Indian Pharmaceutical Industry

Yesterday ,Today and tomorrow

Sep 11, 2021

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Agenda


Indian Economy and Healthcare


Indian pharmaceutical industry-Facts


Export Markets


SWOT Analysis


Aspirations 2030


Future outlook


Ambition India

Indian Economy & Healthcare Scenario

Economy to reach USD 5 Trillion by 2025 with estimated GDP growth of ~7.8%

Increasing Affordability

- Per capita income to rise 125% from USD 1700 to USD 3650
- Middle class and affluent households to increase by 40 million & 25 million respectively by 2025
- Share of wallet on healthcare to increase from 9% to 13% within a decade
- Small but increasing healthcare insurance (To cross 4% in FY 21)

Improving Medical Infrastructure

- Government - Improving healthcare infrastructure in Tier II cities & Rural areas
- Govt. aided stores to increase access to medicines
- Corporate & Private: increasing hospital beds in Metros & Tier I cities
- Plans to fasten the digitization process in healthcare

Healthcare Access

- Access to medicine pegged at 45%
- India has only 0.9 beds per 1000 individuals; 0.7 physicians per 1000 patients
- Recent national health policy aims to have 100% UHC by 2022

Healthcare Spend

- Govt. spend remains at 1.3% of GDP
- 75% of the patients pay out of pocket

Indian Pharmaceutical Industry-Facts

- The Indian Pharmaceutical industry is expected to grow to USD 100 billion by the end of 2025 and USD 130 B by 2030
- Pharmaceuticals exports from India stood at USD 16.3 Billion in FY 2019-20
- The Indian biotechnology industry was valued at US$ 64 billion in 2019 and is expected to reach US$ 150 billion by 2025.
- The drugs and pharmaceuticals sector has also attracted cumulative foreign direct investment of approximately USD 16.86 billion between April 2000 and September 2020
- In 2017, 46 M&A deals worth USD 1.47 billion were reported in the pharmaceutical sector.
- The Indian pharma industry has grown at a compounded growth rate of (CAGR) of ~11% in the domestic market and ~16% in exports over the last two decades

Indian Pharmaceutical Industry-Facts

- The pharmaceutical industry in India ranks 3rd in the world in terms of volume and 14th in terms of value.
- India's cost of production is nearly 33 per cent lower than that of the US. Labour costs are 50–55 per cent cheaper than in Western countries. The cost of setting up a production plant in India is 40 per cent lower than in Western countries
- India has a skilled workforce as well as high managerial & technical competence in comparison to its peers in Asia.
- India has the 2nd largest number of USFDA-approved manufacturing plants outside the US. India has 2,633 FDA-approved drug products. India has over 700 USFDA-approved company sites, the highest number outside the US
- India's pharmaceutical exports stood at US$ 16.4 billion in 2016-17 and are expected to grow by 30 per cent over the next three years to reach US$ 20 billion by 2020
- The market is expected to grow to US$ 55 billion by 2020, thereby emerging as the sixth largest pharmaceutical market globally by absolute size

India Market

- With 70-80 per cent of market share (in terms of revenues), generic drugs form the largest segment of the Indian pharmaceutical sector
- India supplies 20 per cent of global generic medicines market exports, in terms of volume, making the country the largest provider of generic medicines globally and expected to expand even further in coming years
- Over the Counter (OTC) medicines and patented drugs constitute 21 per cent and 9 per cent, respectively, of total market revenues of US$ 20 billion
- The share of generic drugs is expected to continue increasing; domestic generic drug market is expected to reach US$ 28 billion in 2021
- Due to their competence in generic drugs, growth in this market offers a great opportunity for Indian firms
- Generic drug market is expected to grow in the next few years, with many drugs going off-patent in the US and other countries
- Domestic generic drug market has reached US$ 26.1 billion in 2016

PHARMA EXPORT

- Indian pharma exports reached US$20.7b in FY20 with year-on-year growth of 8.4% (exports size was US$19.1b in 2019) They have grown at a CAGR of 6.2% between 2015 and 2020.

- India exports vaccines to >150 countries. It contributes 40%-70% of the World Health Organization's (WHO's) demand for Diphtheria, Pertussis and Tetanus (DPT) and Bacillus Calmette–Guérin (BCG) vaccines, and 90% of the WHO demand for the measles vaccine9.
- Indian drugs are exported to more than 200 countries in the world, with the US as the key market

- India is the world's largest provider of generic medicines; the country's generic drugs account for 20 per cent of global generic drug exports (in terms of volumes)

- Around 40.6 per cent of India's US$ 16.8 billion pharmaceutical exports in 2016-17 were to the American continent, followed by a 19.7 per cent to Europe, 19.1 per cent to Africa and 18.8 per cent to Asian countries.

- While the global formulations trade value is about US$652 billion (2019), India's share of exports in the global trade was only about 2.5%.

