

Approach Paper

on

***Draft National Pharmaceuticals Policy 2023 for stakeholder
consultation***

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**Department of Pharmaceuticals
Ministry of Chemicals and Fertilizers
Approach Paper on National Pharmaceuticals Policy [2023]**

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Executive Summary:

In an era of rapid technological advancements, evolving global standards, and burgeoning healthcare demands, the National Pharmaceutical Policy (2023) serves as a comprehensive framework to address the challenges faced by Indian Pharmaceutical industries and provide definitive policy interventions to enhance the collective ecosystem. Vision for National Pharma Policy encompasses five key pillars: Fostering Global Pharmaceutical Leadership, Promoting Self Reliance, Advancing Health Equity and accessibility, Enhancing Regulatory Efficiency in Indian Pharmaceutical Sector and Attracting investments.

Despite strong fundamentals, Indian Pharmaceutical Industry faces various challenges, including high degree of import dependence on Active Pharmaceutical Ingredients (API) and Key Starting Materials (KSMs); relatively low pace of development of biologics, biosimilars and other emerging products/ trends; regulation inefficiencies, lack of skilled human resource and access to funding for innovation in Pharma-MedTech domain among others.

While the Department of Pharmaceuticals under Ministry of Chemical and Fertilizers, Government of India has already taken significant measures to address these challenges in last few years, including the implementation of initiatives such as Production Linked Incentives, setting up Bulk Drug Parks, Pharmaceutical Technology Upgradation Assistance (PTUAS) Scheme, the National R&D Policy, and the Promotion of Research and Innovation in Pharma-MedTech (PRIP) Scheme among others, the pursuit of Vision 2047 for AmritKaal necessitates a reinvigorated, concentrated, and results-driven holistic approach. This renewed commitment calls for meticulously crafted initiatives with clearly defined key deliverables, subject to rigorous monitoring demands. As a result, it highlights the necessity for a thorough and all-encompassing strategic Policy that can effectively cater to the diverse requirements of this ambitious undertaking.

With changing global trends, heavy reliance on imports and demand for better therapeutic outcomes, the Indian Pharmaceutical Industry must venture beyond its comfort zone and embrace innovation as an essential element of its vision for global leadership, making it a central pillar of its business strategies. The Vision of the National Pharmaceutical Policy for the Government of India is to establish a healthcare ecosystem that exemplifies excellence, innovation, and inclusivity. It embodies the aspirations of a nation that seeks to harness the full potential of its pharmaceutical industry to provide world-class healthcare to its people and contribute to the global well-being. Moreover, its objective extends to fostering self-reliance in alignment with the "Atmanirbhar Bharat" (and Make In India initiative), rekindling the imperative of prioritizing domestic innovation that is not only sustainable but also aligns with global standards.

INTRODUCTION

1. Background

Indian pharmaceutical industry is the 3rd largest pharmaceutical industry in the world by volume with a current market size of around approx. USD 50 Billion. The country exports pharmaceuticals to around 200 countries and territories in the world, including highly regulated markets such as USA, UK, European Union, Canada etc. and is widely known as 'Pharmacy of the World' [1]. Besides largest number of US FDA approved manufacturing plants outside of the US, India also has several renowned pharmaceutical educational and research institutes and a robust support of allied industries.

The Indian pharmaceutical industry has played a key role in driving better health outcomes across the world by being a large and reliable supplier of affordable and high-quality generics drugs. The vaccine industry in India has proven its capacity for manufacturing at scale (catering to more than 60% of global vaccine demand) [2]. With a potential to grow up to USD 120-130 billion dollars over the next decade, Indian Pharmaceutical ecosystem needs holistic set of policy interventions to help India's pharma industry leapfrog and radically strengthen its position in the world market.

Armed with the triple advantage of cost, quality, and scale in the pharma sector today, the Government of India is placing an even greater than ever emphasis on both strengthening the industry's reputation as a supplier of good quality generic medicines at high production scale and at affordable prices, as well as to extend our capabilities beyond volume to value, which will depend largely on our ability to differentiate through innovation in the next 25 years. Over the last few years, recognizing the need to ensure drug security, reduce import dependence and build domestic manufacturing capacities, the Department of Pharmaceuticals has been implementing three PLI schemes- Pharmaceuticals, Medical devices, and API/KSM/bulk drugs respectively. Further, to build infrastructure, to enable enhanced competitiveness of APIs, financial support has been extended to states for setting up of three Bulk Drug Parks and four Medical Devices Parks, PTUAS Scheme along with introduction of National Policy on Research & Development & Innovation in Pharma-MedTech Sector & Scheme for Promotion of Research & Innovation in Pharma MedTech Sector [3], among others to create an ecosystem for innovation and drive better health outcomes. One of the key drivers for Indian Pharmaceuticals Industry growth would be expansion of the industry's presence in the innovation space which continues to account for 2/3rd of the global pharmaceutical opportunity. Building this presence would generate

