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Pharma Leaders Roundtable

28 November 2023

India Expo Centre, Greater Noida, Delhi NCR

Whitepaper on

Innovation, Sustainability &Growth: Shaping the next decade of Indian Pharma

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Foreword

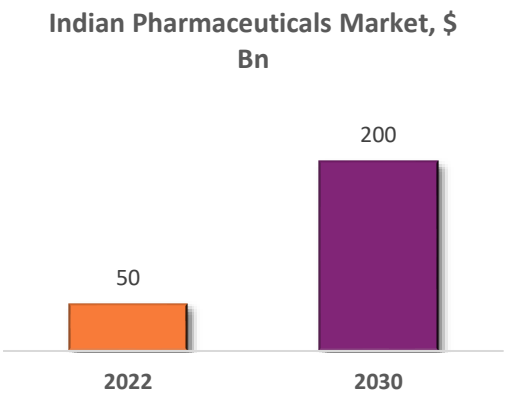
About Pharma Leadership Roundtable 2023

Within the realm of CPhI & P-MEC India, the Pharma Leadership Roundtable stands out as one of the most distinguished and successful events. For the last few years, this exclusive, closed-door roundtable has been eminently successful as a strategic gathering of senior leaders from leading pharma companies fostering thought-provoking discussions. This year's roundtable was focused on dual themes of innovation-led growth and sustainability-focused operational transformation which are the bilateral forces propeling next sphere of scale and competitiveness on the formidable foundation nurtured so far by the Indian pharma industry.

The Indian pharma industry is at cross-roads with multiple growth propelling avenues having strategic merit given the unique foundation and inherent advantages present in India. The leaders at the roundtable ideated together the direction of growth for the Indian pharma industry over the next decade, levers of opportunity, quantum of investment needed and other enablers that will be required to realize the vision and take the industry forward. Weighing on the landscape of current efforts, and structural and systemic challenges, the opportunities to better actualize this collective goal were discussed during the roundtable. With other countries ramping up their pharma sector and bringing the generics manufacturing capability to their ecosystem, the roundtable leaders urged the industry to build on its core (generics, biologics and biosimilars) while strengthening capabilities for manufacturing complex molecules and intensively pursuing the innovation agenda.

During the meeting, the industry leaders delved into the strategic growth levers needed to actualize the ambitious goals which include R&D innovation, cost-efficiency/optimization, integration of digitalization (R&D innovation integrated by digitalization) and rapidly embracing sustainability. The leaders called for strategically adopting the sustainability mandate in a pervasive manner to future proof operations while driving growth with the bilateral forces of -focused innovations (such as green-chemistry solutions) across sub-segments of the industry to accelerate the growth journey, while shifting the focus of the industry from being profit-driven to value-driven which is crucial for long-term growth.

I. Formidable industry foundation – dual forces of the strong domestic market and established footprint in exports

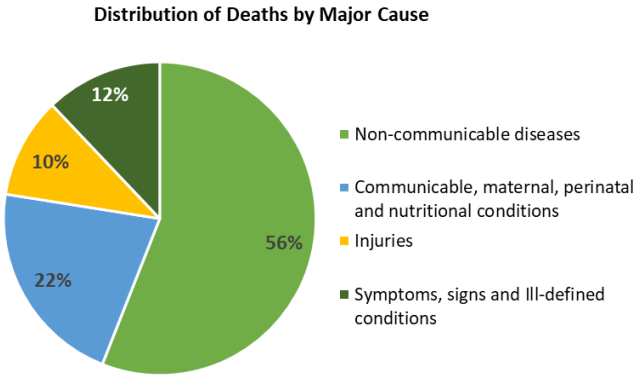


The Indian pharmaceutical industry stands on a strong foundation of manufacturing excellence, scale and research led competitiveness. The industry ranks third in the world in pharmaceutical production by volume and 14th by value. This formidable foundation rests on two strong fulcrums – at one end, a high growth domestic market and at the other end, dominant presence in global pharmaceutical exports. The domestic market and exports contribute almost equally to the scale of INR 4.15 lakh crore (US$50 billion) achieved in fiscal year 2022-23. Robust outlook at both ends and intensive focus on innovation led growth supports the 2030 growth target of US$ 200 billion.

Indian Domestic Pharma Market

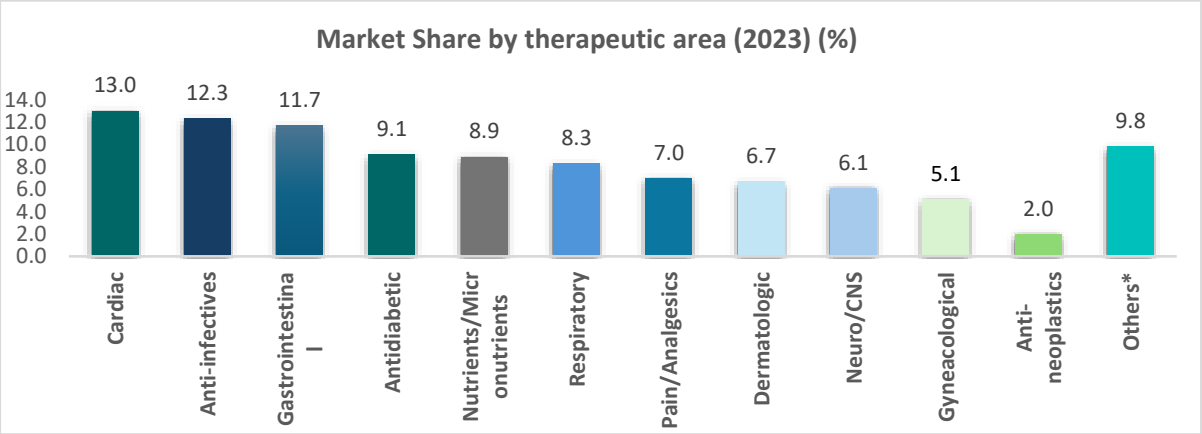
With a CAGR of 11% over the last two decades, the domestic pharma market has scaled to the threshold of INR 2.08 lakh crores (~ US$25 billion) in fiscal year 2022-23. Growth has been fuelled by evolving clinical needs, organic expansion due to improved coverage, spending power and willingness to pay.

