



Indian Pharmaceutical Industry Survey: FY27 Outlook

July 2026

Table of contents

03 Foreword

07 Navigating growth amid headwinds

15 Scaling business through market expansion

20 Identifying growth levers for product development

26 Integrating sustainability and quality assurance

30 Enabling technological transformation

34 Shaping the workforce of tomorrow

41 Strengthening regulatory compliance capabilities

48 Connect with us

49 References

Foreword



Joydeep Ghosh

Partner,
Leader - Life Sciences & Health Care,
Deloitte South Asia
joghosh@deloitte.com

India's pharmaceutical industry has evolved into a globally resilient sector, underpinned by its longstanding position as the "pharmacy of the world". This competitive edge is rooted in the country's cost-efficient manufacturing ecosystem that draws on a vast pool of scientific talent, robust research institutions, and massive production capacity. These strengths have helped Indian firms deliver essential medicines at affordable prices without any compromise on standards, thereby gaining prominence across both highly regulated and fast-growing emerging markets. Moreover, a series of government initiatives, most notably the Production-Linked Incentive (PLI) schemes for pharmaceuticals and bulk drugs, have helped channel strategic investments into critical areas such as advanced process technology, capacity expansion and Research and Development (R&D).

Today, the Indian pharmaceutical industry is prominent on the global stage, ranking third by volume and eleventh by value.ⁱ The ecosystem boasts more than 3,000 firms and roughly 10,500 manufacturing units. The breadth of the Indian generics portfolio is remarkable. It encompasses an estimated 60,000 brands across 60 therapeutic categories, accounting for almost 20 percent of the world's supply by volume. In addition, India hosts the highest number of United States Food and Drug Administration (US FDA)-approved plants outside the US, a testament to the sector's adherence to stringent quality and compliance benchmarks that inspire confidence among international buyers.

Export growth has further supported the sector's expansion. From a modest US\$1.9 billion in FY01, pharmaceutical exports surged to US\$30.5 billion in FY25, a near 16-fold increase, reaching more than 190 countries.ⁱⁱ About half of these shipments are destined for highly regulated markets such as the US and Europe, underscoring the broad international acceptance of Indian medicines. Even during recent geopolitical disruptions, trade-route challenges and volatile demand patterns, the export segment has shown resilience, surpassing US\$31 billion in FY26 and delivering modest year-on-year growth.ⁱⁱⁱ This robust export performance reflects rising global demand for affordable therapeutics as well as sustained foreign investment and confidence in India's manufacturing and regulatory capabilities.

Looking ahead, the industry stands at an exciting inflexion point, driven by digital transformation, cutting-edge research and development and expanding global opportunities. India's strong STEM talent base, the rapid expansion of contract development and manufacturing organisations (CDMOs), and the emergence of a thriving AI-led R&D ecosystem of Global Capability Centres (GCCs) have positioned the country as a hub for next-generation drug innovation. The combined value of the domestic and export markets, estimated at around US\$60 billion in 2025, is projected to double to US\$130 billion by 2030.^{iv} This growth trajectory is propped up by several high-potential segments, including GLP-1 analogues, oncology therapies, biologics and cell-and-gene treatments. Moreover, a looming global patent cliff totalling more than US\$200 billion is expected to open up substantial market space for Indian manufacturers to capture revenue from ageing blockbuster drugs.^v

However, a set of near-term challenges could temper this optimism. Geopolitical tensions, particularly those linked to the West Asia conflict, have disrupted trade routes, driven up freight costs and introduced uncertainties into supply-chain timelines. Besides, the industry's heavy reliance on imported

key starting materials and Active Pharmaceutical Ingredients (APIs), especially from China, creates vulnerable supply chains and exposes manufacturers to price volatility. At the same time, intense pricing pressure in major markets, most notably the US generics segment, combined with consolidating buyers and fierce competition, has squeezed margins. Regulatory scrutiny also remains high, with agencies such as the FDA imposing rigorous compliance standards that increase operating costs and, at times, lead to plant disruptions. Additional headwinds include currency fluctuations, inflationary input costs and rising expectations around environmental sustainability and ESG practices, all of which add layers of operational complexity for Indian pharma firms.

Against this backdrop, Deloitte conducted a survey of CXOs in H12026 from Indian pharmaceutical firms with annual turnovers exceeding INR10,000 crore. The survey seeks to understand how leading companies are preparing for the next wave of development in FY27 and beyond.



Key findings from the survey



The survey findings reflect cautious optimism among Indian pharmaceutical companies as they navigate the opportunities and challenges shaping FY27 and beyond.



Navigating growth amid headwinds

The Indian pharmaceutical industry is poised for sustained momentum in FY27, where CXOs carefully align growth with strategic transformation and disciplined cost management to sustain competitiveness and margins.

Scaling business through market expansion

Leaders plan to adopt a measured expansion approach, combining organic growth with selective inorganic funding sources, while broadening their geographic footprint beyond core markets for diversified growth.



Identifying growth levers for product development

CXOs are strengthening core therapy portfolios while expanding into specialised segments, supported by robust capacity enhancements and a growing focus on advanced R&D areas such as biologics, biosimilars and next-generation therapies.

Integrating sustainability and quality assurance

Incumbents aim to embed sustainability into core manufacturing practices while enhancing quality assurance capabilities, with a greater focus on process improvements, automation and skill development.



Enabling technological transformation

CXOs plan to take a pragmatic approach to technology transformation, focusing on scalable, near-term use cases such as automation and Artificial Intelligence (AI), while fortifying internal capabilities to overcome adoption challenges.

Shaping the workforce of tomorrow

Executives are focusing on a build-and-retain talent model, strengthening internal skill development across manufacturing, digital, and leadership roles, while managing attrition rates across junior and senior levels.



Strengthening regulatory compliance capabilities

CXOs are calling for an ecosystem-driven, tech-enabled regulatory environment, supported by stronger government enablers, collaborative policymaking and global alignment to accelerate market access and enhance competitiveness.

Executives are pursuing a balanced portfolio of growth levers, including revenue expansion and profitability improvement, market diversification, product and capacity enhancement, sustainability integration, technology adoption, workforce development and regulatory and capabilities enhancement. Collectively, these strategic priorities indicate an industry that is not merely reacting to current uncertainties but actively building a more resilient, compliant and future-ready operating model.

Navigating growth amid headwinds





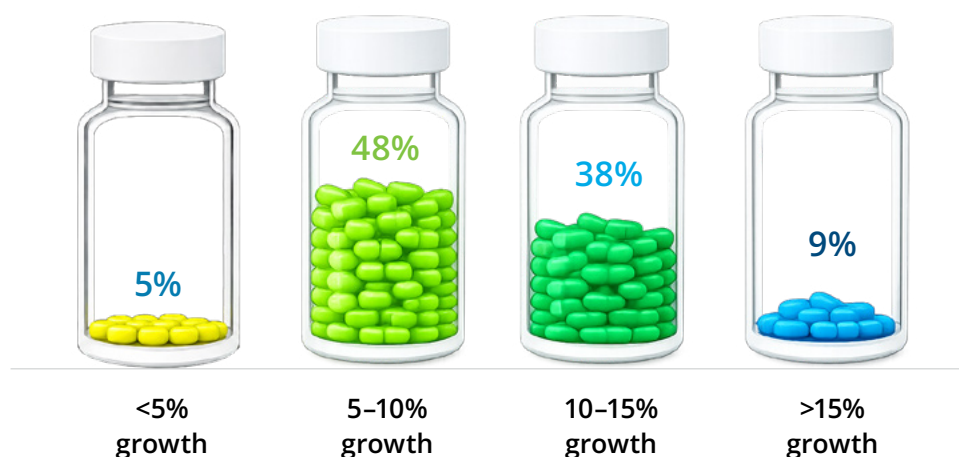
Core takeaways

- **Industry growth outlook:** Majority of CXOs anticipate the pharmaceutical industry in India to grow by 5–15 percent in FY27.
- **Business headwinds and strategic priorities:** The top 5 headwinds are regulatory pressures, approval delays, pricing controls, generic competition and workforce gaps. Top 5 priorities, on the other hand, centre on revenue/product diversification, capex and geographic expansion, cost optimisation, quality enhancement and digital transformation.
- **Profitability and cost optimisation outlook:** Majority of the respondents expect EBITDA to increase by 10–20 percent over the next 2–3 years, with manufacturing and operational overheads identified as the primary area for cost optimisation.

Industry growth outlook

The outlook for India's pharma sector in FY27 appears broadly optimistic, with most expectations clustering around the middle-growth band of 5–15 percent (see Chart 1).

Chart 1: Indian pharmaceutical industry growth in FY27



Almost half of the CXOs (48 percent) expect 5–10 percent growth, pointing to a steady, stable expansion trajectory, similar to the trend observed in the last few years. At the same time, a significant 38 percent expected a stronger growth trajectory of 10–15 percent. In contrast, another 9 percent anticipate more than 15 percent growth,

indicating confidence in Indian pharma exports to witness double-digit expansion in FY27, largely driven by opportunities arising from recent trade engagements with the EU and the US.^{vi} Taken together, the results reflect a positive industry sentiment, with the majority of stakeholders experiencing moderate growth in FY27.

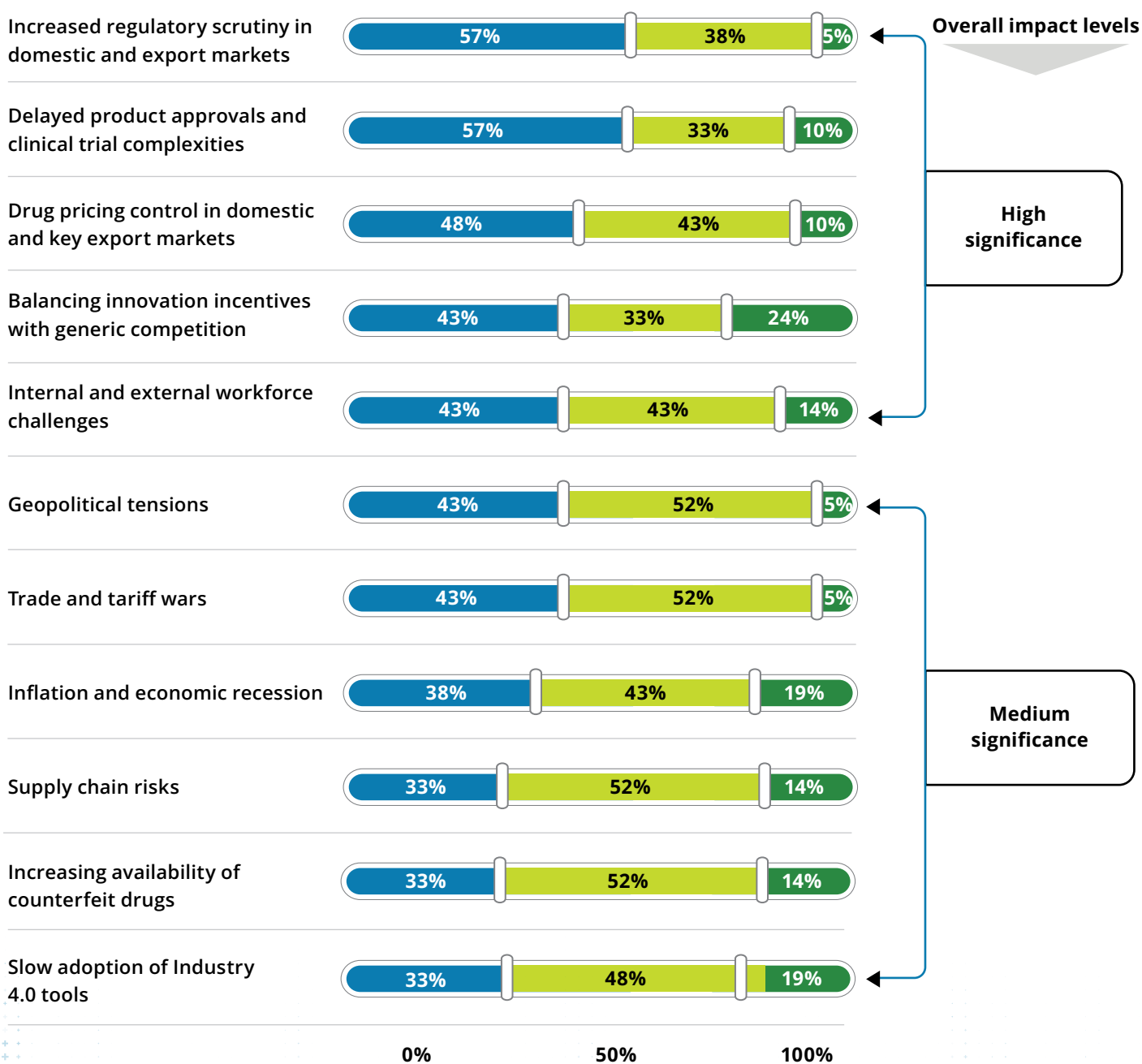


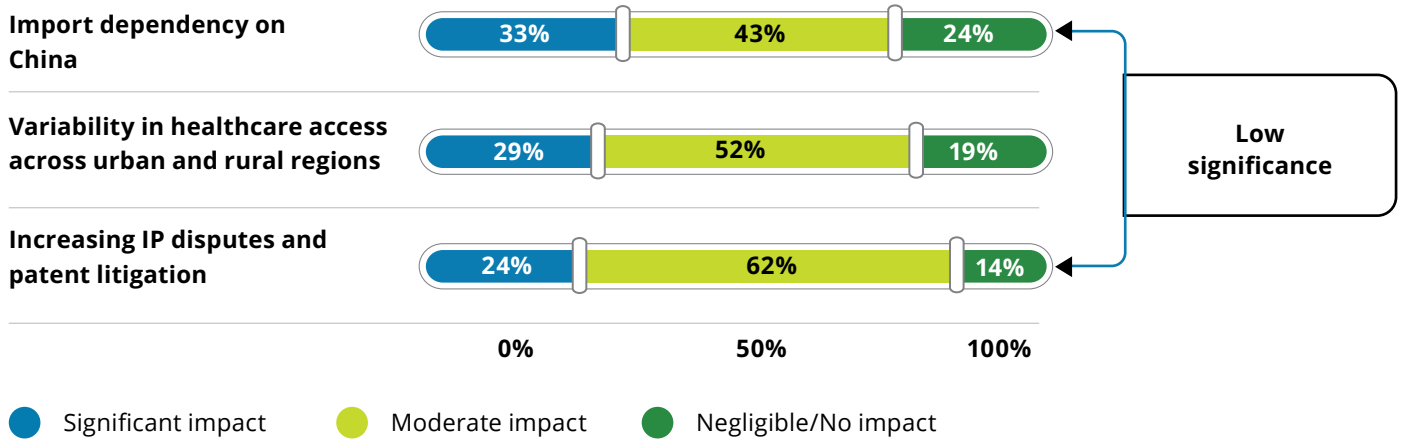
Industry sentiments on the growth outlook are cautiously optimistic, with expectations centred on a sustained and healthy momentum.

Business headwinds and strategic priorities

While the pharma industry is expected to witness positive growth in FY27, companies anticipate several headwinds that require proactive strategic planning (refer to Chart 2).

Chart 2: Impact of key headwinds on business in FY27





More than half (57 percent) of CXOs indicate that increasing regulatory scrutiny across domestic and global markets, along with delays in product approvals and complexities in clinical trials, are likely to have a highly significant impact on business growth. This concern is rooted in a visibly tightening regulatory environment. For instance, the US Food and Drug Administration (FDA) has intensified its inspection approach in recent years, including a rise in unannounced site visits and a sharper focus on areas such as data integrity, documentation practices and quality systems.^{vii} Several Indian pharmaceutical manufacturers have received Form 483 observations over the past year, often linked to data management and compliance gaps, highlighting the increasing expectations from global regulators.^{viii} On the clinical trials front, regulatory oversight is also evolving. For example, the introduction of the New Drugs and Clinical Trials (Amendment) Rules, 2024, effective April 2025, marks a significant shift with mandatory registration of Contract Research Organisations (CROs) and tighter governance of clinical trial processes. While these measures aim to strengthen patient safety and trial integrity, they also add layers of compliance and operational complexity for companies.

Other high-impact headwinds highlighted by respondents are drug pricing controls, balancing innovation with generic competition and workforce challenges. These could potentially affect launch timelines, compliance costs and speed to market.

