US·INDIA
STRATEGIC PARTNERSHIP FORUM

Forging a Resilient Future

India's Opportunities to Expand Pharma Investments, Trade and Global Collaborations

Contents

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Foreword

The global pharmaceutical industry has witnessed phenomenal growth, with the market size projected to reach nearly USD 1.8 trillion by 2027. The growth of this industry and breakthroughs in drug discovery can be attributed to multiple factors, primarily increased investment in R&D and shifts in disease patterns of the patient demographic.

At present, India is a key player in the pharmaceutical ecosystem accounting for over 20% of global pharmaceutical production by volume and approximately 60% of the global vaccine supply.

Thanks to globalization, the pharmaceutical supply chain has undergone various developments such as knowledge transfer, technological advancement, market fluctuations and India has emerged as a key player in complementing global markets through its capabilities in vaccine and generic manufacturing, contract research and manufacturing services, and Active Pharmaceutical Ingredient (API) production. Going forward, a deeper bilateral collaboration with major economies across the United States (U.S.), the United Kingdom (UK) and the European Union (EU) will enhance investments in India due to the cost-effective and rapid pharmaceutical innovation in India. While there has been significant momentum, the caveats remain constant - fractious trade dynamics and geopolitical uncertainty accentuate the need for a set of diverse and resilient supply chains.

There have been various reforms undertaken in India to enhance the competitiveness of the pharmaceutical industry. A significant uptick in clinical trials being conducted within the country, the advent of the Global Capability Centers (GCCs) with a talent pool of over 280,000 professionals, and the highest number of U.S. Food and Drug Administration (USFDA) approved plants outside the US. In addition, India continues to have strategic partnerships with Organization for Economic Co-operation and Development (OECD) and G7 economies, namely the US, the UK, EU, South Korea and these collaborations span across the entire value chain from drug discovery and development to manufacturing and distribution. However, there are multiple impediments hampering the long-term growth and resilience of the pharmaceutical industry such as limited harmonization with international regulatory standards, lack of predictable regulations and a robust Intellectual Property Rights (IPR) framework, and limited inclusion in public payer programs.

This report has been developed post extensive research and sets out to highlight the existing synergies and challenges in the pharmaceutical landscape that limit trade and foreign investment. In order to develop a nuanced understanding of the most imperative bottlenecks, the team also interviewed over 20 industry leaders who provided a comprehensive overview of policy and regulatory hurdles. Through our research and interviews, this paper delineates each policy challenge and provides both short-term and long-term recommended actions, along with a few global best practices.

Going forward, the sustained growth of the pharmaceutical industry will requisite a robust regulatory framework, investment in R&D, and collaboration with major global economies. As a sector of economic and strategic significance, bilateral collaboration is at the core of strengthening the supply chain. Our paper outlines the role played by such partnerships in harnessing India's ability in affordable manufacturing, boosting foreign investment, and enhancing overall access to innovative therapies across the country. Through this report, we aim to encourage a continued dialogue between policymakers and the industry for key reforms that will drive innovation, investment, and allow India to emerge as a trusted trading partner and global leader in the pharmaceutical landscape.

Dr. Mukesh Aghi

President & CEO, USISPF

Executive Summary

India is a major player in the global pharmaceutical industry, being the largest supplier of generic medicines and vaccines and exporting to over 200 countries, including the US, UK, and EU. With growing geopolitical focus on secure supply chains, India's collaboration with these economies is critical for global pharma standards.

This paper explores reforms to help India realize its full trade potential. Recent policy steps include the New Drugs & Clinical Trials Rules (2019) for faster approvals, Patent Amendment Rules (2024) for stronger IP protection, and revised Schedule M for quality compliance. These developments have resulted in some improvements in increasing clinical trials in India and increasing USFDA registrations. While some positive steps have been taken, there are still some areas where improvements need to be brought that align India's pharmaceutical ecosystem with international standards and address persistent industry challenges.

As a part of developing the paper, inputs were taken from industry leaders and public forums to understand the most critical themes that should be addressed to unlock the full potential of India's global pharmaceutical partnership and facilitate expansion of investments within India.

1. Inclusion of international products in public payer programs

Challenges faced	Recommended Action
• Limited inclusion of international products in public payer programs	• The scope of AB-PMJAY may be increased to include innovative therapies, and procurement approach for other government schemes (Eg. CGHS and ESIC) may be referred to for programs like AB-PMJAY. • Enhance HTA framework to better suit India's socio-economic context through application of cost effectiveness thresholds

2. Harmonizing regulatory standards and facilitating increased interoperability

Challenges faced	Recommended Action
• Insufficient harmonization in regulatory standards and limited interoperability	• Amend Rule 101 to make it applicable to all drugs approved by regulators of countries named in the provision • Form a Center-State regulatory coordination cell (joint task force) to coordinate decision-making

3. Implementing and enforcing global IPR standards

Challenges faced	Recommended Action
• Limited alignment of IPR policies and frameworks with global standards	• Enact formal RDP framework under Indian drug regulatory laws • Create a CDSCO–IPO coordination cell to review patent status before granting marketing authorization. • Evaluate Patent Term Extension mechanism for up to 5 years

4. Improving predictability of drug pricing policies

Challenges faced	Recommended Action
• Low predictability of drug pricing policies	• Para 32 of DPCO to provide exemption to patented drugs for pending life of the patent • Amend Para 18 such that price fixation upon revision of NLEM/Schedule 1 to be applicable only to new drugs added

5. Harmonizing quality standards and adherence with International best practices

Challenges faced	Recommended Action
• Existence of gaps in harmonized quality standards and adherence	• Mandate nationwide rollout of revised Schedule M with defined timelines. • Setup a task force under the purview of the DCGI to monitor and ensure compliance with GMP standards.

As outlined in this paper, enhanced bilateral collaborations can unlock powerful outcomes—strengthened supply chain security, faster innovation cycles, expanded access to life-saving medicines, and greater preparedness for future public health crises. Ultimately, the success of these trade relationships will not only be measured by the value, but by their capacity to deliver timely, inclusive, and sustainable health outcomes on a global scale.

01 Introduction and setting the context

The global pharmaceutical industry stands at a critical inflection point in 2025, shaped by accelerating innovation, shifting demographics, and evolving global health needs. The sector is projected to grow at a steady CAGR of 5% between 2022 and 2027, reaching a market size of approximately USD 1.8 trillion by 2027[1]. Key drivers of this growth include breakthroughs in biologics, personalized and precision medicine, next-generation therapies such as gene and cell therapies, aging populations and rising global healthcare expenditures especially in emerging markets[2].

However, this positive trajectory is unfolding against the backdrop of an increasingly complex geopolitical environment. While the COVID-19 pandemic demonstrated adaptability in global healthcare supply chains, it also exposed certain vulnerabilities, prompting nations to reassess their reliance on singular manufacturing hubs and to consider more strategic partnerships. Further, growing strategic competition among major economies has intensified the call for more resilient pharmaceutical ecosystems and partnerships with trusted trading partners.

India has emerged as a pivotal player in the global pharmaceutical landscape, largely due to the sheer volume of its production and exports, skilled manpower, cost advantage and adaptability. Referred to as the "Pharmacy of the World," India is the largest supplier of generic medicines and vaccines globally. Home to more than **3,000 pharmaceutical companies**, India accounts for over **20% of global pharmaceutical production by volume** and contributes approximately **60% of the global vaccine supply**[3]. With a current market size of **USD 65 billion**, the sector is projected to grow to **USD 120–130 billion** within the next decade. This growth trajectory has been accompanied by increased investment into India's life sciences sector. In FY25, foreign direct investment (FDI) into the sector reached **~USD 2.3 billion**[4], with major inflows directed towards biotech, pharma, and med-tech. Lastly, Global Capability Centers (GCCs) have surged in India as multinational companies look to offshore core operational capabilities. In the life sciences and healthcare space alone, there are **over 160 GCCs expected by 2030**, employing over **420K professionals**[5].

