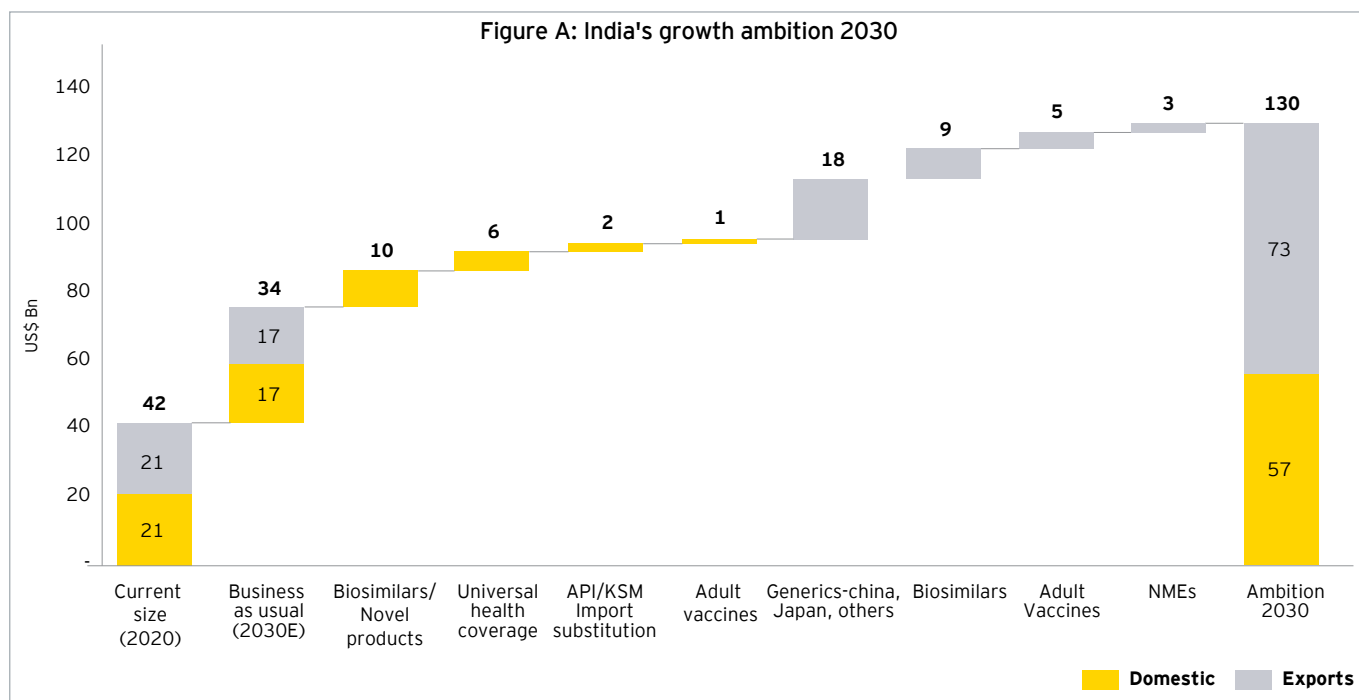
It is imperative that India reevaluates its current role within the global pharmaceutical industry, explore possibilities to consolidate and strengthen its positioning in light of geopolitical and economic shifts, attain self-sufficiency as a globally competitive pharmaceutical industry with innovation as a guiding principle for future growth. This paper addresses the ambition for the current decade in consultation with industry veterans across segments, with inputs from the government, regulators and pertinent industry associations.

From March 2020 onward, the industry has been hit by debilitating restrictions and impediments to reach customers with expectations to operate and supply drugs to those in India and globally. The pharma industry exceeded expectations in responding to this global crisis, supplying drugs to over 150 countries besides meeting all domestic demands. Significant vaccine capacity ramp up has been achieved over the year to augment vaccine administration within India and other countries who are dependent on India for supplies.

The Indian pharma industry has grown at a compounded growth rate of (CAGR) of ~11% in the domestic market and ~16% in exports over the last two decades. While the domestic market has grown at a similar pace to the gross domestic product (GDP), the overall growth has been driven by the industry's leadership in supplying generic formulations to markets across the globe.



Figure A: India's growth ambition 2030



In the 2020-2030 period, we expect Indian pharma industry to grow at a compounded annual growth rate (CAGR) of ~12% to reach at US\$130 bn by 2030 from US\$41.7 bn in 2020. Though the pharmaceutical industry has grown at a CAGR of approx. 13% over the two decades, in the last decade, the CAGR has been ~ 8.5% and it has currently been ~6.2% over the past five years.

In order to attain self-sufficiency and be the real pharmacy of the world, we need to refocus on the next set of avenues to feed the growth engine of this industry, which is of strategic as well as economic significance.

Realizing this ambition will need a concentrated effort from the key stakeholders of the Indian pharmaceutical industry - the payers, providers, policymakers, physicians, pharma industry players, academia as well as a plethora of service providers across the logistics and distribution, IT, capital pools, packaging and other auxiliary industries.

In order to build a holistic consensus, we reached out to industry-wide stakeholders, whose views were sought over countless interactions through a structured questionnaire, coupled with secondary analysis and global primary case studies through EY proprietary research. Future opportunities and the way forward have been duly ratified through industry and stakeholders' roundtables. Key considerations to adopt as

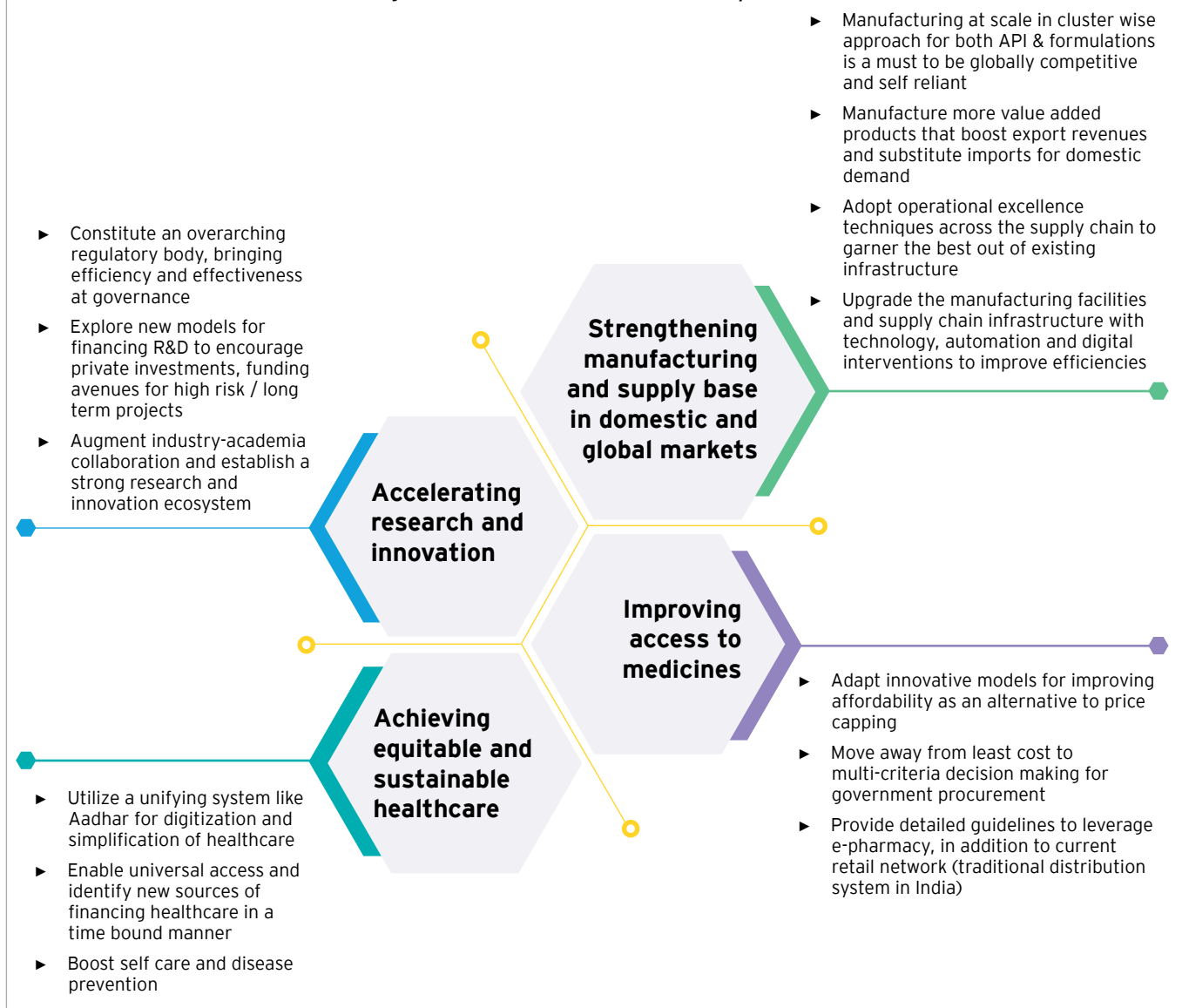
a call to action aimed at industry, academia and government have been outlined for actions going forward.

The opportunities that have emerged have been classified into four sections in this report: Innovation and R&D, Healthcare Delivery, Manufacturing & Supply Chain, and Market Access.

On the domestic front, the ambition translates into a growth rate of 10-11% over the coming decade. Below-average social health indicators and a low proportion of total healthcare spend as a proportion of GDP indicate an opportunity to improve healthcare delivery in the country.

With estimates that the Indian pharma industry supplies over 40% of the generics in the biggest pharma market - the US and about 25% of the prescription drugs in the UK, along with catering to over 60% of the global vaccine demand, India is one of the leading suppliers of pharmaceuticals in the world. While the global formulations trade value is about US\$652 billion (2019), India's share of exports in the global trade was only about 2.5%. With increased pricing pressure on the global generics trade as well as increased competition in India's established export corridors, the current portfolio of products is expected to further extend this divide. The global pharmaceutical trade is expected to reach a size of US\$1-1.3 trillion by 2030, the ambition is to garner a global share of 6-7% by value to attain a size of ~US\$73 billion.

Figure B: Future considerations and way forward





Accelerating research and innovation

- ▶ One of the key action areas that resonated across all interactions was the need to move up the value chain to achieve the ambition and consider way forward to discuss the sets of action needed to be put into place to move up India's share of trade in value.
- ▶ To meet this objective, this section deliberates on set of actions to help the industry move towards this objective including setting up an overarching regulatory body and a Central body to streamline research infrastructure and financing from all government bodies, exploring new models for financing R&D to increase private investments and also make available funds for high risk / long term projects, measures to improve industry-academia collaboration and establish a strong innovation ecosystem, the role of industry to leverage technology for improving productivity and efficiency in research to name a few.



Achieving equitable and sustainable healthcare

- ▶ The increased acceptability of digital technologies has the potential to improve healthcare delivery. This section explores the progress towards achievement of universal healthcare access, establishing efficient processes such as the potential use of Aadhar card to identify as well as simplify the delivery based on healthcare coverage category. The next steps to creating, maintaining and leveraging healthcare data to identify and prioritize focus areas for healthcare have also been discussed in depth.
- ▶ Considerations for enabling teleconsulting, focus on preventive healthcare have also been dealt with, in detail, and the role of the industry, government, healthcare sector and insurers carved out.



Strengthening manufacturing and supply base in domestic and global markets

- ▶ The focus of manufacturing & supply chain initiatives would be to develop capabilities in APIs and enable manufacture of complex generics, bio-similars, gene & cell therapies etc.
- ▶ Ease of doing business is the most important enabler to set up world class manufacturing facilities
- ▶ Attractiveness of manufacturing sector would also need to be enhanced in order to attract the best talent in India and abroad
- ▶ Given the growth ambitions, it is vital to encourage and setup of Pharmaceutical machine manufacturing facilities in India that would result in lower fixed costs, savings in forex and reduction in time to set up additional facilities
- ▶ Strong and all round focus on excellence and compliance is a must to facilitate a "Made in India" phrase that is synonymous with high quality
- ▶ Government would need to bolster the logistics infrastructure for connecting the key pharma hubs in the country in order to facilitate quick and cost efficient movement of goods (including facilities for cold chain)



Improving access to medicines

- ▶ This is the last section that explores the key opportunities that need to be realized in order to improve the market access of the drugs in the country.
- ▶ This section revolves around various global best practices in drug pricing and procurement models, contextualized for developing geographies.
- ▶ Deliberations on digital marketing of pharmaceutical products in India.



Chapter

01

Indian pharma industry:
current scenario and
future potential

Indian pharma industry has grown 10 times in the last two decades driven by its strength in the global generics space.

Growth from **US\$4.2b** in 2000 to **US\$ 41.7b** in 2020¹.

In the last few months, COVID-19 has led to significant geo-economic and geopolitical shifts, with major economies driving self-sufficiency agenda and recalibrating their global business models.

The World Economic Outlook October report projects global growth at nearly **-4.4%** in 2020, which is **~7%** below the forecast in October 2019².

In the light of global changes and keeping India's realities and advantages in mind, this paper aims to revisit Indian pharma's strategy in order to become a preferred global supplier of innovative medicines in the post-pandemic world.

Ambition to achieve **US\$130b** by 2030 at a Compounded Annual Growth Rate (CAGR) of **~12%** from 2020 to 2030¹.

¹ EY analysis

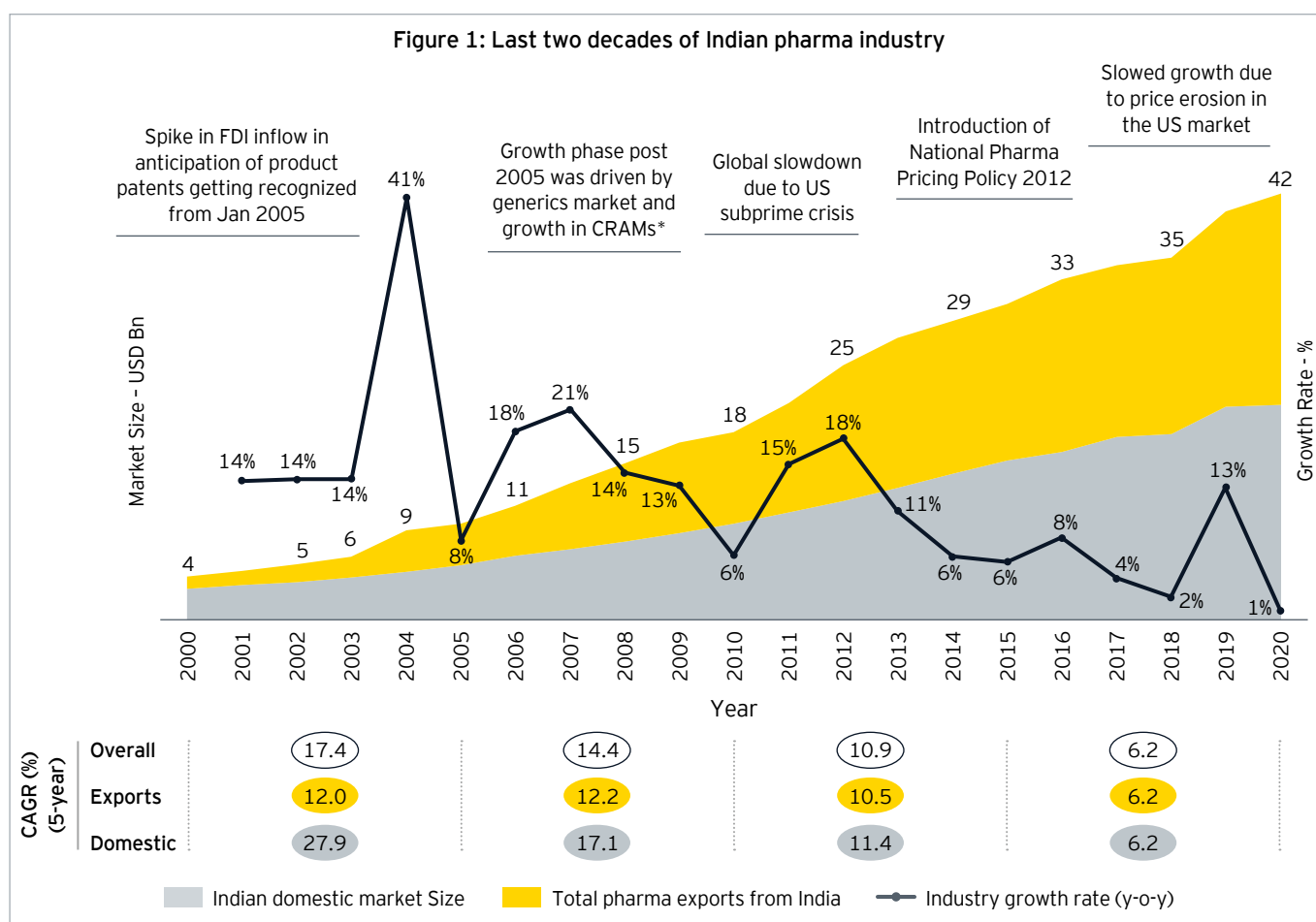
² "World Economic Outlook, October 2020: A Long and Difficult Ascent". Available at: <https://www.imf.org/en/Publications/WEO/Issues/2020/09/30/world-economic-outlook-october-2020>

Indian pharma industry landscape

The Indian pharma industry has achieved significant growth in both domestic and global markets during the past five decades. From contributing just 5% of the medicine consumption in 1969 (95% share with the global pharma), the share of “Made in India” medicines in Indian pharma market is now a robust 80% in 2020¹. More importantly, during the same period, the country has also established leading position in the global

generic pharmaceuticals landscape and is now known as the “Pharmacy of the world”. The pharma industry in India contributes more than 20% by volume of the global generics market and 62% of the global demand for vaccines². Popularly called the “archetype of affordable healthcare,” the industry has significantly contributed towards improving public health outcome, both in India and across the globe.

Figure 1: Last two decades of Indian pharma industry



*CRAM: Contract Research and Manufacturing

Source: EY analysis

The pharma sector has been contributing significantly to India's economic growth as one of the top 10 sectors in reducing trade deficit and attracting the Foreign Direct Investment (FDI). The drugs and pharmaceuticals sector attracted cumulative FDI inflow worth US\$16.54 billion between April 2000 and June 2020³. It is of prime importance also due to the trade surplus it

has been generating with pharmaceuticals exports accounting for US\$20.7 billion and imports at US\$2.31 billion in FY20⁴. The industry employs over 2.7 million people either directly or indirectly⁵, and ranks third in terms of volume and 14th in terms of value globally⁶.

¹ A. Sayay, "India can become the pharmacy of the world", The Hindu BusinessLine, May 2020. Available at: <https://www.thehindubusinessline.com/opinion/india-can-become-the-pharmacy-of-the-world/article31516558.ece>

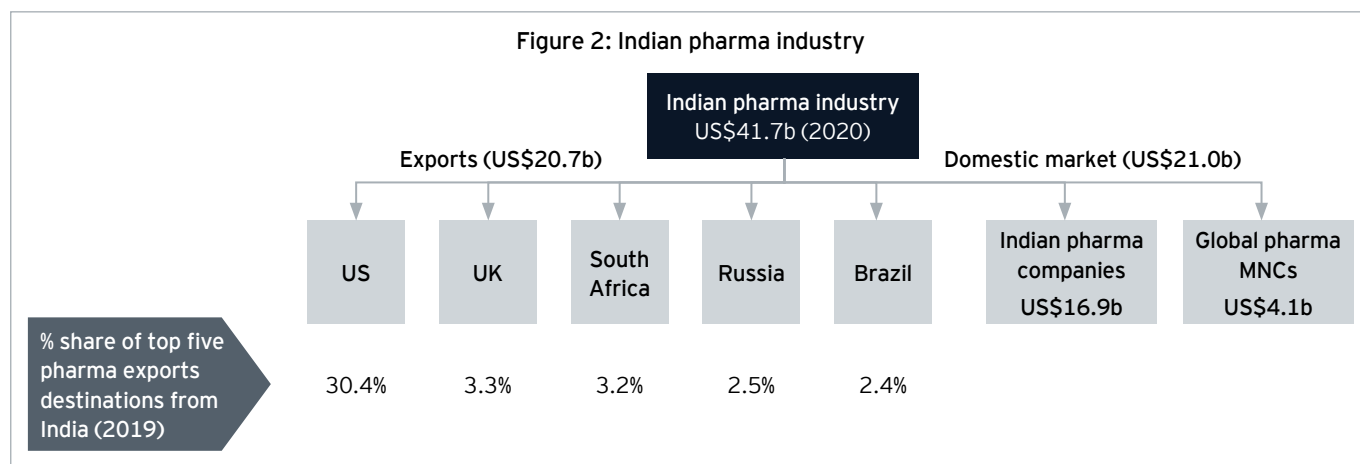
² "Invest India" website. Available at: <https://www.investindia.gov.in/sector/pharmaceuticals>

³ "IBEF" website. Available at: <https://www.ibef.org/industry/pharmaceutical-india.aspx>

⁴ "Trade Map" website. Available from <https://www.trademap.org/>

⁵ "The Indian Pharmaceutical Industry - the way forward" - IPA. Available at: <https://www.ipa-india.org/static-files/pdf/publications/position-papers/2019/ipa-way-forward.pdf>

⁶ "Invest India" website. Available at: <https://www.investindia.gov.in/sector/pharmaceuticals>

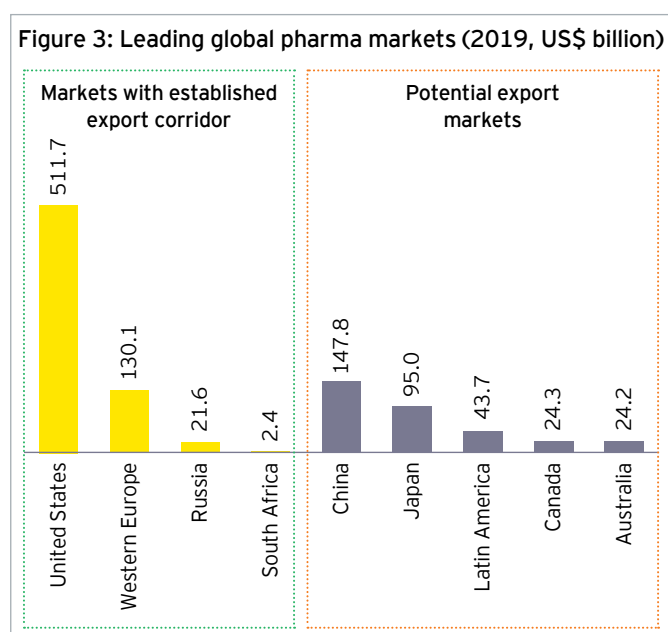


Source: Pharmexcil, available at: <https://pharmexcil.com/uploads/tradestatistics/Countrywiseexports201819.pdf>, EY analysis

Export market

Indian pharma exports reached US\$20.7b in FY20⁷ with year-on-year growth of 8.4% (exports size was US\$19.1b in 2019)⁸. They have grown at a CAGR of 6.2% between 2015 and 2020. This was largely driven by exports of generics drugs to >200 countries (including both developed and developing markets). India is the source of 60,000 generic brands across 60 therapeutic categories². The country accounts for 40% of the generics demand in the US and ~25% of all medicines in the UK³. India also fulfils about 80% of global demand for antiretroviral drugs for Acquired Immune Deficiency Syndrome (AIDS), significantly contributing towards increasing accessibility of AIDS treatments³.

Indian pharma manufacturers export nearly half of the pharma production, both in terms of volume and value, to the US, UK, South Africa, Russia and other countries. However, there remains a significant opportunity, largely untapped across Japan, China, Australia, ASEAN countries, Middle East region, Latin Americas and other African countries. Some of the factors impacting lower penetration of these regions are –relatively slower paced entry strategy, long negotiations cycle, regulations emphasizing on local manufacturing, volatility in the global prices, patent recognitions, disharmony in drug registration process, lack of guidelines on regulation of bio-similars, bio-equivalence studies and delayed market approvals.



Source: EY analysis

In some regions a structured government intervention by way of the existing Free Trade Agreements (FTAs) like the South Asian Free Trade Area (SAFTA), Japan-India Comprehensive Economic Partnership Agreement (CEPA), Association of Southeast Asian Nations (ASEAN) Trade in goods agreement, can benefit Indian pharma companies to leverage such markets with customised therapeutic offerings. Regions working towards reducing the healthcare costs and with the upcoming patent cliff opportunity across formulations both chemical and biologics, could boost growth, create newer export corridors for Indian companies. Collaboration play (likes of GAVI for vaccine) with international regulatory bodies like International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) would also facilitate access to these markets.

Further in the vaccine market, India exports vaccines to >150 countries. It contributes 40%-70% of the World Health Organization's (WHO's) demand for Diphtheria, Pertussis and Tetanus (DPT) and Bacillus Calmette-Guérin (BCG) vaccines, and 90% of the WHO demand for the measles vaccine⁹.

⁷ "IBEF" website. Available at: <https://www.ibef.org/exports/pharmaceutical-exports-from-india.aspx>

⁸ "IBEF" website. Available at: <https://www.ibef.org/industry/pharmaceutical-india.aspx>

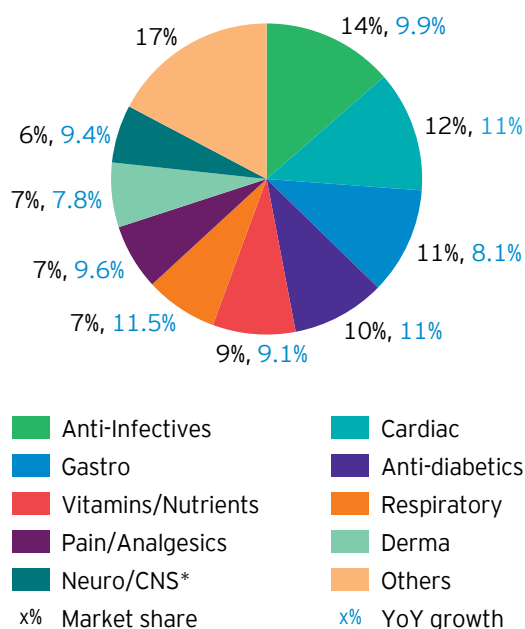
⁹ S. Wasnik, "Why India's booming Pharma companies are finding it tough to get into Argentinean Market", Financial Express, Feb 2019. Available at: <https://www.financialexpress.com/industry/final-frontier-why-indias-booming-pharma-companies-are-finding-it-tough-to-get-into-argentinean-market/1481377/>

In addition, with its strong vaccine manufacturing capability and capacity, India will play a critical role in meeting the demand of COVID-19 vaccines globally. Some of the top global companies have already tied up with Indian companies for manufacturing the vaccines. The world's largest vaccine maker, the Serum Institute of India, has an agreement to manufacture one billion doses of COVID-19 vaccine being developed by AstraZeneca and Oxford. We expect more such collaborations in the near future.

Domestic market

The Indian domestic pharmaceutical market size has reached US\$20.3b in 2019 with y-o-y growth of 9.8% (market size of US\$18.12b in 2018)³. The anti-infective segment is the leading indication with ~14% market share of the total domestic pharma business and continues to witness double digit growth. Other segments that are growing in double digit include diabetes, cardiovascular disease and respiratory. The domestic market has grown at 2.2% during Apr-Sep 2020¹⁰ compared to the same period last year despite a sluggish start to the year due to the pandemic.

Figure 4: Therapy-wise split of the pharma market in India (by value) (MAT* Feb 2020)

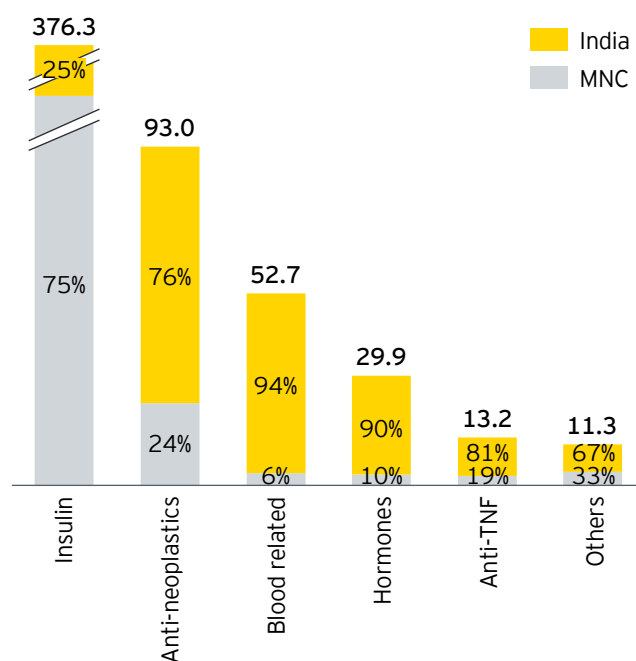


*MAT: Moving annual total; CNS: Central Nervous System

Source: EY analysis

Biosimilars and insulin together constitute less than 5%¹¹ of the total Indian domestic pharmaceutical market. Insulin constitute 65% share due to India's large diabetic population and biosimilars contribute the remaining 35% spread across several therapy areas. Forty five domestic companies account for 45% of biosimilar and insulin sales in India. Apart from insulin, where 75% of the market share is with multi-national companies (MNCs), domestic companies dominate the biosimilars market.

Figure 5: Insulin and biosimilars market in India: split between Indian companies and MNCs (US\$m)

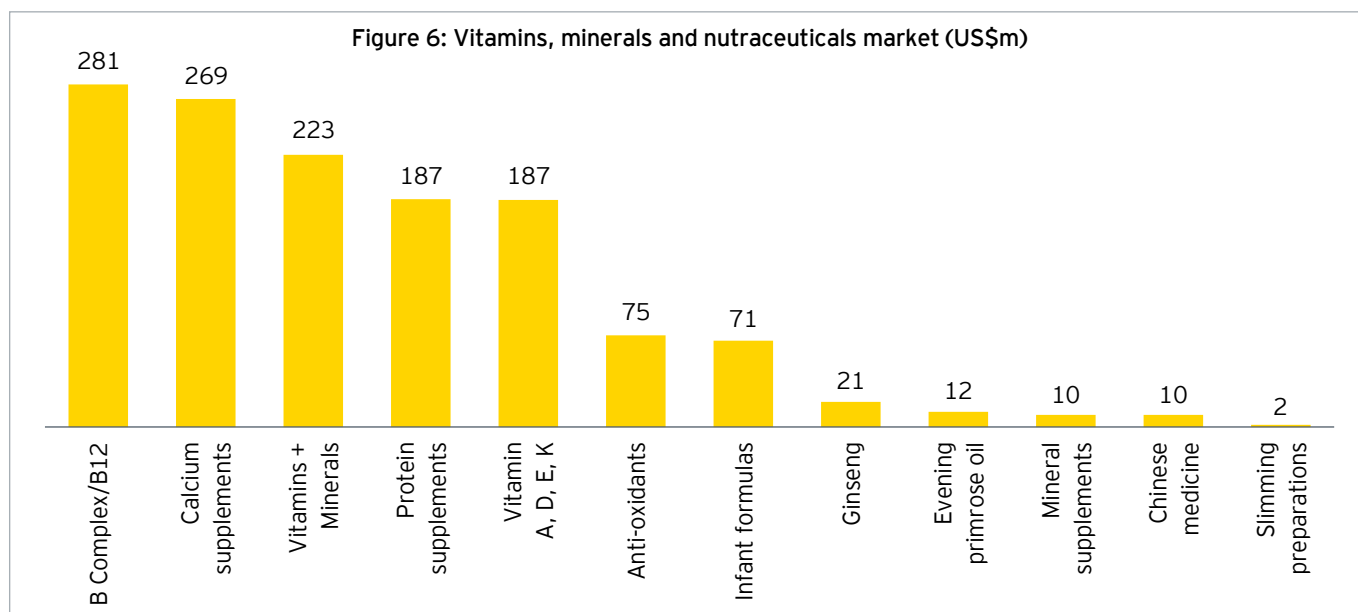


Source: EY analysis

In the vitamins and nutrients market, top five categories constitute ~85% share. Increasing focus on prevention, self care, health and wellness, and awareness about the importance of high immunity is leading to increased consumption of vitamin and mineral supplements and other nutraceutical products.

¹⁰ EY analysis

¹¹ EY analysis



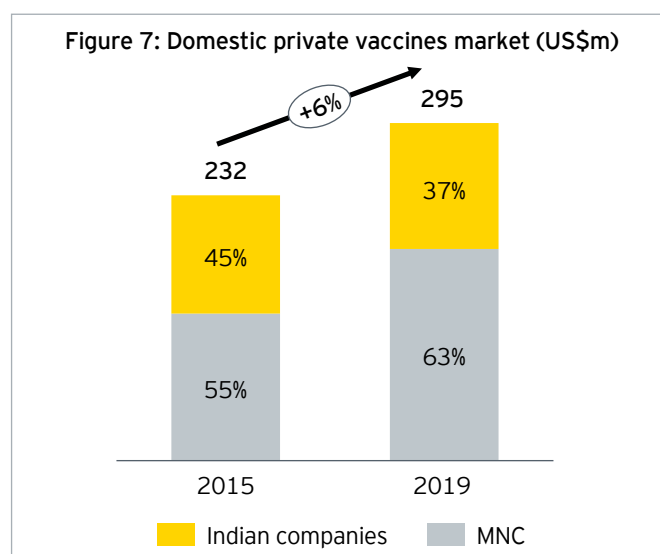
Source: EY analysis

Vaccines constitute ~2%¹² of the domestic pharma market – this includes the consumption under 'Universal Immunisation Program (UIP)' and 'private retail market'. Indian companies supply the bulk of the UIP demand. MNCs dominate the private market in terms of value with 63% share driven by higher priced human papillomavirus, pneumococcal, influenza and meningococcal vaccines.

As discussed in the exports section above, India's strength in vaccine manufacturing is likely to give it an early access to the COVID-19 vaccine. In the Phase I of the vaccination plan, the Indian government will provide vaccines to about 300 million people in the first few months of 2021. This includes nearly 30 million health workers, from both government and private sector, and frontline workers. In the second stage, those above 50 years of age, and those below 50 years of age with comorbidities or with high risk of infection, will be vaccinated¹³.

Several vaccines are already under clinical trials in India. Moderna's vaccine is expected to be priced between INR1,855 (US\$25) to INR2,755 (US\$37) per dose¹⁴. Russia's Sputnik V is expected to cost much less at about INR740 (US\$10) per dose in the international market¹⁵. The Serum Institute of India has

priced the Oxford vaccine the least so far at INR250 (US\$3.42) per dose for the government and INR1,000 in the private market¹⁶.



Source: EY analysis

¹² EY analysis

¹³ "Explained: Who gets Covid-19 vaccine jabs in first two phases, what's the price", Hindustan Times, January 2021. Available at: <https://www.hindustantimes.com/india-news/explained-who-gets-covid-19-vaccine-jabs-in-first-two-phases-what-s-the-price-101610461674570.html>

¹⁴ "Moderna to charge Rs 1855-Rs 2755 per dose for COVID-19 vaccine, says CEO", DNA, Nov 2020. Available at: <https://www.dnaindia.com/world/report-moderna-to-charge-rs-1855-rs-2755-per-dose-for-covid-19-vaccine-says-ceo-2857843>

¹⁵ Russia's Sputnik V COVID-19 vaccine to cost less than Rs 740 per dose in global markets", DNA, Nov 2020. Available at: <https://www.dnaindia.com/world/report-russia-s-sputnik-v-covid-19-vaccine-to-cost-less-than-rs-740-per-dose-in-global-markets-2858235>

¹⁶ "Coronavirus vaccine price: SII CEO reveals how much it will cost", DNA India, January 2021. Available at: <https://www.dnaindia.com/india/report-coronavirus-vaccine-price-sii-ceo-adar-poonawala-reveals-how-much-it-will-cost-oxford-astrazeneca-covid-19-2865835>

COVID 19 impact: geo-economic shift and evolving healthcare and life sciences trends

As per the trends so far, the COVID-19 pandemic is expected to have far-reaching effects globally. While it is difficult to predict with certainty the scale and spread of the Coronavirus disease, let alone its impact on international economics, politics and society, it is possible to systematically identify areas of potential vulnerability.

Policy makers are facing unprecedented challenges in financing health especially in low- and middle-income settings. Many health systems are already stretched and underfunded. They have been further constrained by the increasing number of COVID-19 patients demanding care as a result of the pandemic.

It is difficult to predict how international economies will be affected over the coming months, when a so-called saw-toothed recovery is in play. Many geographies are already experiencing the second or third wave of the virus, resulting in new lockdowns and restrictions. Different industries have been differently affected by the virus. Consumer-focused industries like hospitality and travel sectors have been deeply impacted as leisure time is spent at home or closer to home. Technology companies have seen a resurgence given the role 4G and 5G networks, and devices play in connecting individuals when physical distance is a key requirement. Health and life sciences companies, meanwhile, remained relatively less affected by the virus. However, there are now growing signs of sales slowing

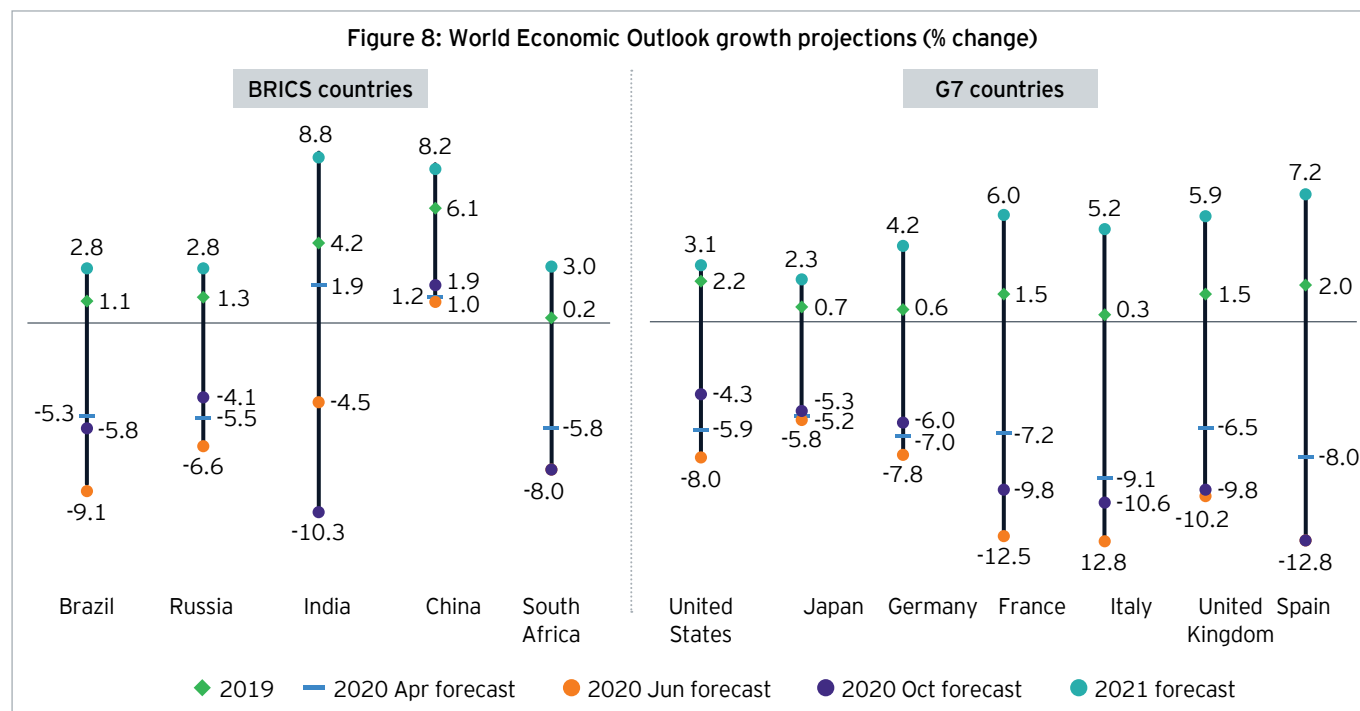
down and impact of currency exchange. Additionally, certain parts of the value chain, namely research and development (R&D) and the supply chain have been heavily affected.

Macroeconomic and geo-political shifts due to the pandemic

The COVID-19 pandemic is affecting economies across the world. Global GDP is constantly shrinking. The World Economic Outlook update in October projected global growth at nearly -4.4% in 2020, which is 0.6% above its forecast in June 2020 and 1.3% below its forecast in April 2020¹⁷. The increase in growth is because of better-than-anticipated second quarter GDP outturns, mostly in advanced economies where activity began to improve sooner than expected after lockdowns were scaled back in May and June and led to a strong recovery in the third quarter.

China is the only country with a comparatively positive outlook in 2020 as it started reopening in April 2020. It also continued the pace of recovery in the third quarter. Exports recovered in China supported by an early restart of activities and a strong pickup in external demand for medical equipment and remote working tools.

Figure 8: World Economic Outlook growth projections (% change)



¹⁷ "World Economic Outlook, October 2020: A Long and Difficult Ascent". Available at: <https://www.imf.org/en/Publications/WEO/Issues/2020/09/30/world-economic-outlook-october-2020>

The April 2020 forecast for India was higher than June forecast. However, our GDP contracted much more severely than expected. As a result, the October report projects contraction by 10.3% in 2020, before rebounding by 8.8% in 2021.

A sluggish turnaround is expected to take place in 2020. Global growth is projected at 5.2% in 2021, a little lower than in the June 2020 WEO update.

In addition to health challenges and economic consequences, geopolitical issues may also have a far-reaching impact on the post-COVID-19 world. The US and China bilateral dynamics has continued for more than two years and has only intensified since COVID-19 started. Many other countries such as India, Vietnam, Malaysia, Indonesia and Japan have experienced conflict with China due to respective legacy pending disputes.

The way the pandemic has been handled has become another reason for geopolitical conflicts to rise. While China is still being questioned for its initial opacity about the outbreak, the WHO and several other countries have drawn criticism for gaps in their coronavirus response. The handling of the COVID-19 outbreak on a cruise liner led to transmission of the virus in Japan. In Iran, a lax response in the beginning led the country to become a COVID-19 hotspot, fueling its spread to the rest of the Middle East. In the UK, the government took time to move from the "herd immunity" stance to roll out a national lockdown strategy. The US has also been criticized for their complacency.

All these macroeconomic and geopolitical shifts indicate that the post-COVID world may be very different. For India, there is an opportunity now to develop a strategy that demonstrates how it can work as a trustworthy partner with other countries to provide safe, effective and affordable medicines.

Focus on equitable and sustainable healthcare

COVID-19 was declared a pandemic on 11 March 2020, six weeks after it was first reported from China as a new respiratory virus. By then 118,000 cases had already been identified in 114 countries, and 4,291 people had died. Within seven weeks, 3,467,321 cases of COVID-19, including 246,979 deaths, were reported in 187 countries¹⁸.

The rapid spread of the virus challenged healthcare systems globally. From the US, that spends the world's largest share on its healthcare system, to the world's most sophisticated European healthcare systems, every country is struggling to manage and contain its spread.

Several measures have been taken in this regard. Some of these include border controls, restrictions on national and

international travel, lockdowns, quarantining contacts of affected patients, diagnostic testing, health screening, contact tracing and use of surveillance apps. Despite these tactics, the massive influx of COVID-19 patients has outgrown the healthcare infrastructure and resources in many countries and the disease is causing extensive loss of life and extreme human suffering. Even the developed countries are relying on makeshift arrangements. For example, use of conference centers as temporary hospitals in the UK and field hospitals in Central Park in New York City. Several approaches are also being used to expand the healthcare workforce. Retired doctors have been asked to return to work and medical students are being recruited in hospitals.

In addition to the insufficient healthcare infrastructure and resources, there have been substantial shortages of essential equipment (e.g., ICU beds and ventilators), diagnostic tests, medical supplies (masks, sanitizers, including personal protective equipment, etc.), and even medicines. The shortage was driven by pace of production not matching the ever-increasing demand, and global supply chain disruption and export bans due to the pandemic affecting different parts of the world over time.

The pandemic also brought to light inequalities in accessing healthcare globally. Poor, minorities and a broad range of vulnerable population (e.g., migrants, people with chronic diseases) have been disproportionately affected by COVID-19. This does demonstrate the importance of innovative vital and working health care systems around the world more than ever.

The COVID-19 pandemic has brought sharp focus on the need for health care reforms to promote universal access to affordable care and bridge geographic, economic and social divisions.

Global disruption in the supply chain

There have been concerns around overdependence on China for active pharmaceutical ingredients (APIs) for quite some time now in India as well in the US and Europe. Last year a representative of the US Defence Health Agency reiterated the national security risks due to increased Chinese dominance of the global API market.

During the last few months, most countries have experienced disruption in pharma supply chain because of their dependency on China for APIs and excipients. While this does not indicate an end to the global supply chain, countries and companies do have supply chain resilience as one of the near-term priorities. COVID-19 has accentuated issues like re-shoring, near-shoring and shortening supply chains.

¹⁸ D. Singer, "Health policy and technology challenges in responding to the COVID-19 pandemic", Health Policy Technol, June 2020. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7191286/>

We already see attempts to re-shore and diversify the pharmaceutical value chain. For example, the US passed the bill 'Securing America's Medicine Cabinet Act (SAM-C)' in 2020, which expands the United States Food and Drug Administration's (USFDA) Emerging Technology Program and authorizes US\$100 million to build Centers of Excellence for

advanced pharmaceutical manufacturing to help therapeutic development and manufacturing in the US¹⁹. Sanofi announced its plans to create a major leading European company, Euroapi, dedicated to production and marketing of APIs to third parties²⁰.

India: preparing to lead in the post-pandemic world

COVID-19 has clearly highlighted the importance of a strong health care system, the lack of which can put an entire nation's economy and society at risk. As India continues to fight COVID-19 and stabilize its economic growth trajectory, it is the right time for the country to apply learnings from the challenges and best practices that emerged during the pandemic. There is a need to swiftly develop the required healthcare infrastructure and make it available to the entire population.

The Indian pharma industry has been a key contributor in improving the country's healthcare and economic outcomes. The pandemic has accelerated several opportunities and challenges for the industry. While the growing trust deficit with China presents an opportunity for India, there is increasing competition from other countries, such as Vietnam and Malaysia. India is also dependent on China for ~two third of its imports of bulk drugs or drug intermediaries.

To emerge as a winner in the post-pandemic world, the industry needs to continue building on its strength and at the same time make a giant leap towards innovation. New capabilities need to be introduced across the business functions to bring efficiencies and to help industry move up the value chain. Government also needs to provide the right enablers and business environment conducive for growth.

The remaining chapters of the report discuss the opportunities, challenges and the way forward for the country to achieve the ambition of equitable and sustainable access to healthcare. It also provides an insight for the industry to achieve the ambition of becoming the preferred global supplier of innovative medicines.

This is an opportunity for the Indian pharma industry to consolidate on its advantages and undertake fundamental reforms to reignite innovation-led industrial growth to meet the target of US\$130b by 2030.

¹⁹ "Menendez, Blackburn Introduce Bipartisan Bill to Increase US Prescription Drug Manufacturing", March 2020. Available at: <https://www.menendez.senate.gov/newsroom/press/menendez-blackburn-introduce-bipartisan-bill-to-increase-us-prescription-drug-manufacturing>

²⁰ "Sanofi to create new industry leading European company to provide active pharmaceutical ingredients (API*)", company press release, February 2020. Available at: <https://www.sanofi.com/en/media-room/press-releases/2020/2020-02-24-16-03-59>




A photograph of two scientists in white lab coats working in a laboratory. The scientist on the left is using a pipette to transfer liquid into a beaker. The scientist on the right is wearing gloves and holding a beaker containing a green liquid. The background is slightly blurred, showing other laboratory equipment and a clean, professional environment.

Chapter

02

**Accelerating research
and innovation**



In order to sustain and build on the good work India has done in the past, the Indian pharmaceutical industry needs to focus on emerging growth areas to move up the value chain.

India is the third-largest global manufacturer of drugs, but it ranks 14th in terms of value¹.

To move up the value chain, India has opportunities in complex generics, speciality pharma, biosimilars and novel biological drugs, vaccines and preventives, and other areas of unmet needs. There is also huge potential to establish the country as the global innovation hub of the future.

Some of the top Indian pharma companies are making significant efforts in all these opportunity areas, but a lot more needs to be done.

To achieve future potential, India needs to establish an entire ecosystem of innovation that brings together the academia/ research institutions, big pharma companies and start-ups/entrepreneurs, medical institutions/hospitals.

The ecosystem should be supported by required enablers in infrastructure, financing, supporting government policies and regulations.

¹ The Department of Pharmaceuticals' website. Available at: <https://pharmaceuticals.gov.in/pharma-industry-promotion>

India has attained leadership in the generic market globally. With increasing cost pressures and competitive environment, the Indian industry now needs to consolidate its position as well as continue to focus on future growth by transitioning towards value chain augmentation. The Indian pharma industry ranks third by volume and 14th by value. All stakeholders, by

way of this study, agreed and aligned on the need to reverse this ranking to become a formidable player in the global pharma market. This ambition can only be achieved if the pharmaceutical sector moves forward with India led innovation around new chemical entities (NCEs) and new biological entities (NBEs)

Opportunities for the Indian pharma industry to move up the value chain

1. Expansion beyond generics: exploring opportunities in biosimilars and NCEs

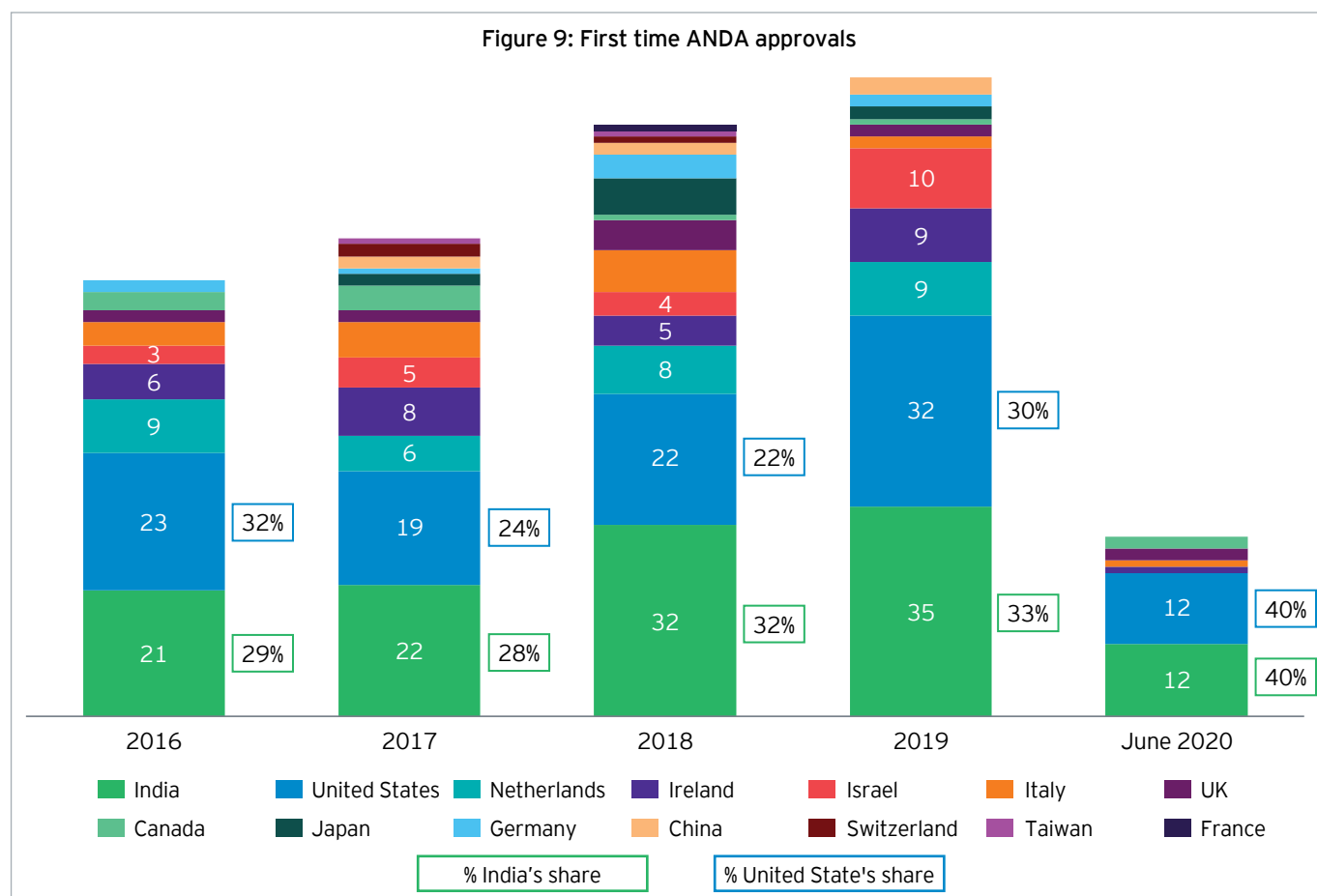
Indian companies are involved in the following R&D models and have developed globally competitive expertise in some areas.

Generics

R&D in generics has been a traditional focus area for most India-based pharma companies.

India's dominant share in the overall ANDA approvals and first-time ANDA approvals by the USFDA is a good reflection of the country's strength in the global generics market. Indian companies received over 35% of total ANDA approvals between 2010 to 2019 (2,046 of the total 5,768 ANDA approvals)², with their share of annual ANDA approvals increasing from 34% in 2010 to over 40% in 2019. Similarly, in the last few years, Indian companies have overtaken US generics firms, receiving the largest number of first-time ANDA approvals. India's share in the first-time ANDA approvals increased from 29% in 2016 to 33% in 2019³.

Figure 9: First time ANDA approvals



Source: USFDA website, EY analysis

² "Indian pharma companies secure 336 ANDA approvals from US FDA during 2019", Pharmabiz, April 2020. Available at: <http://www.pharmabiz.com/NewsDetails.aspx?aid=122237&sid=1#:~:text=In%20the%20year%202019%2C%20Indian,813%20in%20the%20previous%20year>

³ USFDA website, EY analysis

The generics market remains lucrative globally. It is driven by increased push in the US to prescribe generics to contain healthcare costs. The share of generic drugs in the US's total prescription volume has increased from 72% in 2008 to 90% in 2017, driven by loss of exclusivity of patented products in the past decade. Further looming patent expiries will provide a continuing driver for market growth. Drugs worth US\$83b have lost patent protection between 2013 to 2017, and another US\$72b worth of small molecule drugs will go off-patent from 2018 to 2022⁴. The growing volume of the generics market

has attracted several new entrants from India and from other geographies. The rise in competition and consolidation among distributors in the US over the last few years have resulted in price erosion for generic drugs. While Indian companies should continue to maintain their strong position in the global generics market, they can't rely on basic generics exclusively to ensure future growth.



⁴ "US generics market - evolution of Indian players", IQVIA, February 2019. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/india/us-generics-market-evolution-of-indian-players.pdf?_id=1611209375085

Complex generics, biosimilars, vaccines

Focusing on more complex products represents an emerging model for Indian pharma companies, with the potential to bring sustained long-term growth for the sector.

Complex generics

Complex generics hold great potential to drive future market growth. They involve more difficult production processes and therefore face less competition, compared to simple generics. Simple generics constitute only ~20% of the total US generics market by value. Complex generics approvals constituted 12% of total USFDA⁵ generics in 2018, and 11% of approvals in 2019. The USFDA has started new initiatives to further facilitate availability of complex generic drug products and to assist the generic pharmaceutical industry in identifying the most appropriate methodology for developing complex drugs⁶.

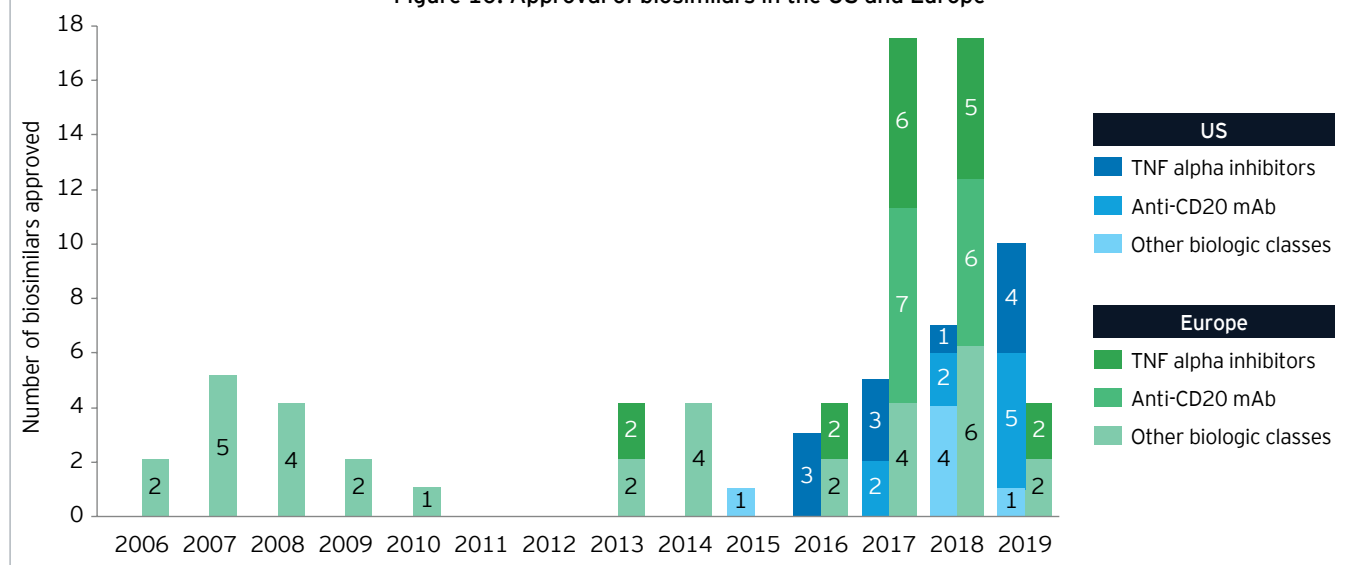
As complex generics are difficult to develop, there is limited competition in this space and hence, they offer higher margins. Seeing the big opportunity, some of the top Indian companies

such as Dr. Reddy's, Zydus, Glenmark, Aurobindo, Torrent, Strides, Lupin, Cipla, Sun, etc. have already started building their pipelines^{7,8}.

Biosimilars

The global biosimilars market size was reported to be US\$11.8 billion in 2020 and is estimated to reach US\$35.7 billion by 2025 growing at a CAGR of 24.7%⁹. The industry has come a long way since the first approval of a biosimilar in Europe in 2006 (Omnitrope from Sandoz/Novartis - a biosimilar version of the human growth hormone somatropin) and in the US in 2015 (Zarxio from Sandoz/Novartis - a biosimilar version of the granulocyte colony-stimulating factor filgrastim)¹⁰. While the initial uptake was slow in both the geographies, increase in the number of approvals in the last five years indicates a positive trend towards the acceptance of biosimilars. Indeed, about 65% of all biosimilars approved in the US gained their approval between 2018 to 2019, while 58% of biosimilars in Europe were approved between 2017 to 2019¹¹.

Figure 10: Approval of biosimilars in the US and Europe



*mAb: monoclonal antibody, TNF: tumor necrosis factor

Source: GaBI reports, EY analysis

⁵ USFDA website, EY analysis

⁶ "2019 Office of Generic Drugs Annual Report", US FDA website, February 2020. Available at: <https://www.fda.gov/drugs/generic-drugs/2019-office-generic-drugs-annual-report>

⁷ "Complex Generic Guidance by US FDA to benefit Indian Pharma Formulators: Ind-Ra", Express Pharma, June 2019. Available at: <https://www.expresspharma.in/latest-updates/complex-generic-guidance-by-us-fda-to-benefit-indian-pharma-formulators-ind-ra/>

⁸ "Desi companies see big business in competitive generics", The Times of India, March 2019. Available at: <https://timesofindia.indiatimes.com/business/india-business/desi-cos-see-big-biz-in-competitive-generics/articleshow/68383208.cms>

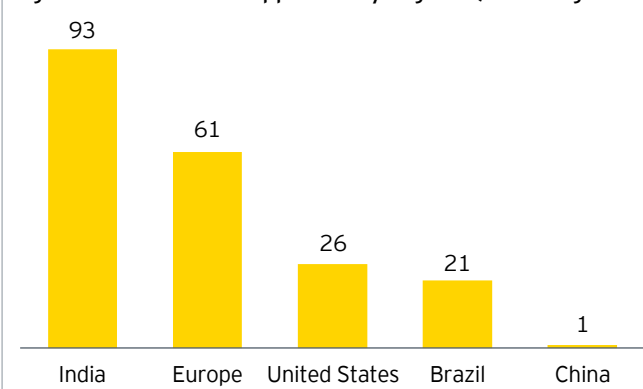
⁹ "Biosimilars Market by Product, Manufacturing & Indication, Region - Global Forecast to 2025", ReportLinker, March 2020. Available at: https://www.reportlinker.com/p04604343/Biosimilars-Market-by-Product-Manufacturing-Application-Global-Forecast-to.html?utm_source=GNW

¹⁰ B. Meher et al., "Biosimilars in India: Current Status and Future Perspectives", J Pharm Bioallied Sci., 2019. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6394151/>

¹¹ EY analysis

The Indian domestic biosimilars market was reported to have generated US\$576 million in 2019, achieving a growth of ~11% over 2018 revenue (US\$520 million)¹². Biosimilars can play an important role in expanding the global market share of the Indian pharma sector in terms of value. India has been leading globally in terms of launching biosimilars in the domestic market. The first biosimilar in India got an approval in early 2000s for Hepatitis B, although no specific guideline was available at that time in the country for the development and marketing of biosimilars¹³. Since then India has made significant advances, and several biosimilars have been developed and marketed in India. According to a WHO survey, India had already approved 93 biosimilars (with at least 50 on the market) by August 2019 compared to 26 in the US and 61 in the European Union¹⁴.

Figure 11: Biosimilars approved by regions (as of Aug 2019)



Source: WHO survey

Biocon, in 2019-20, generated a revenue of INR1,951 crores from biosimilars, which is approximately 30% of its overall revenue. This revenue stream recorded ~30% year-over-year (yoy) growth. The company aims to generate US\$1b (about INR7,460 crore) from the biosimilars segment alone by FY22¹⁵. Biocon has entered the US market (in collaboration with Mylan) with the first biosimilars for Herceptin (Ogivri, biosimilar trastuzumab) and Neulasta (Fulphila, biosimilar pegfilgrastim). It has also established its presence in Europe and Japan.

According to a recent report from Biotechnology Industry Research Assistance Council (BIRAC), more than 52 Indian companies collectively now have over 200 biosimilars in pipeline¹⁶. Despite the largest number of approved biosimilars in India, very few Indian companies have been able to penetrate the US and European markets, which is partially because India's regulatory guidelines are not sufficiently aligned with the guidelines in these markets. India released its first biosimilar guidelines in 2012, and the revised version was released in 2016¹⁷. The new guidelines have been widely appreciated in the global biopharma community, placing Indian companies in a better position. However, more can be done in terms of improving animal testing, raising the number of patients in clinical trials, and tightening biosimilar testing requirements. In addition, India will also need to invest in R&D, manufacturing competency and related technical expertise.

COVID-19 has further increased the demand for monoclonal antibodies (mAbs, biologics) such as tocilizumab, sarilumab and itolizumab for testing on COVID-19 patients. These mAbs are believed to prohibit cytokine storm complications. On similar lines, Zydus Cadila has been exploring the use of long-acting interferon alpha-2b (a biosimilar version is already being commercially manufactured by Zydus Cadila for treating Hepatitis B and C) for treating COVID-19*.

*Company update, available at: <https://zyduscadila.com/public/pdf/pressrelease/Zydus-announces-treatment-with-Interferon-alpha%20.pdf>

Vaccines

As with the generics market, India has established a strong presence in the global vaccines market. The country is now the biggest volume supplier to public market of vaccines, fulfilling over 60% of global vaccine requirements¹⁸.

This has been possible because of an ongoing strategic focus on R&D and mass manufacturing capabilities. In addition to investing in manufacturing capabilities to develop low-cost affordable vaccines, companies have also invested in

¹² EY analysis

¹³ B. Meher *et al.*, "Biosimilars in India; Current Status and Future Perspectives", J Pharm Bioallied Sci., 2019. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6394151/>

¹⁴ H. Kang *et al.*, "The regulatory landscape of biosimilars: WHO efforts and progress made from 2009 to 2019", Biologicals Volume 65, May 2020. Available at: <https://www.sciencedirect.com/science/article/pii/S1045105620300269?via%3Dihub>

¹⁵ "Biocon planning to list biosimilar arm over the next 2-3 years", Mint, July 2020. Available at: <https://www.livemint.com/companies/news/biocon-planning-to-list-biosimilar-arm-over-the-next-2-3-years-11593931649448.html>

¹⁶ "India: The emerging hub for biologics and biosimilars", report by BIRAC, November 2019. Available at: https://birac.nic.in/webcontent/Knowledge_Paper_Clarivate_ABLE_BIO_2019.pdf

¹⁷ B. Meher *et al.*, "Biosimilars in India; Current Status and Future Perspectives", J Pharm Bioallied Sci., 2019. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6394151/>

¹⁸ "View: Is India ready for Covid vaccine? Here's what the country should do", The Economic Times, November 2020. Available at: <https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/view-is-india-ready-for-covid-vaccine-heres-what-the-country-should-do/article-show/79434162.cms?from=mdr>

incremental innovation in vaccines for some common diseases. These innovations include introducing an oral equivalent for an injectable vaccine to improve compliance, adjusting their formulation to improve stability, and other tweaks that improve existing products. Examples of the process of incremental improvement include Bharat Biotech's typhoid conjugate vaccine¹⁹ and "eco-friendly" recombinant Hepatitis-B vaccine (free of cesium chloride and thiomersal)²⁰ and Serum Institute's liquid rotavirus vaccine²¹.

Government funding and investment in R&D via agencies such as the Department of Biotechnology (DBT), the Indian Council of Medical Research (ICMR), and the Ministry of Health and Family Welfare (MoHFW) have also played a critical role in boosting India's strength in the vaccines market. The ICMR signed a Memorandum of Understanding (MoU) with the International Vaccine Institute (IVI) to collaborate regarding vaccine R&D²².

The next frontier for India is to focus on R&D in new and complex vaccines, and this imperative has become more urgent due to COVID-19. Companies such as Zydus Cadila and Bharat Biotech (in collaboration with the Indian Council of Medical Research and the National Institute of Virology) have already embarked on this journey, including a novel vaccine for COVID-19 prophylaxis²³.

