

The Indian pharmaceutical industry – the way forward



June 2019

Indian Pharmaceutical Alliance

A-205 Sangam

14B S V Road, Santacruz (W)

Mumbai 400 054

India

The Indian
pharmaceutical
industry –
the way forward

Contents

The Indian pharma industry – contributions to global health outcomes	07
Vision 2030 – defining the growth aspiration	11
Opportunities and challenges for achieving Vision 2030	15
Case studies on driving growth through government support	21
Actions needed to achieve Vision 2030	25
Conclusion	33

Acknowledgements

The IPA would like to acknowledge the CEOs of Member Companies who committed their time to provide insights on Indian pharma's journey up until now and helped generate ideas on triggering accelerated growth of the industry in new product classes and geographies.

We would like to thank Vikas Bhadoria, Jaidev S Rajpal and Vikas Siddeshwar from Mckinsey & Company for their overall guidance and contribution as our knowledge partners. We also thank Priyanka Bagai and Savil Gupta from the McKinsey team, for providing analytical support for the paper.

Finally, the IPA also acknowledges its Executive Council for their continuous support and guidance throughout this effort. None of this would have been possible without their timely involvement and commitment.

1

The Indian pharma
industry – contributions
to global health outcomes

The Indian pharma industry— contributions to global health outcomes

The Indian pharmaceutical industry is the world's third largest of drugs by volume¹. The Industry's journey to annual revenues of about USD 38 billion² today can be attributed to world-class capabilities in formulation development, the entrepreneurial ability of the firms and the vision of the industry to establish India's footprint in large international markets such as the United States.

The industry has played a key role in driving better health outcomes across the world through its affordable and high-quality generics drugs. Increased accessibility to affordable drugs has been one of the key enablers for lowering the disease burden in India. India's per person disease burden measured as Disability Adjusted Life Years (DALYs) dropped by 36 percent between 1990 and 2016 after adjusting for changes in the population age structure. The lowered disease burden was driven by a reduction in infectious and associated diseases from a 61 percent disease burden in 1990 to 33 per cent in 2016³. During the same period, drug penetration in India increased by 50 percent⁴. India has now become Polio-free⁵, as a result of strong collaboration among vaccine manufacturers, healthcare providers, the government and development organisations. The industry has also helped in bringing down the treatment costs of life-threatening diseases such as Chronic Myeloid Leukaemia and Hepatitis C, to less than five percent of the original cost⁶.

While shaping public health outcomes, the industry has contributed to India's economic growth. Estimates suggest that the industry directly and indirectly provides employment to over 2.7 million people, in high-skill areas like R&D and manufacturing⁷. The industry generates over USD 11 billion of trade surplus every year and is amongst the top five sectors contributing to the reduction of India's trade deficit⁸. The Indian pharmaceutical industry has attracted more than USD 2 billion in FDI inflows over the last three years, making it one of the top eight sectors attracting FDI⁹.

Globally, Indian pharma has contributed to improve public health outcomes. India accounts for 60 percent of global vaccine production, contributing 40 to 70 percent of the WHO demand for Diphtheria, Tetanus and Pertussis (DPT) and Bacillus Calmette–Guérin (BCG) vaccines, and 90 percent of the WHO demand for the measles vaccine¹⁰. Estimates suggest that one in every three pills consumed in the United States is produced by an Indian generics manufacturer¹¹. In the UK, approximately 25 percent of the medicines used are made in India¹². In Africa, the availability of affordable Indian drugs contributed to greater access to treatment for AIDS, with 37 percent of AIDS patients receiving treatment in 2009 compared to just two percent in 2003¹³.

1 MakeinIndia, IBEF India Pharma Outlook and Brand India

2 AIOCD, Pharmaceutical Export Promotion Council

3 ICMR, Public Health Foundation and Institute of Health Metrics and Evaluation

4 OPPI Annual Report 2013–14, Census of India

5 WHO Certifies India as Polio Free (Press Information Bureau)

6 Access to Costly New Hepatitis C Drugs: Medicine, Money, and Advocacy, Oxford Journals, Vol 61, Issue 12; Changing the cost of care for chronic myeloid leukaemia, PMC, October 2015

7 Indian life sciences: Vision 2030, FICCI June 2015, Growth estimated by IHS Markit

8 Export Import Data Bank, Department of Commerce, PHARMEXCIL, IDMA report on "Journey towards Pharma 2020 & beyond"

9 RBI Database on Indian Economy, Department of Industrial Policy & Promotion

10 Press Information Bureau; "Affordable Efficacious Medicines – All Roads Leads to India", 2013 report by IDMA; Brandindiapharma.in

11 Gx prescriptions account for 90% prescriptions, Indian companies account for 40% share of Gx prescription, IQVIA 2019

12 UK and India regulators agree deal for closer collaboration to improve public safety, Press Release, Government of UK, 5 October 2015

13 Pharmaceuticals: India's generics flow into Africa, African Businesses Magazine, 19 January 2012

The Indian pharmaceutical industry contributes significantly to public health improvement and economic growth of the country

Public health outcomes



36%

Lower per person disease burden (DALY, 1990-2016)



100%

Eradication of Polio by collaboration between all stakeholders



95%

Lower treatment costs of life-threatening diseases (Hep-C, Leukemia)