Strength

- Strong manufacturing base
- Cost effective manufacturing
- Availability of high-quality skilled workforce
- Excellent marketing and distribution network
- Strong knowledge of Chemistry and Pharmacy
- More than 50 years of experience

Weakness

- Low investments in innovative R&D
- The ability to compete with MNCs for New Drug Discovery, Research and commercialization of molecules on a worldwide basis due to lack of resources.
- Diffused nature of the Indian pharmaceutical industry means that only about 20 to 30 companies are large enough to bear the transactions costs associated with sustained exports to and compliance with entry regulations of the developed markets
- Strong linkages between industry and academia which are essential for growth of the industry is lacking in India.
- Manufacturer of fake and low quality medicines.

Opportunity

- Increased export potential
- Marketing tie ups with multinational companies to sell their products in domestic market.
- Immense scope to position india as a centre for international clinical trials.
- Key player in global pharmaceutical CRAMS business
- Exports of generic drugs to developed markets.
- Expending Biotech market including Biosimilars and Vaccines

Threats

- API threat from China
- Lowering of tariff protection has increased competition in domestic markets resulting in erosion of profitability
- Regulatory actions by agencies due to compliance issues
- Drug Price Control Order puts unrealistic ceilings on product prices and profitability.

Global Pharmaceutical Market

- The global pharmaceutical market in 2021 is expected to grow by 5-8 percent and will reach a level of $1.2 trillion .
- The US will continue to remain the single largest pharmaceutical market, with sales of $320–330 billion USD, up 3–5 percent.
- 150 billion USD worth of patent expiries are expected between 2016 and 2022 and are expected to face generic competition
- The pharmerging countries (17) are expected to grow by 13-16 percent over the next five years.
- In 2012 , the top selling drug was a biological Humira . This trend may continue in future

Global Research & Development

- It takes 10-15 years to develop a medicine or vaccine.
- The research-based pharmaceutical industry currently spends over USD 100 billion(EUR 75 billion) on R&D.
- In 2010, there were 878 medicines in the pipeline for all types of cancer, 193 for diabetes and 303 for rare diseases.
- In 2009, 25 new pharmaceuticals were launched , out of more than 3,050 compounds in development.
- In 2006-2010, the number of new chemical or biological entities launched on the world market fell to 151 from 211 a decade earlier.
- It costs an average of USD 2 billion to develop a single medicine.
- In 2010, five of the 10 leading global R&D firms were pharmaceutical companies.

Today`s Challenges – R&D

- Declining R&D productivity leading to transformation and establishing new innovative business models

Pharmaceutical pipelines are drying out

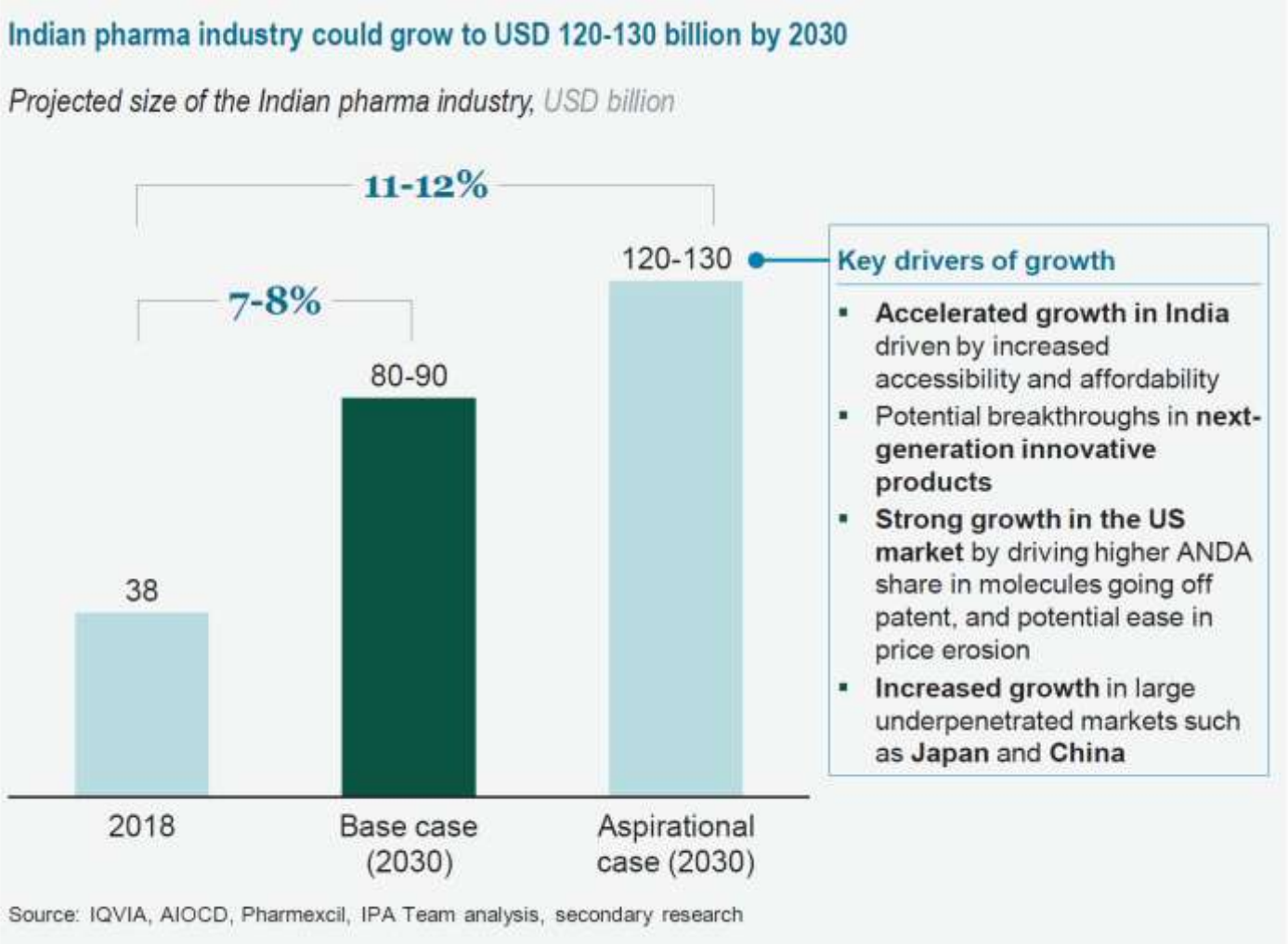
Enabling technologies, new targets and data evolve exponentially

