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भारत के लिए

Organisation of Pharmaceutical Producers of India

# Winning in Indian Healthcare

2024







Boston Consulting Group (BCG) partners with leaders in business and society to tackle their most important challenges and capture their greatest opportunities. BCG was the pioneer in business strategy when it was founded in 1963. Today, we work closely with clients to embrace a transformational approach aimed at benefiting all stakeholders — empowering organisations to grow, building sustainable competitive advantage, and driving positive societal impact.

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Organisation of Pharmaceutical Producers of India

The Organisation of Pharmaceutical Producers of India (OPPI) established in 1965, represents the research-based Global Pharma companies in India. OPPI has been an integral part of the healthcare journey of the country. We remain committed to supporting the nation's healthcare objectives, putting patients at the core of all decision making and collaborating with all stakeholders to find sustainable solutions to realize the collective vision of Health for All.

Our member companies have been serving the country's healthcare ecosystem since pre-independence and continue to remain committed to patient safety and providing quality care in the future as well. As an association, our advocacy decisions, patient commitment and work are always keeping the country first and we embody the spirit of working for 'Bharat Ke Liye'; driven with innovation to find solutions for unmet medical needs, collaboration with government stakeholders, and co-creation with partners coming together to address the nation's healthcare challenges. We are committed to the Hon'ble Prime Minister's clarion call of 'Jai Vigyan and Jai Anusandhan'.

# Foreword

India's healthcare sector is on the brink of a **transformative reform**, fuelled by robust economic growth and increasing demand for quality healthcare.

Global Pharma companies have played a pivotal role in the evolution of healthcare sector in India, bringing in **innovative technologies, patient support programs and investments in local capabilities** to serve the community needs. As the country now looks to capitalize on its value potential, Global Pharma companies in India will play an integral role in driving forward the change.

The '**Winning in Indian Healthcare**' report by BCG and OPPI offers crucial insights for Global Pharma companies to navigate and thrive in this dynamic market. Highlighting the potential for growth, this report **addresses the key drivers and challenges of winning in the market, emphasizing strategic initiatives and government support needed for success.**

As India progresses towards becoming a global economic powerhouse, this report can serve as a vital guide for Global Pharma companies committed to contributing to the nation's healthcare transformation.





## From the OPPI Director General's desk



**Anil Matai**

Director General,  
OPPI India



“India continues to be a beacon of global innovation, and an economic bright spot amidst global uncertainties. Proactive measures by the government and industry players have ensured a robust pharma ecosystem, with tailwinds that position the Indian healthcare market on a high growth trajectory for many years to come.

The Government in its visionary ‘Viksit Bharat’ blueprint, wants to make India the Pharma Powerhouse of the World. And in this quest, it is undertaking various initiatives to help improve the ease of doing business and achieve the sector’s true potential.

We believe the Indian Pharma Market has the potential to be ~\$120 Bn<sup>1</sup> by 2030, indicating a strong headroom for growth for market players. A strategically thought-out India-specific strategy will be required to capitalize on this potential.

This report examines the current industry landscape, key expected changes and opportunities that lie ahead. It also assesses how global corporations have witnessed success (from pharma and other sectors) in growing their portfolio in India. We believe that this report can serve as a blueprint and a strong call to action for all industry stakeholders in helping strengthen their India plans and unleash the growth potential that lies ahead.”

1. Includes domestic sales and exports

# Industry Voices



India is a growing economy with the healthcare sector evolving rapidly, and we are optimistic about the significant growth potential that it presents. **The government's strategic reforms and emphasis on quality** have made India a key market for us. We look forward to expanding our footprint here, contributing to the country's healthcare advancements, and bringing AbbVie's innovative solutions to India.

— Suresh Pattahil, Managing Director and General Manager,  
AbbVie India



Over the past decade, numerous global companies from the pharma and other sectors have achieved significant success in expanding their brands and portfolios in India, underscoring the country's potential. Many of these Global companies have re-engaged with India, leveraging the **improved infrastructure** to conduct global trials for their drugs. **Regulatory reforms, including Rule 101, are a significant step forward**, making it easier for us to **launch new drugs approved in key global markets**. India's growing economy and the **government's commitment** to improving infrastructure make us optimistic about long-term investments in this dynamic market.

— Bhushan Akshikar, Managing Director,  
GlaxoSmithKline Pharmaceuticals India Ltd.



The recent changes in India's regulatory landscape, particularly around intellectual property rights, are highly encouraging. These reforms not only facilitate **easier market entry for Global Pharma companies but also create a more predictable and supportive environment for innovation**. As we continue to invest in India, we are confident that these changes will drive significant growth in the coming years. In the last 5 years, we have seen double digit growth in India, with aspirations to double the business in the next 3-4 years for both our new and existing drugs.

— Prathima Reddy, Managing Director,  
Merck Specialties Pvt. Ltd.



India's healthcare sector is experiencing rapid growth with its vibrant digital landscape, dynamic startup ecosystem, and immense talent serving as key catalysts. The healthcare industry is further encouraged by the strides being made towards creating a stable and predictable policy environment. This progress fuels our optimism for a future where innovative therapies can reach more patients in India faster.

— Sanjay Sharma, Managing Director,  
Bristol Myers Squibb India



The Indian government's strategic focus on boosting the Pharma sector is noteworthy. **By addressing critical issues like clinical trial waivers for globally approved drugs**, India has made it **easier for Global Pharma companies to introduce innovative therapies**. We are excited about the prospects of expanding our presence in India, a market that promises significant growth potential and offers a **lucrative environment for long-term global pharma investments**. We are also hopeful of a **stronger IP protection regime** in the years to come to further strengthen the access to innovative medicines for patients in India.

— Amitabh Dube, Country President,  
Novartis India



**The evolving landscape in India offers significant potential for collaboration and innovation** to drive positive transformations in the healthcare sector. Johnson & Johnson is committed to expanding boundaries of medical innovation and equipping our teams with the expertise and foresight necessary to bring advancements to healthcare delivery in India.

— Jayashri Kulkarni, General Manager,  
Johnson & Johnson Innovative Medicine, India and South Asia



Since 2016, India has seen policy reforms such as the National Patent policy, which has considerably **reduced the incidence of infringements** and yielded favourable outcomes. **Our aspirations and investment appetite for India remain high**, backed by a strong pipeline of innovative therapies that we will be launching shortly. In addition, we are also tapping into the **vast human resource capability** of this country — as evidenced by the establishment of our Global Capability Center (GCC) in Bangalore for R&D. The nation's **digital innovation stack** is advancing rapidly, and we see India as the cradle of digital innovations globally.

— Vineet Gupta, Managing Director,  
Eli Lilly and Company Pvt. Ltd.

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Time is Now

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Chapter 1

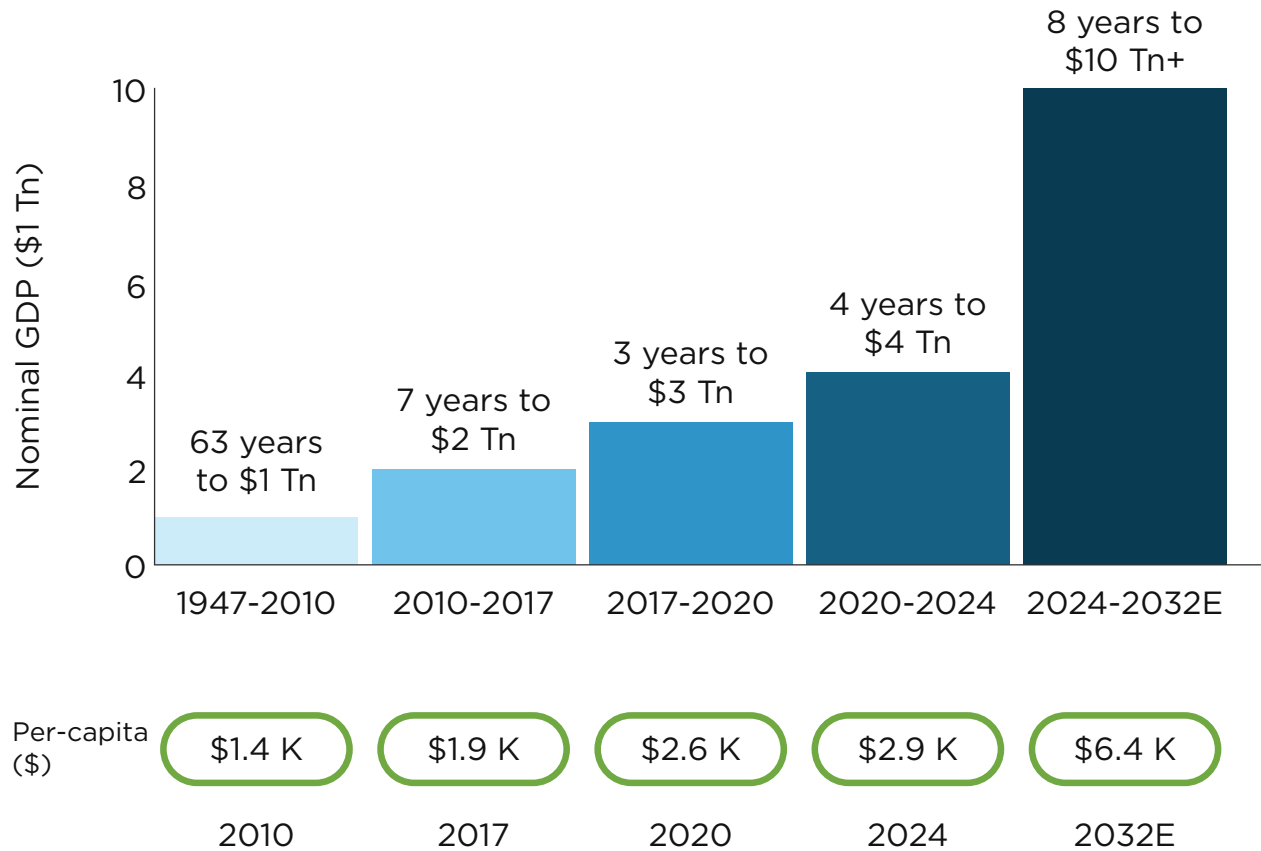
# India Pharma Market Outlook:

Time is Now

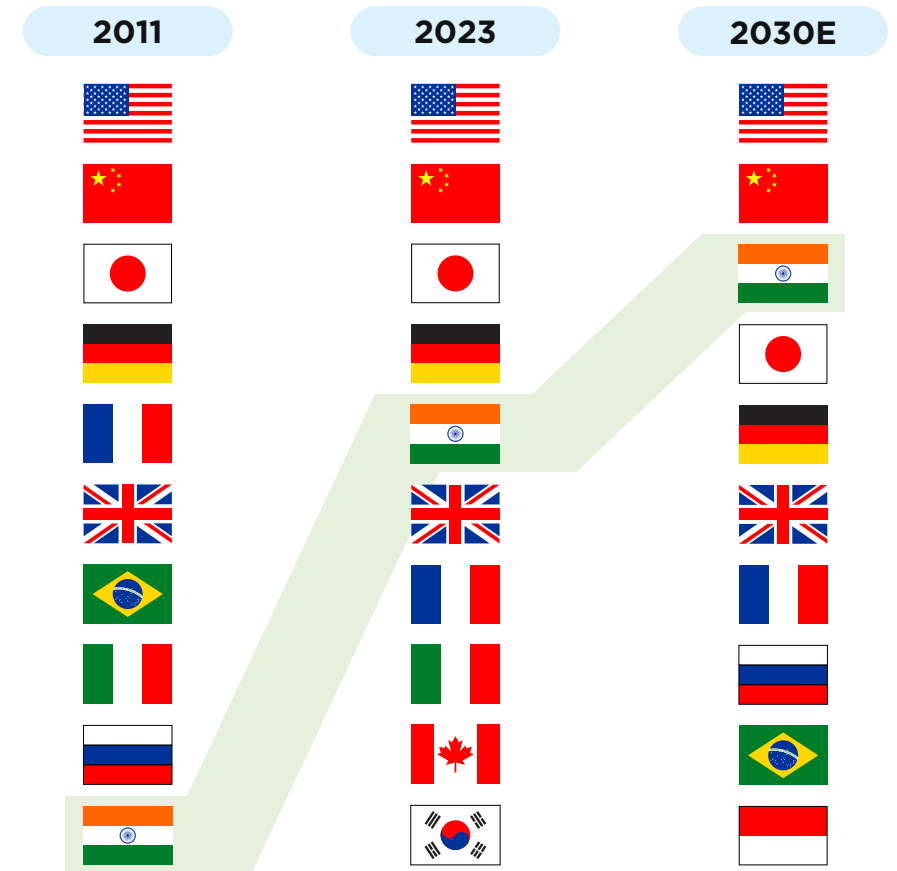


# India continues to be a global bright spot; poised to be \$10 Tn+ economy over the next decade

India to add \$1 Tn every 1.5 years going forward



Expected to be amongst the top 3 GDPs by 2030



Ranking basis nominal GDP

Source: Forecasts by International Monetary Fund, Oxford Economics, The World Bank and Reserve Bank of India, BCG Analysis

# FDI inflows continue to remain strong; global investors are bullish about India

## Higher FDI inflows in India vs. other Asian countries

Country	2022 FDI (\$ Bn)	as GDP %
 China	180.2	1.0%
 India	82.6	2.4%
 Indonesia	21.1	1.6%
 Vietnam	17.9	4.4%
 Thailand	10.2	2.1%
 Philippines	9.2	2.3%

## Global investors are bullish about India

“  
**Goldman Sachs**

India is one of the few bright spots in the global economy. It has a young and growing population, a dynamic private sector, and a government that is committed to reform.

