

The Indian pharmaceutical industry and global market

September 2019

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 from 1990 to 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



USD 10bn

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



USD 2bn

FDI inflows to Pharma industry in last 3 years

Even globally Indian pharmaceutical companies have contributed towards better health outcomes

Shaping global vaccination



60%
Global vaccine production



90%
WHO demand for measles vaccine



40-70%
WHO demand for DPT (Diphtheria, Tetanus and Pertussis) and BCG (Bacillus Calmette-Giuerin) vaccines

Driving access of medicines globally



25%
Medicines made in UK are made in India



33%
Pills consumed in US is produced by Indian generic manufacturer

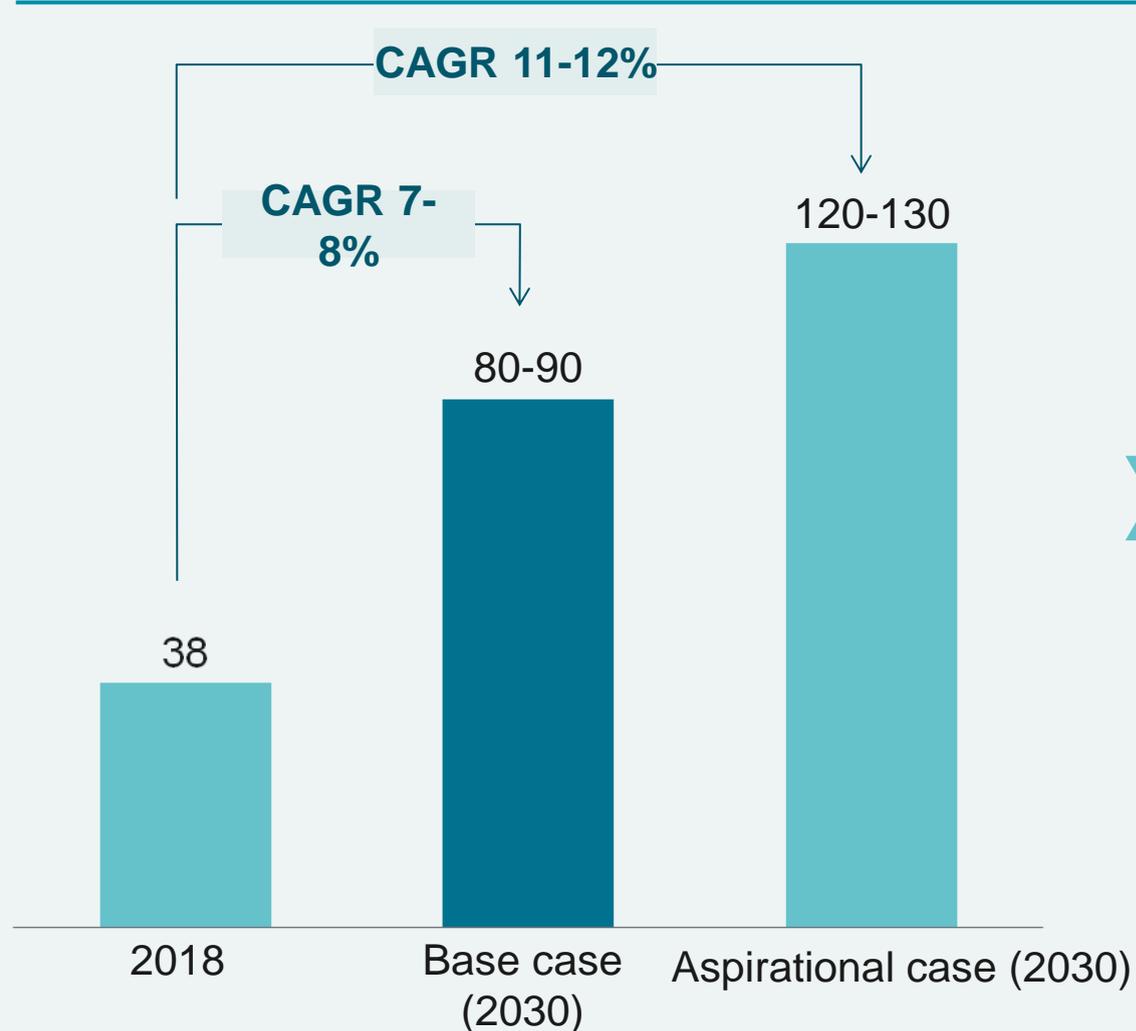


37%
AIDS patients receiving treatment in 2009, vs 2% in 2003 in Africa

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

Vision 2030: Indian pharmaceutical industry aspires to be ~120-130 Bn USD and largest volume producer in the world