In-house developments are increasingly expensive and slow

Biotech‘s creative &dynamic approaches deliver more products cheaper and faster, but not with a higher success guarantee.

Increased need for a paradigm shift to innovatively aligned R&D models and creative organizations with entrepreneurial team management

ASPIRATION 2030



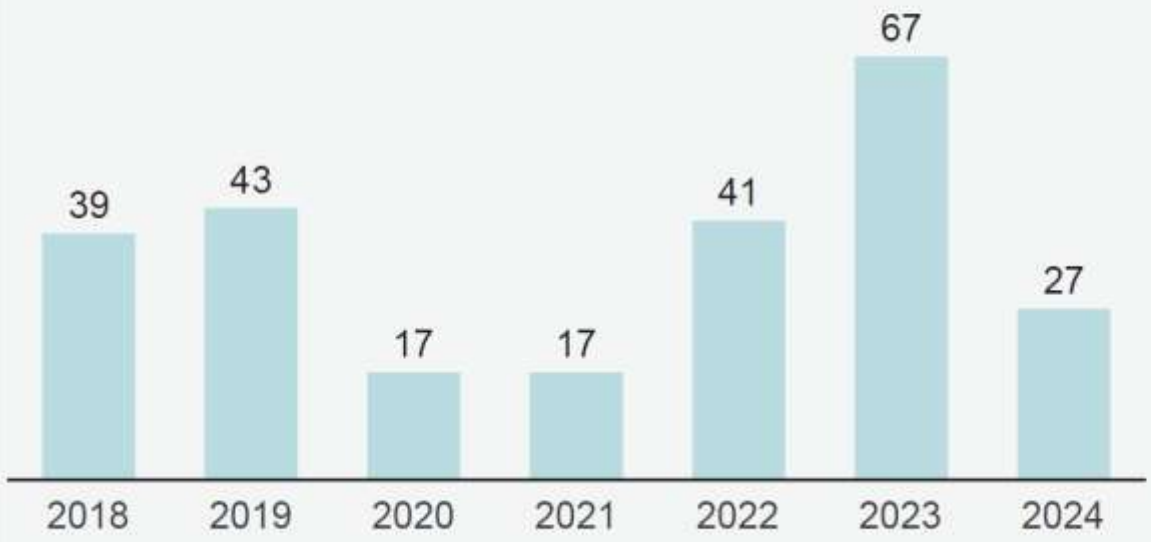
OPPORTUNITIES IN GENERICS

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



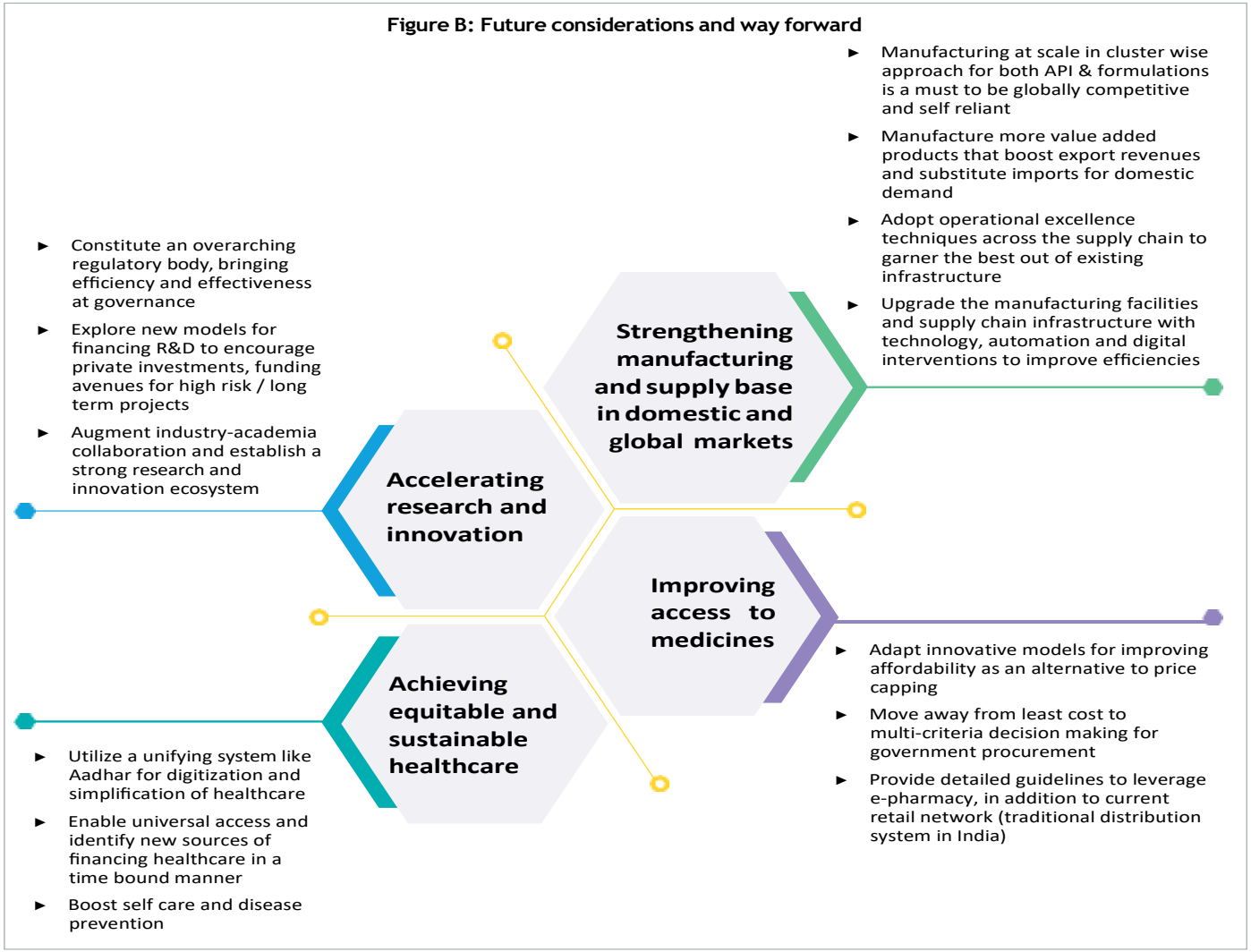
USD 251bn

Total worldwide drug sales expected to go off-patent

Source: EvaluatePharma, May 2018

Future Outlook and considerations

Figure B: Future considerations and way forward



Accelerating research and innovation

- To meet this objective, set of actions to help the industry move towards this objective including :

- Setting up an overarching regulatory body and a Central body to streamline research infrastructure and financing from all government bodies,

- Exploring new models for financing R&D to increase private investments and also make available funds for high risk / long term projects,

- Measures to improve industry-academia collaboration and establish a strong innovation ecosystem,

- The role of industry to leverage technology for improving productivity and efficiency in research

Achieving sustainable healthcare

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

Strengthen Mfg and Supply Chain

- The focus of manufacturing & supply chain initiatives would be to develop capabilities in APIs and enable manufacture of complex generics, bio-similars, gene & cell therapies .
- Ease of doing business is the most important enabler to set up world class manufacturing facilities
- Attractiveness of manufacturing sector would also need to be enhanced in order to attract the best talent in India and abroad
- Given the growth ambitions, it is vital to encourage and setup of Pharmaceutical machine manufacturing facilities in India that would result in lower fixed costs, savings in forex and reduction in time to set up additional facilities
- Strong and all round focus on excellence and compliance is a must to facilitate a “Made in India”phrase that is synonymous with high quality
- 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 percent.

Strengthen API Mfg

- Constructing large dedicated zones and leasing them to private players for operating manufacturing plants.
- 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)

Ambition India

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

Growth from US$4.2b in 2000 to US$ 41.7b in 2020[1].