— **Jim O’Neill,**  
**Former Chairman of Goldman Sachs Asset Management**

“  
**J.P. Morgan**

India has sufficient size and scale to fully replace or fully augment the kind of capacity that global investors and global manufacturers seem to want.

— **Mixo Das,**  
**Asian Equity Strategist at JPM**

“  
**Blackstone**

India is one of the most attractive investment destinations in the world. The country has a young and growing population, a dynamic economy, and a favourable regulatory environment.

— **Stephen Schwarzman,**  
**CEO of Blackstone**

Source: World-investment-report-2023 by UNCTAD

# The 2020s is India's decade | Now is the time to enter and scale



As we look for more avenues of growth, **India is one of the top markets discussed** in our board room discussions.

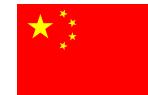
— India CEO, Global Pharma Company



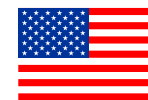
## GDP in 2023 (\$ Tn)



India - 3.7



China - 19.4



USA - 26.9

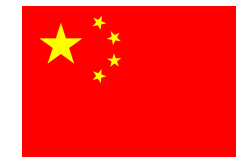


Europe - 17.4

## GDP in 2030E (\$ Tn)



India - 7.6 **(2.1x)**



China - 30.3 **(1.6x)**



USA - 35.0 **(1.3x)**



Europe - 22.2 **(1.3x)**

# India is poised for multi-decade growth

Talent base, Digital Infrastructure and Improving Business Climate will spur future growth and innovation



1

**Strong consumption** growth expected to continue



2

**Sizable government investment** in infrastructure



3

**Manufacturing driven** exports growth

## Enablers

4

Huge talent base with large and growing (young) workforce

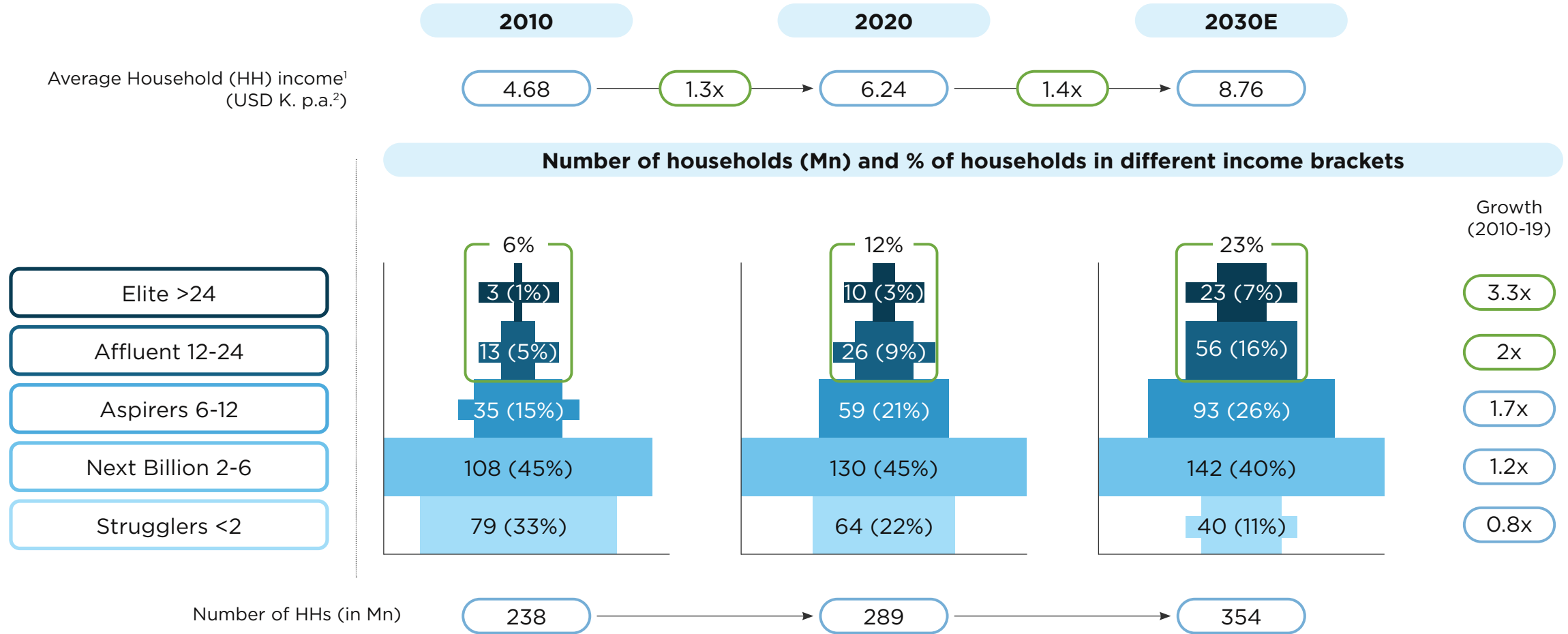
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Pioneering digital infrastructure leading to innovation and efficiency

6

Improved business climate driven by higher ease of doing business

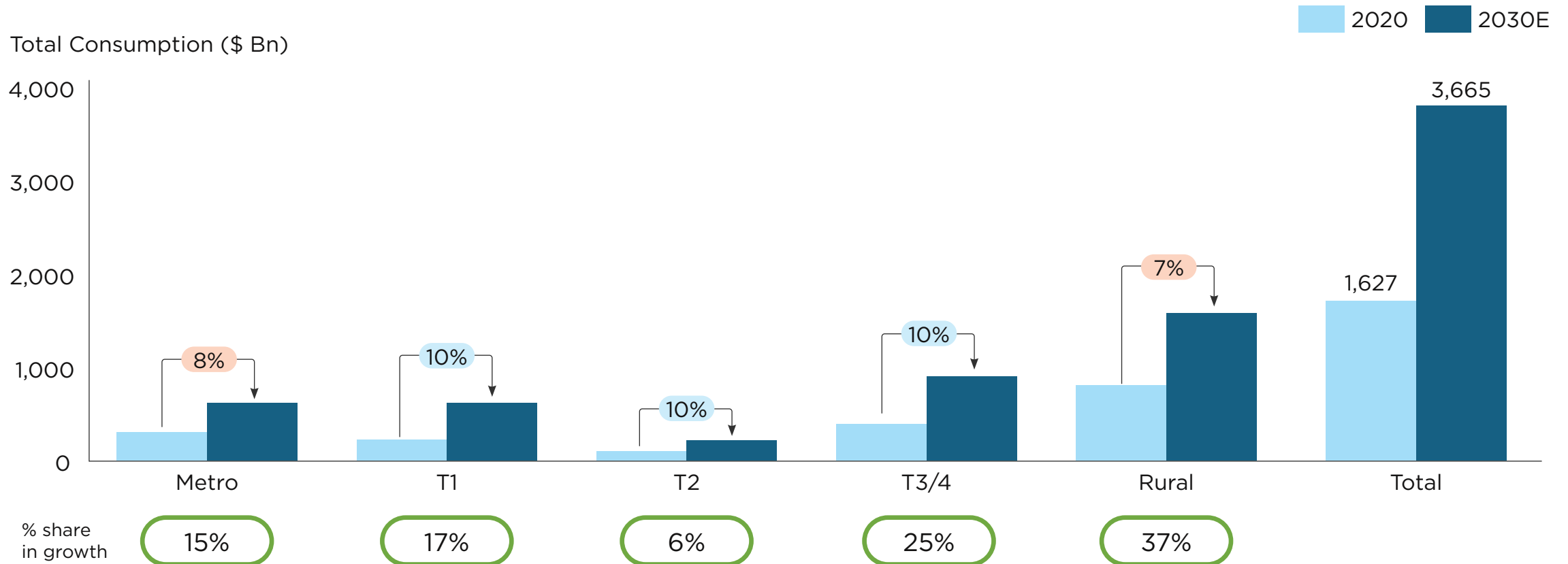
# Affluence is increasing, with ~25% households (80 Mn) projected to be affluent by 2030 (5x in 20 years)



1. Annual household gross income based on 2020 prices; 2. p.a. refers to per annum  
**Exchange rate:** 1 INR is equal to 0.012 USD  
**Source:** BCG CCI proprietary income database, EIU, World Bank

# Consumption growth is expected to be stronger in Tier 1-4 cities

Tier 1-4 consumption to grow at ~10% vs 8% of Metros



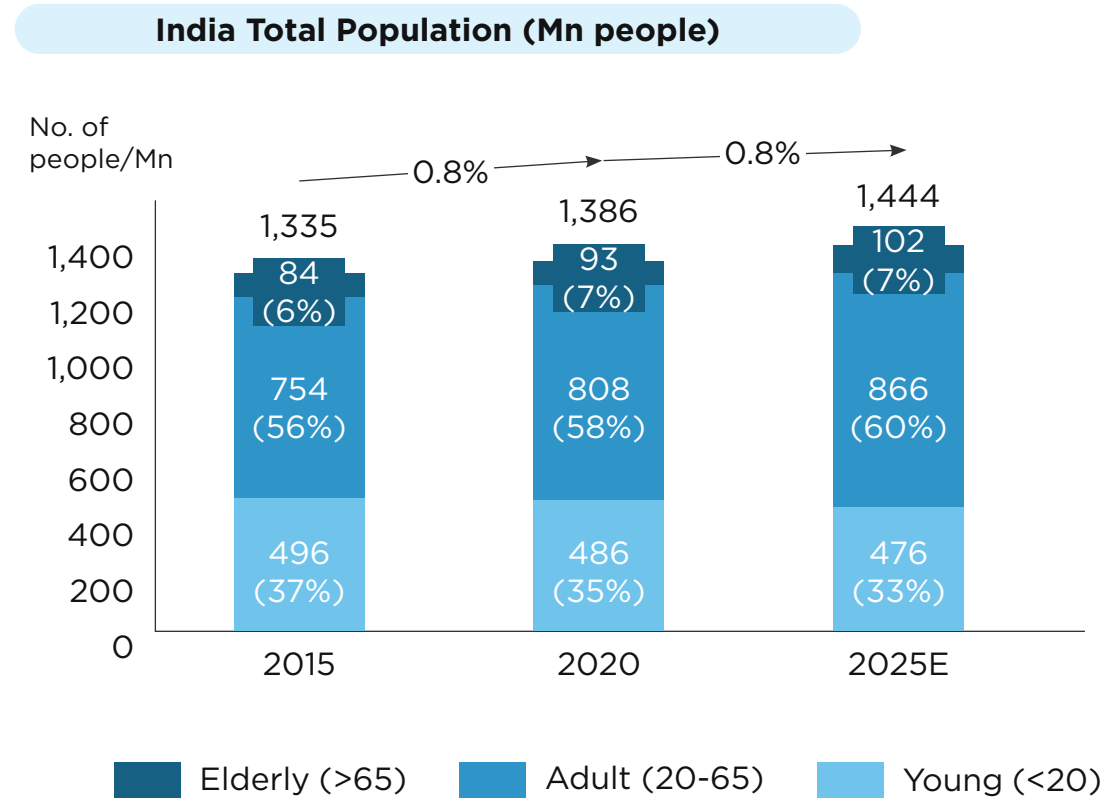
About 50% of future consumption growth coming from tier 1-4 cities