New chemical entities (NCEs) and new biological entities (NBEs)

These products are the major focus for leading multinational pharma companies. Indian companies are beginning to improve their in-house novel drug development with the aim of launching new blockbusters. Developing NCEs and NBEs put Indian companies in direct competition with global innovators. Some of the large Indian pharma companies, such as Zydus, Glenmark, and Sun, as well as clinical research organizations (CROs) and contract development and manufacturing organizations (CDMOs) are already engaged in researching new drugs.

In 2013, Zydus became the first Indian company to launch an indigenously developed NCE, Lipaglyn (saroglitazar), world's first glitazar treatment for diabetic dyslipidemia or hypertriglyceridemia in Type II diabetes, not controlled by statins alone²⁴. The drug was recently approved as the first drug for the treatment of Non-Cirrhotic and Non-Alcoholic Steatohepatitis (NASH) in India (March 2020). Lipaglyn is in second phase of development in the US and is expected to get an approval in 2027²⁵.

Biocon was the first company to launch indigenously developed novel biologics in India. The company launched BIOMab EGFR for head and neck cancer treatment in 2006, and Alizumab (itolizumab) for psoriasis treatment in 2013. Both these novel monoclonal antibodies have been launched in several countries in collaboration with global companies²⁶.

Novel drug development promises high returns, but it also requires high investment of time and resources. While Indian companies have started the journey, there is a need to build a strategic approach in order to move from incremental innovation to becoming a global player in innovative drugs.

¹⁹ Company press release. Available at: <https://www.bharatbiotech.com/typbartcv.html>

²⁰ Company press release. Available at: <https://www.bharatbiotech.com/overview.html>

²¹ "Serum Institute launches new rotavirus vaccine, Rotasiil-Liquid to prevent diarrhoea", Pharmabiz, January 2020. Available at: <http://www.pharmabiz.com/NewsDetails.aspx?aid=120411&sid=2>

²² "ICMR inks deal to promote vaccine development", The Hindu, August 2017. Available at: <https://www.thehindu.com/news/cities/Delhi/icmr-inks-deal-to-promote-vaccine-development/article19536648.ece>

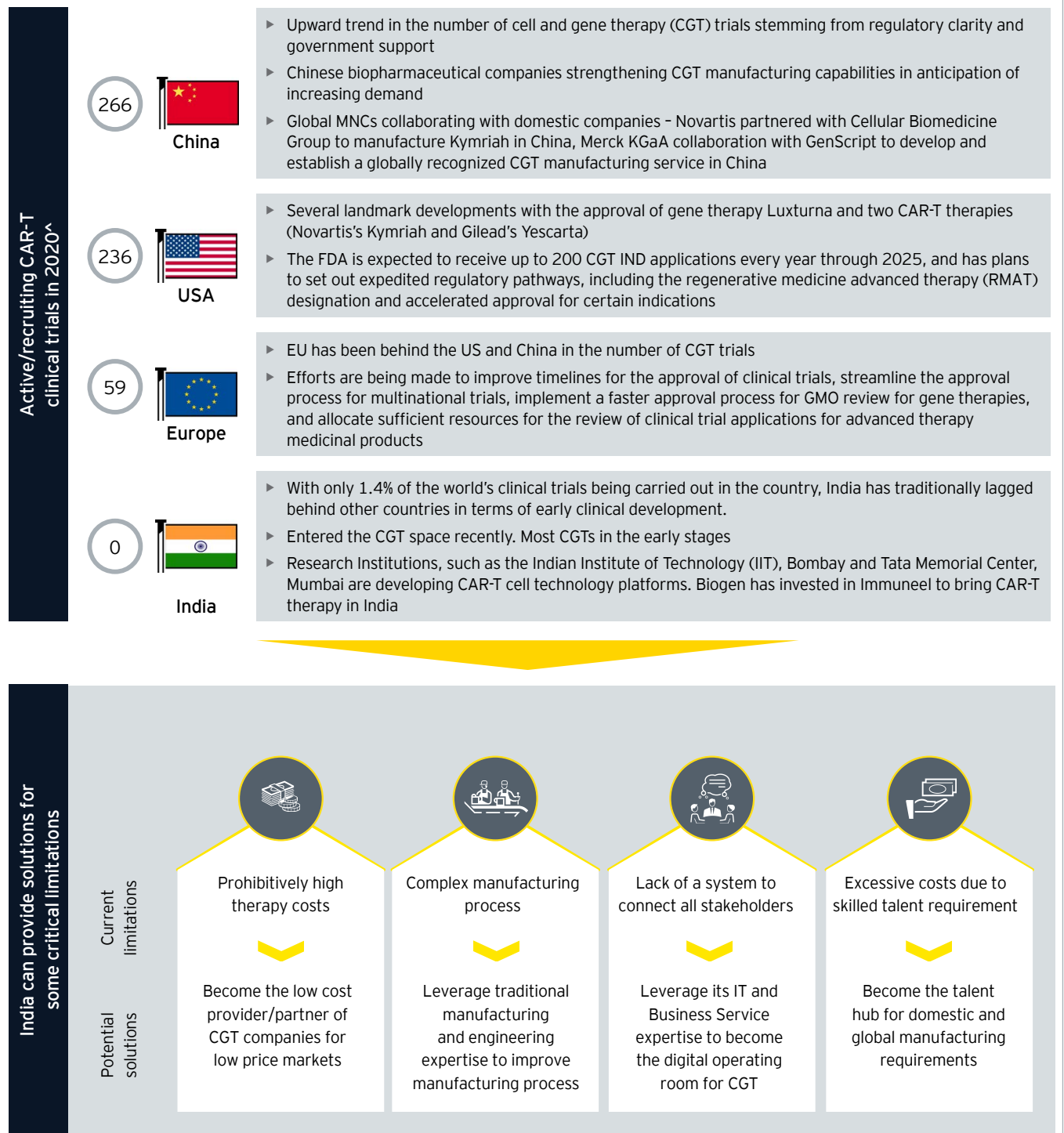
²³ ICMR website. Available at: <https://vaccine.icmr.org.in/covid-19-vaccine>

²⁴ "Zydus Pioneers a Breakthrough With LIPAGLYN, India's First NCE to Reach the Market", PR Newswire, June 2013. Available at: <https://www.prnewswire.com/news-releases/zydus-pioneers-a-breakthrough-with-lipaglyn-indias-first-nce-to-reach-the-market-210205251.html>

²⁵ "Lipaglyn gives Zydus Cadila first mover advantage in lucrative NASH market, says GlobalData", GlobalData, March 2020. Available at: <https://www.globaldata.com/lipaglyn-gives-zydus-cadila-first-mover-advantage-in-lucrative-nash-market-says-globaldata/>

²⁶ "India: The emerging hub for biologics and biosimilars", report by BIRAC, November 2019. Available at: https://birac.nic.in/webcontent/Knowledge_Paper_Clarivate_ABLE_BIO_2019.pdf

Figure 12: Cell and gene therapy: assessing current landscape and exploring future potential



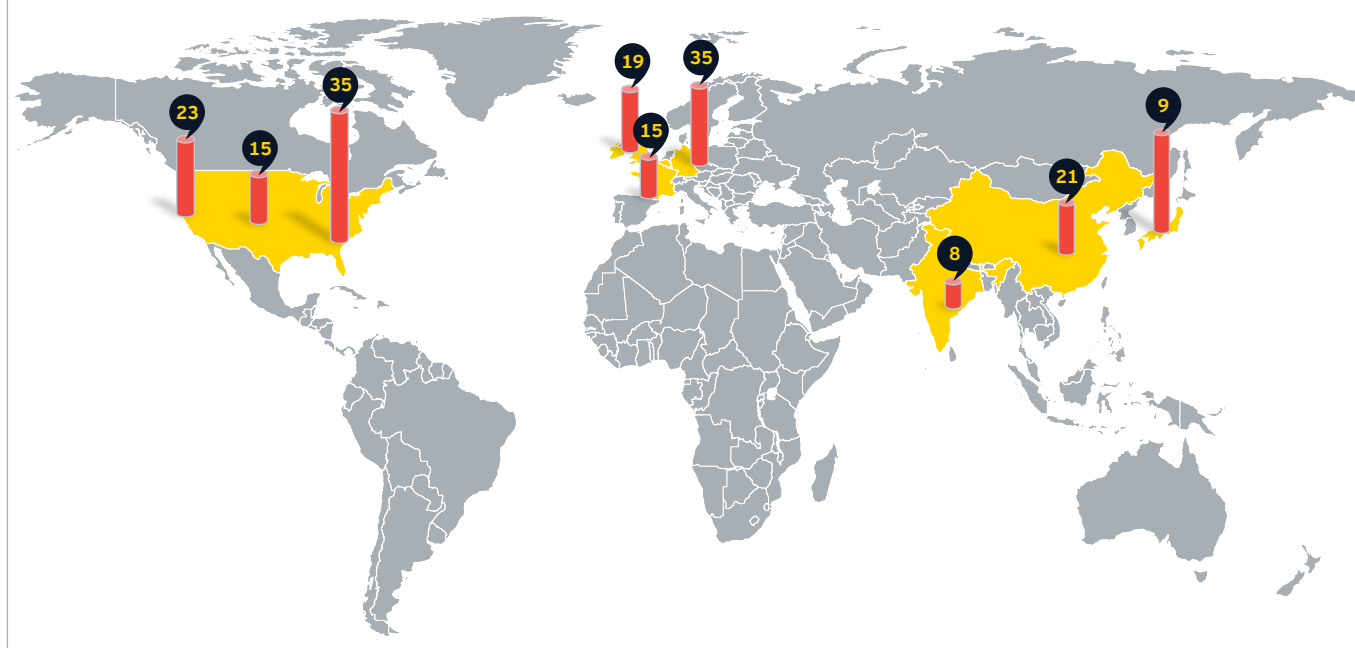
Source: Clinicaltrials.gov, EY analysis

[^]As of Jan 2021

2. Establish India as the global innovation hub

Another strategic opportunity for India is to establish itself as a global innovation hub, ultimately making the country the preferred destination for R&D and manufacturing outsourcing.

Figure 13: R&D and innovation centers of top global life sciences companies*



*List of companies: AstraZeneca, Bayer, Boehringer Ingelheim, Fresenius, GE Healthcare, GSK, Johnson & Johnson, McKesson, Medtronic, Merck & Co., Novartis, Pfizer, Roche, Takeda, Teva

Source: Company reports, EY analysis

At present, the R&D sites and innovation centers of most global life sciences (LS) companies are concentrated in the US and Europe, reflecting the dominance of US and European pharma companies. However, if we compare India with China, India has only half the number of R&D sites and innovation centers run by global LS companies. This highlights the scope to enhance India's acceptance globally in the innovation space²⁷.

Contract research opportunity

The global CRO market was valued at US\$45 billion in 2019 and is expected to grow at a CAGR of 7.9%, reaching US\$59 billion by 2024²⁸. The demand for CRO services will be driven by big pharma as well as by smaller biotechs. In addition to

lower cost, other drivers for companies to outsource R&D include increasing R&D costs and falling productivity, a growing focus on innovative research in niche /specialty therapy areas, increasing trial complexity and the need for specialized skills.

Over the years, India has established itself as one of the preferred destinations for outsourcing research. This has been possible due to the country's strong process chemistry skills and attractive cost-value proposition. Another advantage is the large and genetically diverse population base that makes the country an ideal location for cost-effective clinical research activities and novel drug trials. While India has made significant progress in the R&D field, there is still huge untapped opportunity.

²⁷ EY analysis

²⁸ EY analysis

Key challenges in achieving research and innovation potential

To seize the above discussed opportunities, the country needs to mitigate the following challenges:

1. Need for innovation mindset and related skill augmentation

Biomedical research encompasses basic research, translational research, pre-clinical research and clinical research. All these areas of research need to be tied together through collaboration between scientists involved in basic research, biomedical experts and clinicians.

(i) Inadequate training and motivation for conducting research

One of the biggest challenges hindering the growth of R&D in India is the dearth of talent with requisite training, expertise and skill across the entire research and development life cycle in the realm of pharmaceuticals, biotechnology and life sciences. There are several reasons for this shortfall. One of the most important reasons is that the education and academic institutions are still guided by rote learning instead of practical innovative thinking and the overall lack of resources dedicated for furthering biomedical research.

Less than 0.5% of Indian students pursue a PhD or equivalent level of education. As of 2018-19, only 35% of Indian higher education institutions offered postgraduate programs and just 2.5% offered PhD programs. India is also behind other countries in terms of total number of researchers - according to recent Brookings India report, India has only 216.2 researchers per 1 million population compared to 1,200 in China, 4,300 in the US and 7,100 in South Korea²⁹.

Clinical research capabilities are also in a similar condition in India. A study published in 2016 evaluated the research output from 579 medical institutions and hospitals in India during 2005-2014 and compared the output with some of the leading academic centers globally. The results revealed that only 25 institutions (4.3% of the total evaluated institutions) produced more than 100 papers a year. These institutions contributed over 40% of the country's total research output, while 57.3% of the medical colleges did not have a single publication in that decade. In comparison, the annual research output of the Massachusetts General Hospital and the Mayo Clinic was 4,600 and 3,700 papers respectively. This can be attributed to several factors broadly categorized into limited infrastructure and lack of intent (see figure 14)³⁰.

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In foreign countries, many industry outputs are based on the basic research in academia – this is missing in India.

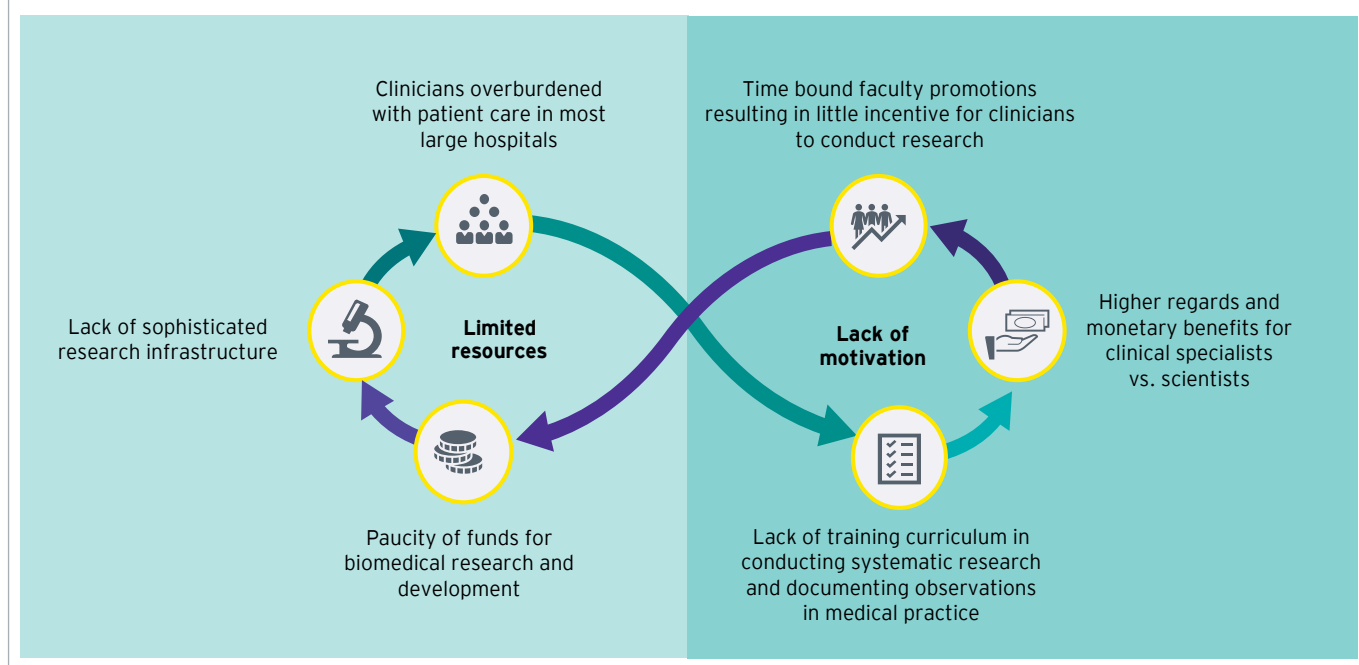
R&D head of a leading Indian pharma company

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²⁹ “Reviving higher education of India”, Brookings India, November 2019. Available at: <https://www.think-asia.org/bitstream/handle/11540/11338/Reviving-Higher-Education-in-India-email-1.pdf?sequence=1>

³⁰ “Medical Research in India: Are We There Yet?”, Delhi Journal of Ophthalmology, October 2017. Available at: https://www.researchgate.net/publication/321463981_Medical_Research_in_India_Are_We_There_Yet

Figure 14: Reasons for limited clinical R&D in India



All these issues need to be addressed systematically to improve the quantity, quality, and relevance of medical research in India.

“

We are facing a big challenge today as the education systems have not trained physicians appropriately on high end clinical research and collecting observational data.

Chairperson and Managing Director of a leading Indian pharma company

”

“

In India there is lack of high-quality basic research in academic institutes, which is so unlike what you see in the US, Singapore and South Korea. This is because there are no incentives for research – promotions are based on tenure instead of performance. This is harming the pharma industry. Unlike abroad, where many of the industry innovations from the drug development research are based on the basic research in the academia, Indian pharma industry has to start from basic research as they have nothing to tap into as far as the academic institutes are concerned.

Even in the medical education curriculum, we have some great learning in terms of clinical acumen especially from public institutions as there are tons of patients, but there is limited focus on medical research.

Chairperson and Managing Director of a leading Indian pharma company

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(ii) Need for increased alignment between academic curricula and industry needs

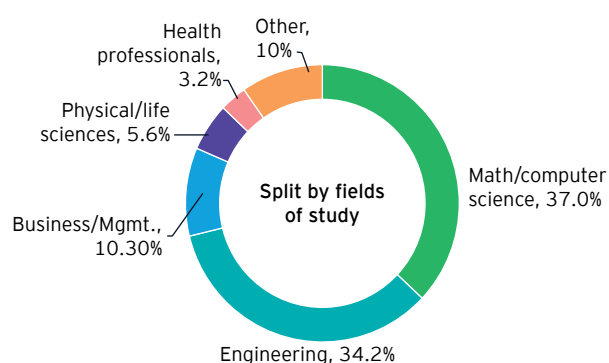
In addition to the already limited availability of talent, there is also a misalignment between the industry needs and academic curricula in Indian universities - both in terms of the curriculum and exposure to the real-world needs. As a result, most talent coming out of the educational institutions is not ready for the demands of the pharma industry.

(iii) Brain drain

Due to the limited infrastructure and opportunities, students often seek universities outside India for further studies, especially in science and technology fields. In 2018, more than 750,000 Indian students were studying abroad and about 28% of these students went to the US³¹. India is the second largest place of origin for international students for the US with about 18% of all international students in the year 2018-19 originating from India (China is the top place with 34% of the US international students originating from the country). More than 70% of Indian students in the US are in STEM fields³².

However, the real issue is not studying abroad. The challenge is that the majority of these students find jobs overseas and never return to India, resulting in ongoing loss of the country's intellectual capital. By contrast, China contributes to the largest share of international students in popular study-abroad destinations (including the US and the UK), but about 8 of every 10 Chinese students choose to return to China after graduation³³. This trend, increasingly pronounced in the past 3-4 years, can be attributed to China's favorable domestic policies towards returnees and their advantages in the country's job market.

Figure 15: Indians studying in the US (2018-19)



³¹ "More than 750,000 Indian students abroad in 2018", ICEF Monitor, November 2019. Available at: <https://monitor.icef.com/2019/11/more-than-750000-indian-students-abroad-in-2018/>

³² Opendoors website. Available at: <https://opendoorsdata.org/annual-release/>

³³ "Chinese students increasingly return home after studying abroad", Quartz, July 2018. Available at: <https://qz.com/1342525/chinese-students-increasingly-return-home-after-studying-abroad/>

“

“Part of our growth strategy is to get into advanced research in India, but it is challenging to find the right talent in this area – starting with expertise in basic research to advanced medical scientific capability.

It is in a way linked to approach of academia in India – the linkage or bridge to pharma industry is not always there. Also, it is hard to attract people from academia and practice to join industry, and difficult to attract senior medical talent from outside to India”.

Head of drug development center India, of a leading global pharma company

”

“

“We do not have talent in India that has experience for the entire product life cycle - from discovery candidate, to target developing, getting regulatory approvals, and going to the market”.

President R&D of a leading Indian pharma company

”

2. Complex regulatory approval process and Intellectual Property Regime (IPR)

In addition to strong talent, the innovation ecosystem in a country also requires strong policy and regulatory frameworks. A strong patent protection incentivizes entrepreneurs to spend effort, money and resources in long and risky drug discovery programs. Patents and exclusive rights enable companies to recover investments and fund future research. At the same time, simple and agile regulatory processes improve the ease of doing business and increase probability of success.

India has taken significant steps towards constructing a robust regulatory and policy framework, however, there are some gaps that need to be addressed.

Intellectual property (IP) regime in India

The India Patents Act 1970 was amended in 1999, 2002 and in 2005 to achieve compliance with Trade-Related Aspects of Intellectual Property Rights (TRIPS)³⁴. Since then, several amendments have been made to the patent rules over the years³⁵, the recent one being in October 2020³⁶, to encourage innovation environment in the country and to keep pace with the rapid technological advancement. To further boost and reward innovation culture in the country, the government declared 2010 to 2020 as the decade of innovation, and also launched initiatives such as Make in India and Start-up India³⁷.

³⁴ U. Racherla, “Historical Evolution of India’s Patent Regime and Its Impact on Innovation in the Indian Pharmaceutical Industry”, September 2019. Available at: https://link.springer.com/chapter/10.1007/978-981-13-8102-7_12

³⁵ Intellectual Property India website. Available at: <http://www.ipindia.nic.in/rules-patents.htm>

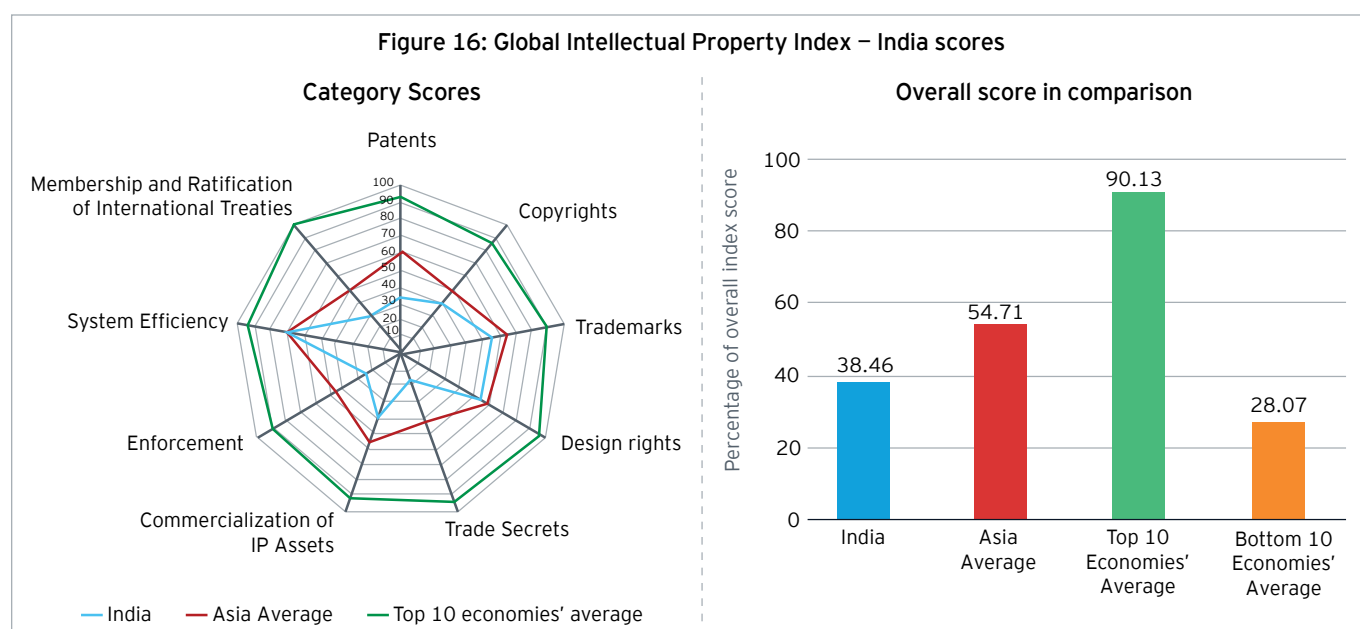
³⁶ “Update: Patent (Amendment) Rules, 2020”, NASSCOM Insights, October 2020. Available at: <https://community.nasscom.in/communities/policy-advocacy/update-patent-amendment-rules-2020.html>

³⁷ “India steps up efforts to boost tech transfer and innovation”, September 2020. Available at: <https://www.lexology.com/library/detail.aspx?q=784564cc-282d-4825-a4fa-533de46b5c5f>

While India has made substantial improvements in the overall patent regime, India continues to lag in comparison to developing and developed geographies. India ranked 40th out of 53 countries in the 2020 edition of Global Intellectual Property Index - this is a drop in position compared to 2019, when it ranked 36th out of 50 countries.

Of note is that even though India's overall position dropped, there has been an improvement in the country's overall score from 36.04% (16.22/45) in 2019 to 38.46% (19.23/50) in

2020³⁸. The increase in the score is reflective of the focused effort by the government to support investments in innovation through increasingly robust IP protection and enforcement. Since the release of the 2016 National IPR Policy, the country has improved its speed in processing patent and trademark applications, increased awareness of IP rights among entrepreneurs, and facilitated registration and enforcement of those rights³⁹. To further strengthen India's position in the developing countries, more steps could be taken to ensure efficient functioning of patent offices, proper enforcement of the IP and faster resolution of any legal issues relating to IP⁴⁰.



Source: Global Innovation Policy Center report 2020

Drug regulatory system

Medicinal products globally are subject to stringent regulations to ensure quality, safety and efficacy for the consumers. Every country has its own regulatory authority, which is responsible to enforce the rules and issue the guidelines to regulate the pharmaceutical sector.

India has established a strong regulatory framework, with latest revision in 2019, "New Drugs and Clinical Trial Rules, 2019" (New Rules 2019)⁴¹. However, there are some gaps in the overall regulatory structure and processes that can be addressed.

³⁸ Global IP center India report. Available at: <https://www.theglobalipcenter.com/wp-content/uploads/2020/01/India.pdf>

³⁹ Public Information Bureau website. Available at: <https://pib.gov.in/Pressreleaseshare.aspx?PRID=1557418>

⁴⁰ FICCI report. Available at: http://www.ficci.in/sector/24/Project_docs/IPR-profile.pdf

⁴¹ "Highlights of "New Drugs and Clinical Trials Rules 2019", Indian Society for Clinical Research. Available at: <https://www.iscr.org/wp-content/uploads/2019/05/Summary-of-new-regulation-final-1.pdf>

(i) Current drug regulatory set up in India resulting in gap in harmonization

In India, the Drugs and Cosmetics Act, 1940 ("D&C, Act") was introduced in 1940 to regulate the manufacture, export, import, distribution and sale of drugs and cosmetics⁴². The overall regulatory supervision is split at the Central and State levels.

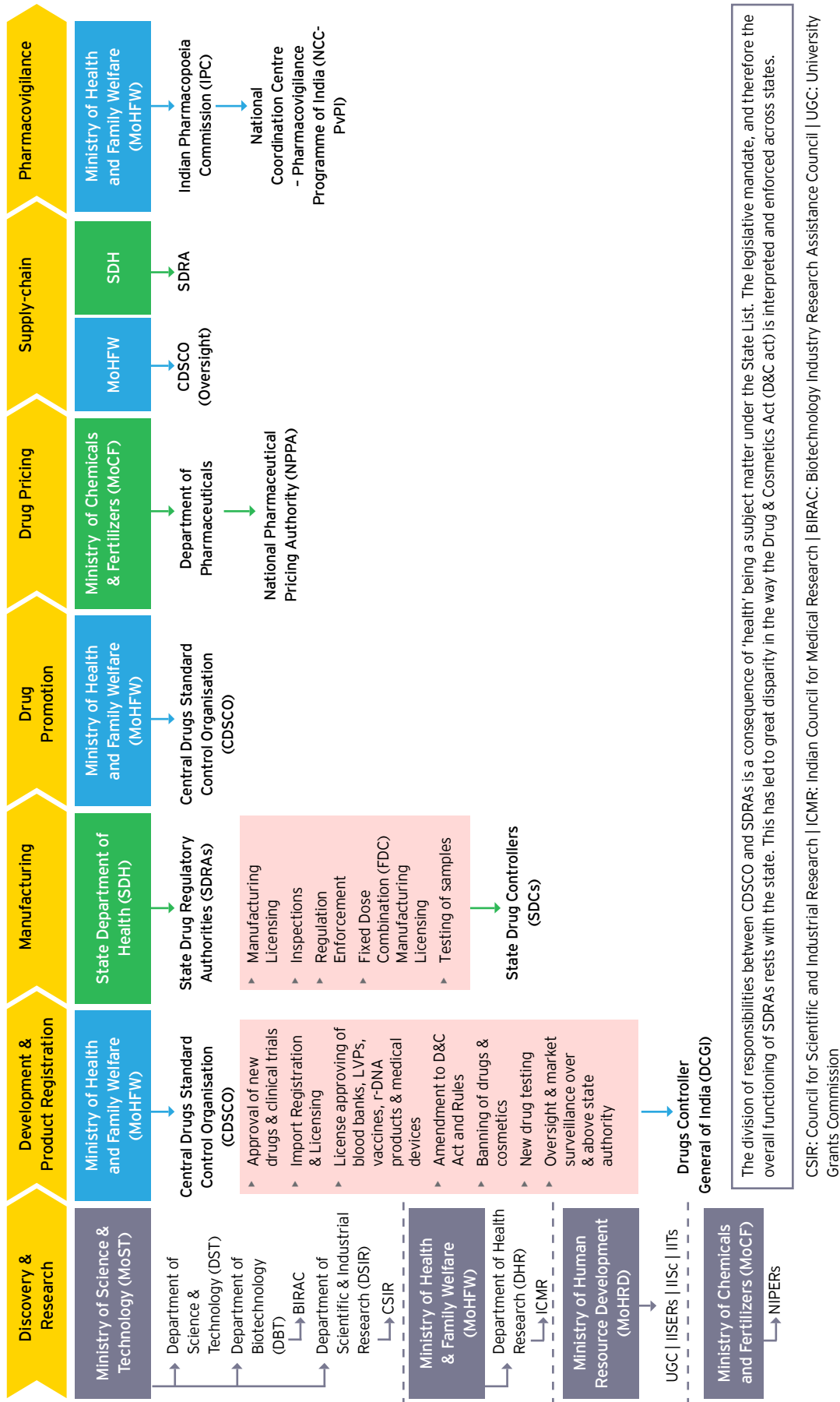
The Central Drugs Standard Control Organization (CDSCO), under the Directorate General of Health Services (DGHS), comes under the purview of the Ministry of Health, Family & Welfare (MoHFW). It is the national regulatory authority and is responsible for granting approvals for clinical trials, new drug products, and certain categories of medicinal products, such as blood and blood products, parenterals (intravenous fluids), vaccines, sera and other high risk products. CDSCO also provides authorization for import and export of medicinal products.

State Drug Regulatory Authorities (SDRAs), on the other hand, functioning under respective state health departments, are responsible for granting manufacturing, distribution and sales licenses, conducting inspections, sampling and testing products, monitoring overall quality control of medicinal products, investigating violations, and prosecuting non-compliant parties, if required. Due to this structural alignment of SDRAs to state health departments under the respective State List, there has been some disparity in the way the Drug & Cosmetics Act is interpreted and enforced across states. The fact that CDSCO does not have direct authority over SDRAs only compounds matters. The existing scenario leads to a situation where there are gaps in the harmonized application of drug regulatory standards across the country. The existing scenario of drug regulatory setup in India is presented below across the pharma value-chain:



⁴² India Code website. Available at: https://www.indiacode.nic.in/handle/123456789/2409?view_type=browse&sam_handle=123456789/1362

Figure 17: Existing scenario of drug regulatory setup in India



Source: CDSCO website; N. Chowdhury et al., Administrative Structure and Functions of Drug Regulatory Authorities in India - working paper 309, 2015

(ii) Extended approval timelines

Another aspect of the drug / clinical trial approval process is that while timelines are specified for various activities, such timelines are not usually met. This is typically owing to additional documentation requested by the regulatory authority and time taken by the applicant / sponsor to provide the same. There are no formally defined mechanism(s) in India for pre-submission discussions with the sponsor / stakeholder.

(iii) Gap in interpretation and implementation of regulations

The "New Drugs and Clinical trials rules 2019" were introduced in India with the aim of promoting clinical research. Along with the rules and regulations, guidance is also being provided in the form of FAQ documents by the CDSCO. However, with the regulatory machinery in place on paper, the same needs to be interpreted and implemented effectively on the ground.

(iv) Limited expertise in conducting, evaluating and inspecting clinical trials

The conduct of a clinical trial requires expertise across multiple domains, including but not limited to medicine, pharmacology / toxicology, statistics, clinical pharmacology / biopharmaceutics, chemistry and microbiology. There is an urgent need for competent personnel to evaluate clinical trial applications and conduct inspections of sponsor sites, investigator sites and ethics committees, in order to determine compliance with globally accepted good clinical practices laid down by the International Council of Harmonization (ICH).

(v) Need for detailed guidelines as industry endeavors to move up the value chain

As the world generics market moves towards complex generics and biosimilars, several companies are building their pipelines based on such medicinal products. It is therefore a need of the hour that the regulatory authority publishes guidance on the most appropriate methodology for the development of such medicinal products, and presentation of evidence needed to support the approval.

(vi) Scope for further harmonization of Indian regulatory with other developed and developing geographies

India is one of the largest exporters of generic medicines in the world, however its regulatory framework does not compare well with those of developed countries and other developing countries; for example, Brazil.

3. Financing constraints and limited infrastructure

At a cross-sector level, India's gross expenditure on R&D as percentage GDP has been around 0.7% (Economic Survey 2018 report) for the past two decades. While the overall absolute spending has increased, the percentage has remained constant since GDP has also increased. This is far lower than the R&D investment levels witnessed in, for example, Israel (4.6%), South Korea (4.5%), Japan (3.2%), Germany (3%) and even in other BRIC countries with China spending 2.1%, Brazil 1.3%, and Russia a little over 1%⁴³. Also of note is that the government has a dominant contribution in the gross domestic expenditure on research and development (GERD) – in 2017-18, Central Government spent 45.4%, state governments 6.4%, higher education 6.8%, and industry 41.4% (4.6% from public sector industry and 36.8% from private sector industry). Twelve major scientific agencies accounted for 99.8% of the R&D expenditure by the Central Government, with 61.4% spent on R&D in defense⁴⁴. This clearly highlights the need for increase in not only public spending, but also private financing that plays a very critical role in driving innovation in a country. According to the Economic Advisory Council to the Prime Minister (EAC-PM), India should target to reach R&D expenditure of at least 2% of the GDP by 2022⁴⁵.

Especially in the pharma sector, the R&D process is long and risky. The cost of development of a novel drug has been estimated to be around US\$2-3 billion, and the average time for development is about 10 to 12 years⁴⁶. It is challenging even for the largest Indian pharma companies to fund multiple innovative R&D products independently without funding support.

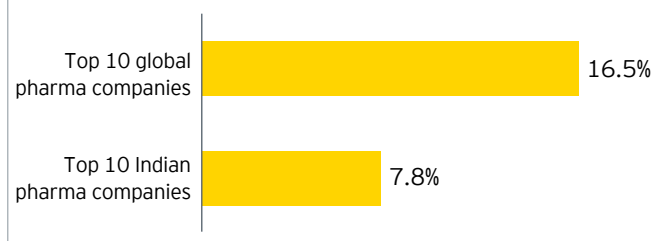
⁴³ At 0.7% of GDP, India's R&D expenditure in science is less than BRIC nations", Business Today, January 2020. Available at: <https://www.businesstoday.in/current/world/india-gdp-randd-expenditure-in-science-is-less-than-bric-nations/story/390874.html>

⁴⁴ Global Innovation Index 2020, WIPO. Available at: https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2020.pdf

⁴⁵ "Growth in R&D expenditure to be targeted 2% of GDP by 2022: PM economic panel", Business Today, July 2019. Available at: <https://www.businesstoday.in/current/economy-politics/growth-in-rd-expenditure-to-be-targeted-2-of-gdp-by-2022-pm-economic-panel/story/367312.html>

⁴⁶ "Tufts Study Finds Big Rise In Cost Of Drug Development", Chemical and Engineering News, November 2014. Available at: <https://cen.acs.org/articles/92/web/2014/11/Tufts-Study-Finds-Big-Rise.html>

Figure 18: R&D expenditure as % of revenue (average of 2015-19)



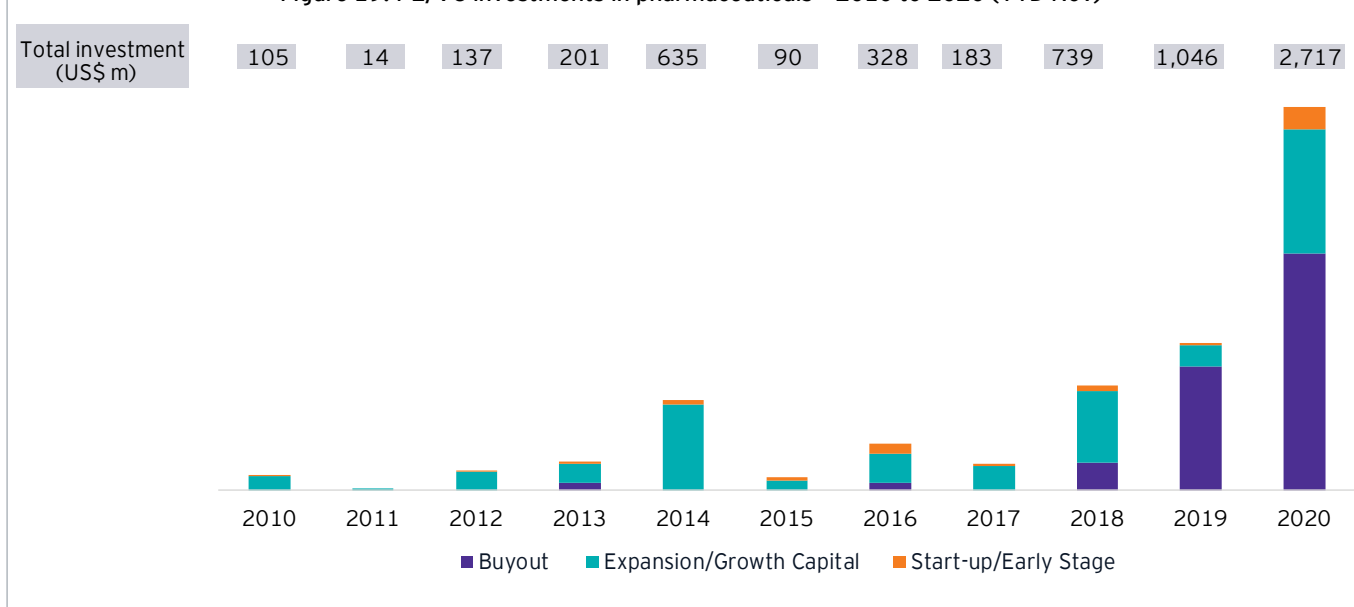
Source: Company reports, EY analysis

In the last few years most of the top Indian pharma companies have increased their R&D investments, but investment as a percentage of revenue remains under half of the investment level recorded by the top ten global companies⁴⁷. A considerable proportion of this investment also goes into generic drug research, leaving insufficient funds for NCE and NBE research. In addition to the high risk associated with R&D investments in innovative research, market factors such as price controls and patent protections also act as deterrents.

The research potential is further limited by inadequate grants and funds by the government bodies, especially for early research projects with start-ups/entrepreneurs and in academia. The procedure to apply for and receive the grants is also very complex.

Private equity and venture financing, which is critical to push the projects to next stage of development, is also currently limited in the Indian market due to the long gestation period and high-risk nature of the pharma R&D. According to EY analysis of the VCCEdge data for the past 11 years (2010 to November 2020), PE/VC investments worth US\$192 billion were made across all sectors. Top six industries constituted ~70% share of the total PE/VC investments – e-commerce 14% (~US\$27 b), infrastructure and real estate/hospitality/construction 13% each (~US\$25 b), financial services 12% (US\$22 b), technology 9% (US\$17 b) and telecommunications 7% (US\$12 b). Pharmaceuticals constituted only about 3% (US\$6.2 b) of the total PE/VC investments during the period, ~45% (US\$2.7 b) of which was in 2020 (YTD Nov) alone.

Figure 19: PE/VC investments in pharmaceuticals - 2010 to 2020 (YTD Nov)



⁴⁷ EY analysis

A significant share of the PE/VC investments in the pharmaceutical sector has been in the form of growth capital, accounting for 48% of all investments. Start-up investments was a meagre US\$0.4 billion (6% of the total PE/VC investment in the sector), of which about 42% (~US\$160m) was in 2020 alone with a majority (~US\$152m) getting invested in Biocon Biologics India Ltd. However, the recent investments in Biocon Biologics is an indicator of the changing realities in the sector post COVID -19 where health has come back on the agenda

for capital pools globally. Covid-19 crisis has exemplified and established the need for collaboration across stakeholder groups, i.e., peer-to-peer, public-private, start-ups with big pharma as well as capital inflow with certain imperviousness to the risks. This trend needs to set and collective gain can be witnessed in medium to long term if we lay down clear goals and objectives and follow through close tracking of initiatives, prioritized for the betterment of health across geographies

Top five growth investments (2010 to 2020)

Target	Investor (company headquarters)	Amount (US\$m)	Deal stake %	Announcement Date
Piramal Pharma	Carlyle Investment Management LLC (US)	490	20	Jun-20
Mankind Pharma Ltd.	ChrysCapital Investment Advisors India Pvt. Ltd. (India)	350	10	Apr-18
Gland Pharma Ltd.	KKR India Advisors Pvt. Ltd. (US)	200	38	Jun-14
Intas Pharmaceuticals Ltd.	Temasek Holdings Advisors India Pvt. Ltd. (Singapore)	160	10	Nov-14
Intas Pharmaceuticals Ltd.	ChrysCapital (India)	132	3	Jun-20

Another major trend witnessed in 2018 is the growing prominence of buyouts – the 11-year period witnessed buyouts worth US\$2.8 billion (46% of the total PE/VC investment in the sector), of which 90% was during 2019 and 2020. Four of

the top five buyouts of the analysis period took place in 2020 and were made by overseas buyers. We expect buyouts led by International PE funds to continue, driving synergy and further collaborations among the portfolio businesses.

Top five buyouts (2010 to 2020)

Target	Buyer (company headquarter)	Amount (US\$m)	Deal stake %	Announcement Date
Aurobindo Pharma, Natrol LLC (US Unit - Natrol)	New Mountain Capital (US)	550	100	October 2020
Kyowa Pharmaceutical Industry Co. Ltd. (Lupin's Japan unit)	Unison Capital Partners IV F L.P. (US)	525	100	November 2020
J.B.Chemicals and Pharmaceuticals Ltd.	KKR & Co. Inc. (US)	496	54	July 2020
Bharat Serums and Vaccines Ltd.	Advent International Corp. (US)	250	60	November 2019
SeQuent Scientific Ltd.	Carlyle Investment Management LLC (US)	210	74	May 2020

Because of financing constraints, some research projects, especially by small start-ups, are abandoned in the early stages itself as the companies are not able to sustain their operations and research efforts beyond the short term.

To build a strong R&D base, it is critical to increase both private and public expenditure on R&D. Public funding is required to strengthen capabilities in basic research, especially in high risk and high priority areas. Private funding commitment, especially from the larger organizations, is critical to convert innovative ideas to successfully commercialized products.

4. Limited incentives from the government

Compared to other developed countries, there are limited R&D related supporting policies and incentives from the government in India. The weighted deduction on R&D expenses in income tax was reduced from 200% to 150% in 2017, and further to 100% from 1 April 2020⁴⁸.

Impact of COVID-19 recession on global R&D spending:

The impact of the COVID-19 on innovation is highly dependent on recovery scenarios and the business and innovation practices and policies in place in different geographies. In any scenario, financial resources—both private and public—will be strained. Countries and corporations alike might find it harder to pursue investments and innovation.

Historically, economic crisis situations have been followed by sustained periods of reduced investment, with the overall impact varying by sectors and countries – some increasing and others decreasing innovation and related expenditures. A similar scenario may be expected after COVID-19.

To counteract the effects of the crisis on economies, most governments in high- and middle-income economies are setting up emergency relief packages. In addition, there is also a strong need to have measures to finance innovation and start-ups. For example, France has extended its liquidity scheme to start-ups. The Chinese rescue package also includes guaranteed loans for start-ups. Some European countries have started setting up special funds to support start-ups. India, too, should allocate funds specifically towards research and innovation to ensure continuity in the ongoing efforts and support new innovations.

Way forward: focusing on research and innovation to achieve growth ambition

India is the third-largest manufacturer of drugs worldwide in terms of production volume, accounting for 10% of the global total. However, India accounts for only 1.5% of the total value of drugs produced worldwide, making it 14th ranked among manufacturing nations⁴⁹. This disconnect between India's relatively high share of volume and low share of value will only be bridged if India intensifies efforts in innovative R&D.

“

We have great minds, but we have just been focussing at re-engineering

Senior government official

”

“

Even though we are the world's largest producer of vaccines and generic drugs by volume, we only account for a very small fraction of the global value chain, that says it all. Innovation and R&D are at the heart of what we need to do going forward, and there lies our value creation opportunity.

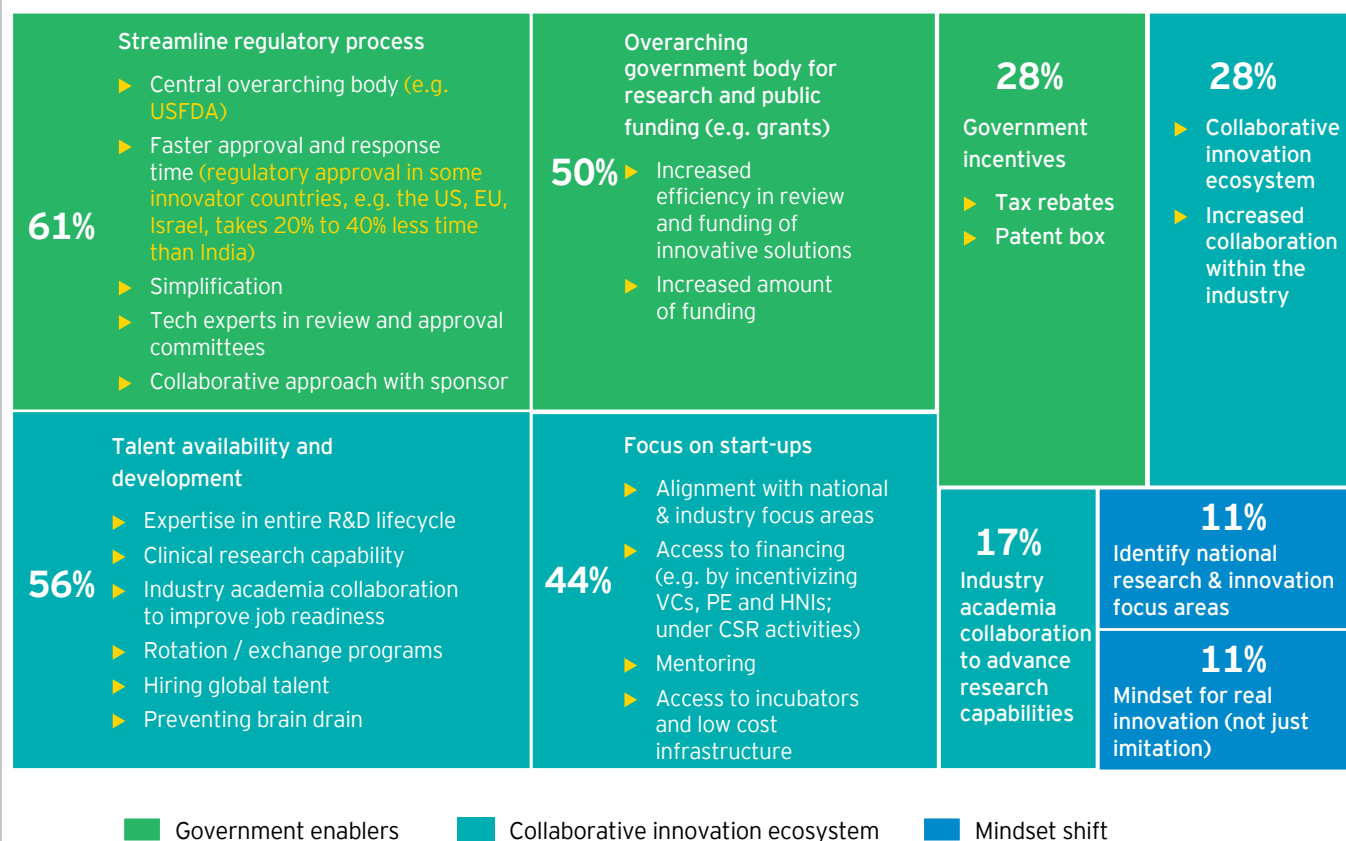
Chairperson and Managing Director of a leading Indian pharma company

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⁴⁸ “New incentives and tax benefits can boost R&D ecosystem for new drug development in India”, GlobalData, March 2020. Available at: <https://www.globaldata.com/new-incentives-and-benefits-can-boost-rd-ecosystem-for-new-drug-development-in-india-says-globaldata/>

⁴⁹ Department of Pharmaceuticals website. Available at: <https://pharmaceuticals.gov.in/pharma-industry-promotion>

Figure 20: Research and innovation enablers



*Percentage reflects number of responders referring the enabler; N=18

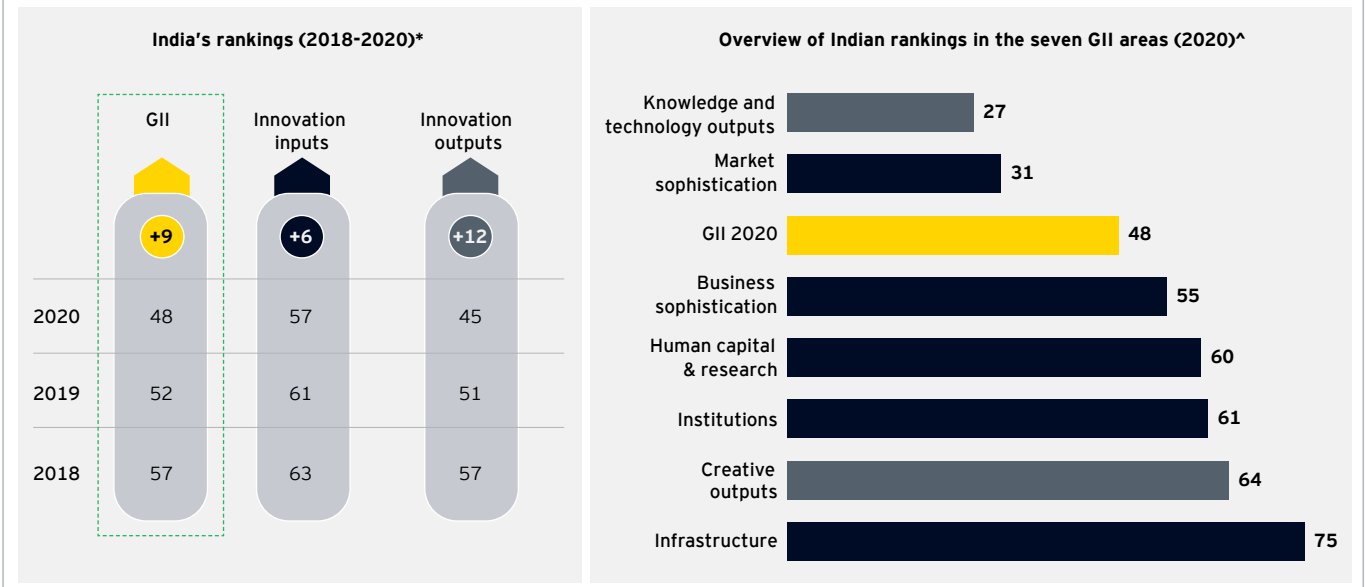
Source: EY primary research

The Global Innovation Index (GII) ranks world economies according to their innovation capabilities across all sectors. According to the 2020 report, over 70% of all R&D spending falls within four industries/sectors: information and communication technologies (ICT) hardware and electronic equipment (23.5%), pharmaceuticals & biotechnology (18.8%), automobiles (15.6%), and software & ICT services (14.4%). R&D spending in the healthcare equipment & services sector is only 2% of global annual R&D spending.

Among the countries, Switzerland led the index in 2020, with Sweden ranked second and the US third. India ranked 48th in 2020, making it to the top 50 for the first time. The country has moved up 9 positions in the last 2 years, driven by the improvement in the innovation outputs (+12). India performs best in knowledge & technology outputs and its weakest performance is in infrastructure. Despite its improved ranking, India is behind several competing countries, such as Singapore (ranked 8th), China (14th), Malaysia (33rd), Vietnam (42nd), and Thailand (44th)⁵⁰.

⁵⁰ Global Innovation Index 2020, WIPO. Available at: https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2020.pdf

Figure 21: Global Innovation Index (GII) – India rankings



*Note: data availability and changes to the GII model framework influence year-on-year comparisons of the GII rankings ^highest possible ranking in each pillar is 1.

Source: World Intellectual Property Organization (WIPO), Global Innovation Index 2020

India needs to develop short- and long-term research and innovation strategies with specific focus areas (such as biosimilars, complex APIs and generics, vaccines, and contract research). These focus areas would play to India's strengths and align with the nation's future ambition of moving up

the product value chain to developing NCEs and potentially personalized medicines such as cell & gene therapies in the coming years. Strengthening India's research and innovation capabilities requires interventions across the dimensions discussed in this chapter.

Strengthening India's research and innovation ecosystem

Research and innovation in pharmaceuticals requires the collaborative efforts of several stakeholder groups: big pharma/biopharma companies, start-ups and entrepreneurs or small pharma/biopharma companies, academic and clinical researchers. These stakeholder groups' efforts further need to be supported by growth enablers. Key enablers include financing, infrastructure and supporting policies and regulations.

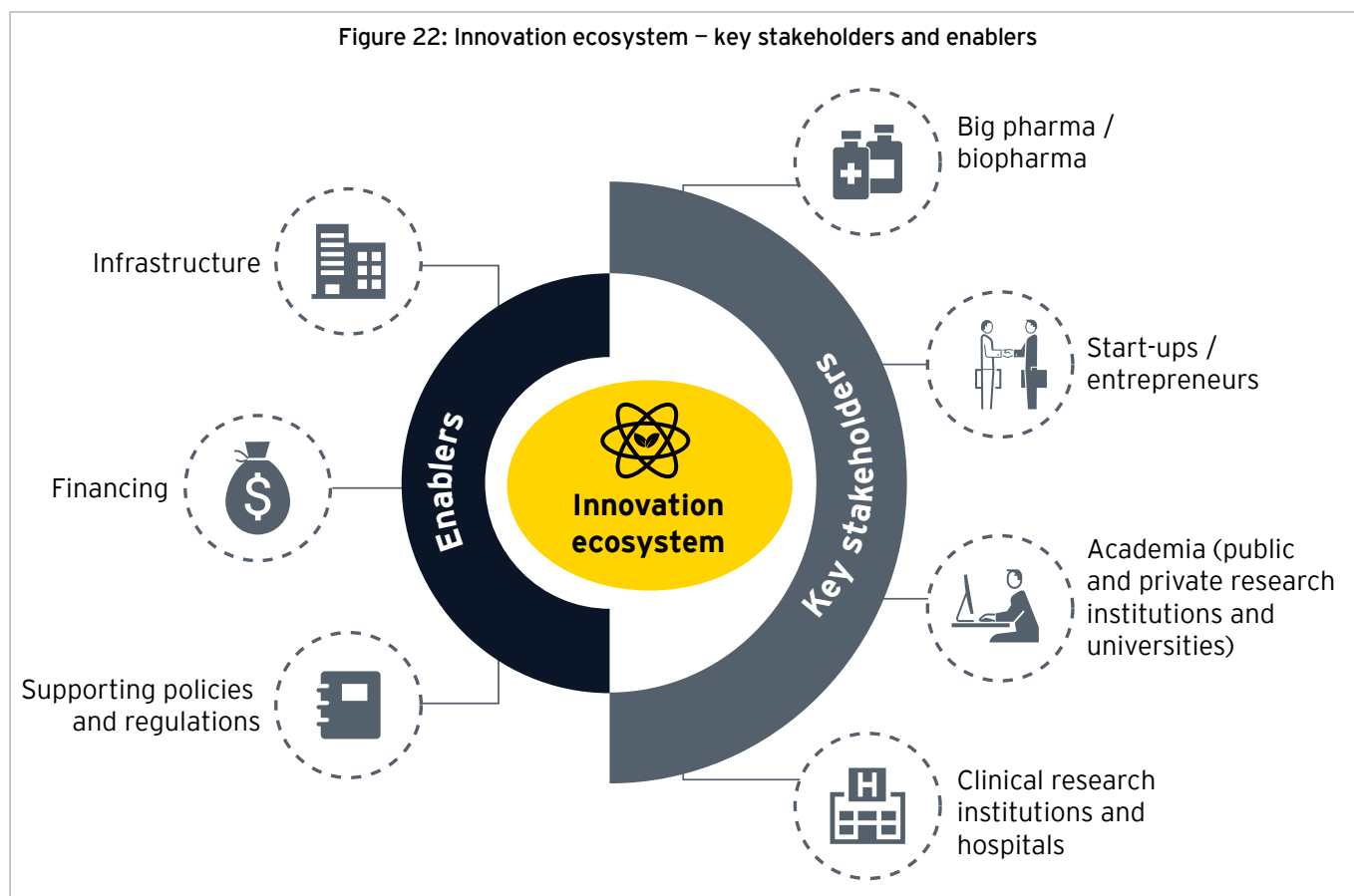
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R&D & innovation requires an entire ecosystem of academics, entrepreneurs, policymaking, investors.

R&D head of a leading Indian pharma company —”

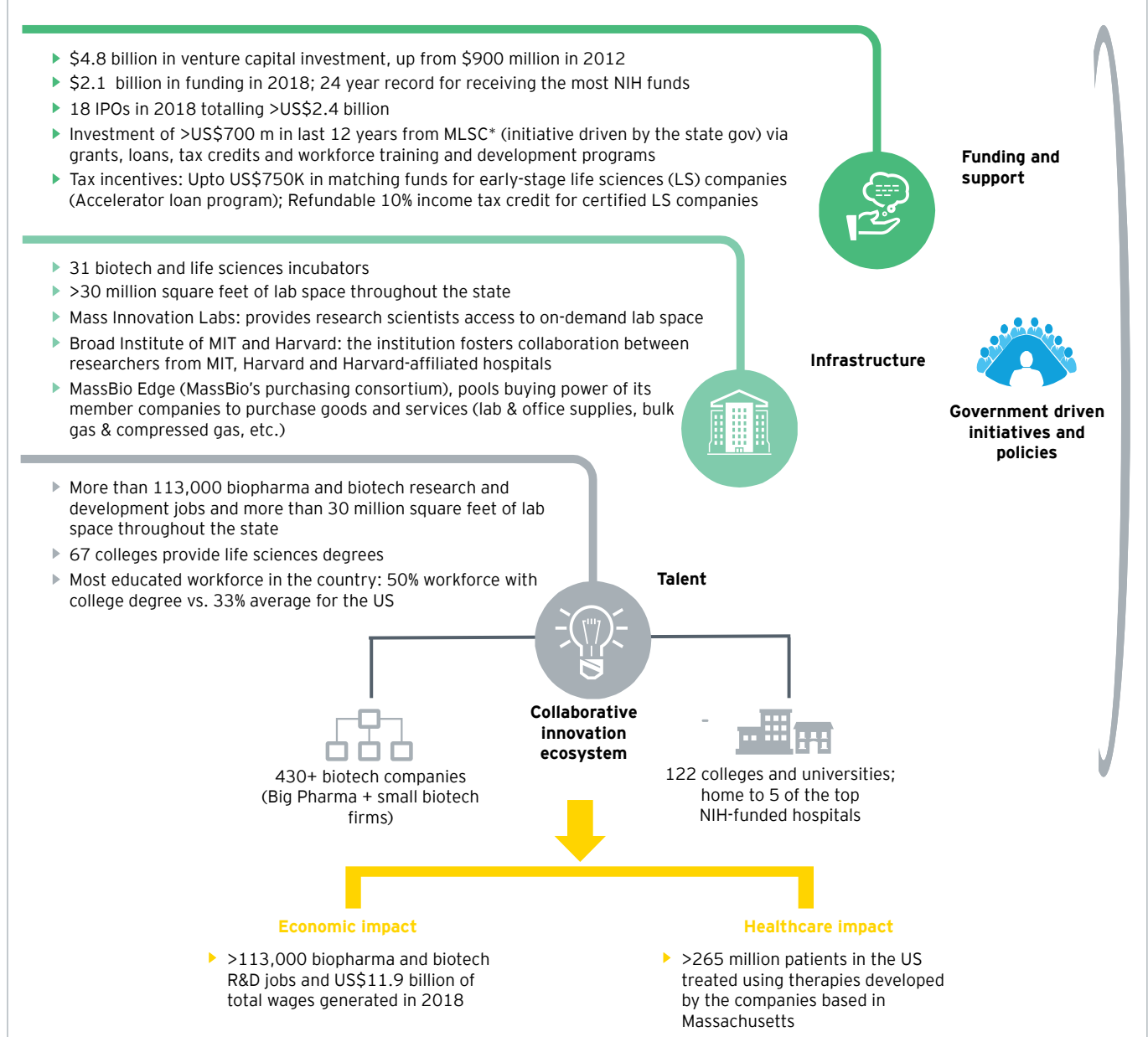
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Figure 22: Innovation ecosystem – key stakeholders and enablers



A very good example of such a robust ecosystem is the world's leading life sciences ecosystem in the Massachusetts (see figure 23). It is a great illustration of the power of investment in innovation driving collaborative partnerships between government, academia, hospitals and the private sector.

Figure 23: Massachusetts Life Sciences innovation ecosystem



*MLSC: Massachusetts Life Sciences Center; NIH: National Institutes of Health;

In this chapter we will look at the role and key focus areas for each stakeholder and consider best practices to establish an ecosystem with the right enablers.

Key stakeholders involved in research and innovation

1. Academia: setting foundation of strong talent and research base

Academia provides the foundation for building the entire research and innovation pyramid in any country. Academia is the source of most critical resources for innovation: talent and basic research.

Following measures can be considered to strengthen the academic base.

(i) Strengthening higher education system and expanding the talent base

India's higher education system is the world's third largest in terms of students, next to China and the United States⁵¹. However, only three Indian Universities – Indian Institute of Technology (IIT) – Bombay (172nd position), IIT-Delhi (193rd position) and Indian Institute of Science (IISc) Bangalore (185th position) – have been included in the top 200 institutes in the Quacquarelli Symonds (QS) World University Rankings 2021, but no university could enter the top 100 list. Overall, compared to last year, 14 institutes slipped in ranking while four institutes improved⁵².

a) Improve the quality of education and infrastructure in higher education institutions (HEIs): Talent with the right skill is the foundation for any country's growth. The government has initiated New Education Policy to equip students with necessary skills and knowledge and to eliminate the shortage of manpower in science, technology, academics and industry⁵³. Several initiatives have been recently launched to strengthen the country's higher education system and promote a culture of research and innovation within institutions. For example:

- ▶ **Education Quality Upgradation and Inclusion Programme (EQUIP):** a five-year plan (2019-2024) to improve the quality and accessibility of higher education. The program aims to double the Gross Enrolment Ratio (GER) in higher education and position at least 50 Indian institutions among the top-1000 global universities

- ▶ **Institutions of Eminence:** 10 institutions each from the public and private sector to be selected as Institutions of Eminence, to help them attain world-class standards of teaching and research. Each Public institute (IoE) will be eligible to receive INR 1000 crore during the 5-year period (2019-2024)⁵⁴
- ▶ **Revitalizing of Infrastructure and Systems in Education (RISE):** scheme to upgrade the research and academic infrastructure to global best standards by 2022. Higher Education Financing Agency (HEFA) has been tasked to mobilize INR 1,00,000 crores for this initiative⁵⁵

b) Increase number of public institutions offering postgraduation and PhDs: According to the All India Survey on Higher Education (2018-19), only 34.9% of all HEIs have postgraduate programs and just 2.5% of HEIs have PhD programs. Further, 34.8% of all colleges run a single program and close to 83% of these are privately managed.

The government should further invest more in expanding India's postgraduate capacity in public institutions to increase the quantity and quality of talent pool available for high end research activities.

c) Set up more national and international mobility programs to foster collaboration and sharing of perspective: To achieve higher quality in research, academia and government should also work together to launch more initiatives to collaborate with other countries on high end research projects. More programs for gaining international exposure, such as internships at foreign research centers/universities or educational exchange programs can be planned for faculty and students. The Scheme for Promotion of Academic and Research Collaboration (SPARC), launched by the Government in August 2018, is an initiative along similar lines⁵⁶.

Similar mobility programs should also be planned between academia and industry. Faculty or researchers from a university could work in a corporate for some time, while people from the industry could play the role of faculty or

⁵¹ "India's Higher Education Needs a Paradigm Shift", The Wire, February 2019. Available at: <https://thewire.in/education/indias-higher-education-needs-a-paradigm-shift>

⁵² "QS World Ranking 2021: Three Indian universities in top 200", The Times of India, June 2020. Available at: <https://timesofindia.indiatimes.com/home/education/news/q-s-world-ranking-2020-three-indian-universities-in-top-200/articleshow/76295989.cms>

⁵³ "India's New Education Policy 2020: Highlights and opportunities", British Council, August 2020. Available at: <https://education-services.britishcouncil.org/insights-blog/india's-new-education-policy-2020-highlights-and-opportunities>

⁵⁴ "Year End Review 2019- Department of Higher Education", Ministry of Education, Posted by PIB Delhi, January 2020. Available at: <https://pib.gov.in/PressReleasePage.aspx?PRID=1598503>

⁵⁵ "Expansion of Higher Education Financing Agency to fund Revitalising Infrastructure and Systems in Education (RISE) by 2022", Press Information Bureau, Government of India, July 2018. Available at: https://www.education.gov.in/sites/upload_files/mhrd/files/PN_HEFA.pdf

⁵⁶ SPARC website. Available at: <https://sparc.iitkgp.ac.in/>

conduct research work in the university. This will help in improving the understanding of needs and challenges on both sides.