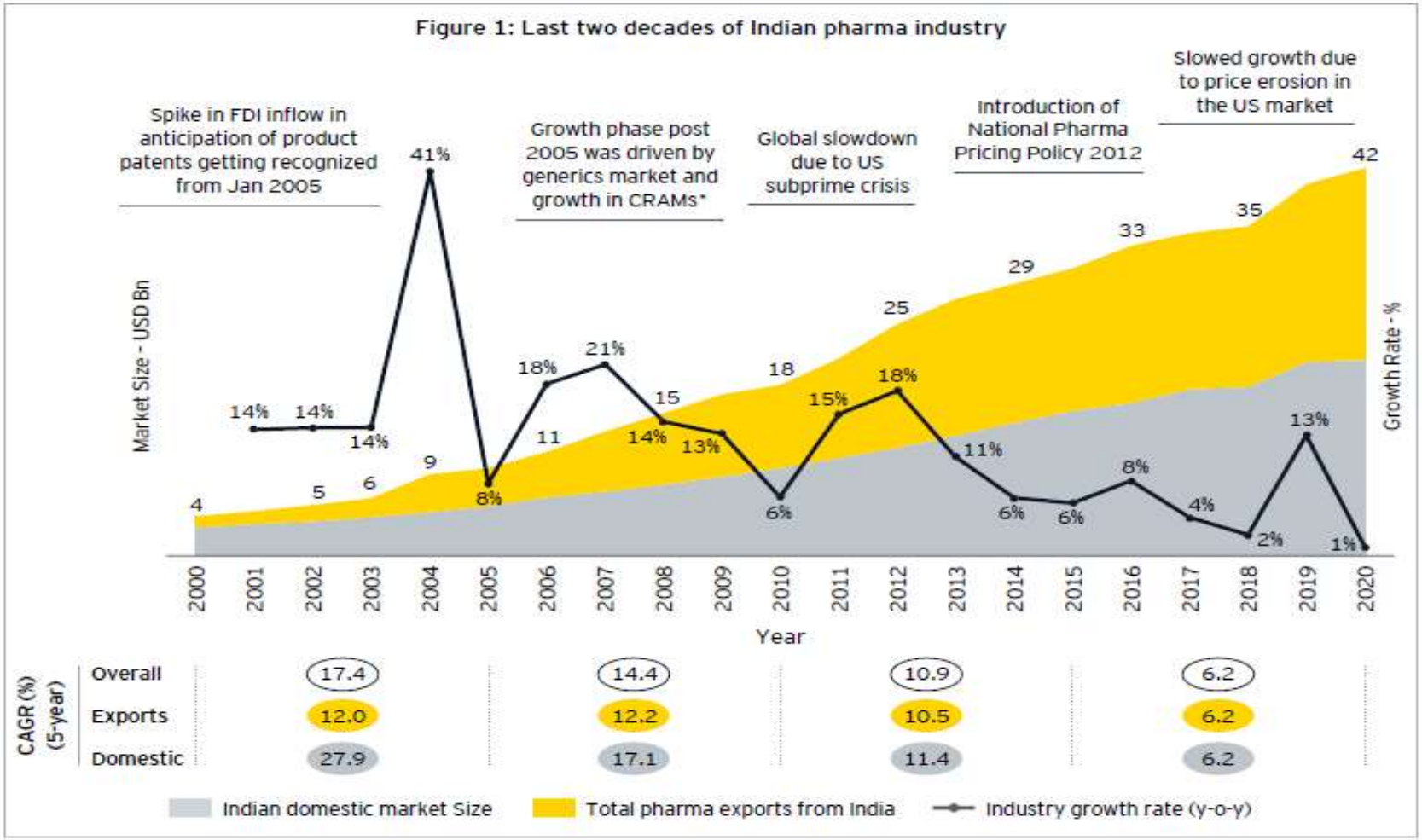
In the last few months, COVID-19 has led to significant geo-economic and geopolitical shifts, with major economies driving self-sufficiency agenda and recalibrating their global business models.

The World Economic Outlook October report projects global growth at nearly -4.4% in 2020, which is ~7% below the forecast in October 2019[2].

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

Ambition to achieve US$130b by 2030 at a Compounded Annual Growth Rate (CAGR) of ~12% from 2020 to 2030[1].

The last 20 years



The Road ahead…

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

India is the third-largest global manufacturer of drugs, but it ranks 14th in terms of value[1].