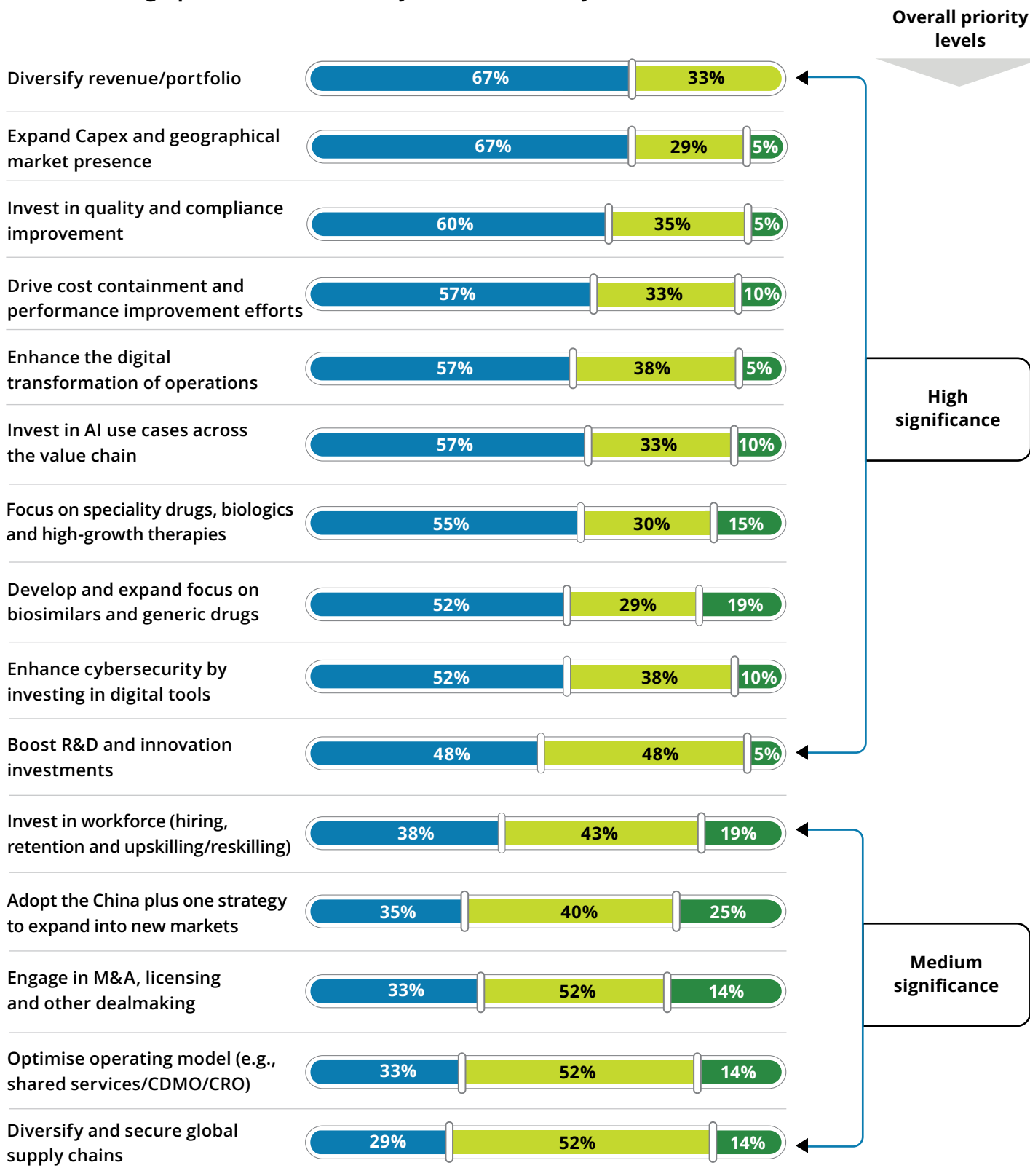
Pricing pressures remain elevated due to the expansion of the National List of Essential Medicines and continued erosion in US generics driven by buyer consolidation.^{ix} At the same time, companies are navigating a difficult trade-off between investing in speciality drugs, biologics and complex generics while sustaining profitability in their core generics portfolio. Moreover, workforce challenges persist, with shortages in specialised roles, thereby increasing operational strain.

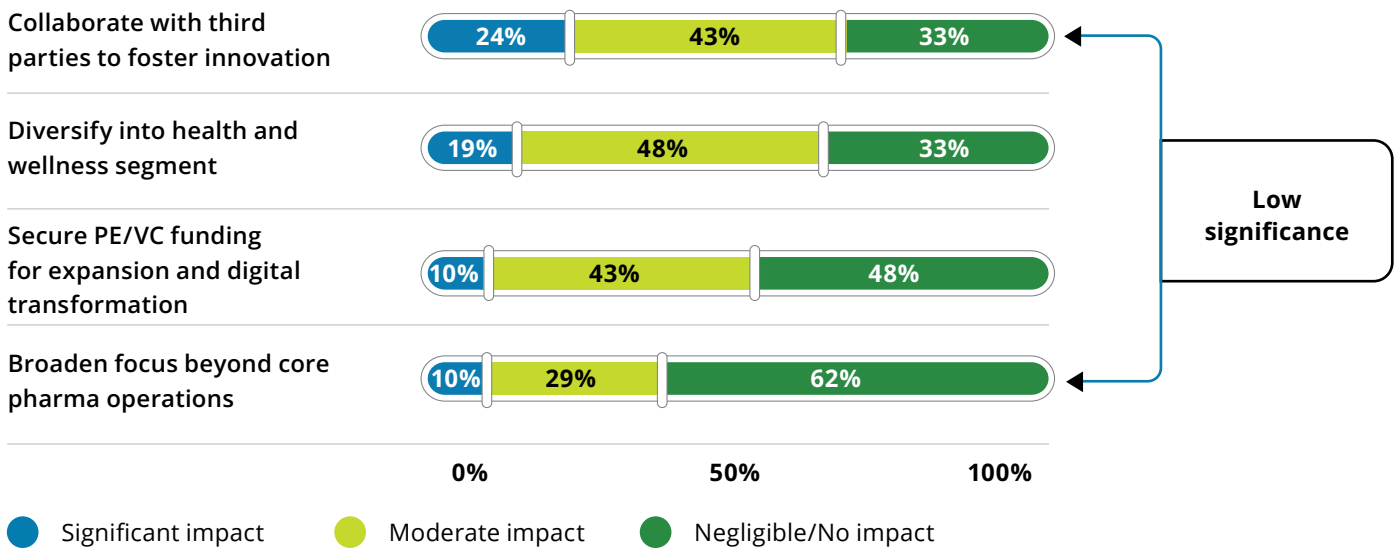
Beyond those key high impact drivers, various structural and macro economic risks are also likely to nudge business performance in a more modest direction. For example, approximately half of the respondents point to geopolitical tensions, trade and tariff uncertainties, supply chain risks (limited availability of raw materials, supply delays, limited real-time tracking, logistic challenges for temperature-sensitive products, etc.), variability in healthcare access across urban and rural areas, the growing prevalence of counterfeit drugs and slow adoption of industry 4.0 tools as some of the key areas that could moderately affect their operations.

Interestingly, import dependency on China, variability in healthcare access across urban and rural regions and increasing Intellectual Property (IP) disputes and patent lawsuits are identified as additional key headwinds. However, CXOs do not expect the impact of these headwinds to be substantial.

To address these headwinds, the respondents have outlined various strategic priorities aimed at increasing resilience and sustaining growth in FY27 (see Chart 3).

Chart 3: Strategic priorities to address key headwinds in 2-3 years





The top-most priority, as identified by nearly 67 percent of CXOs, is diversifying revenue and product portfolios while expanding capex investments and geographical market presence. This approach is largely intended to mitigate risks from drug pricing pressures, geopolitical uncertainties and trade and tariff disruptions, while helping companies reduce dependence on specific markets or therapeutic areas.

Additionally, more than half of the respondents have emphasized investing in quality and compliance enhancements, cost containment and performance improvement efforts, accelerating the digital transformation of operations, scaling AI use cases across the value chain and enhancing cybersecurity frameworks as high-focus areas. These initiatives are collectively expected to help organisations manage compliance requirements more effectively and address complexities in product approvals and clinical trials while maintaining operational agility, accessibility and innovation-led growth. In parallel, companies are also expanding their capabilities in speciality drugs, biologics and other high-growth therapies (per 55 percent of respondents), while increasing their focus on

biosimilars and generic drugs (52 percent) and boosting R&D and innovation investments (48 percent). One of the biggest drivers of this shift is the upcoming patent cliff, with over US\$200 billion in drug sales expected to go off-patent in the next few years.* This creates a huge opportunity for Indian companies to expand their generic and biosimilar portfolios and gradually move up the value chain into speciality medicines and biologics.

Furthermore, companies have identified strategic ecosystem and operational optimisation initiatives as important medium-term priorities. These include investing in workforce skilling and training, adopting the China plus one strategy, actively engaging in M&A, licensing and other deal-making activities to expand capabilities and market access, optimising operating models through shared services and partnerships with CDMO/CRO players and diversifying and securing global supply chains. In addition, diversification into health and wellness segments, securing Private Equity (PE)/Venture Capital (VC) funding for expansion and broadening the focus beyond core pharma operations are other important focus areas, albeit lower in priority, for the respondents over the next two to three years.

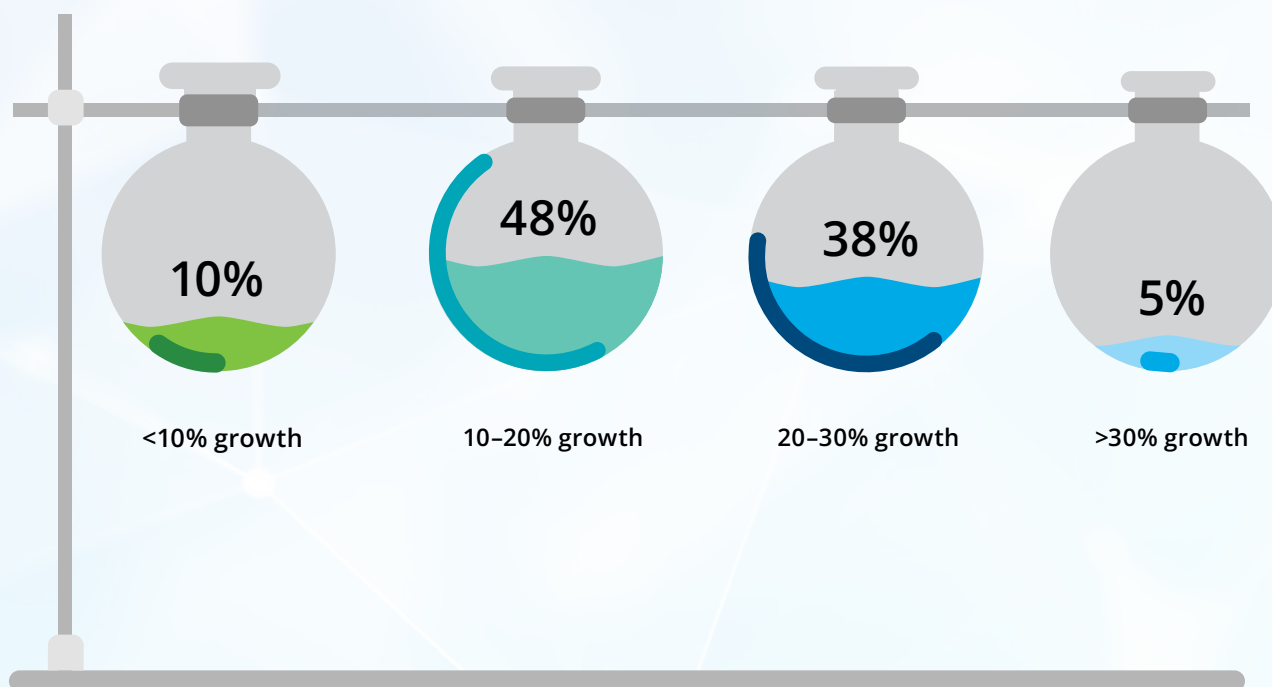


Key strategic priorities include portfolio diversification, digital and operational transformation, ecosystem partnerships and innovation-led growth to mitigate operational headwinds.

Profitability and cost optimisation outlook

The survey indicates a measured profitability outlook for pharmaceutical companies in FY27 (see Chart 4).

Chart 4: Expected increase in EBITDA (2–3 years)

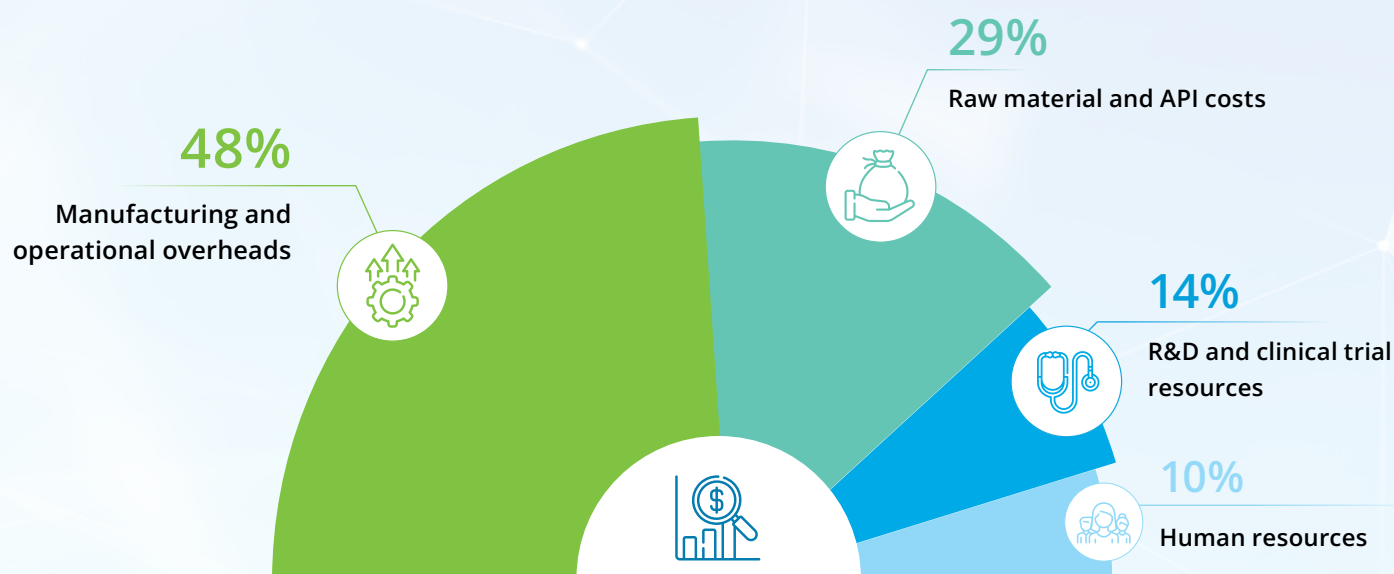


For example, nearly half (48 percent) of CXOs expect EBITDA to grow between 10–20 percent driven by stable domestic demand and operational improvements. Moreover, around 38 percent of participants anticipate EBITDA growth of 20–30 percent supported by increased traction in chronic therapies, which is broadly in line with recent-year trends. Another 5 percent further predict more than 30 percent growth, likely led by scale-up in high-margin products such as complex generics and speciality portfolio expansion. On the contrary, only 1 in 10 CXOs expect EBITDA growth of less than 10 percent, reflecting a cautious stance amid geopolitical uncertainties.



Respondents have also pointed to several key areas that are likely to see cost optimisation efforts to support margin expansion (refer to Chart 5).

Chart 5: Key areas of cost optimisation to improve efficiency and enhance EBITDA growth (2–3 years)



Nearly half of the participants (48 percent) cite manufacturing and operational overheads as the primary area for efficiency improvements, suggesting a strong focus on improving plant utilisation and streamlining operational expenses. Raw material and API expenses (29 percent) emerged as the next big priority, underscoring the critical need to manage input costs and strengthen procurement

strategy to mitigate supply chain turbulence. Interestingly, fewer respondents cite R&D and clinical-trial resources, as well as human resources, as key levers for boosting efficiency. This suggests that companies remain committed to sustaining investments in research capabilities and talent, while pursuing efficiency gains primarily through operational and supply chain improvements.



While CXOs indicate measured optimism for EBITDA outlook, profit improvements will depend on targeted cost optimisation, particularly in manufacturing efficiency, supply chain and operational management.