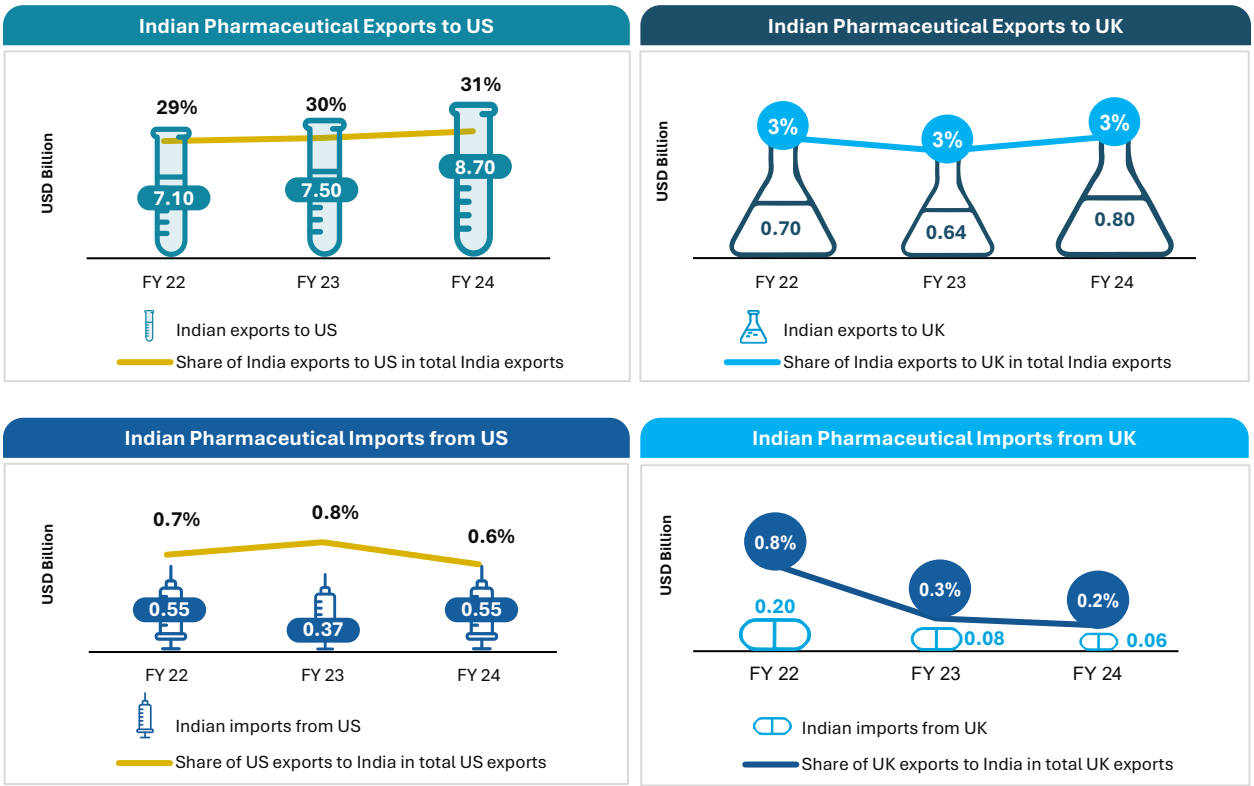
India additionally serves as a global hub, exporting to **over 200 countries**. Some critical markets that India exports to include major economies like the United States (US), United Kingdom (UK) and those in the European Union (EU), fulfilling **40% of US** and **25% of UK generic demand**.

The United States is a global leader in pharmaceutical innovation having an estimated pharmaceutical market size of USD 665 billion[6]. This is driven by its deep-rooted strengths in advanced R&D, biotechnology, regulatory science, and robust intellectual property systems. Additionally, the EU and UK effectively embed robust IP and regulatory frameworks into strategic Free Trade Agreements (FTAs), driving cross-border innovation and regulatory alignment that enhance market access across their USD 550 billion pharmaceutical sector[7].

India's collaboration with these economies is increasingly important in the global pharmaceutical supply chain, given their market leadership, and influence over international regulatory standard.

1. Assessment of the global and Indian pharmaceuticals industry, Crisil report, December 2023
2. Analysing the Global Pharma Industry: Growth Trends and Strategic Outlook for 2024, Pharma Linkage, June 2024
3. Pharmaceutical Exports from India, IBEF, April 2024
4. FDI in India's pharma sector crosses ₹19,134 crore during 2024-25, Economic Times, April 2025
5. Life Sciences giants rush to establish GCCs in India, 160 centers expected by 2030, Economic Times, February 2025
6. U.S. Pharmaceutical Market Size to Hit USD 1107.4 Billion by 2034, Biospace, February 2025
7. Europe and UK Pharmaceutical Market Size, Grand View Research, 2024

Figure 1: Share of India's pharmaceutical exports to US and UK, FY22-FY24 (Pharmaceutical Export Promotion Council of India)[8] ; share of pharmaceutical imports from US and UK, FY22-FY24 (Observatory of Economic Complexity Report)[9]



A closer look at India's pharmaceutical trade dynamics reveals that India's pharmaceutical exports outpace its imports to countries like US and UK.

In FY24, India exports to the US were almost 16 times higher than the US exports to India.

In FY24, India exported approximately USD 8.9 billion worth of pharmaceuticals to the US; and USD 0.8 billion to the UK. In contrast, imports from the US and UK stood at USD 553 million and USD 64 million respectively (Figure 1).

Analyzing the challenges that contribute to this trade imbalance and identifying targeted solutions offers a valuable opportunity to deepen India's partnership with other major economies, such as the US, UK and EU. Strengthening pharmaceutical collaboration will not only advance mutual trade goals but also further boost India's position as a reliable global pharma supply chain partner.

For countries like the US and UK, deeper engagement with India enhances the scalability and cost-efficiency of pharmaceutical innovation and strengthens its supply chain resilience. For India, it opens doors to investment, faster innovation, and broader global market access. This shared commitment, rooted in mutual trust and strategic convergence, not only supports **trade expansion** but also strengthens **global pharma supply chains, accelerates innovation, and fortifies health security**.

Across this paper, India's synergies with global mature economies are explored, along with areas for improvement so that India can unlock the next wave of growth through robust alliances and partnerships with global economies.

8. Trade Statistic, Pharmaceuticals Export Promotion Council of India

9. The Observatory of Economic Complexity

02 Overview of developments – improvements boosting Indian pharmaceutical trade and investments

India has actively been pursing policy reforms to enhance the appeal of its pharmaceutical ecosystem and bring it into closer alignment with international standards. Signs of progress includes a large and rapidly growing pharmaceutical market, a vast pool of skilled scientific talent and a diverse patient demographic.

On the back of these strengths, India has established multiple partnerships with developed economies across the entire value chain, in areas such as research, manufacturing and distribution. Figure 2 provides a summary of the India's existing strengths that can be further leveraged to build global partnerships.

Figure 2: Summary of existing synergies between India and global economies

Forging global partnerships and alliances

India has effectively partnered with multiple countries on topics that span areas like research and development, manufacturing and distribution. These alliances are designed to achieve multiple outcomes like ensure equitable access to medicines, accelerate innovation, and position India as a critical player in global health security and pharmaceutical leadership. Some of the critical partnerships have been highlighted in Figure 3.

Figure 3: Examples of India's global partnerships and alliances

1

Biopharmaceutical Alliance

Countries: India, US, EU, Japan, South Korea

Focus: Policy coordination, R&D support, pharma supply chains, innovation, trade facilitation

2

US-India TRUST Initiative

Focus: Public Private investments to expand Indian manufacturing capacity, including in the U.S., for active pharmaceutical ingredients for critical medicines.

3

India-EU Strategic Health Partnership

Focus: Regulatory harmonization, vaccine development, joint research, digital health, pandemic preparedness

4

NSF-DBT Collaborative Research Framework

Countries: US (National Science Foundation), India (Department of Biotechnology)

Focus: Synthetic biology, biomanufacturing, vaccine tech; joint funding & proposals

5

India-UK Health Partnership

Focus: Genomics, AMR, digital health, disease surveillance, personalized medicine, innovation hubs

6

Supply Chain Resilience Framework

Countries: India, Japan, Australia

Focus: Reducing single-source dependency; supports BIOS (Biological Innovation for Open Society) initiative

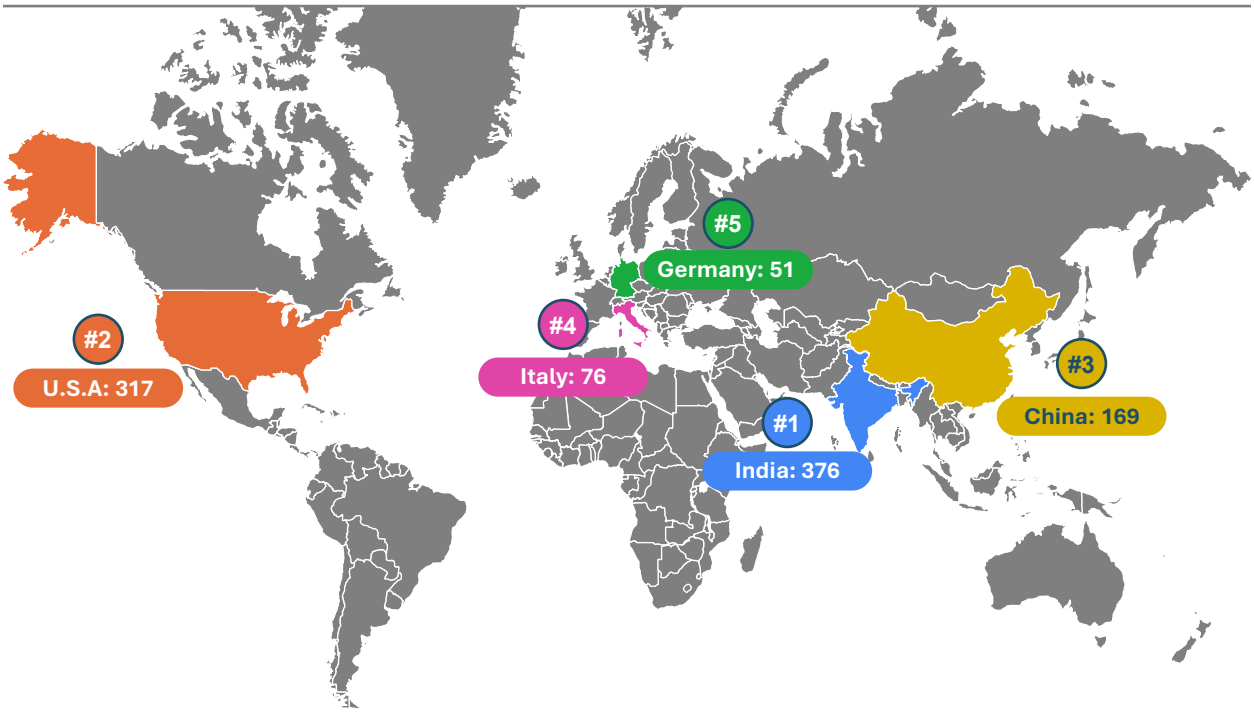
Bridging the gap with international standards through improved manufacturing quality

India consists of 670 USFDA compliant facilities, which is the largest outside the US. Additionally, with 500 API producers, India contributes nearly 8.0% to the global API market, reinforcing its position as a vital link in the global pharmaceutical supply chain.[10,11]

India also houses over 2500 WHO-GMP certified pharmaceutical facilities, along with 286 plants holding EDQM (European Directorate for the Quality of Medicines and HealthCare) approvals.