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

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

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

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

Complex generics, biosimilars, vaccines, NCEs

- Complex generics hold great potential to drive future market growth. They involve more difficult production processes and therefore face less competition, compared to simple generics

- The global biosimilars market size was reported to be US$11.8 billion in 2020 and is estimated to reach US$35.7 billion by 2025 growing at a CAGR of 24.7%

- The Indian domestic biosimilars market was reported to have generated US$576 million in 2019, achieving a growth of ~11% over 2018 revenue of US$520 million

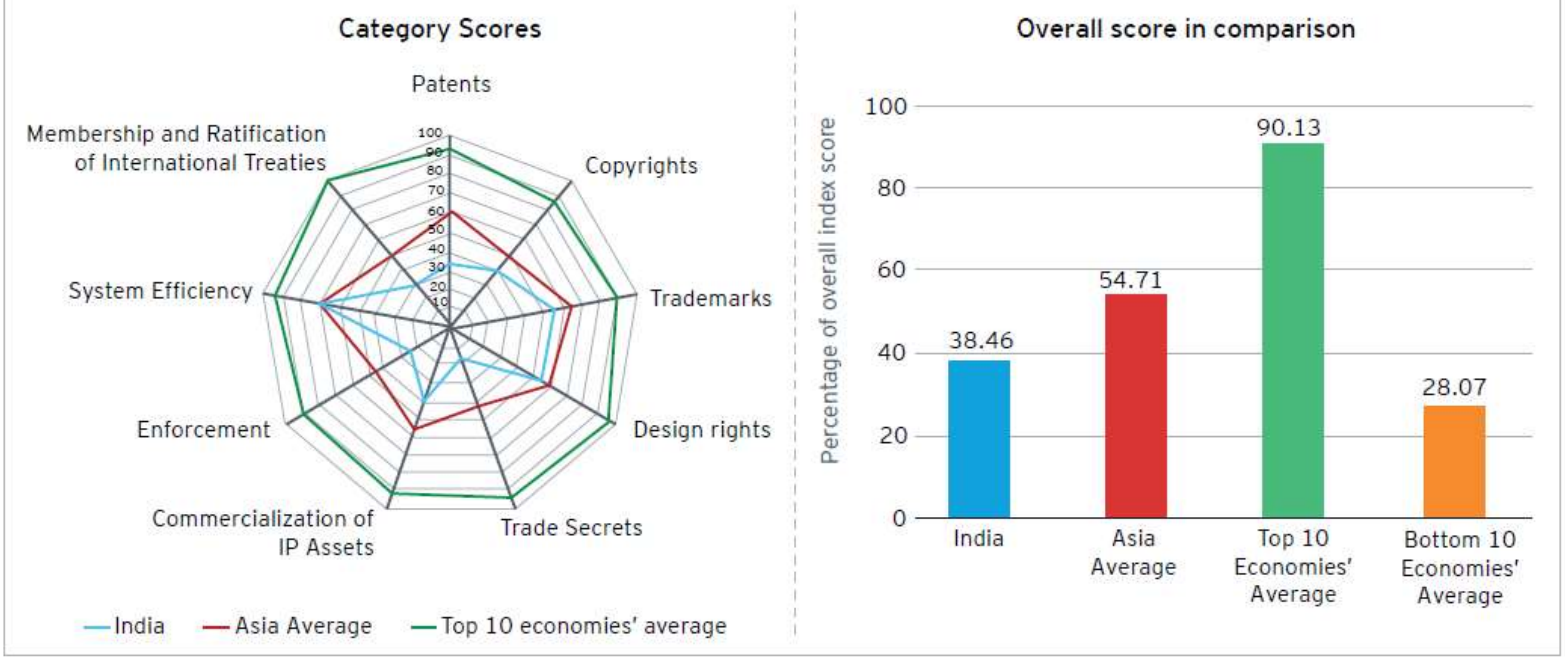
- According to a WHO survey, India had already approved 93 biosimilars (with at least 50 on the market) by August 2019 compared to 26 in the US and 61 in the EU

- India has established a strong presence in the global vaccines market. The country is now the biggest volume supplier to public market of vaccines, fulfilling over 66% of global vaccine requirements