Scaling business through market expansion





Core takeaways

- **Business expansion strategy:** Organic growth is the preferred strategy, with a strong inclination to fund expansion through internal accruals.
- **Geographical sales outlook:** Top 3 geographies to drive sales growth in FY27 are India, North America and Eastern Europe and CIS.

Business expansion strategy

Pharmaceutical companies in the country are planning to adopt diverse strategies and financing methods to drive business expansion over the next 2-3 years.

Chart 6: Preferred approach for business expansion in the next 2-3 years

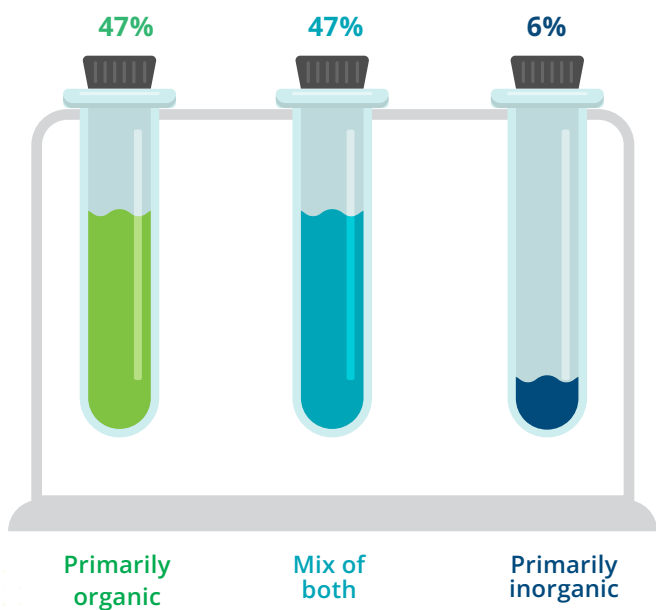
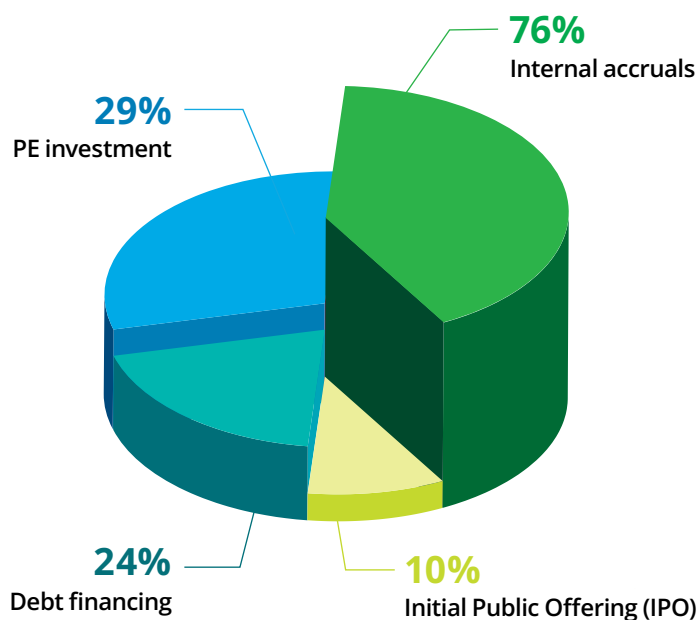


Chart 7: Preferred financing methods for planned expansion



As mentioned in Chart 6, around 47 percent of CXOs prefer an organic growth strategy, focusing on initiatives such as greenfield projects and capacity expansion, amongst others, to strengthen their business footprint. In contrast, only 6 percent reports go for an inorganic growth approach (primarily through mergers and acquisitions), while another 47 percent indicate a preference for a mix of both organic and inorganic strategies to enhance market presence. This distribution closely mirrors broader industry trends observed in the past five years.

Indian companies have largely prioritised organic, capability-led expansion (particularly in manufacturing scale-up and R&D investments), while pursuing inorganic opportunities selectively to bridge capability gaps, access new markets, or enter high-value segments. Together, this highlights that while inorganic expansion through strategic collaborations will remain relevant, most companies continue to view organic expansion as a core driver for market growth.

In terms of financing these expansion plans, internal accruals are the most preferred source of funding, cited by 76 percent of participants (refer to Chart 7^{xi}). This preference is substantiated by the solid balance sheets of leading Indian pharmaceutical firms, which maintain sizable cash and cash

equivalents balances, along with strong retained earnings positions. Consequently, these companies have sufficient internal cash flow and disciplined capital allocation to finance capacity-expansion projects, greenfield investments and other growth initiatives without tapping external capital sources. At the same time, more than half of the CXOs combined see PE deals and debt as vital funding options, indicating they are open to outside capital for large scale growth plans and innovation projects. As companies move beyond traditional generics and increasingly focus on value-added segments such as speciality drugs and complex therapies, they will see increased investment from PE and other external sources to support R&D, capability building and global expansion. Meanwhile, only about 10 percent of the respondents consider an IPO a viable option, highlighting the cautious stance within the pharmaceutical sector. Recent listings have delivered mixed results, while a few strong debuts occurred, many companies experienced modest or inconsistent post listing returns. Given the prevailing market volatility, pricing pressures and heightened scrutiny of valuations, IPOs are seen as a selective, opportunistic option, pursued mainly when a firm requires substantial capital and enhanced strategic visibility that justifies the equity dilution trade off.



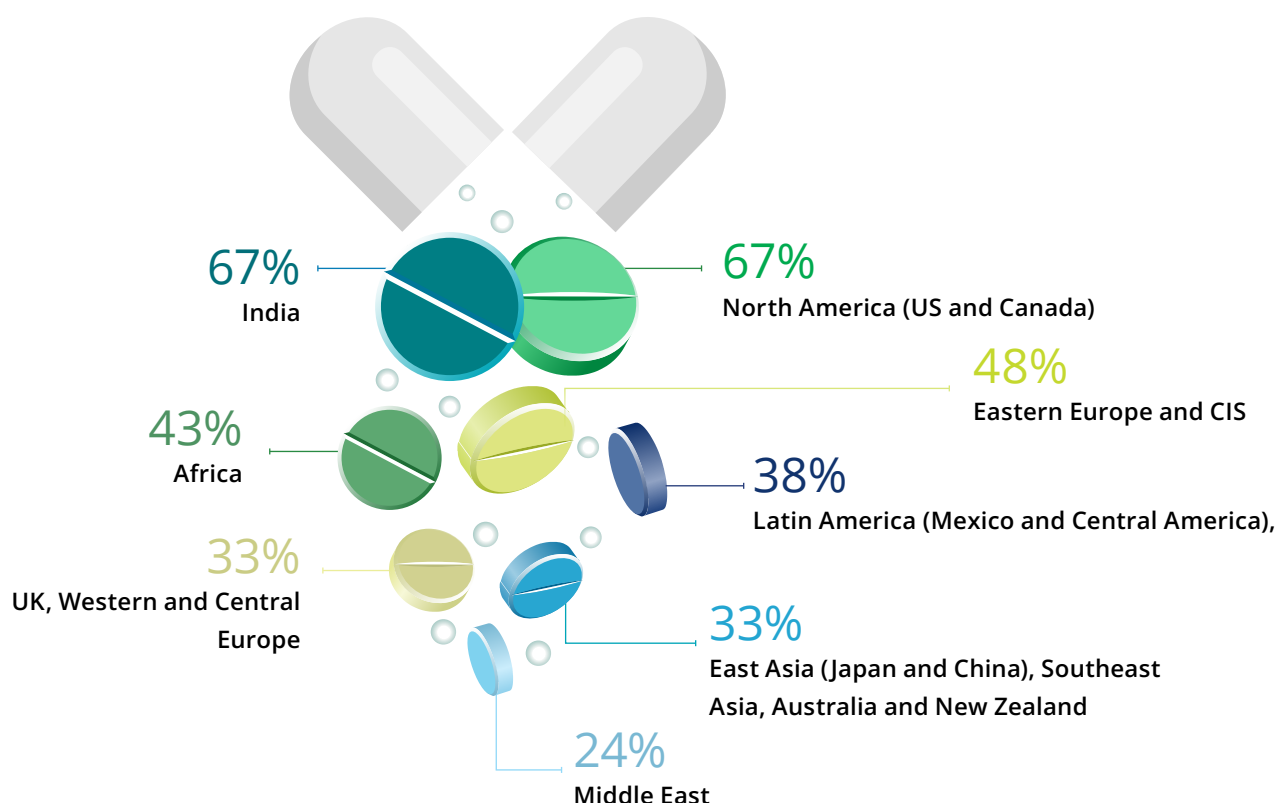
Pharmaceutical companies plan to pursue organic expansion supported largely by internal accruals, while selectively leveraging external funding sources and strategic collaborations to accelerate innovation-led growth.



Geographical sales outlook

The survey responses (see Chart 8^{xiii}) suggest that both domestic and international markets are expected to play an important role in driving revenue growth for pharmaceutical firms in FY27.

Chart 8: Geographies driving sales growth in FY27



Two-thirds (67 percent) of CXOs identify India as a key market for growth, highlighting the continued strength of the domestic pharmaceutical sector. This momentum is largely supported by strong demand for chronic therapies, such as cardiovascular, anti-diabetic, gastrointestinal and central nervous system treatments, along with new product launches and better access to healthcare across the country.

Besides India, North America is also touted as a major growth market by a similar percentage of participants. The region remains particularly attractive for companies with well-established portfolios of generics, speciality medicines and complex products, which continue to see strong demand. The US, in particular, imports about 40–50 percent

of its generic drug requirement from India and will remain a strong export destination for Indian pharma players.^{xiii} Moreover, India's generic medicines and pharma ingredients are set to gain a real boost as the new interim trade framework, announced in February 2026, opens up easier access to the US market. This initiative is part of a broader push to deepen India–US trade and hit a US\$500 billion bilateral target over the next five years.^{xiv}

Beyond these two core markets, several developing regions are also expected to present meaningful growth opportunities. For example, nearly 5 out of 10 respondents have identified Eastern Europe and the Commonwealth of Independent States (CIS) region as key drivers of sales growth.

This is largely driven by strong demand for cost-competitive generics, increasing reliance on imported pharmaceuticals and expanding market access opportunities for Indian manufacturers following supply diversification efforts in the region. Africa and Latin America have also emerged as notable emerging markets for expansion. Due to limited local manufacturing capacity, Africa continues to import around 70 percent of its medicines and 95 percent of Active Pharmaceutical Ingredients (API), with India being one of its main suppliers.^{xv} Latin American countries, particularly Brazil, Peru, Chile and Mexico, are seeing growth driven by gradual regulatory alignment with international standards and a growing preference for sourcing medicines (including generic drugs, APIs and vaccines) from cost-competitive manufacturing hubs such as India.

Furthermore, around a third of respondents point to East (including Japan and China) and Southeast Asia, along with Australia and New Zealand, as regions that could contribute to future sales growth. In many Southeast Asian markets, expanding healthcare coverage and rising demand for branded generics are creating steady opportunities for pharmaceutical companies. Trade agreements within the region, particularly Vietnam, the Philippines and Malaysia, are also making it easier for Indian firms to supply medicines across borders, further supporting market expansion.^{xvi xvii xviii}

A similar share of respondents has also mentioned Europe, including Western and Central Europe and United Kingdom, as an important market. While companies continue to face pricing pressure and strict regulatory requirements in the region, there are still opportunities, particularly in complex generics, biosimilars and contract development and manufacturing partnerships. A good example is the India-UK Free Trade Agreement signed in 2025, which is set to give Indian medicines free trade access to the UK and simplify regulatory approvals, enabling greater market penetration for Indian firms.^{xix}

Lastly, the Middle East has been identified by a relatively smaller group of respondents (24 percent) as a potential growth market. While key markets such as the United Arab Emirates, Saudi Arabia, Oman, Kuwait and Yemen continue to remain attractive destinations for India's affordable medicines and generic formulations, the ongoing tensions in the Gulf region are creating significant logistical challenges for Indian companies. Moreover, government estimates warn that the Indian pharma sector could incur almost INR50 billion in export losses if shipments to the Gulf Cooperation Council (GCC) and the broader East Asia-North Africa (WANA) region are fully disrupted by the current West Asia conflict.^{xx}



While India and North America remain the primary sales anchors, companies plan to increasingly diversify their growth across emerging markets and select developed regions.

