

Indian Pharmaceutical Industry

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India has played a significant role in global healthcare



36%

Lower per person disease burden in India (DALY, 1990-2016)³



95%

Lower treatment costs of life-threatening diseases (Hep-C, Leukemia)¹



100%

Eradication of Polio by collaboration between all stakeholders²



60%

Global vaccine demand Supplied by India⁵



37%

AIDS patients receiving treatment in Africa in 2009 through ARVs V/s 2% in 2003⁶



1 of 3

Pills taken in the US are by Indian manufacturers⁴

¹ Access to Costly New Hepatitis C Drugs: Medicine, Money, and Advocacy, Oxford Journals, Vol 61, Issue 12; Changing the cost of care for chronic myeloid leukaemia, PMC, October 2015;
³ Measured as Disability Adjusted Life Years (DALYs) after adjusting for changes in population age structure; ICMR, Public Health Foundation and Institute of Health Metrics and Evaluation;
⁵ Press Information Bureau; IDMA report;
⁷ Export Import Data Bank, Department of Commerce, PHARMEXCIL, IDMA report on "Journey towards Pharma 2020 & beyond";
⁸ Indian life sciences: Vision 2030, FICCI June 2015, Growth estimated by IHS Market;
⁹ RBI Database on Indian Economy, Department of Industrial Policy and Promotion

² Press Information Bureau, WHO;
⁴ IQVIA 2019;

⁶ African Business Magazine 2012;

Contribution to the economic growth of the country

Global Trade



20%

of total global exports of
generic drugs



3rd largest

Volume Terms



14th largest

Value Terms

Economic Outcomes



2.7 Mn

Jobs created directly
and indirectly



USD 15.2 Bn

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



USD 50 Bn

Total market size in
2021-22

COVID-19 - most unprecedented humanitarian crisis

- ❑ Indian Pharmaceutical industry showed resilience, supplied medicines to over 200 countries
- ❑ The Industry, Government and Regulators worked together and constantly adapted to meet the challenging environment -
 - CEO's meeting every day
 - Collaboration among all stakeholders
- ❑ Biggest vaccination program in the world -

44.7 Million

Total Cases in India

0.53 Million

Total Deaths in India

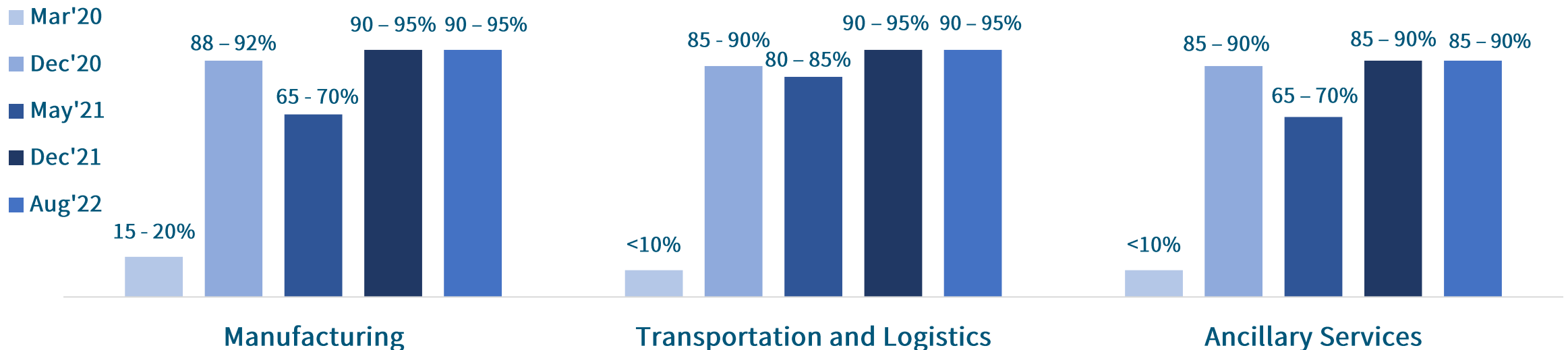
2.1 Billion

Total Vaccination in India

Note: Data as on 20 November 2022

Manufacturing and Supply Chain

- ❑ Industry stepped up to the plate to meet the challenges posed by COVID-19
 - Focus on ensuring global supply of medicines (including those used for the treatment of COVID-19)
- ❑ High-level of engagement with the Government of India :
 - Pharmaceuticals recognized as Essential Goods and Services; Permissions granted for movement of people and materials
 - Resolution of challenges faced by manufacturing facilities; Ensuring continuity of Transport and Logistics;
- ❑ Coordination with industry associations in India and with WHO, IGBA, AAM and others