Rotation programs could also be initiated between scientists in public and private institutions.

“

We can have rotational programs from scientists between public and private sector institutes. This will encourage cross-learning and improve understanding of strengths and opportunities in each of these sectors (public, private). This will also increase the understanding of the needs – the private sector scientists will understand better the healthcare needs, and the public sector scientists will gain the knowledge about actual delivery of innovation to the patients.

Bring foreign research scientists in the public sector research institutes into public sector research institutes of India. This will help in transmitting their knowledge here. Similarly, some of our scientists from public sector could be sent outside

Head of drug development center India,
of a leading global pharma company

”

- d) **Integrate topics on entrepreneurship and innovation mindset in the curricula:** The universities can make a significant impact in creating entrepreneurial ecosystem by providing academic programs that equip students with the knowledge and necessary skills to be an entrepreneur. There can be specific courses for entrepreneurship, or related topics can be included within the overall curricula. Alumni of the institutions who are successful entrepreneurs can also be invited to share their experience to motivate innovation mindset. Several countries such as Australia, the United States and United Kingdom have specific entrepreneurship education programs and courses.

In addition, the students and faculty should be motivated and incentivized to develop their innovative research ideas. The faculty members engaged in their own research activities or mentoring their students should get preference in rewards and promotions. Appropriate infrastructure and funding support should also be provided. Many developed nations encourage and enable the Higher Educational Institutions and other research establishments in setting up entrepreneurial activities, besides permitting the faculty members to engage in scientific enterprises (ventures that leverage scientific research, know-how, inventions, innovations and scientific expertise)⁵⁷.

Establishing technology transfer & business development cells, and permitting institutions to directly gain commercial benefit from IP created within the institute can be very productive in developing a culture of innovation. This will be highly beneficial to the overall innovation ecosystem, as academic institutions are well positioned to conduct basic research which can then be taken forward by other stakeholders in the ecosystem.

⁵⁷ T. Mazzarol and M. Battisti, "The role of universities as catalysts within entrepreneurial ecosystems", August 2016. Available at: https://www.researchgate.net/publication/307925580_The_role_of_universities_as_catalysts_within_entrepreneurial_ecosystems

(ii) Developing industry ready talent

According to the India Skills Report 2020, employability or job readiness in India has remained stagnant for the past three years at around 46% (overall average employability across all sectors). This is partially due to the insufficient infrastructure (including funding) within the educational institutions, outdated curricula, and lack of faculty with required experience and training. Another important factor is the disconnect between the academia and the industry⁵⁸. As a result, the students coming out of educational institutions still lack the industry-relevant skills and knowledge required to be job ready.

There is urgent need for academia, industry and the government to come together and take initiatives that can improve the job readiness of the students.

Government initiatives

In the same direction, University Grants Commission (UGC) issued a Learning Outcome-based Curriculum Framework (LOCF) in 2018 that aims to specify desired outcomes and then decide the curriculum to obtain these outcomes. The outcomes will be determined in terms of skills, knowledge, understanding, employability, graduate attributes, attitudes, values, etc., and should be demonstrated by students upon the completion of the course⁵⁹. All HEIs have been guided to adopt and implement the LOCF from the academic year 2019-2020⁶⁰.

In another initiative, the Government started the ICT Academy in 2009 under the Public-Private-Partnership (PPP) model (in collaboration with the state governments, leading companies from the industry, and National Association of Software Services Companies). This is a not-for-profit society that provides platform to train the teachers in higher educational institutes and enable students get industry ready in the ICT industry (Information and communications technology). Through its various initiatives, ICT Academy has significantly contributed to Skill India, Digital India, Startup India and Make in India⁶¹.

The government can launch similar initiatives that bring industry and academia together in the pharma sector.

Industry and academia collaboration initiatives to enhance curriculum and job readiness

There should be regular interaction between academia and industry to share inputs about evolving industry needs and incorporation in the curricula. In addition, several initiatives can be taken by the industry and academia to upskill the students and increase their understanding and alignment with the actual job requirements.

- **Industry designed training programs as a part of curriculum:** companies can help design specific courses that can be introduced as a part of learning journey in the institutions. For example, Amazon has launched AWS Academy with the aim to 'Bridge the Gap Between Academia and Industry'. AWS Academy provides higher education institutions with a free, ready-to-teach cloud computing curriculum that equips students with the skills required to get hired⁶².
- **Speaker Sessions, workshops and other platforms of interaction with students:** such sessions can be very useful for the students to understand industry trends, different professions and job functions. For example, several colleges in the US and other geographies run the following programs:
 - **Career Discovery Series:** the program aims to educate students on their different career options. The program includes various career panels constituting of alumni and community members from various industries. Each panelist discusses their current position and career path and offers tips and hints for students wanting to get into that career field. The panel discussion is followed by a networking session which provides a great opportunity for students to learn from professionals who have succeeded in their chosen field⁶³.
 - **Job Shadow Program:** The program allows students to shadow an employer host for one day. The activities include observation of daily work, attending meetings/ other activities, touring the facility, and informational interviews, that are beneficial for students to experience the on-ground job activities⁶⁴.

⁵⁸ India Skills Report 2020. Available at: <https://wheebox.com/india-skills-report.htm#>

⁵⁹ "UGC Revises Curriculum Of UG And PG Programmes", BW Education, September 2019. Available at: <http://bweducation.businessworld.in/article/UGC-Revises-Curriculum-Of-UG-And-PG-Programmes/03-09-2019-175631/>

⁶⁰ UGC website. Available at: https://www.ugc.ac.in/pdfnews/8221712_LOCF_eng.pdf

⁶¹ ICT Academy website. Available at: <http://www.ictacademy.in/pages/Aboutus.aspx>

⁶² AWS Academy website. Available at: <https://aws.amazon.com/training/awsacademy/>

⁶³ Career Discovery Series page on the UCI website. Available at: <https://career.uci.edu/career-discovery-series/>

⁶⁴ Job Shadow Program page on the UCI website. Available at: <https://career.uci.edu/undergraduate/explore-a-career/job-shadow-program/>

- ▶ Companies can launch skilling and re-skilling initiatives in collaboration with each other and industry associations to establish an efficient skilling ecosystem in their sectors. For example:
 - ▶ 'FutureSkills' is an initiative by NASSCOM launched in 2018 in collaboration with the IT-ITeS companies. The program aims to skill over 2 million candidates by 2023 on 155+ skills, across 70+ jobs, in 10 emerging technologies and 10 non-tech skills. The portal has been designed as a marketplace and content library where global providers of content and learning come together to offer learners information on the latest jobs, the skills needed for those jobs, learning content, assessments and certifications⁶⁵.
- ▶ Train the trainer programs can be introduced in collaboration with the government to increase the understanding of the faculty about industry and job requirements. For example:
 - ▶ The Ministry of Skill Development & Entrepreneurship (MSDE) launched its 'Train-the-Trainer' program in collaboration with IBM in 2019. The program aims to train over 10,000 faculty members from Industrial Training Institutes (ITIs) across India in Artificial Intelligence (AI)-related education over a period of one year (by 2020). Similar efforts can be replicated across industries and institutes to widen the reach of such initiatives⁶⁶.
- ▶ Companies should provide internships/sponsorships/fellowship to deserving candidates. This can be a mutually beneficial program where the students benefit by getting on-job experience and the company gets tangible outputs. For example:
 - ▶ Several global companies have postdoctoral research programs: Pfizer Worldwide Research and Development sponsors a postdoctoral training program to pursue research in the areas of disease biology, drug delivery and mechanisms of action, and computational efforts

supporting these areas, as well as the engineering of novel therapeutic proteins, vaccines, and nucleic acids. Postdocs can pursue their training at the company's Worldwide R&D campuses around the globe. Fellowship support is offered for up to four years. Pfizer places a strong emphasis on publications, attendance at major international meetings, and career-building activities. Pfizer Worldwide R&D's Annual Postdoc Symposium is a highlight of the training program, bringing together trainees from all of Pfizer's R&D locations for scientific presentations by the trainees, as well as internal and external researchers. The program's core mission is to match high-quality trainees with outstanding mentors and promising research projects⁶⁷.

Similar programs by other global life sciences companies include - Novartis Institutes for BioMedical Research Postdoctoral Program⁶⁸, The Merck Research Laboratories Postdoctoral Research Fellows Program⁶⁹, and Regeneron's Postdoctoral Program⁷⁰.

Academia and industry collaborations are synergistic to each other. The industry benefits from access to innovative research and talent. Academia benefits by getting the required funding, infrastructure and mentoring (technical and commercial) support for moving the ideas from research stage towards commercialization.

Government can also launch initiatives to increase the collaboration between the industry and the academia. An interesting initiative is the Carnot Institutes launched by the France Government – refer to the figure 24 for details.

⁶⁵ FutureSkills website. Available at: <https://futureskills.nasscom.in/>

⁶⁶ Skill India and IBM come together for nationwide Train-the-Trainer program in Artificial Intelligence. Available at: <https://www.msde.gov.in/sites/default/files/2020-01/IBM-partners-MSDE-for-training-of-trainers-in-AI.pdf>

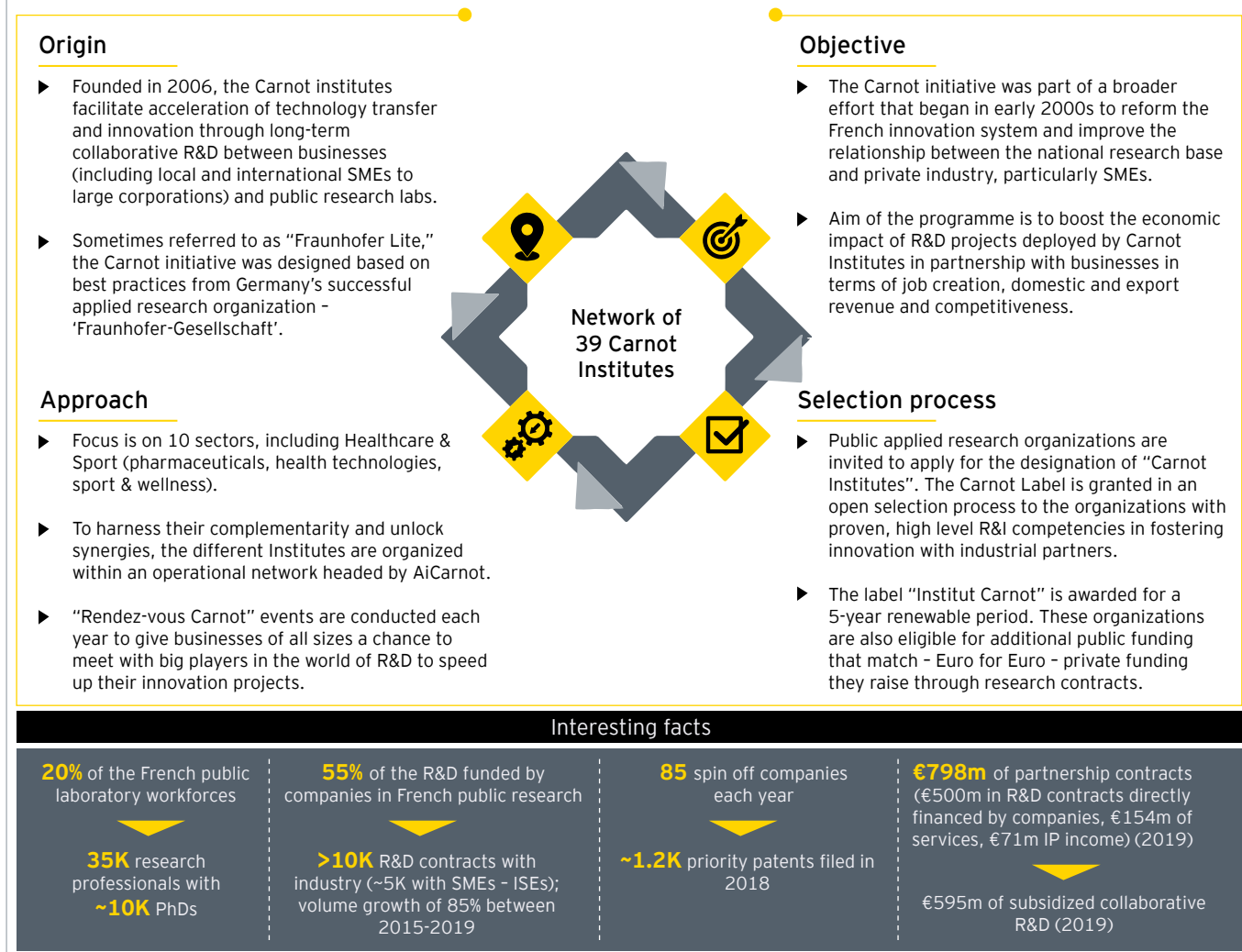
⁶⁷ Company website. Available at: <https://careers.pfizer.com/en/postdoctoral-program>

⁶⁸ Company website. Available at: <https://www.novartis.com/our-science/postdoc-program>

⁶⁹ Company website. Available at: <https://jobs.merck.com/us/en/postdoctoral-research-fellow-program>

⁷⁰ Company website. Available at: <https://www.regeneron.com/postdoctoral-training-program>

Figure 24: Academia industry collaboration case study: Carnot Institutes (France)



Source: The Carnot Network website. Available at: <https://www.instituts-carnot.eu/en/carnot-label>; 21st Century Manufacturing: The Role of the Manufacturing Extension Partnership Program, Appendix 5 - The Carnot Initiative in France. Available at: <https://www.nap.edu/read/18448/chapter/16>

(iii) Prevent brain drain

Some of the initiatives discussed in the previous sections to improve the quality of education and the availability of good job opportunities might reduce the number of Indian students moving out of the country for higher education. In addition to preventing this ongoing “brain drain”, there is a need to launch specific initiatives to bring back talented Indians to the country. These returnees can play a very important role in bringing new learnings and trainings from developed countries that can increase the overall competitiveness of domestic industry. Another approach is ‘brain circulation’ (or ‘brain exchange’), in which case expatriates contribute their knowledge and skills to

their native countries in different ways such as participating in training programs, research projects, etc.⁷¹.

Let us consider some of the efforts made by some other developing countries to bring back talent and convert brain drain to wisdom gain.

- **China:** Though it continues to be the largest source country for internationally mobile students, China has also witnessed the return of large numbers of foreign-trained nationals. In addition to the incentives of China’s growing economy, advanced research facilities, and lucrative job opportunities, the government has offered the following initiatives to encourage return of talent:

⁷¹ Dr. D. Zweig, “Returnees, Technology Transfer, and China’s Economic Development”, June 2009. Available at: http://www.cctr.ust.hk/materials/working_papers/WorkingPaper28-DZ-Returnees_and_Tech_Transfer.pdf

- Chinese national plans for scientific and technological (S&T) development (2006-20), human resources development (2010-20), and education reform and development (2010-20) all place emphasis on recruitment of highly skilled returnees. The aim is to encourage technology transfer by encouraging academic returnees to start their own businesses or join other government/private organizations. The government, in return, provides special incubators, tax cuts, and access to permanent residence in desired cities - in 2017 about 350 industrial and science parks constructed exclusively for the foreign-educated housed over 27,000 enterprises⁷².

The country started this initiative in the late 1980s with the launch of its Torch Plan establishing New High Tech Development Zones (Xin Gao Jishu Kaifa Qu) in cities around China. But to receive special privileges, projects have to involve new technology and should be certified by local S&T.

- **Other programs:** Start-Up Research Grant Program enables returnees to start laboratories, buy equipment, and hire research assistants. Many universities include overseas educational background and visiting scholar experience as key criteria for hiring and promotion, and holders of overseas PhDs can be made full professors immediately upon their return. Fellowships from several Ministries to talented returnees under programs such as 'Bairen jihua' (Hundred Talents Program), 'One Hundred, One Thousand, and Ten Thousands Program', etc. – recipients should have some new idea or technology to win such awards⁷³.

The Chinese talent returning back to the country has significantly contributed to scientific research, technological economy, and academic leadership.

Like China, Taiwan also used a multipronged approach to bring back expatriates⁷⁴. Similar initiatives as discussed above can be adopted by India. A lot of challenges related to talent will automatically get resolved once the ecosystem and infrastructure is in place.

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It is the law of osmosis – you create the higher density and the flow will happen. If the things are done right, you do not need to attract, people will get attracted. China did this – they put everything in place and then welcomed all who wanted to come.

Director of a leading Indian pharma company —”

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⁷² “Technology Transfer via Intellectual Returnees in China's Solar Industry”, Peterson Institute for International Economics, October 2017. Available at: <https://www.piie.com/blogs/china-economic-watch/technology-transfer-intellectual-returnees-chinas-solar-industry>

⁷³ Y. Ma, S. Pan, “Chinese Returnees from Overseas Study: An Understanding of Brain Gain and Brain Circulation in the Age of Globalization”, Front. Educ. China 2015 Available at: <https://link.springer.com/article/10.1007/BF03397067>

⁷⁴ R. Davone, “Diasporas and Development. Available at: <http://documents1.worldbank.org/curated/en/676991468332695451/text/393820Diasporas0development01PUBLIC1.txt>

2. Clinical research institutions and hospitals: augmenting clinical research capabilities

Globally, medical teaching institutions serve as the major hubs of biomedical research. The physicians, with their expertise and the availability of large amount of patient data in the institutions, can make a significant difference in the quality of research outcomes.

India can enhance clinical research capabilities by strengthening research training, incentivizing high impact research activities and allocating appropriate funds. This will motivate more students to pursue research as a profession and enable them to carry out high quality research activities.

(i) Integrating medical research training in the curriculum

The critical first step towards improving clinical research activity and quality is to focus on the skill set. India needs to expand the pool of researchers trained in the fundamentals of clinical research. Several studies have reported that clinical research and clinical trial knowledge are not appropriately integrated into the medical undergraduate and postgraduate curriculum in Indian medical colleges. For example, a study conducted in 2014 in a medical college-cum-civil hospital in Gujarat reported on low awareness of clinical research amongst final year medical students and postdoctoral physicians⁷⁵. Another survey at a tertiary care teaching hospital in Gujarat found that resident doctors are not specially trained on clinical trials (CTs) in their postgraduate curriculum⁷⁶. Similar findings were reported by other studies conducted in some other states such as Maharashtra and Punjab colleges⁷⁷.

A recent survey of doctors from government medical colleges in West Bengal suggests that increased emphasis and proper training on clinical research and clinical trials during graduation and post-graduation encourages more physicians to participate in clinical research during their medical training and afterwards⁷⁸. Training and experience of research early in career also helps in informing residents' career decisions and has been associated with continued professional academic work.

(ii) Encouraging active engagement of medical students and physicians in clinical research

In many countries, such as the US and Europe, research is an integral part of the professional growth of physicians. Physicians are actively engaged in industry-sponsored and academic research. It is important to encourage a similar research-oriented environment in the medical education system in India. Medical institutions in India should include formal, structured research training curriculum covering different dimensions of medical research such as the wet lab, data science, and clinical research. Training should also be provided about research methods, ethics, and approaches to critical appraisal of published research.

Financial and non-financial incentives should be introduced to motivate medical students and physicians to conduct research projects. Examples of non-financial incentives would include publications in peer-reviewed journals and/or commercialization of research being used as a criteria for prioritizing selection of students for postgraduate degrees, as well as recognition and awards via appropriate public forums, among other incentives. Motivation can be further boosted by ensuring that the topic of research is aligned with the physician's interest, and, ideally, has significant potential to improve health outcomes. Financial incentives would include pay increases, grants for attending conferences, promotions, and others.

Collaboration between medical colleges and established research institutes can go a long way towards enhancing the quantity and quality of research outputs. This can be an effective way to increase competitiveness and acceptability of India's research in global peer-reviewed publication. To motivate this, special funds can be set up for innovative projects in collaboration.

⁷⁵ K. Sharma, "Low awareness of clinical research in India amongst final year medical students and physicians: Need for increased emphasis on clinical research in medical curriculum", 2014. Available at: <https://www.amhsjournal.org/article.asp?issn=2321-4848;year=2014;volume=2;issue=2;spage=234;epage=237;aulast=Sharma>

⁷⁶ Dr. R. Malpure and Dr. C. Dumatar, "Awareness of clinical trial among resident doctors - Survey at a tertiary care teaching hospital in Gujarat", Indian Journal of Applied Research, March 2017. Available at: [https://www.worldwidejournals.com/indian-journal-of-applied-research-\(IJAR\)/article/awareness-of-clinical-trial-among-resident-doctors-survey-at-a-tertiary-care-teaching-hospital-in-gujarat/MTEONTc=?is=1&b1=317&k=80](https://www.worldwidejournals.com/indian-journal-of-applied-research-(IJAR)/article/awareness-of-clinical-trial-among-resident-doctors-survey-at-a-tertiary-care-teaching-hospital-in-gujarat/MTEONTc=?is=1&b1=317&k=80)

⁷⁷ S. Gupta *et al.*, "Physician's participation in clinical research - a questionnaire study", Journal of Pre-Clinical and Clinical Research, 2019. Available at: <http://www.jpccr.eu/Physician-s-participation-in-clinical-research-a-questionnaire-study,108899,0,2.html>

⁷⁸ S. Choudhury *et al.*, "Knowledge and perception regarding clinical trials among doctors of government medical colleges: A questionnaire-based study", Perspect Clin Res, 2016. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4840798/>

(iii) Expanding the pool of technically qualified clinical researchers

India can consider introducing more dual-degree courses such as MD-PhD in the United States⁷⁹, and other programs with specific focus on clinical training for physicians, such as National Institute for Health Research (NIHR) Academic Clinical Fellowships (ACF) and NIHR Clinical Lectureships (CL) in the UK. ACF posts get access to Masters-level research training to develop academic skills and spend 25% of their time in research or educationalist training⁸⁰. The fellowship could lead to a PhD (or equivalent), or if applicable a postdoctoral fellowship⁸¹. The CL is intended to follow on from the ACF phase, when the trainee is in possession of a relevant PhD/MD⁸². Similarly, a program has been launched in Singapore to encourage doctors under specialty training to pursue a higher degree in research (either a 3- to 4-year PhD or a 1-year MSc) in order to equip them with research knowledge and skills that would allow them to develop translational research as they develop their clinical careers⁸³.

Another option is to design specific programs that encourage physicians (including those in private or academic clinical practice) to engage in clinical research while maintaining an active role in clinical practice. Programs along these lines have been established, for example, by the Clinical Research/Reproductive Scientist Training Program supported by the National Institute of Child Health and Human Development, Duke University, and the American Society for Reproductive Medicine⁸⁴. Such programs will help physicians to relate clinical experience to research and research knowledge to clinical work and keep them motivated. Efforts should also be made to address time commitment related challenges faced by physicians. To manage time effectively between research and clinical commitments, provision could be made for research administrative support to handle activities such as institutional agreements, patient approvals, and so on.

3. Start-ups: boosting the innovation momentum

With around 50,000 start-ups, India is today the third-largest start-up economy, after the US and the UK⁸⁵. However, India ranked 23rd (with a score of only 5.7) in the "Startup Ecosystem Rankings Report 2020; the US, for reference, had a score of 123.2. The Start-up Ecosystem ranking focuses on innovation outputs and is derived from the number and quality of start-ups in a country and the business environment. Thirty-eight Indian cities were in the list of top 1000 cities for supporting startup ecosystems. Bangalore led the Indian cities with a score of 16.4, followed by New Delhi, Mumbai and Hyderabad - the only four Indian cities among the top 100. Overall, India ranked 6th within Asia Pacific countries⁸⁶. There were more than 2,669 biotech start-ups in India in 2018⁸⁷.

EY conducted a survey in 2018 with 60 life sciences and health care start-ups⁸⁸. According to the survey, the start-ups are working across a range of innovative solutions covering the entire patient life cycle and product (pharma/biopharma drug) value chain (refer to the figure 25). More than one third of the survey participants identified funding as the biggest challenge, followed by regulatory processes and limited collaboration with industry. The survey participants highlighted funding (42% participants), innovation and market potential (38% participants), and government support (23% participants) as the most critical enablers for growth.

“

Start-ups are coming up with innovative ideas, but there is limited collaboration with the industry. We think these start-ups can help and for that we need to bring them closer together.

Head of drug development center India,
of a leading global pharma company

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⁷⁹ Association of American Medical Colleges website. Available at: <https://students-residents.aamc.org/applying-medical-school/article/considering-combined-degree-md-phd-md-mpa-md-mph/>

⁸⁰ NIHR website. Available at: <https://www.nihr.ac.uk/funding/nihr-academic-clinical-fellowships-in-medicine-2021/25719>

⁸¹ NIHR website. Available at: <https://www.nihr.ac.uk/documents/nihr-academic-clinical-fellowships-medical-guidance-for-recruitment-and-appointment-2021/25736>

⁸² NIHR website. Available at: <https://www.nihr.ac.uk/documents/2020-nihr-iat-clinical-lectureship-medical-guidance-for-recruitment-and-appointment/24115>

⁸³ M. Salto-Tellez *et al.*, "How do we Encourage Clinician Scientists in Singapore?". Available at: <https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.545.5004&rep=rep1&type=pdf>

⁸⁴ A. Armstrong *et al.*, "Keeping clinicians in clinical research: the Clinical Research/Reproductive Scientist Training Program", *Fertil Steril*, 2009. Available at: <https://pubmed.ncbi.nlm.nih.gov/19144332/>

⁸⁵ "With persistent pursuit of innovation, India makes to top 50 in Global Innovative Index 2020"; India Science, Technology and Innovation website. Available at: <https://indiascienceandtechnology.gov.in/listingpage/persistent-pursuit-innovation-india-makes-top-50-global-innovative-index-2020>

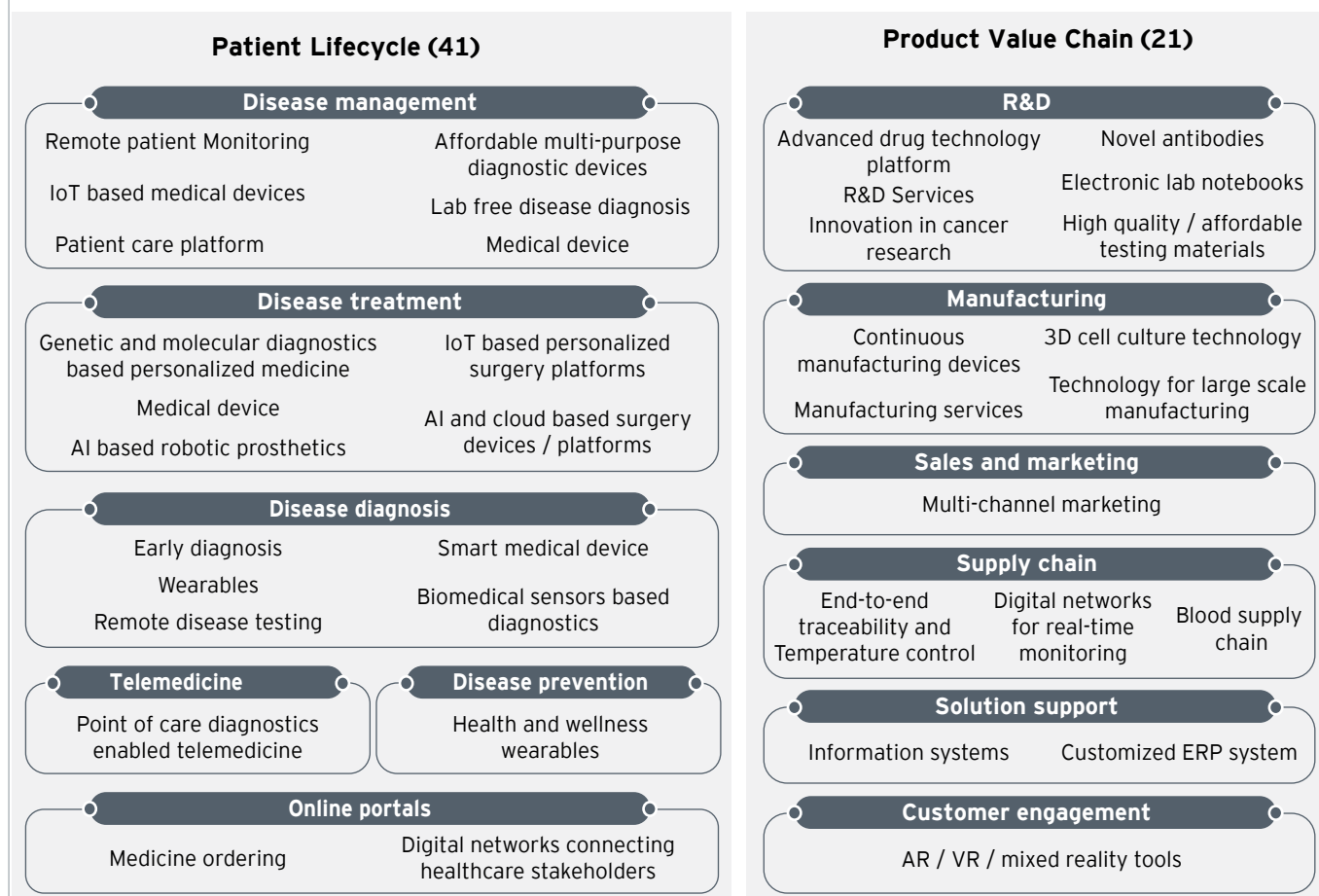
⁸⁶ Startup Ecosystem Rankings Report 2020. Available at: <https://report.startupblink.com/>

⁸⁷ "India Bioeconomy Report 2020, BIRAC, March 2020. Available at: https://birac.nic.in/webcontent/1594624763_india_bioeconomy_rep.pdf

⁸⁸ "Life Sciences 4.0: transforming health care in India", February 2018. Available at: <https://invest-india-revamp-static-files.s3.ap-south-1.amazonaws.com/s3fs-public/2019-03/ey-transforming-health-care-in-india.pdf>

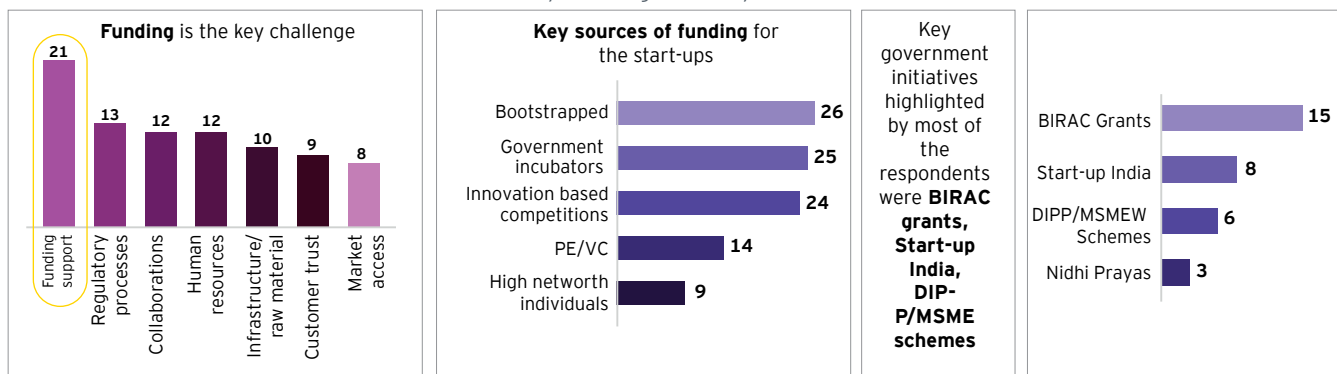
Figure 25

Range of innovative solutions developed by the surveyed start-ups



Other areas: social network for doctors, intelligent labor monitoring devices

Size of the boxes is indicative of the total number of start-ups catering to the respective areas



Source: Analysis is based on a survey conducted by EY in 2018 with the leaders of 60 life sciences and health care start-ups.

BIRAC: Biotechnology Industry Research Assistance Council; DIPP: Department of Industrial Policy & Promotion; MSME: Micro, Small & Medium Enterprises; PE: Private Equity; VC: Venture Capital

“

There is a nice start-up environment in the country – but that start-up environment is fragmented and it fizzles out. Start-ups must adopt a focussed approach by identifying top priorities.

Managing Director, India, of a leading global pharma company

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In addition to the need for significantly higher amount of funds and infrastructure, other challenges in drug research include lack of mentoring support due to the requirement of specialized skills and deep subject/domain knowledge. The long gestation period and high-risk further act as deterrents for entrepreneurs and investors. Even after a product is ready, it takes several years to get the required approvals to market the product. Additionally, one wrong step in drug research can take a start-up back by months or years given the need to re-do the research. For investors, another challenge is the inability to determine potential market value, especially if the idea is new and in very early stages.

The government has taken several initiatives to tackle these challenges. The Department of Biotechnology (DBT), Department of Science & Technology (DST), Council of Science & Industrial Research (CSIR), and Biotechnology Industry Research Assistance Council (BIRAC) are allocating generous amounts of money into the biotechnology start-up ecosystem by providing funds, mentoring, and infrastructure. We will discuss these initiatives in detail in the financing and infrastructure sections of this chapter.



4. Big pharma/biopharma companies: increasing focus on collaboration-led innovation

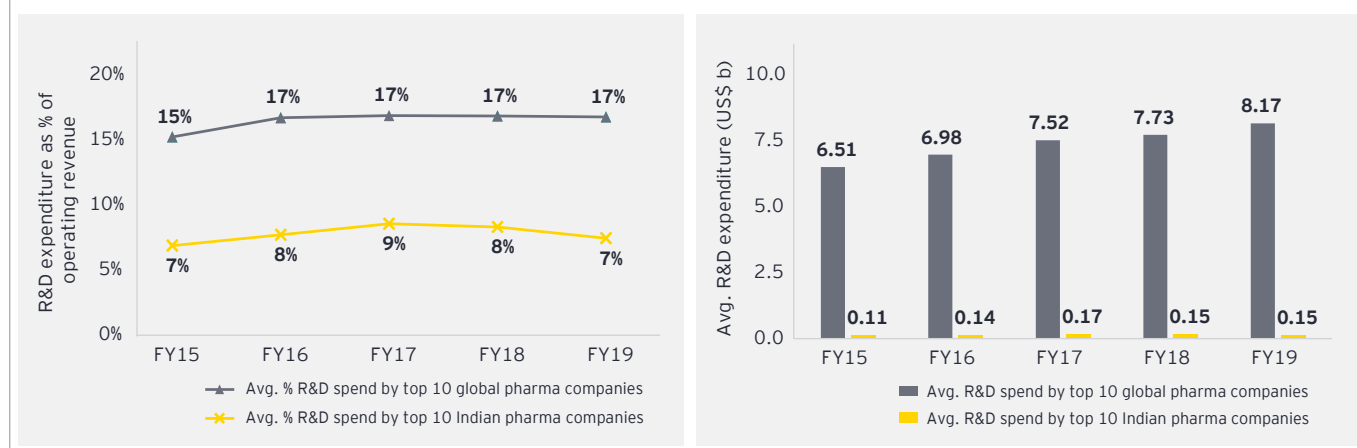
The big pharma /biopharma companies play a very important role not only in drug research and development, but also in realizing the potential of innovation achieved within academia or start-ups, by bringing it to market. The big companies have the onus to boost R&D by promoting both internal innovation (R&D efforts within the organization) and external innovation (R&D projects in partnerships, funding external research projects, etc.).

Internal innovation

The R&D spending trend by the top 10 Indian pharma companies has been stagnant over the last five years (2015-2019). In 2019, the cumulative R&D spending by the top 10 life sciences companies was US\$8.17 billion compared to US\$0.15 billion from the top 10 Indian pharma companies. The difference in spending is significant even if we compare the R&D intensity (R&D spend as a percentage of operating revenues) - the R&D intensity of top 10 global life sciences companies is ~2.5 times that of the top 10 Indian pharma companies⁸⁹.

With the continued focus on generics and biosimilars R&D, the share of novel innovation in the overall R&D investment is already small compared to global counterparts. Hence, there is a need for big companies to reconsider their future portfolio priorities and invest optimally to achieve ambitious innovations.

Figure 26: R&D spend of Indian vs global pharma companies



Sources: Annual reports of Indian pharma companies; Capital IQ Company Screening Report for all Global Companies

Top 10 Indian pharma companies: Sun Pharma, Lupin, Cipla, Dr. Reddy's Laboratories, Glenmark, Aurobindo Pharmaceuticals, Zydus Cadila, Alkem, Torrent, Divis

Top 10 Global pharma companies: Johnson & Johnson, Abbott, Pfizer, Merck, Novartis, Sanofi, Roche, AstraZeneca, GSK, Bayer

External innovation

Life sciences companies globally are challenged by increasingly strained healthcare budgets, patent expiration, increased regulatory scrutiny, and decreasing R&D productivity. In response, Big Pharma has increasingly started to consider sourcing innovation externally through acquisitions/

in-licensing, investments, or in collaboration with smaller biopharmaceutical firms and academia. According to EY analysis, only 45% of all USFDA new drug approvals were won by big pharma companies between 2015 to 2019, and of these approvals about 60% were sourced externally.

Only **45%** of NME FDA approvals were for **Big pharma** between 2015-2019

~55% of all approvals were received by **smaller biotechs**



~60% of the total approvals received by big pharma were externally sourced in this period

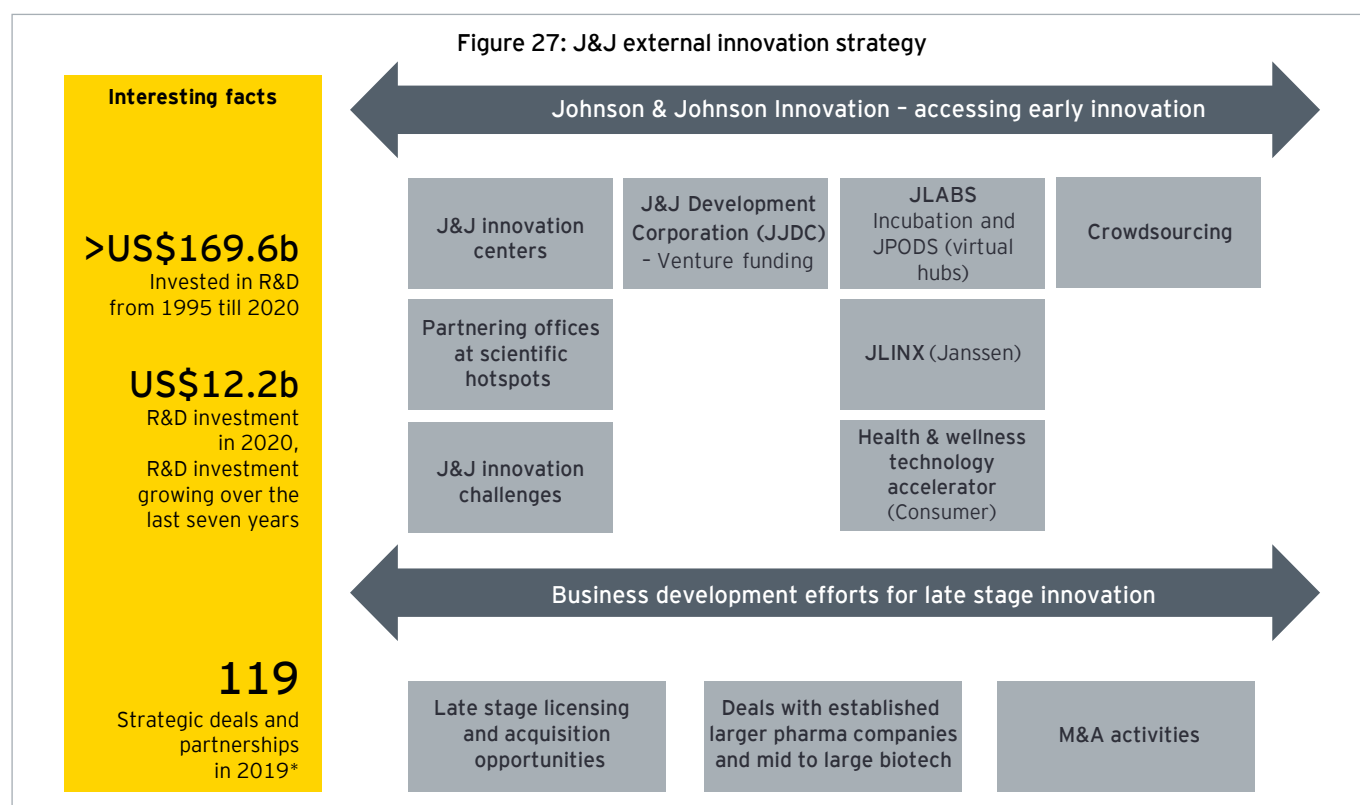
(through collaborations and deals with academia and biotechs)

⁸⁹ Company reports, EY analysis

What could be a better proof than the fact that the first two COVID-19 vaccines approved by the USFDA (i.e., vaccines from Pfizer-BioNTech⁹⁰ and Moderna-National Institute of Allergy and Infectious Diseases⁹¹) – were conceptualized by small biotechs. What has easily taken earlier five-six years for a vaccine development, significant first line of defense against COVID-19 has been achieved in less than a year owing to public private partnership.

Globally, Big Pharma is collaborating with smaller biotechs and academia via several models. Consider the example of Johnson & Johnson. The company has set up an entire framework to

access and support early and late stage innovation externally. Along with traditional mechanisms such as venture funding, J&J Development Corporation (JJDC)⁹², the company has established an ecosystem of 13 incubators (JLABS and JPODS) and 4 innovation centers globally (refer to the figure 27). These incubators and innovation centers have a no-strings attached model, i.e., the start-ups /companies are not required to share their intellectual property or provide any rights. In addition to providing money for setting up working labs and other business infrastructures, the company also provides entrepreneurs with mentoring support and other resources (for example, access to the company's compound library)⁹³.



*Does not include mergers and acquisitions

Source: Company reports

⁹⁰ "FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine" USFDA press announcement, December 2020. Available at: <https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19>

⁹¹ "FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine", USFDA press announcement, December 2020. Available at: <https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid>

⁹² Company website. Available at: <https://njinnovation.com/jjdc>

⁹³ Partnering with Johnson & Johnson, BioWinConnect 22 May, 2019. Available at: <https://www.biowin.org/sites/default/files/inline-files/Johnson%26Johnson.pdf>

Another way major companies attract entrepreneurs is to set up crowdsourcing challenge inviting ideas for innovation in areas where pharma has not historically been strong. Some major Indian pharma companies have also leveraged crowdsourcing techniques to access innovative ideas. For example, Cipla introduced 'Ideate, Innovate, Incubate with

Innoventia' in 2018 to crowdsource and incubate "disruptive" ideas globally across the healthcare spectrum. These concepts ranged across pharma, diagnostics, devices, digital and services. The company incubates, invests, mentors and/or partners with the entrepreneurs who devise the winning ideas⁹⁴.

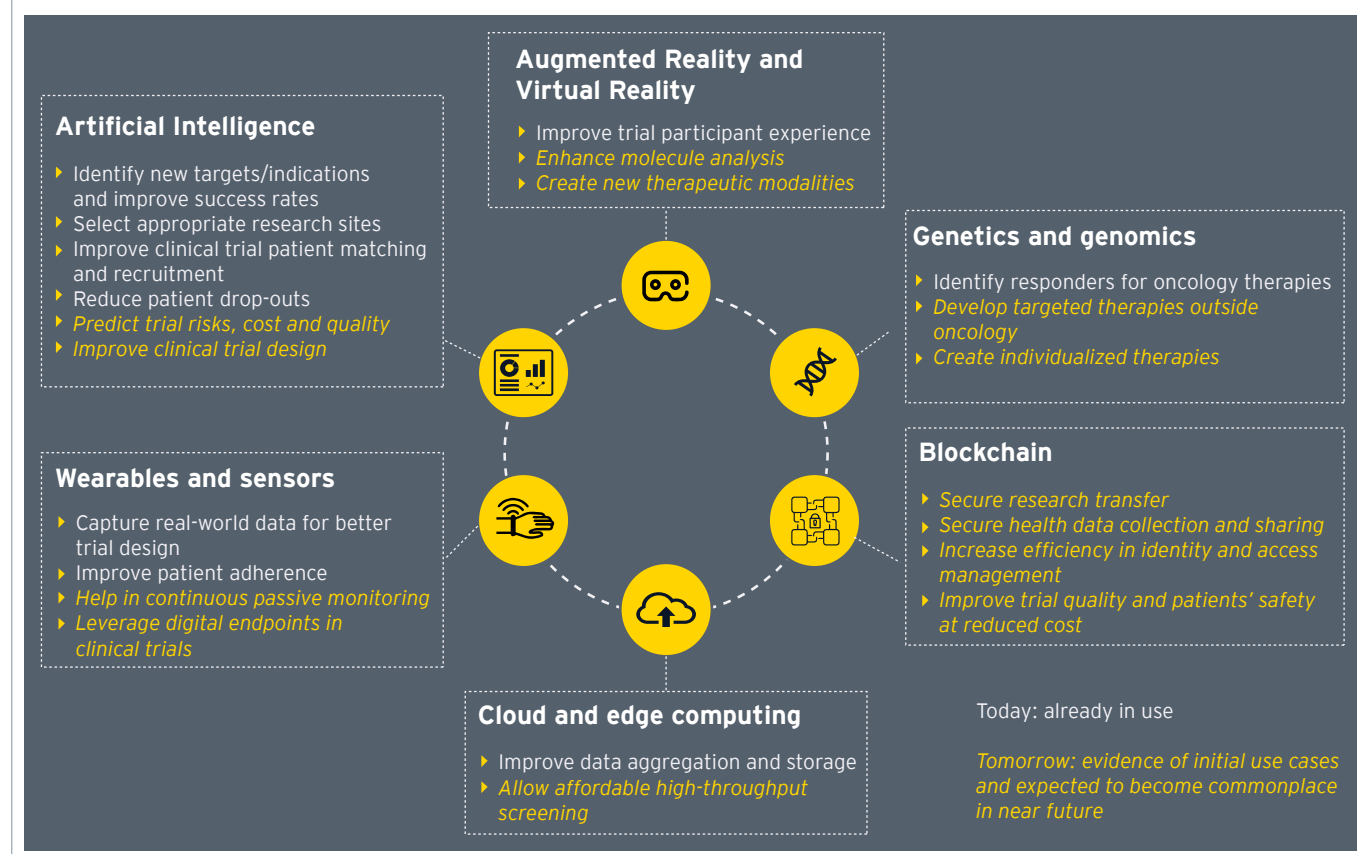
Enablers for boosting research and innovation and strengthening the entire ecosystem

Technology: key enabler across the drug R&D life cycle

All top global pharma companies are leveraging technologies such as artificial intelligence, machine learning, cloud computing, etc. in the drug discovery and research phase to increase productivity and reduce timelines. Clinical development is also becoming virtual. The use of technology during R&D process has only accelerated due to COVID.

Indian companies should also invest in advanced technologies to establish themselves as the preferred global R&D destination and manufacturer of innovative drugs.

Figure 28: Role of advanced technologies in making R&D faster and more cost-effective



*This list is indicative and not exhaustive

Source: EY analysis

⁹⁴ "INNOVENTIA by Cipla plans to invest upto \$15 million in a disruptive healthcare idea", The Economic Times, June 2018. Available at: <https://health.economictimes.indiatimes.com/news/industry/innoventia-by-cipla-plans-to-invest-upto-15-million-in-a-disruptive-healthcare-idea/64448089>

1. Set up advanced infrastructure

Government initiatives

Considering its immense growth potential, biotechnology has been chosen as one of the champion sectors in Make in India initiative⁹⁵. Funds and infrastructure support has been committed under the start-up India initiative.

To provide for specialized facilities required for biopharma research and innovation, government has established incubators and parks for start-ups. The Department of Biotechnology (DBT) has set up nine biotechnology parks and incubators that offer facilities to scientists and small and medium sized enterprises (SMEs) for technology incubation, technology demonstration and pilot studies⁹⁶. The Biotechnology Industry Research Assistance Council (BIRAC) has supported 50 bio-incubators across the country since 2014 to nurture the ecosystem. It has also set up four regional centers to foster and facilitate bio-entrepreneurship and mentor bio-entrepreneurs for transforming innovative biotech ideas into successful and sustainable ventures⁹⁷. The Technology Development Board has funded 36 Technology Business Incubators (TBIs) and Science & Technology Entrepreneur Parks (STEPs) under Seed Support System for start-ups in Incubators⁹⁸.

More of these incubation centers and parks need to be established with a focus on pharma research and innovation. The following measures can be considered to bring in more efficiency in the utilization of existing infrastructure and establishment of new infrastructure.

Efficient utilization of existing infrastructure and establishing new infrastructure

(i) *Synergistic collaboration between all government research bodies*

Different government organizations have launched several initiatives and set up research institutes to support innovation in India. However, these organizations are currently under different departments. For example, the Indian Council of Medical Research (ICMR) is the apex body in India for the formulation, coordination and promotion of biomedical research⁹⁹; the Department of Biotechnology (DoB)¹⁰⁰ and Council of Scientific and Industrial Research (CSIR)¹⁰¹ are under the Ministry of Science and Technology; and the Department of Pharmaceuticals (DoP) is under the Ministry of Chemicals & Fertilizers (MoC&F)¹⁰². NIPERs and other pharma public sector undertakings (PSUs) are under the DoP¹⁰³, while biotech parks are established by the DBT¹⁰⁴, and over 40 labs come under the purview of the CSIR¹⁰⁵, with a further 30 institutes under the ICMR¹⁰⁶.

“

“Multiple agencies (e.g. ICMR / DBT / CSIR, etc.) operate in silos, making central tracking of KPIs harder; also, usage of grants is inaccessible and suboptimal. The government needs to form a central committee with representatives from all relevant agencies that gives direction on research focus areas and encourages collaboration.

R&D head of a leading Indian pharma company —”

⁹⁵ Department of Biotechnology website. Available at: <http://dbtindia.gov.in/schemes-programmes/translational-industrial-development-programmes/make-india-start-india>

⁹⁶ Department of Biotechnology website. Available at: <http://dbtindia.gov.in/schemes-programmes/translational-industrial-development-programmes/biotech-parks-incubators>

⁹⁷ BIRAC website. Available at: <https://birac.nic.in/mii/Map.php>

⁹⁸ Technology Development Board website. Available at: <http://tdb.gov.in/seed-support-scheme/>

⁹⁹ ICMR website. Available at: <https://www.icmr.gov.in/aboutus.html>

¹⁰⁰ Department of Biotechnology website. Available at: <http://dbtindia.gov.in/>

¹⁰¹ Council of Scientific and Industrial Research website. Available at: <https://www.csir.res.in/>

¹⁰² Department of Pharmaceuticals website. Available at: <https://pharmaceuticals.gov.in/>

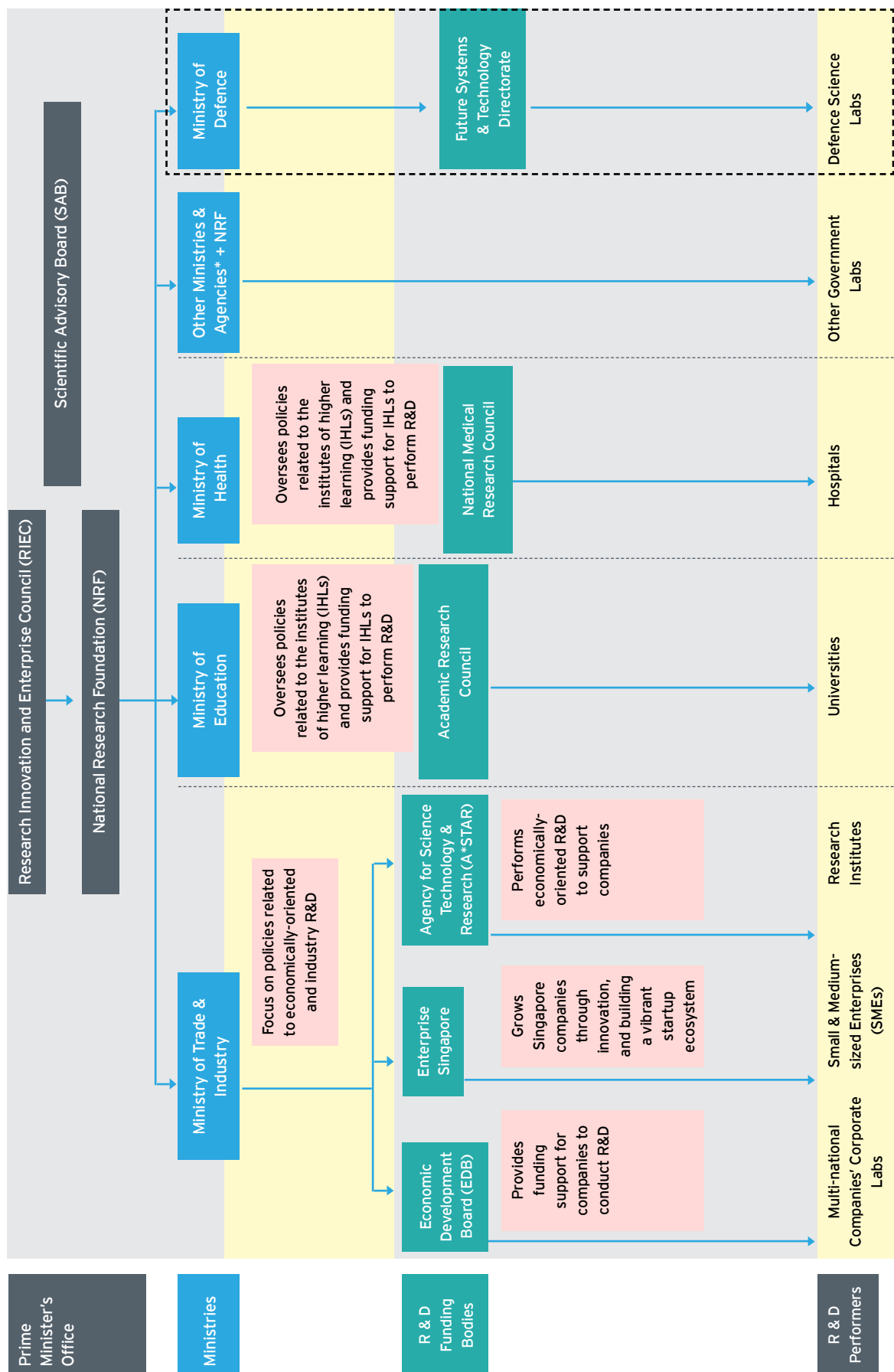
¹⁰³ Department of Pharmaceuticals website. Available at: <https://pharmaceuticals.gov.in/nipers>

¹⁰⁴ Department of Biotechnology website. Available at: <http://dbtindia.gov.in/schemes-programmes/translational-industrial-development-programmes/make-india-start-india>

¹⁰⁵ Council of Scientific and Industrial Research website. Available at: <https://www.csir.res.in/csir-labs>

¹⁰⁶ Indian Council of Medical Research website. Available at: <https://main.icmr.nic.in/institutes>

Figure 29: Research & Development Ecosystem: Singapore



*Ministry of National Development: Runs the National Innovation Challenge on Land and Liveability | Infocomm Media Development Authority: Co-secretariat for the Smart Systems Strategic Research Programme | Smart Nation Program Office: Co-secretariat for the Smart Systems Strategic Research Programme | Singapore National Water Agency: Runs the Clean Water Strategic Research Programme | Energy Market Authority: Runs the Clean Energy Strategic Research Programme

Source: National Research Foundation website

In Singapore, research and development activities are supported by three main pillars: the Research Innovation and Enterprise Council (RIEC), the Scientific Advisory Board (SAB), and the National Research Foundation (NRF)¹⁰⁷.

The RIEC develops policies and long-term strategies aimed at transforming Singapore's capabilities in research and technology. The RIEC is chaired by the Prime Minister and is supported by the SAB. The policies developed by the RIEC are in turn implemented by the NRF which acts as an overarching body overseeing all research and development activities across various technology sectors and ministries under the government of Singapore.

Pertinent to note is that the REIC is comprised of representatives from the government (across multiple ministries), national and international experts from academia and industry. The SAB consists of national and international experts across multiple areas of science and technology¹⁰⁸. The NRF is made up of representatives/bureaucrats from the government, national and international experts from academia and industry¹⁰⁹. Consequently, there is a productive alignment between Singapore's national research and development aspirations as well as industry requirements, which increases possibility of technology commercialization at a later stage.

While academic and medical research are under the purview of the Ministry of Education and Ministry of Health respectively, the Ministry of Trade and Commerce focuses on policies related to economically-oriented and industrial research and development. The Ministry of Trade and Commerce provides funding support for multi-national companies and laboratories to conduct research and development through the Economic Development Board (EDB). The EDB provides companies information on doing business in Singapore, connectivity to potential business partners, insights into the region, and assistance to increase capacity and build new capabilities, in certain cases.

Enterprise Singapore is a statutory board under the Ministry of Trade and Industry in Singapore, established to support small and medium enterprises in Singapore with their activities in the

areas of development, capabilities upgradation, innovation, transformation, and global growth. Agency for Science Technology and Research (A*STAR) is also a statutory board under the Ministry of Trade and Industry in Singapore, which has several institutes under it carrying out economically-oriented research and development activities to support companies. There are other Ministries and Ministry of Defence also which are involved in research activities in other areas and defense respectively.

The Agency for Science, Technology and Research (A*STAR) is Singapore's lead government agency dedicated to advance scientific discovery and technological innovation. The organization's horizontal technology centers develop R&D strategies in four key areas: "Urban and Green", "Artificial Intelligence, Analytics and Informatics", "Health and Medical Technologies", and "Agritech and Aquaculture". These centers pull together multi-disciplinary capabilities cutting across an array of A*STAR research institutes and programs providing R&D capabilities from end to end, across the value chain. Biomedical Research Council (BMRC) and Science and Engineering Research (SERC), along with all the research entities under them, come under the ambit of A*STAR. The agency also has a commercialization arm, A*Ccelerate (commercialization and technology transfer). A*Ccelerate, staffed with IP, technology transfer and commercialization professionals, enables translation of inventions and intellectual capital into marketable products, processes and services. A*STAR Graduate Academy (A*GA) offers a comprehensive suite of undergraduate, PhD and post-doctoral scholarships. The agency also offers collaboration through several models – such as 'many to one strategic partnerships', 'one to one partnerships/projects', 'one to many consortia', 'many to many consortia'. The Joint Planning Hub has representation from different entities of A*STAR. It is responsible for laying down plans and policies for effective implementation of the undertaken projects. The Research Office lends its support by recruiting scientists and researchers, forming a global meld of scientific talent, for the projects under A*STAR.

¹⁰⁷ NRF website. Available at: <https://www.nrf.gov.sg/about-nrf/rie-ecosystem>

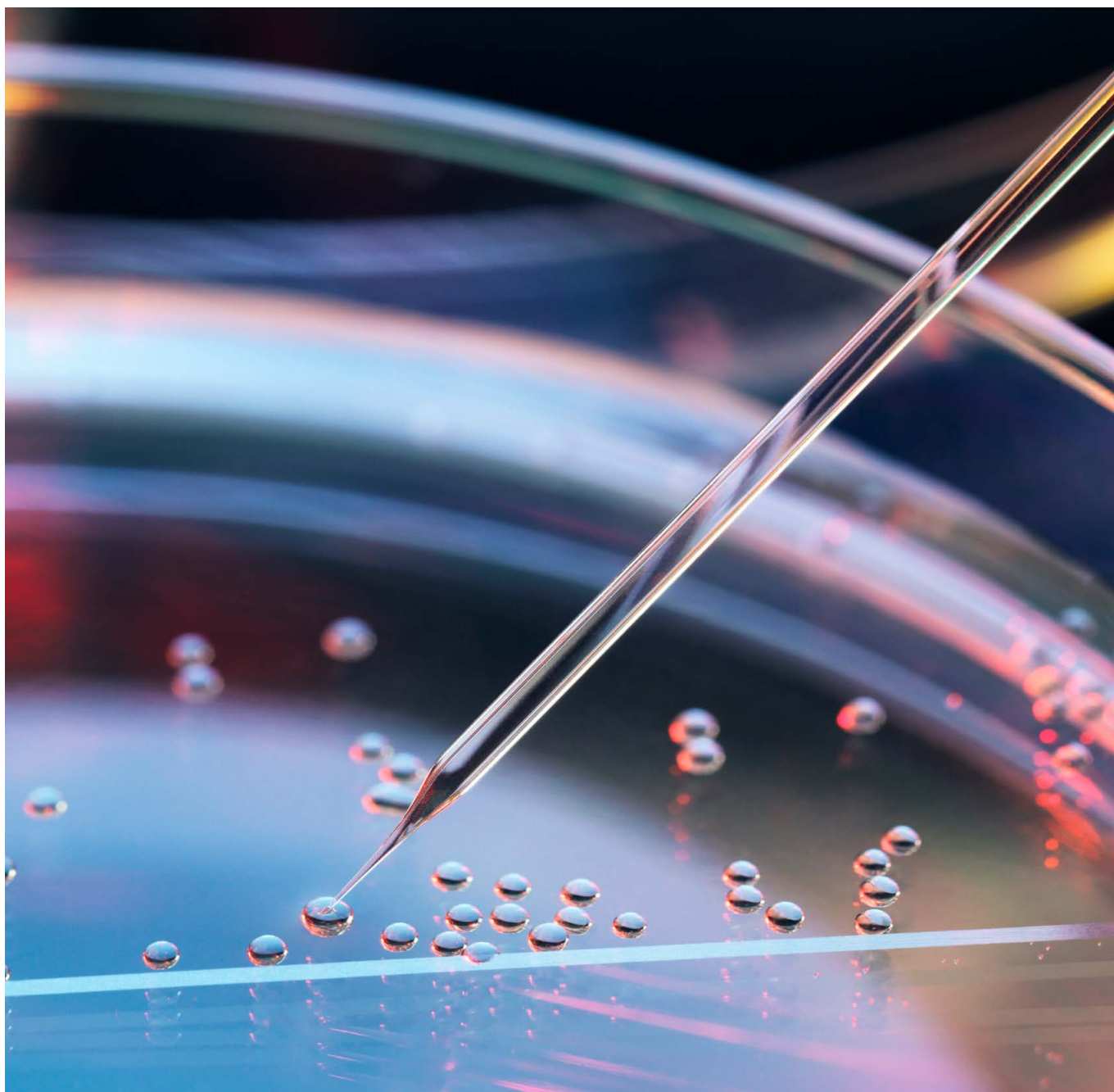
¹⁰⁸ Adviser to NRF, Former President of Nanyang Technological University | 2. Director, Max Planck Institute for Polymer Research | 3. Chairman, Cancer Research UK | 4. Chairman of SAB, Cavendish Professor of Physics, University of Cambridge | 5. President Emeritus, California Institute of Technology | 6. President, Gordon and Betty Moore Foundation | 7. Chief Scientific Adviser for National Security, UK | 8. Adviser to NRF, Former President of Nanyang Technological University | 9. Associate Research Director, The Francis Crick Institute | 10. Senior Vice President, Chief Technology Officer (Artificial Intelligence), Hewlett Packard Enterprise | 11. Former Vice President (Advanced Technologies), GE Global Research Benjamin Peirce Professor of Technology and Public Policy, John A. Paulson School of Engineering and Applied Sciences and Professor of Physics, Emerita, Harvard University | 12. Emeritus Professor, ETH Zurich | 13. Professor of Computer Science and Mathematics, The Hong Kong University of Science and Technology

¹⁰⁹ NRF website. Available at: <https://www.nrf.gov.sg/about-nrf/national-research-foundation-singapore>

National level initiatives are facilities and expertise hosted and managed by A*STAR but funded nationally or by multiple public stakeholders and serve specific national needs, for example, supercomputing, robotics, etc. Joint Institutions are built upon strong public-private partnerships, akin to consortia, comprising members, ranging from global multinational corporations (MNCs) to small and medium enterprises (SMEs), with an aim to accelerate the transfer of innovation from

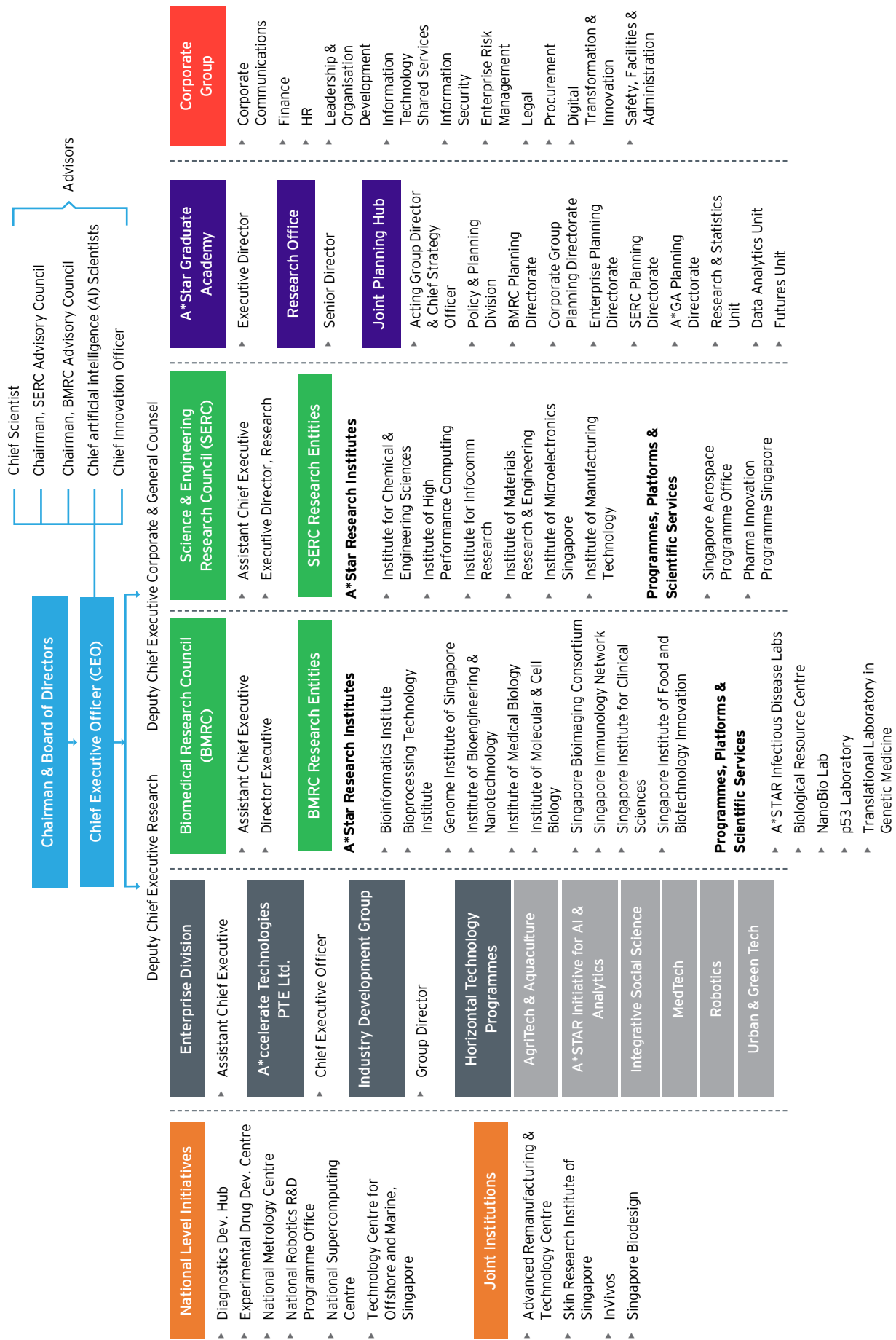
applied research to industrial applications in specific niche areas, for example, manufacturing¹¹⁰.