substantial health benefit for India by enabling development of innovator drugs, New Chemical Entity (NCE), New Biological Entity (NBE), strengthening response to Anti-Microbial Resistance (AMR) and also create a large pool of white-collar jobs and increase industry's contribution to Indian economy to enhance India's differentiation versus other developing economies.

In an era of rapid technological advancements, evolving global standards, and burgeoning healthcare demands, the National Pharmaceutical Policy (2023) serves as a comprehensive framework to address the challenges faced by Indian Pharmaceutical Industries and provide definitive policy interventions to enhance the collective ecosystem. Vision for National Pharma Policy encompasses five key pillars: Fostering Global Pharmaceutical Leadership, Promoting Self Reliance, Advancing Health Equity and accessibility, Enhancing Regulatory Efficiency in Indian Pharmaceutical Sector, Attracting investments.

The policy aims to support this vision by focus on proposed thematic areas outlined in the policy priorities and interventions. The policy acknowledges the need for greater emphasis on encouraging R&D and innovation in emerging trends, harmonization in regulatory approvals and strengthening manufacturing capacities for Atmanirbhar Bharat and supply chain to sustain global competitiveness while meeting Health Goals. By focusing on research-driven innovation, collaboration, and adherence to global standards, the industry can maintain its reputation as a reliable supplier of affordable and high-quality medicines. The National Pharmaceuticals Policy aims to provide a supportive framework for the industry to flourish, setting the stage for a promising future where India remains a global leader in pharmaceuticals. The policy aims to make substantial contributions to India's GDP by boosting local manufacturing, enhancing economic competitiveness, and fostering self-reliance. It also underscores the positive impact of affordability of drugs in improving the living standards of society, addressing critical areas such as accessibility, equity, focus on innovation, streamlining regulatory hurdles. Recognizing the pivotal role of talent and skills, the policy places emphasis on diversity and inclusion as core tenets of enabling employment opportunities and developing a skilled workforce to support the growth of the Indian Pharmaceuticals ecosystem.

In essence, the National Pharmaceutical Policy 2023 recognizes that its true potential lies not in isolation but in its ability to weave a tapestry of collaboration and synergy, creating a stronger, more resilient healthcare system that serves the diverse healthcare needs of the nation while creating global champions out of India. Its primary strategy is to inform, clarify, strengthen, and prioritize India's key goals and parameters in shaping the pharmaceuticals in all its dimensions, including,

investments, access to technology, research and development, development of human resources, and strengthen regulation and policy by indicating a list of time bound quantitative and qualitative goals aligned with the Hon'ble Prime Minister's Narendra Modi vision of Amrit Kaal.

2. Need for the Policy

India, often referred to as the "Pharmacy of the World," boasts a thriving pharmaceutical industry known for its cost-effective generic drug production and robust export capabilities. As the country aspires to secure its place as a global leader in healthcare, it is imperative to have a comprehensive policy framework that can effectively address the multifaceted challenges plaguing the pharmaceutical sector. This policy serves as a guiding light towards achieving healthcare equity, accessibility, affordability, and quality for all citizens. It facilitates the streamlining of regulatory processes, promotes research and innovation, and ensures ethical practices within the industry.

Despite strong fundamentals, Indian Pharmaceutical Industry faces various challenges, including high degree of import dependence on Active Pharmaceutical Ingredients (API) and Key Starting Materials (KSMs); relatively low pace of development of biologics, biosimilars and other emerging products/ trends; regulation inefficiencies, lack of skilled human resource and access to funding for innovation in domain etc. At present, low value generic drugs account for the major component of Indian exports, while a large proportion of the domestic demand for patented drugs is met through imports due to lack in high value production along with the necessary pharma R&D.

By streamlining regulatory processes and encouraging research-driven innovation, this policy not only ensures the availability of safe and affordable medicines but also bolsters India's position as a global pharmaceutical leader. It paves the way for a more resilient and equitable healthcare system, where every citizen, regardless of their socioeconomic background, can access cutting-edge pharmaceuticals, ultimately fostering a healthier and more prosperous India for all. This policy rekindles the vital need to prioritize sustainable innovation that aligns with global standards while placing a paramount focus on the quality and safety of pharmaceutical products.