Identifying growth levers for product development





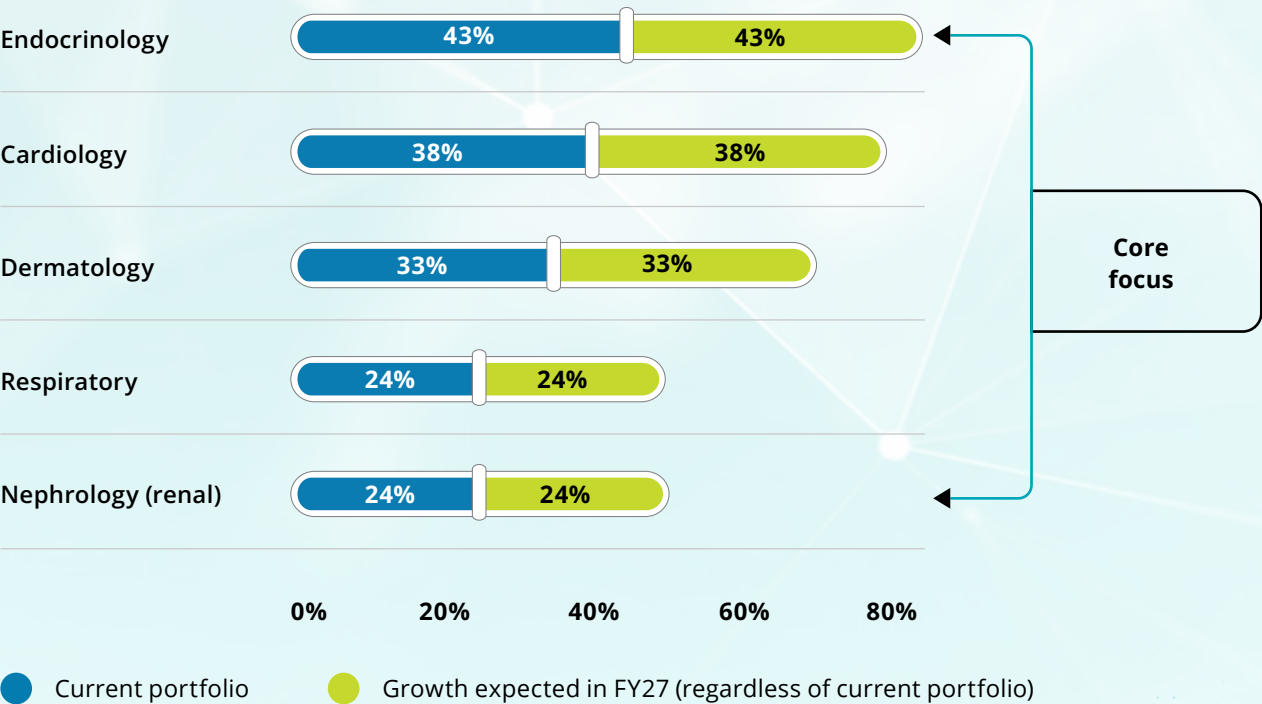
Core takeaways

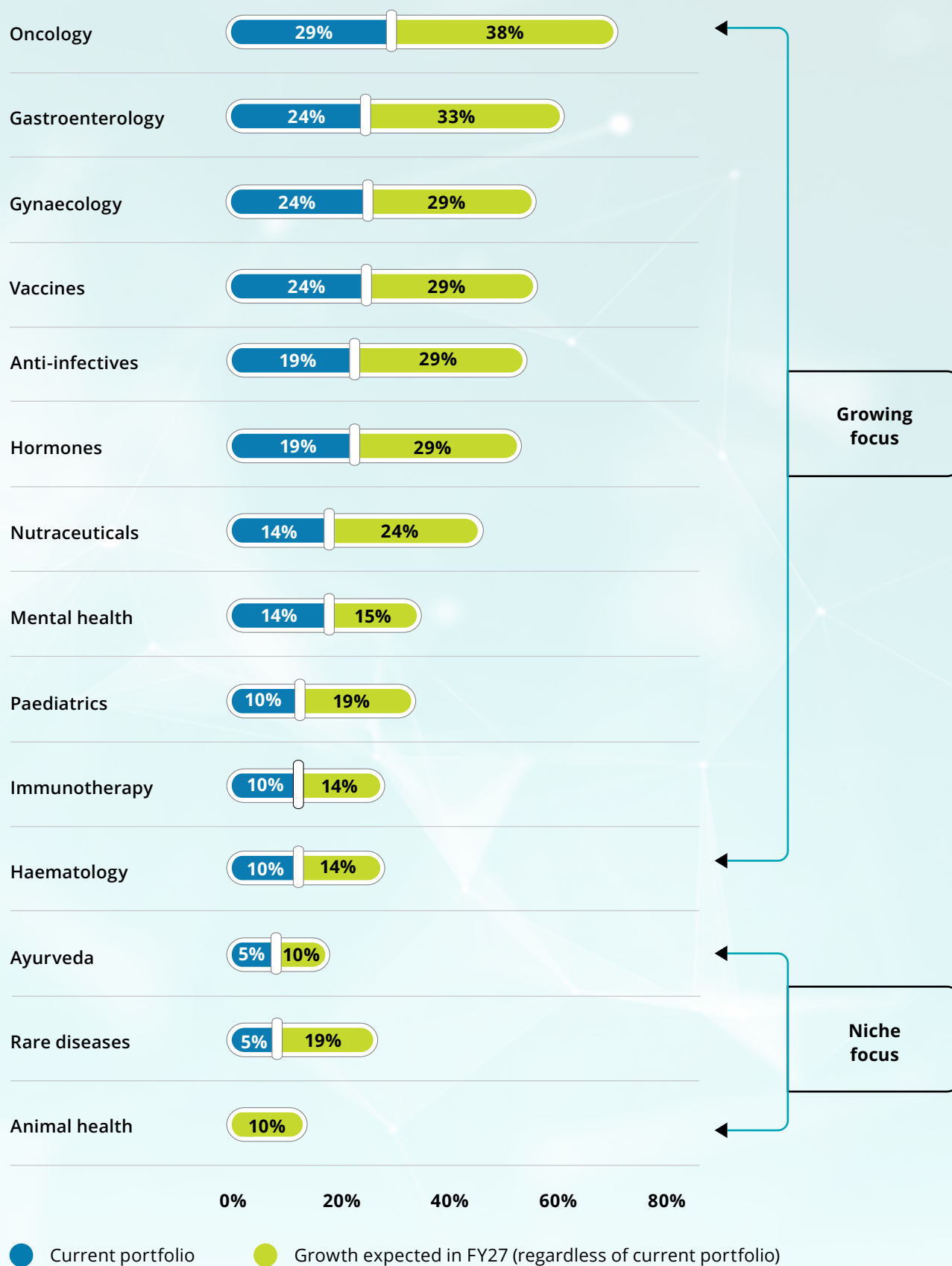
- **Therapeutic portfolio mapping:** Endocrinology tops the list of core focus areas, while oncology is one of the leading growing opportunities for CXOs.
- **Outlook on manufacturing capacity enhancement:** Most of the respondents plan to increase manufacturing capacity by 10–30 percent in the next 2–3 years.
- **R&D and innovation landscape:** Biologics and biosimilars are the biggest focus areas for the majority of the respondents in FY27.

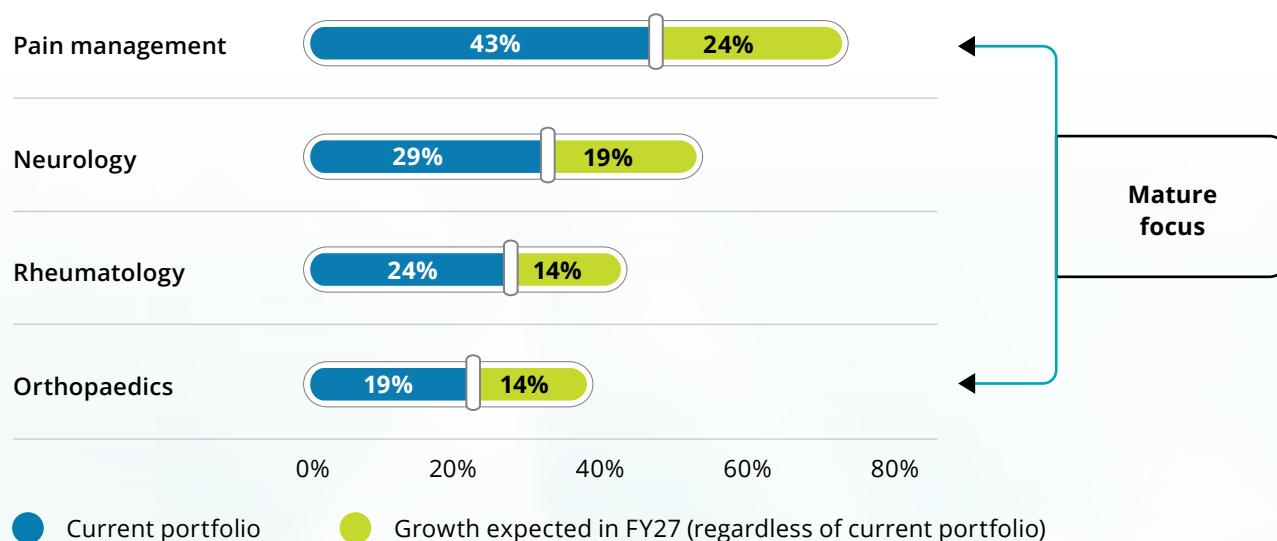
Therapeutic portfolio mapping

The survey responses show diverse alignment between the existing therapeutic portfolio of companies and their expected growth areas in FY27 (refer to Chart 9).

Chart 9: Current portfolio of therapeutics vs future growth areas







Core focus areas represent established therapeutic segments within the existing CXO portfolio and are expected to continue growing in FY27 and beyond. Endocrinology (43 percent) and cardiology (38 percent) lead the pack, with growth expectations closely aligned with current participation levels. This highlights the rising toll of chronic lifestyle diseases, especially diabetes and heart problems, in places such as India and other emerging markets. India, often referred to as the diabetic capital of the world, has over 77 million people living with diabetes, which is also one of the most significant risk factors for cardiovascular diseases.^{xvi} This number is expected to increase exponentially by 2045, highlighting the growing disease burden in the country and will continue to drive the demand for both endocrinology and cardiology therapies. Besides these, dermatology (33 percent), respiratory (24 percent) and nephrology (24 percent) also enjoy a solid foothold today with an equal number of respondents anticipating steady growth in these established treatments in the future.

Growing focus areas comprise several specialised and complex segments that are seeing stronger future interest. A higher proportion of respondents are expecting growth in these segments compared to those who currently have a presence. Oncology, for example, is part of the current portfolio for only 30 percent participants, but nearly 40 percent expect it to grow rapidly in FY27. This

reflects the growing global cancer burden and a wave of targeted therapies. The increased focus on cancer drugs was also reflected in the Union Budget 2026–27, where the government removed basic customs duty from 17 high-cost cancer medicines to reduce the import costs and improve access to these advanced treatments.^{xxii} A similar trend is observed in other therapy areas, such as gastroenterology, vaccines, anti-infectives, gynaecology, hormones, nutraceuticals, mental health, paediatrics, immunotherapy and haematology, where share of respondents betting on growth exceeds current participation levels. This suggests that companies are looking to broaden their focus as disease patterns evolve and consumer interest in preventive and wellness focused health products gains prominence.

In addition, several emerging and niche fields, such as rare diseases (present in the current product mix of 5 percent vs 19 percent expecting growth), Ayurveda (5 percent vs 10 percent) and even animal health (10 percent growth expected), signal early stage opportunities that could become strategic priorities as firms diversify their pipelines.

However, some therapeutic areas appear more mature, with growth expectations trailing their current levels of strong participation. Pain management (43 percent of respondents' product offerings vs 24 percent expecting growth in FY27), neurology (29 percent vs 19 percent), rheumatology (24 percent vs 14 percent) and orthopaedics (19 percent vs 14 percent) fall into this category.

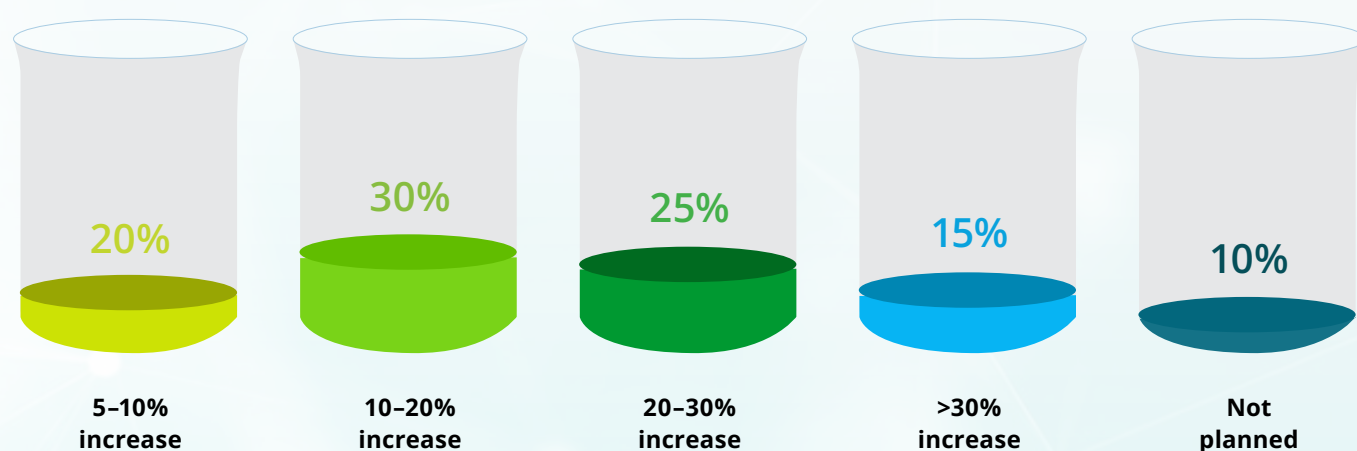


Pharmaceutical manufacturers are expected to maintain strong positions in high-volume chronic therapies such as endocrinology and cardiology in FY27, while expanding into high-growth and specialised segments.

Outlook on manufacturing capacity enhancement

As mentioned in Chart 10, most of the pharmaceutical firms are planning to increase their manufacturing capacity within the next 2–3 years, driven by rising domestic and export demand and the need to scale product pipelines.

Chart 10: Manufacturing capacity expansion plans in the next 2–3 years



About 3 in 10 CXOs plan to increase capacity by 10–20 percent, largely to optimise throughput and support incremental portfolio growth.

Another 25 percent indicate targeting a larger jump of 20–30 percent, while another 15 percent anticipate expansions exceeding 30 percent in the next 2–3 years. These higher expectations are likely aligned with extensive capability upgrades, entry into more regulated or specialised segments, broader strategic bets on emerging therapies and scale-driven opportunities, amongst others.

In contrast, only 2 in 10 respondents anticipated a smaller increase of 5–10 percent in operations, driven by modest efficiency gains and process improvements. Moreover, only one-tenth mentioned no immediate expansion plans, primarily because their current capacity is adequate or they are currently focused on operational efficiency and compliance improvement (e.g., USFDA warning letters) rather than physical expansion.

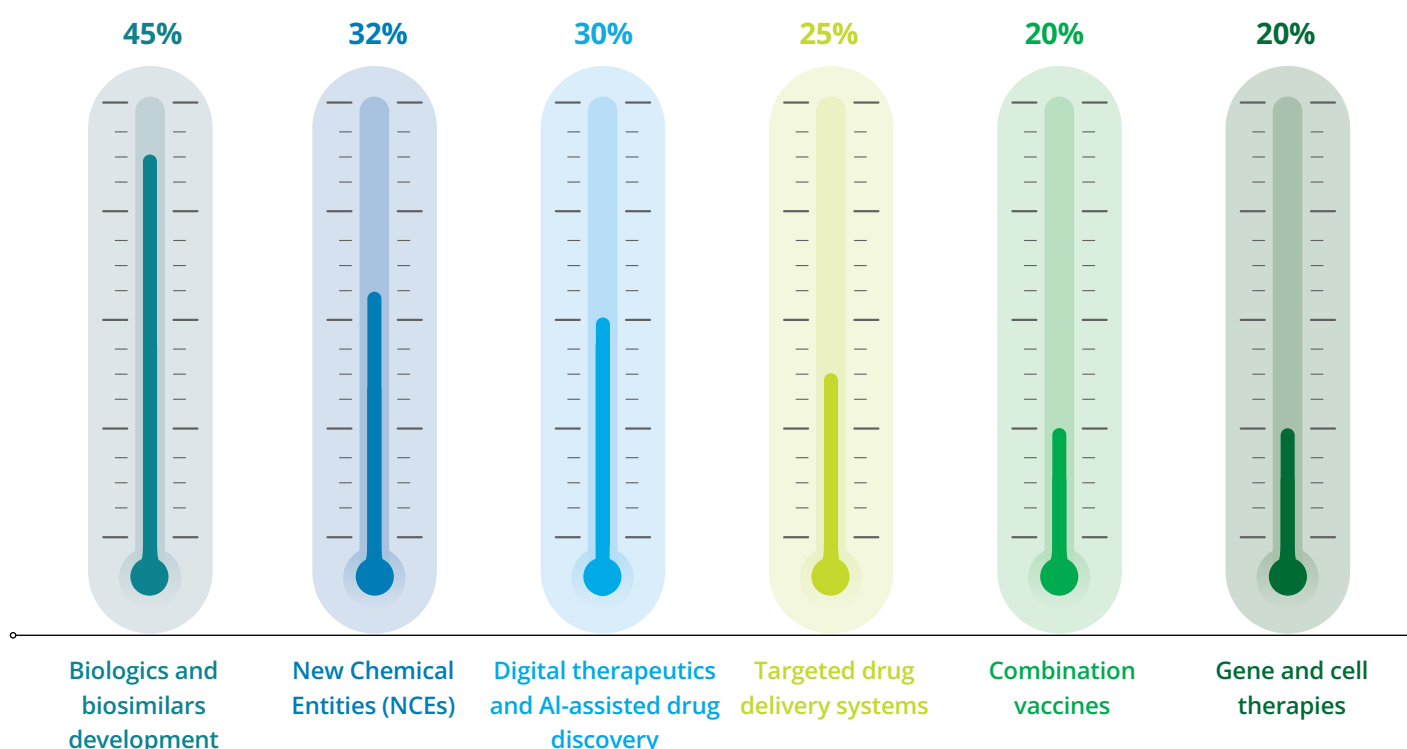


Capacity expansion remains a key strategic priority for companies, with most CXOs planning measured, moderate increases.

R&D and innovation landscape

Survey results (refer to Chart 11^{xxiii}) show that biologics and biosimilars are emerging as top R&D priorities for pharma companies over the next two to three years. Almost half of the respondents (45 percent) have flagged them as a major focus area, which indicates the growing worldwide demand for biologic treatments and the increasing opportunity to roll out cost-effective biosimilars as many biologics approach patent expiry.^{xxiv}

Chart 11: Key areas of R&D and innovation focus in the next 2-3 years



Moreover, New Chemical Entities (NCEs), digital therapeutics and Artificial Intelligence (AI) assisted drug discovery are also drawing significant interest, with approximately 3 in 10 participants ranking these areas as high priorities. This indicates that firms are bolstering their innovation pipelines while tapping digital tools to accelerate discovery, shorten research timelines and make clinical development more efficient.

Targeted drug delivery systems, gene and cell therapy and combination vaccines are seen as the next priority areas. However, only about 20–25 percent of respondents have highlighted them, primarily because they involve high development costs, complex regulatory pathways and the sophisticated scientific expertise for large-scale commercialisation.



Companies are prioritising research on biologics and biosimilars, NCEs and digital-enabled drug discovery in the near term, while gene and cell therapy and targeted delivery platforms are part of longer-term innovation strategy.