Projected size of the Indian pharma market, USD billion



Vision 2030, USD billion

- 1 Accelerate universal health care across India by access to high quality affordable drugs**
- 2 Emergence as an innovation leader to build a global position**
 - Emerge as leader in innovation with aim of launching 3-4 new molecular entities (NMEs) and 10-15 incremental innovation launches annually by 2030
- 3 Largest and most reliable drug supplier with ~120-130 Bn USD Size by 2030**
 - Establishing leadership position in the global generics market
 - Build new markets outside India and US e.g., China, Japan
- 4 Contribute to the growth of the Indian economy**
 - Contribute foreign exchange earnings of at least USD 30-40 bn by 2030 from current earnings of ~11 Bn USD

Achieving these goals would increase Indian pharma industry's global share to 7.0% from current 3.6% (by value)

Headwinds in domestic and international markets have subdued its growth to 7-8% CAGR



Challenges

Key contributing factors

India is yet to achieve universal healthcare access



- **Low doctor-patient ratio:** 29 skilled health workers for 10,000 people vs ~ 41 in China & ~111 in US
- <1/3rd population has health insurance, inability to pay

Need for pricing policy environment favourable to long-term investments



- **Frequent and unexpected changes** to pricing policy

Need for capabilities in innovation



- **Constrained talent pool** with advanced skills (e.g., PhDs)
- **Low collaboration** between academia-industry on innovative R&D
- **Regulatory norms not favouring innovation** (e.g., Stringent clinical trial norms)

Dependence on external markets for intermediates and APIs



- >80% API requirement imported, vulnerability to **supply disruptions & price movements**
- Lack of a cost-competitive domestic **API manufacturing base**

Need for sustaining competitive advantage in the US & exploring other markets and products



- **Moderating growth in US** market due to price erosion
- **Limited presence in other markets** like China, Japan

Increased scrutiny in overseas quality compliance



- **Greater scrutiny from global regulators** on quality norms, requires continuous investment in upgrading quality standards

However, opportunities exist across new geographies and product classes for Indian pharmaceutical players to chart an accelerated growth path

Upcoming patent cliff opportunity for Indian generics players

E.g., Patents for ~\$251bn branded drug sales expire between 2018-24

State sponsored programs to enable UHC

E.g., The Ayushman Bharat Yojana will enable healthcare access for ~40% of the population



Opportunities to achieve Vision 2030

Footprint in large underpenetrated international markets

E.g., Increasing exports to Japan, China, Africa, Indonesia and Latin America

Newer products such as gene therapy, biosimilars, specialty drugs

E.g., Capturing 10% share of the \$60bn biosimilars market could grow Indian pharma industry by 13%

Rich demographic dividend that also offers cost advantages

E.g., 2.25L+ pharmacy students graduate from India's education system; manpower costs are ~33% lower than west

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

Chinese API growth story and policy interventions to foster innovation highlight what is needed to realize the opportunities



China API growth story

Government initiative

Lower set-up and production costs



15-20% lower costs than in India

- Ensuring low capex due to “plug and play” infrastructure: Subsidized land, common waste processing and utilities, flexible labor laws)
- Helping lower operating costs: Availability of cheaper credit, labor and electricity in China

Supportive research and development ecosystem



USD1.6 billion Invested by the government for new drug development

- Creation of a research ecosystem:
 - “Thousand Talents Plan” to attract over 50,000 PhDs through generous funding support (up to USD 75,000/year).
 - Alliances between multinational biotechnology firms and Chinese universities

Chinese Govt. contribution to building innovation ecosystem

Initiative



Slew of regulatory reforms by Chinese Food and Drug Authority (CFDA) since 2015 e.g., new approval mechanism, CFDA joins ICH, Rationalizing clinical trial data requirement