Evolving disease profile and clinical need: While the country continues to make breakthroughs in addressing communicable diseases, maternal health, and nutritional conditions, the expanding threat of non-communicable diseases (NCDs) looms large. NCDs such as cardiovascular diseases, cancers, chronic respiratory diseases, diabetes, etc., are estimated to account for more than 50% of all deaths in India, making them the leading cause of death – ahead of injuries and communicable, maternal, prenatal, and nutritional conditions. Changing lifestyle and consumption patterns of the population have led to an increase in the incidences of chronic ailments. Cardiovascular diseases (CVDs) are the leading cause of mortality in India, with an age-standardized death rate of 272 per 100,000 people, higher than the global average of 235 per 100,000 people. India also has the highest number of people with diabetes in the world, with around 77 million people living with diabetes, and projected to reach 134 million by 2045, according to the International Diabetes Federation. The need to address the growing burden of NCDs is creating a significant opportunity for sector growth. NCDs will drive the demand for chronic therapies and is currently supported by the growth trajectory of cardiac and anti-diabetic drugs.



Indian domestic pharmaceutical market, by therapy area

Non-communicable disease burden and opportunity in the chronic segment: In fiscal 2023, cardiac diseases were the largest therapy area within the Indian domestic formulations market. Evolving market opposition is reflected the relative growth rates expected across therapy areas: with the market for cardiovascular and anti-diabetic therapy area expected to grow at a CAGR of 10-11% and 13-14% respectively from 2023 to 2028 vs 8 - 9% CAGR for anti-infectives during the same period.

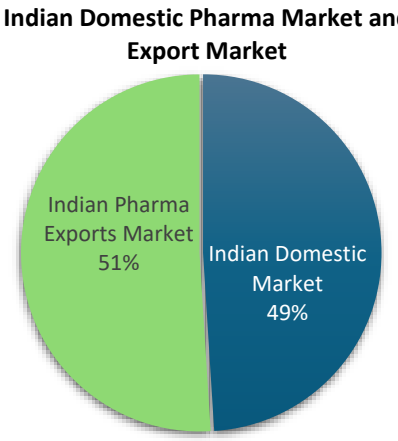


Source: AWACS

Continuing opportunity in infectious diseases: With novel breakthrough drugs in market, the anti-infectives market segment has recorded a decline over the years. Despite this decline, the infectious diseases still call for attention – especially to manage diseases where the burden continues to be high (such as HIV/AIDS, tuberculosis, malaria, and Dengue), to manage the expanding problem of Antimicrobial Resistance (AMR) that is now considered to cause ~1.3 million deaths annually and to be prepared for future pandemics.

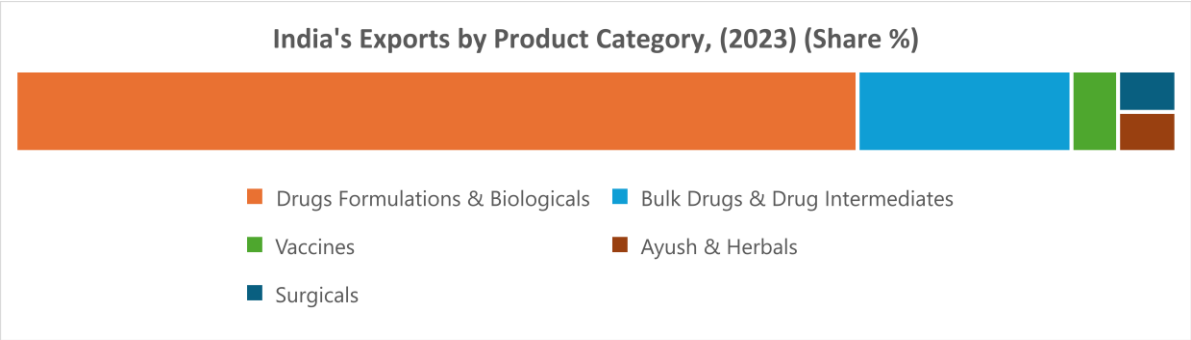
Growth potential in the domestic market spans across both the private and public market segments with the former driven by economic growth, willingness to pay and insurance coverage and the latter driven by the Government's focus on Universal Healthcare (UHC).

Export Markets – Formidable Foundation of Success



India's pharmaceuticals exports stood at INR 2,08,231 crore (US$ 25.39 billion) for financial year 2022 - 2023. India is also the largest supplier of vaccines for global public health supply, exporting to more than 150 countries. Nearly 60% of global vaccines are produced in India. The size of the Indian vaccine industry is approximately INR 14.53 thousand crore (US$ 1.75 billion), and the exports from India valued around INR ~ 7.8 thousand crore (US$ 940 million) in 2022. Continued high demand for generics globally, the promise of affordable and quality-assured pharmaceutical products by Indian companies and a strong R&D engine powering presence in complex formulations and biologicals are all likely to drive sustained growth in Indian pharma exports.

Composition of Indian pharma exports: Drug formulations and biologicals segment comprised 73% of Indian pharma exports in 2023 (~152 thousand crores/US$18.4 billion) with bulk drugs and vaccines being other areas of thrust. While the share of API (or bulk drugs) is relatively lower than formulations, it is notable that competitiveness of several large companies in the formulation segments rests on supply security of backward integrated operations. Thus, overall engagement in API continues to be high and a strong propellent of industry growth.



Source: Pharmexcil

Composition of exports within formulations has evolved progressively with portfolios now expanding beyond the traditional bastion of oral solids into more complex products such as injectables, inhalation et al. Biologicals also continue to gain traction and attract greater share of industry investment. With the first wave of biosimilars (including insulins) now resulting in tangible revenue potential, industry appetite has significantly expanded for investment in assets of tomorrow.

Export destinations – Established presence in high-value regulated markets

Indian companies have an established footprint in high-value-regulated markets - Over 50% of the exports from the country are to highly regulated markets.