Overall, the end result is that all economically-oriented and industrial R&D activities come under a single highly effective governance structure with two levels of multiple stakeholder participation, ably supported by an advisory board consisting of experts across the government bodies, academia and industry.



¹¹⁰ A*STAR website. Available at: <https://www.a-star.edu.sg/>

Figure 30: Agency for Science, Technology and Research – Structure



National Institutes of Health (NIH)

Another example of a unified governance structure for research and development is the functioning of institutes focusing on specialized areas under the NIH in the US.

The NIH is the primary medical research agency of the US responsible for biomedical and public health research. All initiatives and research bodies/institutes involved in healthcare research come within the remit of the NIH. Some key aspects and activities of the NIH include:

- ▶ With more than US\$40 billion worth investment annually, the NIH is the largest public funder of biomedical research globally. More than 80% of the funding is awarded for extramural research through almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions across the US¹¹¹.
- ▶ NIH also awards funds to Research Evaluation and Commercialization Hubs (REACH) designed to speed up the translation of biomedical discoveries into commercially-viable diagnostics, devices, therapeutics, and tools to improve patient care and enhance health. The REACH program merges the strengths of high-impact research institutions with product development expertise and resources from federal and private-sector partners.
- ▶ NIH has 27 Institutes and Centers, each with a specific research agenda, often focusing on particular diseases or body systems.
- ▶ The agency has set up a comprehensive intramural and extramural training and talent development infrastructure. Its 'Research Training and Career Development' division offers programs to help prepare individuals for careers in biomedical, behavioral, social, and clinical research. 'NIH Clinical Center' offers trainings for translational and clinician scientists.
- ▶ NIH Office of Technology Transfer (OTT) connects the inventive discoveries made in the Intramural Research Program (IRP), the CDC, and the USFDA to commercial partners that develop these technologies into products and services that benefit public health¹¹².
- ▶ All Centers under NIH have detailed guidelines on procedures and policies. For example, the NIH Center for Scientific Review provides clear guidelines and criteria for applicants

and approvers of grants. The entire grant approval process is transparent, and involves two levels of review. The first level consists of peer review results in scoring of applications, based on multiple parameters including but not limited to significance, investigator, innovation, approach, etc. The second level involves review by an Advisory Council, after which a decision is reached on the approval / rejection of a grant application. This process is standardized across all NIH institutes, and aims to eliminate bias and variations in the grant approval process. Similarly, the OTT division provides details about licensing opportunities, information about royalty for inventors and licensees, and other policies.

(ii) Performance based criteria for funding and support

A central committee can be set up to coordinate national health and life sciences research policy and its implementation. This committee should regularly monitor and periodically audit the performance and relevance of all initiatives (including the performance of the R&D centers and clusters, efficient utilization of the incubators, accessibility to the grants, research projects, funding/grants, and so on) run by the different organizations.

To make the incubator ecosystem more robust and outcome-focused, there should be periodic assessment of the performance of the companies nurtured by the incubator. The incubators that are not performing well could be closed and more funds could be diverted to high performing incubators. The aim for all incubators should be to self-finance their operations over a period of time.

(iii) Non-public and collaborative sources for infrastructure

To further expand the availability of advanced infrastructure and financing, the government could consider more private-public partnerships by leveraging CSR funding¹¹³ or using competitive tendering processes to select private partners for setting up joint incubators. Israel Innovation Authority's (IIA) Technology Incubators Program is a very good example of PPP. The IIA makes the investment and then the private investors join in for running the incubator. These private investors are selected on competitive basis. Similar model is now being implemented in New Zealand and Argentina¹¹⁴.

¹¹¹ NIH website. Available at: <https://www.nih.gov/>

¹¹² NIH website. Available at: <https://www.ott.nih.gov/nih-and-its-role-technology-transfer>

¹¹³ "Decoding contributions to technology incubators under Corporate Social Responsibility", India CSR, July 2016. Available at: <https://indiaccsr.in/decoding-contributions-to-technology-incubators-under-corporate-social-responsibility/>

¹¹⁴ "Can Israel's startup success be replicated elsewhere?", Israel21c, March 2020. Available at: <https://www.israel21c.org/can-israels-startup-success-be-replicated-elsewhere/>

(iv) Set up big parks and clusters

Parks and clusters provide a very good opportunity for increased collaboration between all the different stakeholder groups – academia/research institutions, hospitals/medical institutions, start-ups, big pharma – which is very important for setting up the innovation ecosystem. In addition, the companies and institutions can also benefit by economies of scale in procuring all material (refer to the Massachusetts innovation ecosystem case study, figure 23). To gain efficiency and reduce costs, a centralized system can be set up at a cluster level to provide support services, such as testing and validation services, legal support for intellectual property and patenting, and so on.

Big pharma

The big pharma/biopharma companies can play a larger role in supporting and integrating with the innovation ecosystem. We saw the example of J&J in the previous section. Most global big pharma companies have incubators or entrepreneur support programs across the world.

We are seeing initial developments in this area in India. In early 2020, as a part of its corporate social responsibility (CSR) initiative, Agilent announced funding support for IIT Delhi to set up an incubator site for bioanalytical science. The set up will support incubated start-ups at IIT Delhi to advance efforts in biotherapeutics¹¹⁵. More such initiatives can be taken up by Indian pharma companies and should prove mutually beneficial to them and the aspiring entrepreneurs.

Academia

Academia can play a big role in facilitating entrepreneurs since they have the required infrastructure (space, labs, instruments, etc.), expertise (teachers, mentors, etc.), networks (connections with industry, government support, etc.) and financing from public and private sources. Several examples of successful on-campus incubators have emerged globally, such as Harvard iLab¹¹⁶, Northeastern University's IDEA¹¹⁷, and The Garage at Northwestern University¹¹⁸. Activities in this direction can be seen in some Indian institutions as well, such as the IITs and IISc. Some global universities are now also setting up off-campus, remote incubators within other innovation ecosystems¹¹⁹. This encourages more networking and integration within the ecosystem.

Another interesting new trend is 'co-location' – academic research facilities bringing small companies within their own walls. A good example is the BioFrontiers Institute (University of Colorado) which has designated space to lease to industry partners, allowing local and national biotech companies to bring scientists and resources on-site and work with university students and researchers¹²⁰.

Another advantage of housing incubators in academia is the difference in innovation mindset and end objective. While, for the entrepreneurs the idea of innovation may focus on return on investment, within academia innovation may be able to focus more on experimenting, which is critical for coming up with disruptive ideas and products. Hence, academic incubation centers in collaboration with industry, can serve as the nurturing grounds for some of the most innovative ideas.

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Academic researchers do not see failure, they see challenge, while an entrepreneur sees failure as a loss of money – so the perspective and focus are different.

Many entrepreneurs drop research because of early failure. This can be taken care of by strong partnership with academia. Failure could be taken up as an academia challenge while the industry could utilize successes and take them forward.

Director of a leading Indian pharma company

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¹¹⁵ “Agilent and IIT Delhi sign MoU to set up incubator site for bio-analytical science in Delhi”, Pharmabiz, February 2020. Available at: <http://www.pharmabiz.com/NewsDetails.aspx?aid=121027&sid=2>

¹¹⁶ Harvard innovation labs website. Available at: <https://innovationlabs.harvard.edu/harvard-i-lab/>

¹¹⁷ IDEA website. Available at: <https://www.northeastern.edu/idea/about-us/>

¹¹⁸ The Garage website. Available at: <https://thegarage.northwestern.edu/>

¹¹⁹ “Academic Incubators Think Beyond Campus Borders to Spark Innovation”, The National Law Review, September 2018. Available at: <https://www.natlawreview.com/article/academic-incubators-think-beyond-campus-borders-to-spark-innovation>

¹²⁰ “Biotechnology building debuts state-of-the-art E-Wing”, August 2017. Available at: <https://www.colorado.edu/biofrontiers/2017/08/31/biotechnology-building-debuts-state-art-e-wing>

Access to data for research and innovation

Along with advanced instruments and labs, medical research also requires a huge amount of data. Government can play a very important role in generating and providing access to data required for research. The government could provide platforms for safe sharing of data from different sources, such as epidemiological databases, patient registries, and historical clinical trial data, among others. With strong data protection and sharing infrastructure, the recently launched National Digital Health Mission (NDHM) can provide a large amount of useful data required for advancing research and innovation.

Drug companies should also, without compromising intellectual property, contribute historical drug discovery data and chemical libraries in the form of open repositories or through federated learning models.

One example of this kind of open innovation is a global pharma company that provides free and open access to selected pre-clinical compounds for non-clinical investigation purposes. The molecules have been designated either as Molecules to Order (with no associated cost) or Molecules for Collaboration. Scientists interested in Molecules for Collaboration are invited to submit a research proposal. If the proposal is chosen, the research is developed together with the company scientists.

Federated learning case study: European project MELLODDY – MachinE Learning Ledger Orchestration for Drug Discovery, a drug-discovery consortium – was established in 2019 under public and private partnership between ten leading pharmaceutical companies (Amgen, AstraZeneca, Astellas, Bayer, Boehringer Ingelheim, Servier, GSK, Janssen, Novartis, Merck), top European universities (KU Leuven, the Budapest University of Technology and Economics), four start-ups, and an Artificial Intelligence (AI) computing platform provider. The platform aims to eliminate the tradeoff between data sharing and security by using federated learning and blockchain. Blockchain offers a method to decentralized machine learning in which chemical libraries continue to be stored securely with respective pharma companies and the machine learning based algorithms travel between data sets for training. With access to over a billion data points relevant to drug development, the platform can more quickly and accurately predict promising compounds for development, all without sacrificing the data privacy of the participating companies¹²¹.

2. Financing the complete cycle from idea generation to market launch

Along with infrastructure support, the government is also playing a significant role in financing research and innovation in the country. Several government agencies provide financial support for research and innovation activities to academics, start-ups, small and medium enterprises (SMEs) in several ways such as grants, low interest loans, equity shares, etc.

BIRAC provides financing support for biotech research and innovation across the product life cycle and stakeholder types (e.g., start-ups, academia, students, SMEs). Below is a summary of some key schemes across the product life cycle:

► Ideation to early stage:

- Biotechnology Ignition Grant (BIG): largest early stage biotech funding program in India. Funding grant of up to INR 5m (as grant-in-aid) over a duration of up to 18-month period to young start-ups and entrepreneurs to build and refine idea to proof-of-concept (PoC). INR 250 crore is committed under BIG¹²². The scheme had supported ~400 projects (including 112 new projects during FY18-19), resulting in the creation of more than 100 start-ups and filing of more than 100 IPs till FY18-19¹²³.
- Other schemes include 'Students Innovations for Advancement of Research Explorations' or SITARE (to support innovative student projects¹²⁴) and 'Encouraging Youth for Undertaking Innovative Research through Vibrant Acceleration/E-YUVA (to promote a culture of applied research and need-oriented entrepreneurial innovation among young students and researchers).

► Ideation to late stage (Intensifying the Impact of Industrial Innovation or i4):

for pulling translational ideas from start-ups, SMEs and Limited Liability Partnerships (LLPs) past PoC to validation, scale-up, demonstration and pre-commercialization of products and technologies¹²⁵.

- Small Business Innovation Research Initiative (SBIRI): launched in 2005 to boost Public-Private-Partnership (PPP) efforts. Provides early stage funding for high risk innovative research in SMEs – up to 50 lakhs of 100% grant to primary + collaborating company (if any). For projects more than INR 50 lakhs, grant provided is INR 50 lakhs + 50% of the cost exceeding INR 50 lakhs¹²⁶. SBIRI had supported 217 projects till FY18-19 leading to the creation of 27 IPs and validation/development of 38 products / technologies.

¹²¹ "The MELLODDY project", FierceBiotech, October 2019. Available at: <https://www.fiercebiotech.com/special-report/melloddy-project>

¹²² BIRAC website. Available at: <https://www.birac.nic.in/big.php>

¹²³ BIRAC Annual Report 2018-19. Available at: https://www.birac.nic.in/webcontent/1576450800_birac_annual_report_english.pdf

¹²⁴ BIRAC website. Available at: https://www.birac.nic.in/desc_new.php?id=581

¹²⁵ BIRAC website. Available at: https://www.birac.nic.in/birac_i4.php

¹²⁶ BIRAC website. Available at: https://www.birac.nic.in/desc_new.php?id=217

- ▶ Biotechnology Industry Partnership Programme (BIPP): a government partnership with industries for support on a cost sharing basis for path-breaking, high-risk research on identified national priority areas. It supports validation, demonstration and pre-commercialization of product and technologies. Funding of 50% of the total project is provided irrespective of the amount with focus on IP creation and ownership retained by the Indian industry and collaborating scientists, wherever relevant¹²⁷. BIPP had supported 214 projects till 31st March, 2020 leading to creation of 31 IPs and validation/development of 52 products/technologies.
- ▶ Promoting Academic Research Conversion to Enterprise (PACE): supports academia to develop technology/product of societal/ national importance up to PoC stage and its subsequent validation by an industrial partner.
 - ▶ Academic Innovation Research (AIR): promotes development of PoC for a process/product by academia with or without industry involvement.
 - ▶ Contract Research Scheme (CRS): aims at validation of a process or prototype developed by the academia by the industrial partner¹²⁸.

PACE had supported 71 projects till FY18-19 leading to creation of 2 IPs and development of 7 products / technologies.
- ▶ Equity funding:
 - ▶ Sustainable Entrepreneurship And Enterprise Development (SEED) Fund: funding support of INR 200 lakhs to selected incubators under BIRAC's Bio-NEST Scheme. These incubators then provide equity support of up to INR 30 lakhs to the most innovative start-ups in the incubators until they are able to raise investments from angel/VC or loans from commercial banks /financial institutions¹²⁹.
 - ▶ Launching Entrepreneurial Driven Affordable Products (LEAP) Fund: funding support of INR 5 crore is provided to selected BioNEXT Bioincubators. The Bioincubator uses the fund to invest up to INR 1 crore per start-up against equity and equity linked instruments. The aim is to enable the selected most innovative start-ups to pilot/ commercialize their products/technologies¹³⁰.
 - ▶ Accelerating Entrepreneurs (AcE) Fund: an equity "Fund of Fund" exclusively for Biotech start-ups. AcE daughter funds are SEBI registered private funds to invest equity in start-ups. AcE Fund makes a maximum capital commitment of up to INR 30 crores or up to 30% of the total aggregate capital commitment amount in each AcE daughter fund. Funding of INR 7 crores is provided to a start-up against equity. The AcE daughter fund invests at least twice the amount contributed by the AcE Fund¹³¹.
 - ▶ Product Commercialization Program Fund (PCP Fund): provides financial support for test-validation in targeted markets and large-scale commercialization once the technology/product is market ready¹³².
 - ▶ Intellectual Property (IP) and Technology Transfer (TT): Patent Assistance Funding Scheme provides assistance for IP protection.

Financing incentives and aids for research and innovation are also provided by other government bodies such as DST, CSIR, DSIR, etc. Challenge grants are also becoming popular, such as 'Grand Challenges India' for healthcare solutions for poor is funded jointly by the Bill & Melinda Gates Foundation and DBT, and implemented by BIRAC¹³³. Like BIRAC, the pharmaceutical industry needs more funding options.

While the government's role as a benefactor through direct benefit transfers (DBTs) for R&D is key to unlocking an innovation mindset in India, it is critical that all funding initiatives are disbursed keeping highly qualified criterions set out by a panel consisting of senior government authorities, industry veterans with proven expertise in evaluating such projects. Financial experts should minutely track outcomes and KPIs to ensure that the entire money allocated in the form of grants or funds is completely accounted for.

¹²⁷ BIRAC website. Available at: https://www.birac.nic.in/desc_new.php?id=216

¹²⁸ BIRAC website. Available at: https://www.birac.nic.in/desc_new.php?id=286

¹²⁹ BIRAC website. Available at: <https://www.birac.nic.in/seedFund.php>

¹³⁰ BIRAC website. Available at: <https://www.birac.nic.in/leapFund.php>

¹³¹ BIRAC website. Available at: <https://www.birac.nic.in/aceFund.php>

¹³² BIRAC website. Available at: https://www.birac.nic.in/desc_new.php?id=629

¹³³ BIRAC website. Available at: <https://www.birac.nic.in/grandchallengesindia/program.php?pid=5>

Innovative funding mechanisms

Long gestation period, excessive risk and uncertainty are the key reasons for limited financing by private investors in life sciences research and innovation, especially during the initial phase of research. The threat of binary risk in the late stages in terms of regulatory approvals adds an extra layer of risk.

To ensure that the life sciences start-ups/entrepreneurs and smaller firms sustain the entire research and innovation period, it is important to adopt some innovative financing and risk-sharing mechanisms. To further increase the availability of financing from public and private sources for research and innovation, especially for truly innovative and high-risk projects, the government should explore and consider some funding models leveraged by other developed and developing countries. The section below discusses a few of such practices.

► Financing options beyond simple grants

- Convertible grants: can be in the form of repayable grant or innovation credit. The repayment is conditional on the success—either technical or commercial—of the innovation project. In another approach, grant can be converted into a loan if the project is successful – for example under the Malaysian Cradle Fund¹³⁴.
- Crowdfunding: a mechanism through which the general public can financially support nascent ideas and entrepreneurs. Crowdfunding can be in the form of donations, loans or equity. Between 2014 and 2015, equity crowdfunding increased by 295% in the UK. In 2015, US\$150b was generated globally through crowdfunding. Capital Cell is Europe's First Dedicated Life Sciences Crowdfunding Platform. It supports early stage companies, with seed stage investment up to £1m.

► Initiatives to boost private investment

- Co-investing with private entities in venture funds: an example is HK\$2b Innovation and Technology Venture Fund (ITVF) launched by the Innovation and Technology Commission (ITC) of Hong Kong in 2017 to encourage VC fund investment in local I&T start-ups. Local or overseas VC funds can become ITVF co-investment partners. VC funds are selected based on a number of criteria

and advice from an independent Advisory Committee comprising of veterans from the business and investment sectors, professionals and academics. The government and each VC fund invest in an approximate ratio of 1:2.

A similar initiative, VentureEU – a €2.1 billion funds-of-funds program, was launched by the European Investment Fund (EIF) and European Commission (EC) in 2016

Israel's Yozma, was another similar successful initiative established by the Israel government in 1993. Yozma invested around \$80m for 40% stake in 10 new VC funds. To further attract foreign investors, the program offered them insurance covering 80% of the downside risk and gave them the option to buy out the government's share at a discount within five years (which was later exercised in eight of the funds)¹³⁵.

- Guarantee programs to mobilize private investment: an example is the European Fund for Strategic Investments (EFSI) – a €21b guarantee program launched in 2015 by the European Investment Bank (EIB) and European Investment Fund (EIF) to trigger €315 billion of additional investment in a three-year duration (till mid-2018). With EFSI support, the EIB Group provides funding for economically viable projects, especially those with a higher risk profile than usually taken on by the bank¹³⁶. After exceeding the initial goal and getting extension of two years, EFSI 2.0 has now also exceeded its second target of supporting €500 billion in investment by 2020¹³⁷.
- Encourage public/private investment in highly innovative, high-risk, long-term ventures
 - Patient capital: it is used to fund early-stage high-risk technology companies, including those involved in healthcare research, with a more long-term view. The UK already has several patient investors¹³⁸. The UK Treasury, in fact, launched the Patient Capital Review in 2017 to provide insights on applicability of such models on developing clusters. In 2018, British Patient Capital (BPC) was launched under British Business Bank (BBB) with £2.5b to invest over 10 years to enable long-term investment in high growth potential companies across

¹³⁴ "Financing Business Innovation - A Review of External Sources of Funding for Innovative Businesses and Public Policies to Support Them", World Bank Group. Available at: <https://openknowledge.worldbank.org/bitstream/handle/10986/23140/91713.pdf?sequence=2&isAllowed=y>

¹³⁵ "What Makes Israel's Innovation Ecosystem So Successful", Forbes, January 2017. Available at: <https://www.forbes.com/sites/davidyin/2017/01/09/what-makes-israels-innovation-ecosystem-so-successful/?sh=4574025370e4>

¹³⁶ EIB website. Available at: <https://www.eib.org/en/efsi/what-is-efsi/index.htm>

¹³⁷ EIB website. Available at: <https://www.eib.org/en/efsi/index.htm>

¹³⁸ T. Hickson, "Patient Capital: A new way of funding the commercialisation of early-stage UK science. Available at: https://www.imperial.tech/media/uploads/files/Patient_Capital_UK_Science_Funding.pdf

the UK¹³⁹. Within a year of its launch, BPC had already collected >£1b and delivered to private VC firms to invest on its behalf¹⁴⁰. Another aim of BPC is to encourage more investors in this asset class by demonstrating that a long-term patient capital investment strategy can produce attractive financial returns. BPC is also working alongside institutional investors to unlock an additional £5b of patient capital investment, making the total corpus a £7.5b¹⁴¹.

With much more patient capital at hand, Sovereign Wealth Funds (SWFs) are best suited to invest in firms with longer incubation times, including healthcare. SWFs are also contributing to the effort of de-risking innovation. Examples include the Russian Direct Investment Fund, the Ireland Strategic Development Fund, and the Abu Dhabi Investment Authority, which are playing a pivotal role in implementing their government's innovation policies¹⁴².

- ▶ Evergreen VC funds: unlike most VC funds, evergreen VC funds have no fixed-term closing date. Syncona (owned by the Wellcome Trust) in the UK is an example of this model, alongside many corporate-owned VC funds such as by Roche, J&J, GSK and Pfizer. They invest for strategic and financial reasons, such as, access to the 'next big thing', horizon scanning etc¹⁴³.
- ▶ Venture debt: a long-term financing provided to an early-stage, usually venture-backed company. For example, EIB offers venture debt to support small, high-risk, highly innovative companies in sectors such as life sciences, biotech, software, 3D printing, robotics, clean technologies and artificial intelligence¹⁴⁴. In addition to being a source of non-dilutive funding for innovator companies, this is also seen by other investors as a quality stamp helping the project attract additional investors¹⁴⁵.
- ▶ Risk-sharing schemes: for example, Serbia has a matching grant program with option for royalties in case of success. The program, sponsored by the Serbian government,

aims to incentivize innovative micro, small and medium enterprises (MSMEs) and stimulate commercialization of R&D. The grant under the program covers a maximum of 70% of total project costs for micro and small enterprises and a maximum of 60% of total project costs for medium sized enterprises, up to a total budget of €300,000 of the budget for a two-year period. The minimum of 30% of the total budget is provided by the grant recipient. Royalty payments are made by the company in the event of successful outcome of funded project (i.e., the project results in any generated revenue)¹⁴⁶.

- ▶ Innovation procurement: can drive innovation from the demand side. It is primarily of two types – pre-commercial procurement (PCP) and public procurement of innovation (PPI). PCP is a way of procuring R&D services aimed at developing innovative solutions in areas where no commercial solutions yet exist. PPI is a way of procuring solutions that are close to the market (R&D is not required) and the public sector acts as launching customer/early adopter. In addition to the benefits of getting first customers with shared risks and benefits, shorter time to market, faster growth and economics of scale, the innovator also benefits by getting more financing from private investors as the PCP acts as a signaling device about the quality and future market potential (including government) of a firm's innovation project. The policymaker, while promoting innovation and economic development, also benefits by getting better solutions to existing challenges at lower cost and with reduced risk.

An example is the Small Business Innovation Research (SBIR) – a PCP scheme introduced in the US in 1982. SBIR mandates use of 2.5% of the federal R&D budgets from all government departments and agencies with large R&D budgets to contract R&D services from SMEs. According to a study by Lerner (1999) on the impact of the SBIR program, the SBIR awardees performed better one

¹³⁹ British Private Equity & Venture Capital Association (BVCA) website. Available at: <https://www.bvca.co.uk/Policy/Political-Engagement/Patient-Capital-Strategy>

¹⁴⁰ "UK taxpayers pour £1bn into venture investments via BPC", Private Equity News, November 2020. Available at: <https://www.penews.com/articles/uk-taxpayers-pour-1bn-into-venture-investments-via-bpc-20201109>

¹⁴¹ BBB website. Available at: <https://venturecapital.news/british-business-bank/british-patient-capital/>

¹⁴² "Global Innovation Index 2020", WIPO. Available at: https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2020.pdf

¹⁴³ T. Hickson, "Patient Capital: A new way of funding the commercialisation of early-stage UK science. Available at: https://www.imperial.tech/media/uploads/files/Patient_Capital_UK_Science_Funding.pdf

¹⁴⁴ "EIB becomes the largest venture debt investor in Europe", March 2018. Available at: <https://www.eib.org/en/press/all/2018-070-first-eib-venture-debt-summit-eib-becomes-the-largest-venture-debt-investor-in-europe>

¹⁴⁵ EIB website. Available at: <https://www.eib.org/en/products/equity/venture-debt.htm>

¹⁴⁶ Innovation Fund website. Available at: <http://www.inovacionifond.rs/programs/matching-grants-program/public-call-for-the-matching-grants-program>

decade after their involvement in the program (in terms of employment and sales growth) than unsupported firms¹⁴⁷. UK also has Small Business Research Initiative (SBRI) PCP under Innovate UK¹⁴⁸. SBRI NHS is specifically for accessing innovative solutions to solve healthcare related unmet needs¹⁴⁹. European commission also has a huge focus on innovation procurement under PPI and PCP. Horizon 2020 – the biggest EU Research and Innovation program with €80b of funding between 2014-2020 – provides funding to start innovation procurements. This funding is targeted at potential buyers of innovative solutions: groups of public procurers, possibly together with other types of procurers that are providing services of public interest and have similar procurement needs (e.g., private, NGO procurers)¹⁵⁰. The European Commission has also launched European Assistance For Innovation Procurement to provide local assistance to public procurers to start new innovation procurement and to promote good practices and reinforce the evidence base on completed innovation procurements¹⁵¹.

Role of academia/research institutions and big pharma

In addition to grants from the government, academia and research institutions can also aim to self-finance a portion of the research and innovation activities by generating money through selling/licensing of in-house innovation, or working in collaboration with pharma companies for research in a specific area. Other innovative ways can also be explored, for example IIT Delhi's Global Alumni Endowment Fund launched in 2019. The endowment model aims to achieve a target corpus of US\$1b over a period of seven years (starting 2019) and will

work towards the development of the University and nurturing innovation (including scholarships)¹⁵². The fund will be powered by donations from alumni, industry and philanthropy. The program has been developed after studying the existing endowment systems of US Universities and other leading world institutes. Similar endowment funds may soon be launched by other esteemed Indian institutions as well¹⁵³.

Big pharma should also play a larger role in supporting and enabling the innovation ecosystem. We have discussed earlier in the chapter about the VC arms and incubators set up by most of the global life sciences companies.

3. Government support – policy and regulations

Several steps can be taken to further strengthen the regulatory framework and expedite the development and launch of new drugs.

(i) Establish an overarching regulatory body

Consideration should be given to restructure the existing drug approval process in India in line with other mature regulatory systems, for example, the US.

In the US, the US Food and Drug Administration (USFDA) is the government agency within the US Department of Health and Human Services (HHS) responsible for reviewing, approving and regulating medical products, including pharmaceutical drugs and medical devices. It also regulates various other products, including food, cosmetics, veterinary drugs, radiation-emitting products, biological products and tobacco¹⁵⁴.

¹⁴⁷ "Financing Business Innovation – A Review of External Sources of Funding for Innovative Businesses and Public Policies to Support Them", World Bank Group. Available at: <https://openknowledge.worldbank.org/bitstream/handle/10986/23140/91713.pdf?sequence=2&isAllowed=y>

¹⁴⁸ "Innovate UK funding competitions". Available at: <https://www.nibusinessinfo.co.uk/content/small-business-research-initiative-sbri>

¹⁴⁹ SBRI healthcare website. Available at: <https://sbrihealthcare.co.uk/>

¹⁵⁰ European commission website. Available at: https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/innovation-procurement_en.htm

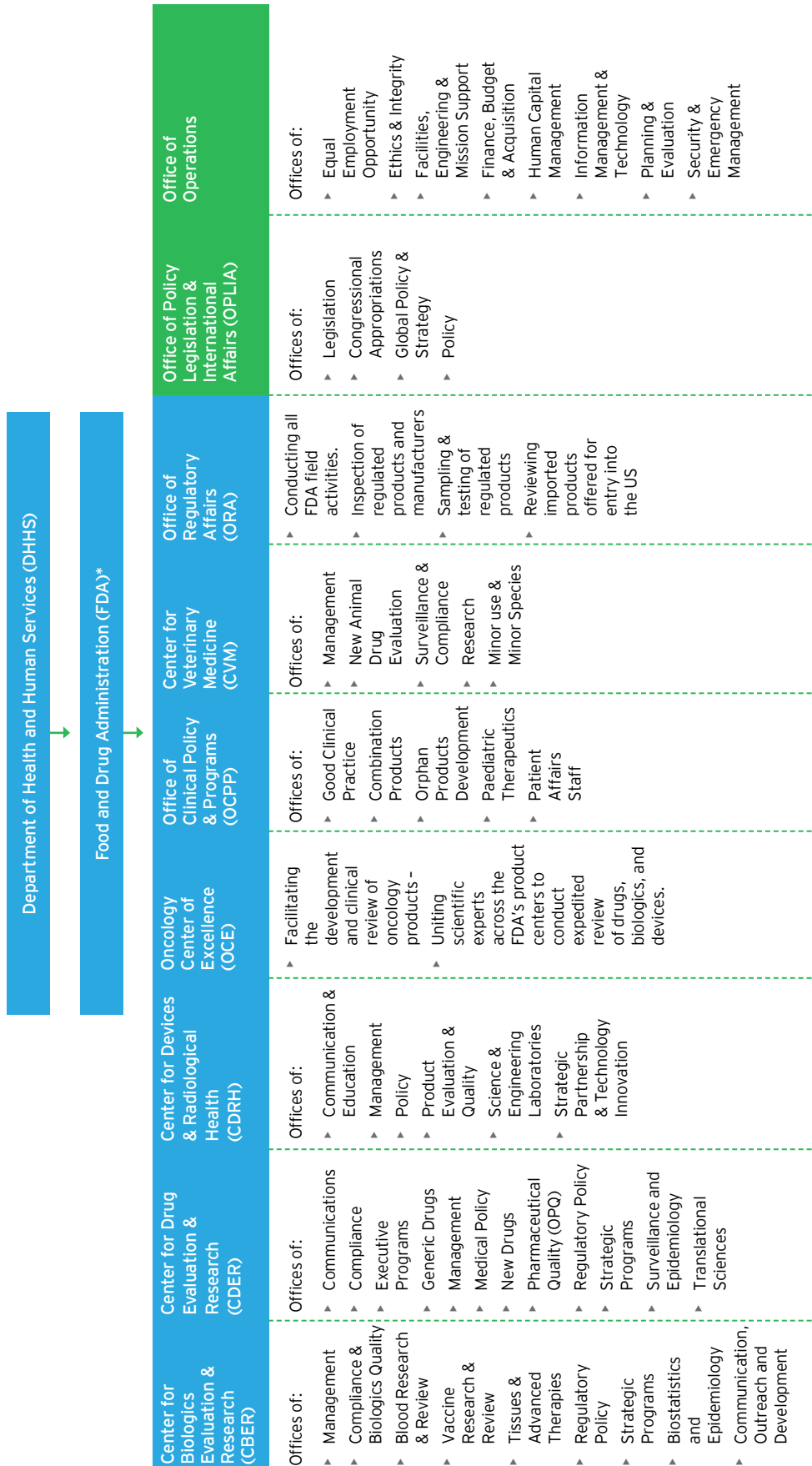
¹⁵¹ EAFIP website. Available at: <https://eafip.eu/about/>

¹⁵² "IIT Delhi Launches Global Alumni Endowment Fund" PR Newswire, November 2019. Available at: <https://www.prnewswire.com/in/news-releases/iit-delhi-launches-global-alumni-endowment-fund-875239256.html>

¹⁵³ "Now, all IITs, IIMs will launch endowment funds to tap successful alumni for donations", ThePrint, March 2020. Available at: <https://theprint.in/india/education/now-all-iits-iims-will-launch-endowment-funds-to-tap-successful-alumni-for-donations/374137/>

¹⁵⁴ HHS website. Available at: <https://www.hhs.gov/>

Figure 31: United States Food and Drug Administration – structure



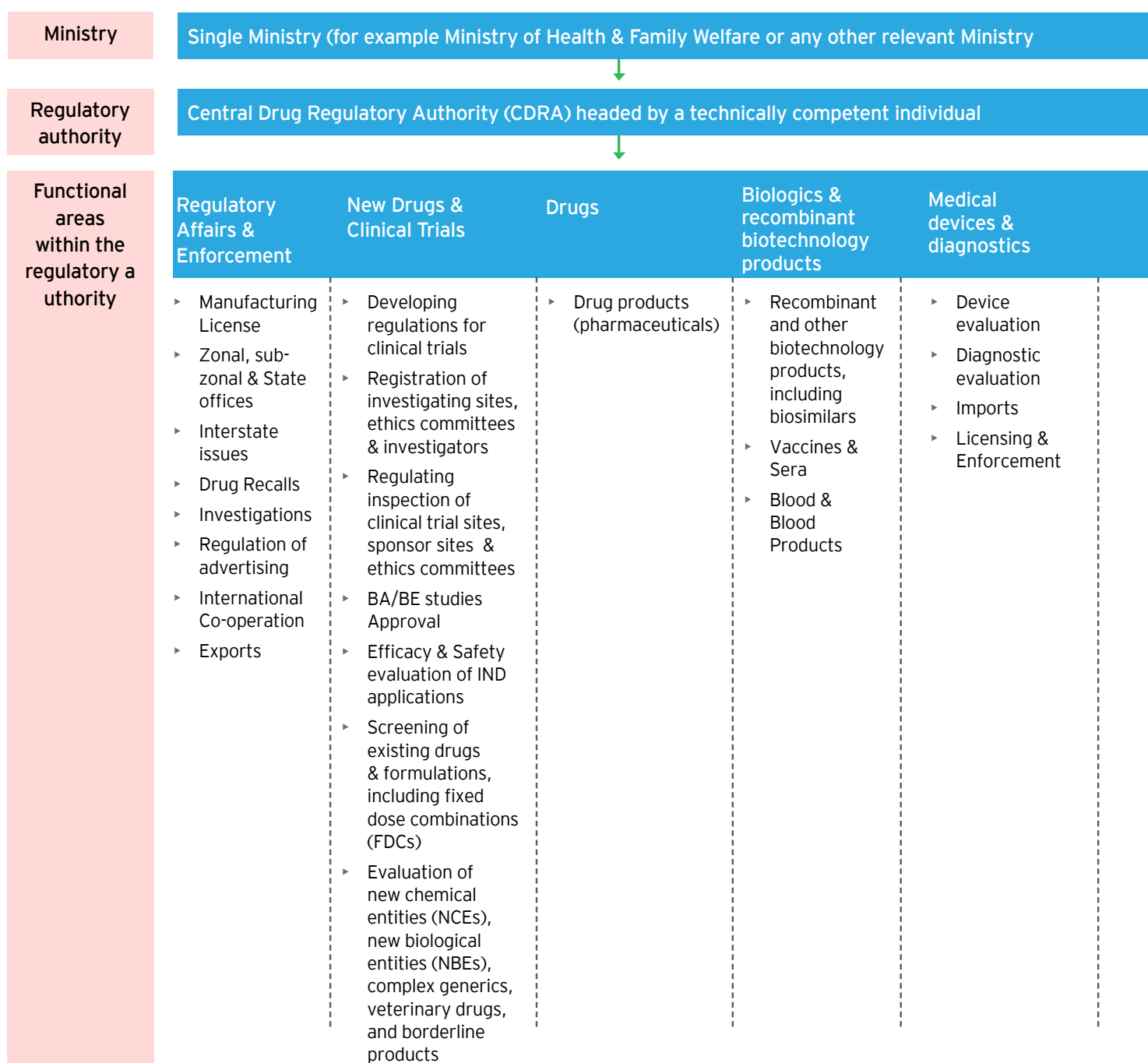
* In addition to the above 9 Centers / Offices, there are other Centers / Offices within the USFDA whose focus is not drugs or devices. These include: (1) Center for Food Safety & Applied Nutrition (CFSAN), (2) Center for Tobacco Products (CTP), (3) Office of External Affairs (OEA), (4) Office of Food Policy & Response (OFPR), (5) Office of Minority Health & Health Equity (OMHHE), (6) Office of the Chief Scientist - National Center for Toxicological Research (NCTR), and (7) Office of Women's Health

Cater to external stakeholders

Cater to internal stakeholders

India should consider establishing a single Central Drug Regulatory Authority (CDRA) with overall ownership of all regulatory functional responsibilities. Consider restructuring State Drug Regulatory Authorities (SDRAs) as Regulatory Affairs and Enforcement Divisions of the CDRA across states, reporting directly to the Head of the CDRA, who is a technically competent individual, as represented below:

Figure 32: Consideration for restructuring drug regulatory setup in India – illustrative structure



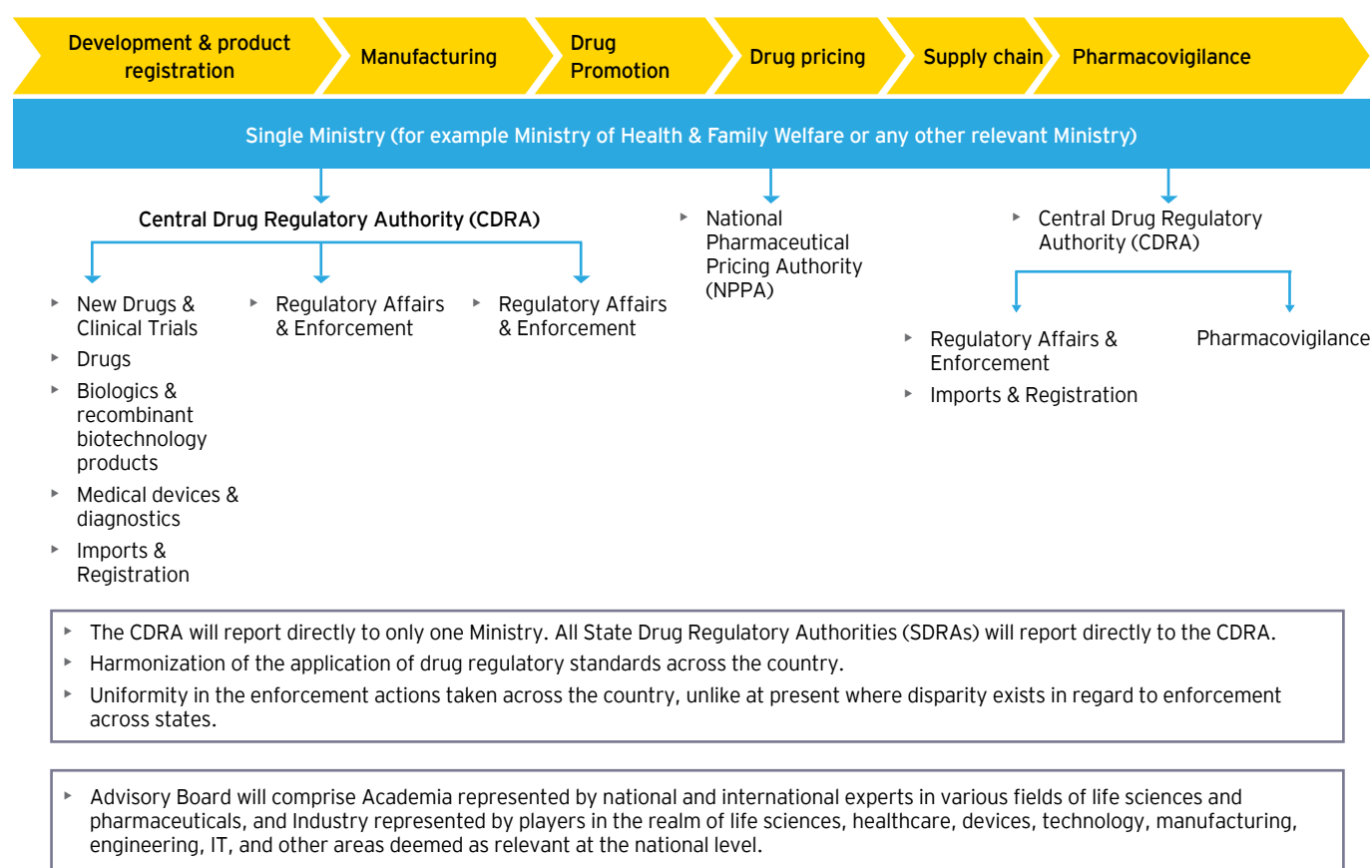
Source: EY analysis

Imports & Registration	Pharmacovigilance	Quality Control Affairs	Legal & Consumer Affairs	Training & Upskilling	Organizational Services
<ul style="list-style-type: none"> ▶ Registration of overseas manufacturing ▶ Overseas inspection ▶ Import licences ▶ Quality assessment of imported products ▶ Managing Port offices 	<ul style="list-style-type: none"> ▶ Safety monitoring of drugs & devices ▶ National Pharmacovigilance Advisory Committee 	<ul style="list-style-type: none"> ▶ Managing all testing laboratories at Central & State level ▶ Monitoring State & private laboratories ▶ Audits & accreditation ▶ Drug Standards ▶ Indian Pharmacopoeia ▶ Harmonization 	<ul style="list-style-type: none"> ▶ Court cases ▶ Parliamentary Affairs ▶ Public complaints ▶ Website ▶ Licensing information ▶ Press & public relations ▶ Publications ▶ Consumer information 	<ul style="list-style-type: none"> ▶ Planning & forecasting ▶ Training evaluation & impact assessment 	<ul style="list-style-type: none"> ▶ Administration ▶ Accounting ▶ Planning & finance ▶ Information technology ▶ Other Supporting functions
Cater to external stakeholders		Cater to internal stakeholders			

Consideration needs to be given for restructuring drug regulatory setup in India across the pharmaceutical value-chain from Development & Product Registration to Pharmacovigilance. The entire value chain can come under one Ministry with Central Drug Regulatory Authority (CDRA) and National Pharmaceutical Pricing Authority (NPPA) as independent regulatory bodies under the said Ministry. All

State Drug Regulatory Authorities (SDRAs) report directly to the CDRA as a part of the Regulatory Affairs and Enforcement Division of the CDRA across states. This will lead to harmonization of the application of drug regulatory standards across the country. Importantly, one envisages uniformity in enforcement actions taken across the country, unlike at present where disparity exists regarding enforcement across states. This is represented in the figure below:

Figure 33: Consideration for restructuring drug regulatory setup in India - illustrative structure



Source: EY analysis

(ii) Develop a formal, well-defined framework for collaboration between product developers and the regulatory authority

It is necessary that clear and detailed guidelines are developed reflecting the expectation of the regulatory authority in terms of information to be provided in different kinds of regulatory submissions. Established timelines should have provisions for limited extension of time for submission of information by the applicant / sponsor. There should be a process in place for formal well-defined pre-submission meetings between the

regulatory authority and sponsors/ stakeholders. This would not only result in saving time and money but will also reflect the overall efficiency of the drug approval system.

Mature regulatory jurisdictions have a formally-defined mechanism in place for discussion with the sponsor prior to the sponsor making their submissions. For example, the USFDA released detailed guidance in 2017 on improving the agency's interactions with product developers. Guidance on 'Best Practices for Communication Between IND Sponsors and USFDA During Drug Development' describes best

practices and procedures for timely, transparent and effective communication. It includes details about the scope of appropriate interactions between the agency's review staff and IND sponsors, the types of advice sponsors can seek from the USFDA, general expectations for the USFDA's response time, and best practices, appropriate methods and frequency of USFDA-sponsor interactions. Guidance has also been provided about whom the sponsor should consult in case timely feedback is not received on inquiries¹⁵⁵.

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Most developed regulatory agencies provide a mechanism for a formal pre-submission scientific discussion with the sponsor. This is especially true for products for rare diseases where it is really a joint development between the regulatory body and the sponsor, not financially but from regulatory, strategic, and scientific perspective.

Working jointly with the regulatory body reduces the chances of misalignment on the requirements during the submission process. This is currently lacking in India.

R&D head of a leading Indian pharma company —

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(iii) Establish regulatory process and capabilities for end-to-end management of clinical trials

Jurisdictions with highly developed regulatory systems proactively provide guidance on the conduct of clinical trials. For example, the USFDA provides guidance on various considerations to be taken while conducting clinical trials, such as but not limited to: general considerations, statistical principles for clinical trials, choice of control group and related issues in clinical trials¹⁵⁶, and more recently, considerations

for clinical trials and guidance on the conduct of clinical trials of medical products during the COVID-19 pandemic¹⁵⁷. There is dedicated office and staff for evaluation of clinical trial documents, and to conduct inspections at investigator / sponsor sites, and ethics committees. They have the requisite manpower with necessary competencies across the above multi-functional domains.

India should also consider providing clear and detailed guidance on clinical trials, covering various age groups and product categories, in addition to general guidance on clinical trials. Special training should be provided to enhance personnel competencies to facilitate efficient conduct of regulatory duties. Selected manpower from existing staff can be upskilled for this activity, while also looking to actively recruit personnel with requisite competencies. Global experts and industry veterans can be included in review committees to bring in a global perspective.

(iv) Create detailed guidelines for drug development process and submission requirements

As more companies start building their pipelines with biosimilars, the regulatory body should come up with guidance on the most appropriate methodology for developing drugs and presenting the evidence needed to support the approval. For example, the Office of Generic Drugs (USFDA) publishes Product-Specific Guidance for Generic Drug Development to share the USFDA's current thinking, and requirements for generic drug development in specific therapy areas¹⁵⁸. Recently the regulatory body has come up with similar initiatives for complex generics as well, and also launched master protocols for efficient clinical trials, intended to expedite development of cancer drugs and biologics¹⁵⁹.

India should set up expert committees to deliberate on the specific nuances that would need to be taken into consideration for complex generics and biosimilars to provide required evidence to obtain regulatory approval.

¹⁵⁵ "Best Practices for Communication Between IND Sponsors and FDA During Drug Development" report on the USFDA website. Available at: <https://www.fda.gov/media/94850/download>

¹⁵⁶ USFDA website. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-trials-guidance-documents>

¹⁵⁷ "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency" report on USFDA website. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency>

¹⁵⁸ USFDA website. Available at: <https://www.accessdata.fda.gov/scripts/cder/psg/index.cfm>

¹⁵⁹ "FDA issues 34 new and revised product-specific guidances", Regulatory Affairs Professional Society, November 2020. Available at: <https://www.raps.org/news-and-articles/news-articles/2020/11/fda-issues-34-new-and-revised-product-specific-gui>

Practices during COVID-19

During the existing COVID crisis we have witnessed the rapid approval and marketing of COVID drugs by Indian companies in the domestic and international markets. This has been possible due to the collective objective of the industry and the government to protect the population from the pandemic. The Central Drugs Standard Control Organization (CDSCO) released the regulatory pathway to accelerate the R&D of COVID-19 drugs and vaccines.

This pathway accelerated development and launch by:

- ▶ expediting reviews and approvals for drugs and vaccines already approved in other countries
- ▶ ensuring speedy permissions for clinical trials
- ▶ enabling processing of applications to import a drug for test and analysis within seven days
- ▶ allowing abbreviated data requirements or waivers for animal toxicity study, clinical study and safety study (assessed on a case-by-case basis)
- ▶ encouraging the approval of applications to manufacture or import drugs and vaccines for test and analysis within seven days
- ▶ facilitating parallel application for the conduct of clinical trials during preclinical studies and abbreviated pathway for COVID-19 vaccine development
- ▶ providing guidance for regulatory pathway for COVID products

This is expected to expedite the drug approval reform process. In May 2020 a high-level panel to reform drug regulatory system was initiated by the government to fast-track approvals. The committee set up by the Ministry of Health and Family Welfare panel comprises of bureaucrats from the Department of Pharmaceuticals and Department of Biotechnology, experts from Indian Pharmacopoeia Commission, Indian Council of Medical Research and All India Institute of Medical Sciences in Delhi, and representatives from industry bodies. The panel aims to leverage some of the best practices that have emerged during the pandemic to reform the drug regulatory system in India in normal times.

Sources:

"Coronavirus pandemic: DCGI to expedite approvals of COVID-19 drugs, vaccines", Moneycontrol, March 2020. Available at: <https://www.moneycontrol.com/news/business/companies/coronavirus-pandemic-dcgi-to-expedite-approvals-of-covid-19-drugs-vaccines-5078651.html>

"Covid-19: Govt panel considers measures to hasten drug approval process", Mint, May 2020. Available at: <https://www.livemint.com/news/india/covid-19-govt-panel-considers-measures-to-hasten-drug-approval-process-11590168701458.html>

(v) Achieve harmonization with global regulatory standards

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) is a co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. It is open to any authority having a comparable GMP inspection system. PIC/S has 54 members from all over the world (Europe, Africa, America, Asia and Australasia)¹⁶⁰. Brazil is a recent applicant for joining PIC/S, and as one of the pre-requisites for becoming a member, it has upgraded its existing national regulation on good manufacturing practices (GMPs) for medicines by adopting a new regulation in 2019, which are in line with PIC/S requirements¹⁶¹.

Developing countries like Brazil, China, Mexico, Nigeria and South Africa are members of the International Coalition of Medicines Regulatory Authorities (ICMRA)¹⁶². The ICMRA works on multiple initiatives, inter alia, crisis management, innovation, pharmacovigilance, and supply chain integrity (interoperability of track & trace systems)¹⁶³. An example of crisis management considering the present COVID-19 scenario, ICMRA members discuss international alignment on COVID-19 policies in strategic meetings held every two weeks¹⁶⁴. These also focus on:

- ▶ pragmatic approaches to COVID-19 response
- ▶ regulatory flexibility in the context of the medical emergency
- ▶ extraordinary measures applied to address common challenges during the pandemic
- ▶ regulatory considerations related to COVID-19 clinical trial management
- ▶ prevention/mitigation of supply issues

Further, ICMRA is also holding international regulatory workshops on important topics to allow for in-depth discussions and to agree on common approaches. In addition to delegates representing 28 medicines regulatory authorities globally, participants also include experts from the World Health Organization (WHO) and the European Commission (EC).

India is presently participating as an observer in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), a forum which brings together regulatory authorities and the pharmaceutical industry to discuss scientific and technical aspects of drug registration¹⁶⁵. India should also explore opportunities of participating in global networks such as PIC/S and ICMRA. India should consider adopting a more stringent system such as the PIC/S, in place of the existing Schedule M of the Drugs and Cosmetics Act, as this will help India in its journey of streamlining its existing drug regulatory framework(s) by adopting international leading practices at the national level. This will also act as a stimulus for the export of drug products considering the global acceptance of PIC/S standards.

Develop a stable pricing policy and strong patent protection enabling long term investment decisions

Frequent and unexpected changes to the domestic pricing policy create an uncertain environment for investments and innovation. The government and other industry stakeholders need to develop a framework that ensures availability and accessibility of affordable drugs for citizens, while ensuring a reasonable return on investment for pharmaceutical companies. Reducing the frequency of policy revisions and agreeing upon the timeline for future revisions should also be considered.

Strong IP laws provide innovators with the necessary confidence and motivation to invest in high-risk research and innovation projects. Several earlier IPR challenges in India were addressed with the 2016 National IPR Policy. Steps could further be taken such as improvement in the patent enforcement and resolution mechanism, detailed guidance on registration requirements and technology transfer, etc. (discussed in the earlier section of the report 'R&D challenges')

¹⁶⁰ PIC/S website. Available at: <https://picscheme.org/en/picscheme>

¹⁶¹ "Brazil's ANVISA is approved for pharmaceutical inspection co-operation scheme - PIC/S", Global Regulatory Partners, December 2020. Available at: <https://globalregulatorypartners.com/brazils-anvisa-is-approved-for-pharmaceutical-inspection-co-operation-scheme-pic-s/>

¹⁶² ICMRA website. Available at: <http://www.icmra.info/drupal/en/participatingRegulatoryAuthorities>

¹⁶³ ICMRA website. Available at: <http://www.icmra.info/drupal/en/home>

¹⁶⁴ ICMRA website. Available at: <http://www.icmra.info/drupal/en/covid-19>

¹⁶⁵ "ICH to Bring India On Board", FDA News, March 2020. Available at: <https://www.fdanews.com/articles/196280-ich-to-bring-india-on-board>

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5S framework for regulatory reforms:

- ▶ **Simplification:** all procedures and processes should be simpler and faster
- ▶ **Scientific:** everything has to be science based to remove subjectivity
- ▶ **Safety:** safety of product and safety of patients should be assured
- ▶ **Speed:** speed of action and decision making in a competitive world becomes very important
- ▶ **Stability:** regulatory and policy stability is critical, it is difficult to do business if there are frequent changes

Managing Director of
a leading Indian pharma company

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Incentives for the industry

The government support and favorable policies is a must to establish R&D and innovation ecosystem in a country. The government of India has provided various tax incentives to foster innovation in the country.

These incentives are available with respect to revenue and capital expenditures incurred by entities for carrying out R&D activities in relation to their businesses, and in respect of their contributions to various institutions for carrying out scientific research. Exemption is also provided from customs duty on imports made by industry for R&D projects.

Areas that need attention

Tax incentives for pharma companies

One of the many ways in which the government has supported pharmaceutical companies in the past and could continue to provide support in the future is by way of appropriate tax incentives particularly for expenditure on research and development such as:

- (i) Full deduction in respect of revenue expenditure and capital expenditure on R&D
- (ii) Weighted tax deduction in respect of in-house R&D facility approved by Department of Industrial and Scientific Research. This deduction was earlier allowed at 200% since 2010 and was reduced to 150% from 2017 and further reduced to 100% from 2020
- (iii) Further, amount paid to an approved research association, college or university for scientific research was eligible for deduction @ 150% from 2010 and has been reduced to 100% from 2020
- (iv) Amount paid to an approved company for scientific research was eligible for deduction @ 125% from 2009 which has been reduced to 100% from 2018

Further, earlier pharmaceutical companies, including companies carrying out R&D, were eligible for certain tax holidays under section 10A, 10AA, 10B, 80-IA, etc. which are discontinued. At the same time, the corporate tax rate has in general been reduced from ~ 34% to ~ 25% .

We have provided below, a few suggestions/ areas that need attention when it comes to incentives to pharmaceutical companies and particularly around research and development. The government of India announced a PLI Scheme for 53 APIs/ KSM/intermediates earlier this year, to increase production of APIs in India and to reduce reliance in import of APIs from other nations. Recommendations take into account, the vision and objective of the government under Atmanirbhar Bharat for the pharmaceuticals sector. Industry wide consensus has been that along with the policy changes and Production Linked Incentives (PLI), tax related incentives specific to pharma sector would go a long way in realizing the objective of the government for self-sufficiency in manufacturing of APIs for life saving and other critical drugs.



R&D related tax incentives

R&D Deductions

Most off-patent products have been copied in India. The real next growth for the industry whether in India or globally will come from innovators. Like in API where adequate focus was not given, other parts of the world took India's place, if India does not focus on innovation, it will lose its current status very soon. The new areas include not just NCEs but also biological and other areas of innovation. These areas of innovation have a much higher cost of R&D compared to creating different process for existing patents. For corporates to fund this innovation and for India to attract global MNCs to invest in this area of innovation, it is not just talent but tax incentives which play a very large role. That is the reason why even the developed world like the US, UK, etc. and the more nimble but growing economies like Singapore, etc. have ensured that tax incentives are there to attract creation of innovation in the country. Tax incentives range from patent box regime where global profits are eligible for very concessional rates of tax, and weighted tax deduction for costs of R&D are provided. Some countries provide both. While technically India can claim that they provide the benefits, in reality the concession is very narrow and therefore not benefiting the country. For India, in addition to becoming a part of the innovation chain, the creation of R&D centers would also lead to more manufacturing facilities for the innovator products (currently our share is not prominent amongst the NCEs in this area).

Industries in India have benefited from lowering of corporate tax rates from ~ 34% to ~ 25%. In parallel government has scaled down quantum based weighted average R&D expenses and currently India allows 100% deduction in respect of capital and revenue R&D expenses from 200% weighted deduction in the past.

When compared to the tax rates and R&D tax regimes in certain other developed and developing countries, India still has distance to cover around R&D tax incentives. Many of these jurisdictions discussed below offer tax rates which are lower than or equal to tax rates in India and yet continue to offer R&D tax incentives in various forms. It is therefore highly desirable for India:

- ▶ to continue R&D tax incentives to promote India as R&D Innovator hub beyond the contract R&D and clinical trials carried out in India
- ▶ to provide weighted average deduction for R&D and contribution to scientific research institutions, universities, etc. in the range of 150% to 300% depending on type of activity
- ▶ to provide R&D incentives even to companies who opt for new tax regime under section 115BAA of the Act thereby availing tax rate of ~ 25%
- ▶ current R&D regime does not specifically include cost of R&D outsourced for calculation of R&D incentives. Outsourced R&D costs should be specifically made eligible for R&D incentives



For the purpose of comparison, we have tabulated below, the tax rates in some of the developed and developing countries and R&D incentives available in such countries.

Parameters	USA	Singapore	Thailand	Ireland	Switzerland	UK
Corporate tax rate	~ 21% (Federal tax)	~ 27% (Development and Expansion Incentive companies can have tax rate of 5% - 10%)	20%	12.5%	Ranges from 12-24%	19%
R&D benefit	<ul style="list-style-type: none"> Provides R&D tax credit depending on incremental R&D spend Currently, R&D spend is deductible, but proposed to be amortized over 5 years from 2022 	Weighted R&D deduction @ 250% of qualifying expenditure	Weighted deduction @ 100% to 300% of qualifying R&D spend	Regular R&D credit @ 12.5% plus additional R&D credit @ 25% resulting in effective R&D credit of 37.5%. Cash refund and transfer of credit to key scientists permitted	Additional R&D deduction maximum upto 50%	R&D Tax Credit @ 12% of qualifying R&D spend in addition to deduction @ 100%
Period of R&D benefit	Continues to be available pre and post tax reforms in 2017	2019-2025	No sunset clause found	No sunset clause found	2019 onwards	From 2013
Outsourced R&D	65% of amounts paid to third parties for research services eligible	Expenditure on R&D work contracted to R&D organization considered for deduction to the extent of 60% of such payment	R&D or outsourced within Thailand or carried out in cooperation with research and education institution abroad is considered	Outsourced R&D expenses are considered subject to certain limits	80% of expenses for R&D carried out by third parties or group companies in Switzerland are considered	

Additionally, there are other organizations/ arrangements related to R&D, taxation of which may also need attention:

- ▶ Taxation linked encouragement for global pharmaceutical companies having R&D centers in India
- ▶ CROs conducting contract research and clinical trials for foreign MNC
- ▶ Monetary incentivization to collaboration agreements between Indian companies and foreign pharmaceutical companies for co-development, co-licensing, etc. products aimed at being launched in Indian market

Innovator organizations should be allowed appropriate benefit for R&D related activities carried out. For example, Singapore allows R&D incentives even in respect of Cost Sharing Arrangements (CSA), wherein the eligible R&D expenditure is deemed to be 60% of the payments under CSA. Thailand and Vietnam currently allow certain tax exemptions to R&D Service Providers/ contractors.

Patent Box Regime

Patent box tax regime (PBR) was introduced in 2016. Under this, tax concession is given on the income from the licensing of the patents. The legislative intent for introducing PBR is to encourage R&D and make India a Global Hub, incentivize companies to locate high value jobs associated with development, manufacture and exploitation of patents in India. Under the PBR, specified royalty income derived by an eligible assessee from patents is subjected to a beneficial tax rate of 10% plus applicable surcharge and cess. Some of the limitations with the current PBR are:

- ▶ PBR may not be beneficial to taxpayer for whom net basis taxation results in taxes less than 10% of gross receipts.
- ▶ Strict condition of development in India and registration in India. Companies with exclusive license for patents in India and other jurisdictions and commercially exploiting the same cannot avail the benefit of patent box regime.
- ▶ Creation of IP is a time and money intensive process. Still, no expenditure for producing IP can be claimed against the income of IP which is taxed only at 10%.
- ▶ Currently, the patent box regime only covers royalty income – other types of income earned out of patent exploitation such as capital gains, income from sale of products manufactured using patents, etc. are currently not covered.

We suggest that the patent box regime be made more inclusive, comprehensive and robust to make it attractive for the pharma companies. Having regard to the patent box regime of some of the developed and developing tax jurisdictions, the following changes may be desirable in the patent box regime:

- ▶ Currently, patent box regime only includes income from India registered patents. It should be broadened to include patents registered outside India and exclusive licenses in respect of foreign patents should be eligible for patent box regime.
- ▶ Widening the scope of patent box regime to include:
 - ▶ Income by way of capital gains
 - ▶ Income from infringement of patent rights
 - ▶ Income from sale of goods manufactured by exploiting patents, should be eligible for patent box regime. In case of sales income, the income attributable to patent box regime may be calculated by appropriate formula for calculating residual profits after eliminating return on marketing activities, etc.
- ▶ If IP is used in house, notional income may be considered eligible for patent box regime
- ▶ Typically, in case of a patent, there is heavy expenditure incurred upfront on R&D, clinical trials and registering the patent. Therefore, it seems desirable that deduction be allowed to the income from exploitation of patents and therefore income from patent box regime should be calculated on net basis by clearly defining the qualifying income and qualifying expenses. The R&D expenses and expenditure incurred on outsourcing towards third parties and towards group companies within India should be considered to be a qualifying expenditure. Further, as mentioned since R&D cost will be incurred in initial years whereas revenue from patents will be generated in subsequent years – the period of carry forward and set off of initial losses/ deductions should be sufficiently long so that the losses are effectively set off against the income under the patent box regime in subsequent years.
- ▶ IP development costs (R&D) should still be allowed for patent box regime and may be allowed to be set off against patent box eligible income.

We have tabulated below, a brief overview of Patent Box regime in certain other competitive developed and developing nations:

Parameter	UK	Ireland	Switzerland	Singapore
Tax rate	10%	6.25%	Net profits from domestic and foreign patents and similar rights are to be taxed separately with a maximum reduction of 90% (rate at cantonal discretion ranges at 10% or 50% in some cantons)	5 to 10%
Eligible Income	<p>Apart from Patent licensing income and royalties, following income is eligible:</p> <ul style="list-style-type: none"> (i) income from sale of patent rights; damages and infringement income (ii) Sales income from the patent or patent protected products (iii) Notional royalty in respect of patented technology used within business 	<ul style="list-style-type: none"> ► Income from managing, developing, maintaining, protecting, enhancing or exploiting of intellectual property (including activities leading to invention or creation of intellectual property) ► Income from sale of goods or the supply of services that derive part of their value from activities described above 	<ul style="list-style-type: none"> ► The profits attributable to the patent box can include royalties, capital gains from the sale of the patent ► Embedded IP income from the sale of products. 	Qualifying IP income refers to royalties or other income receivable by the approved company as consideration for the commercial exploitation of qualifying IP rights
Conditions on patent ownership	<ul style="list-style-type: none"> ► Patents owed or exclusive licenses/ rights to the patents are eligible. Patents granted by the UK Intellectual Property Office, the European Patent Office or certain European patent offices are considered. ► Patents which are applied for may be eligible 	Available in respect of patents and pending patents as being novel, non-obvious and useful	<ul style="list-style-type: none"> ► Patents include patents as defined by European Patent Convention, Swiss Patents Act; and Foreign patents equivalents ► Available in respect of patents and pending patent inventions that are certified by the Controller of Patents, Designs and Trademarks as being novel, non-obvious and useful 	No sunset clause found
Other conditions on development and quantum, etc.	Eligible income to be calculated by applying nexus ratio (R&D cost incurred in UK + R&D cost incurred by subcontracted third parties divided by total R&D cost) to net income from each IP stream (inclusive R&D to connected parties)	Companies carrying on qualifying R&D activities in Ireland or outsources to unrelated third parties outside Ireland (but not to related parties) are eligible	Income from qualifying assets attributable to domestic R&D costs is eligible. Income eligible to be calculated by applying nexus ratio (ratio of qualifying R&D costs related to R&D activities performed in Switzerland by the MNE and by unrelated parties) to the total R&D costs	<ul style="list-style-type: none"> ► Eligible income to be calculated by applying modified nexus approach depending on R&D expenditure incurred by the approved company (including outsourced third-party R&D and R&D undertaken by the company itself) ► substantive commitments in areas of business spending, fixed assets expenditures, skilled jobs and the requisite qualitative aspects such as contributing to the advancement of capabilities and other ancillary economic spin-offs for the wider Singapore economy

The R&D tax incentives and widening of the patent box regime are likely to be in line with the vision of Atmanirbhar Bharat and "Make in India". Widening of patent box regime to include

even manufacturing profits would go a long way to promote culture of innovation coupled with commercialization of such innovation through manufacturing by innovators.