**Note:** City Tier Definition by Population Metros >= 4 Mn, Tier 1 <4 Mn and >1 Mn, Tier 2 >0.5 Mn and <1 Mn, Tier 3 >0.1 Mn and <0.5 Mn, Tier 4 <0.1 Mn and >0.01 Mn  
**Source:** CCI proprietary consumption model, BCG CCI Analysis

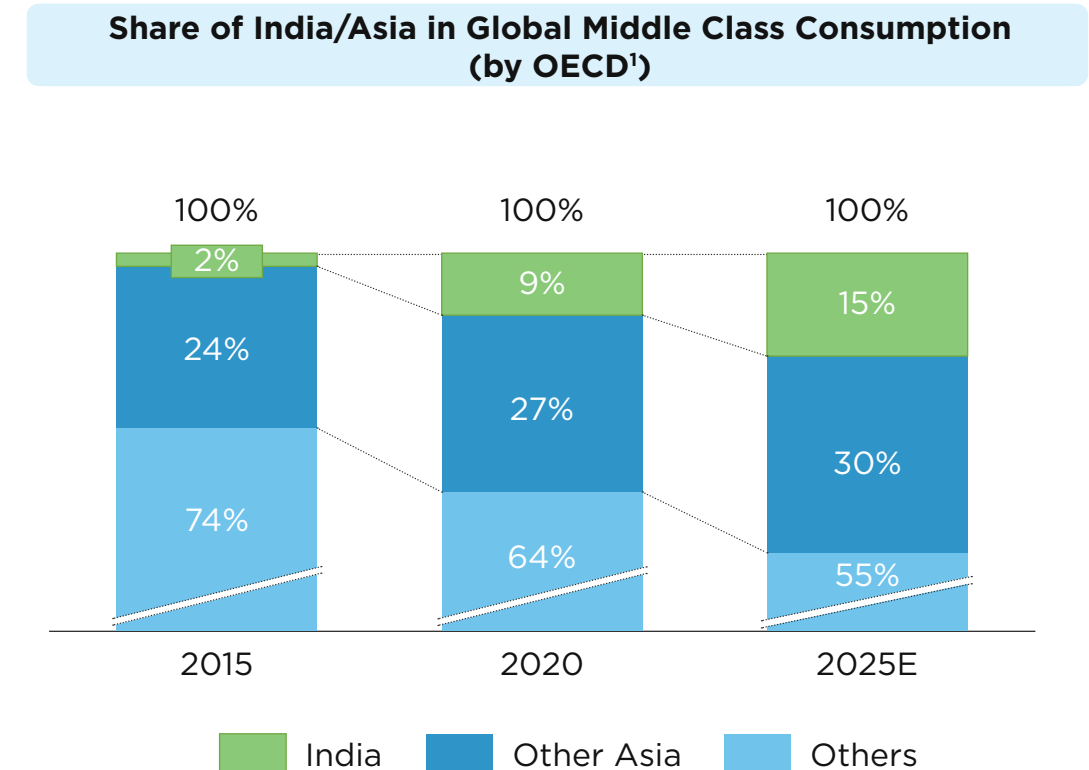


# With an ageing population and rapidly growing middle class, Indian healthcare market is expected to witness sustained growth

India will have a large and ageing population (100 Mn+ elderly) by 2025...



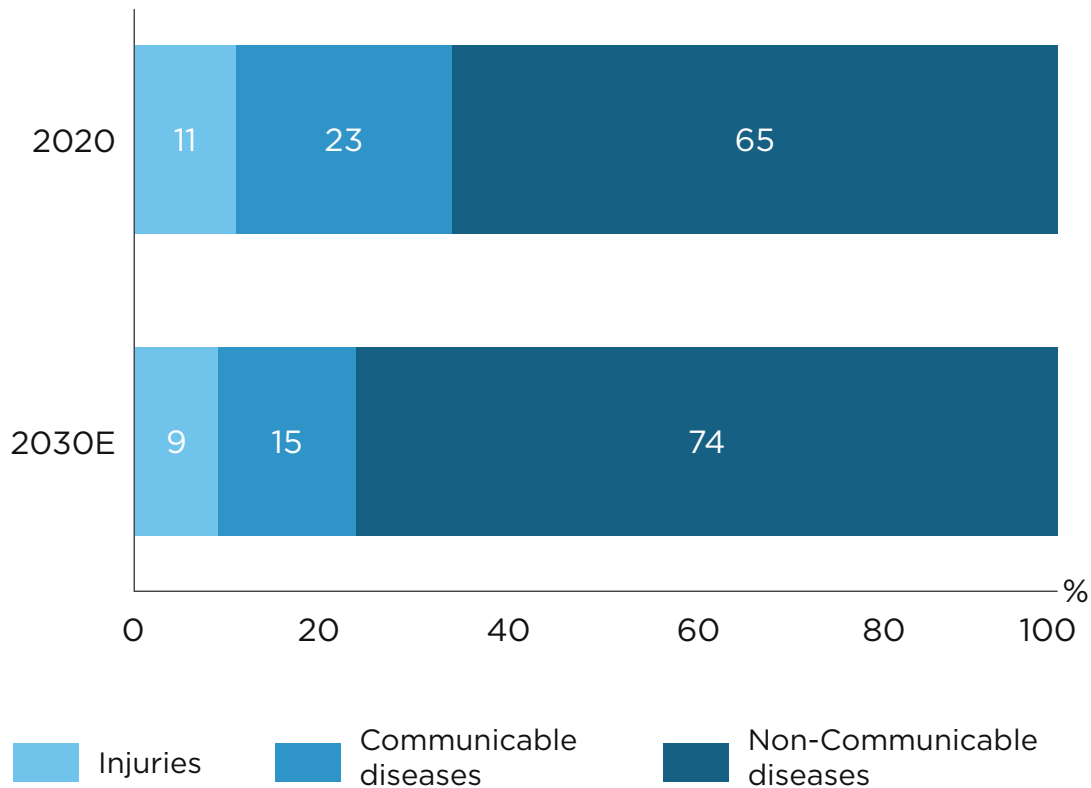
...and a rapidly growing middle class



1. OECD defines the middle class as those earning between 75% and 200% of the median national income  
Source: World bank, OECD, lit Research, BCG Analysis

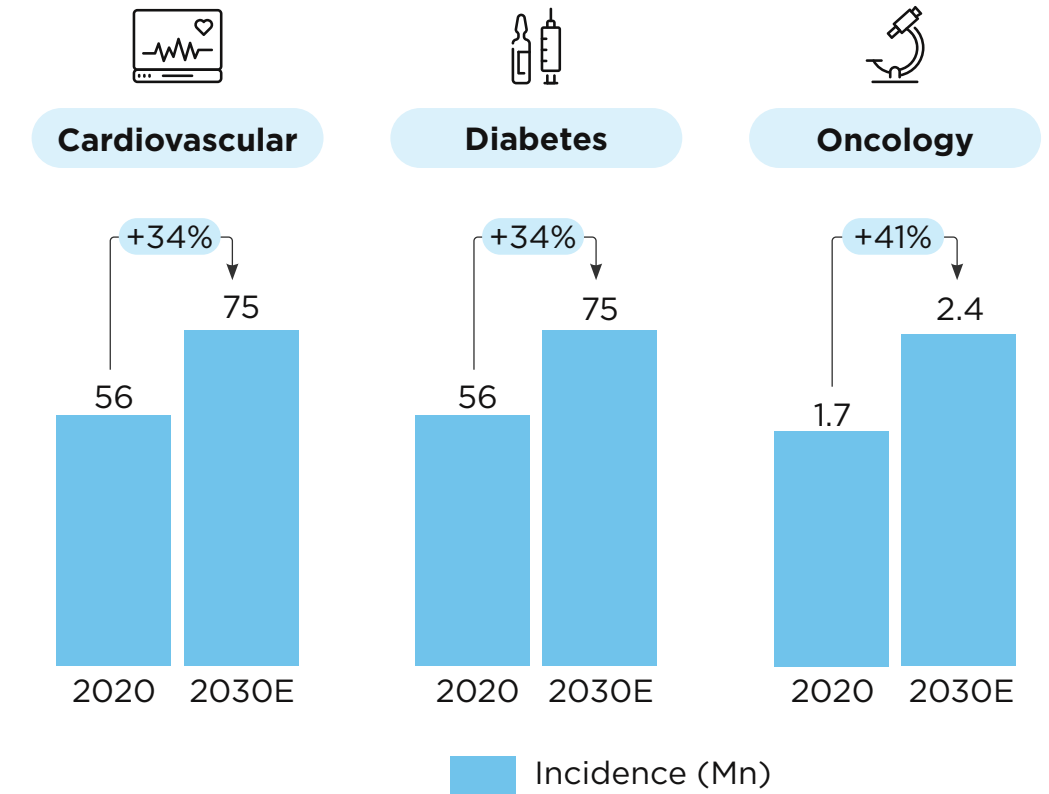
# India's disease profile has shifted significantly in last two decades – NCDs accounted for over ~65% of disease burden in 2020

NCDs<sup>1</sup> are the leading cause of morbidity/mortality in India



Rising incidence of chronic diseases will require innovation in healthcare delivery

Select Examples



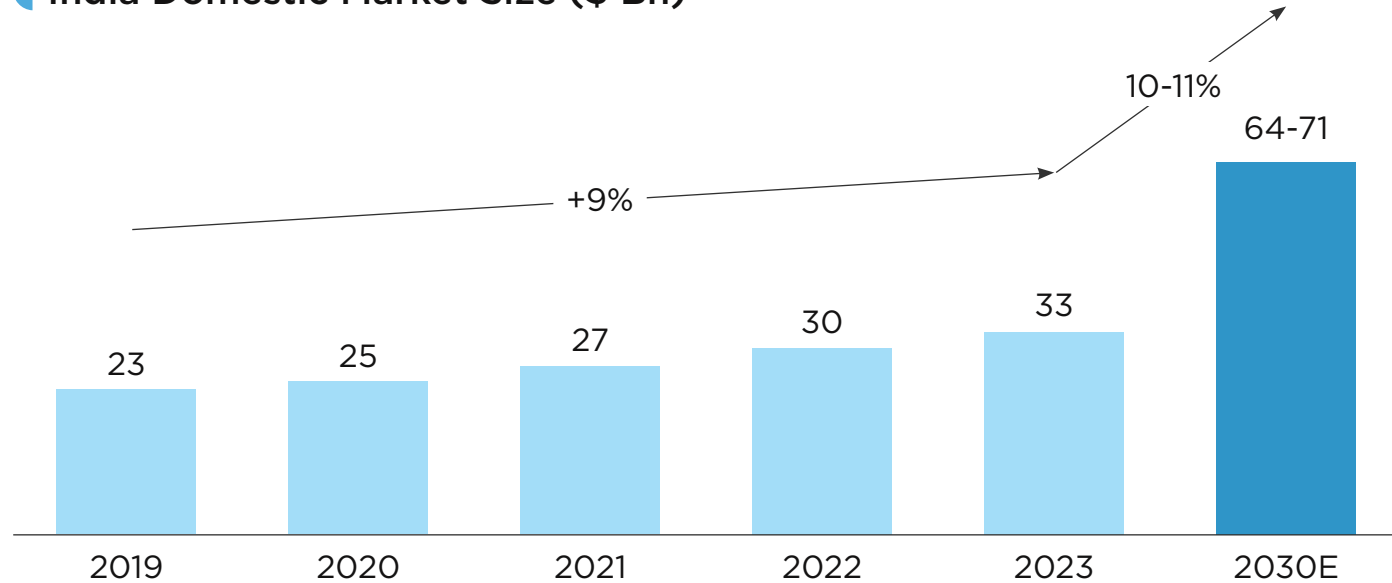
1. NCD: Non Communicable Disease

**Note:** Communicable diseases includes HIV/AIDS and tuberculosis, diarrhoea, lower respiratory and other common infectious diseases, Neglected tropical diseases and malaria, maternal disorders, neonatal disorders, nutritional deficiencies, other communicable, maternal, neonatal and nutritional diseases; Total of deaths (Mortality) and DALYs (Morbidity) have been considered