In FY24, India registered the highest number of USFDA facilities (376) out 1320 new facility registrations globally. Figure 4 depicts the number of registrations across top countries in FY24.

Figure 4: Number of new USFDA-registered generic facilities by country, FY24 (Pharma Compass)[12]



10. Formulating success: The Indian pharmaceutical industry, Invest India, March 2024
11. USFDA inspections of Indian pharma sites gain pace, Hindu Business Line, July 2023
12. India continues to top FDA registered generics facilities, Pharma Compass, November 2023

India's growing manufacturing prowess has led to a significant rise in collaborations with global pharmaceutical companies for large-scale production. Global firms like **AstraZeneca, Novavax, and Codagenix** partnered with Serum Institute of India to manufacture and distribute billions of vaccine doses. Bayer has partnered with several Indian firms to manufacture and distribute innovative therapies such as **Kerendia** (for chronic kidney disease), **Verquvo** (for heart failure), and **Nubeqa** (for prostate cancer) shortly after their global launch[13].

India has also taken significant steps to strengthen its quality assurance framework, enforce stricter compliance, and align manufacturing practices with global benchmarks. Some measures include revising Schedule M to tighten GMP (Good Manufacturing Practices) norms, as well as introducing schemes such as Revamped Pharmaceutical Technology Upgradation Assistance Scheme which offers financial support to MSMEs for upgrading their facilities to meet WHO-GMP standards.

While India has made significant progress to strengthen its pharmaceutical regulatory framework, continued policy reforms are recommended to address challenges pertaining to the circulation of substandard and counterfeit medicines.

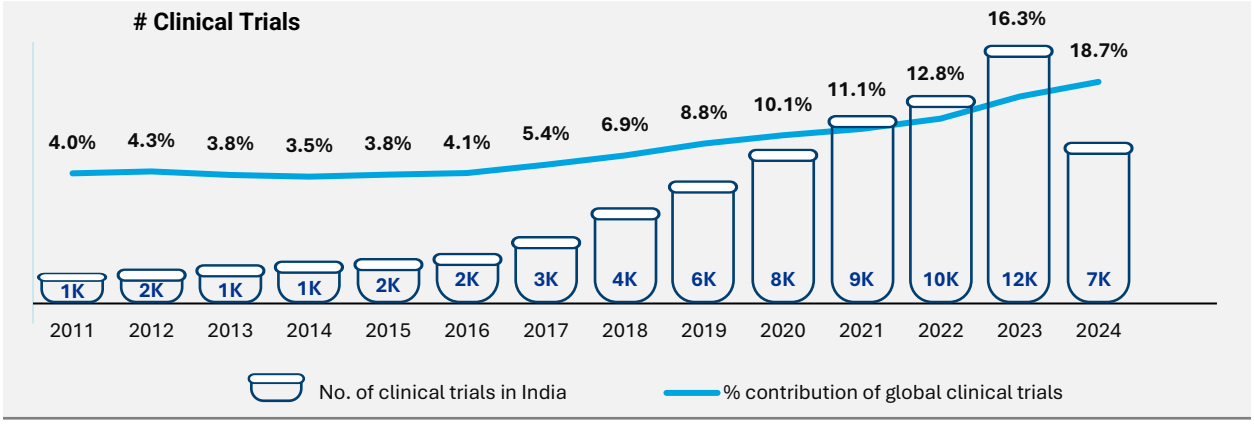
Strengthening enforcement against local distributors and online intermediaries, alongside enhanced cross-border cooperation with neighboring countries, would further reinforce confidence in India's pharmaceutical exports and safeguard patient health globally.

13. AstraZeneca, Bayer, Eli Lilly: Why global pharma giants are betting big on India's healthcare revolution, Fortune India, February 2025

Steadily improving number of global clinical trials conducted in India

Over the last 10 years, there has been a steady increase in the number of clinical trials conducted in India. Figure 5 highlights both the number of clinical trials, and the proportion of those trials conducted in India. This growth has primarily been driven by Phase-2 and Phase-3 trials, which have increased at a rate of 15-18% from 2017 to 2023.

Figure 5: India's contribution to global clinical trials, 2011-2024 (World Health Organization)[14]



The government has introduced amendments to the New Drugs and Clinical Trial Rules 2019 that aim to reduce the time for approvals, enhance transparency, and ensure ethical conduct. If enacted effectively, these reforms could continue to enhance India's appeal as a destination for clinical trials.

Conducting clinical trials in India offers several advantages for companies, including:

Cost-efficiency while ensuring quality: The cost of conducting a clinical trial in India is 30-40% lower[15] than countries like the US and UK, with established mechanisms to ensure quality standards.

Access to diverse patient-demographic: India offers a diverse patient demographic crucial for rare diseases or studies that requisite specific genetic profiles.

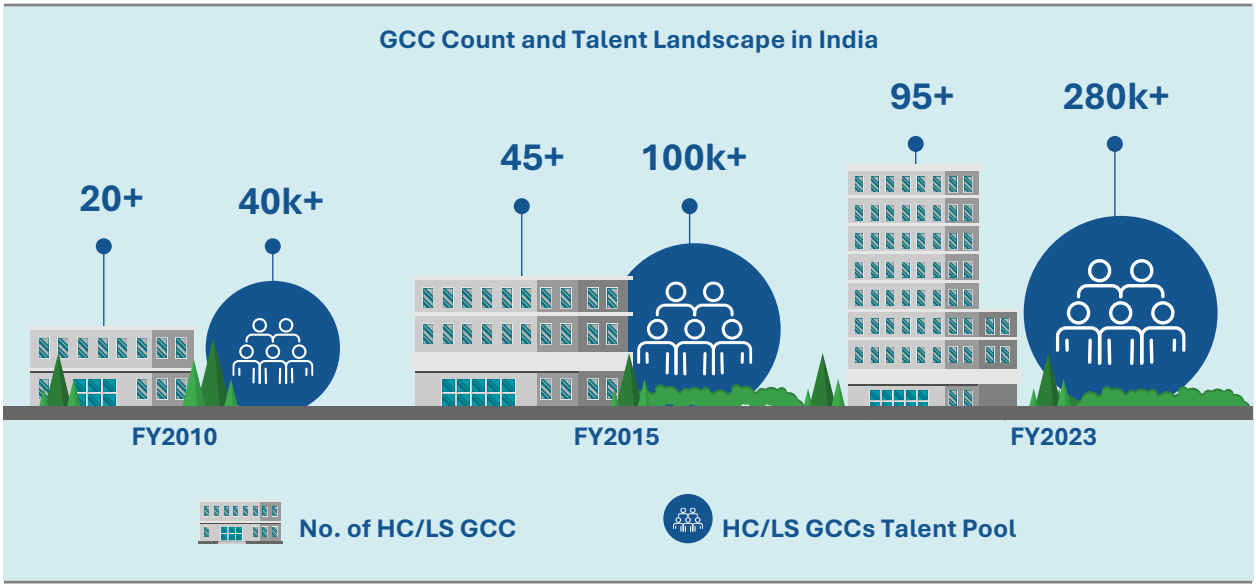
Despite the advantages of conducting global clinical trials in India, challenges in the regulatory framework deter companies from conducting trials in the country. Implementation of reforms would allow India to unlock the next level of growth, and policy recommendations are delineated in subsequent sections

14. Number of clinical trials by country, WHO, 2024
15. Why Clinical Trials in The APAC Region Cost Less, Clinical Leader, September 2023

Expanding Global Capability Centers (GCC) to support global operations

India has become a key destination for life sciences GCCs (Global Capability Centers), with over 95 centers supporting R&D, clinical trials, and digital transformation. Leading firms currently leverage India's expertise in drug discovery, big data analytics, and pharmacovigilance. Figure 6 below denotes the rise of the GCC count and resources in India over the last decade.

Figure 6: Growth of Healthcare and Life Sciences (HC/LS) GCCs in India, FY10-23 (ANSR Global)[16]



With the rapid adoption of AI, data analytics, and machine learning, India's GCCs are accelerating drug discovery, trials, and supply chain efficiency, reinforcing its position as a global life sciences hub. Establishing these GCCs in India allows global pharmaceutical and healthcare MNCs to benefit from lower operational costs while maintaining high-quality standards.