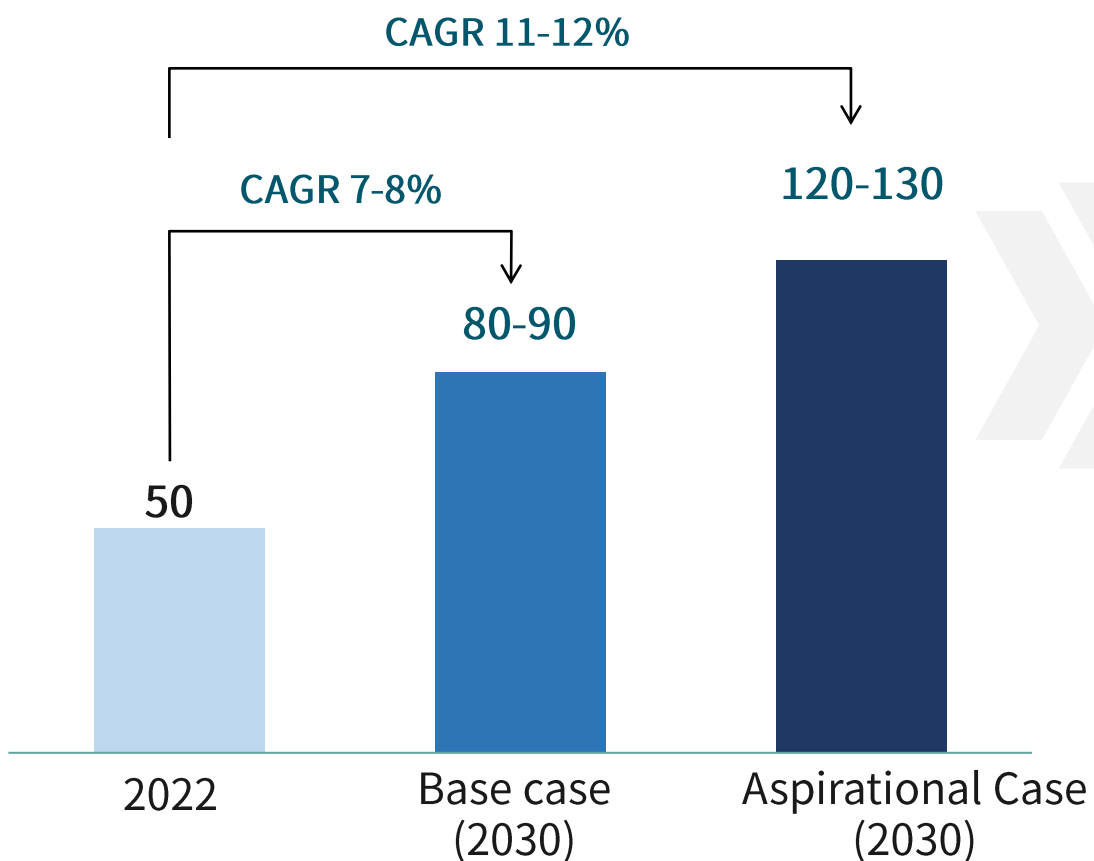


Key initiatives by the Government of India



Vision 2030

Projected size of the Indian pharma market, USD Bn



SOURCE: IQVIA, AIOCD, Pharmexcil

Vision 2030, USD billion

- 1 Accelerate universal health care across India by access to high quality affordable drugs
- 2 Build innovation position by launching 3-4 new molecular entities and 10-15 incremental innovation
- 3 Thrust on self reliance API Policy, going forward
- 4 Largest and most reliable drug supplier with ~120-130 Bn USD Size by 2030
- 5 No 1 in terms of volume and in top 5 in value terms

Bi-lateral Trade of Pharmaceutical Products

Exports

Year	Export to EU Countries (in USD Millions)	Overall Export from India (in USD Millions)	% Export to EU from India
2022-23 (Apr-Jan)	2,236.88	16,323.66	13.70
2021-22	2,150.69	19,396.24	11.09
2020-21	1,888.10	19,384.02	9.74
2019-20	1,592.48	16,289.25	9.78

- Bilateral trade relationship between India and the EU has been consolidating
- The COVID 19 pandemic has highlighted the importance of strong India-EU collaboration, especially in the pharmaceutical sector

Imports

Year	Import from EU Countries (in USD Millions)	Overall Import to India (in USD Millions)	% Import from EU to India
2022-23 (Apr-Jan)	981.27	2,195.51	44.69
2021-22	1,549.40	3,441.35	45.02
2020-21	1,036.65	2,552.52	40.61
2019-20	1,042.29	2,334.67	44.64

- Number of CEPs received (as on Dec 2021)
- Number of companies with CEPs (as on Dec 2021).
- No. of Sites Registered with EUGMP(as on Dec 2021)

Source: Tradestat website, Ministry of Commerce

Challenges

- Delays caused due to batch testing approach
- Delays in appointment of Decentralised Procedure (DCP)
- Timeline for Scientific Advice
- Marketing authorization takes 9-15 months after DCP closure, although guidelines says 30 days after DCP closure thereby delaying launch process for a product in EU
- Lack of timely approvals of variation

Collaboration

- Reliable supplier of affordable medicines
- Addressing issues to achieve greater convergence by easing restrictions on standards, testing, and certification procedures to allow greater availability of the products
- Diversifying Supply Chain for sustainability: Reducing the concentration of supplies from limited sources will be crucial for de-risking the supply chain

Way Forward

- India and EU share close economic and political relationship, there is a possibility of leveraging this closeness to advance patient healthcare
- Significant opportunity to increase trade
- Close cooperation between regulatory agencies in the EU will help in ease of doing business and address challenges
- Partnership between Indian and EU, particularly in pharmaceutical sector, potentially can aid in improving accessibility of affordable medicines to patients
- Partnership to capitalise on emerging challenges and leverage strength

Thank You

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