Future considerations and way forward

Accelerating research and innovation

1 Take a focused approach to intensify research & innovation activities

Define overall pharma / biopharma research and innovation ambition

Stakeholders

Action items

Government, industry	▶ Identify top 4-5 focus areas based on country's public health priorities and achieving global industry competitiveness
Government	▶ Align the entire ecosystem – including the academia, hospitals, and start-ups – with the focus areas
Industry	▶ Provide support to the external ecosystem to move innovation from development to commercialization

2 Establish a strong research and innovation ecosystem

(i) Strengthen talent and research base

Strengthen the higher education system

Improve the quality of education and infrastructure in higher education institutions (HEIs)

Government	▶ Consider launching more programmes like EQUIP and RISE, and ensure effective and timely implementation
	▶ Increase number of public institutions offering postgraduation and PhDs

Set up more national and international mobility programs to foster collaboration and sharing of perspective

Government, academia/institutions, industry	▶ National and international rotation programmes of researchers and scientists between private and public institutions
	▶ Faculty or researchers from a university could work in a corporate for some time, and vice versa

Promote innovation/entrepreneurial mindset in the HEIs and research institutions

Government, academia/institutions	▶ Integrate topics on entrepreneurship and innovation mindset in the curricula
	▶ Incentivize students and faculty members engaged in their own research activities or mentoring students
	▶ Permit academia/institutions to directly gain commercial benefit from IP created within the institute

Developing industry ready talent

Increase industry-academia collaboration

Government, academia, industry	Government <ul style="list-style-type: none"> ▶ Incentivize industry and academia collaboration for holistic development of students ▶ Enable alignment between academia research priorities and industry ▶ Enhance overall curriculum in alignment with industry specific requirements Industry <ul style="list-style-type: none"> ▶ Design specific programmes as part of the curriculum to develop future skills (soft skills and tech capabilities) ▶ Have more forums for establishing engagement and exposure between students and industry: <ul style="list-style-type: none"> ▶ short/one-day programmes (e.g., webinars, speaker series), internships, scholarships, research fellowships, etc.
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Prevent brain drain (brain drain to wisdom gain)

Launch initiatives to bring back talent

Government	<ul style="list-style-type: none"> ▶ Create more opportunities / incentives to encourage talented people to returnees to the country (e.g., as in China) ▶ Provide infrastructure, financing and other enablers to develop idea and start business for returnee; ensure the returnees do not have to deal with bureaucratic and regulatory barriers and experience ease of doing business ▶ Employ intellectual returnees in suitable government roles; enable collaboration with industry and academia
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Establish mechanism for brain circulation/ brain exchange

Stakeholders

Action items

Government

- ▶ Develop a national repository of expatriates by industry / domain / achievement category, etc.
- ▶ Facilitate channels for connections between public and private organizations with relevant expatriates for sharing of knowledge / best practices and working in partnership / collaboration

(ii) Augmenting clinical research capabilities

Improve the quality of clinical research training and experience in the institutions

Government, academia/ institutions

- ▶ Integrate formal, clinical research / clinical trial training curriculum into the medical under- and post-graduate curriculum
- ▶ Introduce financial and non-financial incentives to motivate medical students and physicians to conduct research
- ▶ Increase collaboration between medical institutions and research institutes on high priority research projects

Expand the pool of technically qualified clinical researchers

Government, academia/ institutions

- ▶ Introduce more dual-degree programs such as MD-PhD or MD-MsC and clinical fellowships
- ▶ Provide opportunities to pursue clinical research along with clinical practice for holistic learning and experience

(iii) Leverage technology to make R&D faster and more cost effective

Use advanced technology across the R&D life cycle

Industry

- ▶ Leverage technology to improve productivity and speed during the drug discovery phase
- ▶ Digitize clinical trials to improve efficiency and experience

(iv) Set up advanced infrastructure

Make efficient use of existing infrastructure; expand the existing infrastructure; set up new infrastructure

Government

Gaining efficiency in utilization

- ▶ Ensure alignment and collaboration between all the government organizations providing support for life sciences and health specific research, both in terms of research focus and allocation of funds
- ▶ Establish performance based criteria for funding and support

Expanding the infrastructure

- ▶ Establish incubators, parks and clusters specifically for pharma sector
- ▶ Explore PPP by leveraging CSR funding or using competitive tendering processes to select private partners for setting up joint incubators

Academia

- ▶ Large institutions can provide space for co-location of start-ups with similar research priorities or innovation ideas
- ▶ Make groups of experts to provide mentoring and establish units enabling tech transfer

Industry

- ▶ Provide funding to research institutions and incubators under CSR activities
- ▶ Set up incubators and mentoring teams for start-ups

(v) Financing the complete cycle from idea generation to market launch

Leverage or enable more innovative financing models beyond grants

Government, industry, academia

Government

- ▶ Set up some grants specifically for R&D in the pharma sector; ease the process of getting grants and funding support, especially for the grassroot companies
- ▶ Leverage or enable different/novel financing models: e.g., convertible grants, crowdfunding

Academia

- ▶ Aim to self-finance a portion of the research and innovation activities by generating money through selling/ licensing of in-house innovation, or working in collaboration with the pharma companies
- ▶ Establish innovative ways to secure money (for e.g., the IIT Delhi's Global Alumni Endowment Fund)

Industry

- ▶ Provide funding through venture arms, innovation challenges, grants and scholarships for students / researchers

Launch initiatives to boost private investment

Stakeholders

Action items

- Government** ▶ Co-investment with private entities in venture funds; guarantee programmes

Encourage public/private investment in highly innovative, high-risk, long-term ventures

- Government** ▶ Patient capital, evergreen funds, venture debt, risk-sharing schemes, innovation procurement

(vi) Enabling policy and regulatory frameworks

Establish an overarching regulatory body

- Government** ▶ Consider establishing a single Central Drug Regulatory Authority (CDRA) with overall ownership of all regulatory functional responsibilities
- ▶ Consider restructuring drug regulatory setup across the pharmaceutical value-chain:
- ▶ The entire value chain can come under one Ministry with CDRA and National Pharmaceutical Pricing Authority (NPPA) as independent regulatory bodies under the said Ministry
 - ▶ All State Drug Regulatory Authorities (SDRAs) report directly to the CDRA as a part of the Regulatory Affairs and Enforcement Division of the CDRA across states

Adopt a collaborative role with the drug/product developers throughout the drug development process

- Government** ▶ Come up with guidance on the most appropriate methodology for developing drugs and presenting the evidence needed to support the approval
- ▶ Develop a formal framework for collaboration between product developers and the regulatory authority

Establish regulatory process and capabilities for end-to-end management of clinical trials

- Government** ▶ Develop clear and detailed guidance on clinical trials, covering various age groups and the product categories
- ▶ Provide special training to enhance personnel competencies to facilitate efficient conduct of regulatory duties
- ▶ Include global experts and industry veterans in review committees to bring in a global perspective

Achieve harmonization with global regulatory standards

- Government** ▶ Consider adopting a more stringent system such as the PIC/S

Provide tax incentives and other benefits

- Government** **Tax incentives**
- ▶ Provide weighted average deduction for R&D and contribution to scientific research institutions, universities, etc. in the range of 150% to 300% depending on type of activity
 - ▶ Provide R&D incentives also to the companies who opt for new tax regime under section 115BAA of the Act thereby availing tax rate of ~ 25%
 - ▶ Include outsourced R&D costs in the eligibility criteria for the R&D incentives
- Patent box regime**
- ▶ Make the patent box regime more inclusive, comprehensive and robust
 - ▶ IP development costs (R&D) should still be allowed for patent box regime and may be allowed to be set off against patent box eligible income





Chapter

03

**Achieving equitable and
sustainable healthcare**

Equitable access to healthcare has been a consistent challenge for India for long.

India ranked 145 among 195 countries on the healthcare access and quality (HAQ) index 2016¹

The launch of Ayushman Bharat program demonstrates India's commitment to provide equitable healthcare access to all.

PMJAY*, coupled with the improvement in penetration of private health insurance, has increased the proportion of insured population to 52% in 2017-18, from 37% in 2014-15²

India's ambition of providing universal healthcare access can be achieved by expanding healthcare coverage, establishing robust digital and physical infrastructure, increasing the healthcare workforce and focussing on disease prevention - technology should be ingrained as an enabler across all these streams.

Currently India does not meet the WHO recommendations for healthcare workforce (e.g. number of physicians, nurses) and infrastructure (e.g. hospital beds) and lags other BRIC nations³

* PMJAY: Pradhan Mantri Jan Arogya Yojana

¹ "Measuring performance on the Healthcare Access and Quality Index for 195 countries and territories and selected subnational locations: a systematic analysis from the Global Burden of Disease Study 2016", published in 'The Lancet' in June 2018 - Volume 391, ISSUE 10136, P2236-2271. Available at: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)30994-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)30994-2/fulltext)

² "EY FICCI Report, Re-engineering Indian Health care, September 2016, IRDAI handbook, IRDAI Annual report, National Health Profile, Individual state insurance website, EY analysis

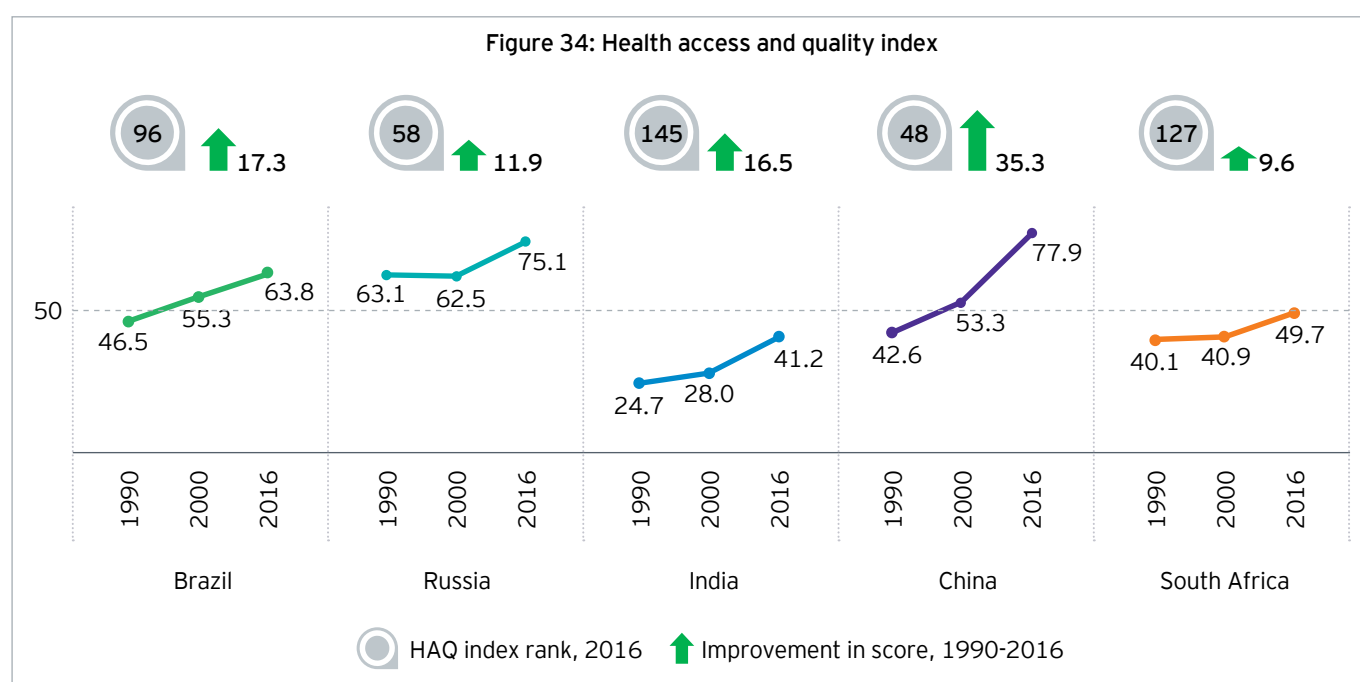
³ WHO website

Opportunities for improving health care delivery

1. Achieve universal healthcare access

Achieving equitable and sustainable healthcare access is a must for a country to achieve economic growth. Being the world's second most populous country, India faces unique opportunities and challenges in the healthcare space. On the healthcare access and quality (HAQ) index, in 2016 India ranked 145 among 195 countries. Although India did make

improvements on the HAQ Index from 1990 to 2016, it is still behind all the other BRICS countries and some of the Asian countries like Bangladesh, Sri Lanka and Bhutan. Although India's score improved from 24.7 in 1990 to 41.2 in 2016, but it is still below the mid-point of the 0-100 point scale. The country's highest and lowest scores for States also widened in this period (23.4-point difference in 1990, and 30.8-point difference in 2016)⁴.



Source: GBD 2016 Healthcare Access and Quality Collaborator

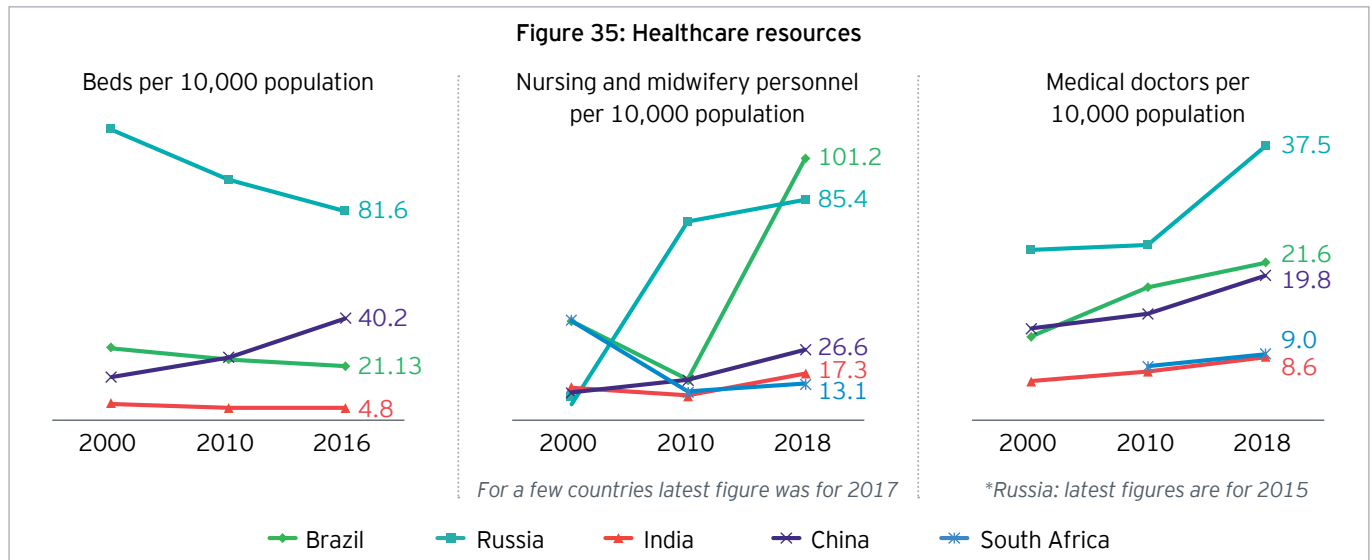
India also lags its peers in public healthcare spending, which is evident from the shortage of healthcare infrastructure. Currently India does not meet the WHO recommendations for the number of physicians, nurses and hospital beds per 10,000 people and lags other BRIC nations on these key performance indicators.

The healthcare infrastructure availability gap is further widened due to urban-rural disparities. More than 65%⁵ of the Indian

population lives in rural areas which have access to less than 30% of the country's healthcare infrastructure. Public health facilities, which provide the majority of healthcare in the rural areas, are mostly limited to primary care centers that provide basic services. A majority of the secondary, tertiary and quaternary care institutions are run by the private sector and are concentrated in the tier I and tier II cities.

⁴ "Measuring performance on the Healthcare Access and Quality Index for 195 countries and territories and selected subnational locations: a systematic analysis from the Global Burden of Disease Study 2016", published in 'The Lancet' in June 2018 - Volume 391, ISSUE 10136, P2236-2271. Available at: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)30994-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)30994-2/fulltext)

⁵ "World Bank" website. Available at: <https://data.worldbank.org/indicator/SP.RUR.TOTL.ZS?locations=IN>

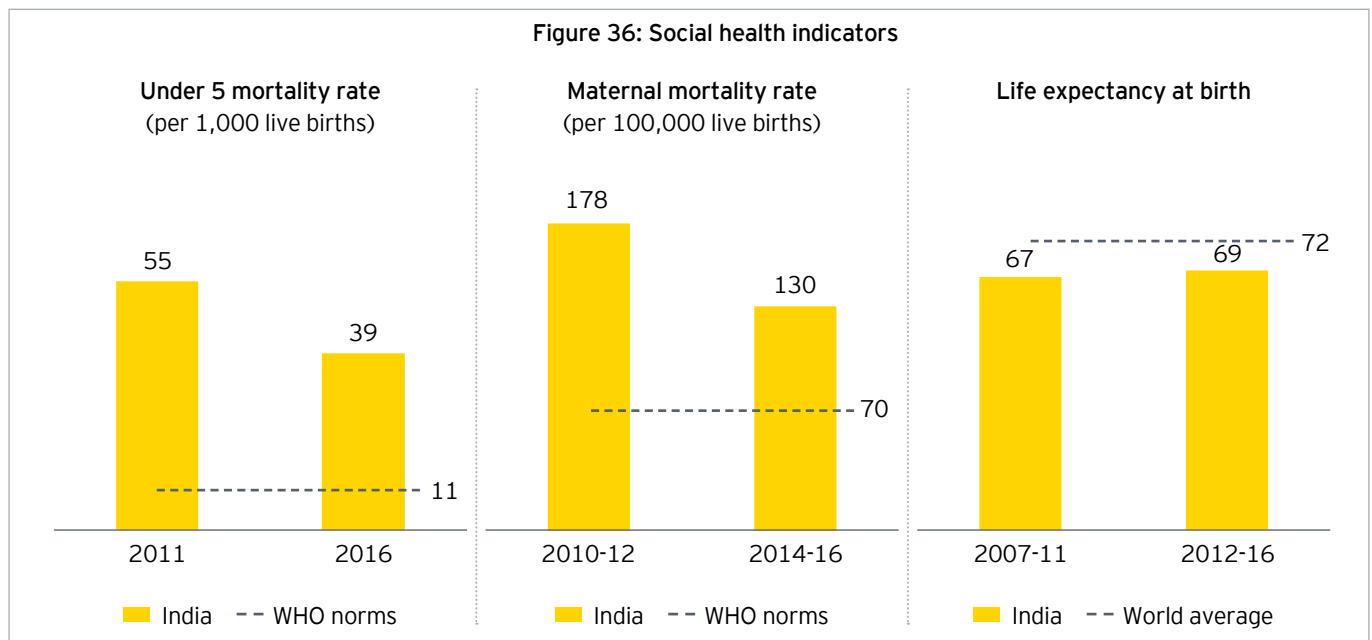


Source: WHO

2. Reduce disease burden

India faces a double burden of disease, with continued high prevalence of communicable and malnutrition-related diseases and steadily increasing non-communicable diseases (NCDs).

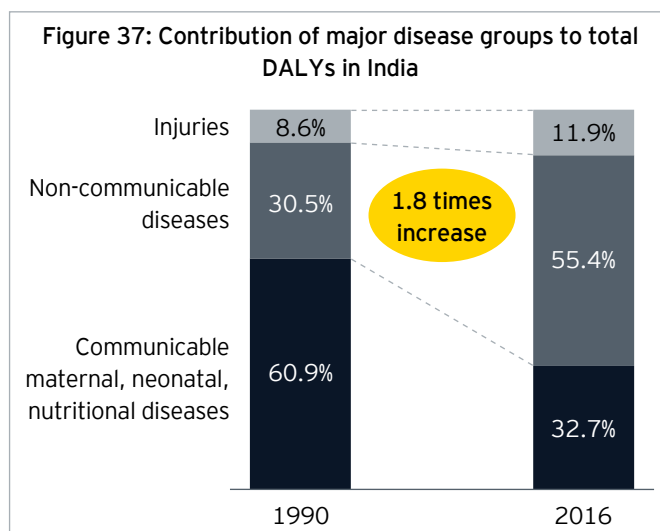
Social health indicators (e.g. infant and maternal mortality, overall life expectancy at birth) have improved over the last five years. However, they are still below the global benchmarks and World Health Organization (WHO) recommended norms. This is driven by the large disparity in healthcare delivery across states, with the most populous states being the laggards.



Source: United Nations Inter-Agency Group for Child Mortality Estimation (UN IGME) 2018, NITI Aayog data for Maternal Mortality Ratio, World Bank Data - Life Expectancy at Birth (years), Sample Registration System, Office of Registrar General & Census Commissioner

Contribution of NCDs to total 'disability-adjusted life years' (DALYs) has almost doubled in the last three decades in India – from ~30% in 1910 to >55% in 2016. According to a WHO report in 2015, about 5.8 million people die from NCDs (heart and lung diseases, stroke, cancer, and diabetes) in India every year. This means that roughly 25% of Indians are at risk of dying from an NCD before the age of 70⁶.

The burden of most communicable and associated diseases dropped during the same period, but about half of the 10 leading causes of disease burden still belong to this group.

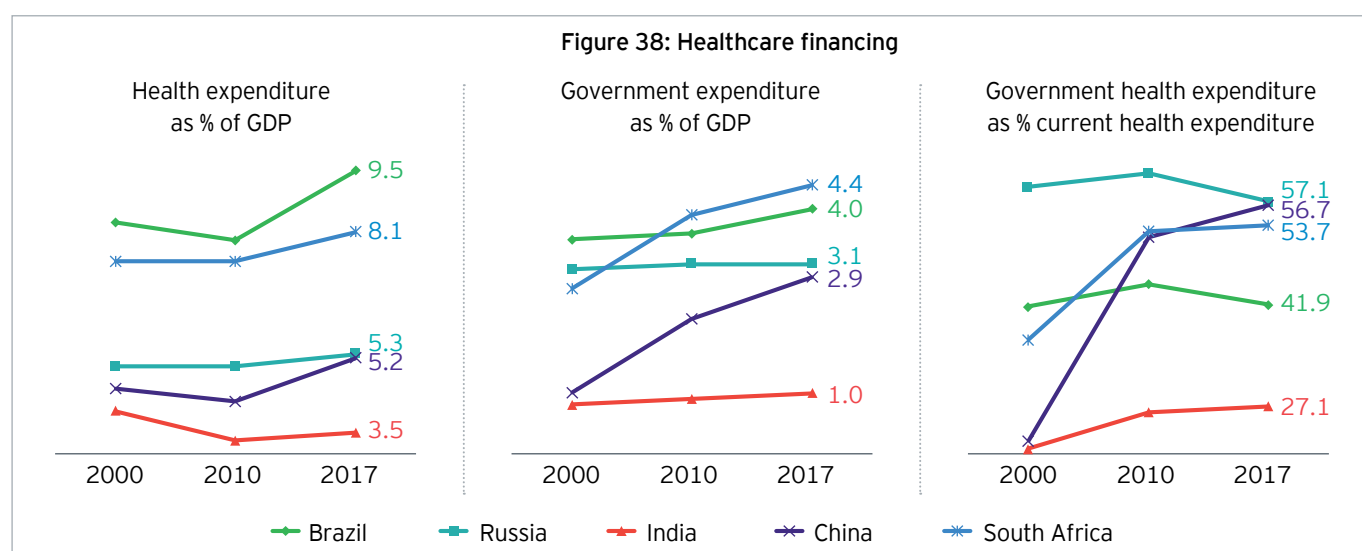


Source: NSSO 71st round Key Indicators of Social Consumption in India: Health, Jan-June 2014, NSSO 60th round Morbidity, Health Care and the Condition of the Aged, Jan.-June 2004, India: Health of the Nation's States 2017, EY analysis

Key challenges in achieving equitable and sustainable healthcare access

1. Limited healthcare funding

As a percentage of GDP, India is one of the lowest spenders on total and public healthcare, including when compared to other BRICS countries.



Source: WHO

At the current rate of investment, India's public healthcare capacity and delivery will continue to be sub-optimal. As such, greater than 70% of capacity and ~60% of inpatient care is being served by the private healthcare system in India⁷.

The government aims to increase the spend to 2.5% of GDP by 2025. This is expected to boost the healthcare infrastructure overall in the country.

⁶ "WHO website". Available at: <https://www.who.int/features/2015/ncd-india/en/>

⁷ S. Zodpey et al, "Universal Health Coverage in India: Progress achieved & the way forward", published in IJMR in April 2018 - 147(4): 327-329. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6057252/>

2. Focus on sick care instead of healthcare

Focus on sick care rather than healthcare has been the cause of burgeoning health expenditure and increasing disease burden across the world, including India.

As discussed in the earlier section, there is a huge disparity in the availability of healthcare infrastructure between urban and rural areas. Such a disparity has compelled India to neglect disease preventive, health promotive, and public health measures. For example, most rural areas have poor primary care infrastructure, resulting in increased risk of NCDs.

Immunization levels for children remain low in the country despite the launch of an immunization program four decades

ago. For adults, there is no government policy on vaccination yet.

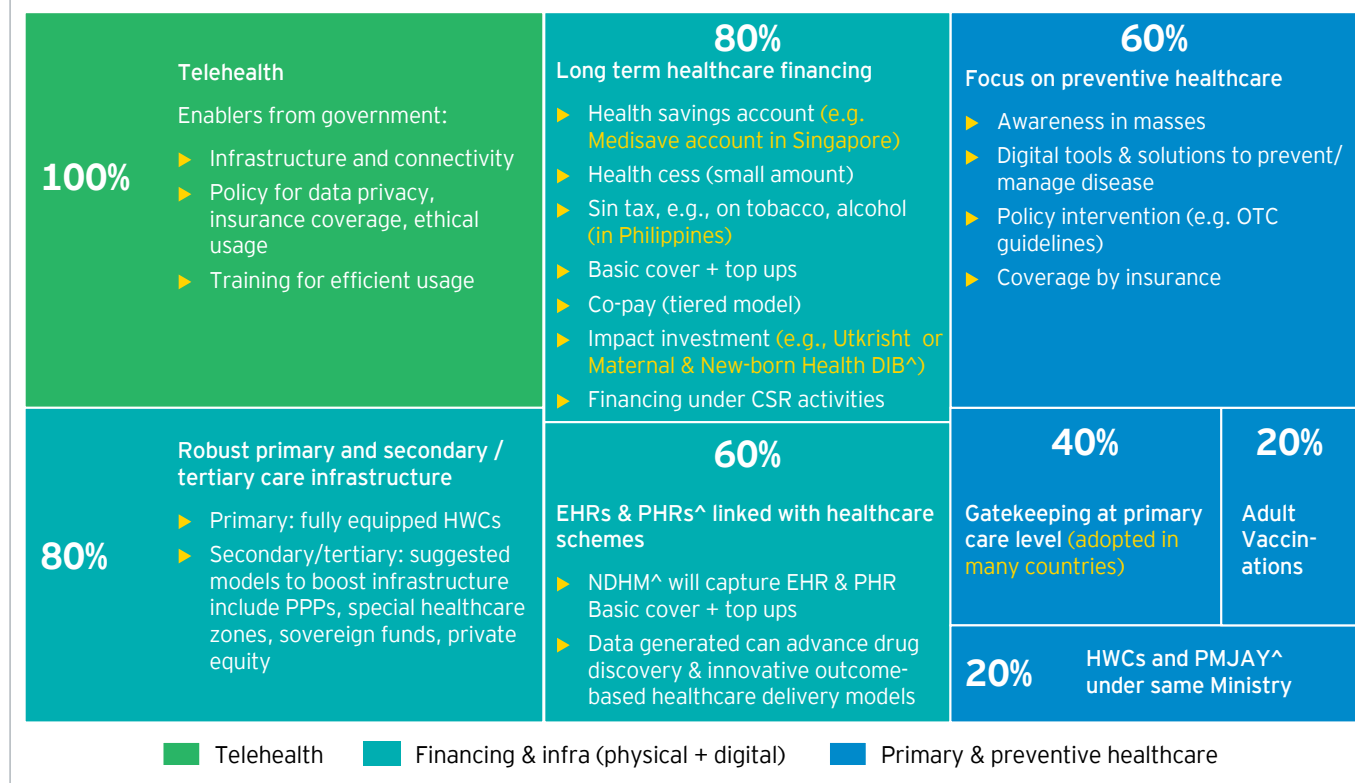
Adding to the burden, there are misaligned incentives in how care is reimbursed. Currently insurers cover in-patient therapy or procedures; payments for consultations or routine check-ups are the responsibility of the consumer. Because they must carry this cost burden, many consumers avoid regular check-ups, which are critical for early identification of disease and its control. In addition to cost, in many parts of India, low awareness of good health and disease prevention practices is another significant challenge – the current mentality of visiting a doctor when the symptoms become severe or intolerable ultimately leads to care being costlier.

Way forward: improving healthcare delivery in India

According to primary research, telehealth and robust primary and secondary/tertiary care infrastructure are important enablers for improving the state of healthcare delivery in India. Sustainable healthcare financing is required to strengthen the

supply side of healthcare delivery, and focus on prevention is important to reduce overall healthcare demand over time. This section focuses on healthcare delivery enablers and best practices.

Figure 39: Health care delivery enablers



#Healthcare delivery section has been covered to the extent it impacts the pharma industry

[^]HWC: Health & Wellness Centre; PMJAY: Pradhan Mantri Jan Arogya Yojana; DIB: Development Impact Bond; EHR: Electronic Healthcare Record; PHR: Personal Healthcare Record; NDHM: National Digital Health Mission; NCD: non-communicable disease

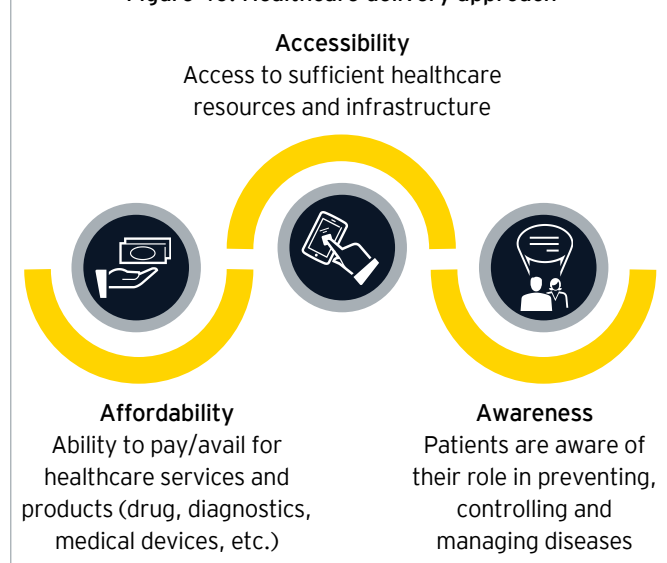
*Percentage reflects number of responders referring the enabler; N=5 ('n' includes most comprehensive responses in terms of coverage of key themes, a few other participants also provided similar inputs on some of these themes)

Source: EY primary research

India needs a three-pronged approach to provide healthcare to the entire population:

1. access to sufficient healthcare infrastructure and resources in the remotest of the areas in the country;
2. improved ability of the masses to afford healthcare services through public and/or private insurance;
3. reduction in disease burden using education campaigns that create awareness and empower individuals to take control of their own health.

Figure 40: Healthcare delivery approach



Source: EY analysis

The following sections provide details about various ways to address healthcare accessibility, affordability and awareness challenges.

1. Achieving universal health coverage (UHC)

In 2017, the Government formulated the National Health Policy (NHP) and set a target to increase the healthcare spend to 2.5% of the GDP by 2025. With the launch of 'Ayushman Bharat'

in 2018, the Indian Government demonstrated its strong commitment to providing healthcare for all, aligned to the SDG 3 goal established by United Nations. The flagship public health initiative has been internationally recognized as a significant step towards achieving universal coverage in the country. The scheme is completely tax funded and the cost is shared between the Central and the State Governments in a 60:40 ratio respectively (with a few exceptions).

Ayushman Bharat has two complementary schemes: 1) health and wellness centres (HWCs) to deliver comprehensive primary healthcare (PHC) services, free essential drugs and diagnostic services to the entire population; and 2) Pradhan Mantri Jan Arogya Yojana (PMJAY) for improving access to hospitalization services at secondary and tertiary level health facilities for bottom 40% of the population (~100 million families). We will discuss the HWCs in detail in the section on 'preventive health'.

PMJAY aims to provide financial risk protection to poor families by covering up to INR 500,000 per family per year for secondary and tertiary health services, from inpatient to post-hospitalization care. The scheme has defined 1,350 medical packages covering surgery, medical and day care treatments including medicines, diagnostics and transport⁸.

Currently a large part of these services are delivered by private healthcare systems, which are paid at pre-decided reimbursement rates. There have been concerns about a large gap between the actual procedure costs compared to the reimbursement rates offered under the Ayushman Bharat scheme. Thailand and Indonesia also use diagnostic case-based group (CBG) tariffs for paying for inpatient and outpatient services at secondary and tertiary care providers. The approach followed by Indonesia for deciding tariffs can be considered by India (refer figure 41)⁹. Efforts should also be made to improve efficiency in public and private hospitals (refer to the Universal Healthcare case studies on page 100 for model adopted by Thailand¹⁰), e.g., by making payments based on quantity and quality of services provided (in patient and out patient).

⁸ "National Health Portal" website. Available at: https://www.nhp.gov.in/ayushman-bharat-yojana_pg

⁹ R. Agustina et al., "Universal health coverage in Indonesia: concept, progress, and challenges", published in 'The Lancet' in January 2019 - Volume 393, ISSUE 10166, P75-102. Available at: <https://www.thelancet.com/journals/lancet/article/PIIS0140-67361831647-7/fulltext>

¹⁰ V. Viroj Tangcharoensathien et al., "Health systems development in Thailand: a solid platform for successful implementation of universal health coverage", published in 'The Lancet' in March 2018 - Volume 391, ISSUE 10126, P1205-1223. Available at: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)30198-3/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)30198-3/fulltext)

Figure 41: Indonesia: Payment for secondary and tertiary care services

Dynamic approach of frequent updating of the CBG tariffs, and recognising variability and heterogeneity



Recognizing variability

- ▶ Health system attributes, hospital capability, quality, and costs are variable. Hospitals are paid according to the class of hospital (class A, B, C, or D)
- ▶ Tariffs for class A hospitals are the highest. National class A referral hospitals are paid with special CBG tariffs, higher than for other class A hospitals, and academic hospitals have higher tariffs than general hospitals.



Recognizing heterogeneity

- ▶ Tariffs are differentiated into five regional tariffs based on the consumer price index
- ▶ Overall, tariffs for private hospitals tend to be 3% higher for inpatients and 5% higher for outpatients than for public hospitals, which receive additional government funds



Frequent updating

- ▶ First tariffs were developed in 2006 from a small number of claims from 15 hospitals
- ▶ The tariffs were subsequently refined three times on the basis of costing data from governmental and private hospitals and claims data collected by the Ministry of Health
- ▶ The refinement is done to enable more flexibility and payment accuracy considering the variance across regions and PCPs, thereby enabling mass customisation

“

There is a need to compensate hospitals basis the care they are providing.

Director, Leading Global Pharma Company

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We should think of a system where public and private are treated the same, and even the public health system has to earn or work for their referral – so they get a notional reimbursement rate, they balance their budgets, and grow from there.

Joint MD, Leading Indian Hospital Chain

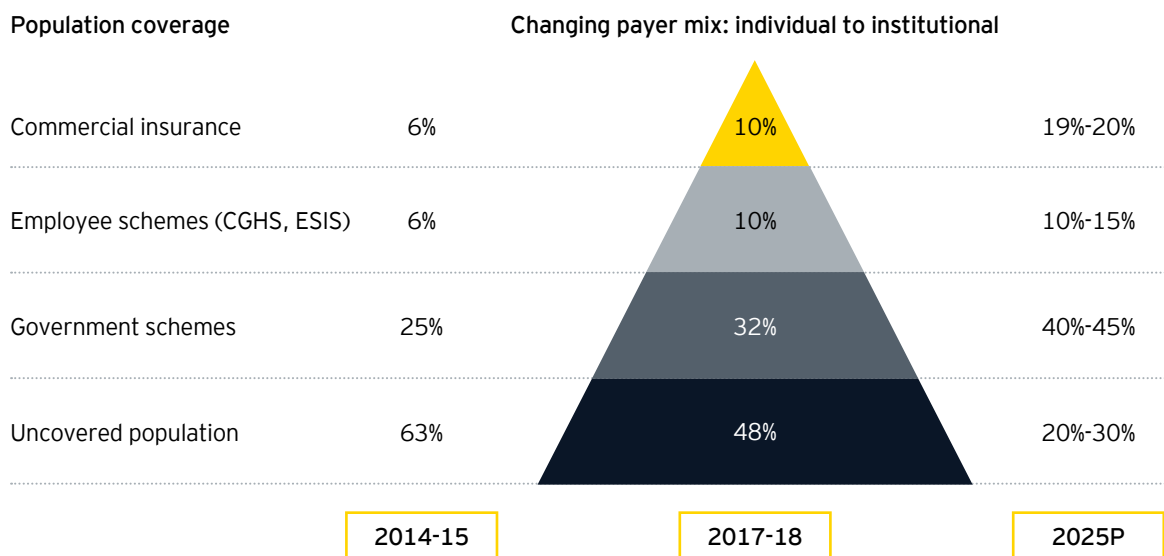
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Expanding the healthcare coverage

PMJAY, coupled with the improvement in penetration of private health insurance, has increased the proportion of the insured population to 52% in 2017-18, from 37% in 2014-15. Coverage is projected to grow close to 70-75% by 2025. By 2030, India can achieve full Universal Health

Cover if Ayushman Bharat expands to include middle class (by increasing coverage from 45% to 65% of population, with the rest of the population under private insurance and employee schemes). By expanding the coverage to include the middle class, the Government will also get the benefit of scale in negotiating with hospitals. Hospitals, on the other hand, can benefit by providing treatment to more patients.

Figure 42: Expanding healthcare coverage



Source: EY FICCI report, Re-engineering Indian Healthcare, September 2016, IRDAI Handbook, IRDAI Annual Report, National Health Profile, individual state insurance websites, EY analysis



Two important aspects of expanding healthcare coverage include - i) steady and sustainable healthcare financing/funding (ii) ease of implementation and usage.

(i) Healthcare financing:

The Government cannot cover the entire set of population with the current level of funding (refer to the figure 43). The

increase in coverage is possible by identifying new steady and sustainable sources of financing healthcare coverage – a few examples have been provided in the figure 44.

Figure 43: Pradhan Mantri Jan Arogya Yojana

Funding requirement analysis		Actual spend in the first year of launch (Sep 2018-2019) ²	
Families to be covered (PMJAY ambition)	10 crore	Total hospital admissions	46.5 lakh
Funding required (Annual premium @INR 5,000*)	INR 50,000 crores	Patient penetration rate	<1% [^]
Funding provided in ¹ FY2020-21 (central+state @60:40 share)	INR 10,667 crores	Average cost per admission	~INR 16 thousand
Funding gap	~INR 39,333 crores	Cost paid for treatment of less than 1% of covered population	INR 7,490 crores

* Assumption based on Neeti Aayog's estimates in 2018 (premium of INR 1,000 to 1,200 per family per annum)³ and current private insurance premium rates (varying between INR 10,000 to INR 40,000 depending on the number and age of people covered)

[^] 46.5 lakh of 50 crore people to be covered under the scheme

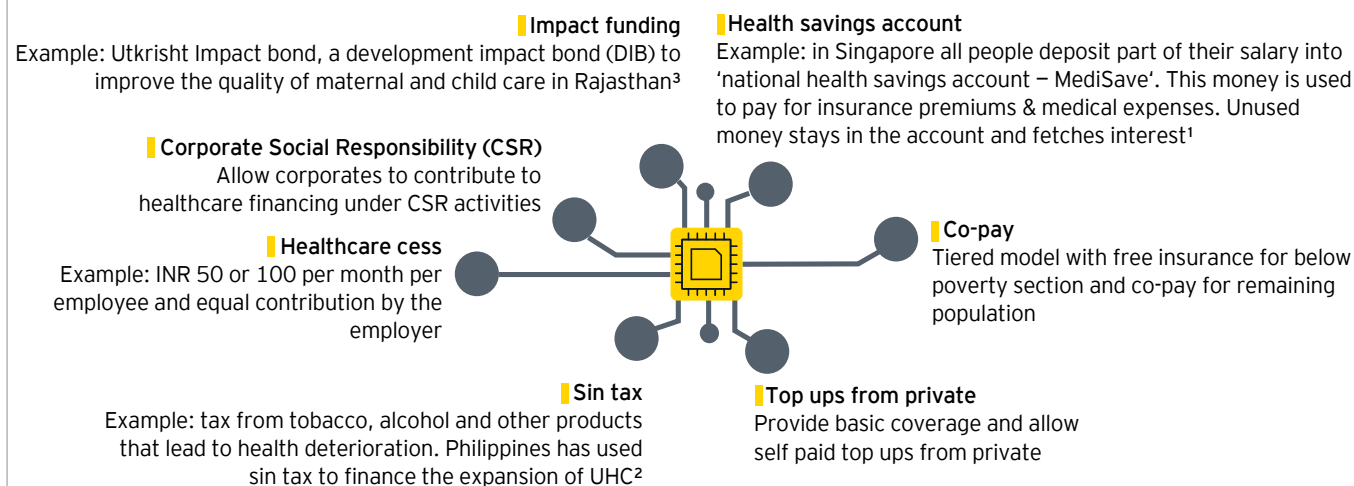
¹ "Allocation to Ayushman Bharat flat, no increase due to low utilisation", BusinessLine, February 2020. Available at: <https://www.thehindubusinessline.com/economy/budget/allocation-to-ayushman-bharat-remain-flat-no-increase-due-to-low-utilisation/article30713169.ece>

² "Government revises packages under Ayushman Bharat Pradhan Mantri Jan Arogya Yojna", Hindustan Times, September 2019. Available at: <https://www.hindustantimes.com/india-news/government-revises-packages-under-ayushman-bharat-pradhan-mantri-jan-arogyayojna/story-JnDJ9BbuHAUt3j97xjW45H.html>

³ "India's challenges with Universal Health Coverage", Healthworld, August 2018. Available at: <https://health.economictimes.indiatimes.com/news/industry/indias-challenges-with-universal-health-coverage/65515072>



Figure 44: Options for financing healthcare and expanding coverage



¹ "Superb Healthcare At Ultra-Low Prices? How Singapore Does It", Forbes, May 2020. Available at: <https://www.forbes.com/sites/steveforbes/2020/05/26/superb-healthcare-at-ultra-low-prices-how-singapore-does-it/?sh=6f500c9e3add>

² "Can sin taxes on tobacco solve funding challenges in healthcare system?", Business Standard, April 2019. Available at: https://www.business-standard.com/article/b2b-connect/can-sin-taxes-on-tobacco-solve-funding-challenges-in-healthcare-system-117011000828_1.html

³ "Innovative health financing models for universal health coverage in Kenya", Intellectap.com. Available at: https://www.intellecap.com/wp-content/uploads/2019/02/Innovative-Financing-Models-for-achieving-Universal-Health-coverage-in-Kenya_March-2019_Final_Print.pdf

“

For subsidy, there needs to be a cross subsidy.

Today we stop at life insurance. All people should have health savings account – this can be incentivized in several ways so people start saving for healthcare.

To sustain good quality care the middle of the pyramid needs to be covered. Government should support by providing a basic cover for a set of diseases and then gradually build up and provide more advanced covers. Co-pay can also be considered as an option. Impact investing is another good mechanism – it is evidence-based approach to bring better outcomes in the population. This is an extremely powerful way to bring a significant change.

Director, Leading Global Pharma Company

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(ii) Ease of implementation and usage

As the healthcare coverage expands to cover the entire Indian population there is a need to develop a system that enables ease of implementation at the healthcare provider (hospital) end and ease of usage for the patients and their families.

There should be a mechanism by which patients are able to go to any healthcare system in India and receive treatment without the need for any approvals or provide information about healthcare coverage type/category or medical history. National Digital Health Mission (NDHM) is a step in the right direction (discussed in detail later in this chapter) towards achieving this goal. Electronic Health Records (EHR) and Personal Health Records (PHR) developed under the NDHM should be interoperable so that they can be easily and securely shared across all public and private hospital systems. Legislation on the security and privacy of EHR and PHR should be developed, including reporting requirements in case of a breach.

Another feature that could be introduced in this entire system is linkage of Aadhar Card with the healthcare coverage type. We can consider this like a system to color-code the Aadhar Card by the category of coverage that enables automatic services getting delivered to patients according to their

healthcare coverage category, e.g., below poverty line, middle-income group, high-income group. We can consider the example of Singapore. The country has a mix of public and private healthcare providers, as well as different tiers of care. There are five classes of healthcare tiers – A, B1, B2+, B2 and C – that range from 100% privately paid and personally chosen service to the most publicly paid, standard service, for which the government pays up to 80% of the costs. While clinical care is not affected by ward class, the type of facilities do vary between the five classes. For example, “A” class gets a private room with bathroom, air-conditioning and other facilities, while “C” class gets an open ward with seven or eight other patients and a shared bathroom¹¹.

The next decade is crucial for India to establish required infrastructure and ensure availability of healthcare workers to achieve the ambition of universal health coverage in the true sense. Refer to the UHC case studies for Thailand and Indonesia (page 100). As India expedites its UHC journey, both countries have some similarities and some differences in the overall demographics and healthcare delivery model, and can provide good reference and best practices.

¹¹ “What Makes Singapore’s Health Care So Cheap?”, New York Times, October 2017. Available at: <https://www.nytimes.com/2017/10/02/upshot/what-makes-singapores-health-care-so-cheap.html>

Universal healthcare coverage (UHC): case studies

Thailand

Indonesia

UHC details

With the launch of the Universal Coverage Scheme (UCS) in 2002, the country has three government-run insurance programmes to achieve UHC:

- ▶ Civil Servant Medical Benefit Scheme (CSMBS) for civil servants
- ▶ Social Health Insurance (SHI) for organised sector employees
- ▶ Universal Coverage Scheme for the rest

National Health Insurance System (NHIS) or Jaminan Kesehatan Nasional (JKN) launched in 2014 by unifying various health insurance and social assistance schemes into a single public entity, Social Security Management Agency for Health (SSAH)

Coverage of population

Entire population is covered in one of the three government-run insurance programmes

- ▶ All residents are required to register
- ▶ Two types of memberships:
 - ▶ contributing members: self-employed, formal sector employees, employers, and retirees
 - ▶ non-contributing members: people living in poverty, near poverty, and disabled
- ▶ With 203 million members in Oct 2018, the NHIS became the largest single-payer system in the world

Coverage of services

A comprehensive benefit package that has continued to expand over the years, and now also includes long-term home and community care for elderly, and home- & community-based psychiatric care

- ▶ Primary care: medical consultation (155 medical conditions) and procedure fees, basic medical diagnostics and pharmaceuticals; family planning services; some preventive services
- ▶ Secondary and tertiary care: 289 groups of outpatient care and 786 groups of inpatient care services, including medical consultation and procedure fees, laboratory work, radiology, drugs, and medical supplies

Financing

General tax revenue is used to finance the CSMBS and the UCS; equal tripartite contributions from a payroll tax paid by employers, employees, and the government fund the SHI

- ▶ Governmental contributions from income tax and tax from cigarette and other tobacco products; district-level payments; grants from overseas development agencies; contribution from contributing members (employees and employers)
- ▶ Private insurance can be used by members for excess or additional coverage of services not included in the JKN

Payment

- ▶ Closed-end payment (capitation and diagnostic-related groups payment within a global budget) is the main mode for >90% of payments; remaining payments are based on fixed-fee schedules for certain services such as dialysis and other high-cost interventions
- ▶ Per capital budgets are based on unit cost and utilisation rates of different types of services

- ▶ Primary care providers (PCPs): two mechanisms (i) capitation, an advance payment per member per month including consultation, simple laboratory tests, and drugs for acute care; drugs for chronic diseases covered separately (ii) claim, for services falling outside capitation
- ▶ Secondary and tertiary care providers: payment based on case-based groups

Best practices

Thailand

**Financial accountability framework**

- ▶ National Health Security Office (NHSO) purchases services from public and private provider networks through annual contractual agreements using the dual payment system of capitation and diagnostic-related groups
 - ▶ Funding is based on requirement (e.g. number of people registered, proportion of chronic diseases managed) and the allocation to health facilities is flexible
 - ▶ Generation of revenue through provision of services encourages public providers to be responsive to patients
 - ▶ Payment of same rates for public and private sector provides a level playing field, leading to increased collaboration from the private sector
- ▶ Robust grievance management and disputes settlement system, and annual public hearing for UCS members increases provider accountability

**Accreditation based quality assurance**

- ▶ Quality is ensured by relying on a step-wise quality improvement process guided by a healthcare accreditation institute (instead of consumer choice and competition based)
- ▶ By 2012, almost all hospitals in Thailand were accredited or had quality assurance processes in place

**Civil Registration and Vital Statistics system**

- ▶ Mandates the registration of all births and deaths and assigns a unique citizen ID number to each citizen
- ▶ Facilitates the transfer of members between the three public insurance schemes for seamless continuity of health coverage

**Evidence based budgets**

- ▶ Health Intervention and Technology Assessment Programme prioritises the inclusion of new medicines into the National List of Essential Medicines and new interventions into the UCS benefit package, enhancing health systems' efficiency

**"Continuum of Care" design**

- ▶ Periodic health examination, used as a risk stratification tool, prevents onset of disease or provides warning of an existing disease

**Robust public infrastructure**

- ▶ Adequately staffed district health system (consisting of health centres and a district hospital), is the backbone of health development
- ▶ In 2014, >80% of beds were in Ministry of Public health (MOPH) or public facilities

**Health workforce development**

- Several efforts to improve the availability of health workers in underserved areas and strengthen primary health care:
- ▶ Three year mandatory rural health-service placement for all medical and nursing graduates (and subsequently dentists and pharmacists) in public and private schools; provision of financial and non-financial incentives
 - ▶ Special track programme for rural recruitment and home-town placement; strengthened regional hospitals as clinical training centres for students in years 3-6 of the special track
 - ▶ Established nursing and midwifery colleges; nursing licensing examination to ensure adequate competencies
 - ▶ Public health schools train other paramedical personnel mostly on 2 year diploma (now increased to 4 years)
 - ▶ Additional workforce of ~14 lakh community health volunteers, each paid about 600 baht, equal to INR 1,200, per month.

Indonesia

**Operated by SSAH, single quasi-government entity**

- ▶ Provides flexibility in management and staff recruitment
- ▶ The SSAH has legal authority to collect and manage NHIS funds and enforce contributions from employers and employees
- ▶ SSAH can directly contract primary care providers (PCPs) and hospitals, and provide payments

**Regulated gating mechanism to improve efficiency and quality**

- ▶ Patients are required to initiate care with PCP
- ▶ To regulate PCP capability, the Indonesian Medical Council has established standard care competencies for the most common 144 diagnoses and 11 medical conditions, beyond which the PCP must refer patients to a specialist (a cap of 5% is placed on referrals to discourage misuse)
- ▶ Referral by the PCP is first to a lower-class hospital (class D, C, or B), from where referral to a top tertiary hospital (class A) can be made if needed

**E-tender platform to procure cheaper medicines**

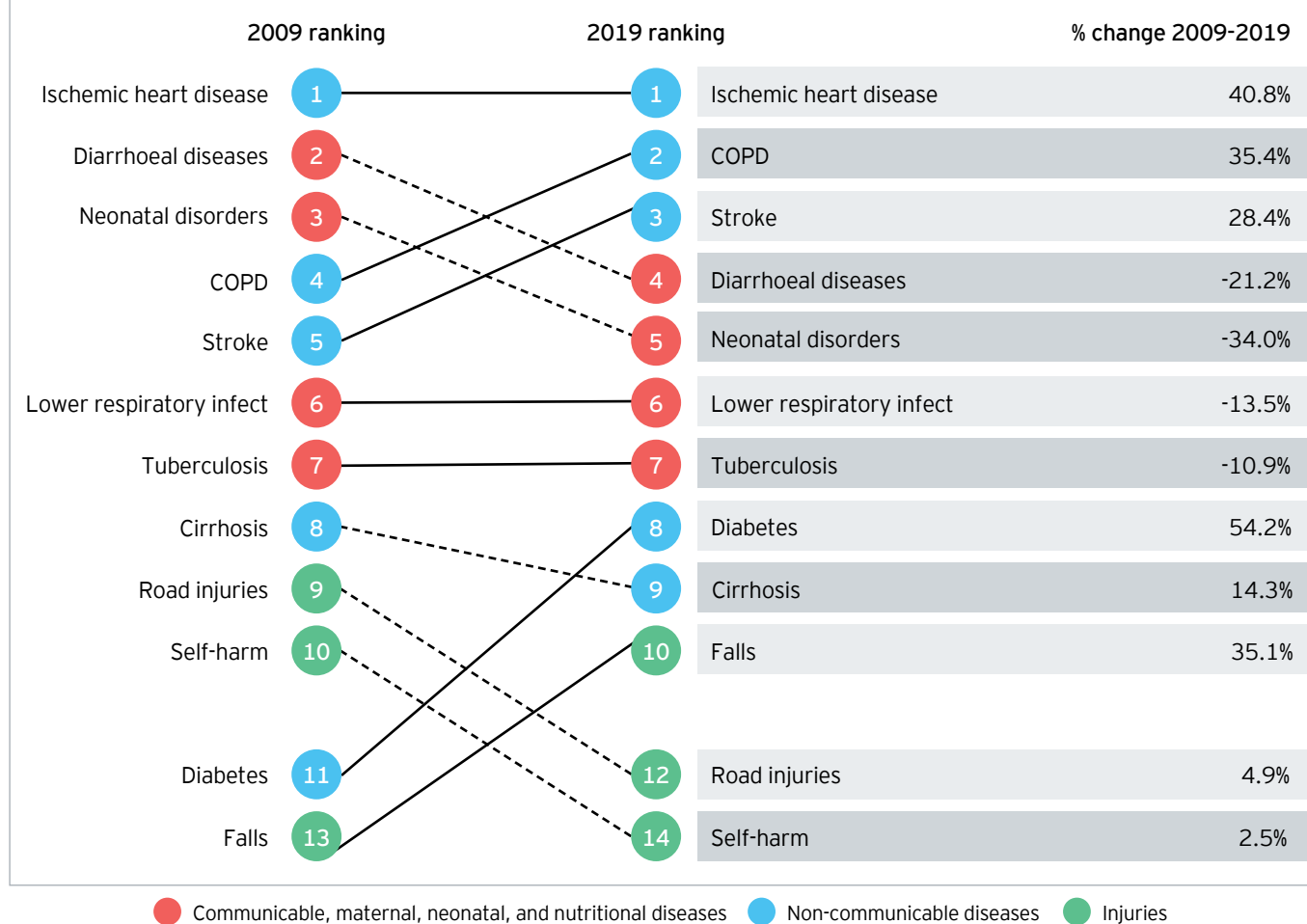
- ▶ To assist PCPs and hospitals to procure cheaper medicines, the government established the e-catalogue, an electronic tender platform in which all pharmaceutical companies submit competitive bids for drug prices
- ▶ To assist pharmaceutical companies in calculating appropriate bids, the Ministry of Health provides estimated volumes needed for each type of drug by province

While there is definitely a need to expand healthcare coverage and delivery capacity by establishing new infrastructure (e.g., number of hospitals, beds, etc.) and increasing the number of healthcare workers at all levels, there is a huge scope to

bring in more efficiencies by leveraging technology. Effort also should be made to reduce the demand for health care services by shifting towards preventive healthcare, which is the next section of our report.

2. Boosting self-care and prevention

Figure 45: Top 10 causes of total number of deaths in 2019 and percent change 2009–2019 (all ages combined)



Source: Global Burden of Disease Study, available at: <http://www.healthdata.org/india>

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Majority of the diseases causing deaths in India are preventable or treatable.

”

The burden of some preventable diseases is rapidly increasing because of changing lifestyle and other factors such as pollution. Given the large majority of the population needing public support for healthcare, increasing burden of communicable and non-communicable diseases, and the limited capacity of the government for health expenditure, robust

primary care is critical for India to achieve the aspiration of universal health coverage.

Even the most well-funded healthcare systems of the world are now shifting focus from disease treatment to prevention, and that is how any country can provide sustainable health solutions to its citizens.

“

Acute healthcare is never going to be a solution for India. The solution lies in primary and preventive care. Preventive care awareness needs to be in the masses in India. The segments where we see more awareness is among the educated middle class, but that is not enough. Where healthcare is becoming debilitating financially is for the poor people.

The number of people requiring acute intervention or having lifestyle diseases is constantly increasing. While communicable diseases have reduced, they still constitute a significant proportion of the disease burden India. At this rate, beds are never going to be enough and the cost of treatment will be huge. This is the time to break the chain. At this point, we must invest in tertiary care, but it cannot be an either-or situation. We need to strengthen both tertiary and primary care over the next decade or so.

MD and CEO, Leading Indian Hospital Chain

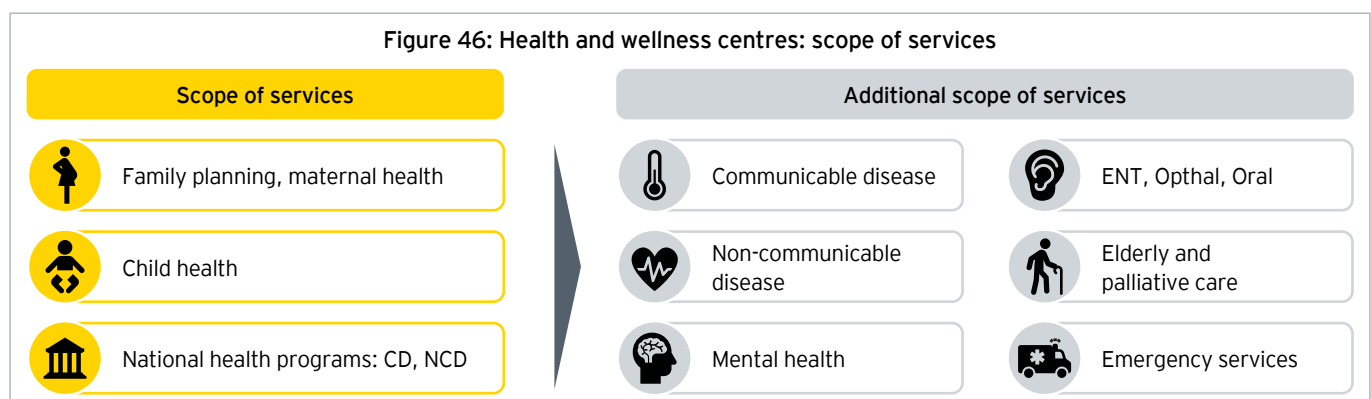
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2.1 Strengthening primary care

Ayushman Bharat aspires to raise awareness about health care and reduce disease burden by promoting preventive and promotive healthcare services, particularly in the rural areas where 70% of the population resides. Its Health and Wellness Centers initiative aims to revamp 150,000 existing Sub-Centers (SCs) and Primary Health Centers (PHCs) - the lowest tier of

the health system - into Health and Wellness Centers (HWCs) by 2022. By March 2020 about 39,000 HWCs were operational across India. The objective of the HWCs is to achieve preventive, promotive, curative, diagnostic, rehabilitative and palliative care across a range of indications (see Figure 46). In addition to comprehensive health care services, these centers also provide free essential medicines and diagnostic services¹².

Figure 46: Health and wellness centres: scope of services



Source: Ayushman Bharat - Comprehensive Primary Health and Wellness Centres, Operational Guidelines; EY analysis

¹² C. Lahariya, "Health & Wellness Centers to Strengthen Primary Health Care in India: Concept, Progress and Ways Forward", Indian J Pediatr, July 2020. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7340764/>

If developed as per the ambition, these health and wellness centers can play a critical role in expanding access to primary care, serving as the foundation of healthcare for all, across the country. But to realize this ambition, India needs thousands of more care providers, including nurses, primary care physicians, and specialists. Indeed, a large proportion of the country's SCs, PHCs, and CHCs are understaffed. The HWCs should also have good physical infrastructure, e.g. advanced diagnostic tools and machines, etc. to provide all services that they are designated to provide. These HWCs should, over time, be able to manage most primary care requirements for communicable and non-communicable diseases, and should act as gatekeepers for all referrals to secondary and tertiary care (refer to the Thailand and Indonesia UHC case studies on page 98). This will reduce capacity requirement in hospitals and the burden on specialists, and also limit health care costs. In addition, managing diseases early on with a robust primary care provision will also reduce chances of increase in disease

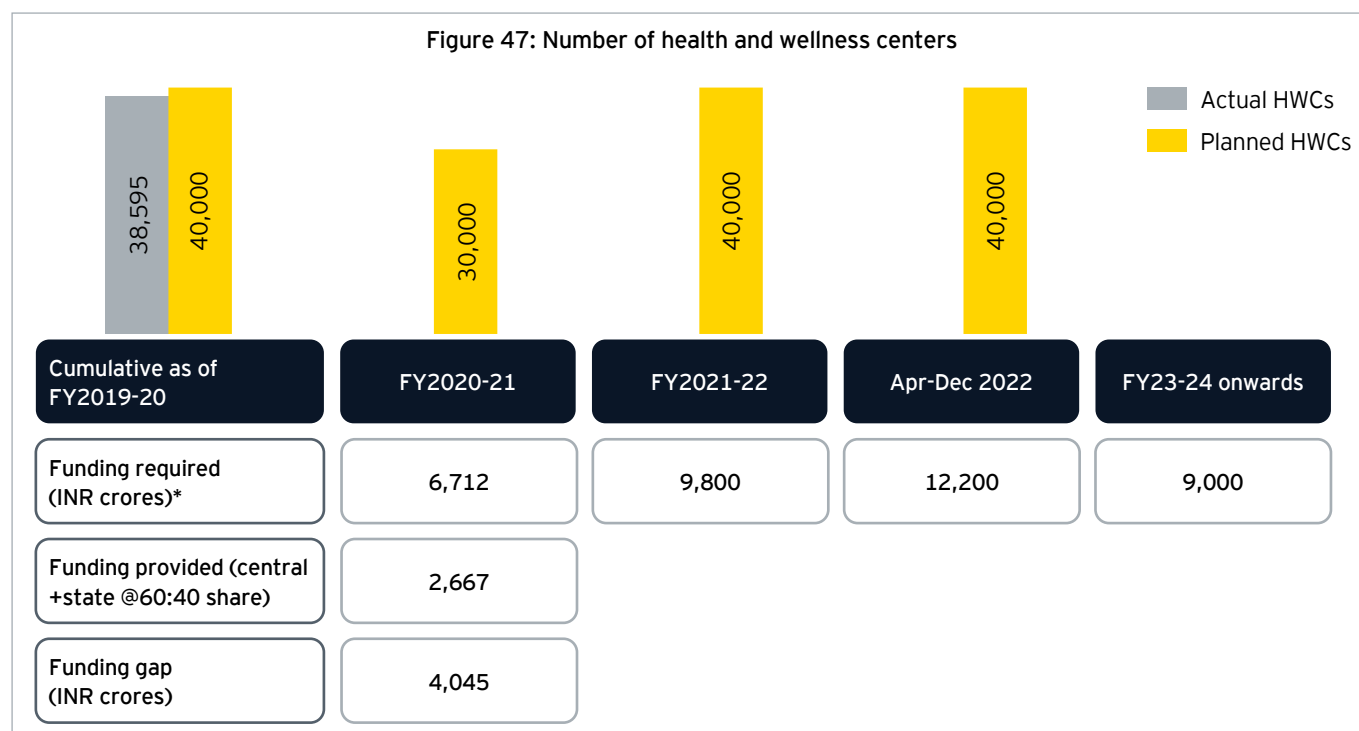
severity and reduce hospital admissions. Studies indicate that the hospitalization ratio in a district is negatively correlated to primary care usage, a 10% increase in primary care usage leads to a 6% reduction in hospitalization.

Key priorities for developing strong primary care infrastructure

1. Availability of appropriate funds

Government should allocate enough funds annually required to revamp planned number of SCs and PHCs to HWCs during the year and run the active HWCs. HWCs should be equipped with all the physical infrastructure, healthcare delivery staff, and medical supplies (including medicines and diagnostics) to fulfil the entire scope of services (including disease coverage) as per the plan. Only then can the HWCs act as effective gatekeepers for referrals to secondary and tertiary services.

Figure 47: Number of health and wellness centers



*Note:

1. Calculated as sum of 'Funds required for upgrading and running planned HWCs for the year @INR 14 lakh / annum' and 'Funds required for running active HWCs at the start of the year @INR 6 lakh per annum'
2. Inflation rates not applied over the years; does not include cost of free medicine and diagnostics

Source: EY analysis; "Ayushman Bharat - Comprehensive Primary Health Care through Health and Wellness Centers", NHSRC. Available at: <http://nhsrindia.org/sites/default/files/Operational%20Guidelines%20For%20Comprehensive%20Primary%20Health%20Care%20through%20Health%20and%20Wellness%20Centers.pdf>

2. Addressing healthcare workforce availability gap

A holistic approach is needed to address the healthcare workforce availability gap in HWCs. The number of seats in institutions should be increased across all roles and levels

to introduce more workforce. Focussed training programmes should be developed to enhance the skillset and role of the existing workforce – e-modules leveraging advanced technology such as augmented reality/virtual reality can be a cost-efficient way to train primary care givers and provide additional

flexibility so that India can achieve scale on this metric more quickly. Like several other countries (e.g., Brazil, Turkey, the US, etc.), new roles of family medicine practitioners can be created (e.g., physician assistants) to ensure that all primary care needs of the population are met within these HWCs.

Refer to the Thailand UHC case study for attracting and retaining rural health workers through a successful multi-pronged strategy including decentralized education, compulsory rural service, financial incentives and the creation of a supportive ecosystem.

3. Leveraging technology to increase competence and efficiency

Technology should be leveraged to further increase the competence and efficiency of the workforce – e.g., interactive symptom screening algorithms, tools for diagnosis and monitoring, point of care devices, and artificial intelligence based clinical decision support. Several tools are already available in India such as ViScope, a handheld device for improving diagnosis of cardiac problems and iBreastExam, an ultraportable wireless device to detect small breast abnormalities without any pain or radiation.

4. Providing telehealth facility and infrastructure

Telehealth, with the required infrastructure (e.g., high-speed data, advanced tele consult platform enabling video consultation, remote diagnosis, sharing of results, etc.), should become an essential feature of HWCs for enabling consults with specialists from larger hospitals in the cities – this can further reduce the need for referrals and enable treatment of individuals in rural areas where demand for trained physicians outstrips supply.

