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

SOURCE: IQVIA, AIOCD, Pharmexcil, IPA Team analysis, secondary research
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-Guiерin) 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

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<th>Year</th>
<th>Base case (2030)</th>
<th>Aspirational case (2030)</th>
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<tbody>
<tr>
<td>120-130</td>
<td>(\text{CAGR 11-12%})</td>
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<tr>
<td>80-90</td>
<td>(\text{CAGR 7-8%})</td>
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<td>38</td>
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**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)

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

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<th>Challenge</th>
<th>Key Contributing Factors</th>
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<tr>
<td>India is yet to achieve universal healthcare access</td>
<td>• <strong>Low doctor-patient ratio:</strong> 29 skilled health workers for 10,000 people vs ~41 in China &amp; ~111 in US  &lt;br&gt; • &lt;1/3rd population has health insurance, inability to pay</td>
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<td>Need for pricing policy environment favourable to long-term investments</td>
<td>• <strong>Frequent and unexpected changes</strong> to pricing policy</td>
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<td>Need for capabilities in innovation</td>
<td>• <strong>Constrained talent pool</strong> with advanced skills (e.g., PhDs)  &lt;br&gt; • <strong>Low collaboration</strong> between academia-industry on innovative R&amp;D  &lt;br&gt; • <strong>Regulatory norms not favouring innovation</strong> (e.g., Stringent clinical trial norms)</td>
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<td>Dependence on external markets for intermediates and APIs</td>
<td>• &gt;80% API requirement imported, vulnerability to <strong>supply disruptions &amp; price movements</strong>  &lt;br&gt; • Lack of a cost-competitive domestic <strong>API manufacturing base</strong></td>
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<tr>
<td>Need for sustaining competitive advantage in the US &amp; exploring other markets and products</td>
<td>• <strong>Moderating growth in US</strong> market due to price erosion  &lt;br&gt; • <strong>Limited presence in other markets</strong> like China, Japan</td>
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<td>Increased scrutiny in overseas quality compliance</td>
<td>• <strong>Greater scrutiny from global regulators</strong> on quality norms, requires continuous investment in upgrading quality standards</td>
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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

**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

**Lower set-up and production costs**
- **15–20% lower costs** than in India

**Supportive research and development ecosystem**
- **USD1.6 billion** Invested by the government for new drug development

### Government initiative

- **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
- **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

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<th>Impact</th>
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<tr>
<td>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</td>
<td>~70% increase In filings of local innovative assets by Chinese firms - ~20 NDAs filed in 2018 vs 4 in 2015</td>
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<td>Range of policies and implementation guidelines to support and regulate digital/analytics disruption in healthcare e.g., NHC detailed the management of online consultation</td>
<td>~40% physicians have used virtual consultation to deliver healthcare services. ~1.5 Mn physicians are active daily on top 3 online platform</td>
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SOURCE: Secondary research
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
- **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
- **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
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

- 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

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**Integrated efforts by industry and government can help to unleash potential**