Integrating sustainability and quality assurance



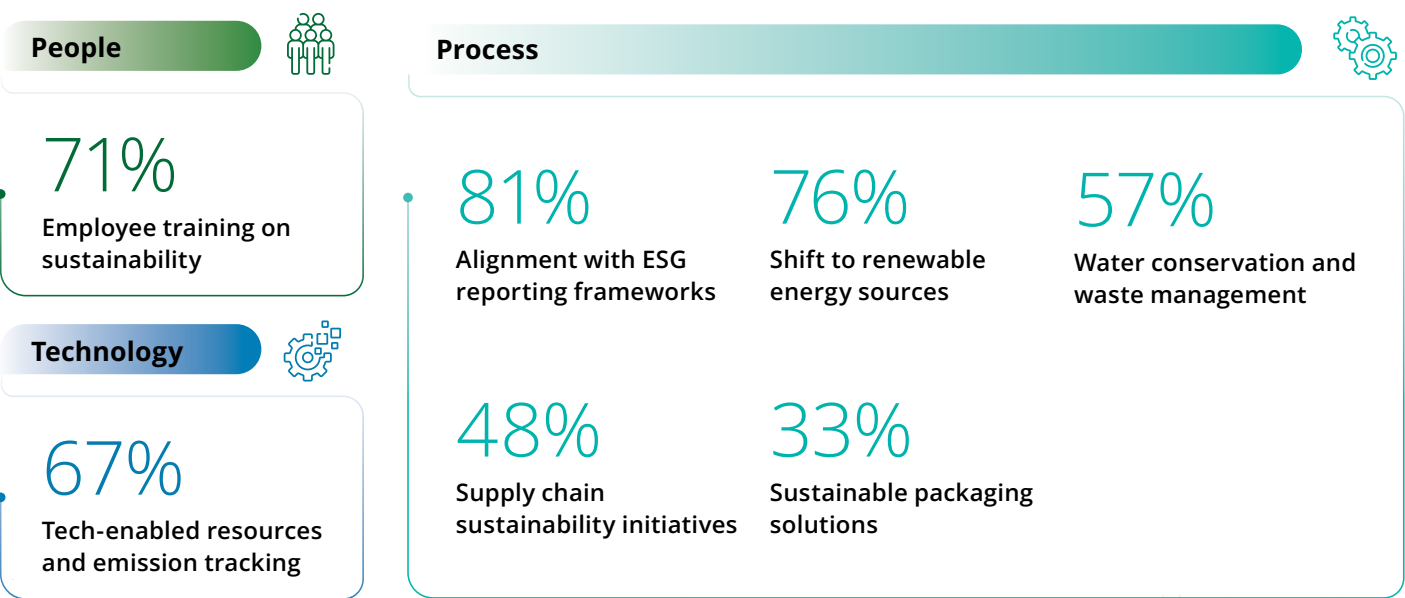
Core takeaways

- **Outlook on sustainable manufacturing practices:** The top 3 sustainable goals across people, process and technology frameworks are alignment with ESG reporting frameworks, shift to renewable energy sources and tech-enabled resources and emission tracking, respectively.
- **Requisites for Good Manufacturing Practices (GMP):** Enhancing employee training and GMP awareness and strengthening In-Line Quality Control (ILQC) and real-time monitoring systems have emerged as the top 2 major priorities for GMP.

Outlook on sustainable manufacturing practices

Sustainability has evolved to become a strategic imperative for pharmaceutical companies in India. This shift is largely driven by the country’s net-zero emissions target by 2070, tightening environmental regulations and increasing scrutiny from global stakeholders. Reflecting this transformation, the survey findings indicate that CXOs are planning to adopt a comprehensive, forward-looking sustainability agenda over the next 2-3 years, spanning across people, process and technology (see Chart 12^{xxv}).

Chart 12: Sustainable manufacturing goals for the next 2-3 years



From a people centric perspective, 7 out of 10 respondents intend to invest in sustainability training for their employees. This aligns with practices observed across leading Indian pharmaceutical companies, where ESG principles are being integrated into enterprise-wide learning frameworks. By building internal capabilities and embedding sustainability into organisational culture, firms aim to ensure that the ESG agenda is owned throughout the workforce and not confined to isolated functions.

On a process front, the survey reveals a strong emphasis on operational transformation. A striking 81 percent of respondents plan to align more closely with established ESG reporting frameworks. This alignment is intended to improve standardisation, transparency and compliance with the increasingly rigorous expectations of regulators, investors and other stakeholders. Next, 3 in 4 respondents intend to shift to renewable energy sources. This underscores decarbonisation as a central pillar of the strategy of Indian pharma companies, with many setting ambiguous targets of raising the share of renewables to 50–100 percent in the near future.^{xxvi}

Water conservation and waste management are also gaining momentum, with 57 percent of participants pledging to strengthen these initiatives. Many leading Indian pharma firms already have 70–90 percent of their sites achieving

water neutrality, zero liquid discharge or high-rate recycling, as cited by various annual reports. Together, these trends indicate that while water and waste initiatives are already relatively advanced at a site level, companies are further scaling these practices across their entire networks to boost enterprise wide sustainability.

Nearly half of the respondents plan to enhance supply chain sustainability, extending environmental stewardship beyond the factory floor to suppliers and logistics partners. Although still emerging, sustainable packaging is attracting attention, as 33 percent of firms indicate plans to develop and adopt more eco friendly packaging solutions. This is in line with broader industry movement, where companies are increasingly exploring bioplastics, paper-based and wood-based bio-polyethylene terephthalate (PET) alternatives to meet evolving sustainability expectations and regulatory requirements.^{xxviii}

From a technology standpoint, 2 in 3 CXOs plan to deploy tech-enabled solutions to optimise resources and track emissions. This highlights an anticipated increase in the use of digital tools to enable better measurement, monitoring and data-driven decision-making in sustainability initiatives.



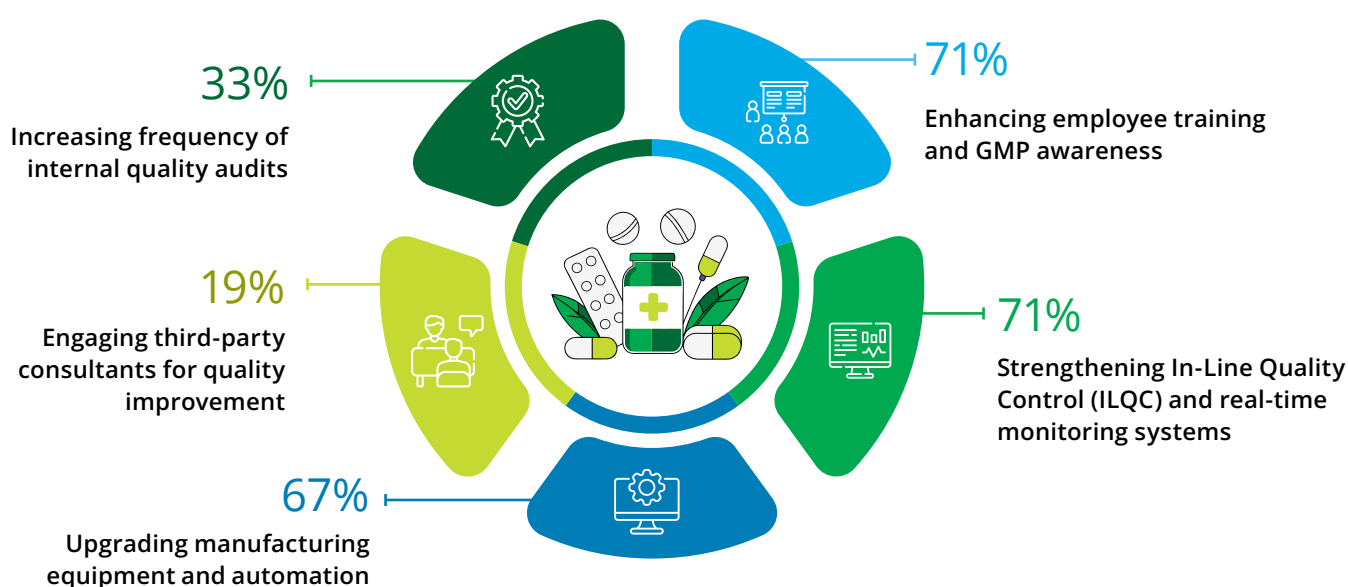
Sustainability is shifting from a compliance requirement to a core driver of operational transformation, with companies prioritising process improvements while building capabilities across people and technology.



Requisites for Good Manufacturing Practices (GMP)

Pharma CXOs are embracing a proactive, systems driven approach to enhance quality and ensure GMP compliance (see Chart 13^{xxix}).

Chart 13: Planned initiatives to ensure GMP compliance



Over the next two to three years, the majority of companies plan to embed quality assurance directly into the production line. About 71 percent of respondents are expected to strengthen ILQC and real time monitoring systems, turning continuous monitoring into a core part of the manufacturing process. This shift is expected to curtail deviations, flag issues at the earliest possible moment and deliver far more consistent product quality.

Human capital is being treated with equal importance, with an equal 71 percent of participants intending to deepen employee training and GMP awareness. By fostering a culture in which the workforce is well-informed about GMP nuances, companies aim to maintain consistently high-quality standards across all operations.

Technology upgrades also feature prominently. Roughly 67 percent of respondents plan to modernise equipment and expand automation, a move expected to reduce reliance on manual interventions, improve precision and reinforce adherence to stringent GMP requirements. Automated systems are viewed as a key lever for minimising human error and delivering reproducible, high quality outputs at scale.

In contrast, fewer organisations are leaning on reactive or external solutions. Approx 3 in 10 plan to increase the frequency of internal quality audits, suggesting a preference for built in quality mechanisms over periodic checks. Likewise, a modest 19 percent are considering engaging third party consultants for quality improvement, underscoring a strategic choice to develop in house capabilities rather than depending on external expertise.



CXOs are expected to invest heavily in preventive controls, skill development and advanced automation — all aimed at delivering higher, more reliable manufacturing quality while ensuring robust GMP compliance.

Enabling technological transformation





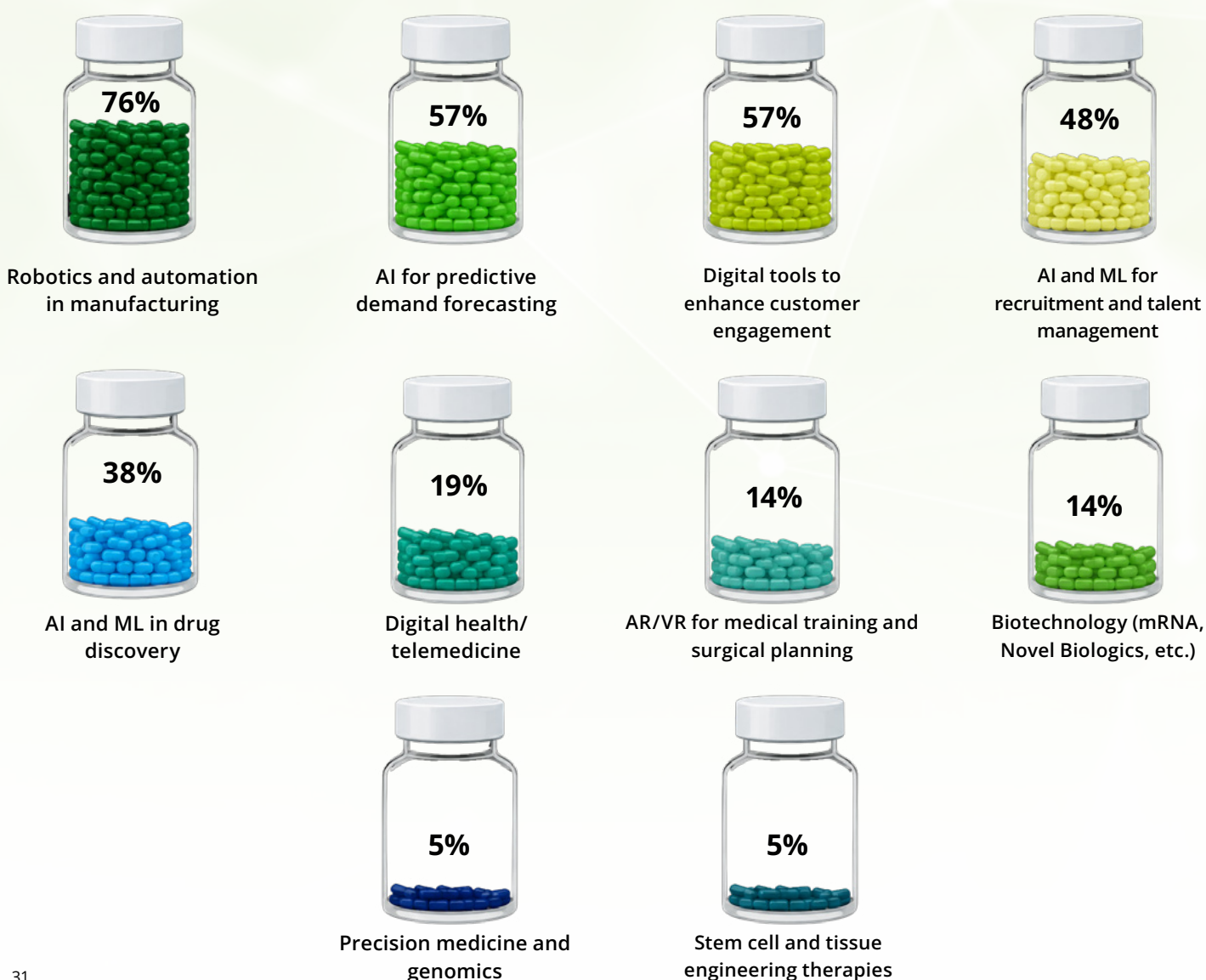
Core takeaways

- **Evolving technology trends:** Robotics and automation in manufacturing lead emerging technology priorities for FY27, followed by digital tools to enhance customer engagement and AI for predictive demand forecasting.
- **Barriers to technological enablement:** Talent and skill gaps have been highlighted as the biggest challenge in tech adoption.

Evolving technology trends

Indian pharma firms are gearing up for a mix of operational, commercial and innovation focused technologies to fuel business growth in the coming years (refer to Chart 14^{xxx}).

Chart 14: Top 10 emerging technology priorities for FY27



A striking 76 percent of CXOs have identified robotics and automation in manufacturing as their top priority, signalling a concerted effort to overhaul production lines with automated machines that can boost throughput, tighten quality control and drive down labour intensive costs. Several leading pharma giants have already deployed automated systems across critical production stages, including robotic filling lines, machine vision-based inspection and packaging automation.^{xxxi} Going forward, such initiatives are likely to scale further across the industry, driving a broader transition towards smart manufacturing systems.

Close behind, 57 percent of firms plan to deploy AI-driven predictive demand forecasting tools together with a suite of digital customer engagement platforms, a combination that will make supply chain operations more responsive to market fluctuations and to enhance the way companies interact with doctors, patients and distributors.

Talent management is emerging as another critical lever. Nearly half of the participants intend to embed AI and

Machine Learning (ML) algorithms into recruitment and workforce-planning processes, aiming to attract specialised skill sets, reduce hiring cycle times and optimise talent utilisation. Moreover, nearly 4 in 10 CXOs are earmarking resources for AI enabled drug discovery programmes to accelerate R&D timelines and improve overall success rates. Common use cases include in silico screening and lead optimisation, biosimilar comparability studies and clinical trial design and patient recruitment, amongst others.

By contrast, demand for next generation and frontier technologies is considerably more measured. Only 19 percent of respondents are focusing on digital health and telemedicine solutions, while 14 percent are eyeing Augmented and Virtual Reality (AR/VR) applications and biotech breakthroughs such as messenger Ribonucleic Acid (mRNA) and novel biologics. Even more niche areas, such as precision medicine, genomics and stem-cell and tissue-engineering therapies, are being considered by just 5 percent of respondents each. Higher complexity, cost and longer development timelines are keeping these technologies on the periphery for now.