**Source:** WHO Global health estimates: Leading causes of DALYs 2000 and 2019; DRG, BCG Analysis

# India's domestic Pharma market has grown rapidly; growth expected to accelerate further

## India Domestic Market Size (\$ Bn)



Global Market Growth (2019-23) 7%

EU Market Growth (2019-23) 6%

US Market Growth (2019-23) 9%

## Factors Driving Healthcare Access



Growing insurance coverage and affordability



Improved infrastructure including hospitals and trained doctors

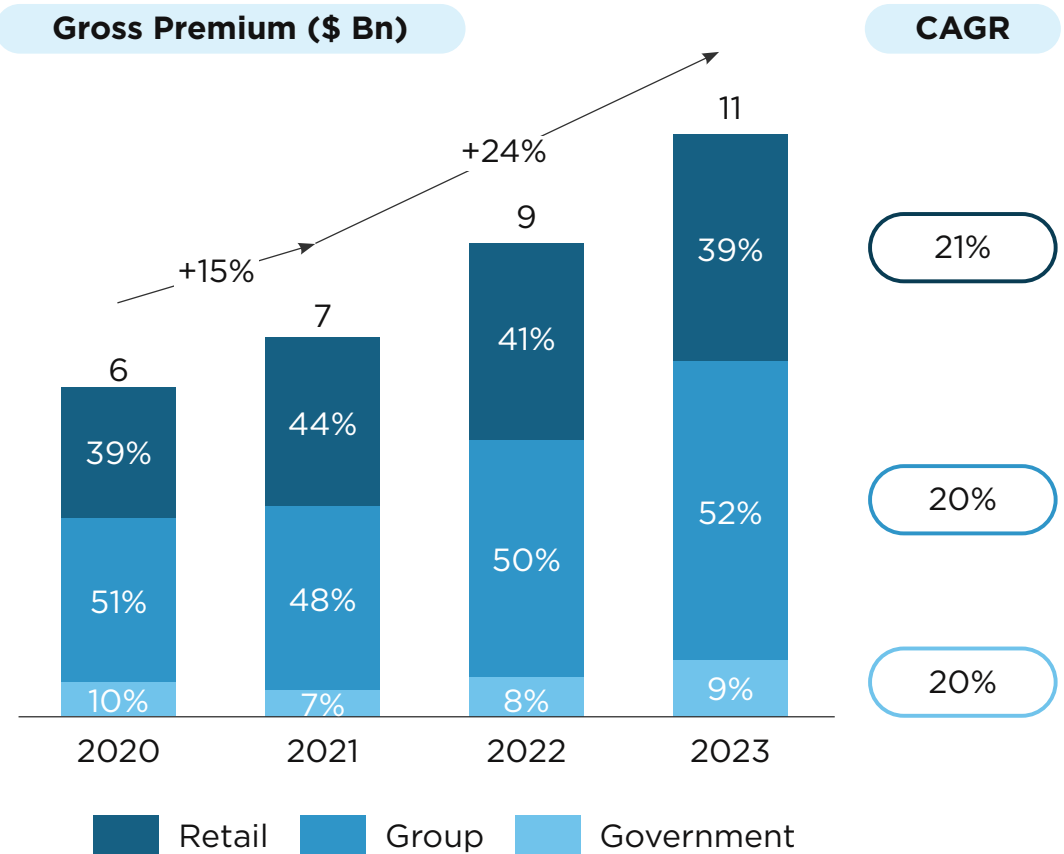



Rising penetration of digital channels including e-pharmacies and e-diagnostics

# Furthermore, India's Health Insurance Market has seen a strong post-COVID growth


India's health insurance market has been witnessing a strong growth

Growth is expected to sustain in future




- 

**Retail**

  - Sustained **increase in lives covered** (population, urbanization, affluence); high growth trajectory of digital channels
  - **Increase in premium per person** (medical inflation, enhanced product features)
  - **SAHIs<sup>1</sup>** expected to sustain **strong growth**
- 

**Group**

  - **SME penetration** expected to increase steadily
  - Indian employers anticipated to increasingly **adopt global corporate standards** to enhance benefits
  - **Price adjustments** post COVID likely to continue
- 

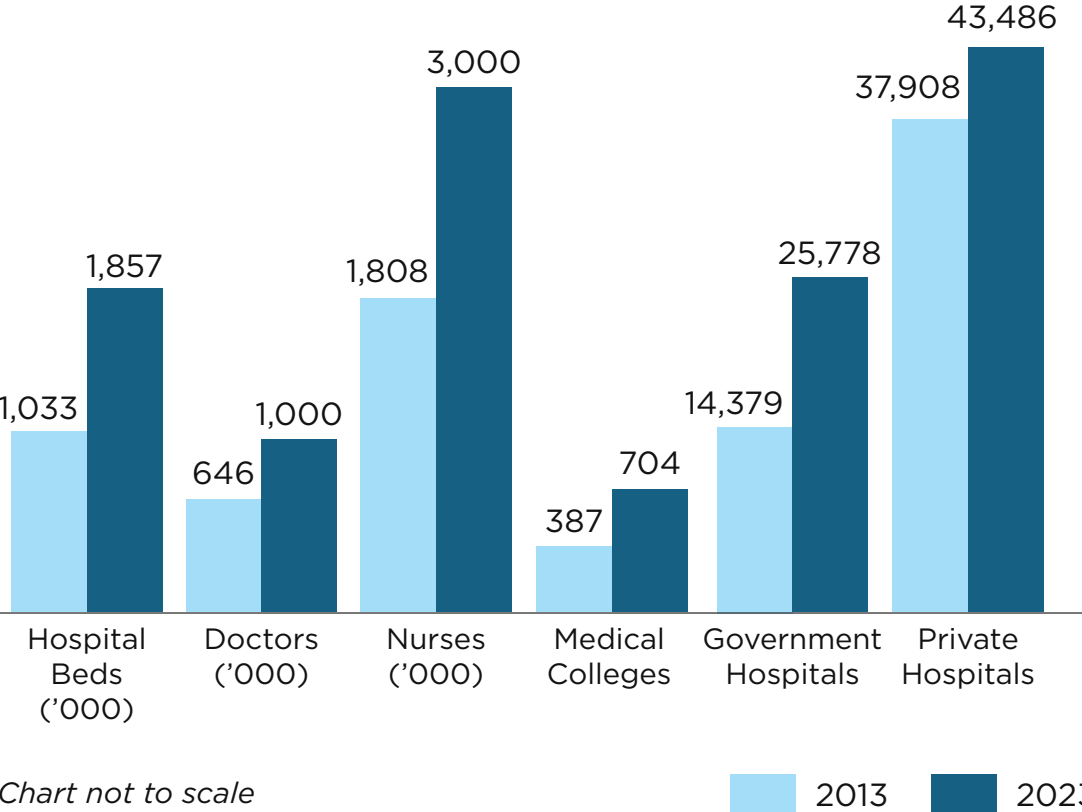
**Government**

  - Further increase in penetration from **AB-PMJAY** (For example, including coverage for citizens aged 70+ years)

1. SAHI: Standalone Health Insurer  
 Source: IRDAI Handbook, Press Releases, BCG Analysis

# India's health infrastructure has experienced notable improvements over the past decade

India's health infrastructure metrics have improved...