Economic outcomes



2.7mn

Jobs created directly and indirectly



USD11bn

Annual trade surplus; One of the top 5 sectors reducing trade deficit



USD2bn

FDI inflows to Pharma industry in last 3 years

2

Vision 2030 – Defining the growth aspiration

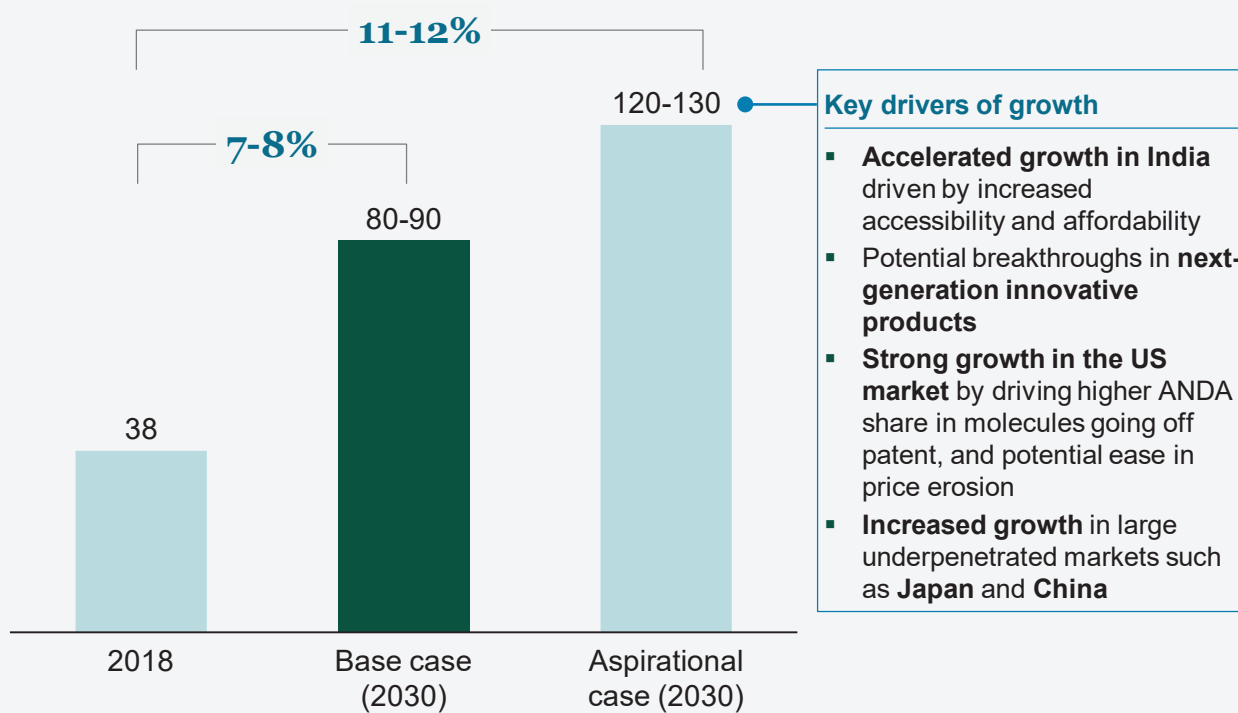
Vision 2030 – defining the growth aspiration

The Indian pharmaceutical industry is poised for growth. Even at current rates of seven to eight percent CAGR, the industry's annual revenues can grow to about USD 80 to 90 billion by 2030. However, it could also set bold aspirations of eleven to twelve percent CAGR, and grow to annual revenues of about ~USD 65 billion by 2024 and about ~USD 120 to 130 billion by 2030. This would require multiple growth cylinders to fire simultaneously, as depicted in Exhibit 2 below.

Exhibit 2

Indian pharma industry could grow to USD 120-130 billion by 2030

Projected size of the Indian pharma industry, USD billion



Source: IQVIA, AIOCD, Pharmexcil, IPA Team analysis, secondary research

Indian pharma industry can embark on a vision of establishing India's global leadership in life sciences, while driving deeper domestic access and affordability. **Industry can work towards four primary goals as part of this vision for 2030.**

-
- **Accelerate the goal of universal health care across India and the world by providing access to high-quality affordable drugs:** Keeping in line with the Government of India's vision of providing universal healthcare for India, the industry can support this goal by providing access to quality medicines at affordable prices. In India, as more and more patients come under treatment, this could help reduce the disease burden substantially. The aspiration could be to make the DALY (Disability Adjusted Life Years) in India and other emerging markets comparable to the developed economies such as the US and UK by 2030 (currently India's DALY is 72 percent higher than China's¹⁴).
 - **Emerge as an innovation leader to build a globally recognized position for India:** We believe the industry can aspire to build a strong innovation pipeline (with three to five new molecular entities launched or in late clinical trial phases and 10–12 incremental innovation launches per year by 2030) and enhance Indian pharma's significance beyond generics, to biologics, new drug development and incremental innovations.
 - **Become the world's largest and most reliable drug supplier and reach USD ~120-130 billion by 2030:** The Indian pharmaceutical industry can aspire to become the world's largest supplier of drugs by volume. This can be achieved by establishing a leadership position in the US generics space, focusing on building one to two 'home' markets outside India, and developing a strong presence in all large markets such as Japan and China.
 - **Contribute significantly to the growth of the Indian economy:** The Indian pharmaceutical industry can contribute substantially to the growth of the Indian economy. The industry can aspire to push the net foreign exchange earnings to around USD 30 billion to 40 billion annually by 2030 from current levels of ~USD 11 billion¹⁵. The industry can also create one to two million¹⁶ additional jobs for the country in the same period, boosting consumption in the local economy.

Achieving these four goals will mean Indian pharmaceutical industry can improve its global market share to ~7.0% by 2030 from current market share of 3.6%¹⁷ by value. It will also mean Indian pharmaceutical market will break into top 5 markets in the world from its current ranking of 11th market by value.

14 ICMR, PHFI, IHME Report (India: Health of the Nation's States)

15 RBI, IPA Team analysis

16 IPA Team analysis

17 IQVIA, AIOCD, Pharmexcil

3

Opportunities and challenges for achieving Vision 2030

Opportunities and challenges for achieving Vision 2030

The Indian pharmaceutical industry's success has been built on the foundations of its distinctive capabilities in key areas of the value chain, such as manufacturing, product development and process innovation. Recently, the industry has been facing headwinds both domestically, and in key global markets (like the US) which have subdued its growth to the existing CAGR of seven to eight percent¹⁸. Nonetheless, many opportunities still exist across new geographies and product classes for Indian pharmaceutical players to chart an accelerated growth path.

3.1. Opportunities

3.1.1. Supporting state-sponsored health coverage programs and a focus on chronic healthcare could enable universal drug access

The Ayushman Bharat Yojana (a centrally sponsored National Health Protection programme) is estimated to benefit 10 crore vulnerable families (about 50 crore beneficiaries or about 40 percent of India's population)¹⁹. It will provide poorer households with affordable access to healthcare facilities, while also improving health insurance penetration. This is an opportunity for the industry to help India's underserved masses with affordable drugs.

Additionally, with the disease burden in India now transitioning towards chronic diseases, there is an increased demand for specialised drugs which are currently more expensive than acute drugs²⁰. The industry is well placed to address this need through affordable, high quality drugs for chronic diseases.