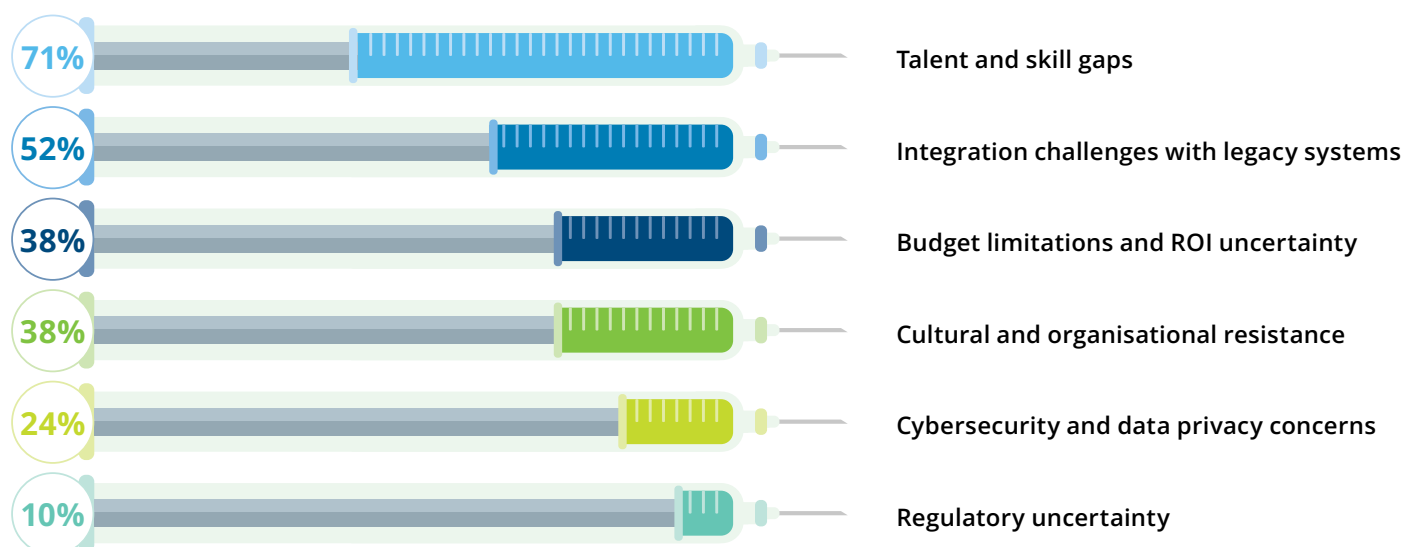
CXOs are expected to prioritise near-term, high-impact technologies such as automation and AI-driven optimisation, while maintaining a measured approach towards advanced and research-intensive innovations.



Barriers to technological enablement

Pharma CXOs anticipate encountering a blend of capability, infrastructure and organisational hurdles as they adopt new technologies (see Chart 15^{xxii}).

Chart 15: Key challenges in adopting emerging technologies



The most pressing obstacle, as flagged by 7 in 10 respondents, is the talent and skills gap. This is further corroborated by recent evidence, which indicates that more than 65 percent of pharma industry leaders in India report a shortage of specialised talent, particularly in areas such as biologics, AI and advanced R&D.^{xxiii} This highlights the growing difficulty of attracting and retaining professionals who can effectively deploy and manage AI and automation-based technological solutions.

Close behind, approximately half of the participants have cited integration challenges with legacy systems, indicating that existing IT foundations often don't mesh easily with modern tools, thereby slowing implementation and scaling efforts. Legacy challenges often stem from fragmented, plant-specific systems, non-standard data formats and disconnected equipment-IT layers. These issues result in slowdowns in AI and automation rollouts, delay real-time data visibility and raise the cost and complexity of transformation.

Financial constraints and cultural dynamics also weigh heavily on technological implementation. Nearly 4 in 10 cite budget limitations and uncertainty around Return on Investment (ROI), reflecting a cautious stance toward large-scale tech investments without clear returns. An equal share of CXOs mention cultural and organisational resistance, revealing internal inertia and the difficulty of driving change across teams and leadership. In addition, 24 percent identify cybersecurity and data privacy concerns as a barrier, emphasising the growing imperative to safeguard sensitive information in an increasingly digitalised landscape.

By contrast, regulatory uncertainty appears to be a relatively minor concern, flagged by only 1 in 10 respondents. This is largely because pharma companies already operate within well-established compliance frameworks and can navigate regulatory ambiguities without significantly hindering tech implementation.



To accelerate technological transformation, pharma companies will need to effectively navigate operational and organisational challenges while strengthening internal capabilities and systems.

Shaping the workforce of tomorrow





Core takeaways

- **Core HR imperatives:** The top 3 HR priorities are upskilling the workforce, leadership and succession planning and employee well-being and mental health.
- **Workforce turnover outlook:** Attrition rate is high (>15 percent) at the junior level and very low (<5 percent) at the senior level.
- **Talent restructuring trends:** Majority of the respondents prefer to increase workforce in 2–3 years.
- **Future-ready organisational skills:** Top 3 essential requisites are manufacturing/operational, digital health and technology adoption and leadership and management development skills.

Core HR imperatives

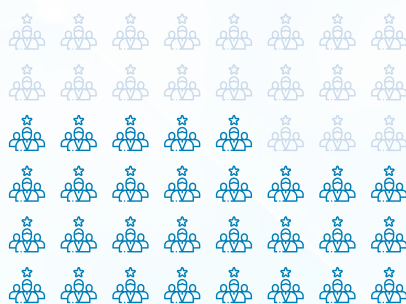
The survey reveals senior HRs are emphasising the development of future-ready capabilities and the strengthening of internal talent pipelines (refer to Chart 16^{xxxiv}).

Chart 16: Top HR priorities in the next 2–3 years



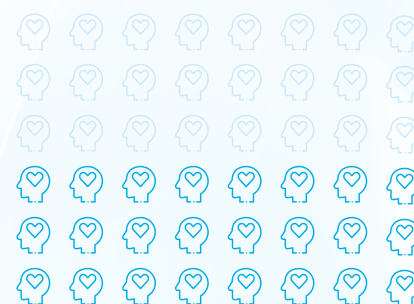
81%

Upskilling workforce



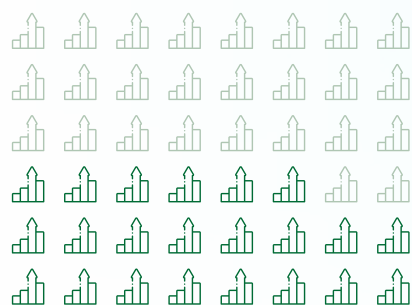
76%

Leadership and succession planning



67%

Employee well-being and mental health



52%

Retention in a competitive market



33%

Diversity, Equity & Inclusion (DEI) initiatives



29%

Attracting top R&D talent

Upskilling the workforce emerged as the top priority, with 8 in 10 senior HRs highlighting it as the most critical focus over the next 2–3 years. This underscores the sector’s growing reliance on advanced digital technologies, stringent regulatory compliance and specialised R&D expertise. Annual reports of leading Indian pharma companies indicate that workforce upskilling has increased significantly over the last 4–5 years, with 70–90 percent of employees receiving annual training.^{xxxv} More importantly, the focus of these initiatives is shifting from traditional compliance training to building capabilities in data analytics, AI and advanced R&D. As the industry undergoes rapid technological and scientific transformation, organisations are prioritising continuous learning programmes, hackathons and cross functional rotations to ensure their workforce remains future-ready.

Close behind, leadership and succession planning are deemed essential by more than three quarters of participants. This reflects a concerted effort to prepare for upcoming leadership transitions and to cultivate a resilient pipeline of leaders capable of navigating complex regulations and driving strategic growth. The pharma industry has been leaning heavily towards internal promotions for CEO and CXO positions over the last five years. While external hiring remains critical for specialised roles, established firms have increasingly prioritised internal succession to maintain business continuity in a complex regulatory environment.

Employee well being and mental health ranked next, acknowledged by 67 percent of respondents. High stakes R&D projects and 24/7 manufacturing shifts have put

mental health stressors front and centre. In response, firms plan to roll out mindfulness modules, on site counsellors, flexible work options and robust pulse surveys to gauge burnout levels. This builds on practices already visible across leading Indian pharmaceutical companies, where employee assistance programmes, wellness initiatives and mental health awareness campaigns are being embedded into broader HR strategies. The underlying intent is to protect productivity by caring for the person behind the data.

Slightly more than half of the survey participants have identified talent retention in a competitive market as another major priority. With intensified competition for skilled professionals across biotech start-ups, contract research organisations and adjacent sectors, companies are focusing on retaining their existing workforce through enhanced engagement, clear career development pathways and competitive compensation structures.

On the other hand, Diversity, Equity and Inclusion (DEI) initiatives received comparatively lower priority as cited by 33 percent of respondents. While organisations recognise the importance of DEI, it remains an emerging focus, often driven by compliance considerations rather than being deeply embedded in core business strategy. Moreover, attracting top R&D talent ranked lowest at 29 percent, indicating a strategic pivot toward bolstering internal capabilities and retaining current talent rather than relying heavily on external hiring in an increasingly competitive and costly talent market.

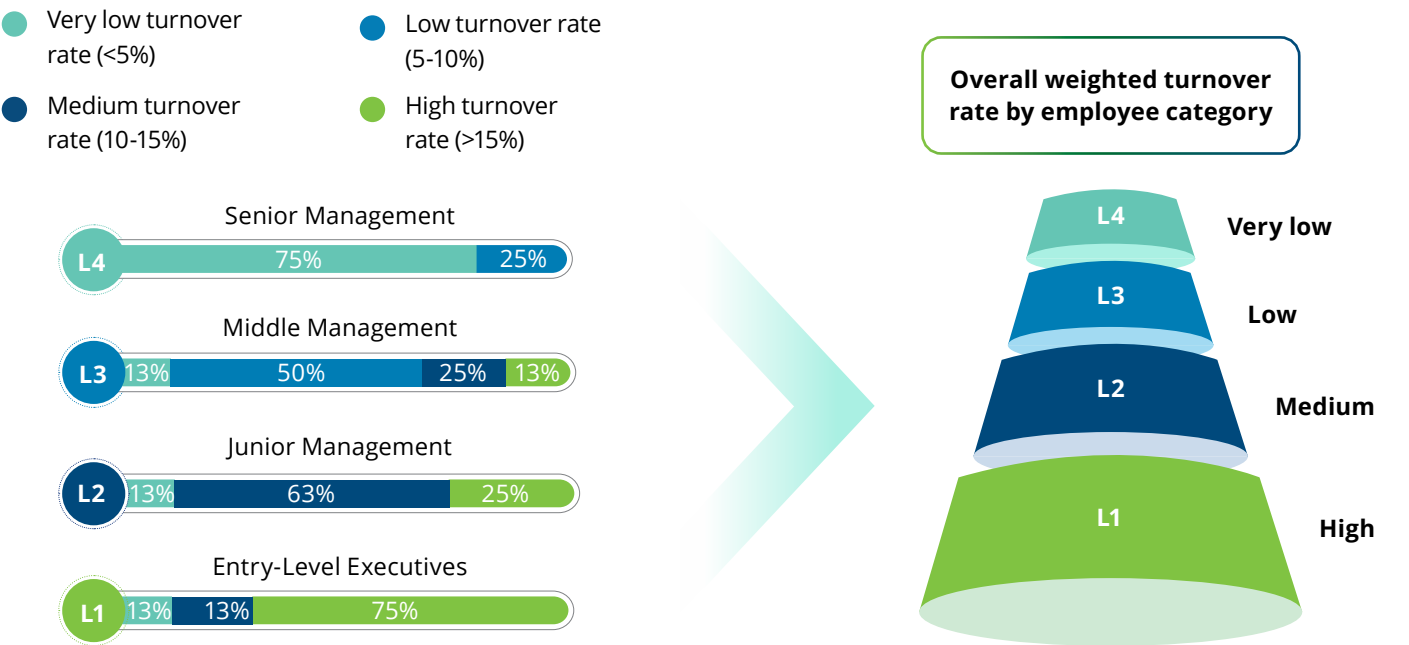


Indian pharma players are clearly shifting toward an “build and retain” talent strategy, prioritising internal capability development to ensure long-term workforce stability.

Workforce turnover outlook

Attrition trends in the Indian pharmaceutical sector reflect a clear gradation across organisational levels, aligning closely with broader industry benchmarks. Overall, the industry’s average attrition rate currently stands at 15 percent across the majority of pharma companies, as of 2025.^{xxxvi} However, the survey findings indicate a clear inverse relationship between employee seniority and turnover expectations within Indian pharmaceutical firms over the next 2–3 years (see Chart 17).

Chart 17: Expected average turnover rate across employee category (2–3 years)



A significant majority of CXOs expect high attrition at the entry level (L1), with three-fourths indicating turnover exceeding 15 percent. This reflects the inherently volatile nature of roles across early-stage R&D, manufacturing operations and sales, where frequent job hopping, aggressive talent poaching and shifting career aspirations are common.

The picture softens but remains dynamic after moving up to junior management level (L2). About two-thirds of participants expect a moderate attrition rate of 10–15 percent. Professionals at this stage are often seeking accelerated career growth, cross functional experience, or moves into high growth arenas such as biologics, speciality pharmaceuticals and GCCs, which keeps the talent market competitive. At the middle management tier (L3), turnover drops

further, with roughly half of the respondents forecasting a relatively low churn of 5–10 percent. Professionals at this stage typically benefit from clearer career paths, deeper organisational integration and increased involvement in strategic and regulatory functions, making them less likely to switch frequently.

Finally, senior management (L4) turnover is expected to be minimal. Three out of every four senior HRs predict attrition rates of 0–5 percent. Leadership positions in pharma are tightly linked to long term business outcomes, regulatory continuity and critical stakeholder relationships, factors that naturally curb mobility and are reinforced through incentives and strategic accountability.

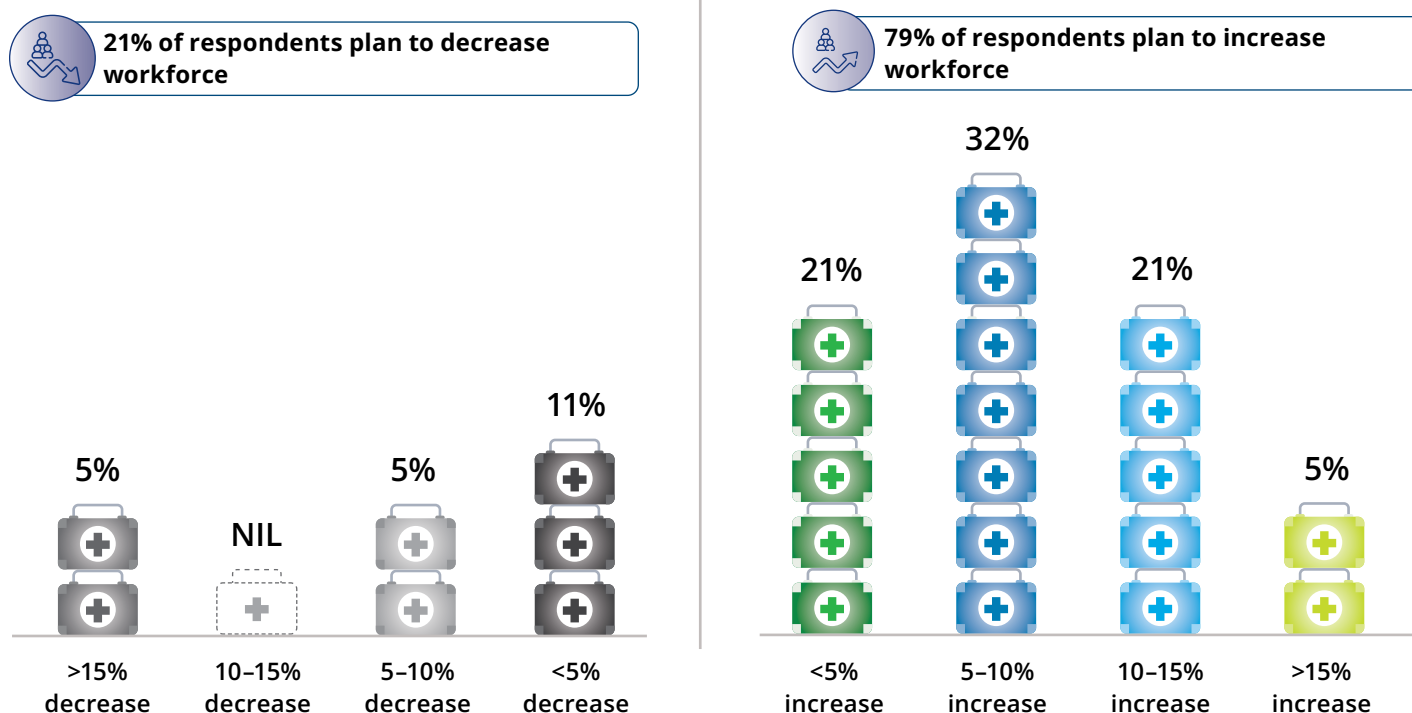


High to medium attrition levels at early career stages make targeted retention strategies critical at the base, while strengthening leadership continuity at the top will help ensure stability in long-term growth.

Talent restructuring trends

Annual report disclosures of leading Indian pharma companies indicate that workforce expansion over the last five years has been measured, with an average annual growth of 3–5 percent.^{xxxvii} Pharma CXOs further highlight a net positive hiring outlook for the Indian pharma sector, with around 79 percent planning to expand their workforce over the next 2–3 years (see Chart 18).