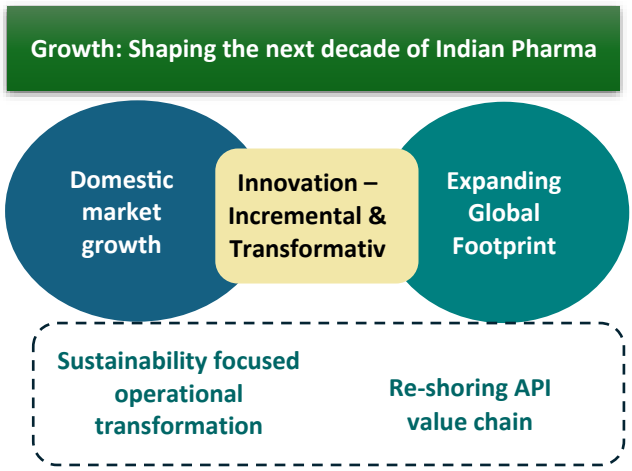
Indian pharma manufacturers export nearly half of the pharma production, both in terms of volume and value, to the US, UK, South Africa, Russia and other countries. Nearly 40% of generic demand in the US and approximately 25% of all medicine in the UK is supplied by India. The top five export destinations for Indian Pharma Industry in 2022-23 were the USA, Belgium, South Africa, the UK, and Brazil.

In addition to presence in high-value regulated markets, enabling wider access to quality-assured medicines in low- and middle-income countries (LMIC) has also been a goal for the industry. Over 50% of Africa's requirement for generics is supplied by the Indian industry.

As we look forward, growth potential is pervasive across global markets. Given the foundation of participation in markets across global regions, there is significant potential for volume and value-driven growth.

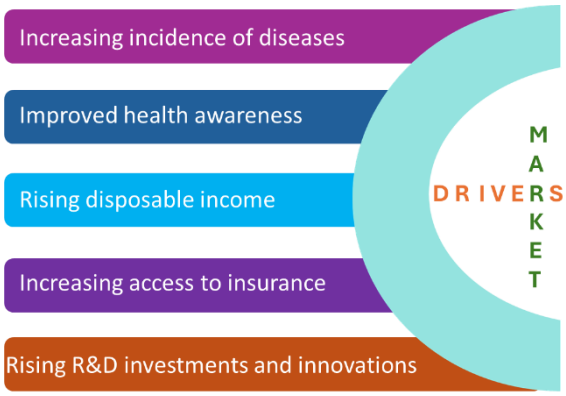
Strategic growth levers for shaping the next decade of Indian Pharma

Shaping the future of Indian pharma



Industry titans at the CPhI India CEO Round Table ideated on directions of opportunity for steering Indian industry's next decade of growth. At one end, pervasive opportunity continues for the industry to deliver affordable and quality assured medicines for domestic and global markets. At the other end, innovation propelled contemporary solutions are equally important to actualize the next sphere of growth. Additionally, operational transformation to embrace sustainability goals and re-shoring of a strong API value chain are critical for nurturing growth combined with a resilient value chain.

i. Domestic market with a focus on affordable access to quality-assured drugs and delivery innovation



Having a large, growth-driven domestic market is a significant catalyst for achieving growth on the global stage. The domestic pharma market is poised for sustained growth with multiple propelling factors including rising income, improved health awareness, expanding incidence of lifestyle diseases, and increasing access to insurance. This demand pull creates opportunities for innovation across the spectrum of value-added complex generics, vaccines, biosimilars as well as New Chemical Entities (NCEs), New Biologics Entity (NBEs), and next-generation therapeutics. Growth potential expands across both major segments – public market and private market.

Public market growth driven by strong government support to improve health coverage, and accessibility of care in equitable manner.

The government envisions industry to surpass the US$450 billion mark by 2047 (~INR 40 Lakh crore) and is continuing to support the industry's growth with several programs. The Government of India (GoI) has been playing a crucial role in creating strong innovation ecosystem in the country by providing the necessary impetus for the industry in the form of incentives, supporting policies and regulation, robust intellectual property protection, infrastructure, and health coverage. Universal Healthcare Coverage (UHC) to ensure all people have access to quality health services including prevention, promotion, treatment, rehabilitation, and palliation without incurring financial hardship, is the goal that GoI intends to realize by 2030.

UHC is fundamental to achieving the other Sustainable Development Goals. Embodying this goal, the Pradhan Mantri Jan Aarogya Yojana (PM-JAY), Ayushman Bharat and Aam Aadmi Bima Yojana (AABY) target to provide 500 million beneficiaries with annual hospitalization cover of up to INR 5,00,000 (~6000 USD) per family. Ayushman Bharat aims to provide a comprehensive need-based health care

service with its two major components Health and Wellness Centres (HWCs) and Pradhan Mantri Jan Arogya Yojana (PM-JAY) (Ayushman Bharat PM-JAY). This concerted focus on UHC and equitable access is likely to drive progressive expansion in demand for drugs and healthcare products and will thus be a critical propellant of sustained market growth.

Ayushman Bharat Health coverage scheme

Ayushman Bharat – PM Jan Arogya Yojana (AB-PMJAY)

- Health insurance cover of up to INR 5,00,000 per family per year
- For tertiary and secondary care
- 35.5 million people treated so far.

Ayushman Bharat – HWCs

- Free and universal primary healthcare
- More than 1,18,000 AB-HWCs, made operational.

(Source: PIB)

Private market growth driven by fundamental economic momentum

Significant share of the current domestic pharma is concentrated in the private market given the high level of out-of-pocket expenditure. Indian private healthcare has established itself as a sophisticated arm of healthcare delivery and often has best in class equipment and technology. Therefore, the sector records high growth on all key metrics such as occupancy and number of procedures. Expanding footprint of healthcare delivery, economic growth, increasing purchasing power and willingness to pay for healthcare imply sustained growth outlook in this segment of the market. The Government's focus on strategically leveraging private sector capacity for the delivery of publicly funded care is also contributing to growth. For instance, 12,824 hospitals out of 28,351 hospitals empanelled under the PM-JAY scheme are private hospitals (45%).