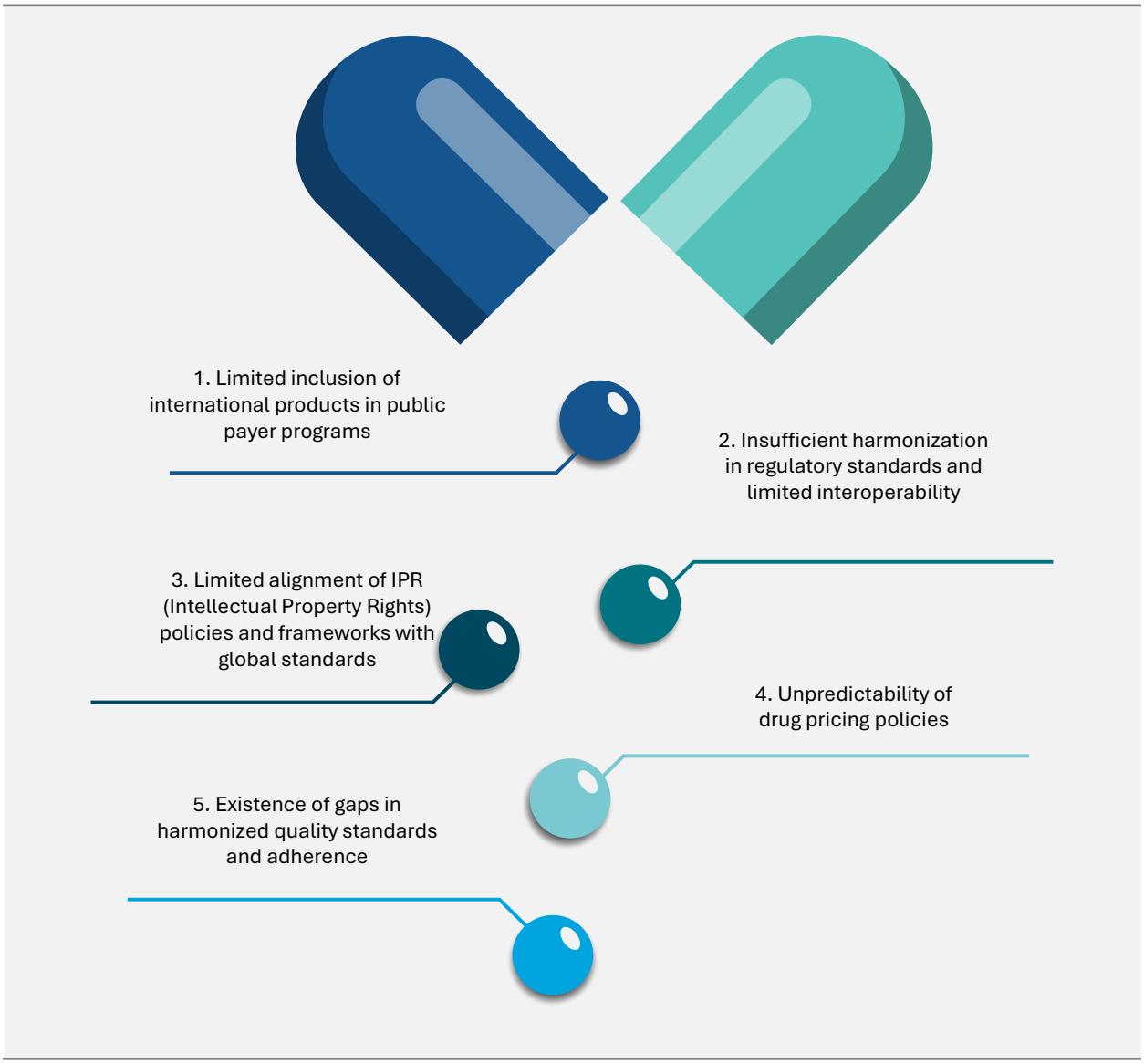
While these synergies offer a strong foundation, challenges around access, regulatory alignment, and innovation incentives continue to limit India's full trade potential. These synergies should be complemented by policies that further align India's pharmaceutical ecosystem with international standards and address persistent industry challenges. The next section outlines the key challenges and actionable solutions that India can implement to build a more balanced and collaborative trade.

16. State of Healthcare and Life Sciences GCCs in India, ANSR, April 2024

03 Way Forward - Overcoming challenges to facilitate expansion in investment, trade and global collaboration

20+ global industry leaders from organizations that have invested in India, were interviewed to understand the challenges that are currently impeding India's long-term resilience and growth. These challenges contribute to our vulnerability in the global supply chain and impact our ability to meet growing global healthcare demands. To unlock the full potential of India's global pharmaceutical partnership and facilitate expansion of investments within India, it is recommended to address these challenges in a timely manner.

The top challenges that were identified include:



The following section details these challenges that limit trade expansion, and the actions needed to address them.

3.1 Enabling inclusion of international products in public payer programs to advance health outcomes, pharma investments and trade

Challenges faced

Limited inclusion of innovative products in public payer programs such as AB-PMJAY:

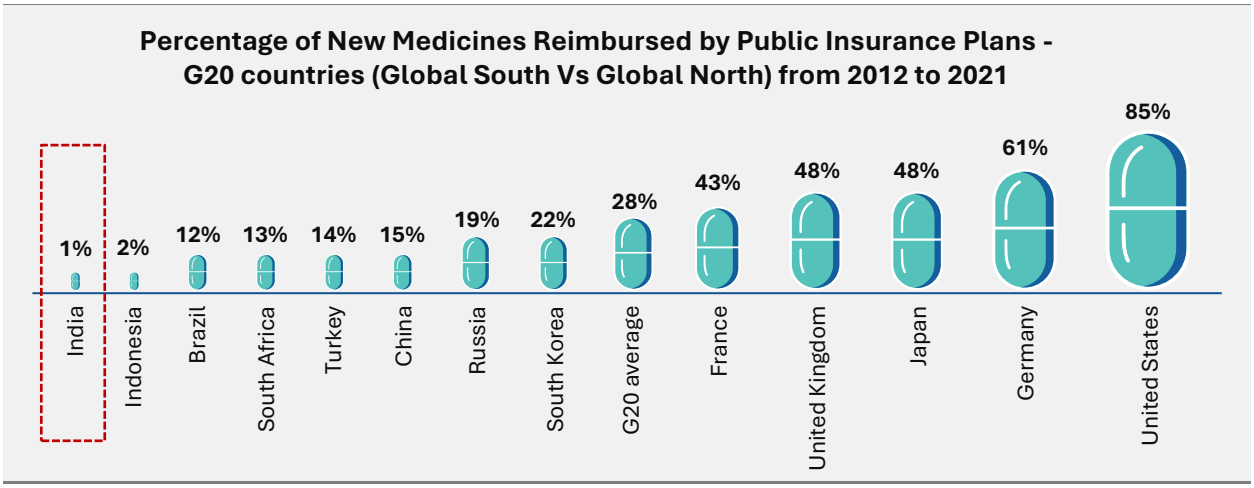
As highlighted in section 1, India's pharma exports to the US and UK continue to exceed India's imports from these countries. One of the reasons for this is the limited inclusion of international innovative products in public player programs like AB- PMJAY.

AB-PMJAY (Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana) is the world's largest public health program which covers medical treatment and drugs for approximately 600 million residents across private and public health facilities. Currently, this program does not include any patented/innovative therapies.

India has the lowest share of innovative medicines covered by public insurance (just 1%) based on data from 2012 to 2021 among all G20 countries

This means that almost all new treatments introduced during that time aren't available to most patients through government health programs. Indian patients do not get access to innovative therapies they may require to drive improved health outcomes; or face the burden of paying out of pocket to access these therapies. This underscores a critical gap in healthcare coverage and highlights the urgent need to expand coverage to include innovative therapies in public reimbursement programs. Innovative pricing mechanisms can be discussed to reduce the cost burden on the government if the scope is increased.

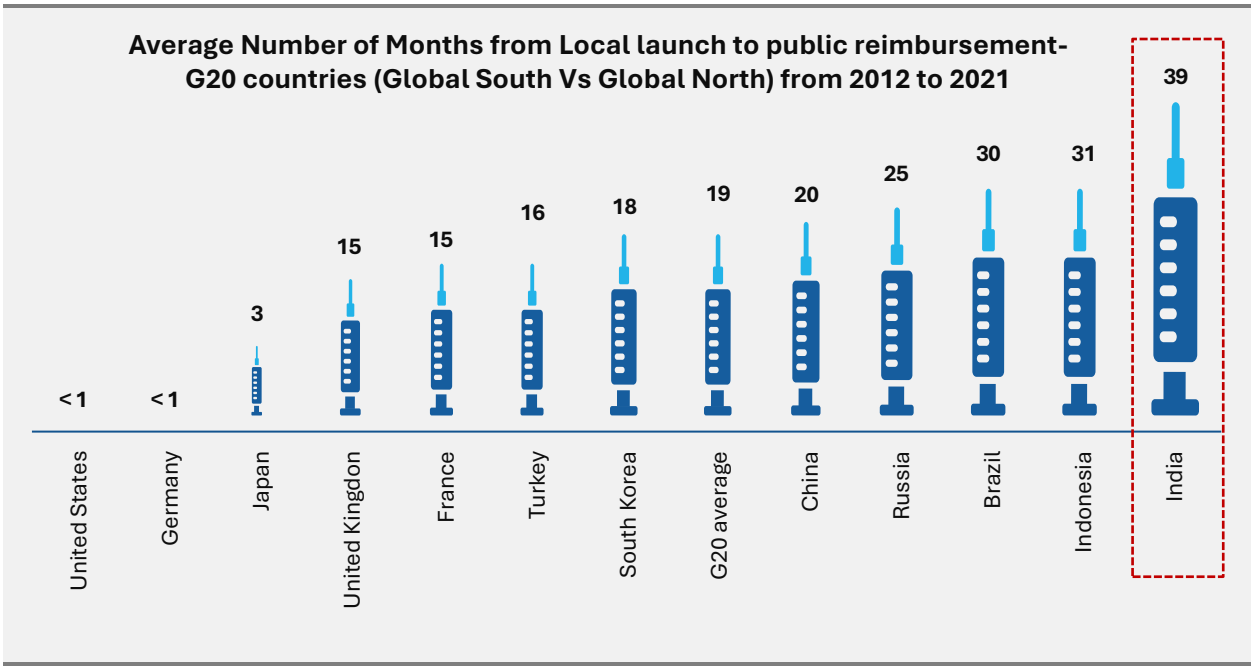
Figure 7: Percentage of New Medicines Reimbursed by Public Insurance Plans - G20 countries (Global South Vs Global North) from 2012 to 2021 (Global Access to New Medicines, PhRMA) [17]