Chart 18: Expected workforce change in 2–3 years



Most of this talent growth is expected to remain measured. For instance, 21 percent of respondents are targeting headcount gains of less than 5 percent, while another 32 percent plan a slight modest uptick of 5–10 percent. This suggests that pharma companies are aligning recruitment with steady business expansion, new capacity additions and rising demand across therapeutic areas, rather than launching large scale hiring drives. That said, around 26 percent of respondents are gearing up for an aggressive workforce expansion of more than 10 percent. This can result from rapid capacity-building requirements in high growth segments such as biologics and speciality drugs, entry into new regulated geographies, the scaling of Contract Development and Manufacturing Organisation

(CDMO)/ Contract Research and Manufacturing Services (CRAMS) operations and high investments in sophisticated R&D and digital capabilities, i.e. areas where talent shortages are acute and demand is accelerating.

At the same time, roughly one fifth of the CXOs (21 percent) expect a modest headcount reduction. For most of them, the cutbacks are limited to less than 5 percent or, at most, 5–10 percent, reflecting optimisation initiatives such as manufacturing automation, productivity gains in sales and the consolidation of support functions. Only a minority (around 5 percent) foresee substantial downsizing of more than 15 percent, typically focused on traditional sales roles, routine manufacturing positions and administrative functions that are likely to being streamlined or centralised.

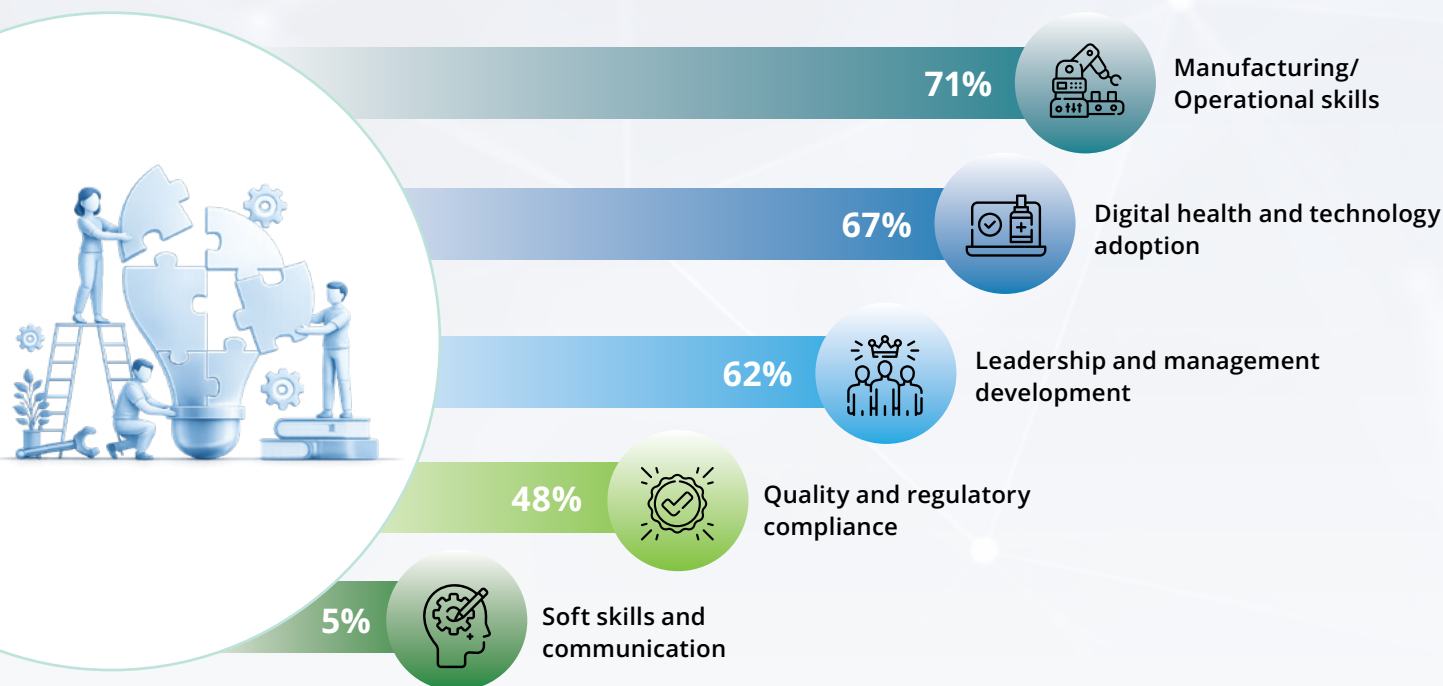


The overall recruitment landscape remains cautiously optimistic, with workforce expansion outweighing reductions as CXOs continue to invest in growth areas while selectively optimising operations.

Future-ready organisational skills

The survey findings highlight that Indian pharma companies are betting on core operational and future ready capabilities over the next three to four years (Refer to Chart 19^{xxxviii}).

Chart 19: Key organisational skills essential for future growth



Manufacturing and operational skills have emerged as the most critical factors, according to 71 percent of CXOs. This suggests that companies are prioritising capabilities for efficient plant operations, scale-up and compliance with global manufacturing standards, such as those of the US FDA and the European Union (EU). This heightened prioritisation is also grounded in recent regulatory trends worldwide. For example, between 2020 and 2023, FDA Form 483 observations indicate that nearly 35–40 percent of manufacturing-related issues were linked to human error or inadequate skill execution, rather than equipment or infrastructure gaps.^{xxxix} Taken together, these factors highlight a clear shift in industry thinking. Upskilling in manufacturing is no longer viewed as a routine compliance requirement but as a critical risk-control lever.

Closely following this, more than two thirds of participants have flagged digital health and technology adoption as a key skill area. This reflects the growing role of data driven R&D, smart manufacturing and digital engagement across commercial functions. Increasing adoption of AI-led drug discovery, real-world evidence and connected manufacturing

systems is reshaping how pharmaceutical companies operate, making digital fluency a core capability rather than a niche skill.

Leadership and management development is another major focus area, with 62 percent seeking capabilities to steer transformation, navigate regulatory complexity and drive strategic growth. Almost half of the respondents further identify quality and regulatory compliance as the next big pillar, especially as firms anticipate stricter scrutiny amid an evolving regulatory landscape. Compliance has always been a fundamental requirement in the pharma industry, but the slightly softer focus (compared to previous skill sets) suggests that many companies already have a sturdy compliance framework and are now ready to branch out into related skill areas.

On the other hand, soft skills and communication training have received minimal attention, which clearly indicates that technical know-how and functional expertise still dominate the industry's talent playbook.



Pharma CXOs are sharpening their focus on manufacturing excellence, digital integration, and leadership capability, reinforcing a skill agenda that is closely aligned with scaling operations and global market positioning.



Strengthening regulatory compliance capabilities





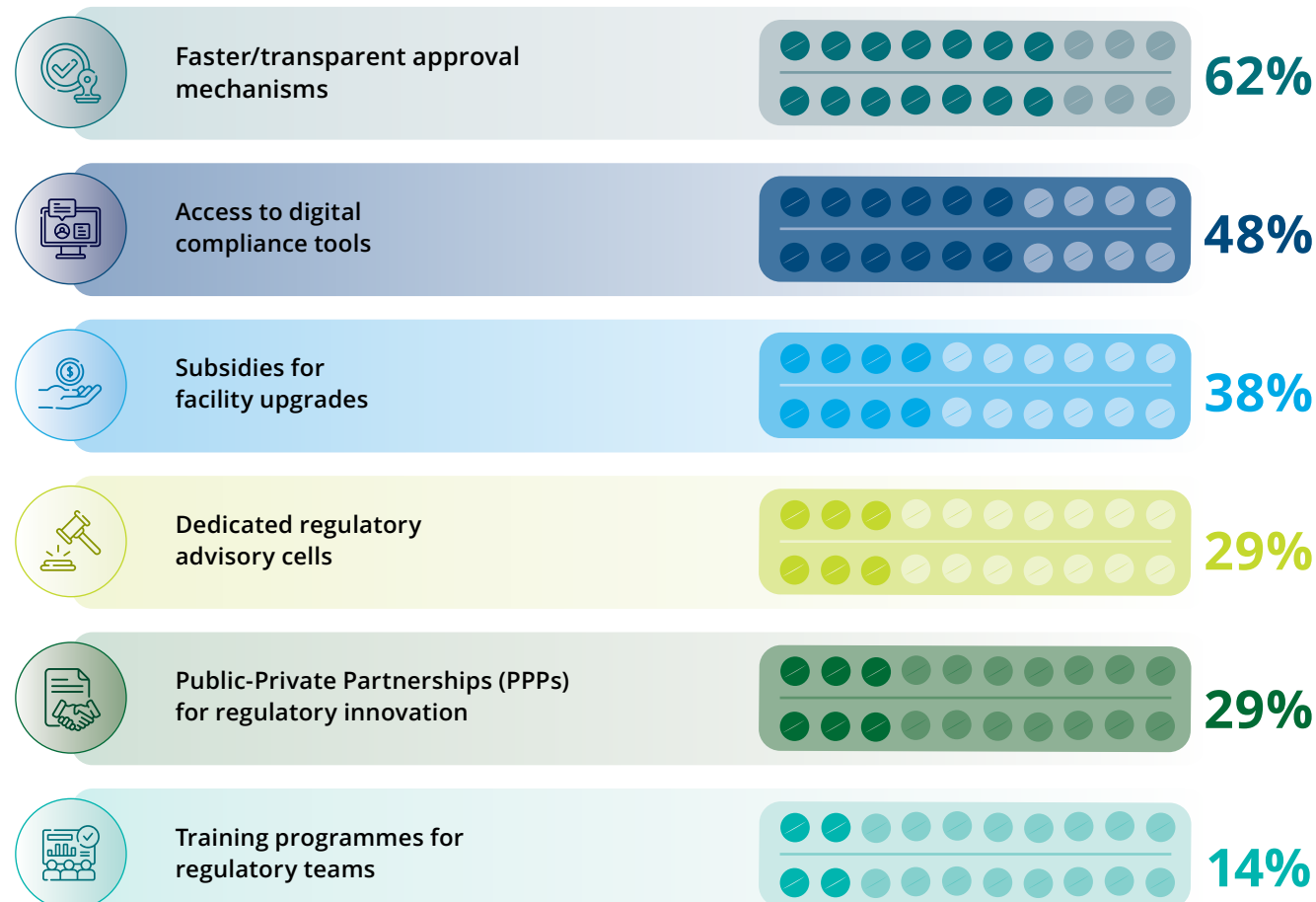
Core takeaways

- **Government enablers for regulatory readiness:** The majority of respondents expect faster, more transparent regulatory approval mechanisms.
- **Key regulatory collaborative frameworks:** The most desired form of collaboration is industry-government task forces for policy design.
- **Technology-led regulatory transformation:** The top 2 requisities are AI-based tools for regulatory submissions and audits and digital portals for faster approvals and compliance tracking.
- **Regulatory reforms to boost exports:** Mutual recognition agreements with key markets (e.g., EU, US) have emerged as the topmost priority.

Government enablers for regulatory readiness

As Indian pharma companies continue to navigate an evolving regulatory landscape, the focus on system-level improvements is becoming increasingly prominent to accelerate compliance (see Chart 20^x).

Chart 20: Types of government assistance to accelerate regulatory compliance



A majority of CXOs (62 percent) highlight the need for faster and transparent approvals. Indeed, in a highly competitive environment where several companies strive to introduce their generic medicines after patent expiration, even small delays may mean losing a first-mover advantage and reduced revenues. For example, case studies from the US generic drug market show that prices can decline by 70–90 percent within the first year of market entry after patent expiration, with the sharpest drops occurring in the first few months after launch.^{xii} This compressed window implies that even a modest 3–6 month delay in regulatory approval can cause a new product to miss the peak selling period, leading to noticeably lower revenues and a smaller market share. Hence, the timeframe of regulatory approvals is becoming a critical determinant of market shares for pharma players in India and worldwide.

Nearly half of the respondents have emphasized the importance of access to digital compliance tools that enable accurate data capture, end-to-end traceability and audit readiness across manufacturing, quality and R&D operations. This is especially because data management, data integrity, data traceability and audit preparedness are now prerequisites for regulatory compliance. However, legacy systems hinder data management and lead to

inspections, especially by international regulators such as the US FDA and the EU. As a result, digitalisation is no longer just a transformational tool; it has become a fundamental requirement for Indian firms.

Around 4 in 10 participants seek subsidies for facility upgrades and certifications to meet evolving global standards. Entry into high-growth segments such as complex generics and speciality drugs requires top-of-the-line infrastructure aligned with global regulators, including the US FDA and EU GMP standards, which necessitates substantial capital investment. Though big companies may afford to absorb such expenses, midsize organisations are likely to find themselves at a disadvantage, leading to a bottleneck in India's climb up the ladder of value.

About 29 percent of those surveyed said they are looking for dedicated regulatory advisory support and public-private partnerships. This indicates the need for closer collaboration between industry and regulators to navigate multi-market regulatory environments. Interestingly, only 14 percent of respondents are seeking training assistance for regulatory teams, suggesting that system-level bottlenecks are more pressing than workforce skill gaps.

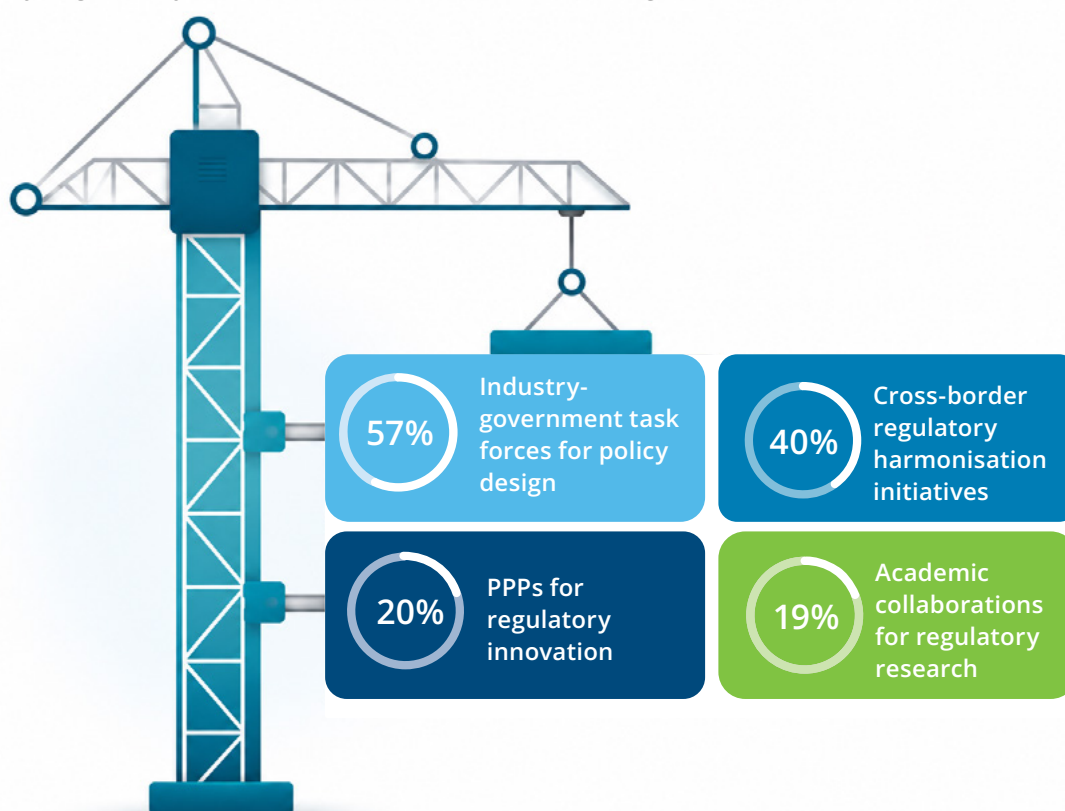


Regulatory compliance is evolving from a firm-level capability to an ecosystem-driven opportunity, requiring coordinated improvements across policy, infrastructure and technology to enable faster market access.

Key regulatory collaborative frameworks

The survey findings indicate that companies are actively seeking direct, outcome-driven regulatory collaboration models to improve policy effectiveness and streamline approvals (refer to Chart 21^{xliii}).