In addition to Government-funded care, expanding coverage in private voluntary health insurance is also a significant growth driver. While currently covering only 9% of the population, the reach of private voluntary health insurance is likely to expand progressively with increasing willingness to pay from individuals as well as the Corporates (for employee health coverage).

Finally, the COVID-led stimulus for penetration of digital health and e-pharmacies in India has served as an additional catalyst for ease of access and expanded access to healthcare and pharmaceutical products.

As a market characterized by branded pharmaceutical products, the private market segment rewards innovation and creates opportunities for functional innovation. The opportunity is pervasive with companies creating differentiated solutions for a wide range of objectives including enhanced patient convenience, improved compliance to dosage regimens, greater assurance on product quality et al. The segment also offers opportunities cross therapy areas to deliver the most contemporary global solutions to Indian patients – including biologics in oncology, cell and gene therapy etc. Industry leaders at the Round Table emphasized the expansive opportunity to deliver best-in-class care for the Indian population and the continued potential for differentiation-led growth in the segment.

ii. Wider access to quality assured medicines across global markets

Growth in India's pharma exports (~ US$ 25 billion in FY 2022-23) rests on both pivots – expanding global volumes at one end and enhancing level of value realized at the other.

Formulation exports powered by emphatic focus on quality, strong domestic value chain and expanding focus on complex products and biologicals:

Emphatic focus on quality – India's reputation as the 'Pharmacy of the World' rests on ability to deliver quality along with affordability. However, the wide industry base has implied complexity around enforcement and errant instances resulting in reputation repercussions for the industry at large. As the country expands footprint of global impact on access to medicines, relentless focus on quality will have to be the non-negotiable norm. Industry leaders at the Round Table exalted the role that national and international regulators are playing in enforcing quality. Shut down of non-compliant units in the last year by the national regulatory authority is a case in point. There has been increased collaboration between global peers such as the USFDA and the CDSCO around knowledge sharing and together enforcing quality. Achieving the industry's growth potential requires industry industry-wide focus on embracing quality as a non-negotiable aspect of the pharmaceutical industry.

Strong domestic value chain and policy thrust such as the Production Linked Incentive (PLI) Scheme: While bulk drugs and drug intermediates constitute a smaller share of exports, it is notable that the competitiveness of Indian formulations is also powered by the strong domestic value chain for API and intermediates in the country. While merchant exports of APIs are low, leading pharmaceutical formulation exporters benefit from cost competitiveness as well as supply security that emanates from captive API manufacturing. As acknowledged by corporate leaders at the Round Table, the current Government-led policy stimulus to re-shore API manufacturing will only enhance supply chain resilience and competitiveness for export growth.

Well-primed innovation engine for complex products: Indian companies have achieved an increasingly expanding share of USFDA generic approvals for injectables, inhalation drugs and 505(b)(2) products. The industry has made sustained investments in nurturing innovation engine and commercial capacity to reshape business composition towards complex formulations. The strategic focus and committed investments are likely to support continued leadership in pharmaceutical manufacturing for highly regulated markets.

Finally, investments in biologicals are likely to be the most critical driver of the next wave of growth. Indian companies have achieved global milestones in biological approvals and have nurtured robust product pipeline of insulins, monoclonal antibodies, and peptides such as GLP-1 et al. As this platform strength and product pipeline translates to revenue, biologicals will contribute to a disproportionate share of revenue and profitability growth of the Indian industry over the next decade.

Sustained momentum in regulated markets, enhanced focus on reaching the underserved markets

Indian companies have an established footprint in high-value-regulated markets. Nearly half of pharma exports from India, both in terms of volume and value, are to the US, UK, South Africa, Russia and other countries. Nearly 40% of generic demand in the US and approximately 25% of all medicine

in the UK is supplied by India. The top five export destinations for Indian Pharma Industry in 2022-23 were the USA, Belgium, South Africa, the UK, and Brazil.

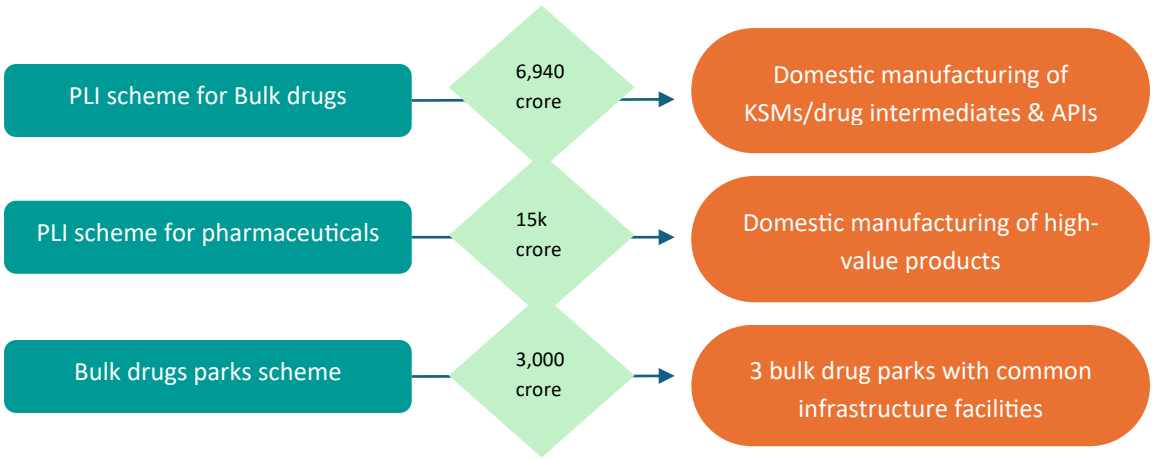
Additionally, India is also a significant source of quality assured generics for most low- and middle-income countries. Playing a critical role around health security, the industry has enabled access to affordable medicines for patients across geographic regions. An illustrative example is an indication such as HIV where Indian companies enabled access to affordable ARV drugs for global use and supply more than 80% of the global requirement. Overall, Indian industry suppliers more than 50% of Africa's requirement for generics across formulation types including complex products.

