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 as 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.

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.

Indian pharma industry can embark on a vision of establishing India’s global leadership in life sciences, while driving deeper domestic access and affordability.

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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.

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.

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-focussed 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.

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.

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.

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).

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.

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.

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.

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.

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:

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.

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:

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

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.

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.

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

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.

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.

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 expediate 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.

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

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

Extending pre-approval of environmental clearance and easing other regulatory clearances (like simplifying the license renewal process)

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

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

Lowering costs of borrowing to set up a plant in these API hubs/SEZs through tie-ups with multilateral financing agencies (e.g., IFC)

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.

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.

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

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.

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.

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.

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., singlewindow 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-offs65,66. The industry expects similar and larger funds to be created across all innovations in the pharmaceutical industry.

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.

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.

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.

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.

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.