17. Global access to new medicines, PhRMA, April 2023

Further compounding the issue is the delay in inclusion of innovative medicines in public reimbursement schemes as shown in Figure 8.

Figure 8: Average Number of Months from Local launch to public reimbursement - G20 countries (Global South Vs Global North) for all new medicines launched and reimbursed by country from 2012 to 2021 (Global Access to New Medicines, PhRMA)[17]



India also takes the longest time to include a product in public reimbursement programs after a local launch—around 39 months, which is much higher than the G20 average of 19 months.

The AB-PMJAY program, which covers ~45-50% of the total India market currently does not reimburse most innovative therapies. Inclusion of innovative therapies in these programs requires such drugs to follow an unsustainable 'cost-effective price determination'. This approach has been seen to require a reduction in prices up to 80%, resulting in the limitation of access to global innovative therapies to this program.

17. Global access to new medicines, PhRMA, April 2023

What needs to be done – Recommended actions:

Background

India's public health programs have limited inclusion for innovative drugs, with AB-PMJAY primarily focused on providing access for generic medicines.

Summary of recommended actions

To address this, the following actions are recommended:

- Use new mechanisms to determine pricing for programs like AB-PMJAY, and rates that have been established in other schemes like CGHS and ESIC may be referred for programs like AB-PMJAY.
- Revise HTA (Health Technology Assessment) framework to be better suited to India's socio-economic context, making it viable for innovative therapies to be included.
- Implement leading practices that incorporate flexible thresholds for cost effectiveness, or modifiers based on nature of illness, therapy area and diseases with low QALY

Action 1: Increase access for innovative products in public payer programs

Current Scenario in India	• India's public health schemes like AB-PMJAY primarily reimburse generic therapies, and have limited coverage for innovative drugs • Cost effectiveness framework currently followed by India work best in high GDP per capita models. In the India context, it results in limited inclusion of innovative drugs in such programs • This limited coverage for the innovative drugs results in patient having to pay out of pocket, creating a significant financial burden to leverage the benefits of innovative therapies.
Short-Term Recommended Actions	• **Expand the AB-PMJAY basket to include innovative therapies. Procurement approach for other government schemes (eg. CGHS) maybe referred to for government programs like AB-PMJAY.**
Long-Term Recommended Actions	• Enhance HTA framework to better suit India's socio-economic context (like provide for multipliers) to make it more viable for innovative therapies to be listed.
Global Leading Practice Examples	**Consideration of government negotiated rates to procure innovative medicines for government employee health programs:** • The Government of India negotiates the rates, and innovative medicines are incorporated based on HCP recommendations into the essential drug list. • After incorporation, government entities can procure and enter direct price negotiations. Once listed as reimbursable, there is no limitation on use and doctors are encouraged to utilize the best and most appropriate medicines for beneficiaries. **Use of flexible Cost Effectiveness Thresholds:** • Countries that enable greater access to innovative medicines use different thresholds for different types of technologies / therapeutic areas. While WHO-CHOICE suggests a cost-effectiveness threshold of 1–3 times a country's GDP per QALY, actual thresholds vary widely across countries depending on their healthcare priorities and budgets. **Use of Modifiers to provide additional flexibility:** • To provide a more quantifiable and equitable framework for prioritization, some countries are adding modifiers to include drugs that otherwise may not meet cost effectiveness thresholds. These are based on kind of disease, severity of illness, innovation of therapy, diseases with low QALYs (e.g. Cancer) etc. Using modifiers helps to avoid having one fixed CET (Cost Effectiveness Threshold) and would instead allow for multi-level CETs for different types of medicines / technologies.

Impact on trade and patient outcomes from including Innovative Drugs in India's AB-PMJAY program – an example from 2 US innovative lung cancer drugs[18]

Trade Potential

- Introducing measures to expand access to innovative drugs in public payer programs can significantly increase demand, thereby broadening the market reach.
- According to current estimates based on available data, the introduction of just two sample innovative cancer therapies primarily indicated for non-small cell lung cancer could generate an annual revenue potential of **~USD 230 million.**
- This in turn increases India's attractiveness as a manufacturing destination for exports and renders the possibility of inclusion in the Global Value Chain.

Patient Impact

- Beyond the financial impact, inclusion of these therapies also holds significant promise for enhancing patient outcomes.
- For Drug 1, **more than 50%** of the patients are expected to extend their life by **at least 5 years**, with further improvement expected as mid-points are not yet reached.
- For Drug 2, overall survival is estimated at **30 months**, which would be double of traditional chemotherapy's current offering.

The expansion of public reimbursement programs to include innovative therapies improves access and affordability. Wider drug coverage and insurance support help reduce costs and ensure essential medicines and healthcare services are more readily available to the public. Timely access to treatment and medications contributes to better health outcomes through improved disease management and overall public health. This has downstream economic benefits such as a healthier, more productive workforce and reduced long-term healthcare spending.

18. Internal analysis based on approved indications of drugs, clinical trial data on therapeutic impact, published pricing of drugs and estimated patient pool with access to AB-PMJAY. Details of calculations provided in Annexure-1.

3.2 Harmonizing regulatory standards and facilitating increased interoperability to drive global investments

India's regulatory framework is not yet completely aligned with international standards (such as USFDA, EMA etc.), resulting in inconsistent approval timelines. As India aims to strengthen its competitiveness and expedite growth, addressing challenges pertaining to regulatory harmonization and limited interoperability will propel timely patient access to new therapies and greater investment.

India's regulatory approval process for new drugs is significantly slower compared to countries like the US and those in the EU. As per a recent study conducted by NCBI (National Center for Biotechnology Information), centralized regulatory agencies like the FDA and EMA provide streamlined, single-window approvals within 6–10 months on average, whereas India's regulatory approval process can take up to 2 years[19]. This places India at a competitive disadvantage in bringing innovative drugs to market efficiently.

Challenges faced

Limited enforcement of reliance mechanisms and approval pathways: India faces regulatory delays and inefficiencies in drug approvals due to non-stringent application of reliance mechanisms and accelerated approval pathways, impacting timely patient access to new therapies.

The Government had introduced the Rule 101 as a part of the New Drug and Clinical Trials 2019, which would waive the need for conducting a local Phase-III Clinical Trial (CT) if the drug is approved for marketing in countries specified by the Drugs Controller General of India (DCGI). Additional conditions for the exemption is if the drugs fall within designated categories, no major unexpected adverse events have been reported, and the company undertakes to conduct Phase IV studies. However, the classification of drugs into these qualifying "categories"—particularly the broad and interpretive criterion of "significant therapeutic advantage"—introduces considerable subjectivity, leading to delays and scope for arbitrary decision-making. Additionally, this rule has not been completely operationalized, with its applications being limited to only a handful of medicines, as well as a clear and transparent process for submitting applications not being established.

Limited harmonization across central and state regulatory bodies: Fragmented regulatory oversight between national and regional agencies results in inconsistent interpretations of rules and requirements across states, duplication of processes, and slower decision-making.

> *"In India, it takes 6/7 months to get clinical trial approved. Due to this reason, global companies prefer shifting focus to other countries."*
>
> ***– US MNC pharmaceutical company"***

> *"With multiple regulatory agencies currently existing in India, there is a need to improve harmonization across agencies to ensure the continuation of regulatory process with the finite available resources"*
>
> ***– Pharma and Biotech company***

19. Evaluation of drug lags for new drugs across India, US, EU and Japan, NCBI, 2018

What needs to be done – Recommended actions:

Background

Regulatory challenges in India are primarily driven by limited enforcement of reliance mechanisms and approval pathways, as well as fragmented regulatory oversight between central and state agencies. The inefficiencies in the drug approval process caused by these challenges result in delays in approval.