Impact

~70% increase In filings of local innovative assets by Chinese firms - ~20 NDAs filed in 2018 vs 4 in 2015

~64% decrease In approval timeline



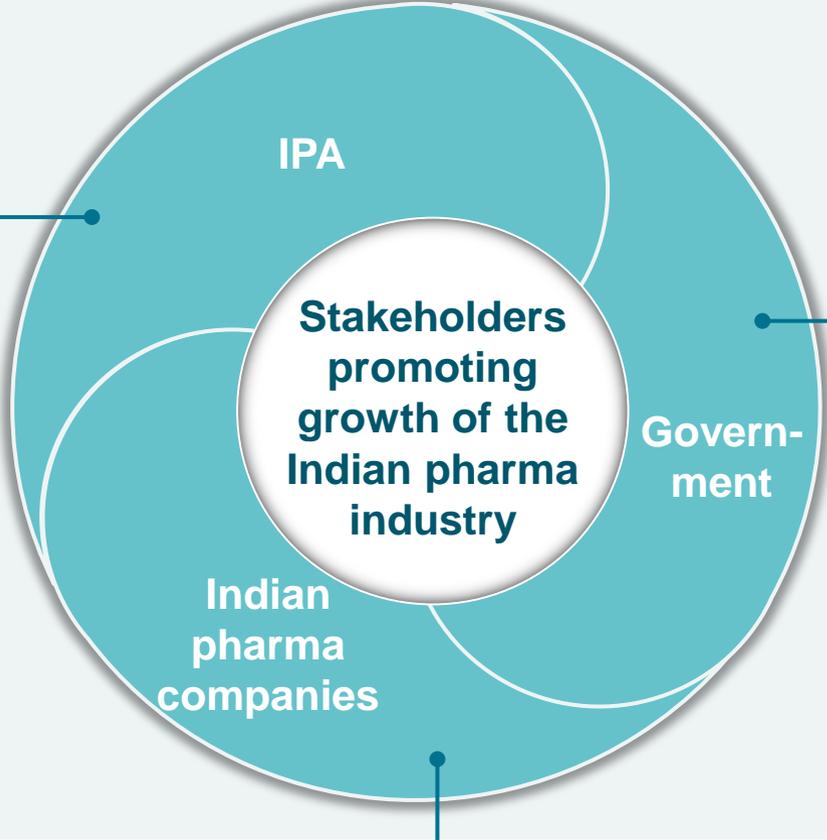
Range of policies and implementation guidelines to support and regulate digital/analytics disruption in healthcare e.g., NHC detailed the management of online consultation

~40% physicians have used virtual consultation to deliver healthcare services.

~1.5 Mn physicians are active daily on top 3 online platform

Concerted efforts and strong collaborations between all stakeholders—Indian pharma companies, the government and regulatory agencies, and the IPA—can help capture these opportunities

- **Communicate** the contribution of Indian Generics to global healthcare industry and regulators
- **Work with Indian missions** abroad for global opportunities



- **Accelerate universal healthcare** access to create a thriving healthcare ecosystem across India
- **Provide plug and play infrastructure** to focus boost API manufacturing
- **Focus on driving innovation** at scale by easing regulations on technological development
- **Collaborate** the creating an independent Ministry for Pharmaceutical

- **Take bold strategic moves** into uncharted territories (like making big bets on markets like China, Japan)
- **Protect the core** through the extensive adoption of new-age digital and advanced analytics techniques to drive newer efficiencies across front-end and back-end operations
- **Drive capability building**, especially on the quality front, with regular and deeper engagement with regulators like the US FDA and other drug authorities

Key thrust areas for Vision 2030

The government can be a key enabler through six strategic interventions



Accelerate universal healthcare access in India

- **Increase government expenditure on healthcare** from ~1.2 percent to 2.5- 3 percent of GDP by 2022 and 5 per cent by 2030, in line with the European and North American economies
- **Provide infrastructural and investment support** needed to bring India’s doctor-patient ratio in line with WHO’s global benchmark e.g., support innovative digital technologies to increase access



Encourage investments: Government support and stability in policy

- **Define a coherent pricing policy** framework aligned with all relevant stakeholders