3.1.2. Pursuing opportunities in newer product classes such as biosimilars, gene therapy and specialty drugs

Until now, the Indian pharmaceutical industry's success has largely been due to production of generics drugs. While the industry was one of the first to initiate biosimilar development and launch in the Indian market (e.g., the first biosimilar to Rituximab, Reditux, was launched by India's Dr. Reddy's in 2007²¹), successes in the developments at scale of next-generation product classes such as gene therapy and specialty drugs have been limited. The enabling environment on supporting development, i.e. Department of biotechnology and regulatory could have played a more facilitating role but are possibly constrained.

Spurring innovation in these product classes can usher-in the next leg of growth for Indian pharma industry. For example, the biosimilars market could exceed USD 60 billion by 2030²². If Indian Pharma industry is able to capture even 10 percent of this market, it could grow by 13 percent. Pharmaceutical companies however, will have to take a long-term view, about 8 to 10 years, to capture these opportunities, since investments in these technologies have high gestation periods. It may also need conducive investment environment in the domestic market to be able to do so.

18 AIOCD, Pharmaceutical Export Promotion Council

19 Ayushman Bharat Initiative, Press Information Bureau

20 ICMR, Public Health Foundation and Institute of Health Metrics and Evaluation, Patel V, Chatterji S, Chisholm D, Ebrahim S, Gopalakrishna G, Mathers C, et al. Chronic diseases and injuries in India. Lancet. 2011

21 mAbs journal extract, National Center for Biotechnology Information

22 Biologics Market: Where Are We Now? Where Are We Going? Accessed on 10th May'19 at <http://fplreflib.findlay.co.uk/images/pdf/bioproduction/Rakesh-Dixit-MedImmune.pdf>

3.1.3. Capitalizing on its rich demographic dividend – India has a large skilled, yet cost-efficient workforce

Over 2,25,000²³ pharmacy students graduate from India's education system (compared to just about 17,000²⁴ pharmacy students graduating in the US). The workforce includes highly-skilled medical practitioners and specialists who bring significant expertise and actively contribute to clinical research. This is boosted by an astute and highly-skilled team of people working in the field of clinical research across the industry and academia. Moreover, availability of a diverse patient pool makes India as one of the most potential destinations for clinical research. Additionally, labour cost efficiencies provide a significant competitive advantage to the Indian companies. Their manpower costs are about 33 percent lower than their western counterparts', on average²⁵. This advantage of skilled labour supply is expected to continue.

3.1.4. Leveraging the patent cliff, with drug sales worth USD 251 billion going off-patent

Patents for branded molecules with cumulative global sales of over USD 251 billion are expected to expire between 2018 and 2024²⁶ (Exhibit 3), opening new opportunities for the industry. The Indian generics industry can benefit substantially from the patent cliff, given an increased Abbreviated New Drug Application (ANDA) share (from 26 percent in 2011 to 38 percent in 2017) and faster time-to-market²⁷. The industry may need to formulate a sharp molecule-level strategy, coupled with superior regulatory and in-market execution excellence.

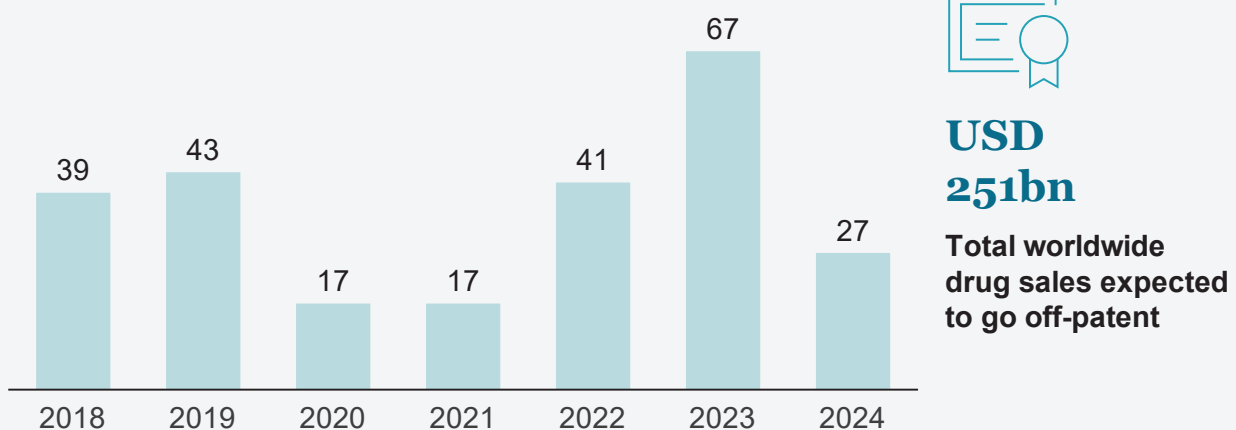
Exhibit 3

Worldwide patent expiration for drug sales worth about USD 251 billion (2018–2024) presents opportunities in the generics market

USD billion

Patent analysis

“Total Sales at Risk” represents the worldwide product sales in the year prior to patent expiry but allocated to the year of expiry



Source: EvaluatePharma, May 2018

²³ All India Survey on Higher Education 2017-18

²⁴ American Association of College Pharmacy

²⁵ POBOS is a leading pharma benchmark covering over 800 plants and 70% of global pharma production, retrieved in 2019

²⁶ 'World Preview 2018, Outlook to 2024' by EvaluatePharma (Accessed from: <http://info.evaluategroup.com/rs/607-YGS-364/images/EvaluatePharma-World-Preview-2018-Executive-Summary.pdf>)

²⁷ IQVIA, US generics market-evolution of Indian player Feb 2019

3.1.5. A footprint in underpenetrated international markets could increase exports

As the industry aspires to become the world's largest supplier by volume, the next wave of growth could come from increasing exports to large and traditionally underpenetrated markets such as Japan, China, Africa, Indonesia and Latin America. For example, the Japanese pharma market was worth over USD 85 billion in 2018, with Indian pharmaceutical companies having a share of less than one percent²⁸.

Penetration in these markets may require a new business model (e.g., partnerships with local manufacturers, distributors, etc.) to adapt to local market requirements. Government interventions and trade-relations support will help in enabling market access for Indian pharmaceutical companies in these markets.

3.1.6. Leverage India's strengths in IT and ITES – optimize new avenues such as OTC

OTC policy or consumerization is a big opportunity for the domestic market as it can help maximize scale and reach. It has the potential to overcome the shortage of doctors in India by enabling and empowering patients and chemists to take care of commonly occurring ailments.

3.2. Challenges

There are seven key challenges impacting the Indian pharmaceutical industry today.

