

# 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

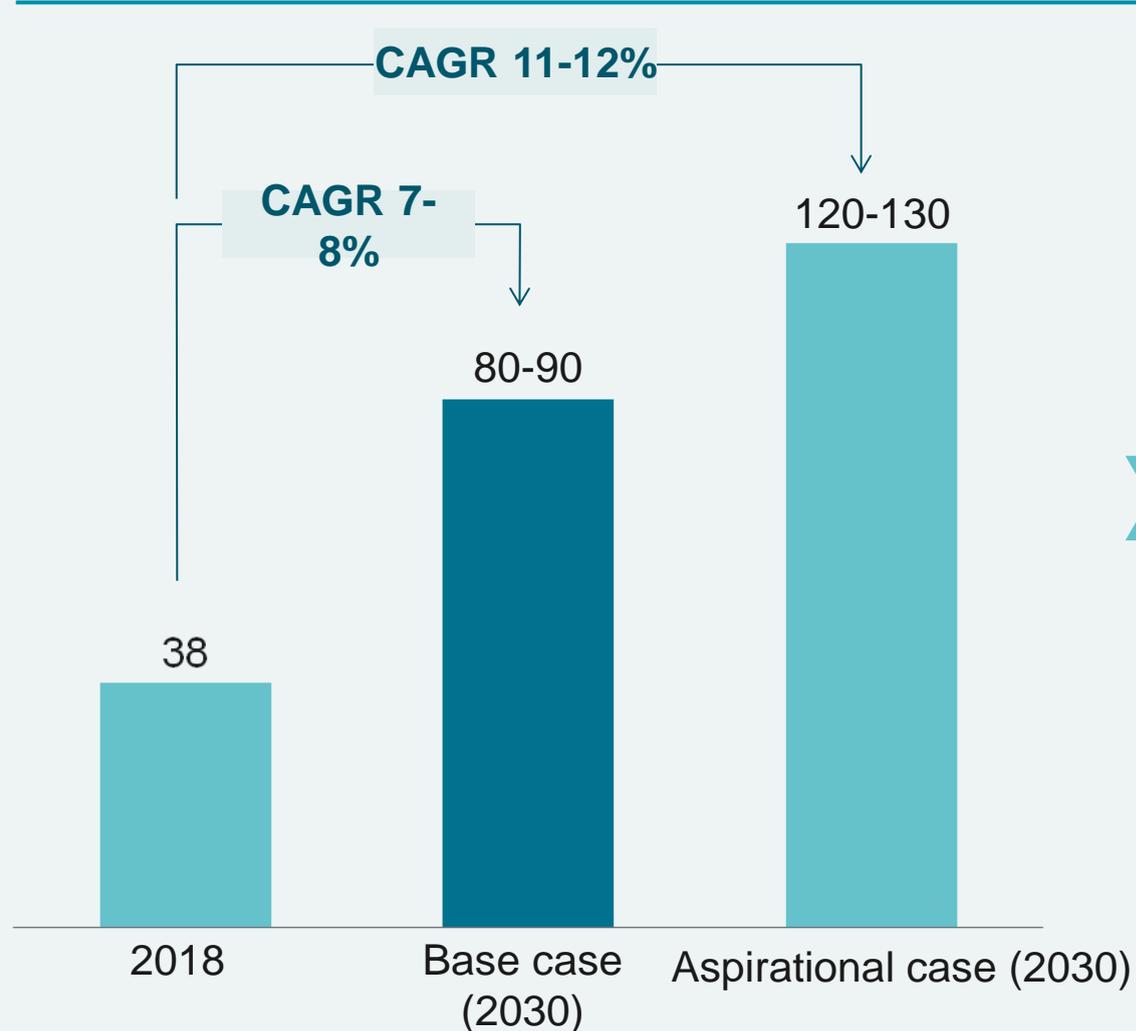


**37%**  
AIDS patients receiving treatment in 2009, vs 2% in 2003 in Africa

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



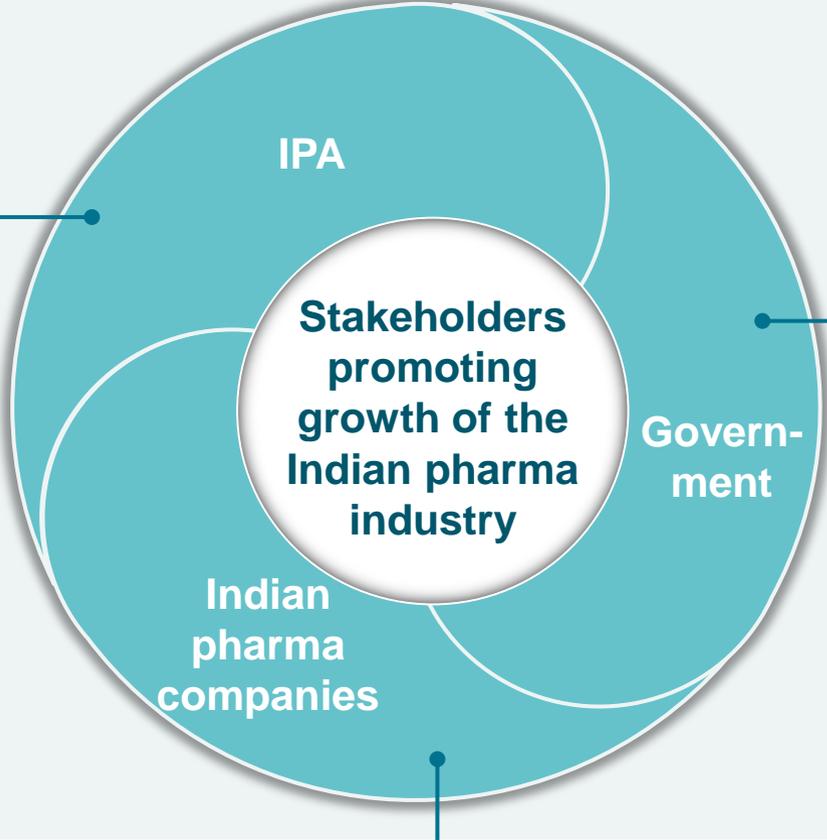
Range of policies and implementation guidelines to