With this unique presence across both high value markets as well as price sensitive markets, leaders a the Round Table perceived opportunity for continued growth in both directions. India can continue to play an important role in enabling access to affordable drugs in a quality-assured manner while continuing to push the boundaries on innovation and product complexity.

iii. Re-shoring API to reduce import dependence, nurture resilient domestic value chain

Backward integrated value chain has been a critical driver of both cost competitiveness and supply responsiveness of the Indian pharma industry in the global markets. However, over the last decade the industry has been exposed to import dependence for several API and key intermediates. COVID-19 pandemic was a reminder of the steep perils of such import dependence. Supply chain disruptions and export bans exposed industry to price fluctuations and continuity risks. In addition to impact on exports of pharmaceutical products, trade issues between countries impacted even assurance around domestic access and led to the Directorate General of Foreign Trade (DGFT) restricting export of medicines for a short period of time. This has led to policy measures supporting API re-shoring through significant private sector investments. This includes:

- Establishment of three API parks with common facilities having a financial implication of INR. 3,000 crores over five years. Maximum grant in aid to each park is INR. 1,000 crores. Minimum area required for each park is 1,000 acres.
- 53 APIs, for which the dependence is very high on China, have been identified for domestic production. Out of the 53 APIs, 26 are fermentation-based and 27 are chemical synthesis based.
- Launch of Production Linked Incentive (PLI) schemes to capitalize the API potential.



Source: InvestIndia

PLI scheme for Promotion of Domestic Manufacturing of Critical Key Starting Materials (KSMs)/ Drug Intermediates (Dis) and APIs in the Country: The scheme, with an outlay of INR 6,940 Cr for six years until FY 2029-30, was formulated to provide financial incentives of 5% to 20% over base year. The scheme is aimed at attaining self-reliance and reducing import dependence in 53 critical KSMs/DIs/APIs. So far, 48 companies have been selected under the scheme.

Due to the PLI scheme, the sector witnessed a 46% increase in FDI inflows from FY 2021-22 to FY 2022-23 and a significant reduction in imports of raw materials in the pharma sector.

The merchant API opportunity: Currently, India is the third largest producer of API, accounting for ~8% of the global API market. More than 500 different APIs are manufactured in India, contributing to ~ 57 % of APIs to the prequalified list of the WHO. In the post COVID world, with the pervasive global thrust on nurturing regional pharma value chains continues, formulation manufacturing is likely to get decentralized but the merchant API opportunity will continue to only expand. With the current policy environment and industry focus on nurturing API capacity, India is positioned to gain greater share of the global market for merchant API.

Opportunity to leapfrog with innovation: The breakthrough research, biocatalysis that won the 2018 Nobel Prize in Chemistry, has evolved into technology and is being used as a powerful method for the development of APIs. Use of enzymes for green chemistry is not new. However, until now it has remained fairly niche and used only for select molecules. As the industry pursues sustained cost competitiveness in API along with de-carbonization goals, biocatalysis provides the opportunity to leapfrog technology and adopt next generation bio-transformation approaches to power India's API growth aspirations.

Biocatalysis is currently the industry's preferred solution not only because it simplifies complex chemistry, facilitates reactions at ambient conditions like temperature and pressure, and reduces manufacturing operating costs, but also because of its environmentally friendly manufacturing. Green chemistry minimizes the number of synthetic steps with current involved steps being as non-hazardous as possible and generating minimal waste.

"*We pioneered enzymatic technology three years ago. It was out of sheer responsibility that we as company decided to move from a dirty chemistry to green chemistry. We have been sustaining our business model and realised this is more efficient, more sustainable, and more profitable. Profit is not only tangible value of money – but how you can uplift a society to a safer planet safer environment*."

- Namit Joshi, Vice Chairman, Pharmexcil; Commercial Director, Centrient Pharmaceuticals

"*We have inaugurated our 42000 sq ft R&D center which will have 76 scientists round the clock working and delivering safe chemistry environment applying green enzymatic chemistry. We are working on 4 APIs, and we are confident to come out with an enzymatic route by June 2024. This reduces pollution loads and provides clean atmosphere. Safe for people working in industry*."

- Satish Wagh, Vice Chairman (A), CHEMEXCIL; Founder and Chairman: Supriya Lifescience Ltd

India's Department of Biotechnology is leading the national programme on biomanufacturing. This national thrust combined with industry pursuit of bio-transformation provides the impetus for leapfrogging technology in the API segment. Collectively, these efforts can energize API growth plans and create the pathway for sustained competitiveness.

iv. Innovation – Steering beyond generics and gaining a foothold in innovative medicines

The opportunity to leverage innovation for growth spans across both incremental innovation and transformative science. Within the realm of value-added products, leaders at the Round Table perceived significant opportunity to continue to deepen innovation to deliver on key tenets of patient convenience, compliance and quality assurance. Value added products could also help expand access by adapting product profiles for ease of delivery in low resource contexts.

"In terms of innovation, big and emerging companies have initiated complex products such as NCEs. Innovation and growth are not a challenge. In India, more than 90% of people still do not have insurance and pay out of pocket. Even today, 60% of people are earning less than INR 200 per day. So, we must look at affordable access."

- Nikhil Chopra, CEO & Whole Time Director, J B Chemicals & Pharmaceuticals

In addition to value added products, India needs to accelerate and intensify efforts move up the value chain to deliver transformative innovation for patients in India and the world. India has been a beacon for delivery of affordable drugs across both high income and low / middle income countries (LMIC).

Achieving the **goal of US$200 billion industry by 2030 and US$450 billion by 2047** requires participation in the larger realm of opportunity in novel drugs and transformative therapies. Generics only comprise US$ 380 billion of the global pharmaceutical market of US$ 1.5 trillion. Hence, aggressive pursuit of global portfolio of innovative medicines will be essential for actualizing the growth aspirations.

While transformative care such as cell and gene therapy become a tangible reality globally, they remain largely inaccessible to patients in LMIC countries considering price tags that north of US$ 500,000 per therapy in many cases. Indian industry can play a significant role in enabling access to transformative next generation care to patients across the world in an equitable manner. Aggressive pursuit of innovation opportunity will be critical for actualizing growth targets laid down.