3.2.1. India is yet to achieve universal healthcare access

Access to healthcare in India is inadequate in comparison to the size of the population. About 29 skilled health workers are available for every 10,000 people in India compared to about 41 in China, and about 111 in the United States²⁹. While India meets WHO's critical threshold of about 23 skilled professionals for every 10,000 people³⁰, it would need to add 1.5 million healthcare professionals (as compared to China), a 42 percent increase to meet the needs of population. This is extremely critical for a 'healthy' India and a thriving healthcare ecosystem.

The inability to pay for healthcare bills is another challenge that Indians face. Indian government's expenditure on healthcare is low (about 1 percent of GDP) compared to 2.5 to 3 percent of GDP of other developing economies such as China, Malaysia and Thailand³¹. With less than a third of Indians having health insurance³², the rest of the population pays medical bills from their own pockets. As a result, they must make tough trade-offs between their healthcare needs, and other necessities. Such challenges need innovative digital interventions to mitigate accessibility shortcomings at optimal costs.

3.2.2. Lack of a stable pricing and policy environment favourable for long-term investment decisions

Frequent and unexpected changes to the domestic pricing policy have created an uncertain environment for investments and innovation. The government and stakeholders would need to constructively engage to develop a framework that ensures availability and accessibility of affordable drugs for citizens, while ensuring a workable pricing structure for pharmaceutical companies.

28 Predictions and areas to watch in global Pharma market head, 2019-23, IQVIA, PHARMEXCIL

29 WHO Global Health Data Repository (2016). Skilled health workers include doctors, nurses and midwives

30 WHO Millennium Development Goals

31 WHO Global Health Observatory data repository, Domestic general government health expenditure (GGHE-D) as percentage of gross domestic product (GDP) (%): China: 3.2%, Thailand: 2.9%, Malaysia: 2.1%

32 National Health Profile Data, April 2019

3.2.3. Lack of capabilities in the innovation space

Indian pharmaceutical companies have been slow to grow in the innovation space (e.g., new molecular entities, complex generics), with a limited government-supported research ecosystem. For example, government policies such as reversing the weighted deduction of erstwhile 200% on spend on R&D, which ends in 2021 has an adverse impact on innovation. A talent pool with advanced skills is limited in India with only 2,000 PhD students enrolled in Pharmacy institutes³³ (compared to over 15,000 PhD students enrolled in the United States³⁴). There is also a gap between the college curriculum and industry's requirements. However, this is part of Life Sciences Sector Skill Development Council's (LSSSSDC) agenda, along with the introduction of apprenticeship.

There is scope to improve collaboration between Government institutes and industry on innovation-focused research initiatives. Pharmaceutical companies often face challenges in securing the participation of government institutes in clinical trials³⁵. Clinical trial approvals in India are subject to stringent regulatory norms. For example, for the placebo arms to be allowed in clinical trials, company sponsors and CROs must comply with multiple DCGI regulations and queries, which make the approval process complex and time-consuming³⁶. Similarly, Biosimilars that are emerging as significant opportunity face cumbersome regulations. There is also a need for removing subjectivity in decisions taken by subject matter experts part of various committees to ensure a predictable and consistent outcome.

3.2.4. Dependence on external markets for intermediates and APIs

Around 80 percent³⁷ of India's requirements for Active Pharmaceutical Ingredients, by volume, are fulfilled by China, putting importers at the risk of supply disruptions and unexpected price movements (e.g., a policy shift by the Chinese government had resulted in a price increase of up to 50 percent for a few molecules³⁸). India has been unable to seize the API opportunity due to inadequate infrastructural facilities like the uninterrupted supply of water and electricity and the lack of scale in 'Special Economic Zones, and limited governmental support in the form of tax incentives, favourable license renewals and capital subsidies. The Katoch Committee recommendations were announced in February, 2015 but little progress has been made towards their implementation³⁹.

3.2.5. Indian pharma's eroding competitive advantage in the US generics market and limited presence in other markets and products

Generics exports, specifically to the US, were a key driver of double-digit growth for top Indian pharmaceutical companies over the last few years. However, growth in the US market is moderating, in part by price erosion – generics prices declined by about eight percent annually between 2015 and 2018⁴⁰. The two main reasons for this price erosion were increased buyer consolidation (from 80 percent of the sales by five to six buyers in 2013, to only three buyers in 2018⁴¹) and higher competition in key molecules. This poses a higher risk to Indian pharma, as the US accounts for a third of the total exports⁴².

33 All India Survey on Higher Education (2018)

34 American Association of Colleges of Pharmacy

35 Expert interviews with Indian pharmaceutical company

36 Perspectives on clinical research, ISCR (Mar 17), PMC5299798

37 "Enhancing Indian exports of pharmaceutical products to China", 2018, PHARMEXCIL

38 Impact of Chinese Goods on Indian Industry: 145th Parliamentary Standing Committee Report

39 Press search, Industry interviews

40 Average SKU Pharmacy Acquisition Price, Source: NADAC Survey, Symphony Health PHAST

41 US Generics Market-Evolution of Indian Player, IQVIA

42 Pharmaceutical Export Promotion Council

The limited presence in key markets like China and Japan continues to be a challenge. Attempts at making inroads into these countries have not gained the desired traction and size as yet due to various regulatory hurdles. Similarly, despite investments by some companies in newer product classes such as biosimilars and specialty drugs, the contribution of non-generics products to the current revenue of pharma companies is miniscule (only 1–1.5 percent of revenues for the top 10 Indian pharma companies originated from biosimilars in 2018⁴³).

3.2.6. Increased scrutiny in quality compliance when supplying to international markets

As the industry expands in different geographies and concerns on the quality of imported drugs increase globally, there will be greater scrutiny from regulators on quality norms. India has faced the highest number of USFDA inspections since 2009 (in 2016, there were 840 FDA inspections in India followed by 593 in China⁴⁴). The industry will need to continuously invest in upgrading quality standards to keep its promise of a 'high quality reliable' supplier of medicines to the world.