The industry operates in a complex and dynamic environment, marked by rapidly evolving technologies, global regulatory standards, and increasing quality expectations. The COVID-19 pandemic has brought to the forefront the role of innovation in expanding the scale, access and affordability of healthcare products. It has also emphasized the urgency of reinforcing the current healthcare infrastructure.

The pandemic served as a reflection, revealing our shared vulnerabilities in the inability to implement proactive measures for robust pandemic prevention, preparedness, and response (PPR) at an early stage. In order to incentivize the global and domestic players to enhance investment and production in diversified product categories, a well-designed and suitably targeted intervention is required to incentivise production of specific high value goods such as biopharmaceuticals, complex generic drugs etc. Research and Development in the Pharmaceutical sector is a capital-intensive, high-risk activity with heavy burden of regulatory oversight, high rates of failure and long product development cycles. Furthermore, India's pharmaceutical manufacturing will have to shift from the existing mindset of focussing on "exceptional quality at low cost" to "exceptional quality at highest value". This would come from focus on innovation and, at the same time, retain the cost competitiveness and scale of India's generic advantage.

Achieving Vision@2047 as set forth by Honourable Prime Minister Narendra Modi will require diligent and focused implementation beginning from the development of detailed work plans, charters, and a governance framework that continuously engages all stakeholders in the government, industry, and academia. Realizing this vision will need the support of the right set of enablers which National Pharmaceuticals Policy aims to address. A coherent policy framework is vital to ensure that Indian pharmaceutical companies can adapt to these changes swiftly, maintain international compliance, and consistently deliver high-quality, safe, and efficacious medicines.

The policy not only promotes regulatory efficiency, research, and innovation but also ensures equitable access to medicines, strengthens healthcare self-sufficiency, and enhances India's global standing in the pharmaceutical sector. It is a critical tool to propel the nation towards a healthier, more prosperous future, where healthcare is both accessible and of the highest quality.

VISION

"Empowering Health for All: Pioneering Excellence in Pharmaceuticals"

Our vision for the National Pharmaceutical Policy 2023 is to empower every citizen of India with equitable access to high-quality healthcare through an industry that exemplifies excellence in innovation, manufacturing, and accessibility. It aspires to establish India as a global leader in pharmaceuticals backed by world class infrastructure and enabling ecosystem, where cutting-edge research and development lead to the creation of innovative and affordable healthcare solutions, fostering a healthier, more prosperous nation and contributing to global health equity. National pharmaceuticals policy aligns with the vision of Amrit Kaal Vision @2047.

MISSION

The policy charts a course for expediting growth in the pharmaceutical sector, ensuring equitable access to high quality medicines, fostering research and development, strengthening regulatory oversight, and nurturing a dynamic Indian pharmaceutical industry. It also aims to foster innovation within the sector, thereby creating a conducive ecosystem for Convergence of Drugs, Data and Devices.

OBJECTIVES

The Objectives of the National Pharmaceutical Policy in India are as under:

1. **Fostering Global Pharmaceutical Leadership:** The policy envisions India's transformation into a prominent global R&D hub for the pharmaceutical industry, shifting from a volume-based to a value-based leadership model, underpinned by world class research infrastructure, thereby enhancing the nation's global standing.
2. **Promoting Self-Reliance:** Aligned with the "Atmanirbhar Bharat" (Self-Reliant India) initiative, the policy aims to fortify national capabilities and sovereignty, endorsing the "Make in India" drive to ensure self-sufficiency in pharmaceutical production with renewed focus on Quality.
3. **Advancing Health Equity and Accessibility:** The policy is committed to advancing health equity by ensuring that quality medicines and healthcare services are accessible and affordable to all citizens, reducing disparities in healthcare access.
4. **Attracting Foreign Direct Investments:** One of the key objectives is to create an environment conducive to attracting foreign investments in the Indian pharmaceutical sector, fostering economic growth, innovation, and global collaborations.
5. **Enhancing Regulatory Efficiency:** The policy underscores the harmonization of regulatory approvals and an emphasis on transparency in pricing mechanisms, streamlining processes, and promoting ease of doing business in the pharmaceutical industry's regulatory framework.