Chart 21: Key regulatory collaborations to enhance future growth



More than half of the respondents have pointed to industry-government task forces for policy design as the most valuable form of collaboration, signalling a strong focus on active policy co-creation. This reflects ongoing practices, where several pharmaceutical industry associations are increasingly engaging with regulators such as the Central Drugs Standard Control Organisation (CDSCO) on areas such as pricing policy, quality standards and regulatory reforms. The expectation is that companies no longer want to wait until a new regulation comes out before taking action; they want to be involved in helping formulate a regulation that is grounded in reality and implementable.

Building on this need for greater alignment, the second most preferred option, chosen by 2 in 5 respondents, is cross-border

regulatory harmonisation. This is particularly relevant for India-based multinational firms that derive significant revenues from regulated markets like the US and Europe. Navigating different regulatory frameworks from agencies such as the USFDA and the European Medicines Agency can lead to product launch delays and financial losses. Hence, harmonisation is not merely an operational improvement but has also become a business development strategy.

In comparison, academic collaborations and public-private partnerships appear to be lower priorities for now. This does not mean companies undervalue long-term innovation or research-led regulatory advancements; the immediate priority is execution with policy clarity, speed and predictability.

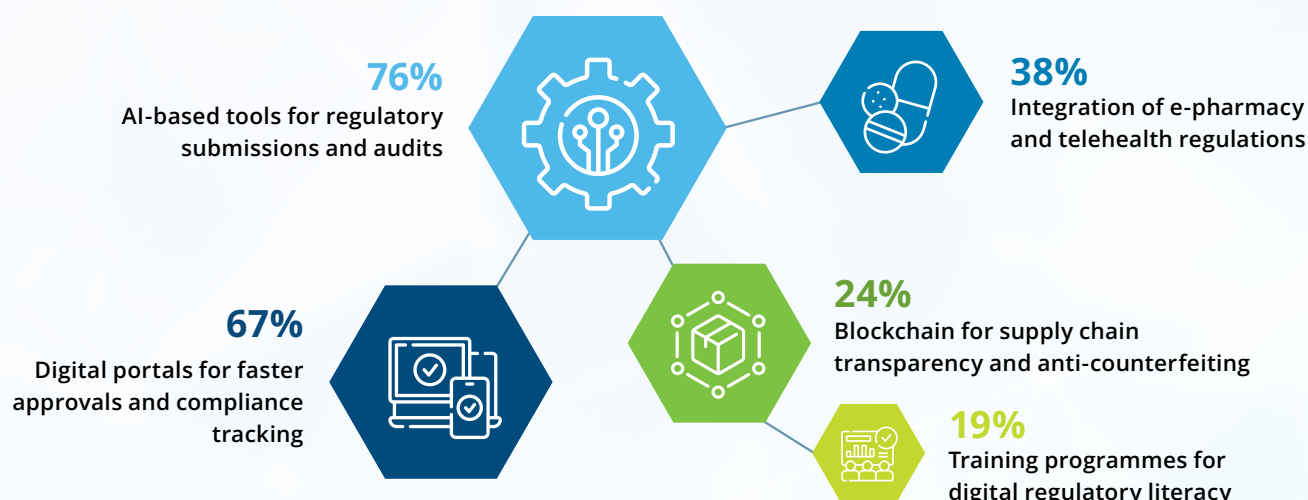


Regulatory effectiveness is increasingly being viewed as a co-created outcome, with organisations seeking a more proactive and influential role in shaping policies rather than relying on traditional regulatory frameworks.

Technology-led regulatory transformation

The survey responses highlight a strong preference for a technology-driven regulatory intervention that can directly enhance speed, efficiency and accuracy of regulatory processes (see Chart 22^{xliii}).

Chart 22: Types of government support to accelerate digital transformation in regulation



The increasing emphasis on AI-driven solutions (as indicated by 76 percent of respondents) reflects a shift from a manual, documentation-centric approach to intelligent automated regulatory operations. For instance, Indian pharma firms handle a large number of global filings, such as Abbreviated New Drug Applications (ANDAs) for the US and Certificates of Suitability (CEPs) for Europe. This often requires manually preparing a similar set of documents multiple times, which can lead to errors. AI-driven systems can automatically compile these dossiers and identify compliance gaps in real time, enhancing consistency and reducing manual efforts.

Around two-thirds of CXOs highlighted the need for digital single-window portals to enable faster approvals and more efficient compliance monitoring. In today's complex pharma regulatory environment, approvals are often handled in separate silos, leading to inevitable delays. While existing government portals, such as CDSCO's SUGAM, and newer initiatives, such as the National Single Window System

(NSWS), have digitised parts of the approval process required for various products, they still operate across multiple interfaces and workflows.^{xliiv} Hence, there remains substantial potential for further evolution towards a more unified digital platform that can standardise these processes for the pharma sector, improve visibility and enable real-time tracking. Next, nearly 4 in 1 respondents view the integration of e-pharmacy and tele-health regulations as the next priority. This reflects a growing need to modernise regulatory frameworks in line with the expanding digital-health ecosystem.

On the contrary, blockchain for supply chain transparency (24 percent) and training programmes for digital literacy (19 percent) receive comparatively lower emphasis. This indicates that emerging technologies and capability-building initiatives are not part of immediate priorities for the majority of organisations. These technologies may gain more traction once foundational digital systems related to faster regulatory submissions and approvals become more established.

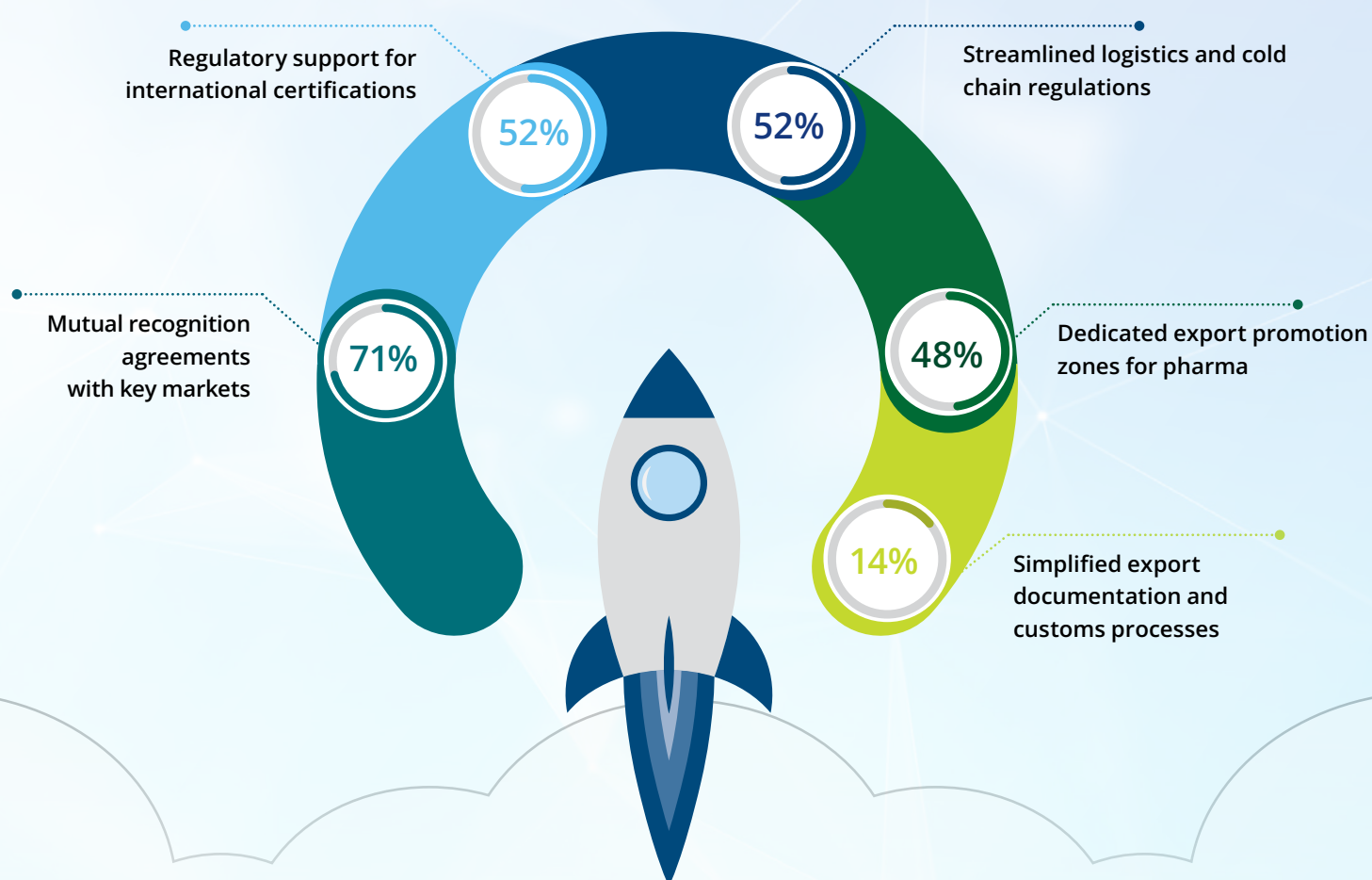


Organisations are prioritising high-impact digital enablers that can fundamentally transform regulatory speed and efficiency, signalling a shift towards technology-led regulatory transformation.

Regulatory reforms to boost exports

The responses indicate a clear emphasis on regulatory alignment with global markets and simplification of export processes as critical enablers of India's pharma export growth (see Chart 23).

Chart 23: Key regulatory reforms to enhance pharma exports



A striking 71 percent of participants have singled out Mutual Recognition Agreements (MRAs) with major markets such as the EU and the US as the top priority. This reflects a strong industry demand to reduce duplicate regulatory steps and to speed up market entry by having Indian standards accepted internationally. MRAs can dramatically shorten approval timelines and lower costs, giving Indian manufacturers a sharper edge in highly regulated markets.

At the same time, more than half of the respondents (52 percent) highlight the need for regulatory backing for international certifications, such as WHO-GMP and EU GMP, as well as simpler export paperwork and customs handling. In other words, companies want both the capability to meet global quality standards and a smoother, less bureaucratic path to getting their products abroad. Reducing paperwork

and easing customs formalities would lessen administrative overhead and improve turnaround times, making exports far more fluid.

Next, another 48 percent have voiced support for dedicated pharma export promotion zones. This points to an appetite for specialised ecosystems that can provide tailored regulatory assistance, infrastructure and operational efficiencies for export focused firms.

By contrast, only 14 percent of participants emphasized streamlined logistics and cold chain regulations, suggesting that while physical infrastructure remains important, the current focus is squarely on regulatory and procedural reforms that can more directly accelerate speed to market and simplify global trade.



Enhancing global competitiveness will depend on reducing regulatory barriers through international alignment and process simplification, enabling faster and more seamless access to key export markets.



Connect with us

Joydeep Ghosh

Partner,
Leader - Life Sciences & Health Care,
Deloitte South Asia
joghosh@deloitte.com

Contributors

Sayantan Sengupta

Acknowledgements

Rishi Malhotra

Srikanth Mahadevan

Remant Kumar Tiwari

Meryl Fernandes

Sampreeti Sen

Shreeti Nair

References

- ⁱIndia's Pharmaceuticals in Global Healthcare, PIB, 21 March 2026
- ⁱⁱIndia's Pharmaceuticals in Global Healthcare, PIB, 21 March 2026
- ⁱⁱⁱPharma exports rose 2% to over \$31 billion in FY26, The Hindu, 21 April 2026
- ^{iv}India's Pharmaceuticals in Global Healthcare, PIB, 21 March 2026
- ^vThe 'Patent Cliff' Revisited: Predicting Stock Impacts of Patent Expiry, DrugPatentWatch, 11 February 2026
- ^{vi}Pharma exports up 9.4% in FY25; industry aims for double-digit expansion in 2026-27, The Economic Times, 21 February 2026
- ^{vii}FDA Announces Expanded Use of Unannounced Inspections at Foreign Manufacturing Facilities, U.S. Food and Drug Administration, 06 May 2025
- ^{viii}Inspection Observations, U.S. Food and Drug Administration, 16 December 2025
- ^{ix}Measures to prevent overpricing and unethical practices, PIB, 09 December 2025
- ^xThe 'Patent Cliff' Revisited: Predicting Stock Impacts of Patent Expiry, DrugPatentWatch, 11 February 2026
- ^{xi}This was a multiple-choice question, with respondents allowed to select more than one option; therefore, the percentages do not add up to 100%
- ^{xii}Same as mentioned in reference xi
- ^{xiii}Indian drug exports get a tariff-free pass in the US, Business Today, 03 April 2025
- ^{xiv}United States-India Joint Statement, The White House, 06 February 2026
- ^{xv}Africa imports over 70% of its medicines, Gavi, The Vaccine Alliance, 14 October 2025
- ^{xvi}India, Vietnam Upgrade Ties, Target \$25 Bn Trade, BusinessWorld, 06 May 2026
- ^{xvii}India inks terms of reference with Philippines, Maldives for trade pact talk, The Economic Times, 16 March 2026
- ^{xviii}India - Malaysia Joint Statement, Ministry of External Affairs, 08 February 2026
- ^{xix}India-UK CETA, PIB, 27 July 2025
- ^{xx}India's pharma exports stare at 5,000 cr losses, The Times of India, 11 March, 2026
- ^{xxi}Cardiac Health in the Diabetic Population of India, European Journal of Cardiovascular Medicine, 30 April 2025
- ^{xxii}Tariff rate on all dutiable goods imported for personal use to be reduced from 20% to 10%, PIB, 01 February 2026
- ^{xxiii}Same as mentioned in reference xi
- ^{xxiv}Biosimilar boom ahead: Patent expirations set to reshape the global biologics market, BioSpectrum, 01 May 2025
- ^{xxv}Same as mentioned in reference xi
- ^{xxvi}Annual reports of various Indian pharma companies
- ^{xxvii}Annual reports of various Indian pharma companies
- ^{xxviii}Navigating the Complexities of Pharma Packaging Sustainability, Biospectrum, 31 August 2025
- ^{xxix}Same as mentioned in reference xi
- ^{xxx}Same as mentioned in reference xi
- ^{xxxi}Annual reports of various Indian pharma companies
- ^{xxxii}Same as mentioned in reference xi
- ^{xxxiii}AI-driven recruitment for pharma's next chapter, Pharmabiz, 17 December 2025
- ^{xxxiv}Same as mentioned in reference xi
- ^{xxxv}Annual reports of various Indian pharma companies
- ^{xxxvi}FY25 Review: Surge in Employment and Salary in Pharma Companies, The Financial World, 18 September 2025
- ^{xxxvii}Same as mentioned in reference xi
- ^{xxxviii}Inspection Observations, U.S. Food and Drug Administration, 16 December 2025
- ^{xxxix}Same as mentioned in reference xi
- ^{xl}Drug Prices, Patent Cliffs, and Generic Competition, DrugPatentWatch, 24 April 2026
- ^{xli}Same as mentioned in reference xi
- ^{xlii}Same as mentioned in reference xi
- ^{xliii}Union Health Ministry Notifies Key Amendments to NDCT Rules, PIB, 28 Jan 2026
- ^{xliiii}Same as mentioned in reference xi



Deloitte refers to one or more of Deloitte Touche Tohmatsu Limited (“DTTL”), its global network of member firms, and their related entities (collectively, the “Deloitte organization”). DTTL (also referred to as “Deloitte Global”) and each of its member firms and related entities are legally separate and independent entities, which cannot obligate or bind each other in respect of third parties. DTTL and each DTTL member firm and related entity is liable only for its own acts and omissions, and not those of each other. DTTL does not provide services to clients. Please see www.deloitte.com/about to learn more.

Deloitte Asia Pacific Limited is a company limited by guarantee and a member firm of DTTL. Members of Deloitte Asia Pacific Limited and their related entities, each of which is a separate and independent legal entity, provide services from more than 100 cities across the region, including Auckland, Bangkok, Beijing, Bengaluru, Hanoi, Hong Kong, Jakarta, Kuala Lumpur, Manila, Melbourne, Mumbai, New Delhi, Osaka, Seoul, Shanghai, Singapore, Sydney, Taipei and Tokyo.

This communication contains general information only, and none of DTTL, its global network of member firms or their related entities is, by means of this communication, rendering professional advice or services. Before making any decision or taking any action that may affect your finances or your business, you should consult a qualified professional adviser.

No representations, warranties or undertakings (express or implied) are given as to the accuracy or completeness of the information in this communication, and none of DTTL, its member firms, related entities, employees or agents shall be liable or responsible for any loss or damage whatsoever arising directly or indirectly in connection with any person relying on this communication.