⁴³ Investor disclosures of top listed Indian pharma companies

⁴⁴ Accelerating Exports of Pharmaceuticals, IPA Report (2017)

4

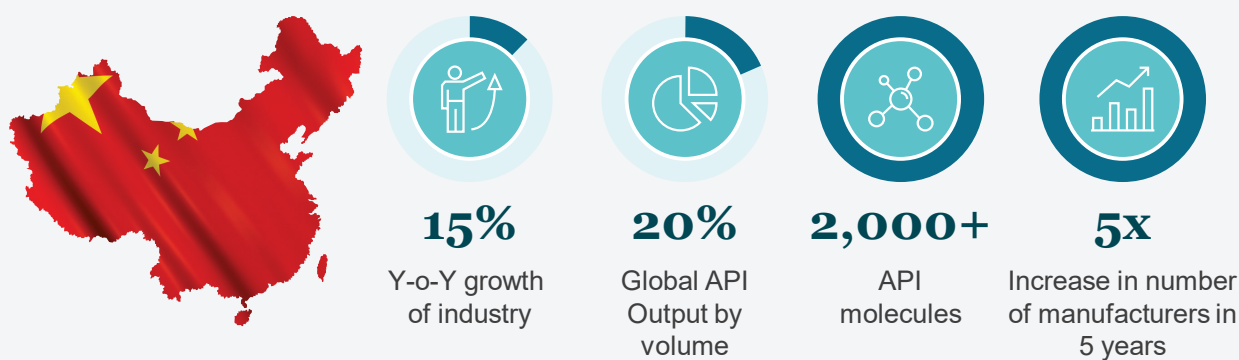
Case studies on driving growth through government support

Case studies on driving growth through government support

Government support in building the start-up infrastructure, resource investment and other policy regulations can be critical in determining the pace of an industry faced with high competition and deteriorating growth. For example, the Chinese government's interventions at the infrastructural and policy levels helped the API industry grow at 14.7 percent to about USD 70 billion (in 2016) vis-à-vis a moderate five to seven percent CAGR for the global API market. The export of APIs has reached USD 29.1 billion, growing by 13.7 percent year-on-year⁴⁵. Exhibit 4 shows how specific government interventions helped create a thriving API industry in China.

Exhibit 4

Chinese Government's initiatives to drive API growth



Lower set-up and production costs

15–20%

lower costs than in India



- **Lower capex requirements due to large Special Economic Zones** (10–15x the size of Indian SEZs) in accessible and resource-rich areas (subsidized land, common waste processing and utilities, flexible labour laws)
- **Lower borrowing costs:** 5–7% vs. 11–14% in India
- **Lower logistics costs:** 1% of total costs in China vs. 3% for India, owing to predictable inland transportation and well-developed transport infrastructure
- **Lower conversion costs** as labour and electricity costs in China are relatively cheaper (average ~11 US cents/kwh vs. 19 US cents/kwh in India)

Supportive research and development ecosystem

USD1.6 bn



Invested by the government for new drug development



- **Creation of a research ecosystem:** Government-focused efforts on attracting China-born scientists through the “Thousand Talents Plan”, attracted over 50,000 PhDs through generous funding support (up to USD 75,000/year). The returning talent helps support major alliances between multinational biotechnology firms and Chinese universities, cancer research partnerships and company-to-company deals e.g., BICI

The Chinese Government has also kick started a new wave of regulatory and policy level interventions to foster innovation locally. These include changes in approval process, rationalizing clinical trial data, creating guidelines for digital healthcare among others. Exhibit 5 details some of these changes and their corresponding impact.




Chinese Government's effort to foster innovation ecosystem have started delivering significant tangible results

	Policy initiative	Lever	Impact
	Slew of regulatory reforms by Chinese Food and Drug Authority (CFDA) since 2015	<p>Rationalizing clinical trial data requirement - accepting IMCT (International Multicenter Clinical Trial) data for NDA</p> <p>New approval mechanism implemented to reduce decrease in approval time for Clinical Trial Approval (CTA)</p> <p>CFDA joins ICH in 2017</p>	<p>~64% decrease</p> <p>In approval timeline – Small molecules CTA timeline has reduced to 9 months (in 2018) from 25 months (in 2015) and large molecules to 8 months (in 2018) from 22 months (in 2015)</p> <p>~70% increase</p> <p>In filings of local innovative assets by Chinese firms - ~20 NDAs filed in 2018 vs 4 in 2015 (small molecules and large molecules)</p>
	Range of policies and implementation guidelines to support and regulate digital/analytics disruption in healthcare	<p>NHC detailed the management of online consultation, internet hospital and telemedicine in Sep'2018</p> <p>State council published new guideline on "Internet plus healthcare" to establish comprehensive healthcare system empowered by internet</p>	<p>~40% physicians</p> <p>Have used virtual consultation to deliver healthcare services.</p> <p>~1.5 Mn physicians are active daily on top 3 online platform</p>

Source: GBI, CFDA, Press search, IPA team analysis

Even in India, there are several examples of carefully crafted and well-managed support to new and growing industries by government and industry associations. Exhibits 6 discusses examples from the Auto, IT and Textile industries where support of the Indian government and industry associations have helped drive growth. A similar vision and a set of interventions are now needed for the Indian pharmaceutical industry.

Government and industry associations support in accessibility, infrastructure and resources has helped drive growth in Auto, Textile and IT industries

	Policy initiative	Lever	Impact
	FAME I and II (Faster Adoption) and Manufacturing of (Hybrid) and Electric Vehicles in India	Demand generation and Accessibility: State-led demand aggregation by including EVs in the public transportation system of 11 states (busses), enhanced adoption of EVs through affordability (price reduction to purchasers) and accessibility (investment in charging infrastructure)	2,61,507 vehicles covered under FAME in 2018; increased from 5,197 (2015)
	Technology Upgradation Fund Scheme for the Textile Industry	Facilitate technology upgradation through credit-linked capital investment subsidy to make the textile industry globally competitive, and to reduce capital costs for the textile industry	INR 5,226 crore Investments made under the scheme with expected employment generation of 45,659
	Online Skilling Platform, Future skills by NASSCOM	Upskilling college graduates and industry personnel in emerging technologies such as internet of things (IoT), robotic process automation (RPA), virtual reality, big data analytics, cloud computing and 3D printing	~2 Lakh members upskilled until Oct 2018 (3 months). Potential to train 20L, NASSCOM in discussion with MeitY to co-fund the skilling service platform and open up for general use (B2C)

Source: NASSCOM Report (Catalyzing the Ecosystem for A Trillion Dollar Digital Economy). FAME-India Scheme (PIB), Implementation of Amended Technology Upgradation Fund Scheme (PIB), IBPS Website (MeitY)

Incorporating learning from such examples by the Indian Government and drug authorities towards pharmaceutical industry will go a long way in creating an ecosystem of change, innovation and growth. The next section provides perspective on potential actions the stakeholders of Indian pharmaceutical industry can undertake to set in motion the next phase of growth.