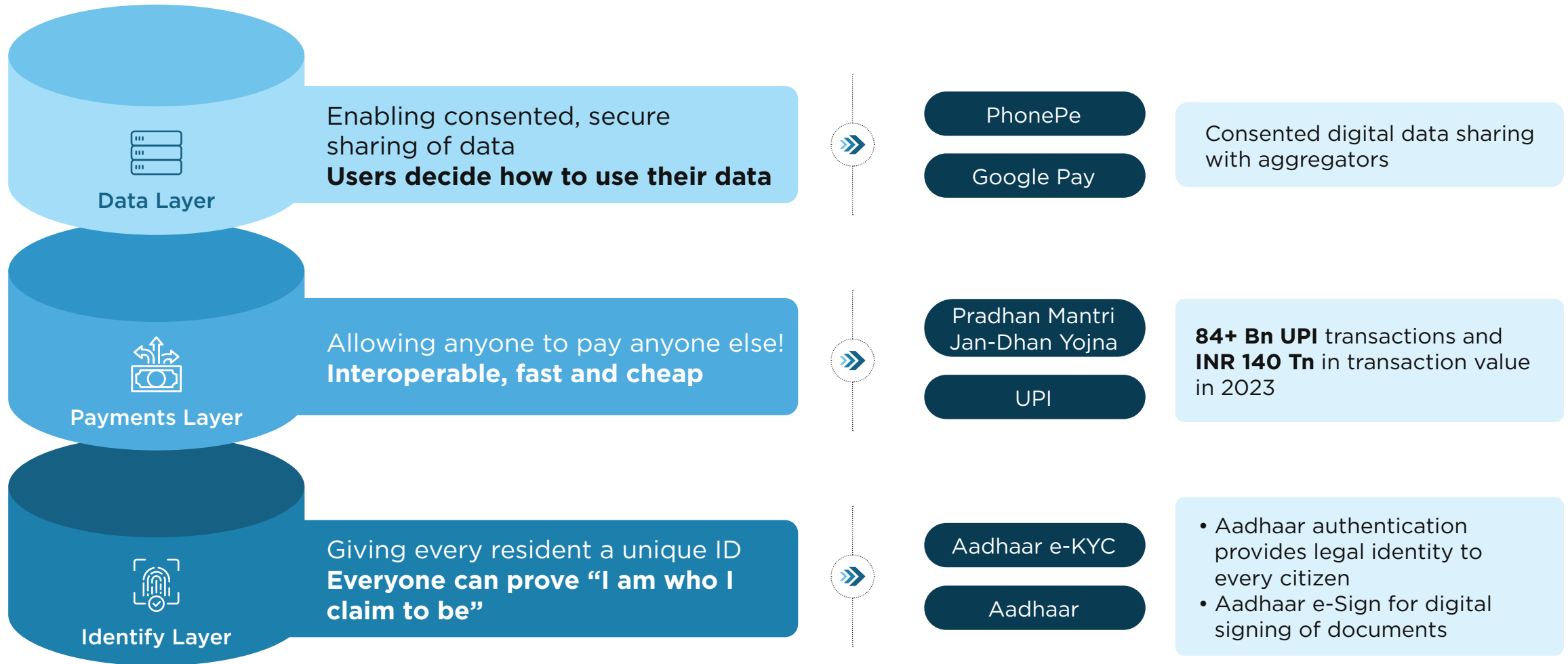


...through multiple structural initiatives

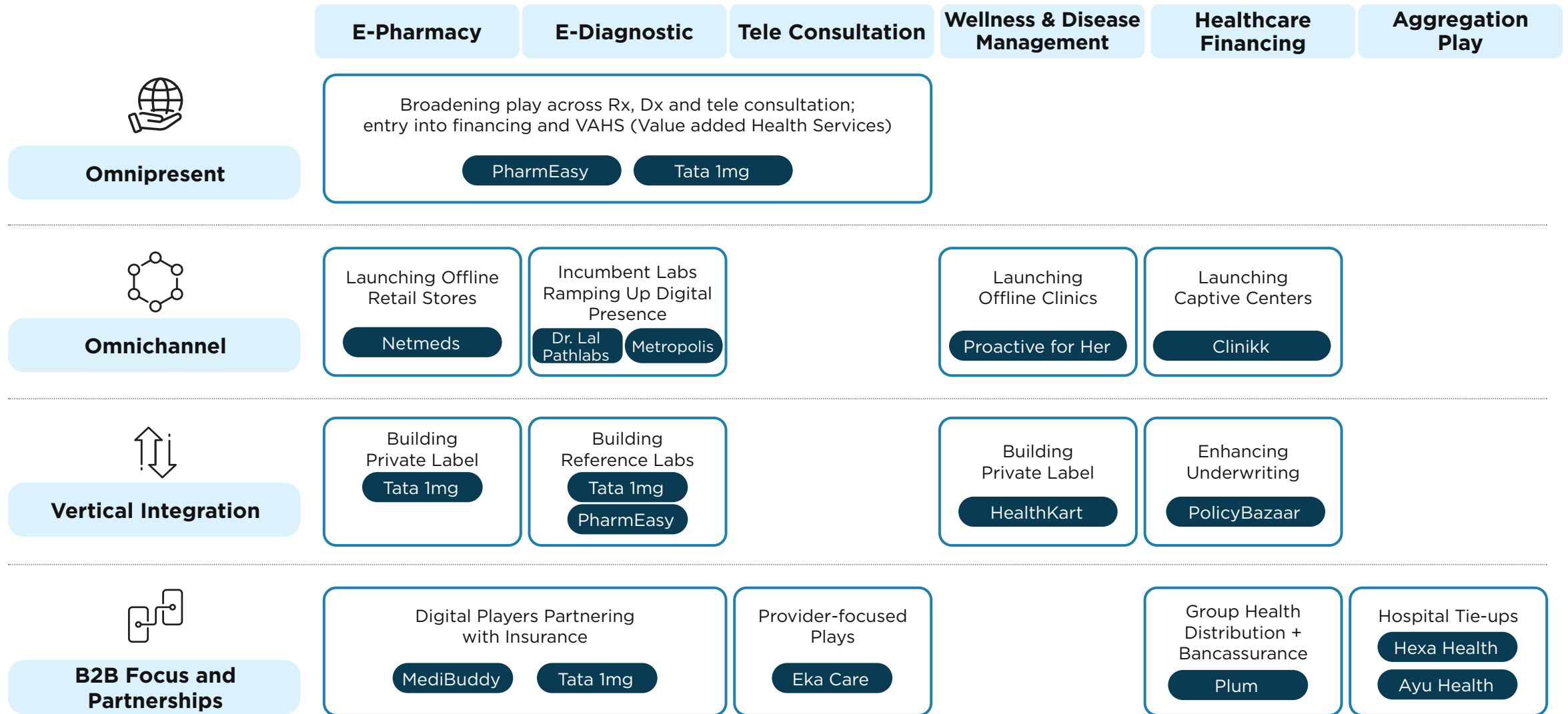
- Increased healthcare budget allocation** from ~\$6 Bn to ~\$10 Bn from 2018 to 2023
- Augmenting existing Primary Healthcare Centres (PHCs) with private sector supported satellite clinics to **improve access to healthcare in rural areas**
- Training and recruitment** of more medical professionals
- Renovating** existing facilities and **expanding patient capacity**
- Increase in number of AIIMS<sup>1</sup>** from 7 in 2017 to 19 in 2023
- ~200 K health and wellness centres** set up for comprehensive primary care in past 4 years

1. AIIMS: All India Institute of Medical Sciences  
 Source: Secondary research, Expert Interviews, WHO, World Bank, MoHFW, National Health Profile, Analyst Reports, BCG Analysis

# India's digital stack is accelerating innovation and growth



# Game changing innovations in digital health are underway



Source: Management Information, Expert Interviews, BCG Analysis



Chapter 2

# **Global Pharma Companies in India:**

Poised for Growth  
Despite a Few Hiccups

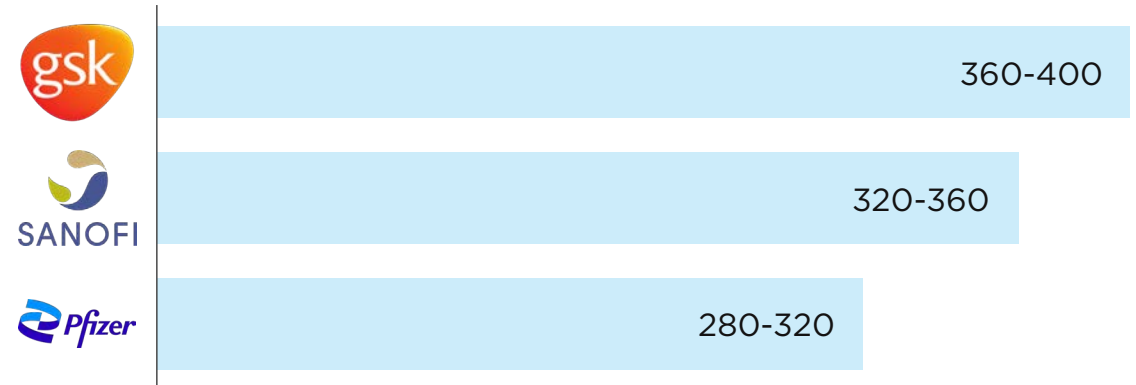


## Global Pharma companies have built sizable businesses in India

Total Sales across Global Pharma companies (2023)

**\$4-6 Bn**

### India Sales (\$ Mn) — 2023



— ”

We have a very sizeable business in India and are now looking for a double digit growth in our core therapies.

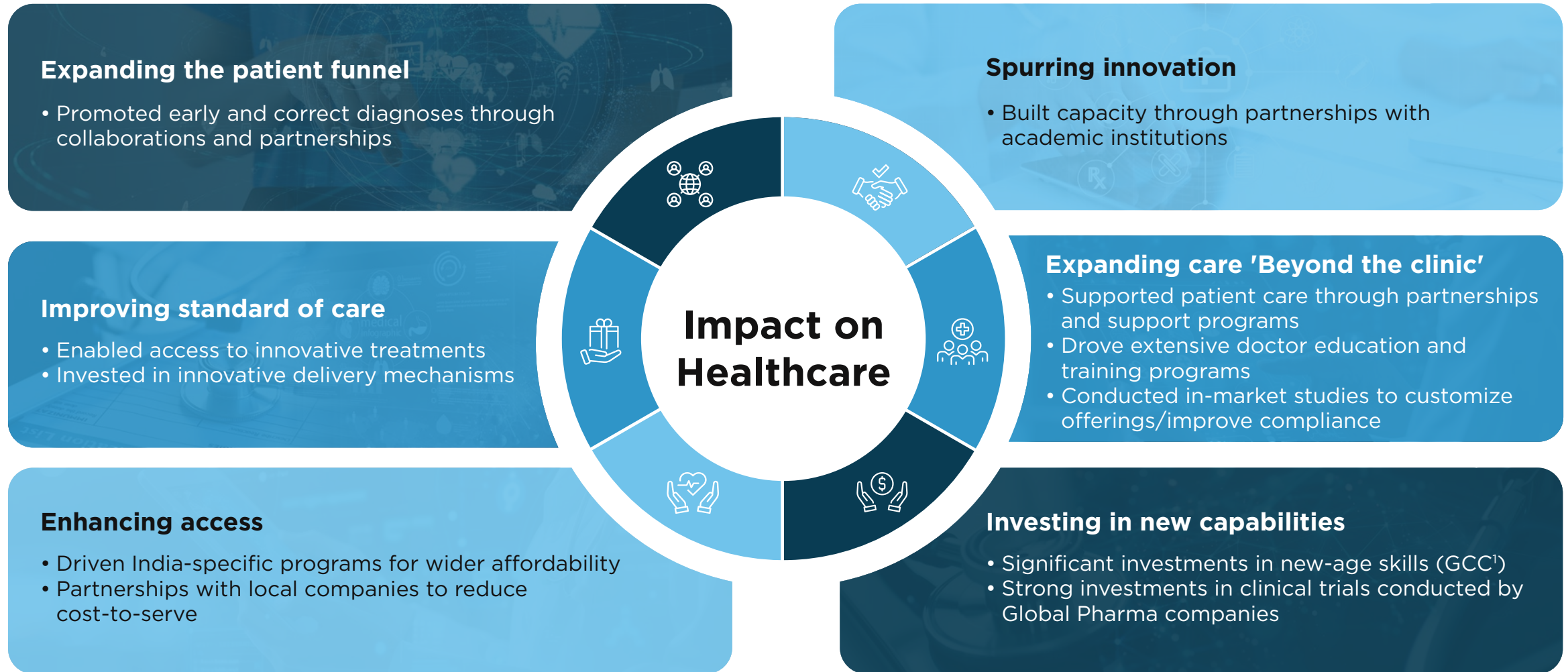
— **India CEO,**  
**Global Pharma company**

— ”

India is a strategic market for us, with many new innovative therapies (our core strength) in the launch pipeline.

— **India MD,**  
**Large Global Pharma company**

# Global Pharma companies have made a notable impact on the Indian Healthcare ecosystem



1. GCC: Global Capability Centers

## Roche's Partnerships to improve Healthcare Infrastructure



- In partnership with ECPM<sup>1</sup>, and MAHE (Manipal Academy of Higher Education) - Roche India launched an executive training program in **drug development and regulatory science**
- Consisted of a 9-month online program that was designed to equip participants with the latest advancements in drug development, regulatory strategy, and business considerations

---

Roche also launched its Clinical Trial Excellence Project, with the aim of enhancing the clinical trial and research capabilities of public health institutions.

This initiative seeks to position government hospitals as CoEs<sup>2</sup> for Clinical Research. In its 1<sup>st</sup> phase, Roche onboarded 9 hospitals in conducting clinical trials in line with international standards.

1. European Center of Pharmaceutical Medicine 2. CoE: Center of Excellence

## J&J's 10-Year Program for Diagnosis of Tuberculosis



- Partnered with FIND (The Foundation for Innovative New Diagnostics) to build capacity and establish new **TB culture and drug-susceptibility testing facilities** in 7+ sites across India
- Partnered with state governments and NGOs to provide >50,000 X-ray tests, ~21,000 molecular tests and 400 ECG machines to enhance early diagnosis and initiate treatment

---

Novartis has made significant investments in providing diagnostic tools and training technicians for leading cancer hospitals.



## Novartis' Launch of Valsartan; innovations in CML treatment



- Launched Sacubitril/ Valsartan, considered a breakthrough therapy for the treatment of Heart Failure patients with reduced ejection fraction
- Launched multiple innovations in CML<sup>1</sup> - for example, Imatinib, Nilotinib and now Asciminib (1st CML treatment that specifically targets the ABL Myristoyl pocket)<sup>2</sup>

Launched Keytruda, an innovative medicine that is now approved for 17 indications across 10 tumor types in India



Launched Hemlibra - world's first bispecific mAb<sup>3</sup> (Factor VIII Function-Mimetic) for the prophylactic treatment of Hemophilia A, enabling patients to actively participate in the workforce



1. CML: Chronic Myelogenous Leukemia 2. Asciminib targets the BCR::ABL1 myristoyl pocket, maintaining activity against BCR::ABL1, which is resistant to most approved adenosine triphosphate-competitive tyrosine kinase inhibitors. 3. mAb: Monoclonal Antibody

## GSK's focus on innovation



- Strengthened its commitment to preventive healthcare by launching Shingrix vaccine to prevent Herpes Zoster, a painful condition in adults > 50 years
- Additionally, GSK's launch of Single-Inhaler Triple Therapy (Trelegy Ellipta) for COPD<sup>4</sup> which combines 3 medications in 1 inhaler providing superior efficacy in controlling symptoms (vs. other inhalers) and improves patient compliance (once-daily usage)

Novo Nordisk launched Rybelsus, a game changing oral GLP-1<sup>5</sup> for diabetes patients, offering weight management benefits



4. COPD: Chronic Obstructive Pulmonary Disease 5. GLP-1: Glucagon-like peptide-1

# Expanding access to a wider pool of patients through innovative solutions programs

Select Examples

## Pfizer's financial assistance program for Palbace



- Over 4,000 patients benefited from the program since its launch, 56% of total Palbace<sup>1</sup> consumption for free through PAP<sup>2</sup> schemes
- Over 1,000 Below Poverty Line (BPL) patients received 100% free Palbace medicine

Offers Patient Support Programs Sambhav (Nivolumab - Oncology) and Aarambh (Luspartacept - Hematology)



1. Palbociclib 2. PAP: Patient Assistance Programs

## Roche's Launch of 2<sup>nd</sup> Brands for Wider and Affordable Access



- Roche partnered with Emcure Pharmaceuticals to manufacture and market **second-brand of Herceptin (trastuzumab) and Rituxan (Rituximab)**
- Through this partnership, both drugs launched by Emcure significantly widened patient access

Partnered with Cipla for Galvus's<sup>3</sup> co-marketing in India



Partnered with Emcure for distribution of Cardace<sup>4</sup>



3. Vildagliptin 4. Ramipril

## GSK's "Trust in Science" Initiative with Regional Centre for Biotechnology (RCB)



- The Trust in Science program offers **full PhD courses in Biostatistics and Bioinformatics** to equip Indian students for careers in a Data and AI-driven pharma research ecosystem
- **INR 10 Cr** has been invested by GSK and Department of Biotechnology for this initiative which **covers scholarship costs**, monthly stipends and provides expert guidance to students