FOCUS AREAS OF POLICY

National Pharma Policy aims to achieve its outlined objectives by focussing on following priority areas:

1. Nurturing & Promoting Research, Development & Innovation
2. Affordable, Accessible & Equitable Access to Health Coverage
3. Facilitating Access to Funding
4. Regulatory Harmonization: Creating Conducive Regulations including Price Regulation and Transparency
5. Initiate Capacity Building & Development of Skilled Manpower
6. Enhancing Policy & Program Interlinkages
7. International Collaboration
8. Infrastructure Enhancement
9. Leveraging Digital Transformation
10. Sustainability /Reducing Carbon Footprint
11. Strengthening of Intellectual Property

1] Nurturing & Promoting Research, Development & Innovation

The policy is dedicated to creating an environment where pharmaceutical research flourishes, innovation is incentivized, and new frontiers in healthcare are continually explored. Through strategic investments, collaborative partnerships, and incentives for research and development, it seeks to elevate India's pharmaceutical industry to an era of innovation-led growth. By supporting and fostering talent within the country while also encouraging international collaborations, this policy not only advances India's self-reliance but also positions the nation as a pioneering force in driving transformative healthcare solutions, ultimately benefiting both its citizens and the global community. The policy aims to encourage a paradigm shift in the Indian pharmaceutical industry, moving from the conventional approach of "incremental innovation" to embracing "disruptive innovation" with the introduction of novel drugs, devices, and technologies and establishing "Innovation-Hubs" in India embodying Honourable Prime Minister Shri Narendra Modi ethos of - **"Jai Vigyan, Jai Anushadhan"**.

The policy envisages to promote Research & Development in India and complement the Department's National Policy on R&D and Promotion of Research and Innovation in the Pharma-MedTech Sector (PRIP) Scheme. The policy aims to create a supportive ecosystem that is purpose-built to bolster innovation and cross-sectoral research serves as a solid institutional foundation for ensuring sustainable growth within the sector by:

- Building Innovation infrastructure such as Bulk Drugs Parks, Developing Centre's of Excellence (CoEs) in academic and research institutions, innovation hubs for research, technology validation, and product development.
- Foster collaboration between academia and the industry to drive innovation and research.
- Promoting and facilitating multilateral cooperation in affordable, sustainable manner and quality R&D for coordinated approaches in fighting emerging disease threats and capacity building in medical countermeasures with the vision of strengthening the global health architecture - "One Earth, One Health, One Future"
- Contribute to Health System to attain union of equity, efficacy, and efficiency towards developing holistic products profile, with focus on Non communicable diseases (NCDs), Anti-Microbial Resistance (AMR), and rare & neglected diseases along with renewed focus on achieving leadership in m-RNA technologies, cell-gene therapy, other emerging technologies etc.

- Encouraging public-private partnerships, increasing funding for research, and providing tax incentives to boost domestic drug discovery and innovation.

2] Affordable, Accessible & Equitable Access to Health Coverage

The Policy exemplifies an unwavering dedication to ensuring that quality pharmaceuticals are accessible and affordable to all, irrespective of their socio-economic status. Simultaneously, it strives to position India as a global leader in the manufacturing of innovative and cost-effective medications, guided by the principle of 'Vasudhaiva Kutumbakam,' by working on following:

- Enhance accessibility of essential and quality medicines through penetration of PMBJP Kendras in remote areas.
- Digitization and technology upgradation in delivery of services & products under Jan Aushadhi Pariyojana.
- Ensure access of newer pharmaceutical technologies to the domestic manufacturing so as to enhance their capacity and capability to make essential medications affordable and thereby, reducing the financial burden on patients, thus promoting better healthcare outcomes and reducing overall healthcare costs.
- Identifying critical suppliers, de-risking & decarbonising the supply chain, and promoting local sourcing.
- Ensure accessibility & affordability of patient-centric products for better healthcare outcomes for universal health coverage, by building upon partnerships across industry, science and governments.
- Encourage innovation to reduce production costs while maintaining quality as per international norms.

3] Facilitating Access to Funding/ Investments in India

Investments is a key driver of an India's growth journey, and access to finance is particularly relevant for pharmaceutical industry requirements for product development, validation, and scaling. Under the National Pharmaceutical Policy 2023, our strategic focus extends beyond innovation and accessibility; it encompasses the vital aspect of securing funding and investments to drive growth and excellence in India's pharmaceutical sector [4]. Recognizing the significance of foreign direct investments, the policy offers clear guidelines and transparent procedures for foreign investors looking to establish or expand their operations in India's pharmaceutical sector. This promotes technology transfer, knowledge exchange, and capital infusion.