Promote innovation at scale

- **Create research ecosystem supported** by incentives, state-mandated academia-industry collaborations , streamlined regulations and create enabling environment for encouraging start ups



Expand and upskill the talent pool

- **Invest in ‘at-scale’ capability-building** programs to create an industry-ready workforce



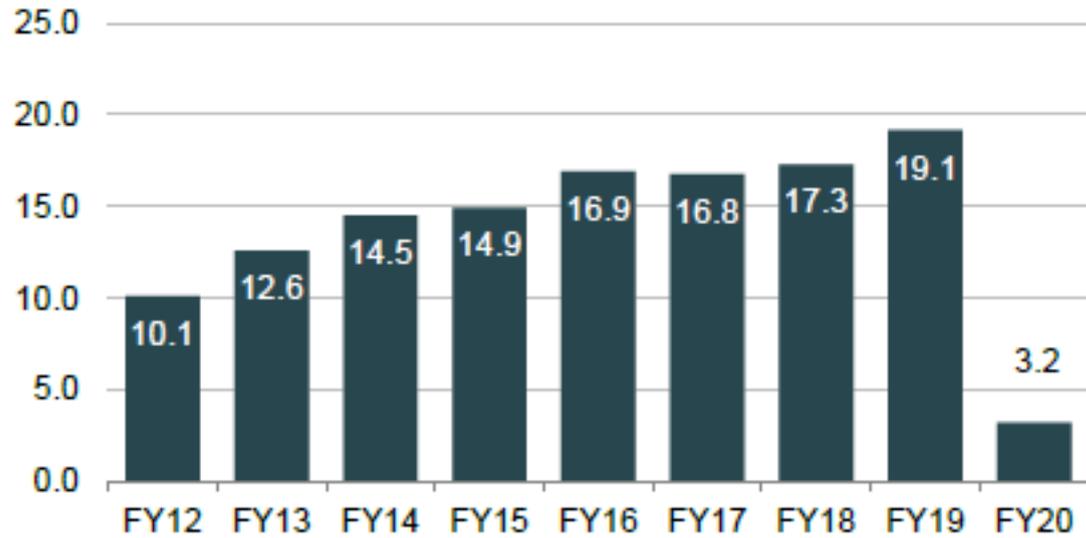
Expand global footprint and collaborate with international regulatory bodies : PICs and ICH, among others

- **Address trade barriers and improve the Indian pharma** industry’s quality perception in emerging markets

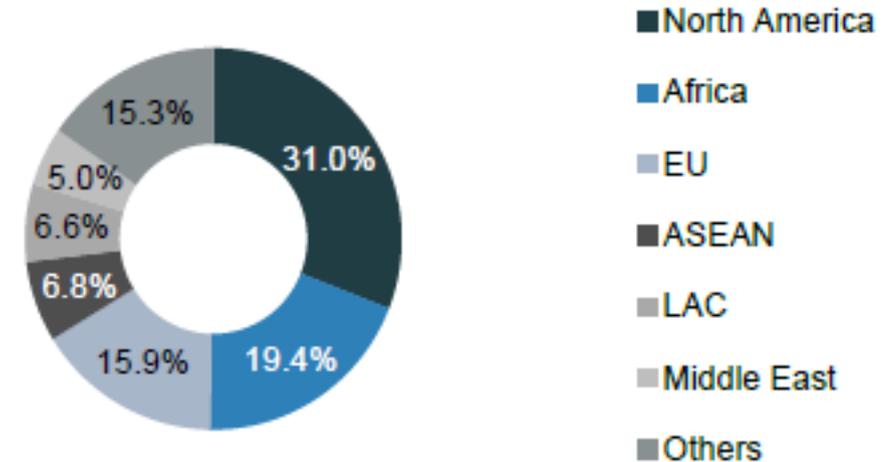
Global Trends

Pharma Export to Continue Witnessing Positive Growth

Pharmaceutical Exports from India(US\$ billion) (up to July 2019)



Major Export Destinations in India's Pharma Export in FY18 (%)