5. Establishing a governance process

A strong governance process should be established to improve the utilization of primary care centers and reduce the load on specialists. A gatekeeping strategy would improve the efficiency of specialists and control the escalations in healthcare spending. Many other developed and developing countries (e.g., Thailand) have very effective gatekeeping mechanism at the primary care level.

Governance in primary care involves a strong commitment to minimizing disease burden through prevention, early detection, and effective management of disease. To achieve this, detailed guidelines should be laid out about the expected roles and responsibilities of health workers at each level. The scope of services to be provided by the HWCs should be clearly defined, explaining conditions or diseases that should be managed in the HWCs and those that should be referred for specialty care. Performance evaluation criteria for healthcare providers at all levels should also be an important section in the governance process.

2.2 Reducing the burden of non-communicable diseases through effective prevention and disease management

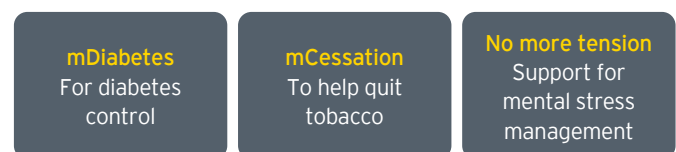
Under the Sustainable Development Goal 3.4, the Government's target is to reduce by one third premature mortality from NCDs by 2030 through prevention and treatment, and promoting mental health and well being.

The increasing incidence and mortality of NCDs has led to greater awareness for wellness and health among all generations of people. The government of India has also launched initiatives, such as the "National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular disease and Stroke" (NPCDCS), with the aim to increase awareness of risk factors, set up infrastructure (like NCD clinics, cardiac care units), carry out screening at primary health care levels for early diagnosis and promote proper treatment and disease management.

The following measures should be adopted to prevent and effectively manage NCDs.

2.2.1 Leveraging technology for creating awareness and effective disease management

The government has leveraged social media for health promotion. Mobile apps, such as mDiabetes and mCessation, have been launched to increase awareness about prevention and control of NCDs. While these apps are useful, more can be done to increase awareness in the masses about the availability and benefits of using such apps.



More technology-based solutions can be made available for empowering patients, and enabling physicians and care delivery teams to effectively diagnose and manage chronic diseases.

An innovative digital solution for non-communicable disease prevention, control and care is Mexico's CASALUD that has been incorporated as public policy into the National Strategy for the Prevention and Control of Pre-obesity, Obesity and Diabetes of the Federal Government since 2013. The CASALUD model is based on five pillars¹³.

¹³ R. Tapia-Conyer *et al.*, "Enablers and inhibitors of the implementation of the Casalud Model, a Mexican innovative healthcare model for non-communicable disease prevention and control", July 2016. Available at: <https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0125-0>

- ▶ The first pillar is the proactive prevention and detection of NCDs, and includes two systematic risk assessment tools: (i) MIDO health-carts located at easily accessible public locations including supermarkets, transportation hubs, community centers and schools (ii) MIDO backpacks, a portable module with wireless connectivity that can enable screening in households. The MIDO integrates patient health assessment equipment including devices for measuring blood pressure (BP), blood glucose, urinary proteins, height and weight with a digital patient health screening questionnaire enabling mass screening and identification of individuals at a pre-disease stage. The screening is followed by personalized treatment in case a disease is diagnosed and/or counselling and lifestyle recommendations at the healthy or pre-disease stage.
- ▶ The second pillar is evidence-based chronic disease management, and includes Chronic Disease Information System (SIC) and a Digital Portfolio for healthcare professionals. Physicians can capture patient data on NCD care on SIC, and can also access their lab tests and other results, and SIC analysis, based on which they can then prescribe lifestyle changes and the most appropriate pharmacological treatment.
- ▶ The third pillar is continuous monitoring of medication supply chain through AbastoNET – an online information system that standardizes metrics for stock management at primary health clinics (PHCs).
- ▶ The fourth pillar is capacity building through continuous medical education, and is executed through the Online Interactive Platform for Health Education – PIEENSO in Spanish. The platform confers two degrees with academic endorsements of national and foreign universities. The first degree is a 110-hour Online Certificate to increase physicians' knowledge about NCDs. The second is a 40-hour practical course where physicians solve real-life cases and test their knowledge in practical settings.
- ▶ The fifth pillar is patient engagement and empowerment, including assessment of the knowledge, confidence and skills to prevent and manage chronic diseases, plus tools to implement related behaviours.

Figure 48: Mexico's CASALUD – digital solution for NCD prevention, control and care



*HCP - Health Care Professional

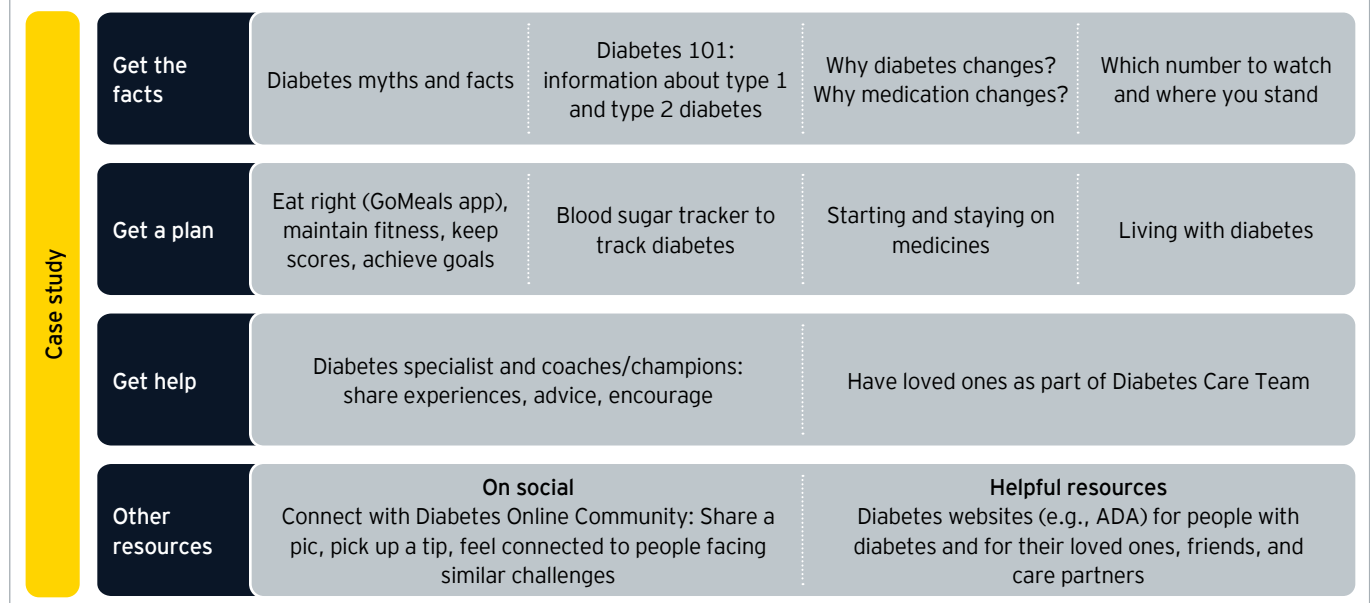
Source: GSMA, Carlos Slim Foundation

CASALUD began its pilot phase in 2009 in seven Mexican states. Within seven years (by 2016), it had been implemented in 130 PHCs in 25 out of the 32 Mexican states through a public-private partnership arrangement between Carlos Slim Foundation (FCS) and federal and state governments. The entire model is developed and financed through the FCS –

neither the public healthcare system nor its users/beneficiaries incur any additional costs.

The pharma industry can also play a core role in enabling people to prevent and manage disease better by providing beyond product solutions – an example of such an initiative by a global pharma major is referenced below (figure 49).

Figure 49: A comprehensive personalized disease management program by a global pharma major



Company reports, EY analysis

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E-consulting, E- Pharmacy, E- diagnostics will address the NCD awareness with AI driven digital solutions.

Director, Leading Global Pharma Company

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2.2.2 Policy enhancement to enable collaborative efforts for increasing awareness and empowerment of the masses

The government can also collaborate with the industry and NGOs to spread more awareness among the masses about health and wellness, disease prevention and disease management. This can be achieved by developing systematic promotional strategies for key diseases in collaboration with other stakeholders. There is also a need to revisit certain policy interventions that were issued decades back. For example, the Drugs and Magic Remedies (Objectionable Advertisement) Act was issued in 1954. It prohibits advertisement of certain drugs

& magic remedies for diagnosis, prevention and treatment of diseases. A set of mandatory, legally-binding guidelines or codes could be developed focusing on drug promotion, marketing and advertising. Currently, the pharmaceutical industry is only voluntarily required to adhere to “Uniform Code of Pharmaceutical Marketing Practices” (UCPMP).

Another important area requiring policy intervention is in the over-the-counter (OTC) space. The ongoing pandemic has brought a lot of awareness about self-care and wellness. Issuing OTC guidelines will empower people and pharmacists to make informed decisions about health and wellness supplements and medicines for common ailments. Usage of OTC products and medicines has huge potential to reduce overall health care

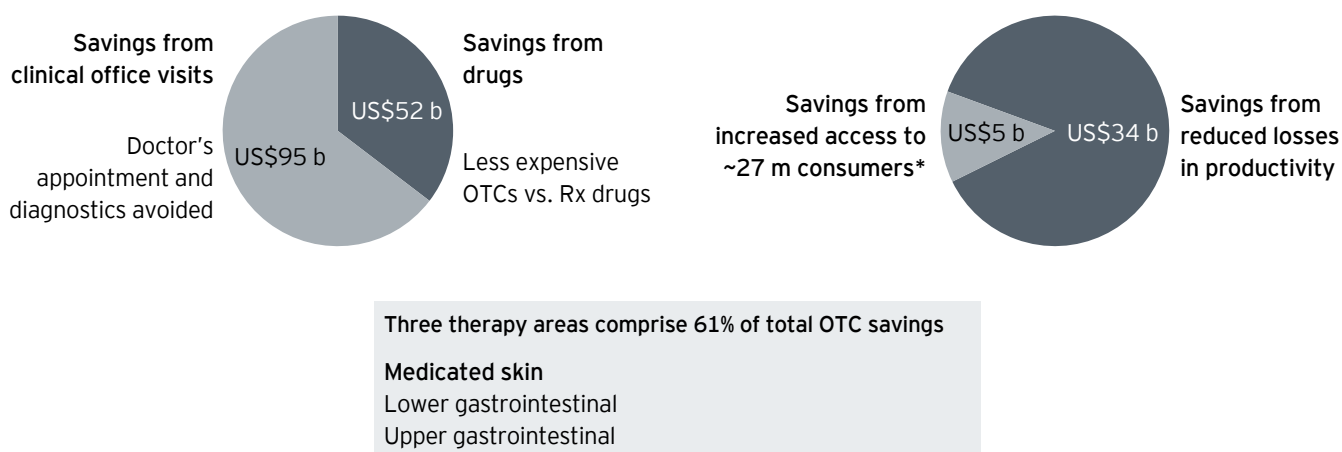
costs. Take the case of the US for example, where OTC drugs result in annual savings of nearly US\$185 billion (refer figure 50 for details). To reap the benefits of OTC consumption, detailed, evidence-based guidelines should be rolled out after considering the best practices and loopholes in other

geographies where OTC is regulated. The guidelines should also include requirements for the marketer to provide relevant details and tools for consumers to self-diagnose small ailments and identify the right OTC product or the need to consult a doctor.

Figure 50: OTC as a category helps in reducing healthcare costs while broadening access

OTC drugs create substantial value for the US healthcare system annually, **US\$146 billion in savings** due to alternative treatment availability...

...and **US\$39 billion** due to better access and process



*Consumers who would not seek medicines if they were available as Rx instead of OTC

Source: CHPA report, March 2019

2.2.3 Upgrading insurance products to cover health & wellness and outpatient services

The Insurance Regulatory and Development Authority of India (IRDAI) Regulations encouraged insurers to reward policyholders for wellness and preventive aspects for the first time in 2016. Since then, some of the big insurers in India have started incentivizing healthy behaviours and preventive healthcare by giving reward points of up to 10 to 30% of annual premium. In November 2019, IRDAI released 'draft on guidelines on wellness and preventive features/benefits'. Guidelines suggested insurers to offer in the product outpatient consultations or treatments and health check-up diagnostics¹⁴. These benefits will encourage policyholders to go for routine check-ups instead of deferring them for the fear of high cost. This will result in earlier diagnosis, or sometimes even prevention of disease, hence saving all the potential higher costs of treating the disease. Guidelines for wellness have also

been enhanced, e.g., insurers can offer discounts on premiums or increase the sum assured at the time of renewals based on the wellness regime of policyholders in the preceding policy period. These improvements over time mean that insurance products are slowly shifting from securing oneself against big illnesses requiring hospitalization to providing care for daily health needs.

2.2.4 Vaccination for preventable diseases

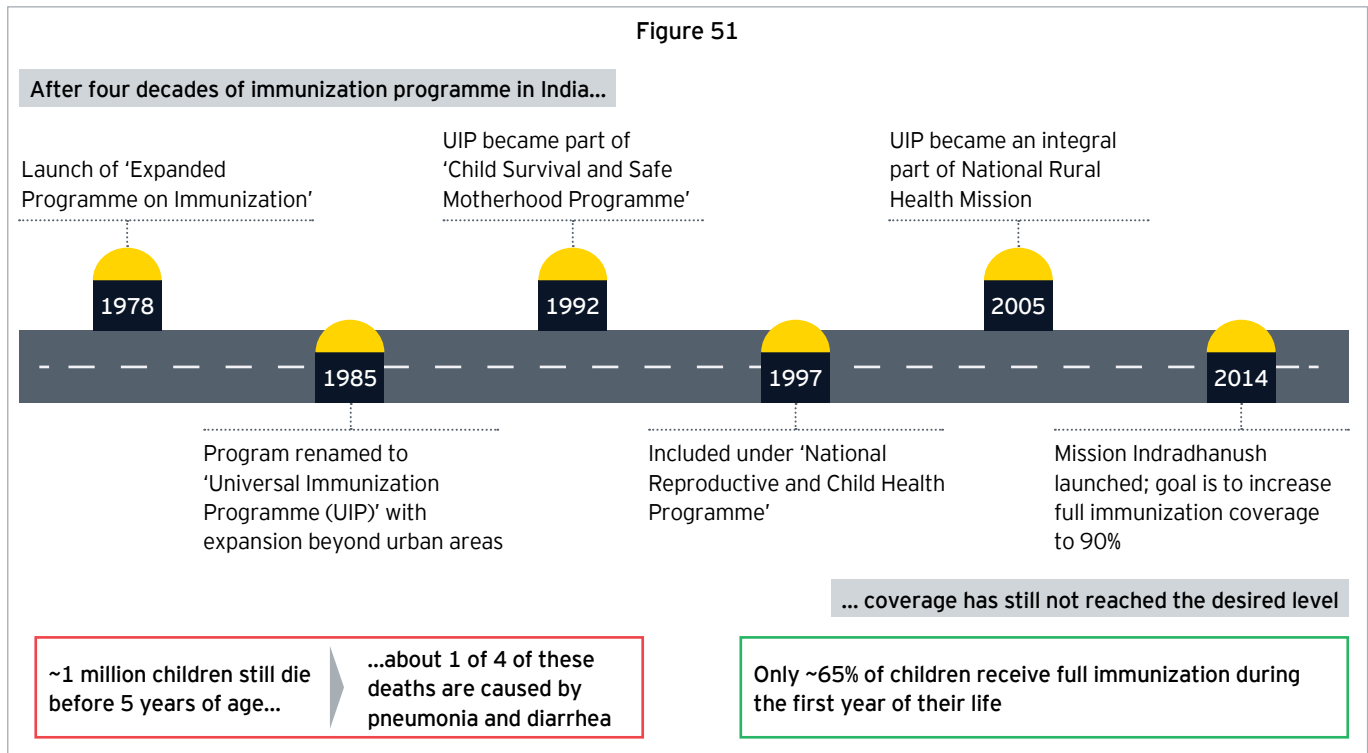
In 1978, India first launched its major immunization programme for protection of children from preventable life-threatening conditions¹⁵. The current universal immunization programme (UIP) provides free coverage against 12 vaccine preventable diseases. Nine are covered at the national level and three others – rotavirus diarrhea, pneumococcal pneumonia and Japanese Encephalitis – are covered regionally¹⁶. Plans are currently underway to expand use of both the rotavirus and pneumonia vaccines.

¹⁴ "Irdai calls for wellness features in health insurance plans", Financial Express, November 2019. Available at: <https://www.financialexpress.com/money/insurance/irdai-calls-for-wellness-features-in-health-insurance-plans/1765196/>

¹⁵ C. Lahariya, "A brief history of vaccines & vaccination in India", April 2014. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4078488/>

¹⁶ National health mission website. Available at: <https://nhm.gov.in/index1.php?lang=1&level=2&sublinkid=824&lid=220>

Figure 51



Source: EY analysis

A child is said to be fully immunized if the child receives all required vaccines in the first year of life as defined by the national immunization schedule. The two major milestones of UIP have been the elimination of polio in 2014 and maternal and neonatal tetanus in 2015. However, despite the immunization programme running for the last four decades, only 65% of children are fully immunized on time. About one million children still die of vaccine preventable diseases in India every year before their fifth birthday, with a quarter of these due to pneumonia and diarrhoea¹⁷.

There is also more work to be done on adult immunizations. Several adult vaccines are now available and can provide protection against some critical diseases such as tetanus, human papillomavirus (HPV), hepatitis, typhoid, Japanese encephalitis, meningococcal disease, pneumococcal disease and influenza¹⁸. People with chronic diseases (such as diabetes, heart disease, chronic kidney diseases, etc.) and the elderly are more at risk of infectious diseases and are highest vaccination priorities.

Effective adult vaccination programmes can not only save a lot of money for healthcare systems and families, but can

make a huge difference in reducing disease related morbidity and mortality. Only one vaccine is nationally recommended for adults – tetanus toxoid (TT) during pregnancy for the protection of newborns against tetanus. To improve overall uptake of the vaccines, there is a need to create more awareness in the masses about the importance of vaccination, and possibly to fund initial programmes, especially for high-risk groups, as has been done for immunization programmes for children. Coverage of adult vaccination by insurance products can also boost its uptake.

Whether it is NCDs, communicable diseases, or vaccine-preventable diseases, the Indian population has to take more accountability of their own health. COVID-19 has resulted in greater awareness among people about the need for prevention of disease, e.g., frequently washing hands, wearing masks, etc. for protecting themselves from the infection. It is time to ensure that this consciousness about disease prevention continues and expands. The government should promote physical wellbeing by shaping individual health-related behaviour and prevent the development of key risk factors of chronic diseases.

¹⁷ Unicef website. Available at: <https://www.unicef.org/india/what-we-do/immunization>

¹⁸ CDC website. Available at: <https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf>

Figure 52: Burden of vaccine preventable diseases in India

Cervical cancer	Rubella	Hepatitis B	Diphtheria	Influenza/flu
<ul style="list-style-type: none"> ▶ 2nd most common cancer and 2nd leading cause of cancer death in India ▶ ~97,000 women diagnosed each year ▶ ~60,000 (60% mortality rate) of them die 	<ul style="list-style-type: none"> ▶ 40-45% of women in the childbearing age susceptible to Rubella ▶ >2 lakh babies born with birth defects because of Rubella infection during pregnancy 	<ul style="list-style-type: none"> ▶ ~300,000 new cases each year ▶ ~205,286 deaths annually related to chronic hepatitis 	<ul style="list-style-type: none"> ▶ US CDC data indicates that in countries with last diphtheria booster before age 6 years, about half of all diphtheria cases are in people more than 15 years of age. This prevalence is highest in India 	<ul style="list-style-type: none"> ▶ During monsoon, 20% of all hospital admissions have influenza positivity ▶ ~40,000 deaths occur due to Influenza annually

Source: A. Rath et al., "Vaccine Preventable Diseases in Indian Adults-Burden & Prevention", *Infect Dis Diag Treat*, 2017; R. Dash et al., "Towards adult vaccination in India: a narrative literature review", 2019

S. Kolhapure, "Towards adult vaccination in India: a narrative literature review", December 2019. Available at: <https://www.tandfonline.com/doi/full/10.1080/21645515.2019.1682842>

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Some positive changes have come out of COVID: increased focus on healthcare by people and government. Prevention has become important, especially when there is no better cure than wearing mask, social distancing, how to cough, where not to spit

Top official at an Indian Regulatory body for Hospitals

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3. Embracing telehealth as an enabler to bridge the healthcare demand and supply gap

Globally, India is one of the fastest technology adopters with significant mobile and internet penetration. India holds the second spot (after China) on various dimensions of digital adoption, such as mobile phone and internet subscriptions. In addition, people in India are now more aware and involved in their own health and disease management. This presents a huge opportunity for India to expand digital health.

Telehealth emergence due to COVID-19

Telehealth is not a new concept. In India, Apollo Telemedicine Networking Foundation (ATNF) is the oldest and largest multispecialty telemedicine network¹⁹. The Sankara Nethralaya and the Aravind Eye Hospitals in Tamil Nadu and the Tripura Vision Centre in Tripura also have successfully used telemedicine to conduct screening of eye diseases (teleophthalmology) in rural areas among the general population.

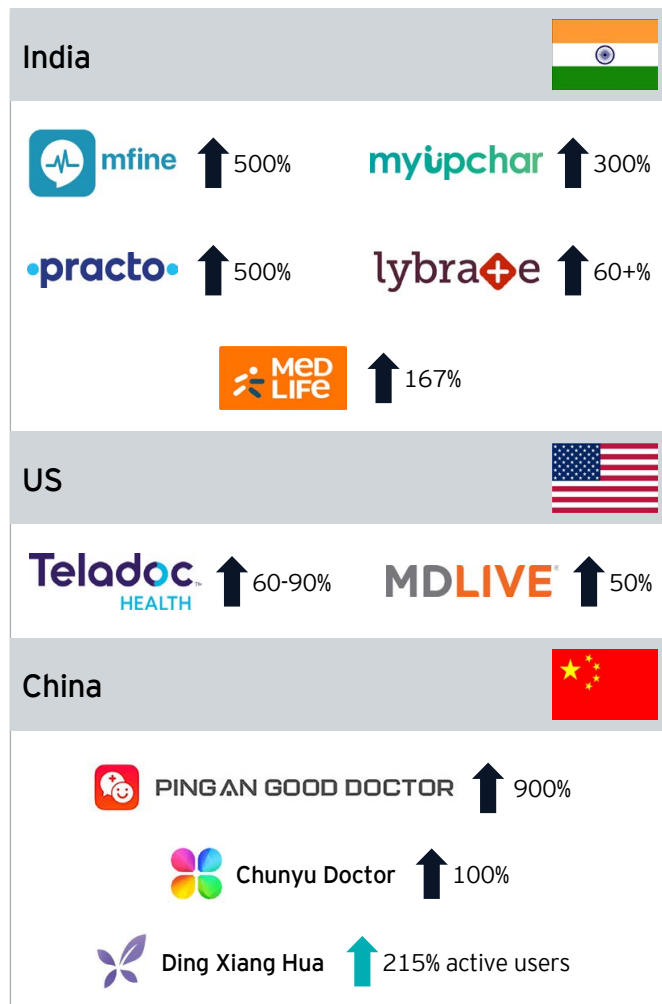
Kerala Oncology Network or the Onconet-Kerala, which launched in 2001, is another one of the most successful telemedicine projects in India. This initiative uses telemedicine to detect, diagnose and treat cancer; services linked to pain management and follow-up show how telemedicine can support the whole patient journey.

Teleconsultation holds the promise to provide healthcare access even to the remotest regions in the country, while also bridging the gap between healthcare infrastructure availability and demand. However, pre-COVID these initiatives were being explored in pockets. The need for physical distancing as a result of frequent lockdowns has led to an emergence of telehealth globally and in India. To avoid going to hospitals or clinics, patients are now willing to consult physicians online for acute and chronic diseases. Healthcare providers have integrated teleconsultation platforms and scaled-up their existing digital offerings. For e.g., Fortis Healthcare has witnessed a shift in outpatient department (OPD) consultations with 10% of pre-COVID-19 consultations moving to the teleconsultation platform²⁰.

¹⁹ V. Mohan, "Tele-diabetology to Screen for Diabetes and Associated Complications in Rural India", *J Diabetes Sci Technol*. - 8(2): 256-261, March 2014. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4455413/>

²⁰ "Telemedicine is the new call for action at the moment", *Indian Express*, May 2020. Available at: <https://indianexpress.com/article/lifestyle/health/in-telemedicine-virtual-healthcare-future-scope-india-mindsets-doctors-6421192/>

Figure 53: Rise in teleconsultations during pandemic



Globally, virtual primary care consultations increased from 5% to 95% between January to May 2020. Practo reported that five crore Indians accessed healthcare services online during the first phase of lockdown between March 2020 and May 2020. On an average, a typical user consulted a doctor online twice a month which led to a drop of 67% in in-person visits. Eighty percent of these telemedicine patients were first-time users and 44% came from non-metro cities²¹. Leading healthcare chains in India are doing 200-500 tele-consults per day with a few star doctors doing 8-10 consultations. Platforms have seen up to a 500% increase in the number of online consultations post-COVID-19.

“

Even when COVID goes, telemedicine is here to stay. Doctors in India were stymied by the lack of clarity – whether I can, or I cannot, and if they would be taken to the court. But on 25 March 2020 the Medical Council of India amended the ethics part of rules and the telemedicine practice guidelines were issued – it has certain lacunas, but I am sure they will get better over time. But I think the dissemination of the knowledge that telemedicine is legal has not reached the nth degree. So its potential is not being fully harnessed. But over time telemedicine consults will become a regularity

Top official at an Indian Regulatory body for Hospitals

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Similar trends were observed in the US where health systems reported 50-170 fold increases in the number of virtual healthcare visits as compared to the period before COVID-19 emerged. In the UAE, six telemedicine solutions were approved for use in late April. Private hospitals in the UAE are doing 150-300 consults per day²². Similarly, leading platforms in China also witnessed a massive growth in telemedicine usage²³.

Telehealth potential to improve healthcare access

Technological advancements in the recent past have paved the way for healthcare professionals to communicate with their patients, breaking down the barriers that can impede patients' access to medical care. Teleconsultation has opened doorways to access healthcare in multiple ways. It is expected to revolutionize the dynamics of the clinical practice.

²¹ “The role of telemedicine in an evolving healthcare environment”, Insights by Practo. Available at: https://s3-ap-southeast-1.amazonaws.com/www.practostatic.com/marketing/images/pdfs/Practo_Insights_Report.pdf

²² “UAE opens access to new telemedicine applications and facilitators”, Healthcare IT News, April 2020. Available at: <https://www.healthcareitnews.com/news/emea/uae-opens-access-new-telemedicine-applications-and-facilitators>

²³ “As the Coronavirus Spreads, Healthcare Goes Digital”, February 2020. Available at: <https://www.bain.com/insights/as-coronavirus-spreads-healthcare-goes-digital-snap-chart/>

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Teleconsult is a positive move for both doctor-patient and the industry. It is economic for both patients and physicians, and especially useful for chronic diseases and for follow ups

MD, Leading Indian Pharma Company

There is still some way to go for teleconsulting, but it is going to be useful for improving access to remote/underserved areas, and for follow-ups.

MD & CEO, Leading Indian Hospital Chain

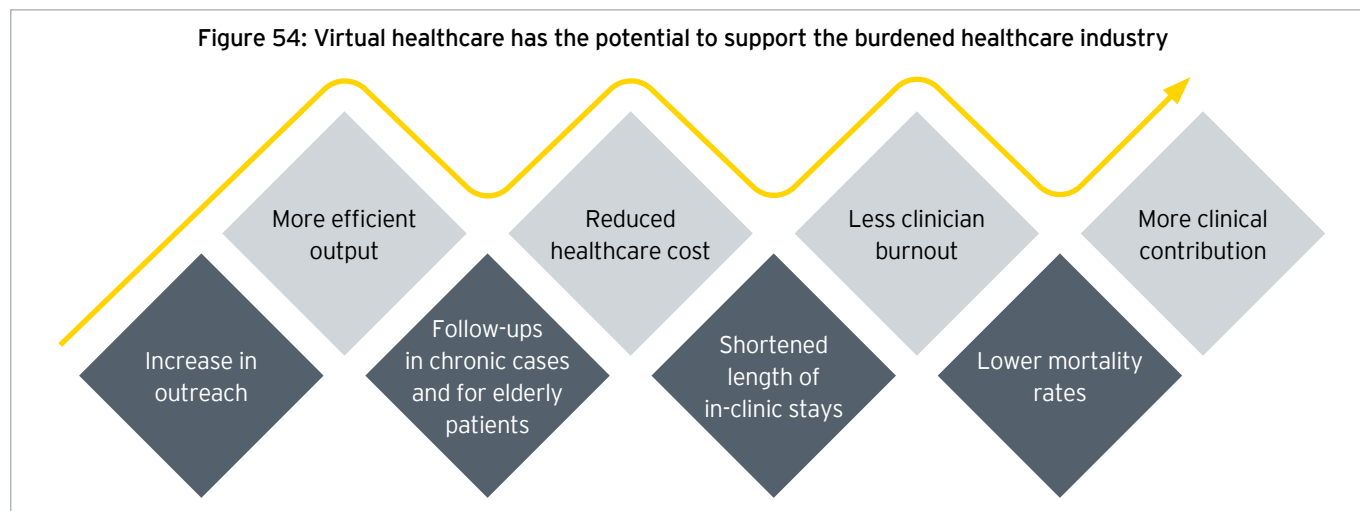
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Through telehealth, patients in remote or rural areas can get consultations with specialists in cities. A virtual visit provides patients with access to specialized healthcare at their convenience without making it essential for them to be physically present at a doctor's clinic. Elderly patients, terminally ill patients and patients with chronic diseases can better manage their disease by consulting physicians virtually in a timely manner at a lesser cost and without having to travel

to the hospital or physician's clinic every few days - this can also minimize re-hospitalizations and reduce cost of care.

Doctors also benefit from telemedicine as they are able to provide assistance to existing patients online while increasing their reach to new patients within the same geography or new geographies. Another advantage is the ability to manage records digitally and the facility of e-prescriptions.

Figure 54: Virtual healthcare has the potential to support the burdened healthcare industry



Source: EY analysis

Potential barriers that can limit telehealth adoption

To reap the true benefit from telemedicine, some barriers need to be addressed. Many physicians, especially senior specialists, and consumers in the rural areas are not technology-savvy and may need support initially to get familiar with the platform. Another challenge is the genuineness of teleconsults - these

should not be used as a means to increase the purchase of medicines on e-pharmacy.

According to EY primary research, patients' major concern is the lack of trust on virtual care and data privacy issues. For doctors, they want platforms that follow ethical practices and do not uberize them. Doctors are not comfortable maintaining patients' data privacy and confidentiality.

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It is an inflection point. Teleconsult is a very powerful enabler for rural India. In a country where we not only have shortage of specialists and doctors, but a significant geographic skew in that 80% of these doctors are in the top 20 cities, teleconsult is a very powerful scenario.

What we should not see happening is people using the legislation on teleconsult as a mechanism to get people to buy pharmacy medicine.

Second is data privacy. A good architecture of protection of patient privacy if put in place and followed overcomes the problems, and the benefits of the systems far outweigh some of the risks.

Joint MD, Leading Indian Hospital Chain

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These barriers can be overcome by establishing technically advanced and secure teleconsultation platforms and policy interventions.

1. Establishing teleconsultation ecosystem integrating all stakeholders involved in care delivery

To sustainably scale teleconsultations and achieve its potential, there is a need to build a teleconsultation ecosystem that integrates all key stakeholders digitally. The stakeholders include service providers such as doctors and paramedics, fulfilment centers such as pharmacies and diagnostic labs, and payers such as patient-consumers or insurance agencies. The teleconsultation platform should link these stakeholders digitally and enable exchange of data by mutual consent through standardized digital registries. The platform should

also have an integrated mechanism to pay for the consultation either by self or through insurance.

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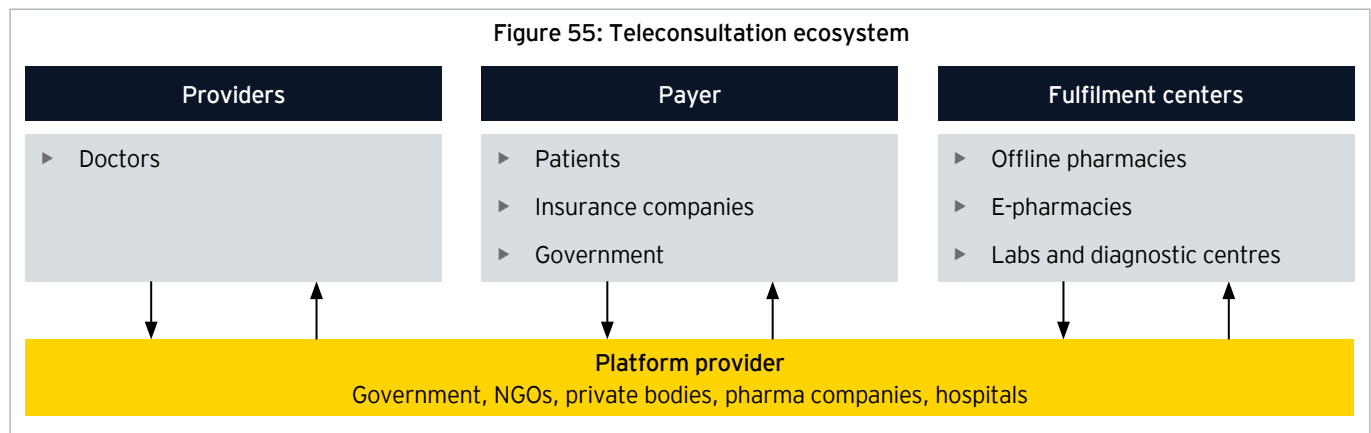
Telemedicine is part of digital transformation of healthcare in India.

One, it will require dissemination down the line, and second it will require a payment mechanism that is easier than present.

Top official at an Indian Regulatory body for Hospitals

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Figure 55: Teleconsultation ecosystem



Source: EY analysis

We are witnessing an explosion in teleconsultation platforms by health-tech start-ups, NGOs, pharmaceutical companies, e-pharmacy companies and hospitals. In the future, multiple agencies are likely to play the role of platform providers. In response to the growing need for teleconsultation, pharmaceutical companies are also proactively engaging with teleconsultation platform providers to enable doctors and patients to connect. EY surveyed the top 12 pharmaceutical companies in India. About 80% of the companies interviewed had already tied-up with one or more marketplace teleconsultation platforms, 8% had launched their own platforms, while the rest were evaluating different means to adopt teleconsultation.

As one of the key pillars of the health ecosystem, pharmaceutical companies have a strong and significant influence on shaping the teleconsultation maturity cycle. By engaging with teleconsultation platforms, pharma companies are providing a channel for doctor and patient connects. In the long run, the transaction data securely captured in the platform can help pharma companies in developing strategic insights for fostering revenue growth.

Figure 56: Reasons for pharmaceutical companies to set up their teleconsultation platform



Source: EY analysis

India will soon transition to 5G with Long-Term Evolution (LTE) 4G accounting to 64% and 5G accounting for 18% of the subscriptions in 2025²⁴. 5G is expected to provide better speed, capacity, security and decongest perpetually strained networks. This may facilitate better connectivity for innovative 5G healthcare applications.

2. Enablers for sustainability and scalability: governance and policy, technology, infrastructure

Connected smartphones coupled with sensors can capture an ever-expanding range of data for disease diagnosis and management.

In India, the Ministry of Health and Family Welfare (MoHFW) in collaboration with Niti Aayog, the Board of Governors (BoG) and the Medical Council of India issued the latest telemedicine guidelines in March 2020²⁵. This has enhanced the purview of telemedicine and reduced some concerns among doctors and patients. Importantly, the guidelines allow the use of artificial intelligence (AI) and machine learning (ML) tools to assist a medical practitioner in counselling a patient. The guidelines specifically permit doctors to provide teleconsultation for prescribing medicines, provide counselling and impart health education to patients from any part of India. Further, in May 2020 the Insurance Regulatory and Development Authority of India (IRDAI) declared that all insurers offering an outpatient department cover must pay for the costs of telemedicine as well. In addition, National Accreditation Board for Hospitals & Healthcare Providers (NABH) has initiated work on digital health standards for accreditation of telehealth providers.

In another recent move, the Prime Minister of India announced the government's National Digital Health Mission (NDHM) on 15 August 2020²⁶. The programme is a part of the Government's National Digital Health Blueprint aimed at using technology to improve health care delivery.

NDHM is a digital health ecosystem under which every citizen will have a unique health ID (containing details of their diseases, medical history, physicians consulted, diagnostic reports, medication etc. in a common database), digitized health records, registry of doctors and health facilities. This ID will be applicable across states, hospitals, diagnostic laboratories and pharmacies and will allow secure sharing of data. Complete ownership of the records will remain with the patient.

The INR 144 crore NDHM will be led by the National Health Authority and will be integrated with other Government health programmes, such as the Ayushman Bharat and the

²⁴ "Ericsson Mobility Report". Available at: <https://www.ericsson.com/49da93/assets/local/mobility-report/documents/2020/june2020-ericsson-mobility-report.pdf>

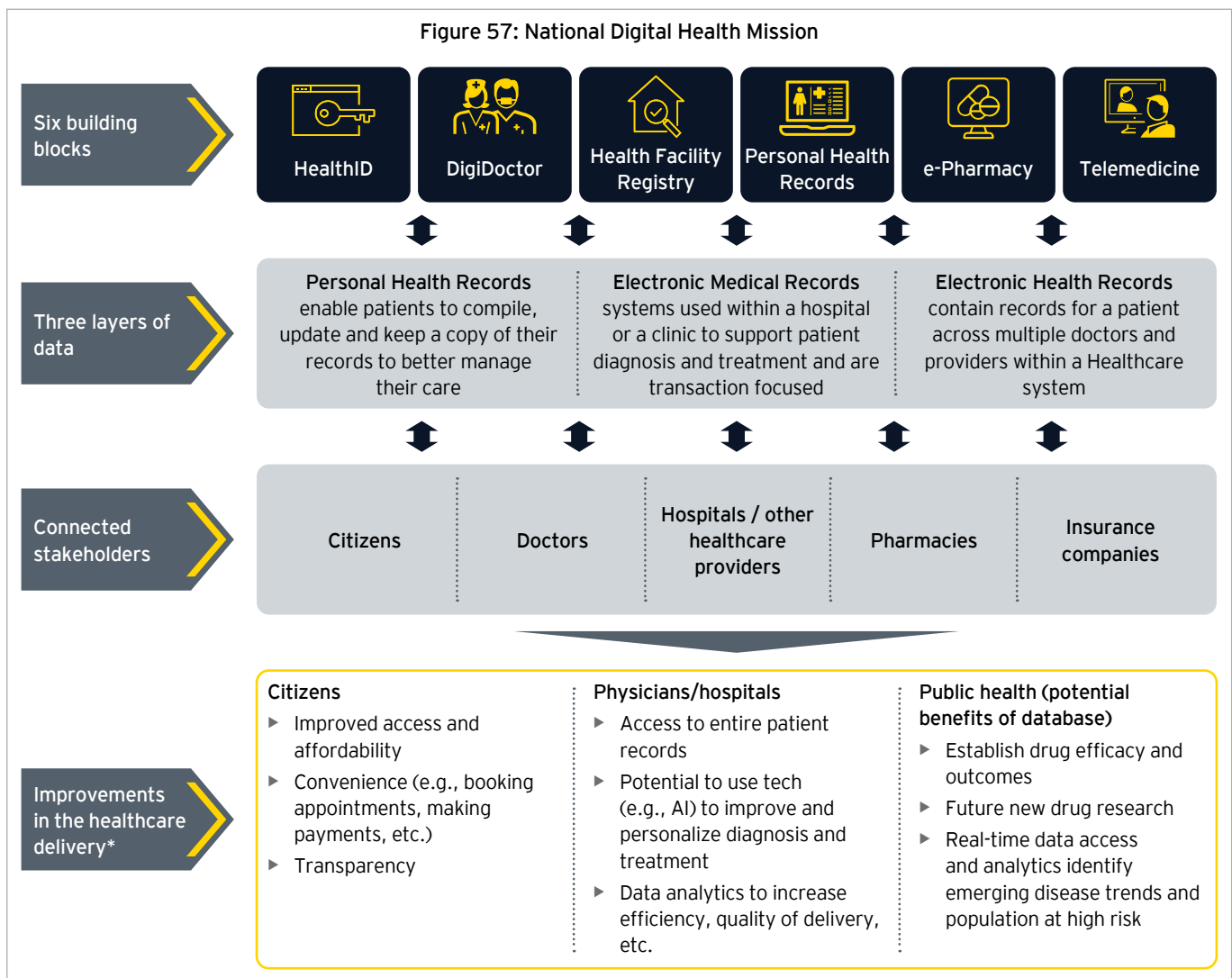
²⁵ "Covid-19: Health Ministry, NITI Aayog release guidelines for telemedicine amid", BusinessLine, March 2020. Available at: <https://www.thehindubusinessline.com/news/covid-19-health-ministry-niti-aayog-release-guidelines-for-telemedicine-amid/article31173424.ece>

²⁶ "India takes first step towards universal health coverage with Digital Health Mission launch", ThePrint, August 2020. Available at: <https://theprint.in/health/india-takes-first-step-towards-universal-health-coverage-with-digital-health-mission-launch/482258/>

tuberculosis programmes. This is an important step in putting together a digital health ecosystem in place that will support universal health coverage and achieving of the UNSDG goal 3.8 (the SDG goal 3.8 includes: achievement of universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for

all). All stakeholders will benefit in different ways. Citizens will get improved access to healthcare at a lower cost. Physicians and hospitals will be able to better manage patient load and will get access to entire patient records. The entire database thus generated can further be utilized to advance innovative healthcare research, thus improving public health.

Figure 57: National Digital Health Mission



*The list is indicative and not exhaustive

Source: EY analysis

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Digital is a run-time application that no organization can go without, and all the more so for healthcare. So, the foundational stuff is really the national digital health mission, which is collected data in a clean structured semantically interoperable manner. From that foundation you then begin to build layers and layers of analysis.

Personal health record (PHR), in addition to electronic health record, is critical for person-centric care. From PHRs you build the continuum of care and from there you build the models of appropriate care.

Telemedicine is like the first stepping stone for that vision of connected care. You use blockchain to ensure data security and you use artificial intelligence-based models to ensure clinical efficacy. Data modelling and standards are the foundational building blocks, and bandwidth and connectivity are the enablers.

If you take this even further, the combination between the genotype and phenotype will be where in the next five years India can be. If we get there then we do not have to worry about 1.3 billion population, we can pick vulnerable populations and treat them at $1/10^{\text{th}}$ the cost using a preventive route.

India can become the frontrunner in creating islands of this future model, it could be significantly transformational. This is a long-term story, but in 3-5 years horizon we can show that the incidence of disease in the selected cohort is lower than the overall disease incidence because of the following:

- ▶ Level 1 is improving the social determinants of health – clean drinking water, sanitation, vaccination, other basic amenities.
- ▶ Level 2 is compliance to medication, blood pressure, diabetes etc.
- ▶ Level 3 is dividing the population and finding those with propensity to these diseases so that you then proactively care for them and reduce the disease burden
- ▶ Level 4 is to phase 1 detections. About 62% of cancer patients come to us in India in stage 2 and 3. Story is equally bad in cardiac – all angioplasties are 2-vessels, 3-vessels, 4-vessels, we should have found them when the first vessel was slightly blocked.

Joint MD, Leading Indian Hospital Chain

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Future considerations and way forward

Achieving equitable and sustainable healthcare

1 Achieving universal health coverage

Increase the percentage of covered population/ achieve full universal healthcare

Stakeholders

Action items

- Government**
- ▶ Consider tiered model for providing healthcare coverage, e.g., free insurance to the below poverty line section and co-pay model for the remaining population
 - ▶ Provide basic insurance, and allow self-paid top-ups from private insurance

Consider new sources for financing health care

- Government**
- Examples of sources of financing:**
- ▶ Health savings account
 - ▶ Corporates allowed to contribute to health care financing under CSR activities
 - ▶ Sin tax, especially from tobacco, alcohol and other products that lead to health deterioration
 - ▶ Healthcare cess: can be a small amount (e.g., INR 50 or Rs 100 per month) per employee and equal contribution to be made by the employer
 - ▶ Impact funding

Reconsider the payment process for secondary and tertiary care service to public and private hospitals

- Government**
- ▶ Conduct periodic assessment and revision of reimbursement tariffs for the secondary and tertiary services. Revision of tariffs should consider important parameters such as health system attributes (quality, capability, etc.), regional variances in the consumer price index, etc.
 - ▶ Bring more parity in the payment mechanism and amount of tariffs for the same type and quality of service between private and public institutions

Establish efficient and simple process for receiving and providing healthcare as healthcare coverage expands

- Government**
- ▶ National Digital Health Mission is expected to be an important enabler
 - ▶ In addition, linkage could be made to Aadhar card about the category of health care coverage to enable automatic delivery of services to the patients without the need for patients

2 Boosting self-care and prevention

(i) Strengthen primary care

Establish a milestone-based plan to achieve the goal of revamping the 150,000 Sub-Centers (SCs) and Primary Health Centers (PHCs) into fully functional Health and Wellness Centers (HWCs) by 2022

- Government**
- ▶ Allocate requisite funds on an annual basis to revamp planned number of SCs and PHCs to HWCs during the year and run the active HWCs. The HWCs should be equipped with the requisite physical infrastructure, healthcare delivery staff, medical supplies (including medicines and diagnostics) to fulfil the entire scope of services (including disease coverage) to be delivered as per the goal

Develop required healthcare workforce for staffing the HWCs

- Government**
- ▶ Increase the number of seats in the institutions to introduce more workforce at all levels
 - ▶ Increase local training programs to increase the number of paramedics and nurses in rural areas
 - ▶ Develop focused training programs to enhance the skillset of the existing workforce. E-modules leveraging advanced technology such as augmented reality/virtual reality can be a cost efficient way and provides the flexibility to the people to do these trainings according to their pace and schedule
 - ▶ Set up programs in public hospitals for a few compulsory postings for all physicians and medical staff (e.g., first posting or at least one posting) in the rural areas or tier 2/3 cities
 - ▶ Consider introducing new roles of family medicine practitioners (e.g., physician assistants) to ensure that all primary care needs of the population are met within the HWCs

Use technology to increase efficiency and competence of healthcare workers

Stakeholders

Action items

Government

- ▶ Provide tools and training to the paramedics and nurses to improve efficiency and competence, e.g., symptom screening algorithms, tools for diagnosis and monitoring, point of care devices, and clinical decision support
- ▶ Artificial intelligence / machine learning based algorithms can be leveraged for segregating patients into high and low risk categories to enable provision of care to the high risk population on a priority

Set up telehealth facility and infrastructure in every HWC

Government

- ▶ Telehealth, with the required infrastructure (e.g., high-speed data, advanced tele consult platform enabling video consultation, remote diagnosis, sharing of test results, etc.), should become an essential feature of HWCs for enabling consults with specialists from larger hospitals in the cities

Establish strong governance process and gateway mechanism for effective delivery of primary care services

Government

- ▶ Develop detailed guidelines about accountability (expected roles and responsibilities, scope of services to be and not to be provided) and performance evaluation criteria for the entire healthcare workforce in the HWCs (e.g., community workers, Auxiliary Nurse & Midwives, nurse practitioners, pharmacists, medical officers, etc.)
- ▶ These HWCs should over time act as gatekeepers for all referrals to secondary and tertiary care

(ii) Reduce the burden of NCDs through effective prevention and disease management

Leverage technology for spreading awareness and enable effective disease management

Government, hospitals, industry

- ▶ Develop digital solutions that empower consumers and patients to prevent, screen and manage chronic diseases.
- ▶ Industry and hospitals should provide tools and services to empower patients to take care of their own health

Launch initiatives that expedite shift from sick care to health & wellness and disease prevention

Government, industry

- ▶ Collaborate with the industry, patient organizations, non-government organizations, etc. to expand and expedite efforts for increasing awareness in masses about health and disease prevention
- ▶ Provide detailed guidelines for over-the-counter medicines to enable people and pharmacists to make informed decisions about health and wellness supplements and medicines for common ailments

Spread more awareness about the importance of vaccination for preventable diseases

Government

- ▶ **Infant vaccination:** Increase awareness about the need to adhere to the vaccination schedules; use digital tools for reminders
- ▶ **Adult vaccination:** Increase awareness about the benefits of adult vaccination: diseases with high prevalence can be prioritized in the beginning, and slowly the other vaccine preventable diseases can be targeted

Consider upgrading all insurance products to cover health & wellness and outpatient services

Government, insurers

- ▶ Design all health insurance products to encourage and incentivize healthy behaviors, preventive healthcare and early diagnosis

3 Embrace telehealth to bridge the healthcare demand and supply gap

Establish secure teleconsultation ecosystem integrating all stakeholders involved in care delivery

Government, industry, hospitals

- ▶ Establish reliable teleconsultation platform that brings all stakeholders together and allows sharing of information ensuring data protection and privacy; the platform should also have an integrated mechanism to pay for the consultation either by self or through insurance
- ▶ Provide training to physicians, paramedics, healthcare delivery personnel and patients to use teleconsultation platform, especially in the rural areas

Set up enablers for sustainability and scalability: governance and policy, technology, infrastructure

Government, hospitals, industry, insurers

- ▶ Develop detailed guidelines to address the remaining challenges and queries about the usage of telemedicine post the issue of telemedicine guidelines in March 2020
- ▶ Establish strong architecture to ensure patient data privacy; define accountabilities and penalty for non-adherence
- ▶ Include details to define ethical teleconsultation practices and penalty for non-adherence
- ▶ Consider providing guidelines for coverage of telehealth in the insurance products.



A person wearing glasses is looking at a digital display. The display shows a complex pattern of vertical lines with horizontal bands of color (red, green, blue, yellow) on a dark background, resembling a DNA microarray or a data visualization. The person's hand is visible at the bottom right, interacting with the screen.

Chapter

04

Strengthening
manufacturing and
supply base in domestic
and global markets

India is known as the “pharmacy of the world”.

India supplies over **60%** of global demand for vaccines, **40%** of generic demand in the US and **25%** of all medicine demand in the UK¹.

India has established a large network of pharmaceutical manufacturers who cater to demand across the world.

India has more than **10,500** pharmaceutical manufacturing facilities catering to demand from more than **150** countries in the world, with many that are compliant and certified on U.S. Food and Drug Administration (USFDA), World Health Organisation - Good Manufacturing Practice (WHO-GMP), Medicines and Healthcare products Regulatory Agency (MHRA), etc.².

India can aim to further strengthen its position by garnering a larger share in world pharma trade by manufacturing value-added products.

The Indian government is actively encouraging private sector to take up manufacturing across the pharma value chain. It has recently introduced active pharmaceutical ingredient (API) schemes, such as, bulk drug parks, PLI schemes, etc.

¹ 'Invest India' website. Available at <https://www.investindia.gov.in/sector/pharmaceuticals>

² "Invest India - National Investment Promotion and Facilitation Agency" website. Available at <https://www.investindia.gov.in/sector/pharmaceuticals>

Opportunities to improve manufacturing and supply chain

Manufacturing and end-to-end supply chain management are critical components in the pharmaceutical industry. In today's competitive world, success is defined by managing manufacturing operations and supply chain costs most optimally to keep the cost to serve and inventory levels lowest while maintaining highest levels of service. In addition to these three difficult to balance levers, managing product quality, compliance to relevant regulatory frameworks, and safety of products, assets and people are additional responsibilities that leaders of supply chain and manufacturing in pharmaceutical firms need to meet.

The COVID-19 crisis has created significant amount of disruption in the pharma supply chain, both on the demand and the supply side. Key impacts were felt in terms of manpower availability, packaging/ancillary material availability and logistics operations continuity. Discontinuation of international passenger traffic reduced availability of flights to North America and Europe, making the pharma industry to rely on freight operations alone. Availability of APIs sourced from countries like Italy, Spain and China, who were strongly affected during the start of the pandemic, was also a sporadic concern. However, with proactive measures from the central government as well as state and local authorities, operations have mostly come back to normal with large part of the industry operating with activity similar to pre-COVID-19 level.

Over the last few decades, India has done exceedingly well in the pharmaceutical industry by developing an impressive manufacturing infrastructure especially for the formulations segment. We have achieved a good scale and competitive cost to serve within the global industry. However, the industry is at a cusp today wherein not only would we need to protect and continue to strengthen our position in the formulations business but also regain our strength in the API business.

India has set an ambitious target to increase the pharma industry's size to US\$130b by FY2030 from the current value of US\$41.7b (FY 2020). This indicates a CAGR of ~12% wherein it is expected that the domestic market will grow by 7%-8% and exports by 15%-16% to achieve this target³. The pharmaceutical industry can therefore emulate the information technology sector or the textiles and apparel sector and become one of the success stories to drive India's growth to become a powerful nation economically in the time to come.

While for a completely new industry and one that did not require huge amount of assets or capital, India could seize the

opportunity in the information technology sector. It was able to attain world leadership on the strength of its knowledgeable workforce. However, in case of the pharmaceutical industry, plenty of challenges remain. First and foremost being capital and technology intensive industry, and the advancement in thought capital led by the developed world. Secondly, pharmaceuticals is an old industry and developed countries have set up very sophisticated infrastructure. India would need to catch up with the best in the world in this regard. Thirdly, pharmaceutical manufacturing requires acquiring land, construction and commissioning of plant and machinery, all of which requires significant amount of capital, that is a scarce resource for a country like India. Finally, manufacturing in India is not a sought after field for the best talent in the country. With all the above factors and more, for the country to achieve the target, a well thought out strategy needs to be executed in a proper manner over the next decade.

To realize the potential, there is a need for Indian pharma companies aided by the government and regulatory bodies to concentrate on their supply chain and manufacturing operations, amongst other areas. However, the current government realizes the importance of manufacturing in the economy and over the last five to six years, a lot of focus has been dedicated to the sector to provide jobs to our vast workforce. Pharmaceutical industry is well poised to fulfil that promise. It has already employed an estimate of 2.7 million people⁴, most of them deployed across a massive network of thousands of plants within the country. The industry is therefore perceived as a potential job creator. Though the shop-floor would need to become much more productive and leaner in terms of manpower deployment, but given the growth ambition, manufacturing would still hold lots of promise to fulfil the "Make in India" initiative. In order to cater to India's growth ambition of US\$130b by 2030, there would be a need to augment the supply side by:

- **Setting up additional infrastructure:** Setting up of large scale plants (both API and formulations) would be of paramount importance for India to help achieve its target by 2030. The country also needs to set up its manufacturing facilities and logistics infrastructure to handle movement of goods across borders and within the country with ease. It also needs to provide for skilled and capable manpower that understands pharmaceutical operations (from a GXP point of view related to manufacturing, quality, maintenance, utilities, engineering, etc.).

³ Please refer executive summary chapter of this report

⁴ The Indian pharmaceutical alliance position papers - The Indian Pharmaceutical Industry - the way forward, June 2019. Available at <https://www.ipa-india.org/wp-content/uploads/2020/10/indian-pharmaceutical-industry-way-forward.pdf>

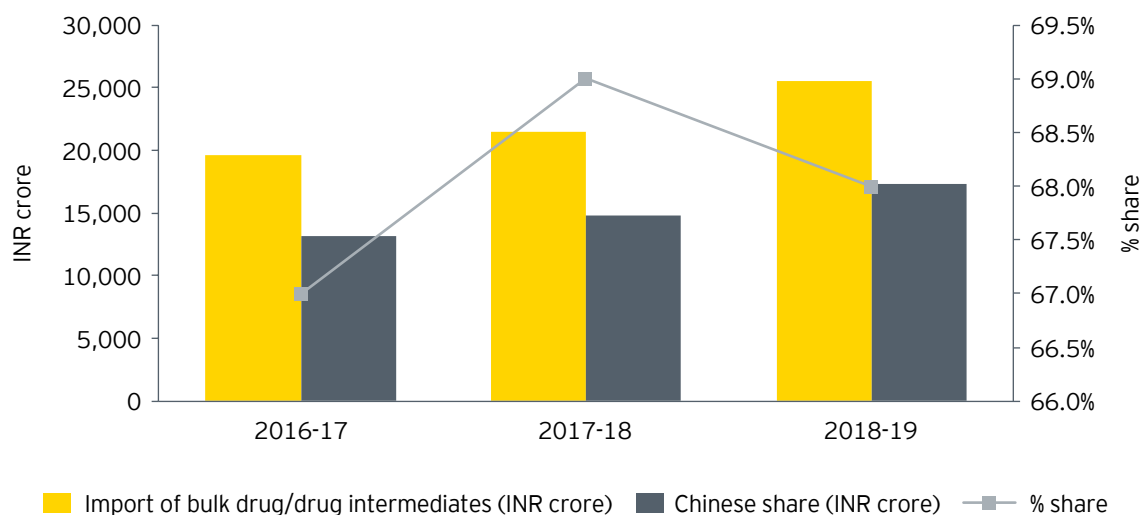
- **Moving up the value chain:** Manufacturing drugs can also pump up India's growth ambition. These drugs have better realizations which can reduce the gap between India's ranking in volume (third in the world) and value (14th in the world)⁵. This can be achieved by addressing the right categories/dosage forms and picking up the right markets and customers across the world. This aspect also ties up very well in terms of the focus on R&D (covered in Chapter 2 of this report). It is but logical that we build up our manufacturing expertise and capability to support planned enhancement in our pharmaceuticals R&D setup.
- **Productivity improvement and operational excellence:** It includes measures that would allow existing and new plants to produce more from current manufacturing ecosystem – machines, materials, manpower and space. This aspect is often ignored but would be of paramount importance as setting up additional infrastructure in pharmaceutical industry is time consuming, given that processes involved in acquiring land, commissioning machinery, recruiting manpower and obtaining validations are long.

Opportunities that beckon Indian pharma industry

1. Build scaled up API capability to improve self sufficiency as well as achieve competitive suppliers of key APIs and key starting materials (KSMs) globally

Bulk drugs would continue to form the backbone of a robust and self-reliant pharmaceutical industry in India. While in the past, India was quite self-reliant in bulk drugs, since 1990s, the scenario has changed completely leading to potential vulnerabilities in our drug security regime. In 2018-19, India imported ~70% of the API requirements from China which is largely antibiotics and vitamins. In 2018-19, India had imported bulk drugs and intermediates worth US\$2.4b from China⁶.

Figure 58: API imports from China



Source: Technology Information, Forecasting and Assessment Council (TIFAC) API report released in July 2020

An important strategic imperative for the country is to revive and significantly grow API production that would go a long way in achieving self reliance (Atmanirbhar Bharat) within the next few years. During the COVID-19 pandemic, the world has witnessed huge disruptions in the overall supply chain. A lot of Indian formulation manufacturers have also faced challenges

in continuing their businesses because of their dependence on imports. Prices of APIs rose rapidly given geopolitical shifts that have happened making Chinese suppliers anxious about future demand. To eschew such risks in time to come, it would require us to set up facilities to manufacture APIs that are cost-efficient and this opportunity is here and now.

⁵ "Invest India - National Investment Promotion and Facilitation Agency" website. Available at <https://www.investindia.gov.in/sector/pharmaceuticals>

⁶ "Trade promotion council of India" website. Available at <https://www.tpci.in/indiabusinesstrade/blogs/api-dependence-indian-pharmas-health-hazard/>

2. Grow existing pharma manufacturing infrastructure in the areas of branded generics, speciality pharma, biosimilars and innovator drugs for unfulfilled needs

India has created a formidable infrastructure for manufacturing finished dosage forms (FDF). It has the distinction of having the largest number of U.S. Food and Drug Administration (USFDA) compliant pharma plants (more than 262 including APIs) outside of the US and has more than 2,000 World Health Organisation - Good Manufacturing Practice (WHO-GMP) approved pharma plants⁷.

It is a clear leader in providing generics to the world with almost a 20% market share⁸. Another notable aspect is a third of all vaccines produced in the world originate from India. This stupendous success has been largely built on the basis of significant cost advantage in producing drugs in India. With the geopolitical shift that the world is witnessing, this is the time when India needs to reconsider its position and push for an even larger role in the global formulations trade based on the value and not the cost play. While the opportunity beckons India to take further lead, there are threats with

many countries realizing the importance of self reliance and therefore, the tone going forward has to be on building capabilities in complex and synthetic drugs, bio-similars, cell and gene therapies, etc. Given the existing momentum and capabilities built, there are ample opportunities for us to further grow the formulation supply of drugs in the world.

3. Re-organization of supply chains worldwide

Supply chain has to run as a well-oiled machine that brings in all complexities associated with global supply chain to serve the patient at most optimal costs. Pharma supply chain has become completely globalized over the past two decades mostly driven by cost optimization and other efficient measures. However, the pandemic has led to new concerns and fears related to availability and supply security in the minds of public health officials, regulators and politicians across the world. It has forced the stakeholders to re-organize the existing supply chains to de-risk dependence on one country and broad base suppliers. This presents a very good opportunity for Indian companies to garner a larger share in the global trade by attracting/incentivizing companies that want to relocate their plants and broad-base their supply bases in an attempt to reduce dependence on a single country.

Key challenges faced by manufacturing and supply chain

1. World scale API facilities rely on abundant supply of water and cause massive pollution

While we build out a vibrant API supply base at world scale levels, it is important to be cognizant that such large scale plants would require abundant sources of water supply as one of the inputs and also generate huge quantities of liquid, solid and air pollutants. While India plans to put up capacities in API, there is a need to deal with adequate provision for effluent treatment and safe discharge to meet environmental needs. The government is visualizing a few bulk drug parks which would help API players and perhaps other chemical producers in the cluster. This would require a closer examination of the treatment facilities in order to de-risk the threat of pollution. There is also a need to roll out innovative technologies to minimize pollutants, convert effluents into less harmful substances and ensure their disposal so that they do not deteriorate the environment.

2. Pharmaceutical companies have costly input factors and underwhelming operational efficiency

Like any other industry, pharmaceuticals industry requires various inputs in order to produce the required drugs. These include raw materials, power and fuel, labour costs and productivity, setup costs in terms of land, buildings, plant and machinery, logistics costs, efficiency, etc. While India has made rapid strides in matching the quality of inputs in terms of quality and costs, the country has a long way to go compared to the best in world. The cost of most of the inputs for an overseas manufacturer located out of China or the ASEAN countries is much lower as compared to India. This definitely puts our manufacturers at a loss. Moreover, when it comes to plant operations, Indian companies are lagging behind in extracting the best out of their machines (in terms of fully loaded overall equipment effectiveness - OEE), people productivity or other input factors such as specific consumption of utilities, costs incurred on maintenance, etc.

⁷ "Invest India - National Investment Promotion and Facilitation Agency" website. Available at <https://www.investindia.gov.in/sector/pharmaceuticals>

⁸ "Invest India - National Investment Promotion and Facilitation Agency" website. Available at <https://www.investindia.gov.in/sector/pharmaceuticals>

3. Cost escalations in raw materials and logistics

During the pandemic, the entire industry witnessed escalations in set of costs pertaining to:

- (i) API and certain other input material (e.g., solvents) prices
- (ii) freight costs (both air and sea)
- (iii) operating costs due to enhanced safety and social distancing norms

This increase in cost is much higher than cost savings realized due to reduction in travel and other overhead costs during the pandemic. China raised prices of KSMs and APIs imported by India by 20%-30% during the pandemic. This increase is likely to cause a decline in profit margin by at least 4%-5% over the year even when some of these escalations were passed on to the customers⁹. Given the disruption across the world, pharma industry would need to deal with cost increases by implementing various improvement techniques, such as, operational excellence, digital interventions and innovation.

“

Cost of transportation is too high in India. India does not have its own shipping vessels. There is a need for a different system for the same.

Vice president of a global pharmaceutical company

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4. Localization and repatriation of supply base

Some governments are already demanding and incentivizing local/national supplies of key medicinal products and devices. The US government has already started awarding contracts to local companies on essential medicines and some activities are ongoing in Europe as well. The US government is intending to shift back its generics supply chain and this trend can have strong impact on Indian pharma companies as the US government controls/influences almost half of pharmaceutical

purchases within the country. About 40% of the generics demand in the US and 25% in the UK is supplied by the Indian pharma industry. Also, more than 60% of the vaccine demand from all around the world is also fulfilled by the Indian pharma market¹⁰. In 2019, India exported ~30% of total formulation export to the US¹¹. Some initial estimates suggest a significant portion of the essential medicine supplies can be brought back to the US in the longer run. If this assessment is true, Indian pharma companies will be negatively impacted as a smaller proportion of their plants are in the US as compared to other global majors who have a larger proportion of their production capacities from plants based out of the US.

5. Logistics and supply chain challenges

As India aspires to grow its the pharmaceutical industry, it would need to revamp its complete logistics infrastructure to move and store its raw materials and finished goods across the country, lest it becomes an impediment. A category of pharmaceutical products (liquids, injectables, vaccines, complex drugs) require specialized storage and transportation facilities across the end-to-end shipment with temperature and humidity requirements as prescribed by the regulatory authorities.

While India is vast in terms of geographical spread, our infrastructure in terms of storage and transportation of goods is inadequate as compared to the developed world or even some of the emerging markets such as China, Malaysia, Philippines, Vietnam and South Korea, to name a few. Our ports, airports, railways, roads and waterways are lagging far behind as compared to global standards of facilities, automation and above all, speed of movement. Availability of cargo vessels, containers, storage, trans-shipment and warehousing facilities demand major augmentation to run a streamlined supply chain. As pharmaceutical and other industries in the economy would grow in size and volume over the next decade, it would place a huge stress on every element of the supply chain. Apart from the infrastructure across the length and breadth of the country, even within the four walls of a plant, management of inward/outward logistics, loading/unloading, warehousing, movement within a plant, freight planning and transportation need improvement in order to achieve end-to-end efficiencies that would otherwise reduce attractiveness and growth of the sector.