The Policy recognizes that a robust pharmaceutical ecosystem requires both visionary ideas and financial resources which it aim to achieve by:

- Aim to offer a welcoming and conducive climate for foreign investors, enabling them to contribute to the growth and global prominence of India's pharmaceutical industry. These investments will not only create employment opportunities but also stimulate innovation, ultimately benefiting the healthcare landscape and the economy at large.
- Foster cooperation with foreign governments, investors, and financial institutions to cultivate a favourable FDI climate in these sectors by enabling technology transfer, providing opportunities to Invest in Bulk Drug Parks and Medical Device Parks to bolster production capacities, and open avenues for joint partnerships with National Institute of Pharmaceuticals Education and Research (NIPERs).
- The policy focuses on the provision of appropriate fiscal and non-fiscal incentives for pharmaceuticals innovations by introduction of direct/ indirect funding support to promote India as an innovation hub. The interventions would be in compliance with multiple treaties with foreign countries wherein inter alia the Government of India has committed to non-discriminatory treatment of foreign investments in the country.
- Encourage private sector investment through risk-based financing and venture capital support.
- Along with recent schemes and interventions like Make in India, Ayushman Bharat program, Heal-in-India, Start-up mission, the policy encourages private investments, series of funding from Venture Capitalists, and also Public-Private Partnership (PPP).
- Promote Indian pharmaceutical exports with assistance from Pharmexcil by upholding high-quality manufacturing standards and compliance with international regulatory requirements, strengthening India's position as a global pharmaceutical hub and harmonization with International Standards.
- It aims to create a favorable environment that attracts both domestic and international investments, facilitating the infusion of capital into the industry. This policy strives to reduce bureaucratic hurdles, streamline approval processes, and provide financial incentives for research and development initiatives. By fostering a conducive climate for investments, it not only enables the expansion and modernization of pharmaceutical infrastructure but also encourages collaborations between academia and industry.

4] Regulatory Harmonization: Creating Conducive Regulations including Price Regulation and Transparency with focus on Quality

Regulation both in approvals and pricing must be carefully carried out while ensuring adherence to fair market transactions, ethical compliances, environmental protection, and maintaining appropriate government oversight for meeting International Quality Standards. In the case of emerging frontier technologies that are disruptive in nature and constantly evolving, regulatory development must catch up and keep pace with the rapid technology development and scientific breakthroughs. At Policy core lies the imperative of regulatory harmonization, a strategic move designed to create an environment that fosters innovation, ensures affordability, and prioritizes transparency within the pharmaceutical sector and complements the work of National R&D Policy.

- The policy aims to align India's regulatory standards with international best practices that balances innovation with safety, reducing compliance burdens, ensuring that pharmaceutical companies can seamlessly adhere to global standards. This harmonization not only streamlines the research and development process but also enhances the credibility of Indian pharmaceutical products on the global stage.
- To simplify licensing system to avoid duplication of efforts and to ensure better coordination among different regulatory authority CDSCO, DCGI etc.
- In order to enhance ease of doing research and business and further to balance patient safety with product innovation measures such as creation of a Single Window Clearance System for Licensing of Pharmaceuticals co-opting all the stakeholder departments / organizations such as CDSCO, DCGI, MeitY, DAHD, etc, enhancing the Role of Indian Standards like BIS and designing a coherent pricing regulation, will be followed. The policy also supports exploring feasibility roll-out of a mandatory track and trace mechanism for products to ensure that high quality drugs reach patients.
- Create equilibrium between social, economic, & governance aspects through facilitative, balanced & progressive policy and regulatory framework.
- While ensuring that essential medicines remain affordable to all, the policy seeks to strike a balance that encourages fair pricing without stifling innovation. By monitoring and regulating drug prices, it aims to reduce the financial burden on patients while maintaining a conducive environment for pharmaceutical companies to thrive.
- Implement a rational and transparent drug pricing mechanism to ensure fair pricing of medicines, balancing industry sustainability with affordability for patients.

- It seeks to establish mechanisms that prevent price manipulation and arbitrary increases, thus safeguarding the interests of consumers while providing a predictable environment for pharmaceutical companies to thrive. This approach not only assures citizens of affordable healthcare options but also boosts investor confidence, as it brings stability to the market.
- Policy aims to complement National R&D Policy work on regulatory streamlining by supporting process optimization, development of technology based/enabled platform, regulatory capacity, and legislation.

Regulatory harmonization, price regulation, and transparency are not just administrative processes but tools to ensure that patients have access to high-quality medicines and healthcare services when they need them the most.

It fosters an ecosystem where Indian pharmaceutical companies can compete on the international stage, not just in terms of cost-effectiveness but also in terms of quality, innovation, and ethical practices.