## Pfizer INDovation Program



- Pfizer INDovation Program, in partnership with Social Alpha, Niti Aayog, IIT Delhi, DoP and NIPER (Ahmedabad) supports **incubation of healthcare start-ups** to bring their innovative technologies to life
- Focus on developing **novel healthcare solutions**, including diagnostic innovations, drug delivery platforms, medical devices, and training of healthcare workers
- Pfizer has awarded nearly **\$1 Mn in grants to 40+ startups** and worked in partnership with the Indian government and local universities as part of this initiative

# Extend the care to 'Beyond the Clinic' — Improving patient care and overall experience

Select Examples

## Pfizer's Physical Help Desks in Key Cancer Hospitals



- Pfizer, in partnership with the NGO Doctors For You, has initiated projects to setup **physical help desks at 14 high burden cancer hospitals** across India
- Overall aim is to improve the treatment experience for **cancer patients and their caregivers throughout their treatment journey** by focusing on non-clinical services such as logistic support, financial linkages, and psycho-social services
- The project has positively impacted lives of **6 L+ direct and indirect beneficiaries**

Blue Tree program provides support in improving overall patient experience, ensuring that patients receive comprehensive support and care beyond the pill



Keytruda's patient support programs have dedicated personnel, in virtual and in-person settings, supporting the patients end-to-end across their treatment lifecycle



## New age skill development through GCCs

- Global Pharma companies contribute heavily to **human capital development** through GCCs<sup>1</sup>
  - 78k+ K FTEs are employed across depth and breadth of pharma capabilities (drug development, IT and digital capabilities, commercial analytics and other support functions)

Operates NOCC<sup>2</sup> in Hyderabad, ~8 K FTEs focusing on drug development, manufacturing supply and quality, and digital and IT



Opened **innovation hub** in Hyderabad, to expand the company's drug discovery and digital capabilities



1. GCC: Global Capability Center 2. NOCC: Novartis Corporate Center

## Novo Nordisk's investments in Clinical Trials in India



- Invested significantly in Clinical Trials over the last 20 years, with contribution of **7-10% to global patient load**, presence across **270 medical centers and 150+ dedicated FTEs**
- Initiated major phase 3 trial programs in 2023, for CagriSema (Cagrilintide / Semaglutide) in T2D<sup>3</sup> and Obesity (about 1,000 patients in 70+ sites), and Ziltivekimab in ASCVD<sup>4</sup> and HF<sup>5</sup> (up to 1,500 patients in 110 sites)

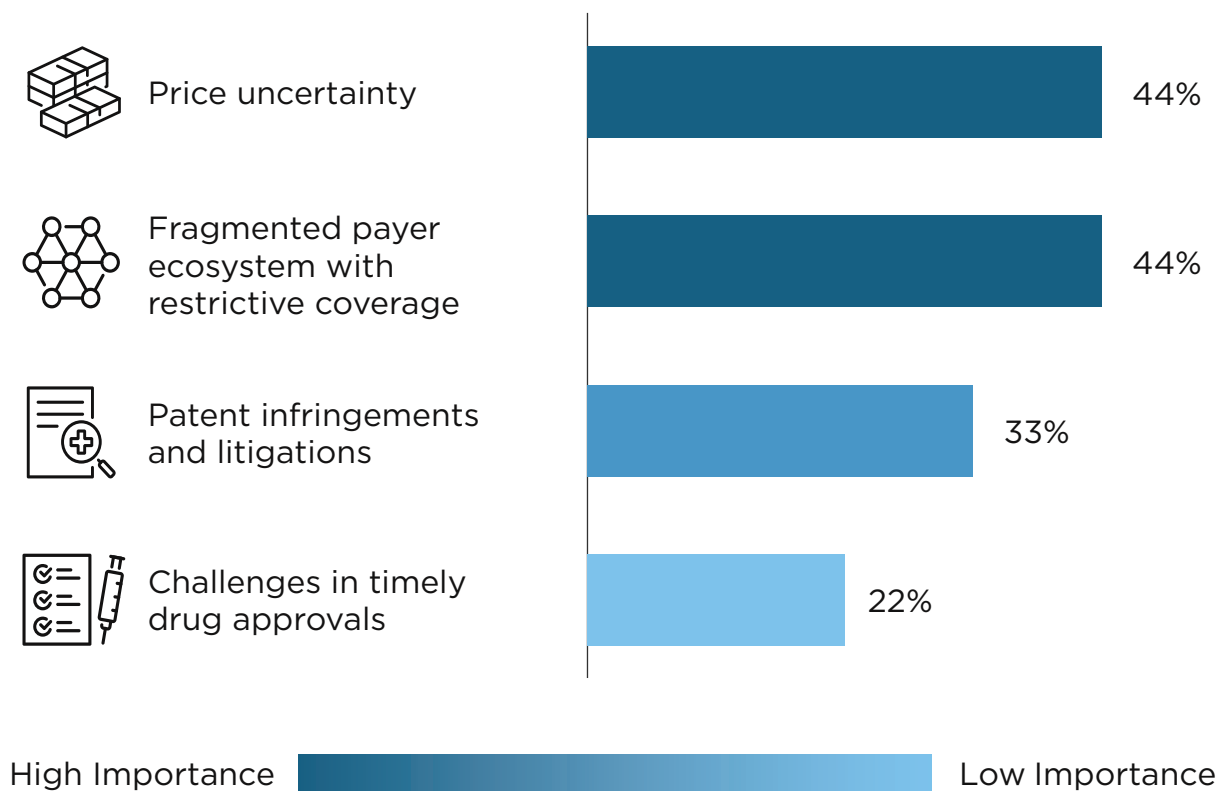
3. T2D: Type 2 Diabetes 4. ASCVD: Atherosclerotic cardiovascular disease 5. HF: Heart failure



# Historically, a few hiccups have constrained growth for Global Pharma companies in India

## Top concerns for Global Pharma leaders

% leaders ranking the issue in top 3 concerns limiting growth  
(from OPPI Executive Member Survey 2024)



— ”

India's **regulatory environment has been difficult to navigate.** The IPR policy is a bit reactive and pricing regime is also unpredictable.

— **India CEO,  
Global Pharma company**



— ”

Historically there have been challenges in timely drug approvals in some therapy areas like Neurology and Immunology.

— **India CEO,  
Global Pharma company**

## Uncertainty in price controls has impacted confidence to invest



NLEM inclusion creates price ambiguity. Every 4 years, **7-8% of my product top-line is eroded** due to inclusion as an essential medicine.

— India CEO,  
Global Pharma company



We are **clubbed in the same cost bucket as some contract manufacturers** whereas we spend more for higher quality standards.

— India CEO,  
Global Pharma company

### Key Challenges

#### Uncertainty around inclusions of products

**Unpredictability** of product inclusion/exclusion in list of essential medicines

#### Concerns on price setting mechanism

Pricing not linked to conversion price variance across manufacturers (for example, level of adherence to GMP norms which may impact end price)

Price increases not linked to the change in raw material costs (especially valid in post COVID period)

Estimated impact from price control on product economics

20%

Average Impact on Revenue

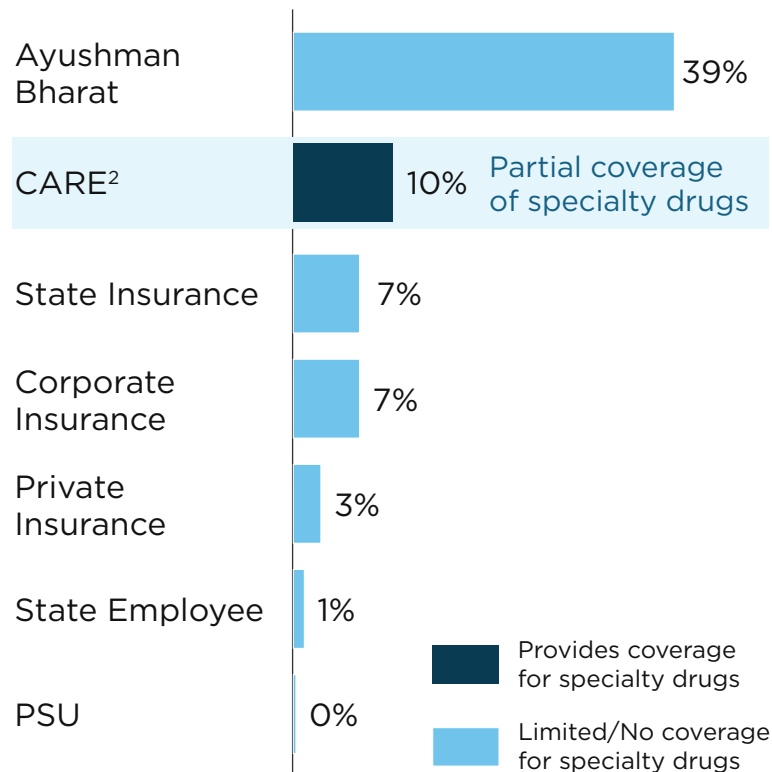
10-12%

Average Impact on Net Profits

# Access to specialty drugs continues to be constrained by non-uniform payer coverage

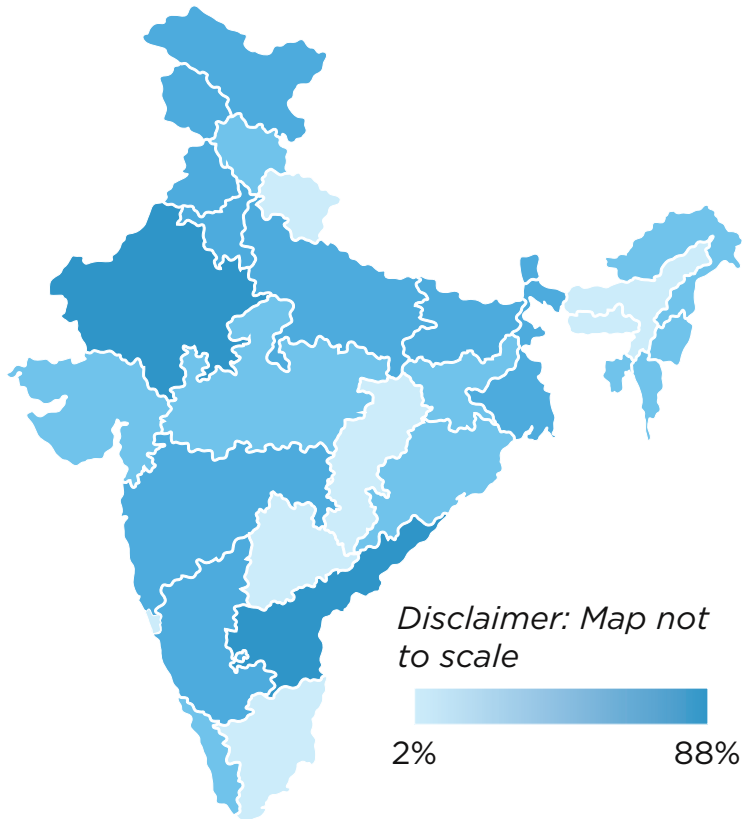
Only 10% of Indian population are covered for specialty drugs

% Population (Mn), 2020



High variance in insurance coverage across states

% Households with >1 insured member (2019-21)<sup>1</sup>



Public payers have different coverage and tendering processes

Variances in public procurement

“  
**One Time/Annual Tenders by States**  
 State tenders can sometimes be only one-time purchases or follow an unpredictable time table for purchases.  
 — Former MD, Global Pharma company

“  
**Formulary listing in ESIC<sup>3</sup>**  
 Significant challenges in getting drugs listed in ESIC formulary — can take more than 12 months of engagement to get products listed and thus see uptakes.  
 — Former MD, Global Pharma company

“  
**Bottom-up demand generation in Army (at start)**  
 At the start, you need to work with the 5 key institutes of Army to generate threshold demand, before your product can be listed in the central formulary.  
 — Former MD, Global Pharma company

1. National Family Health Survey (2019-21) 2. CARE: CGHS, Army, Railways, ESIC 3. ESIC: Employees State Insurance Corporation  
 Source: BCG Analysis

# Some IPR barriers have delayed launches, but recent government actions offer respite



State governments **don't look at the patent status while granting manufacturing approvals.** This leads to multiple legal battles.

— India CEO,  
Global Pharma company



Local Indian company was given manufacturing authorization for Sitagliptin 4 years after patent grant to MSD

MSD approached the Delhi High Court for an infringement case. The court ruled in favour of MSD 2 years later



We have seen pre-grant oppositions being **filed without strong basis** just to delay product launches.