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

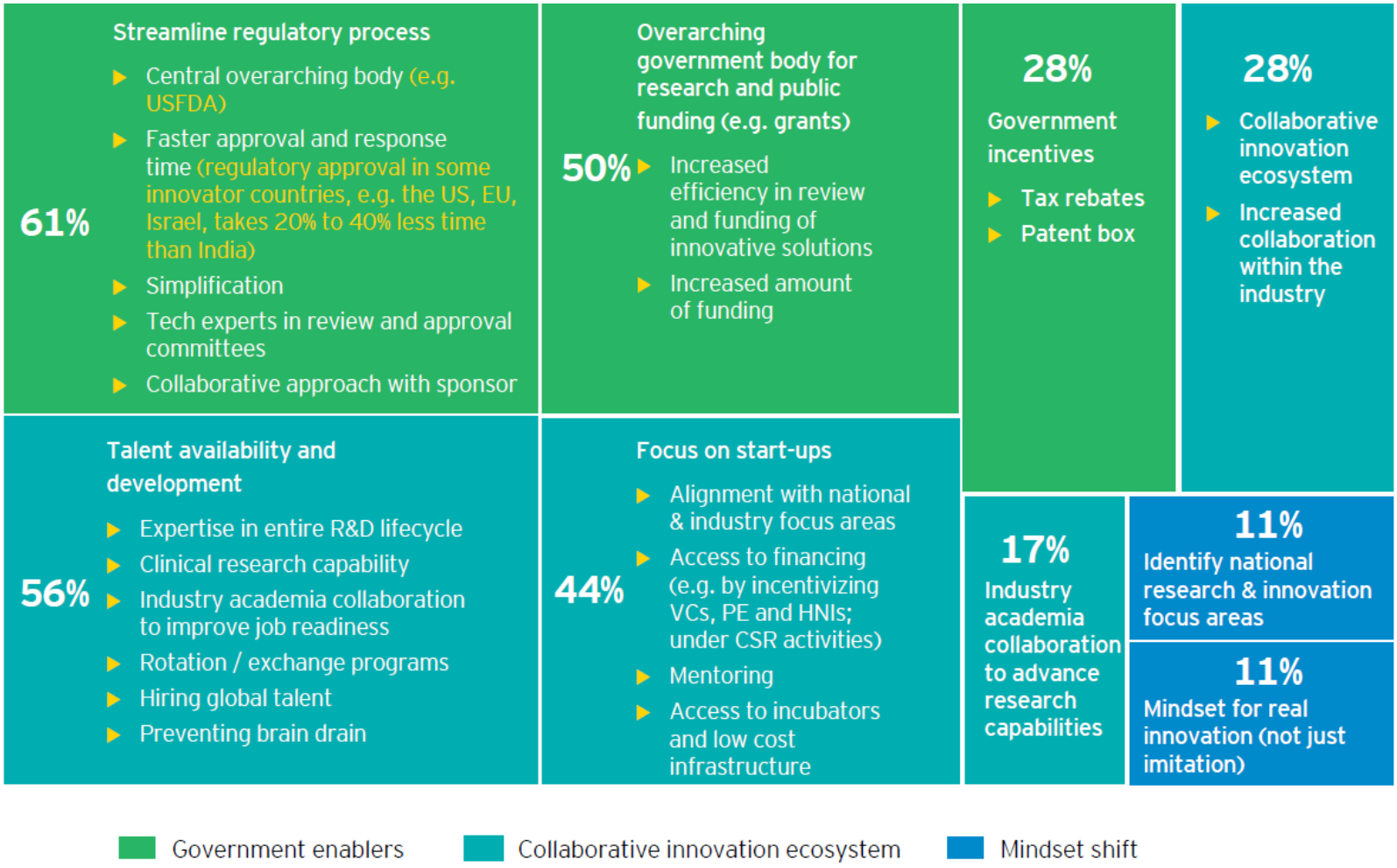
IP Index

Figure 16: Global Intellectual Property Index – India scores

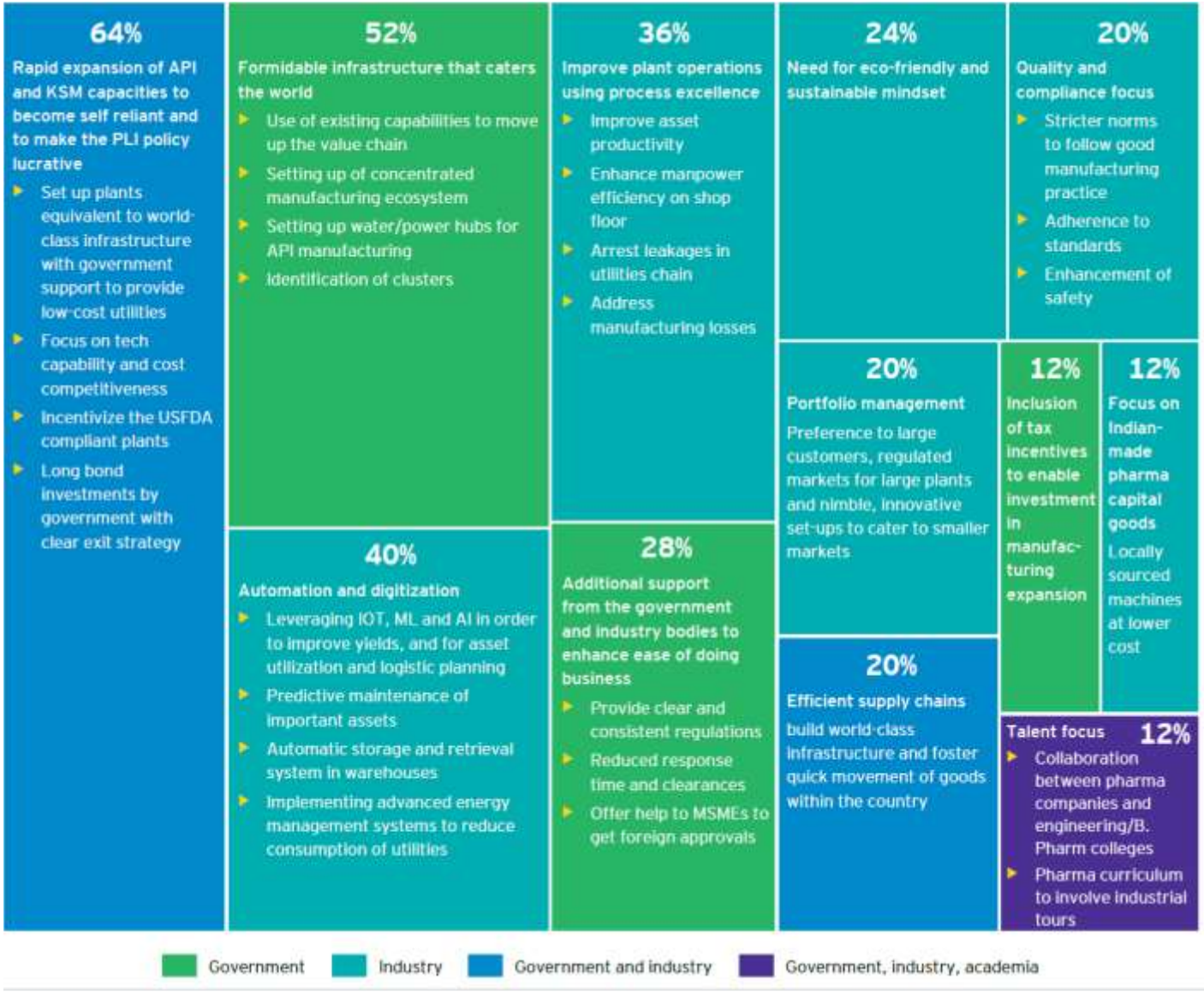


Source: Global Innovation Policy Center report 2020

Research and Innovation enablers

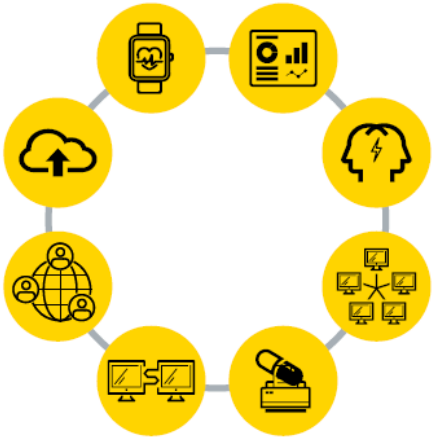


Manufacturing enablers



Future belongs to Patient centricity and agility

Figure 64: Role of advanced technologies in making pharma manufacturing and supply chain patient centric, agile and self learning



Artificial Intelligence

- Preventive/predictive maintenance, demand planning, inventory management, quality control/management
- *Automated synchronization, prediction and scenario simulation*
- *Prescriptive analytics and execution*

Augmented Reality and Virtual Reality

- Improve workforce efficiency
- Enhance employee training experience
- *Provide remote assistance to on-site workers*

Wearables and sensors

- Track and manage remotely
- Improve workforce efficiency and safety
- Monitor assets in real time

Blockchain

- *Tracks and verifies drug quality*
- *Helps in label management*
- *Provides chain of custody for individualized therapies*

Cloud-based platforms

- Storage and management of data
- *Enable integrated manufacturing and supply chain network*

3D printing

- *Print personalized dosages*

Online platforms

- Online pharmacies
- *Direct to consumer delivery of medicines*
- *Provide supply chain safety information exchange across geographies*

RPA*