Summary of recommended actions

To address this, the following actions are recommended:

- India should broaden Rule 101 to cover all drugs approved by trusted global regulators and set up a fast-track cell within CDSCO.
- Setup of a joint coordination task force to ensure stronger harmonization between central and state regulatory bodies.
- In the long term, gradually integrate CDSCO and state functions into a single central regulatory body while preserving state-level execution through zonal offices
- Become a permanent member of the International Council for Harmonization (ICH), to enable interoperability of regulatory standards and approvals

Action 1: Implement reliance models and other expedited approval pathways

Current Scenario in India	**Reliance Model and other Expedited Approval Pathways** • While Rule 101 has been established, it is only applicable to a limited category of drugs (such as Orphan drugs, gene and cellular therapies, pandemic drugs, defense use drugs, drugs with significant therapeutic advancement etc.). This leads to a subjective application of reliance model mechanisms for drug approvals. • Non-standardized implementation of Rule 101 has also resulted in cases of denial of approval due to lack of clinical trials in India, or lack of Indian participants in global trials • The 'significant therapeutic advancement requirements' category creates subjectivity and redirects the application back to SEC committees. **Accelerated Approval Pathways** • India's accelerated approval pathways, while established, is still evolving in terms of predictability and transparency. • Systems for enforcement and monitoring of post-marketing surveillance are also still developing, resulting in delays in confirming safety and efficacy of products, potentially delaying final approvals.
Short-Term Recommended Actions	**Reliance Model and other Expedited Approval Pathways** • **Amend Rule 101 to make it applicable to all drugs approved by regulators of countries named in the provision; remove category limitations.** • **Develop and disseminate standardized SOPs among Subject Expert Committee (SEC) members to enhance awareness and ensure consistent implementation of Rule 101.** • **Create fast-track cell within CDSCO to process reliance-based applications.** **Accelerated Approval Pathways** • **Enhance regulatory-industry interface through pre-submission meetings / rolling reviews.**
Long-Term Recommended Actions	• **India should become a permanent member of the International Council for Harmonization (ICH), to enable interoperability of regulatory standards and approvals, thereby reducing time taken for drugs developed in India to reach the world.**
Global Leading Practice Examples	**Implementation of Reliance Model and Accelerated Approval Pathways:** • Countries implement **Reliance Models** and **Accelerated Approval Mechanisms** to improve access to innovative therapies while maintaining safety and efficacy standards. These approaches allow regulatory agencies to leverage decisions made by trusted counterparts, prioritize urgent medical needs, and fast-track approvals based on early clinical data. • For example, the USFDA recognizes approvals from stringent regulatory authorities like the EMA, PMDA (Pharmaceuticals and Medical Devices Agency), and Health Canada to expedite registration. Similarly, China's National Medical Products Administration (NMPA) has introduced reforms to shorten clinical trial approval timelines and prioritize drugs urgently needed for clinical use.

Action 2: Bring about harmonization across central and state regulatory authorities

Current Scenario in India	• India has a federated and fragmented regulatory system – Central Drugs Standard Control Organization (CDSCO) oversees new drug approvals, while state drug authorities control manufacturing, sales, and distribution. • Delays are observed in obtaining state licenses for production despite CDSCO approval.
Short-Term Recommended Actions	• Form a Center-state regulatory coordination cell (joint task force) to facilitate decision-making and standardize interpretations. • Roll out integrated digital platform between center and states for end-to-end tracking of approvals.
Long-Term Recommended Actions	• Gradually integrate CDSCO and state functions into a single central regulatory body while preserving state-level execution through zonal offices.
Global Leading Practice Examples	• Establishment of a **unified, centralized regulatory framework**: Countries maintain harmonization across different regulatory authorities through the establishment of a unified regulatory framework that coordinates enforcement, inspections, and compliance standards across jurisdictions. • Countries like the United States, through the USFDA, and Japan, via the PMDA exemplify this approach. These agencies oversee nationwide regulatory activities, ensuring uniform implementation of quality standards and inspection protocols

Standardized regulations would minimize compliance risks, reduce inconsistencies, improve predictability, and foster trust among stakeholders. Institutionalized industry-government forums would ensure that policies remain responsive to innovation and evolving healthcare needs. Regulatory clarity and expedited approvals would improve patient access to affordable, high-quality medicines, benefiting both the healthcare system and the broader population.

3.3 Implementing and enforcing global IPR standards to accelerate innovation and foster more trade

Intellectual Property Rights policies are fundamental to the pharmaceutical industry, as they enable innovation and incentivize R&D investment. Strong IPR frameworks are especially critical in international trade, as they foster trust between countries, encourage technology transfer, and open opportunities for high-value trade.

Strategic IP reforms can unlock substantial investment from global pharmaceutical companies by assuring innovation will be protected across borders. For example: markets with a robust Regulatory Data Protection (RDP) framework consistently attract more clinical trials, driving foreign direct investment, job creation, and technology transfer. By safeguarding proprietary data and incentivizing innovation, RDP would not only accelerate R&D but also strengthen high-value manufacturing capabilities, positioning India as a strong and competitive player in global pharma supply chains.

Strengthening India's IP regime is not just about alignment with global norms—it's a strategic move to unlock investment, drive innovation, and build a future-ready pharmaceutical manufacturing base.

India ranks 58th out of 125 countries in overall strength of IP framework as per the Property Rights Alliance International IP Index.[20] Further, India is also a part of USTR's Priority Watch List in the Special 301 Report, with the U.S. encouraging continued improvements to facilitate increased transparency in India's patent processes[21]

Challenges faced

- **Unavailability of a regulatory data protection framework:** India currently does not have a regulatory data protection framework. However; India has recently announced a review of its approach to safeguarding clinical and regulatory data in new-drug approvals. In early October 2025, the Central Drugs Standard Control Organization (CDSCO) invited stakeholder feedback to ensure a level playing field between innovators conducting local clinical trials and subsequent applicants relying on those data.

- **Unavailability of patent term extensions:** India does not have the provision for providing patent term extensions, to accommodate for delays in market authorization on account of regulatory processes or patent grant approvals. This limits the ability of the pharmaceutical companies to maximize their market exclusivity period and also compresses the timelines for conducting comprehensive clinical trials, which subsequently impacts the attractiveness of investments in the country.

- **Absence of patent linkages:** India does not have a mechanism, such as patent linkage, to resolve patent disputes before an infringing product is launched on the market. The absence of integration between patent approval and drug market authorization processes limits regulatory visibility into subsisting patents, thereby constraining the ability to proactively track and enforce patent compliance.

The challenges faced in enforcement of IP policies in India result in delayed timelines in granting patents, as well as tedious processes for resolving disputes. The average time from filing to final decision on patent applications in India is **~49.5 months (> 4 years)**, as compared to the US, where it is done within **24-30 months** and within **12 months** for prioritized examination. This in turn reduces the commercial viability of entering the Indian market.

20. International Property Rights Index, Property Rights Alliance, 2024
21. Special 301 Report, USTR (Office of the United States Trade Representative), 2025

What needs to be done – Recommended actions:

Background

Challenges in India's IPR policies include unavailability of regulatory data protection framework, patent linkage, and patent term extensions.

Summary of recommended actions

To address this, the following actions are recommended:

- Introduce a formal robust regulatory data protection framework, offering defined exclusivity periods.
- Establish a strong coordination mechanism between CDSCO and Patent Office to verify the patent status before granting market authorization.
- Enhance the Sugam portal to publicly disclose new drug applications to improve transparency.
- Implement patent term extension mechanisms of up to 5 years to compensate for any delays caused during regulatory or administrative processes.

Action 1: Introduce robust regulatory data protection and exclusivity

Current Scenario in India	• India does not have a formalized RDP framework in the Drugs and Cosmetics Act or IP laws, or a dedicated pathway for biologics data exclusivity. • However, the CDSCO does allow generic manufacturers to rely on the originator's data submitted for approval, even within a short timeframe.
Short-Term Recommended Actions	• Enact a formal RDP framework under Indian drug regulatory laws, offering data protection and exclusivity for NCEs (New Chemical Entities) and biologics matching international standards. This means an RDP of 10 years and 12 years respectively for NCEs and Biologics with RDP term starting from the date of approval in India.
Global Leading Practice Examples	• **Implementation of a formal RDP framework:** Several countries have implemented an RDP framework granting a defined period of exclusivity for their clinical trial data, • The introduction of RDP has long standing benefits, with patients having **threefold more access to innovative medicines** in countries with RDP than in countries without RDP[23]. • In Taiwan, availability of innovative medicines increased by approximately 8 percentage points when it amended the Pharmaceutical Affairs Act in 2017 to establish a framework for RDP and patent linkage[22]. Further in Japan and Croatia, clinical trials increased by 3.5 times and 1.5 in the five years following RDP implementation respectively[23].