⁹ News article - Steep rise in prices of Chinese APIs hits Indian drug makers on "Pharmabiz" website June 22, 2020. Available at <http://pharmabiz.com/NewsDetails.aspx?aid=129007&sid=1#:~:text=On%20an%20average%2C%20prices%20of,said%20a%20drug%20industry%20representative>

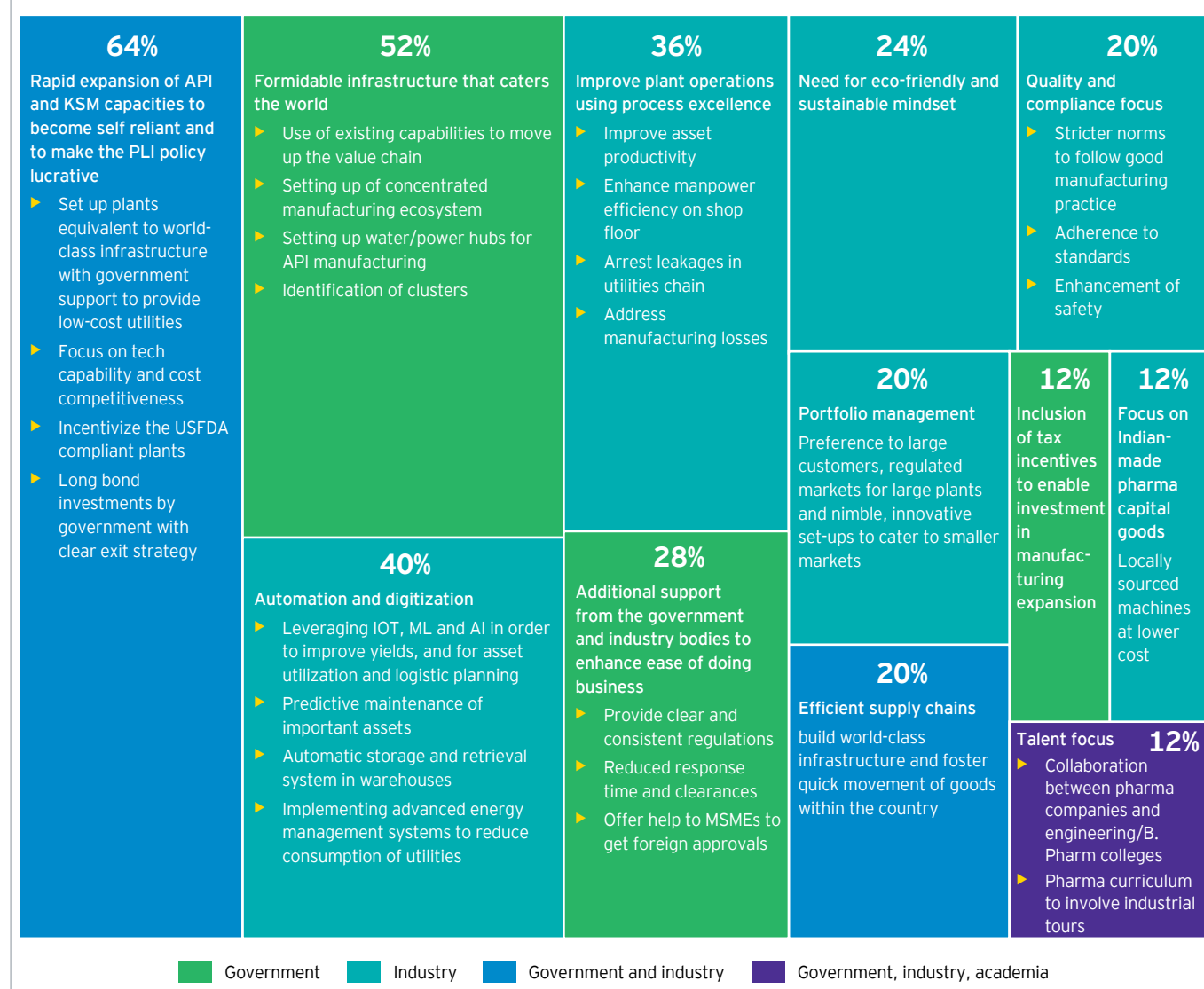
¹⁰ 'Institut Montaigne' website. Available at <https://www.institutmontaigne.org/en/blog/indian-pharma-global-leader-under-pressure#:~:text=Indian%20pharma%20fulfills%20over%2050,USD%2020.03%20billion%20in%202019>

¹¹ Refer to chapter Indian Pharma Industry : current scenario & future potential

Way forward

According to EY primary research, top focus areas include creating an API backbone and augmenting our formulations infrastructure.

Figure 59: Manufacturing and supply chain enablers



*Percentage reflects number of responders referring the enabler; N=25

Source: EY primary analysis

Manufacturing

1. Strengthening primary care

It is ironical that at one time, India was the leading API manufacturer. But over the years, it lost its edge to Chinese counterparts due to cost-effective technologies and large scale of operations which has helped China get a competitive advantage. Large scale pharmaceutical parks having common

utilities that are mostly owned by the government have enabled overseas firms to achieve cost efficiencies that were unimaginable in the past. Apart from utilities, the comparative cost of setting up a plant, sourcing raw materials, employing labor, inward and outward logistics management, etc. is relatively more expensive in India compared to China. India needs to examine and address these issues on an urgent basis with support from the government.

China has created a blueprint of success in manufacturing that is rooted in its large-scale plants that are supported by world-class infrastructure and support from their government. Some of the countries in South East Asia like Vietnam, the Philippines, Indonesia, and Malaysia are replicating this model to attract multi-national companies (MNCs) to shift their factories from China to their countries. This poses a threat to India's ambition to attract global majors to set up manufacturing plants in India.

While India has inherent strengths in manufacturing in terms of vast geographical spread, availability of talent at attractive price points, one of the largest population of English-speaking, science, technology, engineering and mathematics (STEM) graduates and presence of a reasonably large manufacturing sector, there are other structural factors that hinder the growth of manufacturing sector. To be cost-competitive, India would need to do a lot before becoming a preferred source of APIs to satisfy domestic as well as global demand.

“

The whole value chain is very critical, including APIs and intermediates. Globally, we all have relied on China for KSMs, intermediates and to some extent for APIs. That has to change. The government can roll out policies to help promote some part of it. Even with or without it, a lot of investment will continue to happen in India for these materials so it becomes self-reliant. From industry prospective, there is great room for industry to improve on APIs and intermediates.

Managing director of a leading Indian pharmaceutical company

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1.1 Strategic priorities for growing APIs in India

The government should set up large infrastructural facilities such as bulk drug parks, Special Economic Zones (SEZs) that have common facilities and land availability. They should provide incentives and infrastructural facilities to domestic

manufacturers to encourage their interest in the API sector. There is a realization to build current capabilities in both. To fulfil this objective, the government has introduced the following initiatives:

Figure 60: Government initiatives for augmenting domestic manufacturing*

Scheme for promotion of bulk drug parks	Production-Linked Incentive (PLI) Scheme
<ul style="list-style-type: none"> ▶ Construction of three API parks with common facilities ▶ The grant-in-aid will be 90% of the project cost in case of north-east and hilly states and 70% in case of other states. The maximum grant-in-aid for one bulk drug park is limited to INR1,000 crore ▶ The states interested in setting up the parks will have to ensure assured 24*7 supply of electricity and water to the bulk drug units located in the park and competitive land lease rates to bulk drug units in the park 	<ul style="list-style-type: none"> ▶ Innuendo of INR6,940 crores over a period of eight years ▶ Forty-one eligible products for which the PLI Scheme is proposed covers 53 APIs which have been approved by the government ▶ The objective of the scheme is to ensure self reliance and reduce import dependence in critical KSMs/DIs/ API. Financial incentives would be granted under the scheme to successful applicants based on committed investment and other conditions mentioned in it ▶ There have been recent clarifications/amendments in the guidelines under the PLI Scheme which address certain concerns that the industry had with respect to initial guidelines issued by the government

*Production Linked Incentive (PLI) Scheme for promoting domestic manufacturing of medical devices' not covered in the scope of this report

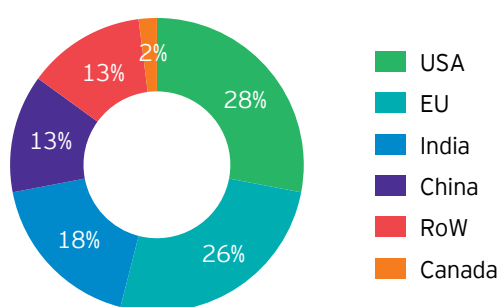
Source: Press release on 27 July 2020 on Press Information Bureau website

Basis the available information, Indian manufacturers of APIs would need to drive significant cost optimization to be able to stand up to the competition and be successful. This would involve coordinated action from the government and the pharma industry on some of the following measures:

1.1.1 Setting up large scale API plants

India has second highest number of FDA-approved API plants outside the US (2019)¹².

Figure 61: % of API manufacturing facilities for all drugs



Source: FDA website. Available at <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>

The dynamics of API manufacturing demand large scale facilities. A successful global firm would have an API plant that has a production capacity of 5000 MT-8,000 MT annually whereas, in India, an average size plant has a capacity between 500 MT-800 MT¹³. Apart from lower capacities, another factor that contributes to inefficiency is plant utilization. Most of the API production units in India run at 30%-40% of their capacity, whereas the capacity utilization of world-class API plants is around 70%¹⁴.

1.1.2 Size of bulk drug parks

The average size of SEZs in India is smaller than that of a typical SEZ globally. There is a need to identify availability of large parcels of land that is situated near ports (for easy global trade) for setting up large parks to enable the creation of an infrastructure that matches global scale.

“

Overall infrastructure should be improved, like setting up of common effluent systems, providing long lease to industries, tackling pollution problem, government providing R&D support to universities. Also, the cost of setting up of a manufacturing plant in India is very high.

Vice president of a global pharmaceutical company ”

1.1.3 Ensure the supply of essential raw materials

With the production linked incentive (PLI) scheme in place, companies are likely to set up facilities to manufacture the identified APIs. To ensure this, the next bottleneck would be to make essential raw materials, such as, key starting materials (KSM), drug intermediates (DI), and APIs available at a price that can match import prices. India is heavily dependent on the import of KSMs which are used in the manufacturing of life saving drugs – cephalosporins, azithromycin and penicillin, to name a few. Therefore, there would be a need to look at the end-to-end value chain for the measures to be successful. The government should also consider introducing another PLI scheme for pharma industry to identify other products (KSMs/APIs/intermediaries, etc.) to boost our ability to ensure un-interrupted supply of quality bulk drugs and to upscale manufacturing capacity thereof. This would be important for India to become 'pharmacy of the world' in a true sense. It would also help the country avoid disruption in supply of drugs and would also benefit the drug security of the country. It would further enhance self reliance (Atmanirbharta) in manufacturing of drugs.

¹² "U.S. Food and Drug Administration" website. Available at <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>

¹³ Based on secondary research

¹⁴ "Trade Promotion Council of India" website. Available at <https://ibt.tpci.in/blogs/the-api-paradox-of-indias-pharmaceutical-industry/>

“

We really need to be around places where there are existing clusters. Instead of going to Odisha, we need to focus on places like Indore, Aurangabad, Gujarat and Ahmedabad that need to be pushed further for manufacturing. When we are looking at infrastructure, we need to understand that there will be a huge movement of foreign workers and if we are not able to make the infrastructure accessible for foreign workers, the multinationals will not decide to set up their companies. Please look for cities which have aero and international connectivity instead of trying to build something completely from the scratch.

Director of a private equity firm

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While API manufacturing is important to be set-up, there are a few risks associated with the process that need to be called out and addressed. These are:

- ▶ **Environmental impact:** It is known that every one unit of API produced generates anywhere between 10-20 times more effluent that has been a deterrent even for Chinese manufacturers¹⁵. There were disruptions in API's supply during 2019, due to the blue-sky plan aimed at limiting pollution in China. While setting up the bulk drug parks, government should provision for adequate effluent treatment facilities (for liquid, solid and air pollutants) to enable the success of the scheme.
- ▶ **Water availability:** The very nature of API manufacturing demands the availability of clean and large amounts of water to carry out chemical synthesis of processes. Bulk drug parks not only need to be located near water bodies but conservation of water would need to be a key theme.
- ▶ **Demand uncertainty:** While API capacity would be ramped up and companies would decide the portfolio of products to be manufactured, a solid sense of demand linked to local and global disease burden would have to be kept in mind to ensure long term success.



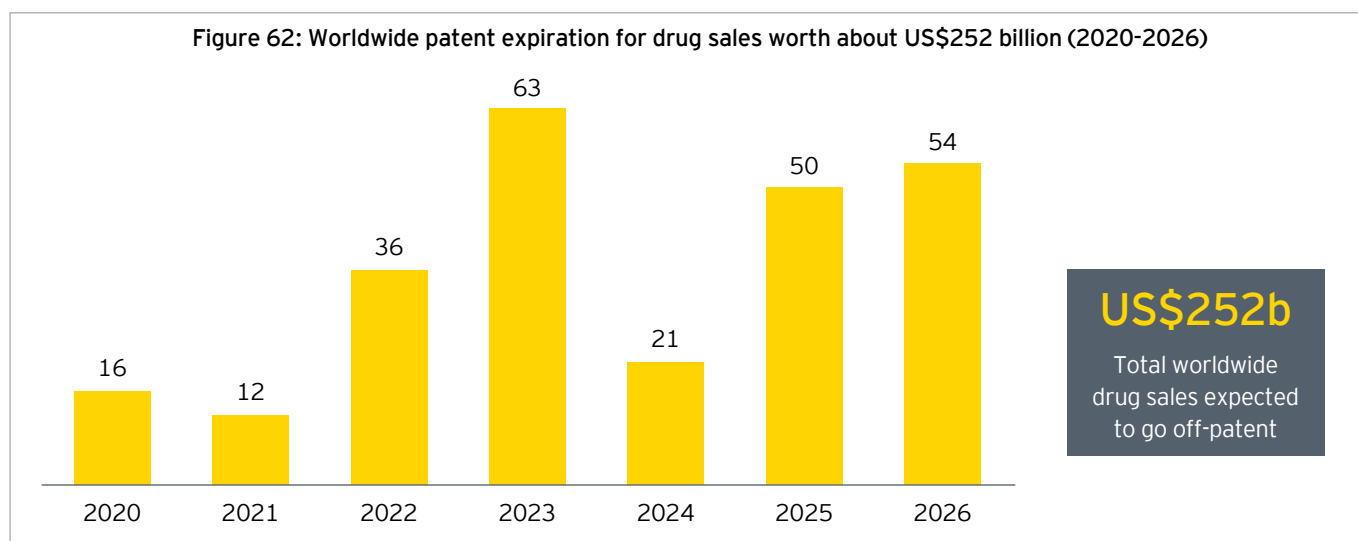
¹⁵ EY internal research

2. Continued focus on formulations

India is very poised to further strengthen its position in the world's formulations business given the formidable infrastructure that already exists. There are some noteworthy developments that are on the anvil that would help the country in this objective. Some of these are:

2.1 Leveraging the next patent cliff

As per estimates, about US\$252b worth of drug sales are likely to get off patent by 2026¹⁶. Some of the Indian companies are now well placed to capture this opportunity as shown by the graph and table below.



Source: Evaluate Pharma - World Preview 2020

Drug	Use	Patent expiry	Names of Indian companies receiving tentative approval to manufacture post expiry of patent
Perforomist	Asthma, COPD	2021	Cipla
Tarceva	Lung and pancreatic cancer	2019	Natco Pharma
Bystolic	High BP	2021	Micro Labs
Truvada	HIV	2021	Cipla, Aurobindo Pharma, Micro Labs, Glenmark Pharma, Alembic
Pradaxa	Atrial fibrillation	2021	Glenmark Pharma, Alembic
Emtriva	HIV	2021	Aurobindo Pharma, Micro Labs
Vimpat	Epilepsy	2022	Sun Pharma, Glenmark, Zydus, Hetero, Aurobindo Pharma
Viagra	Erectile dysfunction	2020	MacLeod's, Dr. Reddy's

Source: Article in The Print on 3 September 2019 - "Lucrative drugs like Viagra, Humira to lose patents but Indian pharma unlikely to gain"

While we not only have to capture the formulations market, it is pertinent to think through backward integration and a plan for API and KSM requirements well in advance.

¹⁶ "Evaluate Pharma World Preview 2020" report

2.2 *Manufacturing of new drug forms*

India needs to systematically garner a higher value share in the worldwide drug trade and it has the potential and proficiency to achieve this by moving up the value chain. To achieve this objective, the country needs to have a two pronged strategy.

2.2.1 *Penetrate in other dosage forms within generics*

Having come off the patent cliff in the last few years, Indian companies have grown multifold in the last few years in the generics segment. As of now, India's formulation strength is largely through oral solid dosage (OSD) and vaccine manufacturing. There is a substantial opportunity in semi-solids, liquids, powders, other injectables and within OSD and a higher contribution from potent forms. There needs to be a focussed effort in this direction and it is the larger firms who have to lead this initiative by opening up the demand from these segments and thereby putting up the required facilities in place to cater to this demand.

2.2.2 *Larger contribution from value-added drugs*

Given India's existing capabilities in formulations, the time is now ripe to start penetrating into the value market by manufacturing complex and specialty generics and even bio-similars. A few companies have started taking some significant steps in this direction, however, it needs to become a larger movement and the government can help companies in this direction. Important considerations here would be the availability of highly-skilled manpower and infrastructure like cold chain management and temperature controls as biologics and plasma are highly-sensitive molecules.

Companies need to invest in building manufacturing capabilities in biosimilars. Manufacturers should focus on upscaling and enhancing capabilities in this area to achieve a strong cost and capacity position against the global players. For further details, refer to biosimilars opportunity section in chapter 2 - R&D of this report.

2.3 *Upgrade and expand already existing manufacturing units*

India also has more than 10,500 plants that manufacture drugs¹⁷. However, most of these plants are contract manufacturers for not only Indian companies but also for the world. To gain a more substantial market share in the world, India would need to incentivize these plants to achieve scale.

A key theme would be to encourage and facilitate large chunk of companies owning contract manufacturing plants to do development work and file new drug applications (NDAs) in various target markets so that they can start manufacturing drugs that they own.

Also, most of the companies are over-dependent on one or two manufacturing units which cause risks to business continuity. Hence companies should invest in expanding to build capacity for future growth which will also alleviate supply chain risks.

2.4 *Low-cost manufacturing of branded drugs and repurposing of formulations*

Indian generic companies have taken the effort to develop new molecular entities (NMEs) and incremental innovation drugs. These efforts can drive Indian pharma companies to achieve growth in the branded pharmaceuticals market. This will require the companies to upgrade their workforce. Eventually, this might even attract global pharma companies to shift their units for branded drugs to India. Formulation repurposing can offer positives like low development cost, lower turn around time (TAT) and high success rate.

To achieve cost competitiveness, a consolidation among smaller plants is required while balancing the need to support small and medium enterprises. India would also need highly-skilled employees in medical-technical, pharma-technical and engineering backgrounds.

The following are some of the challenges that India needs to overcome to sustain cost competitiveness in case of generic formulations:

- ▶ Increased number of SKUs which makes the supply chain complex and low on volumes, further disturbing their productivity and costs
- ▶ Pressure on margins has increased due to price regulation
- ▶ Companies in developed markets are enhancing their productivity to beat India's conversion cost, these companies are being preferred as they are near global customers
- ▶ Other countries like China are expanding from APIs to formulations, moving up the value chain by way of opening their markets through expedited approval corridors, acquiring critical technologies on the way

¹⁷ "Invest India" website. Available at <https://www.investindia.gov.in/sector/pharmaceuticals>

3. Enhancing manufacturing attractiveness

While both API and formulations sectors are growing, certain common elements that need to be borne to facilitate the growth of the industry as a whole would be:

3.1 Input factor costs

To address cost competitiveness, the government is actively fostering the cluster approach wherein amenities like power, steam, compressed air, air-conditioning, effluent treatment, etc. are set up in large pharmaceutical parks and it acts as a service provider to private firms that set up large scale manufacturing plants. This model would enable control of input factor costs thereby translating into lower and competitive prices of the end product. The government can look into the substitution of imports in a detailed format by setting up a task force that will identify the feasibility, complexity and process technology required to manufacture APIs in India at a price comparable to imports.

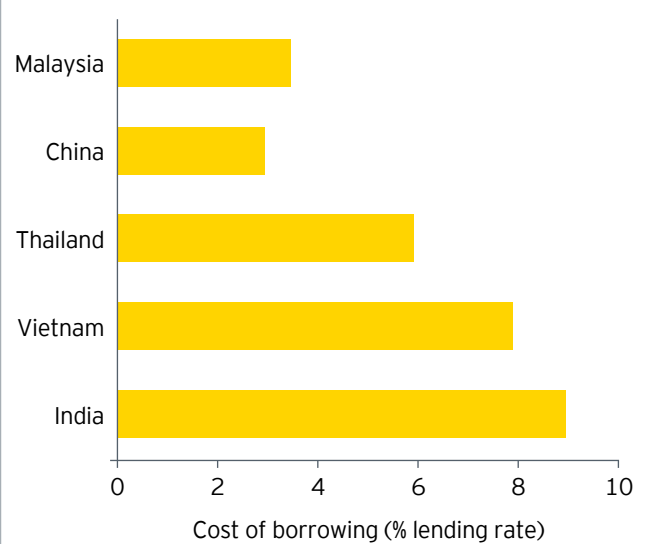
3.2 Capital equipment

A world-class pharmaceutical plant requires cutting-edge machines that manufacture products at high speed with precision and reliability that is consummate with quality and compliance standards. Such machines are available from European (Italy, France and Germany) or South Korean manufacturers. The import duties taxes on these machines are in the higher slab and when pharmaceutical plants are set up, manufacturers end up importing these machines resulting in three to five times higher cost of capital equipment. Therefore, fixed costs are already bloated even before a product has been manufactured. For the country to produce drugs at competitive prices, this issue needs to be addressed steadily. Indian capital goods manufacturers could be encouraged for technological tie-ups with leading pharmaceutical equipment providers or foreign companies could be encouraged to set up capital machine manufacturing facilities in India.

3.3 Financing institutions and cost of borrowing

To set up large scale plants, companies would require capital that is available at attractive terms. In the past two decades, developmental financial institutions in India have wound up leaving a gap in financing of large-scale projects that have a long lead time for commissioning and commercialization. Our retail banks do not have appetite for a longer moratorium on term loans that hamper the financial feasibility of greenfield and brownfield projects. Even where rupee or foreign currency denominated loans are available, the effective cost of borrowing is relatively high, leading to further burden on the financial performance.

Figure 63: Cost of borrowing in emerging markets



Source: Bank lending rates have been considered for India (Dec 2020), Malaysia (Oct 2020), China (Dec 2020), Thailand (Oct 2020) - tradingeconomics.com; Vietnam (2020) - theglobaleconomy.com

During the disruption due to COVID-19, interest rates in the Indian economy have reduced significantly. Through better policies (fiscal and monetary) and finance management, these rates need to be sustained.

4. Improve plant operations

Indian pharmaceutical manufacturing has come a long way and over the years, has cultivated a very impressive all-round capability for manufacturing of drugs in India.

At this juncture, the most important aspect to continue its leadership in formulations would be to continue providing drugs of the highest quality at attractive price points. While, there are structural factors in terms of higher land prices, higher capital costs and lower availability of cheap utilities that push up the cost of manufacturing drugs, the Indian pharmaceutical industry can do well to further improve the operations of the plant to world-class levels of utilization and productivity that could counter and balance the increase in fixed and operating costs.

Typical fully loaded overall equipment effectiveness (OEE), productivity (both asset and labor), specific consumption of utilities, yields, expenses on repairs and maintenance, stores, consumables, etc. even in professional set ups are way behind the world-class standards. True OEE for Indian plants is between 30%-50% whereas for world-class plants, would be more than 60%¹⁸.

¹⁸ EY internal study and benchmarking

The mindset in manufacturing and top leadership in an organization needs to undergo a huge change and we need to adopt world class manufacturing standards in India.

4.1 Overall equipment effectiveness

There has to be a clear roadmap to achieve 75%-80% of OEE levels in critical manufacturing segment as compared to 40%-50% that we typically witness in India¹⁹. While on one hand, a company needs to tie up on the demand side (forecasting, demand aggregation, sales and operations planning (S&OP) processes and supply planning) to reduce the planned idle time and the number of changeovers, even on the supply side, there are adequate tools and techniques available that could be adopted to systematically improve the OEE. Even for some of the best formulation plants, almost 30%-40% of the time is lost in idle time, changeovers and planned downtimes and another 15%-20% is lost in unplanned downtime and inability to operate machines at their highest possible speed/performance because of lacunas in maintenance practices²⁰. Most of the SKUs are run on speeds that are closer to lower end of the validated range and not close to the highest attainable speeds. During the runs, there are several unplanned stoppages (minor and micro stops) that typically take a few seconds to 15 to 20 minutes to rectify that constrain from attaining world-class levels of OEE. In this regard, pharmaceutical industry could do well to adopt the best practices from consumer goods industry.

4.2 Productivity of people

A typical shop-floor labour spends almost 50%-70% of their shift times on non-value added (NVA)²¹ activities and essential non-value added (ENVA) activities due to shift shrinkages and lack of simple automation, apart from having significant waiting times and delays due to motion and transportation. Labor productivity could be improved by two to three times over the course of three to four years by eliminating NVAs and ENVAs. Over the last few years, there has been a substantial shift in having contract labor on the shop-floor. The industry has adopted this transition without realizing the true cost and adverse impact of having non-permanent employees even if that is to handle non-core areas of manufacturing. For this strategy to be successful in delivering gains, process orientation and standard operating procedures have to be very minutely written and imbibed in the permanent and non-permanent workforce. Efforts have to be made to finalize work standards and rate the labor force as per the defined standards in order to match the productivity standards in a shop-floor environment. Some best practices could be leveraged from auto-mobile original equipment manufacturers (OEMs) in terms of the definition of line balancing and work standards that are prevalent in the industry.

4.3 Other shop-floor improvement areas

Manufacturing conversion cost encompass - utilities, repairs and maintenance, salaries and wages, stores and consumables, etc. In all these cost heads, there exists a significant potential to improve the efficiency thereby making an impact on the bottomline.

For example, each of the utilities circuit needs to be examined at three levels – generation, distribution and consumption to tackle wastage and operational efficiencies. In a typical plant, energy losses are pegged at 30% due to inefficiencies in generation and leakages in distribution²². There is also a tendency to over design from a consumption point of view by provisioning a larger amount of utilities to carry out a process. Understanding the real energy requirements by conducting mass and energy balance both on the demand and supply side of utilities could curtail the overall power and fuel bill in a company, which contributes considerably to the manufacturing conversion cost.

Similarly, maintenance requires a good understanding of machines and their various sub-sections, assemblies, parts and components. Having a technical mastery over the functioning of an equipment requires a few years and capabilities that need to be developed inhouse to ensure that both maintainers and operators understand machine related anomalies early by tracking various parameters. These pertain to wear and tear, current signature, heat, noise, vibration, oil analysis (as applicable) and taking corrective and preventive actions using sophisticated root cause analyses.

There also has to be a well thought out manufacturing strategy that embraces best practices in asset care, engineering, process control and optimization, data and fact-based management, continuous improvement and quality management systems. Most of these dimensions are not explored in the context of manufacturing and render the performance on the shop-floor to very basic levels. Indian companies should strive to reach world-class maturity levels in plant operations.

Ultimately, given the vast footprint of manufacturing in a pharmaceutical company, any gains in operational excellence would increase financial performance thereby counterbalancing higher costs due to other structural factors related to higher capex, input costs, etc.

¹⁹ EY internal study and benchmarking

²⁰ EY internal study and benchmarking

²¹ EY People Advisory Practice estimates

²² EY internal study across plants

5. Upgradation of manufacturing technology

To be able to garner a larger share of the market, there would be a need to change the perception and ensure that India is known for manufacturing high-quality drugs. This would require our manufacturing plants to be best in class in terms of technological infrastructure. This means that they should have latest machines and stable, consistent, predictable, compliant, and verifiable processes. This may require large and medium scale companies to modernize their plant and machinery in a bid to continuously attract more demand from India. With majority of stakeholders re-aligning themselves in the supply chain across the world post-COVID-19, India would need to emerge as a destination for manufacturing drugs with high precision and consistency. Additionally, to fulfil better share in value-added drugs, there is a need to enhance companies' manufacturing capability. Complex drugs require sophisticated machinery for micronization, encapsulation, etc.

In light of the above, India would need to automate and digitize existing plants to not only adhere to the required standards but also to meet precise control and predictability of the quality of product.

Transformation is taking place around technology up-gradation on the shop-floor worldwide. India is missing out on it due to inordinate focus on the front end. The mindset in the country needs to be changed, and manufacturing and operations need to be elevated so that it is not relegated to a position of non-significance. While the back-end would continue to be a cost center, the realisation of capabilities in this space would give a huge and lasting competitive edge to companies, industry and India.

To ensure cost effectiveness, process technologies that have already been developed need to be identified and scaled up for industrial use. For example, the University of Calicut found a method to produce Penicillin using waste fruits by applying solid state fermentation technology instead of the submerged fermentation technology²³.

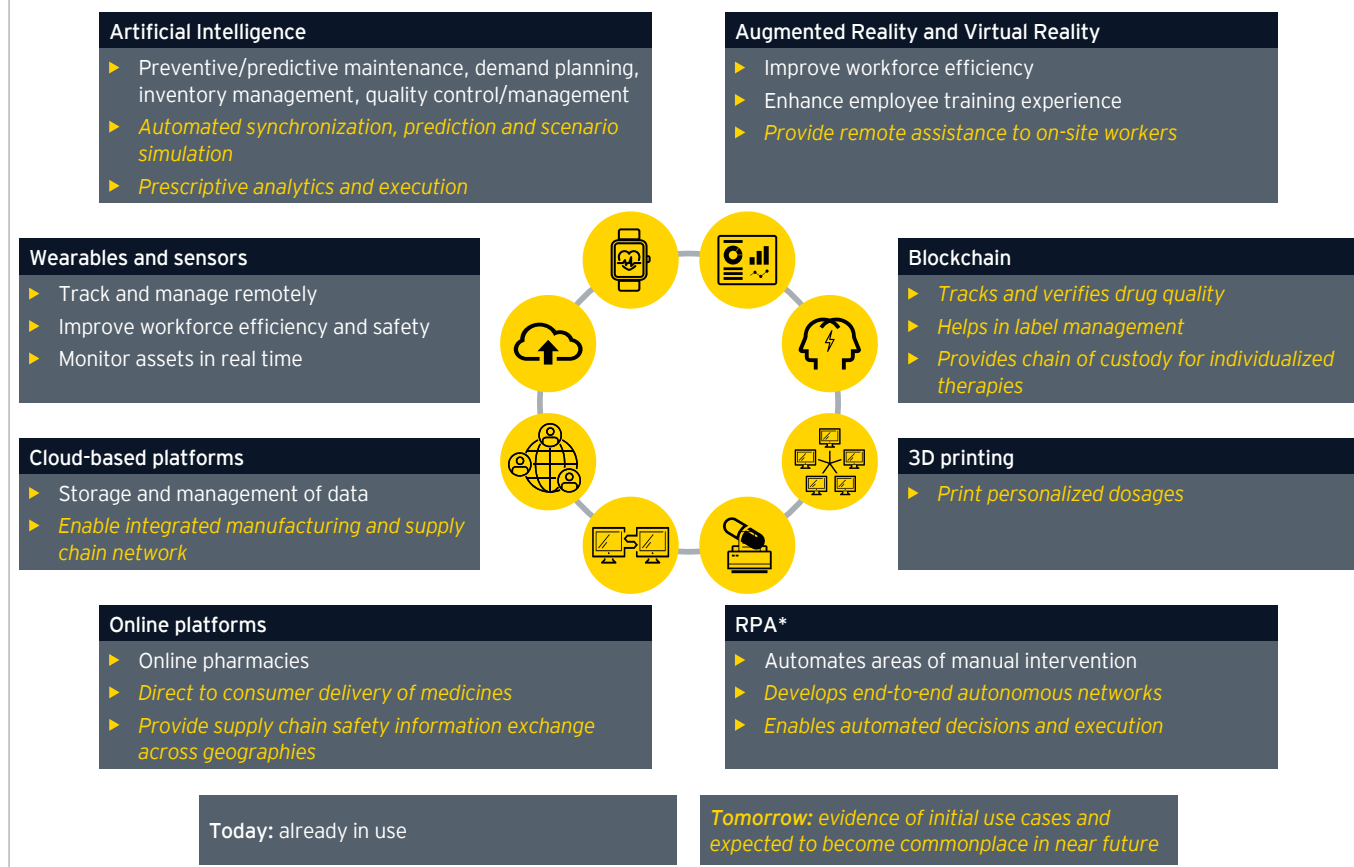
Emerging technologies in the realm of Industry 4.0 is revolutionizing the shop-floor by leveraging Industrial Internet of Things (IIoT), Artificial Intelligence and Machine Learning algorithms, three dimensional (3D) printing, machine vision, advanced physical robotics and parametric optimization for improvement. Pharmaceutical industry needs to evaluate Smart Factory related advancements like the other sectors have done in India and not lag behind in its adoption lest we lose the edge in manufacturing.

Condition based predictive maintenance (CBPM) uses artificial neural networks to improve reliability and OEE while decreasing life-cycle cost by optimizing planned stops and cost of maintenance. Smart maintenance uses augmented reality and sensors which enable the operator to identify equipment and get all the relevant technical details. Manufacturing energy management system (MEMS) connect all utility consumption and costs through IIoT with production and provides a detailed view of consumption by site, crew, shift, equipment and product. This enables site level investigation of utility cost saving opportunities through supply renegotiation or alternative energy approaches. It also enables accurate budgeting and forecasting of utility's usage and cost and validation of energy bills.



²³ "Express Pharma" website. Available at <https://www.expresspharma.in/guest-blogs/reducing-indias-import-dependence-on-apis-a-possible-way-out/>

Figure 64: Role of advanced technologies in making pharma manufacturing and supply chain patient centric, agile and self learning



Source: EY analysis; * Robotic Process Automation

This list is indicative and not exhaustive

6. Focus on quality and compliance

For India to become a major hub in pharmaceutical manufacturing, quality orientation is of utmost importance. Hitherto, Indian made goods have been cast as poor quality, but there have been wheels of change with some industries leading the way – auto/auto-components, information technology, information technology enabled services (ITES), gems and jewellery. Though the examples are sporadic, but selectively, even some goods produced in heavy engineering industries are making their way into global markets notably. These include the industries in capital equipment, heat exchangers and defence equipment, to name a few. Perhaps time is now ripe to make “Made in India” a mark to be respected in the world for quality and the pharmaceutical industry can lead this transformation for the country.

To achieve this, the pharmaceutical industry has to recognize that quality orientation can provide competitive advantage vis-a-vis other players. While a lot of focus is already given to quality within the sector, Indian players have to improve their strategic understanding of the same. On the shop-floor, the predominant approach is still quality control and reduced

emphasis on assurance. We are at a crossroad where Indian firms have to adopt the principles of “quality by design” and therefore move towards having processes that are predictable, robust, compliant and consistent so that testing requirements could be reduced without impacting product quality.

Some of the major quality challenges could be resolved using advanced analytics. Recurring quality issues can be studied by root cause analytics. Predictive maintenance can be used to predict breakdowns during operations and can also be used for real-time monitoring and error corrections. This can majorly help in improving the overall quality of pharmaceutical products during manufacturing. Companies can deploy quality management systems to identify risks from insights collected from lab reports, logs, etc. These can be addressed by putting a governance in place. Digital has also enabled employees to coordinate with each other using messaging apps to reduce machines' downtime. For instance, a company has introduced an app for its employees to raise any quality concerns. In essence, this would translate into reduced cost of quality/compliance which can help improve its financials while ensuring that Indian products are rated highest in quality across the world.

7. Focus on talent

In order to be effective in manufacturing, it is important for the operations workforce to be capable and high performing. The main issues that the workforce faces in pharmaceutical manufacturing are:

- ▶ Lack of preparedness at the entry level
- ▶ Manufacturing is not an attractive proposition for best students
- ▶ Gap in industry-readiness of students coming out of academic institutions due to low familiarity with the shop-floor
- ▶ High lead time for on-boarding and training for new joiners
- ▶ Lower top-down focus on cost efficiency as compared to auto-mobile, consumer goods industries
- ▶ Pharma hubs are in areas with not enough facilities; hence, the industry fails to attract talent

In this context to attract the best talent and that too in large numbers, the pharmaceutical industry needs to create a similar appeal that the information technology (IT) industry did about 20-25 years ago. India's success in IT came from the country's ability to strategize and create a pioneering ecosystem that fostered growth at scale. This ecosystem has largely rested on the capability of the workforce that has made India significantly better than most other countries in IT sector.

Similarly, the pharmaceutical industry should set up academic institutes, including collaboration with the industry to orient students early on with the operational aspects of pharmaceuticals - both APIs and formulations - in areas of manufacturing, quality assurance, quality control, maintenance, supply chain, process engineering, technology transfer and project execution. Academia alignment with the industry has been discussed in detail in the R&D chapter.

While the academic institutions would need to provide appropriate inputs and prepare the workforce to adapt to the shop-floor, the industry would need to identify upskilling and training courses for its employees with technical process and technological inputs. They may also set up dedicated support systems near the manufacturing hubs for specific skills like quality, maintenance, environment, health and safety (EHS), etc.

“

Mindset and culture needs to change to attract more talent to manufacturing instead of management. Artificial Intelligence, augmented reality should now be a part of manufacturing. This will promote people to join manufacturing. Salaries need to be increased, the management needs to see manufacturing as a profit center rather than a cost center

Vice president of a global pharmaceutical company

”

Figure 65: Examples for focus on talent

Cipla Technical Academy	Lupin's 'Learn and Earn' initiative
<ul style="list-style-type: none"> ▶ Collaboration of the Government of Goa and CIPLA ▶ Launched in 2018 ▶ Skill development programme for 10th and 12th standard students, classroom training + hands-on training ▶ Aseptic Techniques Programme for freshers who are pursuing B.Sc., M.Sc., diploma, B. Pharm etc. Six-month training at the academy, followed by on-site training 	<ul style="list-style-type: none"> ▶ Collaboration of Yashwantrao Chavan Maharashtra Open University and Lupin ▶ Conceptualized in 2010 ▶ It is a three-year program for students who have passed 12th standard and have financial constraints ▶ This initiative is taking place in Goa, Tarapur and Aurangabad in Maharashtra, Indore in Madhya Pradesh and Sikkim

Source: "Rohan Khaunte" website - Launch of CIPLA Technical Academy ; Article in Express Pharma on Sep 14, 2018 "Lupin Learn and Earn programme to train 1000 graduates by 2020"

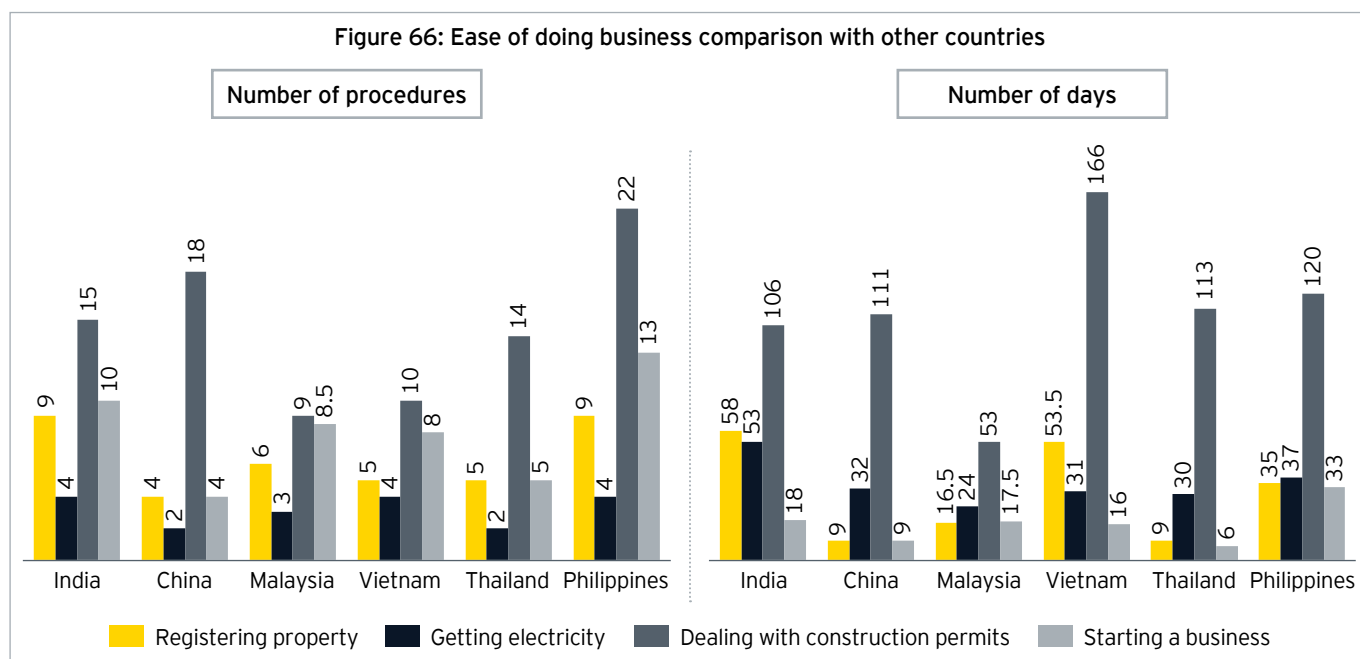
8. Additional support from the government and regulators

Setting up manufacturing facilities in India continues to be a challenge more so in comparison to other countries.

8.1 Ease of doing business

It is the most important parameter for India to attract not only foreign investment but also to make the existing industry cost competitive to invest in plant and buildings. The government could incorporate export incentives, easier duty structures and

bring in transparency on regulatory approvals. Through 'Invest in India', the Indian government can reach out to probable investors and endorse Indian pharmaceutical space. India ranked 63rd in 2019 in the World Bank's ease of doing business rankings²⁴. Different states in India have varied approval processes which is perceived as a major challenge for investors who want to set up manufacturing facilities. This issue can be addressed by the establishment of an overarching body (Refer to R&D chapter). Some of the key challenges faced by the players are procedures and time required to start a business in India. The same is depicted through charts given below:



Source: "doingbusiness.org" website. Available at <https://www.doingbusiness.org/en/reports/global-reports/doing-business-2020>

8.2 Encourage foreign MNCs to set up large scale plants in India

Post the COVID-19 pandemic, many MNCs are looking to diversify sourcing and shift their operations to other countries. India is politically stable with good political and trade relations with leading markets around the world such as Japan, the US, etc. India is also one of the world's fastest growing economies with growth rate of 7% to 8% in the past few years²⁵. The center has set up a committee of joint secretaries from different ministries and departments to analyze how to attract foreign investment. Tamil Nadu Chief Minister Edappadi K Palaniswami has set up a task force and is trying to get companies from Japan, Taiwan, Singapore and the US²⁶.

8.2.1 Security of assets

India's country risk has been perceived to be higher due to a few reasons -threat of terror attacks, civil unrest, and political and industrial strikes. Industrial assets have not been targeted much, and the country has made rapid strides in arresting industrial strikes. However, this is an area that would need long term addressal by building India's image of being a safe country to invest. The government and industry has to work to create a congenial and safe environment across large industrial belts that are free from any strife and other backlash that may hamper law and order situation.

²⁴ "Global Market Estimates" website. Available at <https://www.globalmarketestimates.com/market-report/india-api-industry--market>

²⁵ "The Conversation" website. Available at <https://theconversation.com/indias-economy-how-the-worlds-fastest-growing-nation-went-off-the-rails-129714>

²⁶ "The Hindu Business Line" website. Available at <https://www.thehindubusinessline.com/economy/as-mncs-head-for-the-exit-door-in-china-india-has-to-make-its-move/article31484219.ece>

8.2.2 Security of IP

Many global MNCs are shy of investing in India due to the perception of losing their intellectual property or thought capital, given the local laws related to IP protection. While the laws have been updated in the past, their communication and execution on ground has to be widely publicized across the world to address this area to build confidence amongst the global giants that India is a safe place to invest.

8.2.3 Taxation and judiciary

Global MNCs are also wary of the archaic taxation laws in India. The country's image had been tarnished by a few notable judgements wherein taxation was applied retrospectively. Such instances always escalate risk perception. Besides, the system of metting out justice through our courts and legal system is too slow to build any assurance within the global community to come forward and invest in the country. Government authorities need to take up industrial disputes and perhaps build a fast track mechanism, when it comes to laws and regulations related to corporates.

Finalize the RoDTEP scheme to bring clarity on incentives available

Recently, the government has substituted the Merchandise Export Incentive Scheme (MEIS) with the Remission of Duties or Taxes on Export Products Scheme (RoDTEP) in a response to notifications from the US government and the World Trade Organization (WTO) in relation to the export schemes under dispute to make them more compliant with the provision of the Multilateral Agreement on Subsidies and Countervailing Measures (SCM Agreement). However, due to the COVID-19 pandemic, the exact working and rate calculation mechanism under the RoDTEP has not been finalized. Since the pharmaceutical industry has been a beneficiary from the MEIS scheme, there are apprehensions that the new scheme might not be able to equalize the benefits to the industry which would affect the profitability of pharmaceutical companies.

It is recommended that the government should work expeditiously to bring clarity on the mechanism and rate calculation. It should also clarify the rates for reimbursement under the RoDTEP scheme and find avenues to equalize the earlier benefits for pharmaceutical industry in line with the MEIS while being compliant to the WTO.

9. Standards specific to the pharmaceutical industry

Government along with industry bodies need to define pharma-specific industry standards on the lines of telecom and information technology industry. This will induce standardization and harmonization across the industry and help the MSME sector to improve the quality and compliance levels. Standards could be defined in various other areas, such as:

- ▶ Shop-floor standard on the kind of data that should be available from machines
- ▶ Protocols should be defined for the integration of manufacturing and ERP systems. This is a major threat to cyber security
- ▶ Requirements from quality management systems in terms of quality control and quality assurance
- ▶ Standards could be identified and clearly defined for key equipment manufactured



Supply chain

1. Need to create a strong market-facing supply chain

The COVID-19 crisis has exposed the fault lines in the globally integrated supply chain. The existing capital light model with continuous replenishment from plants based out of India may need to give way to a stronger supply chain at the end market. With the end of the COVID-19 crisis being uncertain, and high possibilities of intermittent outbreaks and movement restrictions, it is imperative to create an inventory and asset-heavy market to face supply chain. For the important export markets like the US, the EU, etc., this may lead to investing in people, processes and working capital to create a larger safety buffer in case of eventualities and adverse scenarios.

2. Strategic portfolio management to realize overall efficiencies

For Indian companies to realize efficiencies in the overall cost to serve, there has to be a well thought-through go-to-market strategy. Indian pharma companies have grown phenomenally and have created capabilities to serve all kinds of markets (North America, Europe, Japan, Russia, Africa, rest of the world (RoW), etc.) and that too in diverse dosage forms. However, orders are still taken on an opportunistic basis. Going forward, there needs to be a strategic focus on which products, markets and customers that the companies need to serve. For realizing overall efficiency in the end-to-end supply chain, focus should be on serving markets on an in-depth analysis of the actual/real cost to serve, thereby focusing on markets with stable demands for the longer term.

With the focus on moving up the value chain, pharma companies need to evaluate which new products need to be added, i.e., are they complex generics, bio-similars, or cell and gene therapies. This has to be in collaboration with the recommendations in the R&D section, chapter 2 of this report, wherein Indian firms need to research on molecules apart from generics and also move up the value chain. Additionally, even from the customer side, marketing and sales functions need discipline in customer relationships to ensure larger order sizes and continuity of order pipeline in order to reap the benefits of scale in the supply chain. Ensuring order sizes that are large for customers who are with suppliers for a long term, would enable the backend functions to run larger campaigns, source APIs in larger quantities (and therefore ensure security), achieve better results of larger batch sizes and the associated supply chain benefits (lesser machine idle time, changeovers, yield losses, power and fuel cost). All this may contribute to a significant end-to-end improvement of fixed and variable costs.

Apart from these measures, our industry needs to penetrate further in regulated markets. While the quality requirements in markets like the US, the UK, Japan and other developed

countries are higher, the remuneration and stability of demand is also higher making it an attractive proposition. In this respect, government and industry bodies can help Indian firms to spot opportunities in regulated markets for specific drugs and other medicines by channelizing them so that the industry can tap the potential. For businesses' growth and their seamless expansion, Indian embassies and consulates have the potential to open pharma helpdesks to encourage the potential customers to get information about availability and capabilities of Indian pharmaceutical firms.

In order to cater to small markets and orders, innovative/nimble solutions should be implemented. The suggested model for pharma companies is to have a combinatorial model where there could be many plants configured to serve large markets and one or two smaller plants or sub-plants to serve smaller orders efficiently.

3. Enhancing logistics and supply chain

While bigger gains are likely to come by improving manufacturing operations and through better portfolio management, others can be achieved by managing supply chains more effectively and efficiently. Industry has to consciously look for ways and means to run streamlined supply chains that use larger truck sizes, higher load-ability and inventory optimization. The government needs to play the crucial role of developing the infrastructure of airports, ports, roads, railways and waterways to move goods within the country in a fast and cost-effective manner. Since most of these sectors are largely controlled by the government, there is a need to accelerate the pace of development in building this infrastructure especially around some key trunk routes in Telangana, Gujarat, Himachal, North East and Maharashtra from a pharmaceutical industry perspective. Apart from transport infrastructure, India requires warehousing and trans-shipment capabilities to store products in cold chain.

4. Leverage automation and digitization of supply chains

Pharma supply chains in India are very complex for generic companies. While sourcing of raw materials, lab chemicals, consumables, etc. is from multiple countries, sales are targeted to multiple countries besides meeting domestic demand. Given lead time for conversion from raw materials to finished goods, both within APIs and formulations, supply chain management needs to match world-class standard with the latest digitized tools and best practices. Supply chain processes like demand sensing, demand aggregation, running S&OP processes, supply planning and monitoring require sophisticated logics and optimization techniques to bring in the required efficiencies.

5. Promote India and knowledge management

To achieve India's ambitious target of increasing the market size by 2030, there needs to be a push from all stakeholders. However, it is equally important to change the perception of India in the minds of the world. All stakeholders in the ecosystem need to collaborate and promote our already-established network of pharma companies. While large companies can spend on promoting their products, smaller companies would need government's support in this area.

North America, the EU (Italy, Germany, Spain and France), the UK, Japan, Russia and South Africa are easily the most important markets in terms of their size and attractiveness (realization/unit) for the Indian pharmaceutical sector. Indian Government has presence in these countries and together with industry bodies, there is a need to systematically build on the following three critical aspects:

5.1 Promote "Brand India"

The Government of India and various industry associations need to open a pharma desk in the target countries and disseminate the capabilities of Indian companies in a concerted manner. The desk could consider conducting industrial tours regularly to facilitate potential client companies to visit Indian companies to cover width and depth of manufacturing capabilities across dosage forms for value-added products.

It is also important to have links with the regulatory authorities in these countries. These include the US Food and Drugs Administration, the UK Medicines and Healthcare products Regulatory Agency, Health Canada, Therapeutic Goods Administration Australia, European Medicines Agency, and Federal Institute for Drugs and Medical Devices (Germany). The pharma desk should also work actively with local regulators to understand their expectations from drug manufacturers in India and accordingly disseminate information freely for them to access it.

India can also promote "Brand India" by publicizing pharma specific events that are taking place in the country around the world to allow participation from foreign companies.

The pharma desk should also actively solicit foreign MNCs in important countries to set up and expand manufacturing facilities in India.

5.2 Identify opportunities

The pharma desk should also liaise locally and determine potential opportunities for fostering pharmaceutical trade in that country by understanding its healthcare system and other key players, such as pharmaceutical companies, local governing bodies, and how the drugs are sourced and disseminated. This knowledge can potentially identify important stakeholders with whom connections could be made by Indian players. The disease burden in respective countries has the potential to help understand the demand for various drugs that could be made available back in India for companies to cater to, and develop and manufacture products accordingly.

There is already a precedent wherein during COVID times, Indian missions abroad have gleaned such information as the worldwide supply chains witnessed major disruptions and there was shortage of essential and desirable items across countries. Such approaches and practices need to be continued, going forward.

5.3 Knowledge management

It is important to understand the best practices, technologies and advancements related to pharmaceuticals in the target markets. Emphasis should be given on innovation and discoveries from a technical standpoint. Additionally, there is a need for government bodies to understand the latest advancement in plant and machinery in the developed world, especially in Germany, Italy and France, where a lot of capital goods are being sourced from.

Besides these steps, the government should take the lead to develop Centres of Excellence that glean the best practices from other countries and disseminate to Indian companies (more importantly the MSME sector) to help them grow and become more efficient.

Future considerations and way forward



Strengthening manufacturing and supply base in domestic and global markets

1 Manufacturing

(i) Focus on API

Achieve cost leadership & sustainability

Stakeholders

Action items

- | | |
|------------|---|
| Government | <ul style="list-style-type: none"> ▶ Support setting up of large SEZs/Parks, provide cost efficient utilities and incentivise through schemes (API, PLI etc.) ▶ Facilitate growth through targeted schemes for API and PLIs to incentivise the industry |
| Industry | <ul style="list-style-type: none"> ▶ Set up plants at scale (especially existing large firms) |

(ii) Continued focus on formulations

Moving up the value chain and retain cost leadership

- | | |
|------------|---|
| Government | <ul style="list-style-type: none"> ▶ Enable the industry (SMEs in particular) by providing research and financial assistance |
| Industry | <ul style="list-style-type: none"> ▶ Invest in capabilities to manufacture value added drugs for long term sustenance |

(iii) Enhancing manufacturing attractiveness

Capital equipment

- | | |
|------------|---|
| Government | <ul style="list-style-type: none"> ▶ Encourage setting up of capital equipment industry in India |
|------------|---|

Development of financial institutions

- | | |
|------------|--|
| Government | <ul style="list-style-type: none"> ▶ Set up financial institutions that support setting up large projects – higher moratorium and variable interest rates |
|------------|--|

(iv) Improve operations of a plant

Improve productivity

- | | |
|----------|--|
| Industry | <ul style="list-style-type: none"> ▶ Focus on operational excellence techniques and improve margins to counterbalance cheaper imports |
|----------|--|

(v) Manufacturing technology upgradation

Cutting edge technology

- | | |
|----------|---|
| Industry | <ul style="list-style-type: none"> ▶ Upgrade to latest technology to provide superior products |
|----------|---|

(vi) Quality & compliance focus

Quality assurance rather than quality control

- | | |
|----------|---|
| Industry | <ul style="list-style-type: none"> ▶ Incorporate quality by design principles and analytics to reduce cost of compliance and cost of quality ▶ Cultural transformation for greater awareness and commitment to quality and compliance |
|----------|---|

(vii) Talent focus

Preparedness at entry level

- | | |
|--------------------------------|--|
| Industry, academia, government | <ul style="list-style-type: none"> ▶ Collaboration with the industry and academia to orient the students early on with the operational aspects of pharmaceuticals |
|--------------------------------|--|

Improve attractiveness of pharma manufacturing

Stakeholders

Action items

Industry

- ▶ Lessons learnt from the success of the Indian IT industry in attracting and retaining talent at scale
- ▶ Bring Indian talent back from developed world to lead operations of large corporates

(viii) Additional support from government

Setting up of manufacturing units

Government

- ▶ Further streamline ease of doing business and encourage MNCs to increase manufacturing footprint

Industrial tours

Government, industry

- ▶ Organise country-specific industrial tours – for customers, for large manufacturers to invest in India and for local suppliers to visit target markets

2 Supply chain

(i) Strategic portfolio management to realize overall efficiencies

Product portfolio

Industry

- ▶ Supply Chain strategy needs to target regulated markets, value added products and large customers with stable demand

Agile and innovative solutions

Industry

- ▶ In order to cater to small markets and orders, incorporation of innovative solutions, e.g., apart from mega plants, there can be 1-2 small, agile plants with a lower cost to serve, etc.

(ii) Enhancing logistics and supply chain

Logistics

Industry

- ▶ Build efficient logistics that will lower costs and provide end to end integration and digitization

Government

- ▶ Improve transport infrastructure and warehousing facilities to allow quick movement of goods and optimise costs
- ▶ Encourage private sector and MNCs to invest in building logistics infrastructure

(iii) Promote India and knowledge management

Promote brand India

Government, industry

- ▶ Set up pharma desks in target countries and disseminate the capabilities of the Indian companies in a concerted manner
- ▶ Pharma specific events in India need to be publicised abroad for foreign companies to participate

Knowledge management

Government, industry

- ▶ Set up knowledge management hubs to help disseminate trade, technology and sector knowledge



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Chapter

05

Improving access to
medicines

Access to medicines (essential and innovative) is low and uneven in India due to affordability and availability challenges.

According to estimates from different sources, **50-80%** of the Indian population is not able to access all the medicines they need¹.

With the objective to improve access to medicines, government has launched Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and pricing controls for essential and lifesaving medicines.

Jan Aushadhi Kendra is one such retail initiative of the Indian government to improve availability at every part of the country, at most competitive prices. It is one of the biggest retail pharma chains globally with more than **6,200 outlets** as of March 2020².

Further enhancements can be made in supply chain management and tendering process for PMBJP. There is also a need to use innovative approaches to improve access to medicines beyond price controls.

The chapter explores best practices from developed and developing geographies for tender process and innovative approaches to improve access.

¹ M. Rituparna *et al*, "Essential Medicines: An Indian Perspective", Indian J Community Med. 2015. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4581141/>

² "1,000 Jan Aushadhi outlets by 2024: Minister", The Times of India, March 2020. Available at: <https://timesofindia.indiatimes.com/city/patna/1000-jan-aushadhi-outlets-by-2024-minister/articleshow/74541839.cms>

According to the United Nations Development Programme (UNDP), global access to medicines is: "Having drugs continuously available and affordable at public and private health facilities or drug outlets that are within one hour's walk of the population"³.

In India, access to essential medicines remains limited and inequitable. In this chapter, we will discuss current opportunities and challenges, and way forward to improve access to essential and innovative medicines in India.

Opportunities for improving access to medicines

1. Improve overall access to essential medicines

According to World Health Organization (WHO), "essential medicines are those that satisfy priority health care needs of the population; these are intended to be available at all times in adequate amounts, in appropriate dosage forms, with assured quality, and at a price the individual and community can afford"⁴.

India is the pharmacy of the world, but its own populace doesn't get to benefit entirely due to inherent structural and systemic reasons. According to estimates from different sources, 50%-80% of the Indian population are not able to access all the medicines they need⁵.

2. Improve availability of medicines in rural areas

Despite the presence of more than 850,000 retailers overall, about 60% of the Indian market remains underserved⁶. The situation is even worse in rural areas where people lack medicines beyond those to treat acute conditions such as common cold. According to EY's primary survey, physicians based out of tier 2 and tier 3 cities highlighted the absence of crucial diabetic medicines such as sitagliptin, teneligliptin or even insulin. As a result, they are limited to prescribing medications as per availability, which delays treatment process and contributes to the chronic disease burden.

Challenges

1. High out of pocket expenses

As discussed in the earlier chapter, India has an extremely high out-of-pocket (OOP) expenditure as a proportion of current health expenditure - at 61%⁷, India is far behind the world average of 20% (WHO data for 2016)⁸.

The scenario is similar at the state level as well, with households bearing the burden for health expenses. In Bihar and Uttar Pradesh (country's most populous state), OOP expenses represent 80% and 75%, respectively, of the total health expenditure. Some states do relatively better, such as Karnataka, Himachal Pradesh and Gujarat, but even their OOP expenses constitute half of the total health expenditure⁹.

About 55 million Indians are pushed into poverty annually due to unaffordable healthcare, and about 60% of this (33 out of 55 million) is due to expenditure on medicines alone¹⁰. In addition, high OOP expenses may result in non-adherence to prescribed medicines thus adversely impacting patients' health, especially those with chronic diseases.

One reason of high OOP expenditure on health in India is that most insurance schemes do not cover daily medical expenses. Other challenge is low availability of medicines in public health facilities because of which patients are forced to buy medicines on their own.

³ "Indicators for Monitoring the Millennium Development Goals", UNDP. Available at: <http://mdgs.un.org/unsd/mdg/Resources/Attach/Indicators/HandbookEnglish.pdf>

⁴ WHO website. Available at: https://www.who.int/medicines/services/essmedicines_def/en/

⁵ M. Rituparna *et al*, "Essential Medicines: An Indian Perspective", Indian J Community Med. 2015. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4581141/>

⁶ "e-pharmacies: Need to remove policy vacuum", Policy Circle, October 2020. Available at: <https://www.policycircle.org/economy/industry/e-pharmacies-need-to-remove-policy-vacuum/>

⁷ "Patients spend double of what the govt does on them", Business Line, March 2019. Available at: <https://www.thehindubusinessline.com/economy/patients-spend-double-of-what-the-govt-does-on-them/article26449603.ece>

⁸ P. Singh *et al*, "Medicines in India: accessibility, affordability and quality", Brookings India, March 2020. Available at: <https://www.brookings.edu/research/medicines-in-india-accessibility-affordability-and-quality/>

⁹ "Do poor people in the poorer states pay more for healthcare in India?", BMC Public Health, July 2019. Available at: <https://bmcpublihealth.biomedcentral.com/articles/10.1186/s12889-019-7342-8>

¹⁰ "15 Healthcare schemes in India that you must know about", Oxfam India, December 2018. Available at: <https://www.oxfamindia.org/blog/15-healthcare-schemes-india-you-must-know-about>

2. Low availability of medicines in public health care facilities

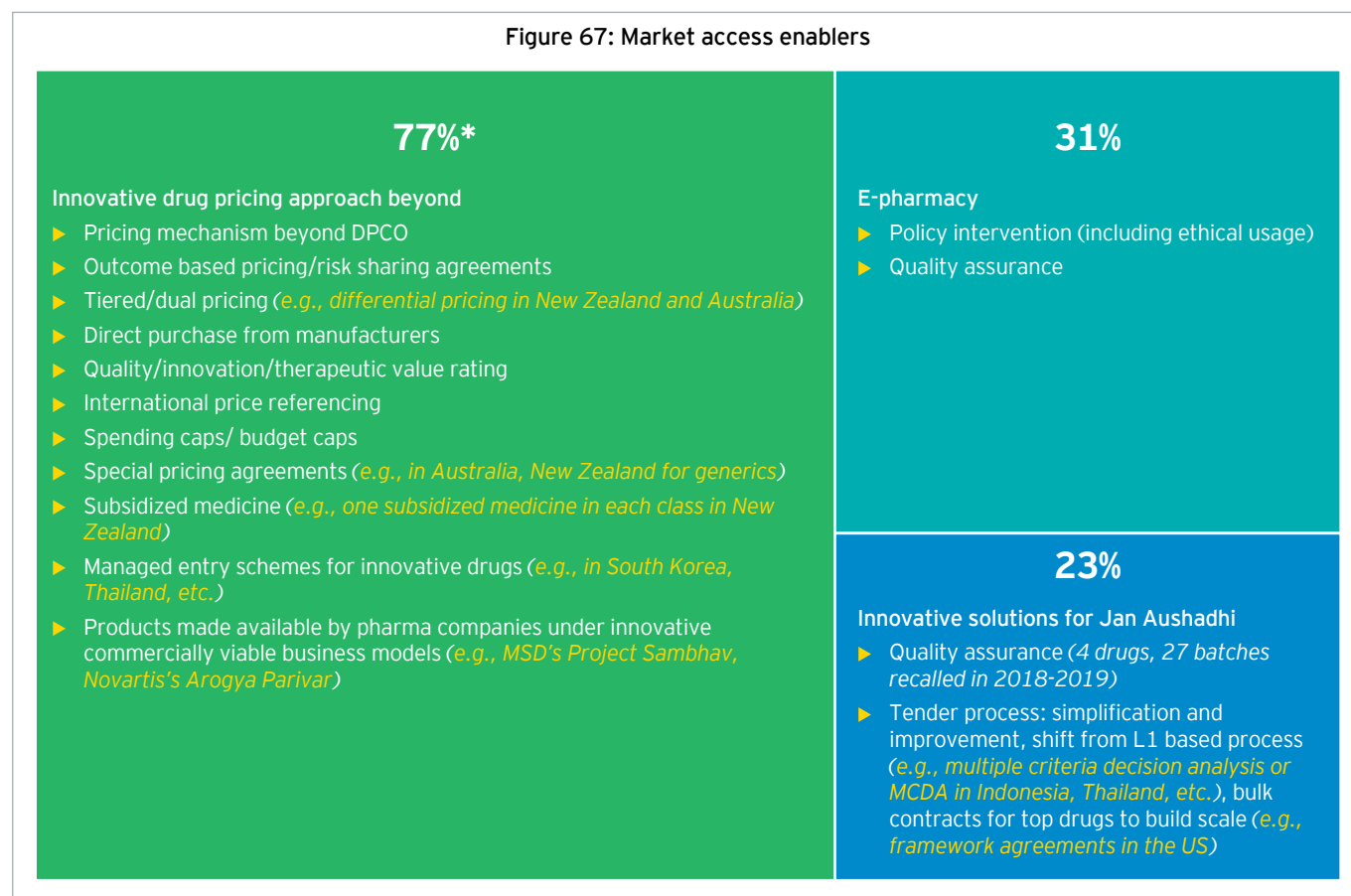
The goal of the public healthcare facilities is to provide access to medicines at lower costs or for free, and hence, they play an important role especially for the poor patients. Hence, it is critical to ensure that public healthcare facilities have sufficient stocks of all essential medicines.

An earlier survey revealed that the median availability of a basket of essential medicines was 0%-30% in the public sector in six locations in India¹¹. Similar other studies and surveys carried out in different Indian states such as Maharashtra and Bihar have revealed unavailability or insufficiency in stocks of essential medicines in primary health centers (PHCs). Another survey on the expenditure pattern of state government on medicines shows wide-ranging differences from as little as less than 2% to as much as 17%¹².

Way forward

According to EY's primary research, about 80% of the respondents highlighted the need to adopt innovative approach for drug pricing in India to improve access to medicines. Jan Aushadhi and e-pharmacy were also identified as potential enablers in improving access to medicines.