- Automates areas of manual intervention
- *Develops end-to-end autonomous networks*
- *Enables automated decisions and execution*

Today: already in use

Tomorrow: *evidence of initial use cases and expected to become commonplace in near future*

New Business models

New major non exclusive trends are now appearing and will reshape the entire business model of the pharmaceutical industry;

- Drugs could become a piece of an integrated "**therapeutic solution**" in response to a pathology and to a given context and will no longer be the dominant or unique component of care
- The **“personalised medicine**” approach could provide novel targeted therapeutics, novel diagnostic tools and potentially novel disease prevention strategies
- In adapting the offer to the needs and the requirements of each country or region the industry will have to **provide “customised and affordable products including vaccines”**

Emerging Trends In Indian Pharma

- Major shifts in market demands and response strategies , epharmacies.
- More focus on quality and cGMP compliance
- Heightened Regulatory Scrutiny
- Access and Pricing Pressures to continue
- Focus will shift from treatment to prevention.
- Provide integrated solutions (from diagnostics to personalized therapeutics) for near total management of the disease process
- Arrival of “New Players” in vaccines and Biologics
- Increased healthcare spending by the government
- Greater international regulatory cooperation.
- Expansion of Biotech, Biopharma . Biosimilar products.

THANKS

ANY QUESTIONS ?