— India CEO,  
Global Pharma company



**Pre-grant oppositions** filed against Entresto (Novartis) in 2016 were resolved in favour of Novartis in December 2022

## Key Challenges in IPR Environment



Missing linkage of patents validity (held centrally) with state level manufacturing and marketing approvals



Sizeable opportunity cost of delayed patent infringement resolutions



Inadequate government monitoring of potential patent infringements



Pre-grant oppositions which can delay launch and reduce protected period

Companies spend sizeable energy and resources in managing legal resolutions

# Concerns on SEC<sup>1</sup> approvals process observed in the drug approval process, mitigations expected in the future

## Key Challenges

— ”

Typically, members are drawn from public institutions that may not have the same expertise / patient load for the target indications. Sometimes, SEC finds it difficult to constitute panel with right level of TA expertise.

— India CEO,  
Global Pharma company



SEC may not have the **relevant therapy area representation** for a thorough review

— ”

SECs **need to be nimbler and agile**. There are some instances of red-tapism and prolonged approval timelines.

— India CEO,  
Global Pharma company



Drug approvals can be delayed due to **prolonged response times** from the SEC

1. SEC: Subject Expert Committee  
Source: Expert Panel Interviews

# Recently approved and upcoming government policies are expected to streamline several of these challenges



## Patent Breach Risks



2016 IPR policy has **reduced infringements and we have seen positive outcomes** in litigations. However, linkage of manufacturing authorizations with patents is vital to reduce further breaches.

— India CEO, Global Pharma company



## Drug Approval Hurdles



The SEC has become relatively more responsive and have digitized submissions. However, there is a **strong scope for improving TA<sup>1</sup> expertise and regulation knowledge** within the committee.

— India CEO, Global Pharma company



## NPPA Price Controls



There is still a lot of **unpredictability in the pricing regime** in the country. Very difficult to gauge when our product will be put under NLEM.

— India CEO, Global Pharma company

## Key Highlights

- New IPR policy launched in 2016 supported IPR awareness, administration and filing of patents
- Since 2015, 4 out of 5 litigations have gone in favour of the innovator
- Government hasn't issued any compulsory licenses since 2012
- State-level manufacturing and marketing authorizations granted without patent validation
- Defined target timelines for response from SEC upto 90 days (previously undefined)
- Digital applications enabled through SUGAM portal
- Reference countries specified under Rule 101 for CT waivers
- SEC committees may not include therapy area representation
- Unpredictability in NLEM schedules discourages investments in branded generics
- Missing quality-based pricing tiers within NLEM orders

● Policy in place and implemented

● Policy under discussion

● Policy to be established

1. Therapeutic Area  
Source: Expert Panel Interviews

# Additionally, select changes to government policies/regulations can go a long way in enhancing overall market attractiveness

## Establish Quality-based Price Controls



- **Institution of quality-based pricing tiers** in NLEM orders
- Separation of **molecules with different MoA<sup>1</sup>** in price controls

83%

## Streamlining SEC Review Process for New Drug Approvals



- Constitution of **SMEs<sup>2</sup> relevant to the drug** and TA<sup>3</sup>
- **Defined guidelines** on approval criteria like number of patients required for trial waivers

70%

## Linkage of Patents to State FDA Authorizations



- **Validation of patents** while granting manufacturing and marketing authorities by state government
- **Stronger monitoring** and resolution process for IPR infringements

39%

1. Mechanism of Action 2. SME: Subject Matter Expert 3. Therapeutic Area 4. Rescaled w.r.t. min. and max. scoring  
Source: OPPI Executive Survey 2024



Relative Importance of Government Initiatives (Average % Rating on a Scale of 0-100<sup>4</sup>)

# A bright outlook | Most leaders recognize the changing environment and are planning investments to drive future growth

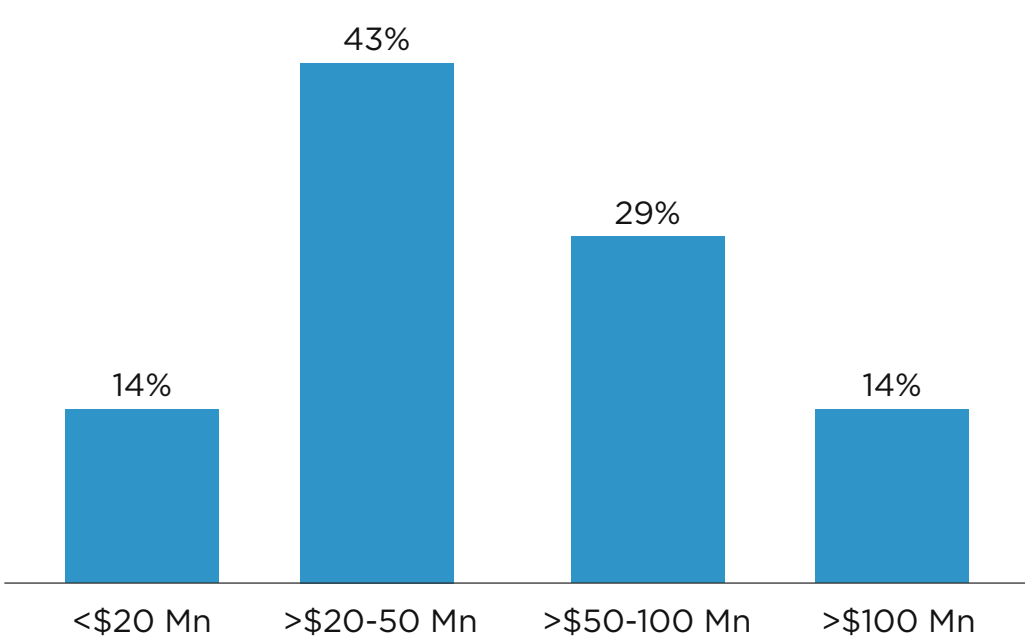
Global Pharma company leaders have high expectations of future growth in India...

**70% Global Pharma companies expected to witness 10%+ annual growth in next 5 years**



...and are planning to ramp up investments in India

**~85% Global Pharma companies are planning invest >\$20 Mn over the next 5 years**



Source: OPPI Executive Member Survey 2024







Chapter 3

**Learnings from other  
Global Non-Pharma  
Companies:**  
Establishing the  
Codes of Success

# 5 common themes emerge across successful Global companies in India



## Select case studies that demonstrate potential codes of success



Adopted regional cluster model to get deep consumer insights and adapt offerings

Adapted products to India and localized manufacturing

Customized go-to-market strategy

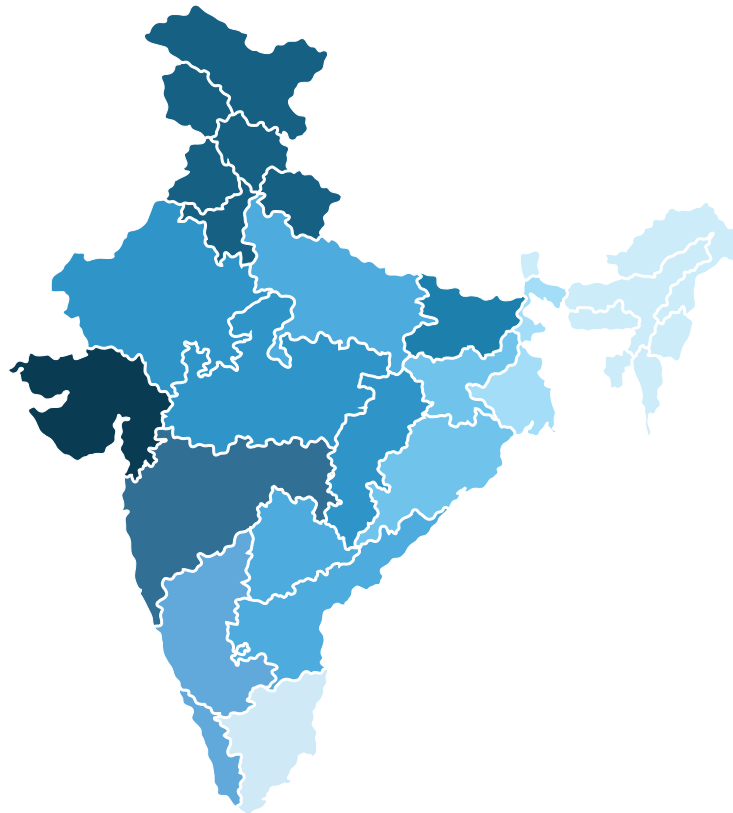
# HUL | Adopted a 'Fit to India' model across its portfolio to win in the market

HUL recognized the need to tailor its GTM for local consumers through establishing regional clusters

14

Segmentation of the Indian FMCG market into 14 homogeneous consumer clusters basis:

- Business Size
- Future Goals/Focus for each cluster
- Demographics and historical landscape



15

Delegated decision making rights to 15 Country Category Business Teams (CCBT) for product variants, trade spends and local marketing

The model has enabled creation of successful regional variants



Ponds Light moisturiser, specifically designed to perform in hot/humid weather



Pepsodent Clove Oil and Salt toothpaste launched in South India, catering to local preferences



Relaunched Wheel with improved formulation in Southern states, to compete in mass washing powders segment



Creation of multiple price-tiers for Rin washing bar, to shift consumers from local brands in Uttar Pradesh



Different formulations of tea in North (focus on colour) vs. East (focus on aroma, flavour)

# HUL | Target product offerings for each segment

HUL has customized its offerings for different customer segments

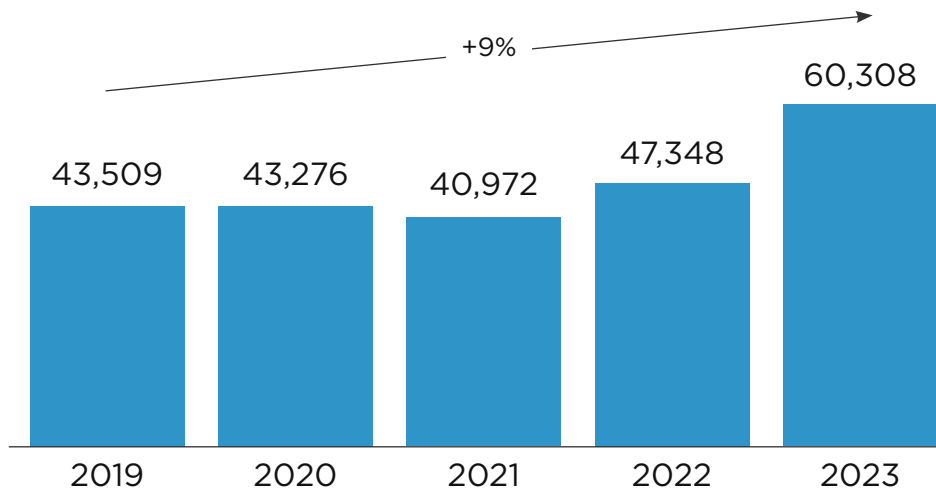


Source: Company website, Press Search, BCG Analysis

# Hyundai | Integrated Korean technology and consumer understanding in its India operating model

Hyundai has established itself as the 2<sup>nd</sup> largest auto player in India...