Intensification of investments to build on foundation laid during the last decade:

Several Indian companies have already embarked on the pathway of drug discovery and development with the goal of innovating for Indian and global markets. Dr Reddys' subsidiary Aurigene, Glenmark and Alembic's subsidiary Rhizen all boast of out-licensing success stories. Zydus Lifesciences and Biocon have launched drugs developed from in-house pipeline in the Indian market. Aurobindo and Sun Pharma have made acquisitions in the US to acquire specialty assets in oncology and ophthalmology respectively. Laurus Labs and Dr Reddys have in-licensed cell and gene therapy solutions being advanced to patients in India with the promise of affordability. Young ventures in India are pioneering transformative next generation solutions including gene editing an cell therapy.

The journey of innovation is already an identified priority in most large Indian pharma companies. A pipeline of more than 5,000 startups has also nurtured with strategic ecosystem development efforts over the last two decades. The growth potential is acknowledged and is prioritized. Building on this foundation to realize economic and clinical impact in an endeavour straddled with a high threshold of binary risk calls for intensive commitment, catalytic policy support, deeper efforts to energize institution-industry innovation platforms and, very importantly, rapidly enabling access to capital for innovation investments.

Complementing industry focus on pursuing the innovation opportunity, policy enablement is signalled with the recently introduced National Policy on Research & Development & Innovation in Pharma-MedTech Sector & Scheme for Promotion of Research & Innovation in Pharma MedTech Sector.

Scheme for Promotion of Research and Innovation in Pharma-MedTech Sector (PRIP): the objective of this scheme with a budget outlay of INR. 5,000 crores for period of five years (2023-24 to 2027-28) is to transform Indian pharmaceuticals sector from cost based to innovation-based growth by strengthening the research infrastructure in the country, to promote industry-academia linkage for R&D in priority areas and to inculcate the culture of quality research and nurture our pool of scientists.

***Scheme has 2 components** –*

Component A: Strengthening the research infrastructure by establishment of 7 Centres of Excellence (CoEs) at National Institute of Pharmaceutical Education & Research) NIPERs - These CoEs would be set up in pre identified areas with a financial outlay of INR 700 crores.

Component B: Promoting research in pharmaceutical sector by encouraging research in six priority areas like New Chemical Entities, Complex generics including biosimilars, medical devices, stem cell therapy, orphan drugs, Anti-microbial resistance etc., wherein financial assistance will be provided for the Industries, MSME, SME, Startups working with government institutes and for both in- house and academic research. The component has a financial outlay of INR 4,250 crores.

Source: Pib.gov

Continued focus on incremental innovation and accelerating participation in transformative innovation will both be critical anchors for Indian pharma's growth in the next decade.

v. Sustainability – Operational transformation to shape the industry of tomorrow

Focus on sustainability is now a wide phenomenon in the Indian pharma industry with initiatives covering the entire expanse of opportunity – upstream innovation in manufacturing processes, energy usage, packaging and distribution. With several companies setting emission reduction goals, the decade ahead is likely to be marked by green transformation reshaping operations.

The industry's sustainability focus dovetails India's explicit goals around emission reduction. India's green transition is focused on achieving India's five energy commitments (Panchamrit) and the ultimate goal of Net Zero emissions by 2070. India has set Nationally Determined Contribution (NDC) targets for achieving 50% of its total installed capacity from non-fossil-based energy sources, 45% reduction in emission intensity by 2030, and key steps towards achieving Net Zero by 2070. Updated NDC represents the framework for India's transition to cleaner energy during the period 2021-2030.

India's Journey towards Net-zero by 2070

- Raise non-fossil fuels-based energy capacity to 500 GW by 2030
- Meet 50% country's energy requirements using renewable energy sources by 2030
- Carbon intensity of GDP to be reduced to 45% by 2030
- Reduce total projected carbon emission by 1 billion tonnes by 2030

Net-zero emissions by 2070

Spelt out focus with several companies defining explicit and specific goals

Sustainability is emerging as a major focus for the Indian pharmaceutical industry as a whole. Leading pharma companies in India have laid out explicit science-based targets and are taking proactive action towards achieving operational transformation.

The pervasive focus includes implementation of sustainability at various steps of drug development, manufacturing, and distribution – from using bio-manufacturing for upstream transformation, energy-efficient processes and technologies to using eco-friendly packaging materials and optimizing transportation routes to reduce emissions and energy consumption. Other approaches include promoting recycling and responsible disposal of pharmaceutical waste and expired or unused medicines, water conservation measures, risk management, etc.

> *"Journey on sustainability in Dr. Reddy's evolved two decades ago. We are the early adopters of sustainability and ESG reports. We released our first sustainability report along with annual report in 2004. We started with zero liquid discharge at our API facilities and evolved to manage solid waste and recycling. In last couple of years, we have been committed to ambitious goals on sustainability – related to carbon neutrality in operations (includes Scope 1, 2 and also 3 to bring down carbon consumption by our suppliers 12.5% Y-o-Y), and we are planning to be completely on renewable energy by 2030 (currently at 40%). This is operating in isolation of business – core to the goals of business leaders (goals in addition to finances)."*
>
> - Deepak Sapra, CEO (API and Services), Dr. Reddy's

Examples of energy transformation include Cipla acquiring 32.49% stake in India-based AMP Energy Green Eleven to build captive solar power plants for operations, Granules India announcing a greenfield facility in partnership with Greenko to implement its vision around sustainability and ACG's facilities in Maharashtra operating on green energy from 12 MW solar parks generating 45,000 units of power every day.

Upstream innovation for greener operations: Sustainability focus is driving significant transformation in how Indian industry produces drugs. Green chemistry is now a major thrust with bio-transformation being pursued across reaction processes for production of several API and intermediates. With due investments in technology led transformation, green chemistry can power sustainability goals while maintaining, and potentially improving, profitability. Enzymatic bio-catalysis and continuous manufacturing are two of the most prominent trends in this direction. For example, Centrient's antibiotic production processes are based on fermentation, selective enzymatic catalysis and eco-friendly science, resulting in high-quality generic pharmaceuticals with significantly lowered environmental footprints. The company achieved 45% overall energy efficiency in 2021, 50% improvement in relative CO2 efficiency, and 25% water reduction.