5

Actions needed to achieve Vision 2030

Actions needed to achieve Vision 2030

Concerted efforts and stronger collaborations between all stakeholders – Indian pharma companies, government and regulatory agencies, and the IPA – can accelerate growth.

Indian pharmaceutical companies need to take bold strategic moves into uncharted territories (like making big bets on markets like China, Japan or developing technology platforms like biosimilars, and next-gen APIs like ionic liquids). At the same time, they need to protect their core through the extensive adoption of new-age digital and advanced analytics techniques to drive newer efficiencies across front-end and back-end operations.

Capability building, especially on the quality front, with regular and deeper engagement with regulators like the US FDA and other drug authorities, can build trust with regulators. More and more frequent dialogue between industry and the Indian regulators on key areas of concern, will be helpful in arriving at joint recommendations on policies that will help industry to grow further.

The Indian government and its regulatory bodies have a bigger-than-ever role to play in driving the next wave of growth for the pharmaceutical industry. Enabling policies and a supportive ecosystem would help the industry achieve Vision 2030. The government has already launched some initiatives that could strengthen the industry:

- **Increased budgetary allocations for healthcare to boost the domestic market:** Budgetary allocations for the Union Ministry of Health and Family Welfare grew by 18.6 percent over five years (total health budget allocated to the Ministry for FY 2016 to 2020)⁴⁶. **The Ayushman Bharat Yojana** launched in September 2018 aimed at providing affordable healthcare to over 50 crore beneficiaries (about 40 percent of India's population)⁴⁷.
- **Increased focus on attracting pharma investment:** Governments in states such as Andhra Pradesh and Uttar Pradesh have announced their intentions of setting up pharma parks⁴⁸. This is a welcome move and is expected to provide a competitive advantage to Indian pharmaceutical companies in the global arena.

There are seven other key areas where targeted initiatives by the government could help facilitate higher growth for the industry:

5.1. Accelerate universal healthcare access by strengthening the healthcare infrastructure and using digital technologies

The government could consider taking initiatives along two axes – creating primary healthcare infrastructure and making healthcare facilities affordable to the public.

- **Provide infrastructural and investment support:** Investments are needed to bring India's doctor-patient ratio in line with WHO's global benchmark⁴⁹. To increase supply of doctors, the government could consider upgrading district hospitals into medical colleges. Further, the use of digital/remote consultation facilities can ensure increased utilization of these doctors. The 2019 Digital India Report by the McKinsey Global Institute (MGI) identified telemedicine and evidence-based consultation as mitigating solutions to improve the access and quality of professional medical consultation for the rural population⁵⁰. However, penetration levels are still low. Today, less than 10 percent of India's more than 26,000 Primary Healthcare Centres have telemedicine facilities⁵¹.

46 Press search: <https://www.livemint.com/budget/news/health-budget-focuses-only-on-ayushman-bharat-other-schemes-ignored-1549049697730.html>, <https://www.indiabudget.gov.in/previousub.asp>

47 Ayushman Bharat Initiative, Press Information Bureau

48 Department of Industries, Government of AP, NiveshMitra UP

49 India has 0.8 physicians per 1000 persons as against WHO recommended 1.0 per 1000, Global health workforce statistics, World Health Organization, 2016

50 MGI Digital India Report (2019)

51 Press search

Public-Private Partnerships may be leveraged to expand telemedicine facilities. For example, the ‘Telemedicine network’, a PPP between the Government of Andhra Pradesh and Apollo Hospitals, has facilitated about 19 lakh consultations in one and a half years, with over 1.2 lakh specialist tele-consultations⁵².

In China, medical technology has witnessed steady success. Ping An Good Doctor placed ‘one-minute clinics’ across eight provinces and cities in China, providing healthcare services to more than three million users. Such unstaffed clinics employ AI to provide remote consultations for over 2000 diseases. Each clinic has more than 100 categories of common drugs available. If unavailable, users can purchase them online through the Ping An Good Doctor App and receive drug delivery in one hour, provided by nearby cooperative pharmacies⁵³. Such a model could be useful for India where the doctor-patient coverage is even lower.

Further, Electronic Health Records (EHR) and the digital management of chronic diseases can help to create a steady demand for related medicines. Such low-cost digital innovations, which also ensure replicability, would require infrastructure and capability support from the government for large-scale adoption.

In addition to the above initiatives, the government could aim to increase expenditure on healthcare from about 1.2 percent to 2.5 percent of GDP in the next 5 years, and about 5 percent by 2030, in line with the developed European and North American economies⁵⁴.

- **Empower citizens to bear the costs of medical care** by expediting the implementation of universal health coverage. Ayushman Bharat can bring 40 percent of the marginalized population under state-funded insurance cover⁵⁵. All intended beneficiaries can be adequately covered by ensuring implementation across hospitals. Improving access to healthcare will broaden possibilities to all healthcare ecosystem players including pharmaceutical companies.

5.2. Create a stable and supportive regulatory environment for the industry

Two areas where regulatory interventions can aid the growth of the industry are:

- **Reducing the uncertainty around pricing:** A coherent pricing policy framework that is aligned with all relevant stakeholders of the industry can reduce pricing uncertainties. Reducing the frequency of policy revisions and agreeing upon their periodicity can help resolve confusion and revive the trust of pharmaceutical companies towards the government. For example, for regulatory affairs such as labelling, the pre-determined interval could be set as six months to one year. It may help to set up a periodic review policy, mandating continuous engagement with all relevant stakeholders.
- **Simplifying the regulatory approval processes:** In emerging areas such as biosimilars where R&D investments are 10–20 times higher than for generic products, regulatory approvals can cause inordinate delays and cost overruns. Initiatives like reducing the number of agencies involved or stipulating a maximum time-limit for approvals (currently over two to three years) and simplifying the required documentation and modes of submission, can facilitate growth.

52 Potential for telemedicine in India

53 Ping-good-doctor-launches-commercial-operation-one-minute-clinics-china

54 WHO Global Health Observatory data repository, Domestic general government health expenditure (GGHE-D) as percentage of gross domestic product (GDP) (%)

55 Ayushman Bharat Initiative, Press Information Bureau

5.3. Explore the creation of an independent Ministry for Pharmaceuticals

To protect and promote the industry's interest, the government could set up a dedicated Union Ministry of Pharmaceuticals. With an independent secretariat, the ministry may be able to simplify policy making and expedite investment approvals. Such a ministry can be modelled on the lines of the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy known as AYUSH (created in 2014), or the Ministry of New and Renewable Energy which aims of upgrading quality standards, strengthening research and promoting the renewable energy sector. The current set of regulators in the pharmaceuticals sector (CDSCO and NPPA) could be brought under the aegis of the new ministry for better coordination and quicker decision making. However, the ministry will need to be established with a well-defined mandate/charter of goals to develop and promote the pharmaceutical sector and be adequately empowered to make a tangible difference.