Revenue (INR Cr)



**India entry:** 1996 (First automobile sold in 1998)

**Employees:** ~8750 (India)

**Products:** Creta, Venue, Xcent, i20 (Passenger cars, SUVs)

...by offering products that were tailored to meet the needs of Indian consumers



## Fit to market products

### Modified product offerings for the Indian market

- Greater ground clearance in cars to account for quality of Indian roads
- Increased leg-room in rear-seats as most cars are for family-use

### Localization of global R&D efforts to meet the needs of the Indian market

- Modifications on global models (like improving ground clearance and dashboard for Creta) done locally at Hyundai India Engineering Centre



## "Indianized" supply model

### Localized manufacturing with more than 90% of models sold in India being manufactured in India

In addition, using India as an export hub (exports to 80+ countries from India)

# Hyundai | Crafted a locally enabled organisation structure to drive growth



## Fine-tuned dual reporting structure

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For example, in functions like Finance and HR, Hyundai manages balance of coordination and execution between Korean and Indian entities



## Focus on driving local agility in operations

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For example, India Engineering Center focuses on India localization and also supports global component development efforts



## Dedicated local capabilities in select functions

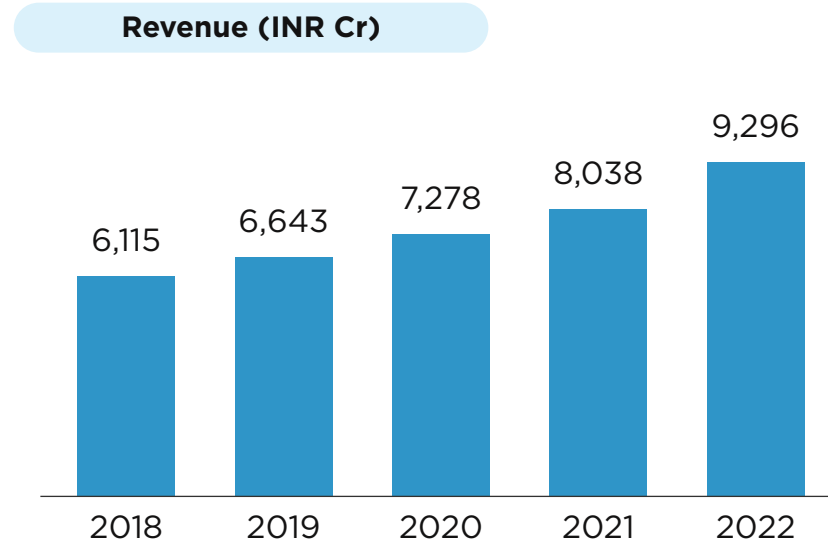
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For example, Consumer Insights capability to drive locally-relevant product adaptations



# Mondelez India | Driving market leadership through localized GTM strategies and emotion-driven marketing

Mondelez India holds confectionary market leadership with ~\$1 Bn+ in sales



**Industry:** FMCG-Confectionary  
**India entry:** 1948 (then operating under Cadbury)  
**Employees:** ~3,500 (India)  
**Key Products:** Dairy Milk, Tang, Bournvita, Oreo, 5 Star

Innovative GTM and marketing strategies that drove market penetration and consumer engagement



**Customized GTM strategy**

**Product line-ups complementing visi-coolers used by mom & pop stores**

- Best in class innovation in local go-to-market



**Surgical Product Positioning**

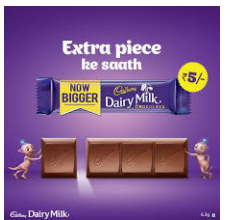
**Redefined India's gifting occasion by targeting emotional sensitivities of local consumers**

- Tapped into culture of celebration to target chocolate towards occasions (for example, Cadbury Celebrations, #BrothersWhoCare)



**Value-based Pricing strategy**

**Lower price points (INR 5 and INR 10) to drive local penetration**



Chapter 4

# **The Road Ahead:** Preparing for Future Disruptive Growth



# Eight key codes of success to Winning in India

## Decipher your core target population

High scale possible even in sub-segments of population (for example, India's affluent population comparable to UK)



## Know your Rxers

Engage early, meaningfully, and strategically



## Pricing in India, for India

Pricing tailored to local reality



## Invest in patient access programs

Partner with multiple stakeholders to improve access



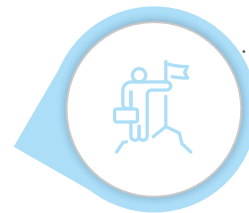
## Empower your local teams

Finding the balance between local deployments and global standards



## Win even before you launch

Start dissemination of therapy knowledge 18-24 months prior to launch



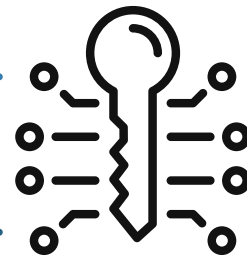
## Leverage partnerships

Partnerships with academic institutions like IITs/NIPERs and local players for capacity building



## Expand the patient funnel

Invest in patient screening and diagnostics, early identification for improved outcomes



# Maximizing these 8 codes will set you up for success (1/2)



**Decipher your core target population**



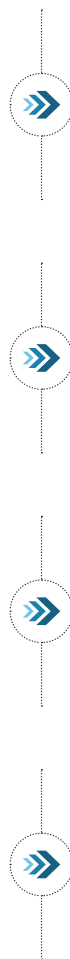
**Know your Rxers**



**Pricing in India, for India**



**Invest in patient access programs**



## Highlights and Examples

High scale possible even in sub-segments



GSK did significant early engagement of core Rxers (Pulmonologists) prior to launch of Nucala (targeting Severe Eosinophilic Asthma in adults), disseminating clinical data and RWE<sup>2</sup> prior and during launch phase<sup>3</sup>.

MSD introduced its DPP4<sup>4</sup> therapies in India at a significantly lower pricing (~INR 40 per tablet in India) to deepen access to diabetic treatments in India.

MSD followed a multi-pronged approach to augment awareness and patient outreach for Gardasil<sup>5</sup>, collaborating with Government bodies (ICMR, MoHFW), local NGOs (like PATH), and international organisation GAVI and WHO apart from regular KOL channels.

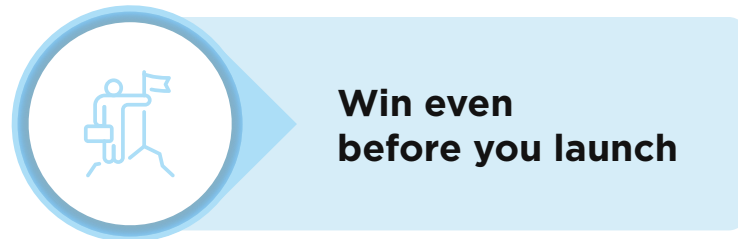
1. Average disposable household incomes adjusted for PPP for Canada: \$30.8 K; UK: \$28.7 K 2. RWE: Real World Evidence 3. Company annual reports 4. DPP4: Dipeptidyl Peptidase-4 5. Vaccine to protect individuals aged 9 to 45 against diseases caused by 9 types of HPV (e.g., cervical, vaginal etc.)

Source: BCG Analysis, Expert Panel Interviews

## Maximizing these 8 codes will set you up for success (2/2)



Roche implemented a **unique cluster-based, decentralized** operating model that empowers clusters to make localized decisions, which in turn has delivered strong business results and reinforced Roche India's strategic importance within the company's global portfolio.



Multiple companies have now started **customizing their indication specific data presentations** according to the practice/specialty type of target HCPs<sup>1</sup>, making the data more relevant in their context.



Pfizer **partnered with NIPER Ahmedabad and others<sup>2</sup> (Pfizer INDovation)** to support startups building high-quality, affordable diagnostics with quick turnaround time, that can be used in low-resource settings. 6 startups, selected after multiple rounds of screening and jury presentations, will receive a grant of INR 25 L each, along with incubation support for 12 months.



Roche has partnered with doctors through **"The Blue Tree Program"** to conduct biomarker tests across cancer types (2500+ diagnostics test kits distributed). This has **benefitted 17 K+ patients in India** to access timely diagnostics and treatment.

1. HCPs: Healthcare Professionals 2. Department of Pharmaceuticals, NITI Aayog and Social Alpha are the other anchor partners

# Additionally, Global Pharma companies may consider differentiated operating models for mature brands

## Key Considerations for Operating Model Selection



### Strategic Importance of Portfolio, Including Future Pipeline

Even near LOE, **some products are important to a company's TA specific product line.** We would not consider divesting the older products in the TA

— Former MD, Global Pharma company



### Enhancing In-market Competitiveness

Global Pharma companies will often partner with domestic companies to **increase their market competitiveness**

— India CEO, Global Pharma company



### Current Market Reach

Need to **go deeper into the country for branded generics.** If we don't have that reach, we will look to get that through co-marketing agreements

— Former MD, Global Pharma company

Source: Expert Panel Interviews

## Operating Model Options



Product licensing and distribution agreements



Second brand launch with lower pricing

## Select Examples



Novartis entered into **agreements with JB pharma** to enhance access competitiveness of select ophthalmology products



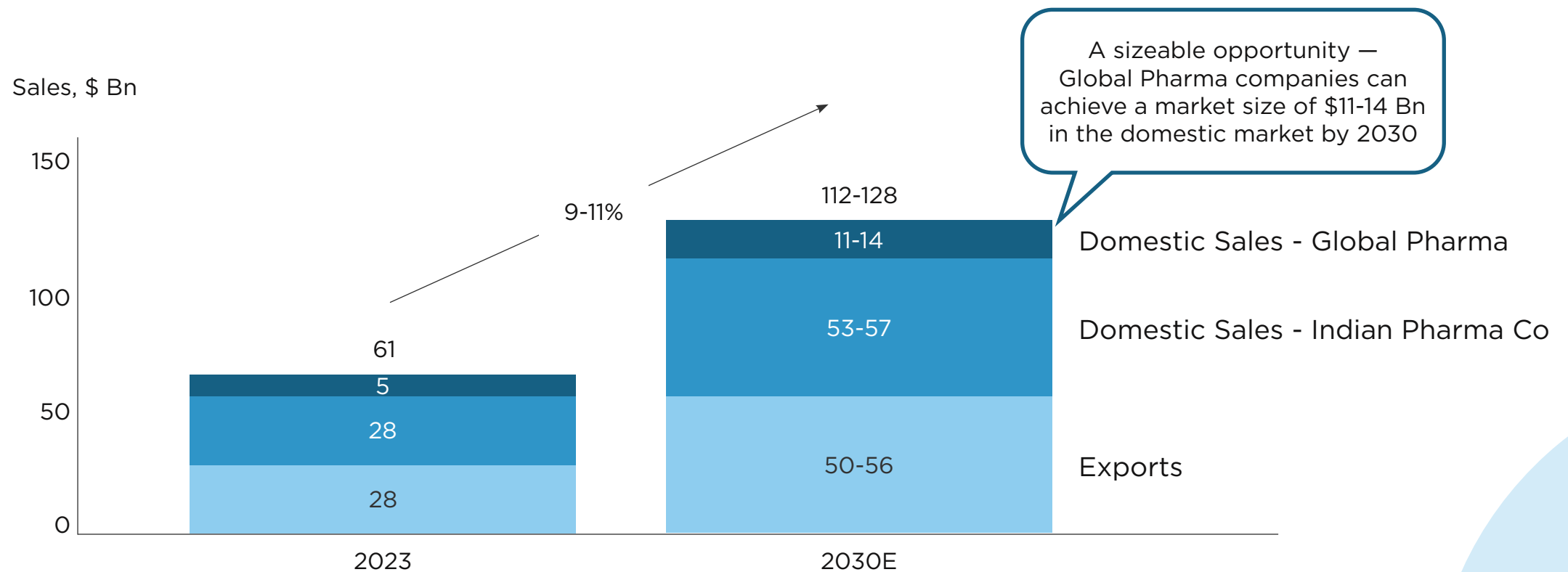
GSK appointed **Goapptiv as super-stockist** for non-promoted brands to improve access, reach



4 years after Brilinta's launch in India, AZ partnered with Sun Pharma to launch an **affordable brand Axcer to drive reach in Tier 2+ regions**

# Indian Pharma Market is poised to double by 2030, creating significant opportunity for Global Pharmacos

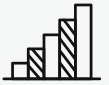
## Opportunity for Global Pharma Companies to capture disproportionate growth



# Strategic Imperative | 3 springboards for growth

## Launch Excellence

### Launch considerations for pipeline products



Market assessment



Segmentation and targeting



Access and pricing



Positioning and messaging



Execution organisation and capabilities



KOL advocacy

## Shaping and Investing in the Market

### Ensure wider access to treatments



KOL engagement and therapy shaping



Finetuning pricing and patient support programs



Salesforce excellence, powered digitally



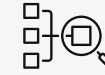
Partnerships to expand patient awareness and early screening



Investments in patient diagnostics

## Lifecycle Management

### Drive higher product Lifetime Consumer Value



Leverage co-marketing and distribution models



Evaluate line extensions for brands



Access and pricing programs (including second brands)





# Acknowledgments

This report has been co-authored by Boston Consulting Group (BCG) and Organisation of Pharmaceutical Producers of India (OPPI). We thank all the participants for their contributions in developing this report.

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This report is a joint initiative of Boston Consulting Group (BCG) and OPPI. We thank all the participants for their valuable time and thought-provoking inputs, that have helped towards enriching the contents of this report.

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Organisation of Pharmaceutical Producers of India

