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Policy and regulatory reforms needed to accelerate local pharmaceutical manufacturing in Nigeria: A comparative analysis with India and Bangladesh

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Abstract

Local pharmaceutical manufacturing is increasingly recognized as a strategic pillar for health security, industrial development, and economic resilience in low- and middle-income countries. Many African health systems remain heavily dependent on imported medicines, exposing them to foreign exchange volatility, external supply shocks, and weak bargaining power in global markets. In contrast, countries such as India and Bangladesh have leveraged targeted industrial policies, regulatory reforms, and export-oriented incentives to build competitive generic pharmaceutical industries that supply both domestic and international markets. Nigeria, despite its large population and sizeable medicines market, has yet to fully translate its demand potential into strong local manufacturing capacity. This paper examines the policy and regulatory reforms required to accelerate local pharmaceutical manufacturing in Nigeria through a comparative analysis with India and Bangladesh. It reviews key enablers including medicines pricing policies, intellectual property flexibilities, fiscal and tax incentives, quality regulation, and alignment between industrial and health-sector strategies. The analysis highlights how predictable regulatory pathways, streamlined registration processes, and strong national regulatory authorities have supported growth and international accreditation in comparator countries. In Nigeria, by contrast, fragmented policies, infrastructural deficits, inconsistent enforcement, and limited access to affordable long-term financing continue to constrain investment and technology transfer. Building on these contrasts, the paper proposes a reform agenda for Nigeria focused on regulatory strengthening, harmonized industrial–health policy coordination, targeted incentives for active pharmaceutical ingredient (API) and formulation production, and regional market integration. By repositioning local manufacturing as both a health security and industrialization priority, Nigeria can reduce import dependence, support quality-assured medicines production, and enhance its role in regional pharmaceutical value chains.

Keywords: Local Pharmaceutical Manufacturing; Nigeria Health Industrialization; Regulatory Reform; Comparative Policy Analysis; India and Bangladesh Pharma; Medicines Security and Access

1. Introduction

1.1. Background: Global pharmaceutical supply chain vulnerabilities

Global pharmaceutical supply chains have become increasingly exposed to disruptions driven by concentrated manufacturing hubs, geopolitical tensions, and fluctuating international trade conditions [1]. Many countries rely heavily on a small number of producers for active pharmaceutical ingredients (APIs), creating bottlenecks that magnify the effects of export restrictions, shipping delays, and raw material shortages [2]. The growing complexity of regulatory environments further strains cross-border pharmaceutical flows, especially when demand surges or supply shocks occur [3]. These vulnerabilities were highlighted in recent global crises, during which disruptions cascaded rapidly from

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manufacturing nations to low- and middle-income import-dependent markets [4]. Such systemic fragilities underscore the importance of building diversified and resilient pharmaceutical production ecosystems that can withstand external shocks while ensuring continuous access to essential medicines [5]. Emerging economies that have strengthened domestic production demonstrate that strategic industrial policies can significantly reduce exposure to volatile global supply conditions [6].

1.2. Nigeria's pharmaceutical dependency and industrial potential

Nigeria remains highly dependent on imported medicines and APIs, sourcing the majority of its pharmaceutical inputs from Asia, especially countries with large-scale manufacturing capacity [7]. This structural dependency has constrained the country's ability to stabilize medicine prices, maintain consistent supply, and build self-sufficient production capacity during periods of global instability [8]. Despite these limitations, Nigeria possesses significant industrial potential, with a large domestic market, a growing private sector, and an expanding pool of technical expertise [9]. Local manufacturers currently operate far below optimal capacity due to infrastructure constraints, regulatory inconsistencies, and limited access to competitive financing [10]. Strengthening domestic production is widely regarded as a strategic necessity for achieving long-term supply security and reducing exposure to import-driven vulnerabilities [3]. Leveraging Nigeria's demographic and economic scale could help position the country as a regional pharmaceutical hub capable of meeting local needs while contributing to continental supply resilience [7].