5] Initiate Capacity Building & Development of Skilled Manpower

To facilitate the development of a skilled workforce aligned with the evolving demands of the pharmaceutical industry, encompassing a diverse range of disciplines from research and development to production and regulatory affairs. The policy aims to develop a skilled and diversified talent pool which is competitive in the global scenario by:

- Invest in training programs, skill development, and continuous education for healthcare professionals, researchers, and manufacturing personnel to elevate the pharmaceutical sector's capabilities. The policy aims to upskill faculties in NIPER as well w.r.t. evolving landscape of Pharma Med-Tech Industry to impart best education to new talent pool of incoming students.
- Create qualifications aligned with Skill India to train professionals across the pharmaceutical value chain.
- To address the current deficiencies in education and research within the pharmaceutical sector and to guarantee the provision of high-quality education and training for a skilled workforce capable of meeting the evolving demands of the rapidly advancing pharmaceutical industry.
- Establish courses to produce skilled human resources for advanced manufacturing and research.
- This policy aims to promote entrepreneurship, encourages a culture of start-ups and establishment of incubation funds, promote Industry-Academia Linkages

where Industry can directly take active role in upskilling of Students through training and taking lab driven research to market by facilitating access to mentorships.

6] Enhancing Policy & Program Interlinkages

In the dynamic landscape of healthcare, the success of the National Pharmaceutical Policy 2023 hinges not only on its intrinsic elements but also on its ability to seamlessly interlink with existing policies and programs. To maximize its impact, the policy acknowledges the importance of synergy and collaboration across various sectors and initiatives. There are several Departments and policies that are directly and indirectly Inter-Linked with Pharmaceutical ecosystem, contributing to its growth and development. These policies need to make their instruments interoperable, to create a set of conducive conditions that enable the Indian Pharmaceutical ecosystem.

- By enhancing policy and program interlinkages, the National Pharma Policy 2023 aims to synchronize its goals with broader national objectives such as universal healthcare access, innovation-driven economic growth, and sustainable development. This collaborative approach ensures that the pharmaceutical sector becomes an integral part of the holistic healthcare ecosystem, reinforcing the policy's commitment to accessible, high-quality healthcare for all.
- Collaboration at Inter Ministerial Level (DoHFW, AYUSH, ICMR, DBT) and at inter-departmental level to integrate pharmaceutical policies and objectives with broader healthcare initiatives, enhancing the overall health system's efficiency and effectiveness.
- Through these strategic interlinkages, the policy leverages the strengths and resources of multiple stakeholders, including government agencies, industry players, research institutions, and civil society. It creates a harmonious convergence of efforts that not only accelerates the achievement of pharmaceutical policy objectives but also contributes to the overall advancement of India's healthcare landscape.
- Facilitating the identification of synergistic opportunities between different sectors and leveraging the strengths of different policies and resources to maximise the impact on pharmaceutical ecosystem will channelize resources, investments, and support to areas that have the most potential for success.

National Pharmaceutical Policy 2023 recognizes that its true potential lies not in isolation but in its ability to weave a tapestry of collaboration and synergy, creating a

stronger, more resilient healthcare system that serves the diverse healthcare needs of the nation.

7] International Collaboration

Given India's extensive dealings with numerous countries, it is crucial to study and comprehend the problems encountered by the sector. Understanding international needs and areas of cooperation can build trust and confidence in Indian pharmaceutical products. Further, it can significantly increase acceptance and create channels to assess country-specific needs, ultimately paving the way for more substantial investments in the sector.

The international collaboration will boost the global standing of India's pharmaceutical sectors by addressing challenges, attracting investments, fostering innovation, and promoting regulatory harmonization. Bringing together various stakeholders and facilitate constant communication and cooperation with foreign governments, organizations, and industry players is crucial to achieving these objectives and ensuring the continued growth and competitiveness of Indian sectors on a global scale.

- **Access to Markets:** Facilitating market access for Indian pharmaceutical companies in foreign countries by addressing trade barriers, tariffs, and regulatory hurdles.
- **Supply Chain Integration:** Coordinating with international partners to create more efficient and resilient pharmaceutical supply chains which caters to both domestic and global demands.
- **International R&D Collaboration:** Collaborating with international research institutions and laboratories, with the institutes like National Institute of Pharmaceutical Education & Research (NIPERs), to foster innovation and research in new and emerging areas of healthcare. This may include joint research projects, capacity building, skilling, and training in compliance with international quality standards and regulations among others.
- **Health Diplomacy:** Collaborating with foreign governments and organizations on global health initiatives, such as vaccine distribution, disease control, and pandemic response.
- **Trade Agreements:** Negotiating trade agreements and partnerships for advanced technology transfer, IPR protection, expanding local manufacturing plants, international clinical trials among others.
- **Bolster the Global Presence of Indian Pharmaceutical and Medical Device Products and Companies:** Collaborating with international partners to promote and expand the reach of Indian pharmaceutical and medical device products and companies worldwide with assistance from Pharmexcil through driving

initiatives such as joint marketing efforts, and partnerships with global distributors and healthcare providers.