5.4. Focus on API manufacturing to reduce the reliance on imports

The government could provide plug-and-play infrastructural support in dedicated zones for manufacturing APIs, in line with the Chinese SEZ model by:

- a. Constructing large dedicated zones and leasing them to private players for operating manufacturing plants. Geographically, such SEZs could ideally be situated next to ports (for easy global trade) and away from densely populated areas
- b. Extending pre-approval of environmental clearance and easing other regulatory clearances (like simplifying the license renewal process)
- c. Setting up common utilities such as solvent recovery and distillation plants, power and steam units, effluent treatment plants, warehousing, etc., to make smaller units economically viable in these zones
- d. Adopting innovative models for land acquisition and commercialization to minimize upfront capex investments for the industry. For example, leasing out land to the industry by charging minimal upfront costs followed by annual rent to recover land costs
- e. Lowering costs of borrowing to set up a plant in these API hubs/SEZs through tie-ups with multilateral financing agencies (e.g., IFC)
- f. Enabling existing production facilities to grow at-scale and develop capabilities to manufacture complex molecules, by facilitating collaborations with CSIR labs and universities to improve process technologies (e.g., yield improvement)

Many of these suggestions have also been voiced by independent government committees such as the Katoch committee⁵⁶.

⁵⁶ Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, File No. 35022/10/2015-PI-III/PI-II(Pt)

The government can look at import substitution in more detail and come up with policies which may encourage API production in India. For example, the government can setup a task force/working group aimed at boosting the domestic manufacturing of the top 50 to 70 import APIs. The task force can collaborate with government research agencies to identify the feasibility, complexity and process technology required to manufacture these APIs in India at prices comparable to importing. This study can be then be made available to the industry to act upon. At a policy level, this can be coupled with designing and implementing a clear anti-dumping policy to protect the domestic players against price wars that might follow to ensure a stable demand scenario.

5.5. Promote innovation by creating a research ecosystem, and make India a life sciences innovation hub

Our analysis across countries and industries suggest that fostering an innovation ecosystem or hub will require interventions across three dimensions.

■ Targeted regulatory and tax interventions by the government

Globally, government support through competitive tax breaks on R&D investments, capital gains, technology transfers, etc. as well as regulatory interventions/simplification have spurred innovation hubs. For example, reducing GST for all drugs to a uniform five percent and not just limited to life saving drugs can help reduce the cost of drugs.

Implementing differential tax rates for innovative companies could help them attract more investments. For example, 'Patent box' as a regulation allows concessional tax rates for incomes from intellectual property. India introduced patent box in 2016, whereby royalty incomes from patents developed and registered in India are taxed at a concessional 10 percent (plus applicable surcharges)⁵⁷. However, investments could be made more lucrative by either decreasing the concessional tax rate further (e.g., In Ireland, Knowledge Development Box levies a corporate tax rate of 6.25 percent on qualifying R&D profits⁵⁸), or by expanding the qualifying income to include incomes from the patented products, products incorporating the patented invention, as well as incomes from the sale of patented rights, as in the UK Patent Box⁵⁹.

Similarly, to encourage private sector R&D investments, the government could consider going back to 200 percent tax breaks for 'R&D investments' that require larger investments and longer time resource commitments by private companies (e.g., new molecular entities and biosimilars development). Rewarding incremental innovation, both on drugs and packaging of devices can also be a favourable initiative.

■ Support streamlined norms for clinical trials

Clinical trials are an important component of innovation and the government has been trying to streamline the norms and rules. The new Drugs and Clinical Trials Rules, 2019 is a step in this direction. Initiatives such as waiving off local clinical trials for the drugs approved and marketed in the European Union, the UK, Australia, Canada, Japan and the US and, setting timelines for disposal of application (thirty days for clinical trials in India and ninety days for drugs developed outside India) are aimed at promoting clinical research in the country⁶⁰. However, there is still scope for further simplification. The process timelines may shorten if the regulatory body codifies the most appropriate methodology for developing drugs and presenting the evidence needed to support the approval.

57 The Finance Bill 2016, Union Budget (India)

58 Irish Tax and Customs website

59 Government of UK website

60 [New Drugs and Clinical Trials Rules 2019 G.S.R. 227\(E\), CDSCO Gazette notifications](#)

For example, the Office of Generic Drugs (FDA) publishes Product-Specific Guidances for Generic Drug Development to share the FDA's current thinking, and requirements for generic drug development in specific therapy areas⁶¹.

The industry may also benefit from a simplified approval process, by dissociating protocol approvals from other design requirements (such as investigator(s) consent, ethics committee registrations and centre selection). Increased transparency in clinical trial compensations awarded by the DCGI might help reduce the stigma among sponsors and CROs for conducting clinical drug trials in India.

- **Support health-tech start-ups and create an investor-friendly environment for PE/VC players**

A stable business environment with streamlined regulations is critical to attract foreign capital. While the Government has moved significantly on this dimension (our Ease of Doing Business ranking improved from Rank 100 in 2017 to Rank 77 in 2018⁶²), start-ups could benefit from policy improvements in registration (e.g., single-window clearances), and access to low-cost financing (through well-defined bankruptcy norms). Revisiting the capital gains tax for specific 'life sciences' investments, in line with the overall vision for the pharmaceutical sector, can increase PE/VC interest and investments in the industry.

The government could complement the private sector's efforts by boosting its share in R&D investments from 25 percent to 35 percent⁶³. This could be done by creating and allocating larger funds for investments in life sciences R&D projects and start-ups. Co-funding research projects is common in developing countries (e.g., about USD 12 billion allocated to drug development between 2010 to 2015 in China by the Ministry of Health and Ministry of Science and Technology⁶⁴). Even in India, such funds have been planned by the Department of Pharmaceuticals to upgrade existing units and incentivize biotechnology entrepreneurship. For example, the Biotechnology Ignition Grant Scheme (BIG) provides assistance of up to USD 5 million to biotech start-ups to establish and validate proofs-of-concept and to enable the creation of spin-offs^{65,66}. The industry expects similar and larger funds to be created across all innovations in the pharmaceutical industry.