support and regulate digital/analytics disruption in healthcare e.g., NHC detailed the management of online consultation

~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



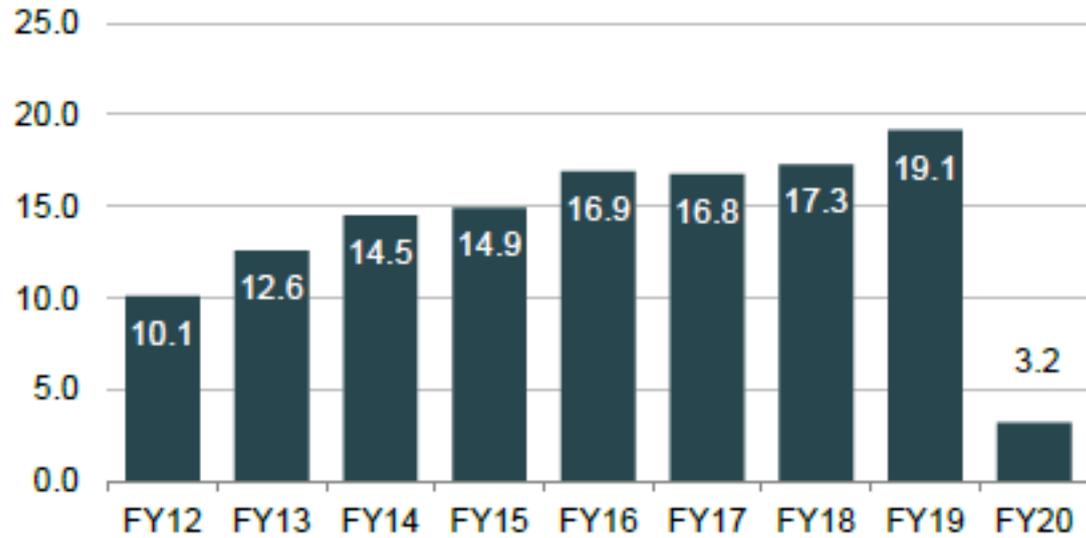
## Expand global footprint and collaborate with international regulatory bodies : PICs and ICH, among others