Figure 67: Market access enablers



*Percentage reflects the number of responders referring the enabler; N = 15

Source: EY primary research

¹¹ M. Rituparna et al, "Essential Medicines: An Indian Perspective", Indian J Community Med. 2015. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4581141/>

¹² M. Rituparna et al, "Essential Medicines: An Indian Perspective", Indian J Community Med. 2015. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4581141/>

Jan Aushadhi Pariyojna to improve access to medicines

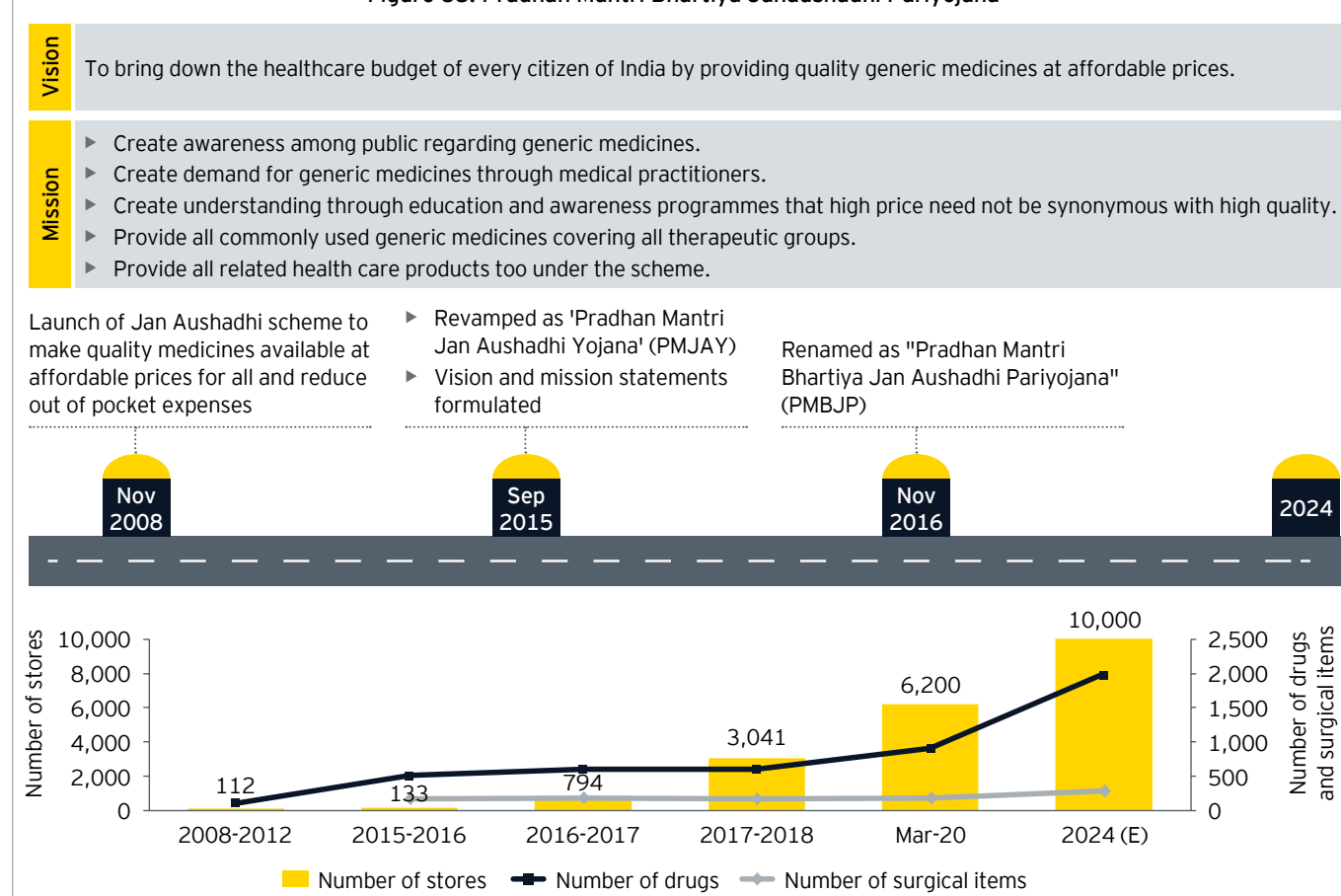
The Jan Aushadhi scheme was launched in 2008 with the aim of making quality medicines available at affordable prices for all and to reduce out of pocket expenses, particularly for the poor and disadvantaged. The scheme was revamped in September 2015 as 'Pradhan Mantri Jan Aushadhi Yojana' (PMJAY), and again renamed as "Pradhan Mantri Bhartiya Janaushadhi Pariyojana" (PMBJP) in November 2016¹³.

Jan Aushadhi Kendra is the biggest retail pharma chain globally with more than 6,300 outlets as of March 2020 across 726 districts in the country¹⁴. These outlets sell more than 900

kinds of medicines and 174 kinds of surgical items covering all therapeutic areas. The government aims to increase the number of stores to 10,000, medicines to 2000 and surgical items to 300 by 2024¹⁵.

More than 1.25 crore people across the country buy medicines from Jan Aushadhi stores (data as of March 2020). Total sales of these stores crossed INR 390 crore in FY 2019-20 leading to total savings of approximately INR 2,200 crore to the citizens as these medicines are 50%-90% cheaper than the average market price¹⁶.

Figure 68: Pradhan Mantri Bhartiya Janaushadhi Pariyojana



Source: Bureau of Pharma PSUs of India (BPPI) Jan Aushadhi Annual Reports, EY analysis

The scheme initially did not pick as per the plan and ambition. While the uptake has improved in the last few years, both in terms of number of stores and product basket (number of medicines and surgical items), the initiative hasn't yet fully

realized its ambition of making medicines affordable and reducing out of pocket expenses due to challenges outlined below.

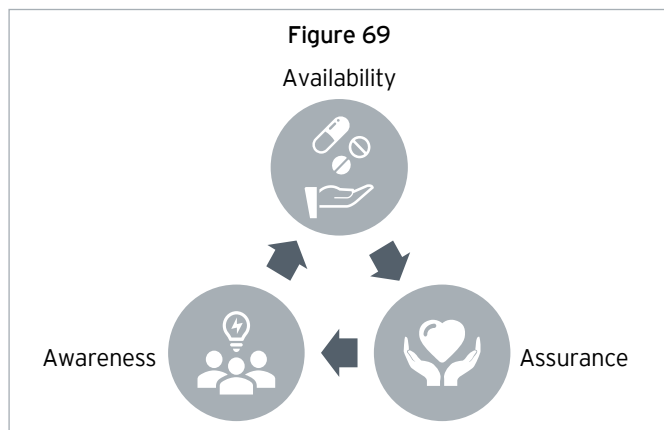
¹³ "Pradhan Mantri Bhartiya Janaushadhi Pariyojana" website. Available at: <https://www.india.gov.in/spotlight/pradhan-mantri-bhartiya-janaushadhi-pariyojana>

¹⁴ "PMJAK pharmacists deliver essential services & medicines at doorstep of patients, elderly to fight COVID-19", All India Radio News, April 2020. Available at: <http://www.newsonair.nic.in/Main-News-Details.aspx?id=385061>

¹⁵ "1,000 Jan Aushadhi outlets by 2024: Minister", The Times of India, March 2020. Available at: <https://timesofindia.indiatimes.com/city/patna/1000-jan-aushadhi-outlets-by-2024-minister/articleshow/74541839.cms>

¹⁶ "Prime minister Narendra Modi to interact with Jan Aushadhi Kendras through video conferencing", PIB Delhi, March 2020. Available at: <https://pib.gov.in/PressReleasePage.aspx?PRID=1605513>

Key challenges and steps taken



1. Awareness

There is a need to promote generic medicines, both among people and physicians. As per surveys¹⁷, the general public is not aware of generics or of their cost savings via this program.

Initiatives to increase awareness

The government recently launched the Jan Aushadhi campaign to educate people about generic medicines' potency. *Jan Aushadhi Divas*, started on 7 March 2019, is now celebrated every year to create awareness about the scheme and generic medicines¹⁸. Jan Aushadhi Sugam app was also launched in August 2019¹⁹. The app helps to locate nearest PMBJP kendras and check the availability of medicines with their prices²⁰.

2. Assurance (quality)

Many who are aware of generic medicines are wary of buying them as they associate high cost of the drug with high quality and efficacy. Physicians are also reluctant to prescribe drugs by generic names as they feel that a low-quality drug might impact the health of their patients. Frequent drug recalls (refer to the table below) are further strengthening this perception.

Drugs produced under the Jan Aushadhi scheme go through quality tests. However, several high-profile product recalls have perpetuated their stigma as lower quality²¹.

Year	Number of drugs recalled	Number of batches recalled
2016-2017	8	8
2017-2018	21	31
2018-2019	19	40
2019-2020	4	27

Source: "Several drugs at Jan Aushadi Kendras recalled over quality test", Deccan Herald, February 2020. Available at: <https://www.deccanherald.com/state/top-karnataka-stories/several-drugs-at-jan-aushadi-kendras-recalled-over-quality-test-804507.html>

“

I don't know what my patient will get if I write a generic drug. I can trust the name of a good brand if I know it is being manufactured by a good company. I need to know that the right drug is in the capsules.

A top official at an Indian regulatory body for hospitals”

Initiatives to ensure high drug quality

Several procedures are in place to ensure quality, starting from stringent quality assurance criteria for applying for the tender to testing of samples. To ensure high quality, medicines are procured from WHO GMP (Good Manufacturing Practices), cGMP and Central Public Sector Undertakings (CPSU) manufacturers. Each batch of drugs is randomly tested by National Accreditation Board for Testing and Calibration Laboratories (NABL) accredited laboratories to ensure their quality and conformance with required standards. However, recent recalls highlight that there are still gaps that need to be addressed²².

¹⁷ V. Thawani *et al.*, "Why the Jan Aushadhi Scheme Has Lost Its Steam in India?" J Pharmacol Pharmacother, 2017. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5642129/>; "A Study on Awareness of Jan-Aushadhi Medical Store", Available at: <https://www.scribd.com/document/420965292/A-Study-on-Awareness-of-Jan-Aushadhi-Medical-Store>; S. Sadiq *et al.*, "Knowledge, attitude, and practices towards Jan Aushadhi scheme", 2017. Available at: <http://www.njppp.com/fulltext/28-1493609998.pdf>; N. Johnson *et al.*, "Perception toward low-cost generic medicines and their usage among dental patients visiting community outreach programs in the peripheral areas of Bangalore South: An exploratory cross-sectional survey", 2020. Available at: <https://www.jiaphd.org/article.asp?issn=2319-5932;year=2020;volume=18;issue=4;spage=308;epage=312;aulast=Johnson?type=0>

¹⁸ "Jan Aushadhi Divas: A day to create awareness about generic medicines" Jagran Josh, March 2020. Available at: <https://www.jagranjosh.com/current-affairs/jan-aushadhi-divas-a-day-to-create-awareness-about-generic-medicines-1583555755-1>

¹⁹ "Mobile application-"Janaushadhi Sugam" launched for locating outlets and searching Generic medicines", August 2019. Available at: <https://pib.gov.in/Pressrelease-share.aspx?PRID=1583141>

²⁰ "Over 325000 people are using "Janaushadhi Sugam" Mobile App to access Janaushadhi kendras", DD News, April 2020. Available at: <https://pib.gov.in/newsite/PrintRelease.aspx?relid=202663>

²¹ "Several drugs at Jan Aushadi Kendras recalled over quality test", Deccan Herald, February 2020. Available at: <https://www.deccanherald.com/state/top-karnataka-stories/several-drugs-at-jan-aushadi-kendras-recalled-over-quality-test-804507.html>

²² "Pradhan Mantri Bhartiya Janaushadhi Pariyojana" website. Available at: <https://www.india.gov.in/spotlight/pradhan-mantri-bhartiya-janaushadhi-pariyojana>

3. Availability

Many reports in the last few years have highlighted shortage of medicine and stock-outs. There have also been concerns around the supply-demand gap – the demand for some medicines exceeds supply while in other cases, supply outstrips demand.

Some of these mismatches arise from India's complicated tendering process. The tendering process itself is a time-consuming activity, sometimes resulting in delays. There are also issues around replacement of expired stocks – while the branded generics are replaced, the generic medicines are not replaced to the pharmacy.

Initiatives to improve availability

To address some of these issues, the government is taking a more active role in stock management and supply. A central warehouse in Gurgaon and additional regional warehouses have been set up. Each store is connected with real-time tracking software system to ensure availability of supplies, with the goal of holding six months' worth of stock for fast-moving drugs, four months for average-moving drugs, and two months for slow-moving drugs. Systems Applications and Products in Data Processing (SAP) based end-to-end supply chain management system has also been implemented.

While these new improvements are promising, a lot more needs to be done considering the magnitude of current challenges and the aggressive ambition of the government (refer the figure 68 for the targets set for 2024).

Further interventions

i. Leverage technology to streamline demand and supply management

There is a need to establish transparent, connected and agile networks to track end-to-end drug movement. It is also important to leverage advanced technology (e.g., blockchain) to track quality and avoid any possibilities of counterfeit. The system should be able to track and alert about potential shortages, as well as identify excessive stocks of medicines nearing expiry. Determining desirable stocks for each medicine by locations, and implementing automated synchronization, prediction and scenario simulation for increasing forecast accuracy may help in addressing supply-demand gaps.

ii. Improve tender/procurement process

Several studies suggest the usage of Most Economically Advantageous Tender (MEAT) or Multiple Criteria Decision Analysis (MCDA) approach for tender appraisal. This approach requires assessment to be based on a number of criteria instead of being based primarily on lowest price of the drug. The criteria can be defined by the involved stakeholders as appropriate and effective in the setting of a specific country. Most European countries now follow MEAT approach. Many countries such as Indonesia, China, Thailand, and Egypt are adopting MCDA for procurement. (refer to the case study on page 152 for details)²³.

“

Tender processes should integrate new-age practices, for e.g., outcome-based model can be used instead of L1 models.

MD of a leading global pharma company —”

Another good practice based on a study is to use framework agreements or long-term contracts that provide terms and conditions under which smaller repeat purchasing orders may be issued for a defined period of time²⁴. Framework agreements benefit the procurement body by saving time and resources, and ensuring good quality of drugs and supply security. The manufacturers, in turn, are incentivized to invest in assets (for example, equipment, increased manufacturing capacity, personnel training, administrative/operating procedures), specifically tailored to better serve government orders and achieve efficiencies of scale. (refer to the case study on page 153 for details)²⁵.

These best practices for tender process can also be leveraged to improve the national- and state-level programs for procuring medicines for public healthcare systems. In addition, joint and bulk procurement mechanisms should be promoted, e.g., Tamil Nadu Medical Services Corporation, which has also been adopted by some other states such as Rajasthan.

²³ N. Maniadas et al., “Shaping Pharmaceutical Tenders for Effectiveness and Sustainability in Countries with Expanding Healthcare Coverage”, Appl Health Econ Health Policy, October 2018. Available at: <https://pubmed.ncbi.nlm.nih.gov/29987759/>

²⁴ L. Arney et al., “Strategic contracting practices to improve procurement of health commodities”, Glob Health Sci Pract, June 2014., Available at: <https://pubmed.ncbi.nlm.nih.gov/25276589/>

²⁵ L. Arney et al., “Strategic contracting practices to improve procurement of health commodities”, Glob Health Sci Pract, June 2014., Available at: <https://pubmed.ncbi.nlm.nih.gov/25276589/>

Mexico is another good example of centralized procurement. As a result of increasing costs due to universal health coverage, in 2008, the Mexican government decided to centralize drug price negotiation process for single-source or patented medicines for all public institutions. In this context, the Coordinating Commission for Negotiating the Price of Medicines and Other Health Inputs (CCPNM) was established that allowed the government to reap benefits from the combined bargaining

power. Consolidated purchasing through CCNPM and other pharmaceutical procurement reforms have led the government to save 7%-15% annually. In addition to financial gains, introduction of CCPNM has also led to overall improvement of the procurement process. The industry has also benefited from the organized and more unified process, increased exchange of information, and greater certainty regarding sales volume, which in turn facilitates planning²⁶.

WHO's* definition of tender:

"Any formal and competitive procurement procedure through which offers are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender/offer is the most **advantageous**".

The WHO notes that tendering should be conducted with the goal of purchasing high-quality, consistent and effective products; therefore, the decision on which supplier(s) is awarded the contract should not be based solely on the price.

Similarly, a 2010 report from the European Parliament noted that prioritizing lowest-cost offers over those that are the most economically advantageous can weaken innovation and global competitiveness.

**World Health Organization collaborating centre for pharmaceutical pricing and reimbursement policies*



²⁶ "Mexico's coordinating commission for negotiating the price of medicines and other health inputs", July 2016. Available at: <https://publications.iadb.org/publications/english/document/Breve-14-Mexico-Coordinating-Commission-for-Negotiating-the-Price-of-Medicines-and-Other-Health-Inputs.pdf>

Findings from 'systematic literature review' – Study I*

Study objective

While tenders can reduce acquisition costs, they may also expose the healthcare system to risks, including drug shortages, quality trade-offs, and ultimately, compromised patient health outcomes.

The literature study was conducted to examine the effectiveness and impact of tendering in different healthcare settings to establish good tender practices and develop guidance for countries with expanding healthcare coverage (CEHC).

Findings and recommendations for 'developed geographies'

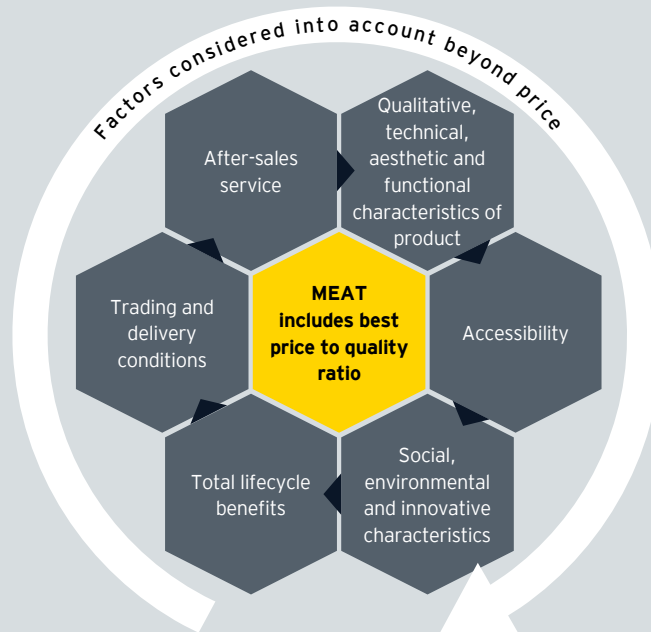
Principles of NHS procurement

Price shall not be sole or over-riding factor in decision-making process. The Most Economically Advantageous Tender (MEAT) approach should be used in tender appraisal. Providers should be required to demonstrate that their services offer the best possible value for money. This assessment must be based on a number of criteria for evaluation. These include price, quality, sustainability, innovation and technical merit ('Principles of NHS procurement').

European Union regulations

MEAT approach has been recommended across all sectors in the European Union regulations

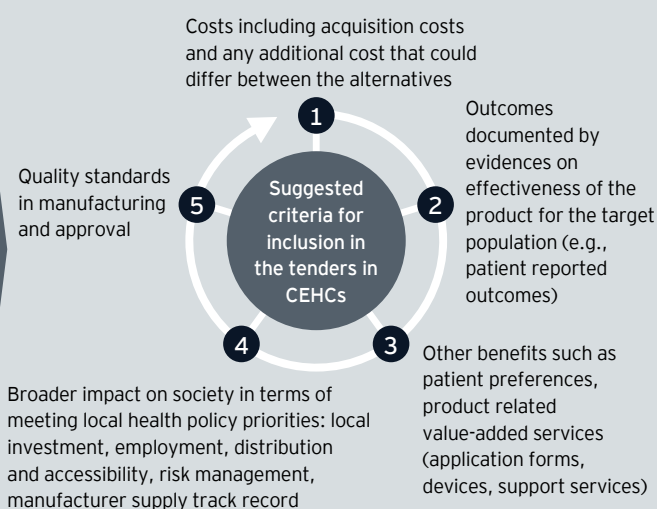
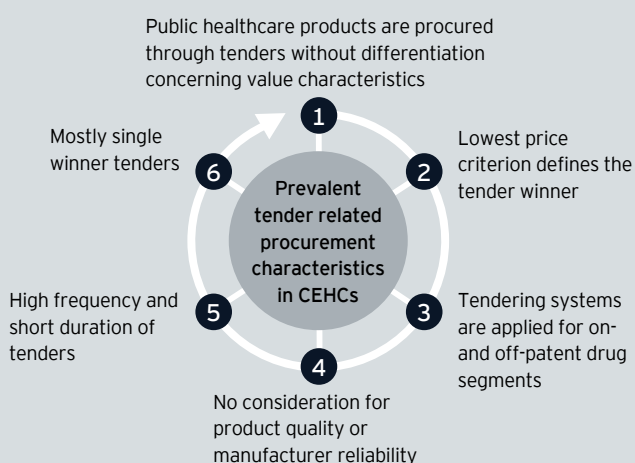
While lowest price was the prevailing award criterion, some countries have advanced to select the MEAT approach.



Findings and recommendations for CEHCs

The survey revealed specific behaviours or characteristics of procurement through tenders in CEHCs, which may elevate the risk for the occurrence of undesirable side effects

Literature review and survey recommendations: clear principles should guide pharma tenders in CEHCs to foster a sustainable and affordable supply with minimum risk of unwanted side effects



Criteria can be defined by involved stakeholders as appropriate and effective in the setting of a specific country. Indonesia has defined such multiple criteria decision analysis (MCDA). Usage of MCDA in decision making for off-patent medicines is also emerging in several other countries such as China, Thailand, Egypt, etc.

*Systematic literature review details: relevant reports published between 1995 and December 2017 were retrieved through electronic searches (performed in August 2017 and January 2018) in PubMed, Google Scholar, and the Cochrane Library databases. An online survey was also conducted between March 2017 and July 2017 by individual experts in CEHCs (such as Algeria, China, Egypt, Indonesia, Lebanon, Malaysia, Pakistan, the Philippines, the Republic of Korea, Russian Federation, South Africa, Thailand, Turkey, Ukraine, the United Arab Emirates and Vietnam) to describe tender practices in CEHCs

Source: EY analysis; Nikolaos Maniadakis et al., 'Shaping Pharmaceutical Tenders for Effectiveness and Sustainability in Countries with Expanding Healthcare Coverage', July 2018

Findings from 'semi-structured literature reviews and interviews' – Study II

Study objective

- ▶ Identify strategic procurement and contracting practices of the U.S. Department of Defense and the U.S. Department of Veteran Affairs that may be suitable for public procurement systems in developing countries.
- ▶ Review key characteristics of these strategic practices as well as case studies of their use by other national governments and multilateral agencies.

Findings and recommendations for 'developing countries'

Current challenges in tendering process of developing countries

- ▶ Public-sector entities continue to use archaic procurement methods for essential medicines and health commodities.
- ▶ Reliance on inflexible forecasts and current practice of floating tenders multiple times a year contributes to long lead times, stock-outs and commodity insecurity. It also hampers manufacturers' ability to plan and respond to the government's needs.

Suggested best practices

- ▶ Framework agreements used by the U.S. federal government is a strategic procurement practice that may also be suitable for global health supply chains.
- ▶ Such agreements are common in the U.S. and the United Nations procurement systems and in other developed countries and multilateral organizations.

Definition of framework agreements

Long-term contracts that provide terms and conditions under which smaller repeat purchasing orders may be issued for a defined period of time.

Type of framework agreements

Long-term agreements (LTAs), task-order contracts, indefinite-quantity contracts, call-off contracts, umbrella contracts, rate or running contracts, system contracts, general service agreements, blanket purchase agreements, and standing offers.

Two stages of framework agreement process

Single-supplier

First stage

A single contract is awarded to one supplier through a competitive procurement.

Second stage

Multiple call-off orders are placed directly against the contract throughout the duration of the agreement.

Multi-supplier

A contract for the same good or service is signed with multiple suppliers.

Different ways - secondary bidding process for each call-off order, ranking of suppliers according to preference or capacity, rotation of orders among suppliers, or assigning fixed order amounts to each supplier in the initial contract.

Advantages of framework agreements



Procurement/healthcare body

Significantly saves the procurement time and resources by avoiding repetition of all steps for each purchase.

Benefits of centralized purchasing through demand aggregation, with flexibility in purchase quantities and delivery schedules.

Supply security, as a shortfall by one supplier can be compensated for or replaced by another supplier on the contract.



Manufacturer

Manufacturers are incentivized to invest in assets (for example, equipment, increased manufacturing capacity, personnel training, administrative/operating procedures), specifically tailored to better serve government orders.

Drug pricing mechanisms to improve affordability

India's drug prices are among the lowest in the world. However, they are still out of reach for a large percentage of the population due to high out-of-pocket expenditure. To tackle affordability issues, price control mechanisms have been in place since 1955 when the government first imposed price ceilings under Section 3 of the Essential Commodities Act²⁷. The early drug price controls were enacted by the Drugs (control of prices) Order in 1963 under the Defence of India

Act. In 1966, the provision was framed into the Drugs Prices (Display and Control) for new drugs developed by research outside the ambit of price control. From 1970, Drug Price Control Orders (DPCO) were issued in accordance with the Essential Commodities Act, 1955. Several amendments have been made to the DPCO in the past five decades²⁸. Different mechanisms are used for pricing control of scheduled and non-scheduled drugs.

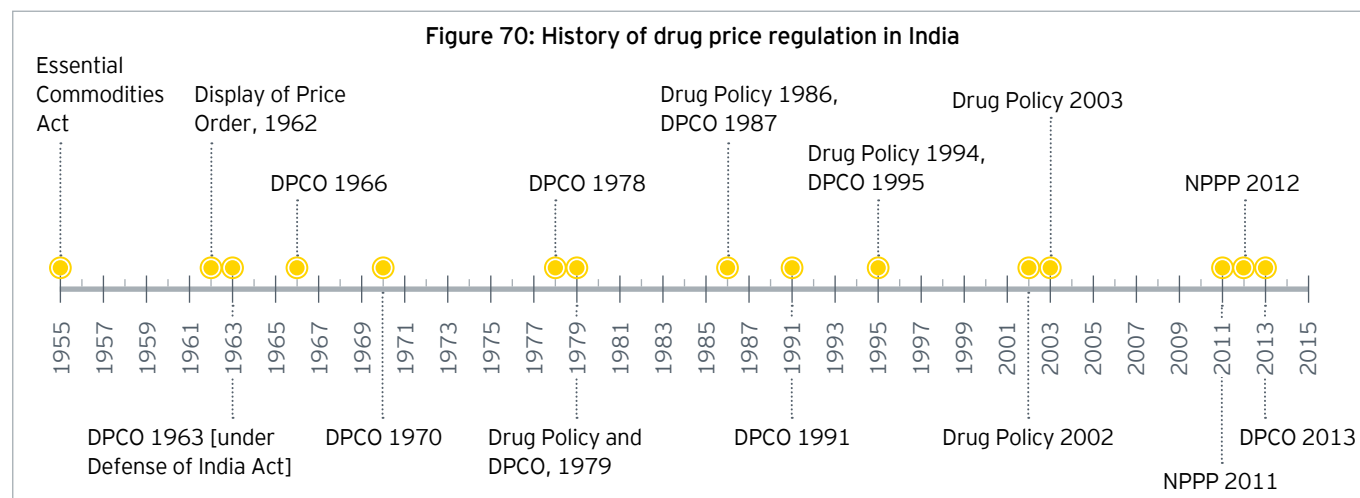
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Pricing control is required in Indian context, but there should be more consensus-based flexibility and room for innovation-led pricing.

Director of Corporate Services of a leading Indian pharma company

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Figure 70: History of drug price regulation in India



Source: E. Boswell Dean, "Who Benefits from Pharmaceutical Price Controls? Evidence from India", Center for Global Development, Working Paper 509, April 2019. available at: <https://www.cgdev.org/sites/default/files/who-benefits-pharmaceutical-price-controls-evidence-india.pdf>

Pricing control of Schedule I medicines (essential medicines)

With the aim to satisfy the country's priority health care needs, the first National List of Essential Medicines (NLEM) in India was developed in 1996 covering 279 drugs. The NLEM was then revised and published after seven years in 2003 (covering

354 drugs)²⁹. The NLEM is revised every few years to align with changing healthcare needs in the country due to evolving disease burden. The NLEM 2011, and subsequently NLEM 2015 were included as Schedule I in DPCO 2013. The latest one, NLEM 2015 includes 376 drugs and 857 formulations³⁰. The government appointed an experts' committee in 2019 to prepare a new NLEM to tackle emerging diseases³¹.

²⁷ The Essential Commodities Act, 1955. Available at: <http://legislative.gov.in/sites/default/files/A1955-10.pdf>

²⁸ "The genesis of drug price control", Pharmabiz, January 2008. Available at: <http://pharmabiz.com/printarticle.aspx?aid=42905&sid=9>

²⁹ M. Rituparna et al, "Essential Medicines: An Indian Perspective", Indian J Community Med. 2015. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4581141/>

³⁰ "Health ministry to conduct first stakeholders meet for revision of NLEM 2015 on July 25", Pharmabiz, July 2019. Available at: <http://pharmabiz.com/NewsDetails.aspx?aid=117114&sid=1>

³¹ "Industry welcomes revised NLEM list to tackle emerging diseases", Pharmabiz, November 2019. Available at: <http://pharmabiz.com/NewsDetails.aspx?aid=119158&sid=1>

The National Pharmaceutical Pricing Authority (NPPA) was set up in 1997. It enforces the provisions of DPCO³². The price of all Schedule I drugs is controlled by fixing the ceiling prices, i.e., by limiting the highest price companies can charge for the drug. The ceiling price policy has been in place for more than two decades now. Market-based pricing methodology is currently followed where ceiling price is calculated by taking the average price for all branded generics and generic versions with 1% or above market share of the drug formulation. The prices of the drugs can only be increased annually³³. This policy is not applicable for indigenously-developed patented new drugs and fixed-dose combinations (FDCs).

Before 2013, the DPCO followed a cost-based pricing mechanism. The drug prices were then fixed by the manufacturers based on their manufacturing costs plus reasonable profit margins. The shift to market-based pricing was done to make it more sustainable, both in terms of ease in developing and implementing the ceiling prices, and allowing drug companies to earn reasonable profit.

Challenges associated with drug price controls

There has not been any detailed systematic study to measure the impact of pricing controls on improving access in India or other developing countries. However, a few articles and literature review do provide some view of the overall impact of pricing controls.

A study spanning 19 developed countries over a 13-year period (1992 to 2004) found that regulations significantly reduced pharmaceutical revenues, with direct price controls having the biggest impact of them all³⁴. Legislations led to reduced drug costs in the short-term, but they had a negative impact on future innovations and led to delays in launch of new drugs.

In 2015, IMS Health released a study on the impact of price control. The study was based on extensive quantitative data analysis of growth and volume trends, and in-depth qualitative interviews with industry stakeholders and policy makers. The study suggests that regulations that push for price levels are

unlikely to improve access to medicines in India, especially in the rural areas where it is most desirable. The study also highlighted that keeping the prices below market value cause suppliers to withdraw from the market, thus negatively impacting supply of medicines and decreasing their competitive intensity. A 75% decline in new launches post 2011 was also identified^{35,36}. Similarly, an IIM Ahmedabad research paper on the impact of price controls on drug sales volume strongly suggests that there was a significant decrease in sales volume post-price control, indicating decreased access for patients³⁷.

Another study reported the following theoretical and empirical effects of price ceiling placed on essential medicines in India between 2013 and 2014³⁸:

- ▶ Prices declined amongst both directly-impacted and competing products. But this was accompanied by a reduction in the sale of price-controlled and closely related products, preventing trade that would have otherwise occurred.
- ▶ The sale of small, local generics manufacturers was most impacted registering a 14.5% decrease in market share and a 5.3% decrease in sales. These products tend to be inexpensive but are also of lower average quality.
- ▶ There was differential impact by consumer types. The benefits were largest for quality-sensitive consumers, while poor and rural consumers, who were already suffering from low access to medicines, were negatively impacted.

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A lot can be done in pricing. Need to go beyond pricing – perceived as deterrent to growth.

MD of a leading Indian pharma company

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³² NPPA India website. Available at: <http://www.nppaindia.nic.in/wp-content/uploads/2018/10/1766E.pdf>

³³ “All you wanted to know about: DPCO”, Business Line, September 2014. Available at: <https://www.thehindubusinessline.com/opinion/All-you-wanted-to-know-about-DPCO/article20876551.ece>

³⁴ N. Sood *et al.*, “The Effect Of Regulation On Pharmaceutical Revenues: Experience In Nineteen Countries”, Health Affairs, 2008. Available at: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.28.1.w125>

³⁵ “Price control unlikely to improve access to medicines in India: IMS study”, Pharmabiz, July 2015. Available at: <http://pharmabiz.com/NewsDetails.aspx?aid=89417&sid=2>

³⁶ “Price-control as a regulatory philosophy fundamentally dents the image of a country”, ETHealthWorld, June 2018. Available at: <https://health.economicstimes.indiatimes.com/news/medical-devices/price-control-as-a-regulatory-philosophy-fundamentally-dents-the-image-of-a-country/64633212>

³⁷ A. Sahay *et al.*, “Does Pharmaceutical Price Regulation Result in Greater Access to Essential Medicines? Study of the impact of drug price control order on sales volume of drugs in India”, Indian Institute of Management Ahmedabad, India - January 2016. Available at: <https://web.iima.ac.in/assets/snippets/workingpaper-pdf/2217512512016-02-01.pdf>

³⁸ E. Dean, “Who Benefits from Pharmaceutical Price Controls? Evidence from India”, Center for Global Development, April 2019. Available at: <https://www.cgdev.org/publication/who-benefits-pharmaceutical-price-controls-evidence-india>

In addition to the above study, several articles have reported the following challenges and industry's response regarding the same:

Business profitability-related considerations

- a) Inability of manufacturers to increase the price of the drug in proportion to the increase in the cost of a raw drug material and skilled human resources, leading to continued decrease in margins over time.
- b) In other instances, small-scale manufacturers that are selling drugs at prices much lower than the ceiling price have faced significant profitability challenges due to inability to increase price beyond 10% per annum.
- c) Manufacturers face challenges related to permissions required to withdraw an essential drug from the market. In some cases, as pharma companies stopped production of drugs under control because of lower margins, there was a dominance of substandard and spurious drug manufacturers in the category.

General behavioural response by manufacturers

- a) Stopped promoting essential drugs, as a result, the sales declined for the medicines with capped prices and increased for other medicines.
- b) Started promoting fixed-dose combinations (FDCs) or other dosages (non-standard dosages) that are not included in the NLEM.

“

Government should buy directly from the industry through a tendering process and then distribute it in any form that they see fit.

Director of corporate services of a leading Indian pharma company

”

Pricing for non-scheduled drugs

There is no price cap for non-scheduled drugs, i.e., the marketers can fix their own prices. Once the price is fixed, an annual increase in price of 10% is allowed keeping in view the annual inflation. The increase in drug prices is monitored by the NPPA³⁹. In some cases, only a 10% increment in annual price has been a concern for the industry. For example, if the price of a drug is already on the lower side or if there is relatively higher increase in the manufacturing costs (e.g., due to increase in the price of active pharmaceutical ingredients or bulk drugs).

In addition to the check on annual increase in price, the government has special powers under Para 19 of the DPCO 2013 to bring any item of medical necessity under price controls⁴⁰. In 2014, prices of 50 diabetic and cardiovascular drugs (108 formulations), not included in the NLEM, were fixed in public interest⁴¹, followed by fixing the prices of knee implant systems and cardiac stents in 2017⁴². In 2019, the government placed a trade margin cap of 30% on 42 anti-cancer medicines⁴³.

Approach for innovative drugs

According to the DPCO 2013, patented drugs except those that are indigenously-developed, come under price control if they are included in the NLEM. The indigenously-developed patented drugs do not come under the purview of price controls for a period of five years from the date of commencement of commercial production of the product⁴⁴. The NLEM 2015 included the following patented medicines, namely, entecavir, raltegravir, sofosbuvir and trastuzumab⁴⁵.

However, the following revisions have been made as per the DPCO 2019:

- ▶ Drugs by foreign MNCs that are patented in India will be exempt from price control for a period of five years, starting from the day of commercializing the drug in the country (same as the indigenously-developed patented drugs)⁴⁶.
- ▶ Drugs for orphan diseases have also been exempted from the price control with the aim to incentivize R&D efforts in the space.

³⁹ NPPA website. Available at: <https://nppaimis.nic.in/nppaprice/newmedicinepricesearch.aspx>

⁴⁰ "NPPA invokes Para 19 of DPCO to cap knee implant prices, may face challenge in court", Moneycontrol, December 2020. Available at: <https://www.moneycontrol.com/news/economy/policy/nppa-invokes-para-19-of-dpco-to-cap-knee-implant-prices-may-face-challenge-in-court-2364017.html>

⁴¹ "Prices of 108 diabetes, cardiac formulations fixed: NPPA", The Economic Times, July 2014. Available at: <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/prices-of-108-diabetes-cardiac-formulations-fixed-nppa/articleshow/38372299.cms?from=mdr>

⁴² "After cardiac stents, government now caps knee implants price, cuts prices by up to 69%", The Economic Times, April 2017. Available at: <https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/after-cardiac-stents-government-now-caps-knee-implants-price/articleshow/60088338.cms?from=mdr>

⁴³ "NPPA caps trade margins to 30% for 42 anti-cancer drugs", BusinessLine, February 2019. Available at: <https://www.thehindubusinessline.com/companies/nppa-caps-trade-margins-to-30-for-42-anti-cancer-drugs/article26390238.ece>

⁴⁴ "Patent experts welcome DoP's decision to deregulate prices of patented orphan and innovative drugs", Pharmabiz, January 2019. <http://www.pharmabiz.com/NewsDetails.aspx?aid=113316&sid=1>

⁴⁵ "National List of Essential Medicines 2015". Available at: <https://www.nhp.gov.in/NHPfiles/NLEM%2C%202015.pdf>

⁴⁶ "Patent experts welcome DoP's decision to deregulate prices of patented orphan and innovative drugs", Pharmabiz, January 2019. <http://www.pharmabiz.com/NewsDetails.aspx?aid=113316&sid=1>

Another recent step to motivate innovation is the flexibility to increase the annual price by 15%-20% for the drugs that are relaunched with incremental innovations such as reduced side effects, or user-friendly administration techniques such as skin patches. This will also be applicable for drugs included in the NLEM⁴⁷.

Need to explore new ways of improving access to medicines

Pharmaceutical pricing is an important consideration for all countries, especially in the context of making essential medicines affordable to the entire population. This is also critical to encourage innovators to price drugs to recover the due costs of discovery and substantial risks undertaken to invest in unmet needs and new diseases.

The World Health Organization (WHO) holds that 'affordable and fair' price is one that can reasonably be funded by patients and health budgets and simultaneously sustains research and development, production and distribution within a country⁴⁸.

To achieve sustainable affordability in India, the government may consider the following measures:

- ▶ Follow a consensus-based approach between industry and government. For example, the prices of branded prescription drugs have been regulated in the UK since 1957, in accordance with a voluntary agreement called the Pharmaceutical Price Regulation Scheme (PPRS). The agreement is between the Association of the British Pharmaceutical Industry (ABPI) and the UK Department of Health, and applies to all branded, licensed prescription drugs available to the National Health Service (NHS). PPRS aims to secure reasonable prices for the NHS while ensuring that the industry can achieve a fair return on its investment in R&D⁴⁹.
- ▶ Use approaches such as special pricing agreements (as used in Australia), differential pricing (as used in New Zealand and Australia), bundling (as used in New Zealand), specialized medicine by class (as used in New Zealand) (refer figure 71).

- ▶ Set up innovative contracts for bulk procurement (e.g., as done in the UK) of essential medicines.
 - ▶ For example, negotiate directly with the manufacturers to provide discounted medicines for public consumption through government and allow free pricing in the market (driven and controlled by market competitiveness).
 - ▶ Set up long-term contracts for large volumes (for e.g., ~50% of total consumption of the drug) of top essential drugs with top manufacturers (for e.g., top five of them) and distribute the remaining volume to MSMEs. This will allow the top manufacturers to invest in building capacity and achieve benefits of scale, while also ensuring that there is enough competition from other big and mid-size manufacturers in the market.
- ▶ Set up government/public manufacturing capacity for some of the most critical drugs, starting from key starting materials and active pharmaceutical ingredients to finished formulations.
- ▶ Establish managed entry schemes (MSAs) (e.g., in South Korea and Thailand) or value based contracts (VBCs) (e.g., in the US and European markets) for innovative patented drugs or drugs for rare diseases⁵⁰ (refer to examples from other countries in the figure 71).

“

New-age concepts of pricing models are required in India. There are lot of examples globally – tiered pricing, outcome-based pricing, etc.

MD of a leading Indian pharma company

I am a strong believer in pay for performance. Even for drug pricing, it needs to be performance based.

Senior Vice President, Global Medical Affairs of a leading Indian pharma company

”

⁴⁷ “Modi govt allows 15-20% price hike in medicines that have ‘innovations’”, The Print, December 2019. Available at: <https://theprint.in/health/modi-govt-allows-15-20-price-hike-in-medicines-that-have-innovations/337346/>

⁴⁸ WHO website. Available at: <https://www.who.int/teams/health-product-and-policy-standards/medicines-selection-ip-and-affordability/pricing-financing>

⁴⁹ L. Hannah, “Is the Current UK System of Pharmaceutical Price Regulation Working”, February 2017. Available at: <https://www.hausfeld.com/news-press/is-the-current-uk-system-of-pharmaceutical-price-regulation-working>

⁵⁰ N. Vergheze *et al.*, “Government pharmaceutical pricing strategies in the Asia-Pacific region: an overview”, J Mark Access Health Policy, 2019. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6461095/>

Figure 71: Best practices from other countries for drug pricing and procurement

Generic medicines	Innovative medicines
<p>Special Pricing Agreements (SPAs)</p> <ul style="list-style-type: none"> ▶ <i>Australia</i>: manufacturers can set higher public list price that is offset through rebates to government based on pre-determined criteria such as volume. ▶ <i>New Zealand</i>: the country practices bundling whereby the government offers subvention for a particular drug if the manufacturer agrees to discount prices on one or more of its other marketed medicines in the formulary list. This allows the government to attain price reductions for mature products and release funding for new therapies. <hr/> <p>Subsidized medicines by class in New Zealand</p> <ul style="list-style-type: none"> ▶ There is at least one fully-subsidized medicine in each medicine class. Patients pay additional costs if the price of another medicine in the class is higher than the price of the subsidized medicine. <hr/> <p>Differential pricing in New Zealand and Australia</p> <ul style="list-style-type: none"> ▶ The government reimbursement is capped based on the reference price (based on the lowest-priced medicine for the group), but manufacturers are free to charge any price in the market. 	<p>China's strategy to reduce cost of patented drugs</p> <ul style="list-style-type: none"> ▶ In 2017, China cut costs of patented medicines by ~70% as a precondition for their eligibility for government insurance schemes, without tampering the process of granting patents. This improved the affordability of drugs, while protecting the revenues of pharma companies. <hr/> <p>Managed entry schemes (MES)</p> <p>These are forms of SPA that enable access to and/or reimbursement for medicines subject to specified conditions. These agreements address uncertainty about medicines' performance, uptake and health outcomes.</p> <p>Types of MES include price-volume agreements (PVAs), refunds if medicines do not work as expected, and performance/ outcome-based/value based risk-sharing agreements (RSAs).</p> <p>Countries such as South Korea, Taiwan, Thailand and New Zealand practice MES in one or more forms.</p> <ul style="list-style-type: none"> ▶ <i>South Korea</i>: PVA related price cuts require several conditions to be met. For instance, if consumption of a drug is 30% higher than predicted, the manufacturer provides the local drug subsidizing agency, National Health Insurance System (NHIS), a price reduction of up to 10%. ▶ <i>South Korea</i>: use contract-specific risk-sharing agreements that rely on metrics such as total sales, per patient cap, etc. ▶ <i>South Korea and Thailand</i>: performance based risk-sharing for medicines to treat cancer and rare diseases, where clinical benefits of a drug in each patient are monitored and costs are covered by the manufacturer if the drug fails to demonstrate effectiveness. ▶ <i>Thailand</i>: a maximum volume threshold is calculated for high-cost on-patent medicines by estimating the number of eligible patients and the duration of the intervention. Costs exceeding the threshold are covered by manufacturers.

Note: the list of best practices and examples is indicative and not exhaustive

Source: 'Government pharmaceutical pricing strategies in the Asia-Pacific region: an overview', *Journal of market access and health policy*, 2019, Vol. 7

Another factor that contributes to increase in overall drug prices is the complex supply chain starting from the stockist to the retailer. Rationalizing trade margins can be another way to improve affordability. A WHO report recommends regulating distribution and retail chain mark-ups as part of the overall pharma pricing strategy⁵¹.

- ▶ Mark-ups that include a regressive component (i.e., a lower mark-up for higher-priced products) have been found to result in better outcomes than fixed percentage mark-ups.

- ▶ Remuneration/mark-up regulation can be used to provide incentives for supplying specific medicines (e.g., generics, low volume medicines, reimbursable medicines) or to protect specific patients or population groups (e.g., vulnerable groups, remote populations).

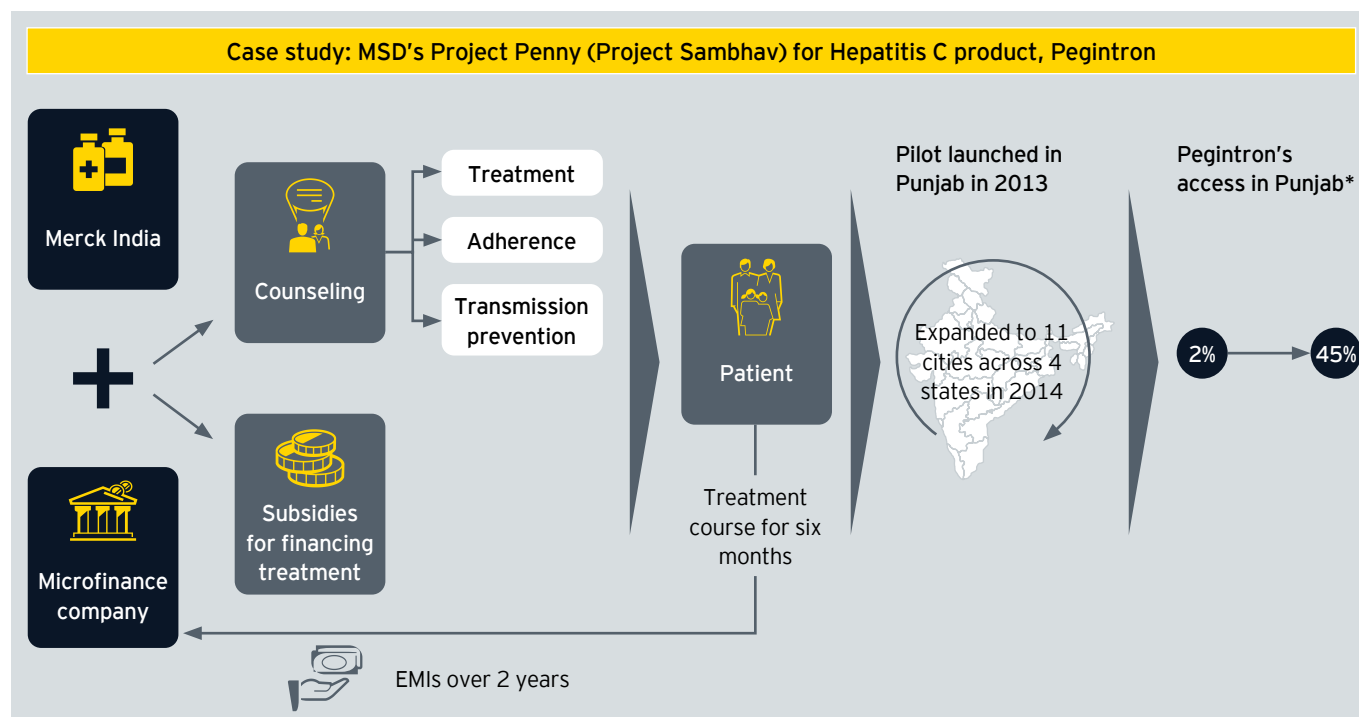
⁵¹ "WHO guideline on country pharmaceutical pricing policies", 2015. Available at: https://www.who.int/medicines/publications/pharm_guide_country_price_policy/en/

Role of the pharma industry in improving access to medicines

In addition to the efforts by the government to achieve sustainable affordability, some companies have also launched innovative initiatives that are designed to promote access using commercially-viable business models. For example, Merck Sharp & Dhome (MSD) launched Project Sambhav (Project Penny) in India in 2013. This is an innovative micro-financing program, in partnership with financing institutions in India, which allows patients to pay for treatment costs for the hepatitis C drug 'Pegintron' over an extended period of time. In addition, there is also a component of disease education and management for the patients. Project Sambhav addressed

an important social need, while it simultaneously, allowed the company to create a market in place which was missing⁵².

Novartis also initiated 'Arogya Parivar' or 'Healthy Family' in 2007 to improve rural reach. The program builds local, sustainable capabilities for healthcare, including education, infrastructure and products, for people living at the base of the pyramid. This program quickly demonstrated the feasibility of approach by breaking even 30 months after launch and increasing sales by nearly 300 times in 10 years. After the success of the program in India, similar programs were rolled out in Vietnam and Kenya (adapted to the local needs and disease patterns)⁵³. Refer to the case studies for details.

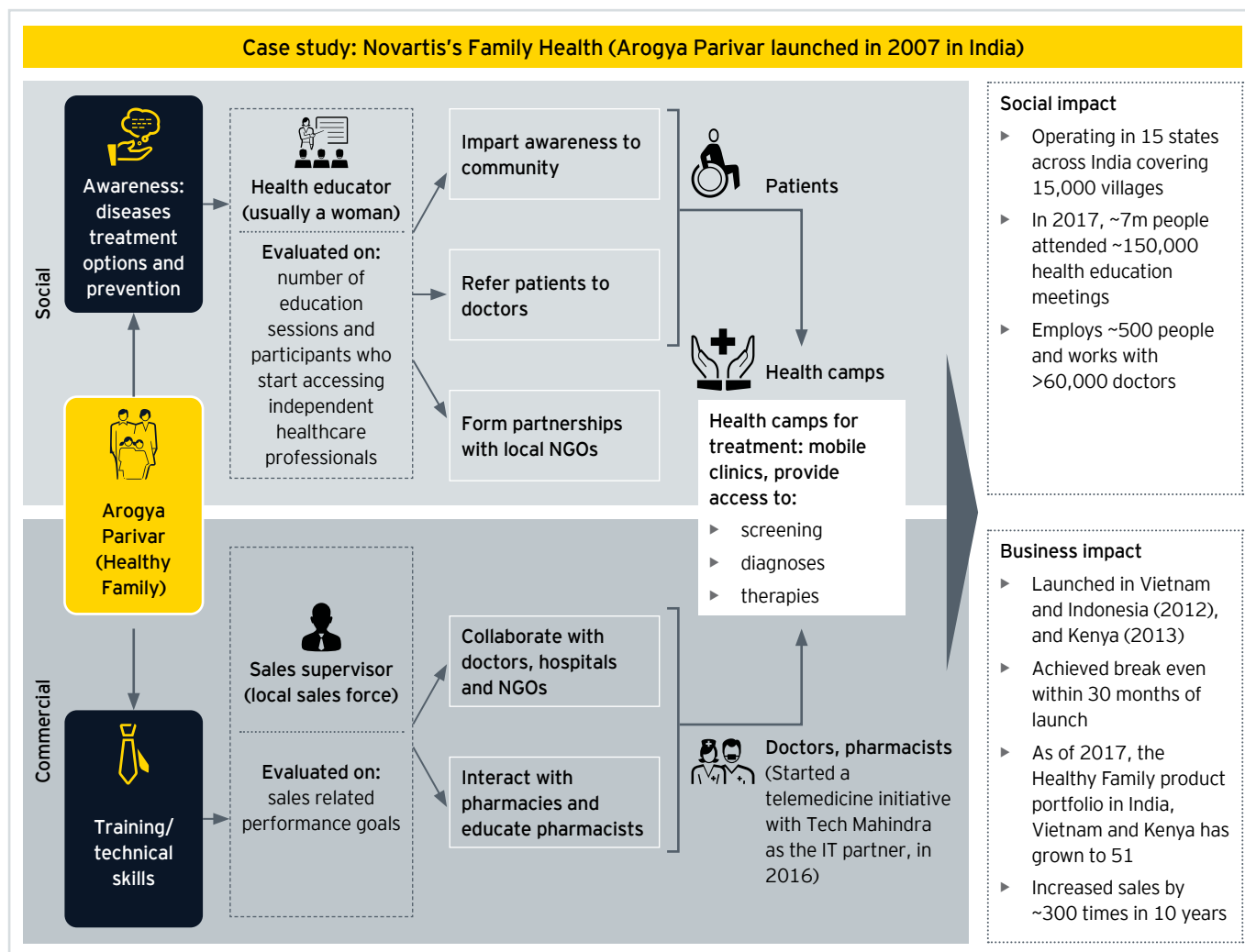


*Patients with limited or no insurance coverage

Source: Company report, available at: https://www.msdrresponsibility.com/wp-content/uploads/2015/10/MRK_Executive_Summary_2014.pdf

⁵² A. Sood et al., "Impact of "Sambhav" Program (Financial Assistance and Counselor Services) on Hepatitis C Pegylated Interferon Alpha Treatment Initiation in India", Int J Health Policy Manag, 2018. Available at: https://www.ijhpm.com/article_3540_95096ce36d6180eb8bc74a83c95d2fd5.pdf

⁵³ Company website. Available at: https://www.novartis.com/our-company/corporate-responsibility/expanding-access-healthcare/novartis-social-business/healthy_
<https://www.novartis.com/sites/www.novartis.com/files/2017-healthy-family-report.pdf>



Source: Company reports

E-pharmacy has the potential to improve access of medicines

E-pharmacy holds the potential to improve accessibility of medicine to even the remotest corners of the country. The first online pharmacy was started in the US in late 1990s. In India, the e-pharmacy space is still at a nascent stage. The market was estimated at US\$0.5b in 2019⁵⁴ with companies such as NetMeds, PharmEasy, Medlife and 1mg dominating the market. It is projected to reach US\$4.5b in 2025 at a CAGR of 44% for the period 2019–2025, representing about 10%-12% of the pharmaceutical sales (up from 2%-3% levels in 2019)⁵⁵.

The need for social distancing during the pandemic has strengthened the adoption of e-pharmacies globally. Online pharmacies across the world, including India, have reported a significant increase in orders during the lockdown period.

Figure 72: Increased adoption of e-pharmacy during pandemic



Sources

¹<https://www.pharmacist.com/article/mail-order-drug-delivery-rises-during-coronavirus-lockdowns>

²Increase in prescription nominations from last week of March'20 to first week of June'20; <https://www.chemistanddruggist.co.uk/news/prescription-nominations-online-pharmacies-rise-covid-19-coronavirus-eps>

³<https://www.livemint.com/news/india/the-coming-of-age-of-e-health-platforms-11590324836814.html>

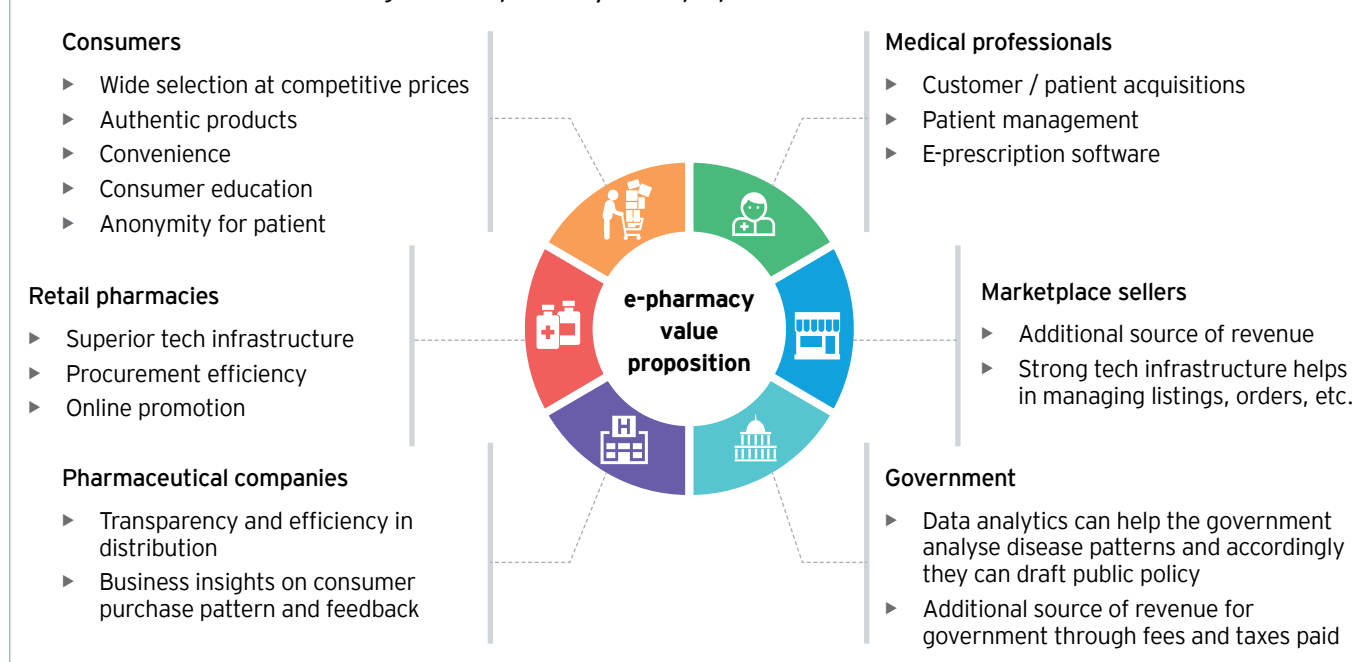
E-pharmacies offer a convenient and an affordable way to purchase medicines. Coupled with teleconsultations, they can provide quick access to quality healthcare for patients in remote areas. Some e-pharmacies have expanded their reach and serve at least 90% of the pin codes in India. The distribution time in remote locations can vary between seven to ten days. E-pharmacies offer strong value proposition to doctors in rural areas and tier-3 cities. During primary interactions with EY, many doctors from rural areas mentioned that they encourage patients to purchase medicines from e-pharmacies as local

pharmacies' stocks are limited. Given the access, doctors are able to prescribe a wide range of medicines, which enable them to provide better care. Both the pharma companies and the government benefit by getting access to digital data and increasing reach to the patients. Some pharma companies are leveraging e-pharmacy platforms with patients as a channel to increase awareness about diseases and their management. The following snapshot sums up the value proposition that e-pharmacies offer to stakeholders in the value chain.

⁵⁴ "Mitsui & Co. Global Strategic Studies Institute Monthly Report", March 2019. Available at: https://www.mitsui.com/mgssi/en/report/detail/_icsFiles/afield-file/2019/05/17/1903_sakai_e.pdf

⁵⁵ EY survey, June 2020

Figure 73: E-pharmacy: value proposition to the stakeholders



Source: EY analysis

Current challenges

The e-pharmacy space faces challenges related to operational management and stakeholder expectations.

Complex supply chain and counterfeit











The pharma supply chain in India is complex with several carry and forwarding agents (CFAs), and more than 8,50,000 retailers. A large number of stock keeping units (SKUs) (>250,000) further increase the complexity of stock management, especially with variation in brand preference across geographies. For e-pharmacies, holding inventories of 2.5 lakh SKUs across geographies is a challenge⁵⁶. With fragmented and unorganized supply chains, chances of the product being counterfeit becomes higher.

Stakeholder expectations

According to EY's primary research, all stakeholders – patients, doctors and pharma companies – agree that e-pharmacies provide access and convenience benefits. However, they also have concerns related to data privacy, prescription genuineness, medicine substitution, quality, stock availability and timely delivery. The table below captures the concerns by stakeholder type and the response of e-pharmacies regarding the same.

⁵⁶ EY survey, June 2020

Figure 74: Stakeholders' views on multiple issues highlighted in the EY survey

							
		Data privacy	Substitution	Operating model	Private labels	Discounts	Reach
Concerns	 Pharma Co	► Unclear regulatory guidelines	► Strong concern	► Procurement through certified channels	► Not concerned about competition	► Conflicts with offline channel	► Most orders from metros ► New localisation models
	 Patients	► Concern about prescription privacy	► Some prefer doctor prescribed vs low cost alternatives	► Medicine authenticity is a major concern	► Preference to known brands in consumer segments	► Primary driver	► Delivery time is higher
	 Doctors	► Concern about data sharing by platforms	► Prefer to be consulted before substitution	► Concerned about prescription abuse	► Not concerned	► Not concerned	► Increased reach in rural areas
POV	 E-Pharma	► Secure platform; Prescription data safe	► Substitution in case of stock-outs; no ghost prescriptions	► Procured from certified distributors	► Medium to long term	► Discounts to rationalize: 15-17% vs 20-25% in past	► Some players serving all pin codes

Source: EY analysis

Potential solutions

Use of technology and partnerships to resolve supply chain and access related issues

E-pharmacies are leveraging technology to optimize inventory using strong analytics of purchase orders and sales data. These also provide real-time visibility of secondary data to pharmaceutical companies along with sales analytics at regional levels.

To address issues related to access, e-pharmacies are partnering with local medicine stores. Region-wide partnerships with brick and mortar stores is expected to begin by 2021. Some e-pharmacies are also extensively focusing on acquiring distributors and turning them around to gain supply chain efficiencies. Adopting a click and mortar model with offline stores has the potential to further reduce the delivery time to serve the acute customer segment as well.

Government regulations and strong governance can help in addressing data privacy and drug quality concerns

The e-pharmacy sector needs regulatory and policy interventions. Pharmaceutical companies have been cautious to partner with e-pharmacies even though they believe that online sales may represent 10%-12% of the medicine sales in the next five years⁵⁷.

The government has been working on providing a governance structure and regulations to address all these concerns. The government is expected to pass draft regulations on e-pharmacies in the next few months. This will create a favourable environment for e-pharmacy operations and attract funding to scale up the segment. Lack of necessary guidelines around patient data privacy and sole liability on doctors to protect their data is a major issue as per the EY survey. We expect the stakeholders to share liability with regards to patient data. Once regulations around substitution are strengthened and doctors' consent becomes mandatory, equity among the stakeholders – doctors, patients, pharmaceutical companies and e-pharmacies will improve.

We also expect the creation of digital infrastructure in the long run to streamline the operation of e-pharmacies. The following initiatives are expected to be rolled out:

- Access to prescription through Digilocker, a centralized registry
- Creation of a centralized electronic medical record (EMR)/ electronic health record (EHR)
- Digital trail of transactions with batch numbers to manage counterfeits
- Audit trail to manage abuse of prescriptions

⁵⁷ EY analysis

Future considerations and way forward



Improving access to medicines

1 Achieve drug affordability sustainably

Improve overall efficiency and sustainability of Jan Aushadhi Pariyojna

Stakeholders	Action items
Government	Tendering process for drug procurement <ul style="list-style-type: none"> ▶ Consider shifting from lowest price-based decision criteria to Most Economically Advantageous Tender (MEAT) or Multi-Criteria Decision Analysis (MCDA) approach based on several criteria, formulated on value driven characteristics, e.g., product related value-added services, quality and supply track record, investment in innovation, etc. ▶ Use framework agreements or long-term contracts. This can help the procurement body by saving on time and resources and ensuring good quality supply security. The manufacturers, in turn, are incentivized to invest in assets, specifically tailored to better serve government orders and achieve efficiencies of scale ▶ These tendering practices can also be leveraged to improve the national and state level programs for procuring medicines for public healthcare systems. In addition, joint / bulk or centralized procurement mechanisms can be considered
Government	Use technology to bridge demand and supply gaps <ul style="list-style-type: none"> ▶ Establish transparent, connected and agile networks to track end-to-end drug movement. The system should be able to track and alert about potential shortages, as well as identify excessive stocks of medicines nearing expiry ▶ Determine desirable stocks for each medicine by locations, and implement automated synchronization, prediction and scenario simulation for increasing forecast accuracy
Government	Quality assurance <ul style="list-style-type: none"> ▶ Procure medicines from reliable manufacturers based on prior track record ▶ Keep penalties for not meeting quality standards and supply commitments (e.g., timelines, quantities) ▶ Use technology, such as blockchain, to track quality of medicines and avoid any possibilities of counterfeit
Consider other options of improving affordability of essential drugs instead of only price controls	
Government	Best practices followed by other countries <ul style="list-style-type: none"> ▶ A consensus-based approach between industry and government. For example, regulation of the prices of branded prescription drugs in the UK based on voluntary agreement called 'Pharmaceutical Price Regulation Scheme' between the Association of the British Pharmaceutical Industry and the UK Department of Health ▶ Special pricing contracts/differential pricing: buy drugs from manufacturers through tendering process or at discounts/rebates for poor population or for public consumption through government schemes and allow free pricing in the market (e.g., in Australia, New Zealand) Other considerations <ul style="list-style-type: none"> ▶ Direct purchase from manufacturers: long-term contracts for large volumes (e.g., ~50% of total consumption of the drug) of top essential drugs with top manufacturers of the drug (top five manufacturers) and distribute the contracts for the remaining volume to MSMEs. This will allow the top manufacturers to invest in building capacity and achieve efficiencies of scale, while also ensuring competition from other big and mid-size manufacturers ▶ Setup government / public manufacturing capacity for some of the most critical drugs, starting from KSMEs/APIs to finished formulations

Improve access to innovative medicine

Government	<ul style="list-style-type: none"> ▶ Establish managed entry schemes, such as price-volume agreements, contract-specific or performance-based risk sharing agreements, payment for pre-agreed maximum value threshold, etc.
Government	<ul style="list-style-type: none"> ▶ Procure drug at discounted prices for government insurance schemes while allowing normal process for granting patents and free pricing in the market
Industry	<ul style="list-style-type: none"> ▶ Become partners to the government in improving affordability, especially for medicines for high prevalence diseases. Introduce innovative programs with commercially viable business model that build local, sustainable capabilities for healthcare, including education, infrastructure and drugs, for people living at the base of the pyramid

2 Improve drug accessibility in tier 2/3 cities and remote areas

Develop e-pharmacy model along with physical retail pharmacies

Government	<ul style="list-style-type: none"> ▶ Develop detailed guidelines for the working of e-pharmacies, including end-to-end operating model, ethical practices, quality assurance, patient privacy, etc.
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Note: refer to the chapter for further details and relevant examples/case studies



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