- Pharma recorded a growth of 10.72% in 2019 with export presence in over 200 countries
- Export grew 13% in first four months of 2019 compared to overall export decline of 1.5% ; Export growth surged to 21.7% in July 2019
- Key top export markets – USA (\$5.82bn), UK (\$630mn), SA (\$619mn), Russia (\$485mn) and Brazil (\$452mn)
- Low presence in China (\$230mn) and Japan (\$147mn)

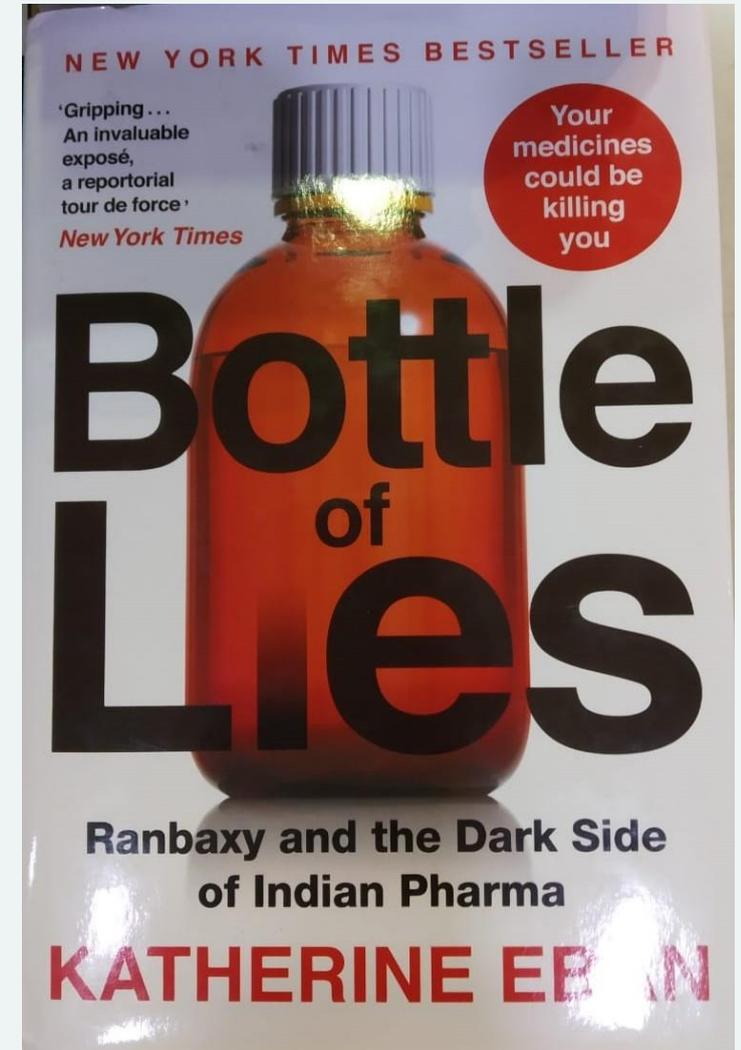
US Market

Key Issues

- Strengthening of distribution power and decline in supply power – price erosion around 15% per annum in last 3 years
- Quality concerns by regulatory authorities
- Regulation restricting supplies to US government
- India's goods trade surplus with us was \$21.3bn in 2018

Way Forward

- 1) Thrust on innovation & complex generic
 - Increase in R&D spending to 8.5% in FY 2018 from 5.3 % in FY 2012
 - Removal from priority watch list of USTR Spl 301 Report
 - Protecting India's TRIPS position in IPRs
 - Strengthening India's image about quality



Markets of Interest

Japan

- Second largest market
- 80% accounts for generic and greater generic push due to aging population
- Non-tariff Barriers (NTBs) in the form of requirement of Bio-Equivalence Studies, delaying market approvals

China

- Third largest market
- 60% of imports of APIs to India in 2019 compared to 1% in 1991
- Emphasis on local manufacturing and Bio-Equivalence Study to create NTBs
- India's trade deficit with china approximate \$57bn

EU

- Generic drugs account for approximate 50%
- Brexit will increase the cost

RCEP

- Sixteen country agreement (10 ASEAN+China+India+Japan+South Korea+Australia+NZ)
- Will open opportunities for pharma sector

Integrated efforts by industry and government can help to unleash potential