- Facilitate Acceptance of Indian standards: Advocating for the recognition and adoption of Indian pharmacopeia standards in global pharmaceutical regulations, facilitating smoother international trade and harmonization of quality standards.
- Enhance Global Collaborations for API Manufacturing: Active Pharmaceutical Ingredients (APIs) are essential components of pharmaceutical products. Collaboration on sourcing raw materials, sharing technology, and establishing joint ventures to manufacture APIs, ensuring a stable and cost-effective supply chain.
- Forging international partnerships for decentralized manufacturing facilities and government-to-government drug distribution initiatives.
- Promote Indian pharmaceutical exports by upholding high-quality manufacturing standards and compliance with international regulatory requirements, strengthening India's position as a global pharmaceutical hub and harmonization with International Standards.

8] Infrastructure Enhancement and strengthening Logistics:

An efficient logistics ecosystem is an important requirement for the pharmaceutical industry ensuring the stability and durability of medicines throughout the value chain. Improvements in the logistics infrastructure can help pharma industry to service patients better and also build competitive advantage. The key issue faced by the pharmaceutical industry in India is relatively higher logistics cost compared to more-efficient economies.

In the present context, Gol's thrust for creation of world class infra facilities at 3 bulk drug parks and 4 medical devices parks across the country mark a sound beginning in enhancing infrastructure and strengthening logistics. Further, various other States too are seen to take initiative in this regard.

The Pharma industry would further benefit from a focus to reduce the Turnaround Time (TAT) and upgrade the capacity and capability of the logistics network in India, including creation of Logistics Parks and creation of dedicated corridors connecting the important pharmaceutical hubs. Emphasis on increasing the digitalization and automation can substantially reduce time and errors. Scaling up the roadways infrastructure will lead to significant optimization in carry capacity. Specifically, for the Pharmaceuticals sector, there is a need to enable faster clearance of temperature

sensitive items while maintaining the temperature monitoring at the desired levels throughout the supply chain, since regulatory compliance in terms of quality, safety and efficacy across the supply chain is imperative

In the context of learning from COVID19 pandemic and growing biopharma sector, it is imperative to upgrade the cold chain capacity and capability in the country to ensure quicker availability of the vaccines, biopharma and health commodities and cater not to just domestic demand but global demand in a competitive manner and seamless integration with global supply chains, given that India is the, 'Pharmacy of the World'. Towards this, the Policy seeks to effectively leverage the PM-Gati Shakti National Master Plan Portal in meeting the various demands of the industry in establishing the Pharma sector as a global hub.

Also, the National Pharma Policy (2023) aims to enhance *Research* Infrastructure where the priority will be to augment existing infrastructure and build a new generation of world-class infrastructure that integrates modern supply chains. Under the Atal Innovation Mission, Government is setting up Atal Incubation Centres (AICs), in the public and private sectors as well as scaling up Established Incubation Centres (EICs). A number of Startup Incubators are already functioning in life sciences, biotech, medical devices and MedTech space under 'Start up India'. However, the current infrastructure is limited and concentrated in a few nascent innovation hubs in the country, emphasizing the need for more high-quality infrastructure. Measures will be explored for strengthening the infrastructure for innovation in Pharma MedTech Sectors in India, including scaling up, creating sub-sector specific hubs, integrating Centres of Excellence with Innovation hubs. Other areas of the policy would include:

- Strengthen domestic testing and certification facilities to ensure high-quality and safe pharmaceuticals.
- Upgradation of Indian Industries infrastructure to include World Health Organization (WHO)-Good Manufacturing Practices (GMP) standards so as to enable them to participate and compete in global markets.
- Encourage the establishment of bulk drug parks and enhance MSME clusters.
- Efforts to digitize available capacities of storage region-wise shall facilitate real-time decision making and efficient operations. The National Industrial Corridor shall complement creation of centres of manufacturing excellence with integrated facilities to enable companies to leverage India's competitiveness in the value chain and increase India's manufacturing prowess beyond generics.
- Optimize end-to-end transport logistics to promote efficiency across the supply chain and supported by IT enabled systems including AI/ML.