22. Taiwan International Patent & Law Office, 2018
23. Regulatory Data Protection, Copenhagen Economics, August 2023

Action 2: Introduce interlinking of patents and new drug approvals

Current Scenario in India	• India currently lacks a centralized system (like the USFDA's Orange Book for listing patent information), which can make patent visibility more challenging. • CDSCO and Indian Patent Office (IPO) operate independently, with no integrated system and no provision for regulator to verify subsisting patents prior to approval of new drugs. This limits regulatory visibility into subsisting patents, thereby constraining the ability to proactively track and enforce patent compliance. • While the Sugam portal facilitates new drug approvals, it does not yet provide the broad accessibility for other companies to proactively assess potential patent overlaps. As a result, patent holders often rely on post-approval litigation to assert rights.
Short-Term Recommended Actions	• **Create a CDSCO–IPO coordination cell to review patent status before granting marketing authorization.** • **Enhance Sugam portal such that new drug applications are made public, ensuring patent holders can take pre-emptive action to protect IP where required.** • **Implement a formal notification system where CDSCO informs patent holders of biosimilar / generic filings.**
Long-Term Recommended Actions	• **Institutionalize a full-scale Indian equivalent of the Orange Book, legally mandated under Drugs and Cosmetics Rules, with regular updates and patent expiration tracking.**
Global Leading Practice Examples	• **Availability of a centralized repository and SOP linking drug approvals to patent status:** Several countries maintain a centralized, publicly accessible repository that lists all approved drugs along with their patent status, exclusivity periods, and regulatory details. • For example, US maintains the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations), which lists all approved drugs along with their patent status, exclusivity periods, and therapeutic equivalence codes.

Action 3: Patent term extension / restoration (not equivalent to evergreening)

Current Scenario in India	• Indian patents are valid for 20 years from the filing date, regardless of regulatory approval delays or administrative backlogs. • Delays during regulatory processes or grant approvals (such as pre-grant opposition which can extend up to 9 years in India, unavailability of patent examiners etc.) are not compensated by IP extensions
Long-Term Recommended Actions	• **Patent Term Extension (PTE) mechanism for up to 5 years may be one way to factor in delays on account of regulatory processes or patent grant approvals.**
Global Leading Practice Examples	**Availability of patent term extensions and amendments:** • Systems which allow for patent term extensions and amendments are available across countries like United States, European Union, Japan, Singapore, etc. • In Singapore, the Patents (Amendment) Act 2004 introduced patent term extensions to consider delays in obtaining marketing approval for pharmaceutical products. • In the US, when delays are caused by the Patent and Trademark Office, the time lost can be regained through Patent Term Adjustments.

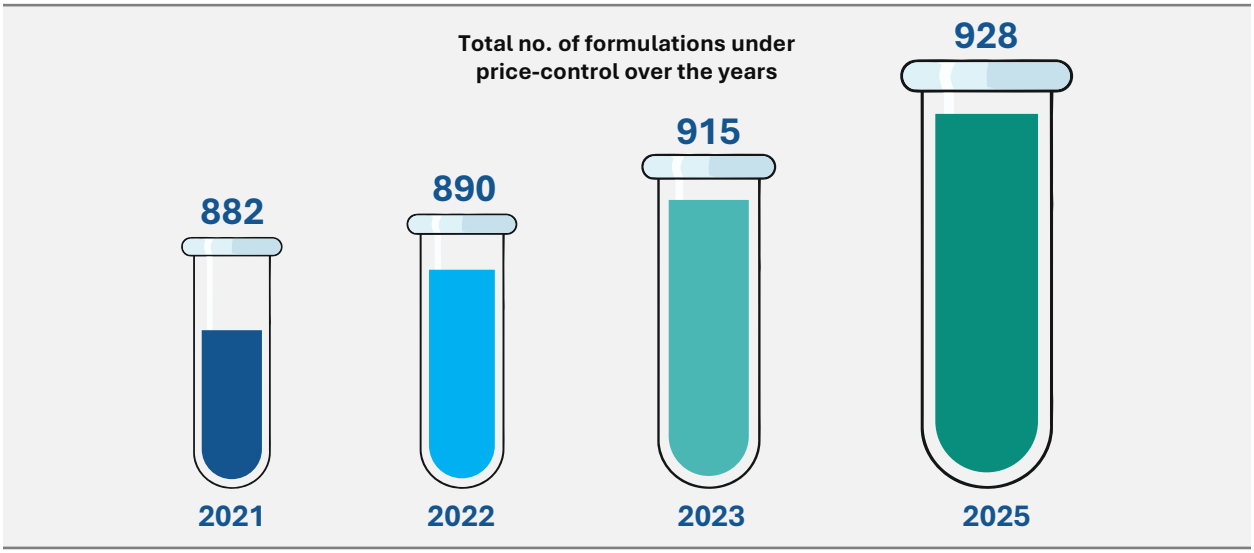
Establishing a more streamlined and innovation-friendly regulatory and IPR ecosystem in India can deliver significant benefits across the pharmaceutical value chain. Digitizing IPR processes would enhance efficiency and transparency by reducing delays, improving enforcement, and minimizing disputes, thereby making drug development more predictable and less resource intensive. These improvements would also boost India's global competitiveness, positioning it as a preferred destination for pharmaceutical R&D and investment.

3.4 Improving predictability of drug pricing policies to promote investments

India's pricing policy for essential drugs is primarily governed by the Drugs Prices Control Order (DPCO) 2013 and regulated by the National Pharmaceutical Pricing Authority (NPPA). The price controls have been introduced with the objective of increasing patient-affordability and accessibility of essential medicines under National List of Essential Medicines (NLEM) released by the Ministry of Health and Family Welfare. However, the current structure of the pricing framework poses challenges in balancing affordability with innovation & sustainable manufacturing costs.

The DPCO 2013 follows a market-based pricing (MBP), where prices are fixed based on the average of brands having market share of at least 1% of the total market. Post-establishment of DPCO 2013, the number of drugs under regulation have gradually increased over the years. Price-controlled drugs account for approximately 17% by value of the overall pharmaceutical market in India[24]. This segment includes essential medicines across various therapeutic categories, such as antibiotics, cardiovascular drugs, antidiabetics, and oncology medications. As of March 2025, The National Pharmaceutical Pricing Authority (NPPA) regulates the prices of approximately 928 formulations under the NLEM[25].

Figure 9: Increasing formulations under price control over the years (Ministry of Chemicals and Fertilizers)[25]



24. Press information bureau, Ministry of Chemicals and Fertilizers, 2020
25. Press information bureau, Ministry of Chemicals and Fertilizers, March 2025

Challenges faced

- **Limited recognition of innovation in price control application:** Paragraph 32 of the Drug Price Control Order (DPCO), 2019 provides a five-year exemption from price control for new patented drugs introduced in India for the first time. However, the duration for this exemption is limited and does not fully mitigate the long-term pricing risks for pharmaceutical companies. Further, both process and product patents are considered for price control protection for India based companies. However, only product patents are considered for products developed outside India.
- **Low predictability of the price-control mechanism and repeated price reductions:** The NPPA can impose price controls under Para 19 of DPCO in an ad hoc and subjective manner. This creates business uncertainty, discouraging investment and strategic planning for pharma companies. Once a drug is brought under price control, it can be subjected to further price reductions in subsequent regulatory revisions. Additionally, under Para 18, prices of drugs already fixed under one round of price fixation are brought down through refixation of prices upon each revision of the NLEM.
- **Narrow applicability of Trade Margin Rationalization (TMR) policies:** Currently, TMR policies are only applicable to 42 anti-cancer drugs in India. There is no comprehensive TMR policy covering the broader pharmaceutical market. Furthermore, the industry requests exclusion of government sales and volumes supplied for Patient Assistance Programs from this policy. This situation results in pricing distortions, leading to an uneven playing field with certain market participants offering higher trade margins.

What needs to be done – Recommended actions:

Background

India's pharmaceutical pricing policies present challenges to innovation and market stability, particularly due to price caps on patented drugs, selective trade margin rationalization, and frequent price re-fixation.

Summary of recommended actions

To address this, the following actions are recommended:

- Exempt patented drugs under Para 32 of DPCO for pending patent life
- Limit price revisions to newly added drugs in the NLEM.
- Apply trade margin rationalization equitably across all products
- Establish rational and predictable pricing policy to foster market access.

Action 1: Recognize Drug Innovation in Price Controls

Current Scenario in India	• India has a uniform pricing policy under DPCO (Drug Price Control Order), having no differential pricing mechanism for patented drugs. • As a result, price caps are present even for some patented drugs, creating a disincentive for innovation.
Short-Term Recommended Actions	• **Para 32 of DPCO to provide exemption to patented drugs for pending life of the patent (compared to only 5 years currently).** • **Equal application to International and Indian companies, i.e. product or process patents accepted for all therapies, regardless of country of origin.**
Long-Term Recommended Actions	• Establish a **predictable pricing policy** to foster a more stable and attractive business environment for pharmaceutical companies, enhancing market confidence and enabling predictability to support long-term market entry planning.

Action 2: Limit price revisions to only newly added drugs in NLEM

Current Scenario in India	• Ceiling prices for all drugs listed within the NLEM are updated upon every revision, creating a continuous cycle of price reductions.
Short-Term Recommended Actions	• **Amend Para 18 such that price fixation upon revision of NLEM should only be applicable to the new drugs being added to the schedule.**

Action 3: Introduce Trade margin rationalization in an equitable manner

Current Scenario in India	• India introduced Trade Margin Rationalization through NPPA, capping margins at 30%–70% for select drugs. • However, there has been no further decision on extending the application of TMR on all drugs to create a more equitable policy.