1.3. Rationale for comparative analysis with India and Bangladesh

India and Bangladesh offer compelling comparative models because both countries transitioned from heavy pharmaceutical import dependency to globally competitive manufacturing industries through coordinated policy reforms, regulatory strengthening, and investment incentives [4]. Their experiences demonstrate how targeted industrial policy, quality assurance upgrades, and API diversification strategies can transform domestic production environments [1]. Nigeria's aspirations align closely with the trajectories these countries pursued, making their transformation pathways valuable references for understanding feasible policy options [9]. Examining these comparator contexts also highlights practical lessons on scaling manufacturing capacity, improving export competitiveness, and implementing coherent regulatory frameworks suitable for emerging markets [6].

1.4. Study purpose, significance, and article structure

This article examines the policy and regulatory reforms required to accelerate local pharmaceutical manufacturing in Nigeria, drawing insights from the experiences of India and Bangladesh to inform context-appropriate recommendations [5]. It highlights how Nigeria can strengthen industrial incentives, upgrade regulatory systems, and enhance supply chain reliability to reduce chronic import dependence [2]. The discussion is structured into sections covering global supply chain vulnerabilities, Nigeria's domestic constraints, comparative lessons, and proposed reform pathways [8]. Collectively, these components provide policymakers with evidence-based guidance on transitioning toward a more resilient pharmaceutical ecosystem capable of sustaining long-term national health security [10].

2. Conceptual and analytical framework

2.1. Defining local pharmaceutical manufacturing capacity

Local pharmaceutical manufacturing capacity refers to a country's ability to produce essential medicines, APIs, and related health products at sufficient scale, quality, and consistency to meet national demand [9]. It encompasses infrastructure strength, technological readiness, human capital availability, and the robustness of national regulatory oversight [12]. In many emerging economies, the evolution of local capacity has depended on the progressive development of formulation plants, investments in equipment, and integration into global supply chains for APIs and excipients [14]. Nigeria's current landscape demonstrates a concentration of manufacturers engaged primarily in formulation rather than full-spectrum production, reflecting limited technological depth and insufficient upstream integration [8]. Manufacturing capacity also includes sustainability factors such as access to energy, reliable utilities, skilled technical personnel, and effective quality management systems that align with international standards [17]. The interplay between scale, competitiveness, and regulatory compliance ultimately determines whether local producers can expand beyond basic generics toward broader therapeutic categories [11]. Strengthening domestic capacity therefore requires a deliberate combination of industrial investment, regulatory upgrading, and supportive market reforms that enable producers to compete with well-established pharmaceutical hubs across Asia and other emerging regions.

2.2. Regulatory governance and industrial policy linkages

Regulatory governance plays a central role in shaping the performance, competitiveness, and credibility of domestic pharmaceutical manufacturing systems [13]. Strong regulatory authorities ensure that medicines meet safety, quality, and efficacy standards while creating predictable environments for private-sector investment [18]. Countries like India and Bangladesh strengthened their regulatory institutions early, enabling them to secure global certifications that expanded export opportunities and attracted significant manufacturing inflows [10]. In contrast, fragmented governance structures and uneven enforcement weaken investor confidence and create bottlenecks in countries still building their pharmaceutical ecosystems, including Nigeria [15]. Industrial policies such as tax incentives, preferential procurement, and API sector development are deeply interconnected with regulatory governance because manufacturers rely on clear and coherent rules to support long-term planning [8]. The alignment of industrial strategies with regulatory reforms fosters competitive pricing, improved supply reliability, and growth of domestic production clusters [16]. Without this policy coherence, manufacturers face uncertainty regarding compliance expectations, funding eligibility, and market access, thereby hampering expansion. Effective governance therefore requires synchronizing regulatory strengthening, fiscal policy, licensing procedures, technology transfer mechanisms, and quality assurance frameworks to ensure that industrial development objectives are supported by strong regulatory foundations capable of sustaining manufacturer growth.