Enablement by input suppliers: Input suppliers are key enablers in this quest for operational transformation. This is true across upstream inputs (excipients, enzymes et al) as well as packaging solutions. Gattefossé India Pvt. Ltd is also well recognized for its sustainable operations in developing excipients and is scored under the 'platinum' category by the Ecovadis Index. Similarly, ACG's

packaging solutions have helped reduce quantum of material used for packaging and have enabled enhanced recyclability.

As Indian pharma scripts the journey of growth for the next decade, transformation to achieve the sustainability goals will pave way for improved competitiveness as well as more resilient operations.

Way Forward:

Recommendations for actualizing the potential

II. Way Forward

Leaders at the Roundtable acknowledged the strong foundation of success achieved by Indian pharma thus far but also stressed the urgent need to catalyze focused investments to actualize the next sphere of growth. The next decade will be pivotal for Indian pharma as the industry pursues the ambitious goal of ~INR 17 lakh crore (US$200 billion) scale by 2030. The cross-sectional panel of corporate leaders emphasized the criticality of pervasive focus on innovation to steer geometric growth and sustained competitiveness. Leaders also pointed to the importance of sustainability focused operational transformation towards future proof growth.

Key recommendations to steer this innovation led growth and sustainability focused operational transformation include:

I. Powering the era of innovation led growth

i. Enhanced level of funding across upstream R&D funding, catalytic equity capital and corporate investments in R&D

I. Upstream R&D investment in translational research

II. Creating access to equity funding for pioneering Indian ventures

III. Expanded R&D investments by corporate India

Upstream R&D investment in translational research

Globally, genesis of disruptive biopharma innovation has most often been in fertile ground of multi-disciplinary academic and research institutions. The journey of the first CAR-T therapy in the world, YESCARTA, is a case in point – marketed by Gilead today, the drug that was the motivation for the ~98.7 thousand crore ($11.9 billion) acquisition of Israeli venture Kite Pharma, the invention originated in the labs of the Weizmann Institute.

Deep rooted translational research engagement in institutions will serve as the bedrock for the innovation pipeline to be primed. Hence, bolstering the core of the innovation ecosystem will be foundational for achieving the growth ambition of ~33 lakh crore ($400 billion) by 2030.

India currently spends only 0.01% of GDP on health research compared to 2% by countries like US (Standing Committee on Health Report, 2022). Key imperatives for growth are significantly enhanced level of public funding for translational research aligned with national priorities, evolving clinical need and global opportunity.

Creating access to equity funding for pioneering Indian ventures

Over the last decade, India has bridged the gap in access to extra-mural funding for research and has seeded pipeline of more than 5,000 ventures in biotech, pharma and medtech through access to non-dilutive funding for young ventures. However, translation of this pipeline to clinically validated solutions and economic value creation is challenged by gaping void in access to venture capital for life sciences innovation led ventures. Within the GoI's Fund of Funds scheme to create venture capital ecosystem in the country, there has been negligible allocation to life sciences focused funds with dominance of technology focused VC funds. Void in equity capital is likely to result in mortality of ventures or flight of ventures to other countries for access to capital.

Sathguru estimates point to > 62 thousand crore (US$7.5 billion) equity capital required for India's pipeline of young ventures in life sciences to advance through preclinical and clinical development stages. Fund of fund schemes focused on life sciences such as BIRAC's ACE Fund should be expanded multi-fold and venture capital ecosystem should be catalyzed with greater allocation of anchor funding from the government to funds committing to venture stage investments in the sector.

Expanded R&D investments by corporate India

Per R&D Statistics published by DST (2022-2023), private sector has only contributed to 36% of the gross expenditure on R&D (GERD) in India. This significantly trails global benchmarks. The silver lining, however, is that pharma and biotechnology sectors have been highlighted as top sectors within the country for private investment in R&D (with pharma being on top of the league tables amongst sectors).

To ride the innovation wave and achieve the 2030 target of a ~16.6 lakh crore ($200 billion) industry, it will be very critical to foster a significantly expanded commitment to R&D investments by industry.

OECD experiences point to stimulating impact of both - fiscal incentives on corporate R&D and government funding of R&D on business R&D investments. The government should consider re-introducing weighted deduction on R&D expenditure, an erstwhile fiscal incentive that no more exists.

Steering into opportunity around innovation driven drugs and vaccines requires industry to embrace steer quantum of technology risk that is binary in nature. Hence, combination of monetary and fiscal incentives will be highly impactful in catalyzing this paradigm shift and enabling industry to embrace the next sphere of technology risk. Programs such as the INR 5,000 crore Research-Linked-Incentive (RLI) scheme

introduced by the Department of Pharmaceuticals are commendable foundational steps and are optimal models that can be expanded in the near future.

Encouraging policy initiatives with significant focus on innovation funding in life sciences: With the National BioPharma Mission (NBM) and PRIP serving as well conceived strategic models, there is significant merit in enhancing multi-fold quantum of such investments given the progressively expanding level of capital outlay required to advance new drugs through Phase I, Phase II and Phase III clinical trials in a global setting. Catalytic funding should go further to spur Indian innovation to global markets.

National Biopharma Mission:

INR 2000 crore ($250mn) World Bank co-funded program implemented by BIRAC, Department of Biotechnology to address pipeline of drugs and medical devices in area of national priority, address infrastructure and skill gaps and nurture capacity in technology transfer.

Scheme for Promotion of Research and Innovation in Pharma MedTech Sector (PRIP):

Launched in August 2023, the INR 5,000 crore (US$ 600 million) scheme is to catalyse shift to innovation growth in Indian pharma and medtech. Pervasive focus across de-risking grants to industry for co-creation of innovation with institutions and for advancing internal pipelines and creation of translational research focused Centers of Excellence in NIPERs**.**

ii. Nurture ecosystem for productive collaborations between industry – academia

Corporate leaders at the round table all converged on the need for pervasive innovation focus. The need for innovation driven growth was perceived across both segments of opportunity – enabling wider access to quality assured drugs for India and other Low and Middle Income countries, and, transforming level of value created by expanding into novel therapeutics and vaccines. Across both spheres of opportunity, there is high need for enhanced level of industry-academic collaborations. To spur this, there is strategic merit in considering the following:

Translational research orientation: Create and fund translational research in institutions with commercialization focus.