- **Creating anchor educational institutions known for cutting-edge research**

All innovation hubs across the world have a strong academic foundation that initiates research, provides talent to the industry and collaborates on key strategic initiatives with long-term impact. A well-funded research institute with the ability to attract global talent is critical to kickstart the cycle of innovation. Setting up the Indian School of Business (ISB) is an example of how getting all key stakeholders together can help create a thriving world-class institute.

In the near-term, the government can accelerate greater collaboration in the innovation programs of existing academic and research institutes by including such contributions in the institution's mandate. Within each such institute, a structured department that acts as a single point window for the industry can be created to coordinate with special groups within the institute (such as surgeons and gynaecologists) for specific clinical trials. Additional incentives to the participating investigators or doctors could help increase participation.

61 OGD Product-Specific Guidances for Generic Drug Development

62 Press Information Bureau- India at 77 Rank in World Bank's Doing Business Report

63 Impact of Chinese Goods on Indian Industry: 145th Parliamentary Standing Committee Report

64 China Global Investment tracker

65 Government vision Pharma 2020

66 Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) (compliance to WHO/ international GMPs)

Earmarking research grants for pharmaceutical developments and increasing the number of pharma-focussed educators can help renew the focus on new discoveries in this sector. Clinical research - related subjects can also be included in the existing curriculum to increase the practical awareness of medical students.

The Government of India can learn from multiple global examples in life sciences. For example, the San Francisco Bay Area, a leader in Biotech, has three esteemed universities - UCSF, Stanford, and Berkeley, integrated with the industry⁶⁷. Boston has seven of the world's top 100 life sciences institutions including Harvard, MIT and the Massachusetts General Hospital⁶⁸.

5.6. Expand and upskill the talent pool

As the industry's product portfolio shifts towards more complex products, the demand for operations and highly skilled personnel for the manufacture of these products will also increase. There is a limited supply of experienced talent for such operations. The government can intervene by helping set up and operationalize industry-wide 'at scale' capability building programs to create a skilled talent pool that can be readily absorbed into the workforce. For example, the Government of Goa has collaborated with Cipla to launch the Cipla Technical Academy. Students with a background in science (undergraduates or graduates holding B.Sc., M.Sc. and B. Pharm degrees or diplomas) undergo a six-month training at the academy, followed by an onsite training. On completion, Cipla may assess to absorb the candidates into their workforce, else The Labour & Employment Department would assist participants to get suitable placements in other organisations⁶⁹.

5.7. Expand and consolidate global footprint and collaborate with international regulatory bodies

Growing and expanding in newer geographies beyond US, such as, China, Japan will be critical for Indian pharmaceutical industry to achieve its vision 2030. Government has a critical role to play in helping the pharmaceutical companies in making this move. This will require deeper relationship with respective Governments to create a favourable policy and regulatory environment. The regulatory authorities in India will have to foster deeper relationships with their international peers.

- **Strengthen the exchange of regulatory best-practices** with global peers by becoming an observer at the Pharmaceutical Inspection Convention (PIC), participate in ICH and closely collaborate with regulatory agencies of countries with large markets (e.g., cooperating with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) to set up its office in India)⁷⁰. This could improve the quality perception of Indian drugs and help expedite approvals.
- **Work closely with the US FDA and other international regulatory bodies** along with the IPA to help communicate key issues faced by Indian pharma companies and drive the required regulatory changes. The government could work with pharmaceutical bodies to understand the latest happenings across the globe for patient benefit. This is with the intention of modernizing the regulatory ecosystem – e.g., Pathways for comb packs, FDCs etc.
- **Communicate the contributions of Indian generics** to the global healthcare industry and regulators. The Indian government and the IPA can jointly work with local medical thought leaders to publicize and promote the contributions made by the Indian pharma industry on shaping public health outcomes. They could also communicate the quality advantages and regulatory adherence of Indian drugs compared to generics from other countries.

67 California Biomedical Industry report (PWC); California Life sciences Action Plan: Taking Action for Tomorrow

68 Super Cluster vol II (PWC)

69 Rohan Khaunte's website: Revenue, IT, Labour & Employment Minister and the VC of IPB, Govt of Goa

70 Accelerating Exports of Pharmaceuticals, IPA Report (2017)

6

Conclusion

Conclusion

The Indian pharmaceutical industry has established a strong presence in the global generics market by delivering high-quality drugs at scale. The industry has made innovations in processes and formulations and developed itself as a reliable, high quality and cost-effective global drug supplier. By making essential drugs affordable and accessible, the industry has captured a leading share in developed economies such as the United States (1 of every 3 pills⁷¹) and the United Kingdom (25 percent of medicines consumed⁷²).

Today, the industry is worth over USD 38 billion and can aspire to grow to USD 120 to 130 billion by 2030 by capitalizing on the tremendous opportunities that lie ahead. However concerted efforts by all stakeholders – Indian pharmaceutical companies, the government and regulatory agencies, and IPA – are needed to achieve the aspiration of eleven to twelve percent CAGR. Indian pharmaceutical companies need to take bold strategic moves into uncharted geographies, products and technologies to reclaim its position as a world-class provider of affordable high-quality drugs. Government support in the form of investments, policy support and regulatory interventions is integral to drive this innovation-led growth. IPA can help accelerate the impact by facilitating greater collaboration between the two.

The government can be a key enabler to achieve this aspiration through seven strategic interventions:

- Accelerate the universal healthcare programme by strengthening healthcare infrastructure and using digital technologies
- Create a stable and supportive regulatory environment for the industry to plan investments
- Explore the creation of an independent ministry for pharmaceuticals to drive focussed policy-making
- Facilitate API production in India by setting up API parks, hubs and SEZs to reduce the reliance on imports
- Promote innovation by creating a research ecosystem, and make India a life sciences innovation hub
- Expand and upskill the talent pool to handle complex technologies
- Expand and consolidate global footprint and collaborate with international regulatory bodies along with the IPA to shape international policies, guidelines and regulations.

We at IPA are committed to catapulting the industry on to a high-growth path and achieve Vision 2030.

⁷¹ Gx prescriptions account for 90% prescriptions, Indian companies account for 40% share of Gx prescription, IQVIA 2019
⁷² UK and India regulators agree deal for closer collaboration to improve public safety, Press Release, Government of UK, 5 October 2015