2.3. Framework for comparing Nigeria, India, and Bangladesh

A structured comparison of Nigeria, India, and Bangladesh requires an analytical framework that integrates regulatory maturity, industrial competitiveness, and market-level dynamics [14]. Such a framework must capture both structural attributes such as API availability, production scale, and export orientation and institutional factors involving policy coherence, regulatory strength, and financial incentives [9]. India and Bangladesh serve as appropriate benchmarks because they share historical trajectories of import dependence, later transitioning into globally recognized manufacturing hubs through coordinated reforms [12]. The comparison therefore focuses on identifying divergences in policy choices, regulatory evolution, infrastructure investment, and human capital development [17]. For Nigeria, examining these dimensions clarifies the barriers that prevent local firms from achieving similar industrial transformation. The framework enables a systematic assessment of how institutional alignment, industrial strategy, and market incentives interact to shape manufacturing performance and long-term sectoral resilience.

2.4. Key evaluation indicators (quality regulation, incentives, market size, IP flexibility)

The evaluation relies on four core indicators that shape pharmaceutical manufacturing performance across emerging markets. Quality regulation captures the strength of national regulatory authorities and their adherence to global standards [11]. Industrial incentives measure tax, financing, and procurement mechanisms that support manufacturing competitiveness [18]. Market size reflects domestic demand potential and its role in attracting private investment [8]. Intellectual property flexibility assesses how TRIPS-related provisions enable generic entry and API development pathways [15]. Together, these indicators offer a balanced lens for comparing structural readiness, policy ambition, and regulatory depth across Nigeria, India, and Bangladesh.

3. Global overview of local pharma manufacturing trends

3.1. Evolution of emerging-market generics industries

The growth of generics industries in emerging markets has been shaped by a combination of industrial policy reforms, regulatory strengthening, and the strategic use of intellectual property flexibilities [16]. Over several decades, countries in Asia and parts of Latin America expanded their pharmaceutical capabilities by prioritizing domestic formulation, establishing local API production, and incentivizing quality upgrading to meet global standards [19]. These industries matured through predictable regulatory environments, expanded technical training programs, and strong government support for export-oriented manufacturing clusters [21]. Global demand for affordable generics accelerated their growth as high-income countries sought cost-effective alternatives to branded medicines. This demand created opportunities for emerging manufacturers to build scale, diversify product portfolios, and integrate into international supply chains [15]. Their evolution also reflects a shift from basic replication of generic formulations toward more sophisticated production, including biosimilars and specialty generics supported by improved technological capabilities [24]. For countries still developing their pharmaceutical sectors, the experiences of these emerging-market leaders demonstrate that generics production can become a central pillar of industrial development, improve medicine affordability, and reduce dependency on volatile import markets [18]. These historical patterns form a foundation for assessing how India and Bangladesh successfully transformed their pharmaceutical landscapes.

3.2. Industrialization strategies in India (export-driven model)

India's pharmaceutical sector emerged as a global powerhouse through an export-driven strategy that prioritized scale, competitive pricing, and regulatory excellence [20]. Policy reforms enabled local companies to reverse engineer formulations, expand API manufacturing, and supply essential medicines to both domestic and international markets [17]. The sector's growth accelerated as manufacturers achieved certifications such as WHO prequalification and approvals from stringent regulatory authorities, enabling them to enter high-value export destinations [23]. Clustering of production in industrial zones supported shared infrastructure, reduced manufacturing costs, and facilitated technology diffusion across firms [16]. Government-backed incentives, including tax benefits and RandD support, further strengthened the industry's competitiveness. India's position as the "pharmacy of the developing world" reflects its ability to meet global demand for affordable generics while maintaining regulatory credibility and deep integration into global supply chains [22]. This export-oriented model demonstrates how consistent policy alignment, long-term investment in skilled labor, and robust API capacity can transform a country into a major pharmaceutical hub. It also highlights the role of strong state–industry coordination in maintaining standards, expanding product portfolios, and managing regulatory risks. India's trajectory provides a critical benchmark for evaluating Nigeria's industrial ambitions within a rapidly evolving global pharmaceutical landscape.