Aligned Incentives: Include collaborations and IP commercialization as metrics for institutional ranking.

Re-institute fiscal incentives for R&D expenditure.

Technology Transfer capacity: Akin to National Biopharma Mission's focus, expand public investments in TTOs and nurture professional cohort of RTTPs

iii. Accelerate universal healthcare access and create reward for innovation in Indian markets

Accelerate universal healthcare access

The most notable development in the recent past in Indian healthcare is the government's astute commitment to achieving Universal Health Coverage (UHC). The Ayushman Bharat Program embodies this vision and enables growth in the healthcare ecosystem combined with the promise of equitable access. However, addressing the overarching goal of UHC calls for rapidly expanding infrastructure and skilled resources, addressing the disparity of rural-urban healthcare system, adopting focus on the whole continuum of care, including early screening and prevention of diseases, and finally, reshaping care outcomes to global standards. Continued focus on mission mode implementation of this goal will be important for realizing the potential of the new Bharat.

Reward for innovation in Indian markets

Several leaders at the Roundtable converged on the expansive opportunity for innovation serving unmet clinical needs in India and other emerging markets. Innovation focused on improving compliance, enhancing convenience, and improving access to drugs were perceived as essential. However, realizing the opportunity at scale calls for a renewed ecosystem around reward for innovation in domestic markets. Opportunity for technology assessment and uptake in public markets, and opportunity to reasonably get pricing reward for innovation are key aspects that call for policy makers' attention.

Further, India has already nurtured a strong pipeline of healthcare innovation that holds potential to transform quality of care and access enabled. However, commercial footprint of most of these solutions are currently limited to cursory adoption in private markets and select pilots in a few States in the public health system. The tendering approach followed for procurement of goods and services in public markets has limited scope for demonstrating innovation potential and strategic merit to government buyers. Several of these innovations can be highly impactful if adopted at scale in the public health system. There is strategic merit in considering measures to further enhance ease of market access for public procurement. Expanded avenues for innovation demonstration to public buyers will enhance discoverability of solution for adoption in the public health ecosystem.

iv. Supportive regulatory environment

There has been proactive engagement between policymakers, regulators and industry to address gaps, strengthen regulatory frameworks and create an enabling ecosystem for innovation to advance to markets in an accelerated manner with high assurance on safety and efficacy claims. The Roundtable leaders stressed on regulatory initiatives such as innovative approaches to evaluate products including use of real-time evidence, decentralized trials, regional trials and adaptive trial designs to achieve this goal. Further, for novel and emerging product categories such as cell and gene therapy, there is need for continued engagement between researchers, industry and regulators to create regulatory frameworks and developments that are transparent, consider in a nuanced manner product and technology risk while not leaning on the side of over-rigouring development pathway in a way that threshold of investments negates access at scale.

As pharma industry pursues the goal of US$200 billion scale by 2030, this close interaction with regulators will be essential for nurturing an enabling ecosystem while maintaining an undiluted position on quality assurance.

II. Accelerating sustainability focused operational transformation

Leading Indian pharma companies have committed to sustainability goals and have defined science based targets. There is now a pervasive focus on operational transformation to enable goals around greening the industry footprint and achieving emission targets. Opportunity for transformation spans across upstream manufacturing operations, inputs and packaging, supply chain and energy use.

Upstream manufacturing | **Packaging & other inputs** | **Supply chain & logistics** | **Energy Use**

Significant advancements have been made in packaging and inputs with supplier led innovation around quantum of material used, recyclability, digitization etc. Supply chain and logistics transformation opportunities are being pursued in collaboration with vendors and ecosystem enablers. Options such as hydrogen and renewables are being explored to optimize energy use. The most complex part of the equation is upstream manufacturing transformation, an area closely linked to India's goals of resurgence in API manufacturing and value chain resilience.

Criticality of goal for India's goals around API resurgence

Criticality of re-shoring API manufacturing and building back a strong domestic value chain has a critical focus for both Indian industry and the government. Supply chain vulnerabilities were exposed during COVID and industry appreciates the strategic advantages of nurturing competitiveness and scale in API manufacturing domestically. Policy imperative is driven by the implications for health security and health system resilience. While industry has been making active investments in API manufacturing, most prominent policy lever has been the Production Linked Incentive (PLI) scheme for incentivizing capacity creation in API manufacturing.

The Sustainability imperative:

API manufacturing is arguable the node of the value chain that is most intensive on carbon footprint. Effluent treatment norms have been in focus for several years now with India implementing Zero Liquid Discharge to minimize environmental impact of chemical manufacturing. However, sustained competitiveness calls for upstream bio-transformation to adopt greener production processes in addition to stringent norms on effluent discharge. Several Indian API companies are now focused on pioneering upstream transformation and have introduced enzymatic biocatalysis for various processes in lieu of traditional chemical processes. For re-shoring competitiveness at scale, it is important that

this transformation is pursued in an accelerated manner across products. Sustainability goals will be far from met until this goal is actualized.

Accelerating bio-transformation in API manufacturing:

Pursuing pervasive opportunity for enzymatic biocatalysis in API manufacturing requires continuum of capability that is currently not integrated in a platform – high throughput screening and enzyme identification, pilot production, immobilization, optimization of enzymatic process in pilot chemical production, enzyme production at scale. While leading companies are nurturing in-house capability as well as pursuing partnerships at various nodes of this value chain, there is urgent need to nurture national capacity for this integrated activity.

DBT's bio-manufacturing initiative:

The Department of Biotechnology's biomanufacturing initiative spans across areas of opportunity and includes focus on bio-transformation opportunity in the pharmaceutical sector. The initiative envisions creation of bio-manufacturing hubs and serving as a catalyst for enabling industry 4.0.

To actualize the API bio-transformation goal in an accelerate manner, there is urgent need to integrate capacity across segments of Indian industry and synergize effectively with emerging policy and public funding initiatives to align with industry interest and focused effort around technology development and deployment at scale.

Corporate Leaders at the Round Table

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