- This policy recognizes that an efficient and robust logistics framework is indispensable for the seamless distribution of pharmaceuticals and medical supplies. By investing in cutting-edge technologies and streamlining supply chains, the policy aims to minimize transit times, reduce wastage, and enhance the overall efficacy of healthcare delivery.

9] Leveraging Digital Transformation:

The policy is expected to provide the required support and directions to strengthen the pharmaceutical ecosystem by leveraging digital capabilities across various aspects into a competitive, self-reliant, resilient and innovative industry that caters to the healthcare needs of not only India but also of the world. This policy acknowledges the potential of digital technologies, such as telemedicine, electronic health records, and data analytics, to revolutionize healthcare delivery and pharmaceutical innovation. By harnessing the power of artificial intelligence, machine learning, and blockchain, it aims to bolster drug safety, supply chain management, and regulatory compliance.

In the knowledge economy, the existing mindset has to change from a “siloes approach towards health data” to a new vision of “convergence of drugs, devices, and data”. The current disparate health data systems, medicines and devices, which create inefficiencies in multi-stakeholder processes and interactions, will have to be streamlined with significant savings and efficiencies for patients, manufacturers, and service

- Invigorate innovations by enabling human capabilities & digital technologies.
- Leverage data to increase the efficiency and efficacy of drug development, production, and distribution.
- Application of integrative technologies as a force multiplier of innovative, sustainable, and efficient growth
- The policy envisions a future where digital platforms facilitate seamless access to healthcare services, enable real-time tracking of drug quality and availability, and empower consumers with information to make informed decisions.
- Promoting the adoption of digital tools and technologies for efficient drug procurement, distribution, and pharmacovigilance.

10] Sustainability /Reducing Carbon Footprint:

- To align with the Hon’ble PM’s vision of “Panchamrita,” focus on reducing the environmental impact of pharmaceutical production, distribution, and disposal, manufacturing by implementing sustainable manufacturing practices in

reducing emissions, waste generation, energy & water consumption and fostering innovation in green technologies.

- Lay down principles and guidelines for ethical research, marketing practices and corporate governance.
- Implement and enforce sustainable manufacturing practices by reducing energy and water requirements, reducing emissions, and reducing waste generated.

11] Strengthening of Intellectual Property:

The Policy is committed to strengthen the Indian Patent Office and facilitate patent applications by fast-tracking the examination of evidence and building a tracking mechanism for the grant of patents. By reinforcing IP safeguards, we not only incentivize pharmaceutical companies to invest in groundbreaking research but also create an environment conducive to attracting foreign investments and collaborations. This strategic move not only safeguards the intellectual property (IP) of our researchers and innovators but also fosters an environment conducive to groundbreaking discoveries as well as strengthen domestic innovation in India.

IMPLEMENTATION AND MONITORING

This policy's value lies not merely in its formulation but in the diligent execution of its multifaceted vision. It requires a collaborative effort between the government, the pharmaceutical industry, healthcare professionals, research institutions, academicians among others. Implementation also necessitates continuous monitoring and adaptation to evolving healthcare dynamics, both domestically and globally. It demands a commitment to fostering a healthcare ecosystem that is equitable, innovative, and globally competitive.

A High-level Task Force will be set up in the Department of Pharmaceuticals under the Minister for Chemicals and Fertilizers to guide and review the implementation of the Policy. The Task Force will draw upon resource persons from Departments and Organizations related to the implementation as the success of the policy requires coordinated action by several agencies.

The Policy will be supported by a ten-year Strategy and action plans that will spell out the policy and programmatic interventions required from time to time within the Policy.

Methodology: Consultation and Drafting Process

The process undertaken for the drafting of the National Pharmaceuticals Policy (2023) was end-user and stakeholder led. Individuals with distinct roles and responsibilities in the pharmaceutical ecosystem were consulted for their thoughts on the current state of play, key challenges and priority areas followed by possible interventions and recommendations to address the challenges and progress towards a desired end-state.

These consultations saw participation from diverse groups consisting of Industry/academic experts and research professionals, Senior Government Officials and other stakeholders who act as catalysts in the interplay of various public and private bodies for nurturing a vibrant pharmaceutical ecosystem. These sessions focused on the four primary priorities – Funding, Infrastructure, Procurement and Regulations. Inputs received were captured and documented for internal purposes.

REFERENCES:

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2. <https://www.investindia.gov.in/sector/pharmaceuticals>
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