3.3. Growth of Bangladesh's pharmaceutical sector (TRIPS flexibilities + industrial support)

Bangladesh's pharmaceutical sector expanded rapidly through deliberate use of TRIPS flexibilities, aggressive industrial policy, and strong government backing for domestic manufacturers [18]. As an LDC beneficiary of extended patent waivers, Bangladesh leveraged its regulatory space to produce a wide range of generics without facing immediate patent barriers, enabling local firms to scale quickly and diversify their product lines [21]. Industrial incentives including reduced import duties on raw materials, investment-friendly tax structures, and targeted financing played a crucial role in shaping manufacturing growth [24]. Regulatory strengthening, particularly through quality assurance reforms and factory inspections, enhanced the sector's credibility and supported its expansion into regional export markets [15]. Collaboration between government, academia, and the private sector helped build a strong pharmaceutical workforce capable of operating modern manufacturing facilities [19]. The sector's evolution reflects how coherent policies, supportive legal frameworks, and sustained public–private engagement can generate competitive pharmaceutical industries in resource-constrained settings. Bangladesh's experience underscores the importance of policy predictability, industrial discipline, and targeted capacity-building programs that position manufacturers to compete effectively in both domestic and international markets.

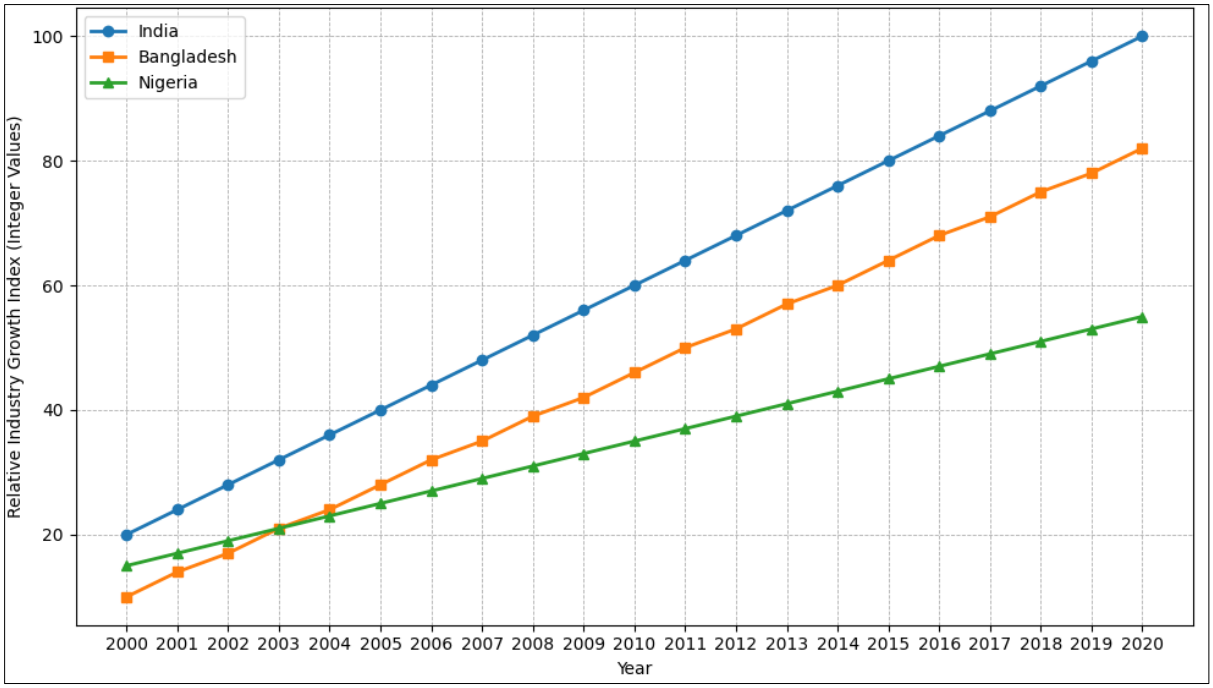

Figure 1 Comparative Growth Trajectories of India, Bangladesh, and Nigeria's Pharmaceutical Industries

3.4. Lessons applicable to the Nigerian context

The trajectories of India and Bangladesh emphasize the value of policy coherence, regulatory strengthening, and sustained investment in manufacturing infrastructure [23]. Nigeria can draw lessons from their strategic use of IP flexibilities, long-term industrial incentives, and structured capacity-building initiatives designed to foster competitiveness [17]. Both countries demonstrate that predictable regulatory environments and strong state–industry collaboration accelerate technology transfer and attract investment [20]. Nigeria's large market provides a foundation for similar growth, but achieving this requires stronger API development pathways, consistent investment in quality regulation, and targeted incentives that address structural barriers limiting domestic production scale and competitiveness [22].