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

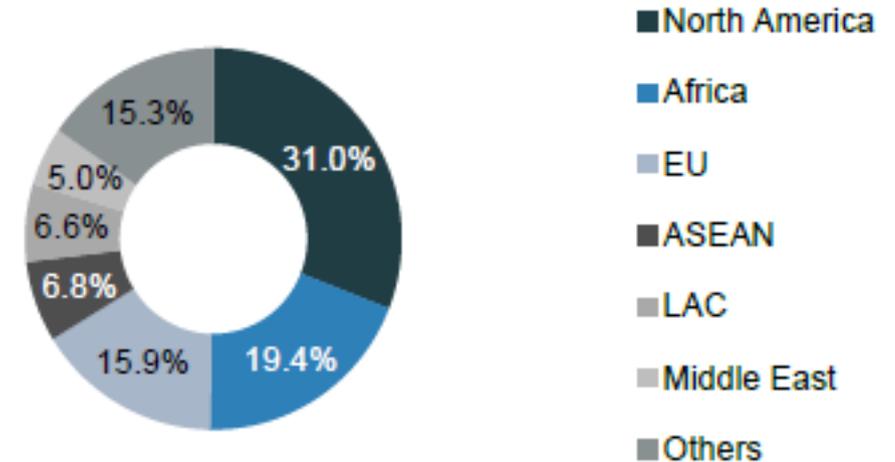
# Global Trends

## 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)

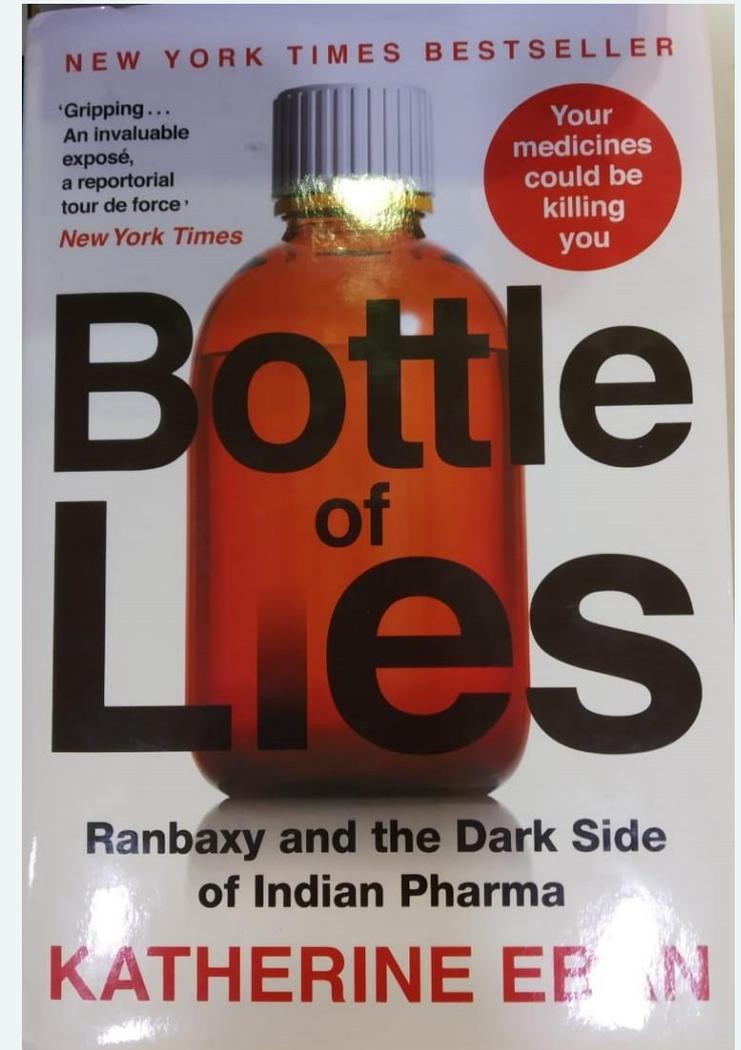
# US Market

## 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**