Short-Term Recommended Actions	• Introduce TMR on drugs, as amendment to DPCO as per the below norms:
	  • Volumes supplied to Government (since Govt is not a trader) and free drugs provided through assistance programs (since these units are not for trade) should be excluded.
	  • TMR should be applied to all products in an equitable and transparent manner.
	• "Price to distributor" should be maintained as the means to set the TMR. [MRP = PTD + (PTD x TM) + Applicable GST]

Transparent and predictable pricing mechanisms contribute to market stability and encourage investment in high-value therapies. This creates a favorable environment for introducing innovative treatments and ultimately improves patient access to advanced therapies. Moreover, aligning pricing policies with global best practices facilitates smoother regulatory approvals and strengthens India's position in global value chain.

3.5 Harmonizing quality standards and adherence with International best practices

Currently, India supplies 20% of the global demand for generic drugs[26], and targets to grow 2x to USD 130 billion by 2030[27]. This journey involves transitioning from high-volume, low-cost generics to high-value, advanced medicines. This goal relies heavily on expanding exports to key markets like the US and EU. To achieve this, India must ensure its pharmaceutical quality standards are on par with global requirements. This not only aims to enhance the country's global competitiveness but also to foster innovation and improve healthcare outcomes domestically.

Challenges faced

- **Non-uniform adherence to GMP (Good Manufacturing Practices):** Many Indian small and medium-scale enterprises struggle to consistently implement GMP norms due to limited resources, awareness, or training; and inconsistent enforcement. This leads to variability in product quality and compliance issues.
- **Non-availability of a stringent and unified inspection model:** The current inspection framework varies across states and does not follow a centralized enforcement, making it difficult to maintain consistency and accountability in quality assurance nationwide.

A stricter enforcement of quality practices needs to be achieved for India to improve its standing as a global leader. Given India's strategic and commercial standing in the global pharmaceutical supply chain, it becomes crucial for the industry to exhibit continued commitment to superior quality control methods.

> *India has some distance to go to reach USFDA standards. First step for improving trade between countries is to understand and cater to each other's regulatory and quality ecosystems.*
>
> ***– Biotech company***

26. Quality control is critical to the Indian pharmaceutical industry's future success, The Times of India, May 2022
27. India pharma industry to reach $130 billion by 2030, The Hindu, November 2023

What needs to be done – Recommended actions:

Background

India faces challenges in uniformly enforcing pharmaceutical quality standards and inspection protocols, particularly due to inconsistent implementation of Schedule M (GMP) across states and limited infrastructure among smaller manufacturers. Additionally, India's inspection model lacks centralized risk assessment and transparency.

Summary of recommended actions

To address these, the following actions are recommended:

- Mandate a nationwide rollout of revised Schedule M with clear timelines and establish a DCGI-led task force to monitor compliance
- Transition to a centralized, digital GMP enforcement and align with global platforms like ICH and PIC/S.
- Deploy a risk-ranking algorithm for inspection prioritization
- Conduct unannounced inspections and publish inspection outcomes

Action 1: Uniform enforcement of Quality Standards

Current Scenario in India	• Schedule M (GMP) implementation in India is not consistent across states and manufacturer categories, with smaller units often having limited infrastructure for compliance.
Short-Term Recommended Actions	• **Mandate nationwide rollout of revised Schedule M with defined timelines, as well as link Schedule M to fast-track approval pathways.** • **Setup a task force under the purview of the Drugs Controller General of India (DCGI) to monitor and ensure compliance with GMP standards.**
Long-Term Recommended Actions	• Transition to centralized, digital GMP enforcement across all states. • Integrate with global regulatory convergence platforms (ICH, PIC/S) to align quality benchmarks.
Global Leading Practice Examples	• **Uniform enforcement of Quality Standards through a centralized entity:** Pharmaceutical and healthcare quality standards are uniformly enforced through centralized regulatory bodies. This ensures consistent compliance, transparency, and global alignment. Examples include Pharmaceuticals and Medical Devices Agency (PMDA) in Japan, the European Medicines Agency (EMA) in the European Union, and the USFDA in the United States

Action 2: Set up a robust Inspection Model

Current Scenario in India	• India conducts inspections through state and central regulators but does not follow a robust centralized risk-assessment model. • Inspection frequency and quality vary across states; and are often scheduled and announced in advance. • Findings are not publicly disclosed – Minimal post-inspection follow-up or enforcement.
Short-Term Recommended Actions	• Develop and deploy a centralized, risk-ranking algorithm for inspection prioritization (API/ Formulation volume, export orientation, past compliance etc.). • Initiate unannounced inspections for cause-based triggers (e.g., export complaints, pharmacovigilance signals).
Long-Term Recommended Actions	• Join global mutual recognition initiatives (e.g., PIC/S) for shared inspection data. • Publish inspection outcomes and introduce industry-wide compliance grading to drive transparency. • Create a unified national drug inspection framework integrating CDSCO and state FDAs.

Aligning India's pharmaceutical manufacturing standards with global benchmarks offers substantial benefits for trade, public health, and industry growth. By adopting internationally recognized practices, such as GMP and ICH guidelines, India can expand its export potential, reduce trade barriers, and attract greater foreign investment and strategic partnerships. Enhanced compliance with global standards also strengthens India's reputation, making it easier for domestic manufacturers to gain regulatory approvals in key international markets. Higher manufacturing standards directly contribute to improved drug quality and patient safety, reducing the risk of recalls and fostering greater trust in Indian medicines.

04 Conclusion

In an era marked by rising geopolitical realignments, health security threats, and an urgent need for resilient supply chains, India's global pharmaceutical partnerships hold far-reaching significance. These partnerships are no longer just an economic opportunity—they are a strategic imperative. Together, India and countries such as the United States, United Kingdom and those in the European Union possess the complementary capabilities to co-lead a new chapter in global health: combining India's scale in affordable manufacturing and vaccine supply with these country's leadership in innovation, R&D, and regulatory science.

As outlined in this paper, enhanced bilateral collaborations can unlock powerful outcomes—strengthened supply chain security, faster innovation cycles, expanded access to life-saving medicines, and greater preparedness for future public health crises. Yet, the path forward is not without challenges. Regulatory misalignments, limited IP protections, and access constraints must be addressed to realize the full potential of these partnerships.

These measures can elevate India's position as a trusted global supplier, attract high-value investments, and foster domestic innovation ecosystems. Moreover, they can enhance India's healthcare resilience, create skilled employment, and ensure faster access to cutting-edge therapies for its population, while reinforcing its leadership in shaping equitable global health outcomes

Looking ahead, the evolution of these partnerships will likely move beyond conventional trade to a more strategic, institutionalized engagement. It can serve as a cornerstone for diversifying global pharmaceutical value chains, reducing overdependence on single-source suppliers, and embedding resilience in healthcare systems worldwide.

Ultimately, the success of these relationships will not only be measured by the trade value, but by their capacity to deliver timely, inclusive, and sustainable health outcomes on a global scale.

In shaping the future of the pharmaceutical sector, India has an opportunity and responsibility to lead with purpose, resilience, and shared vision.

Annexure-I

Methodology to estimate potential from including 2 US Innovative Cancer Drugs in India's AB-PMJAY program

This section highlights the methodology that was followed to estimate the trade potential from including 2 US Innovative cancer drugs in India's AB-PMJAY program. The overall trade potential through the inclusion of the drugs in the AB-PMJAY program has been calculated as per the below formula:

$$Trade\ Potential\ = Addressable\ Population\ (A) * Estimated\ Indications\ covered(B) * Published\ Price(C)$$

a. Addressable refers to the proportion of AB-PMJAY beneficiaries (roughly 40% of population) who would have access to tertiary care (further 30-40%), and biomarker testing (further 40-50%).

b. Estimated indications covered refers to what are the broad indications covered by the two drugs individually (across 2-5 indications for non-small-cell lung cancer), and estimated dosage cycles required (between 5-20 doses depending on indication)

c. Published price references the cost of annual therapy for the drugs considered (ranging between USD 2-28K for the drugs considered)

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List of figures

List of abbreviations

CDSCO	Central Drugs Standard Control Organization
DGCI	Drugs Controller General of India
EDQM	European Directorate for the Quality of Medicines and HealthCare
EMA	European Medicines Agency
EU	European Union
FDI	Foreign Direct Investment
FTA	Free Trade Agreement
GCC	Global Capability Centers
GDP	Gross Domestic Product
HTA	Health Technology Assessments
ICH	International Council for Harmonization
IPO	Indian Patent Office
IPR	Intellectual Property Rights
MNC	Multinational Corporation
NCE	New Chemical Entities
NLEM	National List of Essential Medicines
NPPA	National Pharmaceutical Pricing Authority
R&D	Research and Development
RDP	Regulatory Data Protection
UHC	Universal Healthcare Coverage
US FDA	United States Food and Drug Administration
USD	United States Dollar
WHO-GMP	World Health Organization - Good Manufacturing Practices

Contact Us

In case of any queries, please contact

Divya Pottath
Director – Healthcare
dpottath@usinfoundation.org

Shruti Nagpal
Head – Member Services & Co-Head – Business Development
snagpal@usinfoundation.org

Anushka Shah
Manager – Trade Policy and Critical & Emerging Technologies
ashah@usinfoundation.org

Misbah Sajida Khan
Associate – Healthcare
mkhan@usinfoundation.org

KPMG Contacts

Nikhil Patil
Partner, Life Sciences, Business Consulting
nikhilpatil@kpmg.com

Varun Sridar
Manager, Business Consulting
varunsridar@kpmg.com

Subhashini Kabali
Manager, Business Consulting
subhashinikabali@kpmg.com