4. Nigeria's current pharmaceutical manufacturing landscape

4.1. Industry profile: capacity, key players, and market characteristics

Nigeria's pharmaceutical industry is dominated by formulation manufacturers operating primarily at small to medium scale, with limited upstream capacity for active pharmaceutical ingredient (API) production [24]. Most firms import raw materials, packaging components, and APIs from Asia, reinforcing structural dependence on external supply chains [29]. Key players include a mix of long-standing local companies and multinational subsidiaries that supply essential medicines to retail outlets, hospitals, and public procurement channels [22]. Market characteristics reflect a heavy reliance on branded generics, fragmented distribution networks, and variable quality oversight across facilities [27]. While domestic demand is large and continuously expanding, production capacity often lags behind needs due to infrastructural and financial constraints. Nonetheless, the industry has shown resilience, supported by entrepreneurial activity and increasing private investment in quality upgrades [26]. Despite these advancements, Nigeria's market suffers from import competition, currency volatility, and inconsistent enforcement of pharmaceutical standards [30]. These conditions limit competitiveness and constrain the ability of local firms to achieve economies of scale. To accelerate sectoral growth, Nigeria must strengthen industrial incentives, consolidate the supply chain, and enhance regulatory predictability, drawing inspiration from comparator markets that achieved rapid industrial expansion through coordinated policy action [23].

4.2. Constraints to local manufacturing

4.2.1. Regulatory and quality challenges

Regulatory inconsistencies, slow product registration timelines, and variable enforcement standards remain major barriers to pharmaceutical manufacturing in Nigeria [25]. While efforts have been made to upgrade regulatory capacity, gaps persist in inspection frequency, laboratory testing strength, and post-market surveillance coverage [28]. These challenges hinder manufacturer confidence and complicate compliance, especially for firms seeking international certification. Many facilities struggle to meet stringent global Good Manufacturing Practice (GMP) requirements due to resource limitations and infrastructural deficiencies [22]. Weak coordination between regulatory agencies and industrial stakeholders further limits effective planning and implementation of sector-wide reforms. In contrast, countries like India and Bangladesh achieved regulatory consolidation early, giving manufacturers a stable framework for long-term investment. Nigeria's regulatory environment therefore requires targeted strengthening to ensure reliability, competitiveness, and consistent quality assurance across the production ecosystem [29].

4.2.2. High production costs and infrastructure gaps

Local manufacturers face high production costs driven by unreliable electricity, limited industrial water supply, and dependence on imported raw materials [30]. Energy expenditure alone consumes a disproportionately large share of operational budgets, making locally produced medicines less price-competitive than imports [23]. Poor transport infrastructure, inefficient port operations, and logistics delays further increase overhead costs and extend production timelines [27]. These systemic issues discourage expansion of upstream production and impede the development of vertically integrated manufacturing clusters. In contrast, India and Bangladesh benefited from government-backed industrial zones that provided stable utilities, reduced logistics bottlenecks, and supported cost-efficient scaling [24]. Nigeria's infrastructural environment remains a critical barrier, requiring significant investment to create a competitive production base capable of attracting both domestic and foreign pharmaceutical investors [26].

4.2.3. Limited research, development, and technology transfer

Research and development (RandD) capacity in Nigeria's pharmaceutical sector remains limited due to inadequate funding, weak university–industry collaboration, and insufficient technology transfer platforms [28]. Most local firms

emphasize routine formulation rather than process innovation or advanced product development [25]. Absence of strong API research programs further restricts opportunities for self-sufficiency and reduces capacity to move into higher-value pharmaceutical categories [22]. Countries like India successfully expanded RandD capability by incentivizing partnerships between academia, industry, and global research institutions, enabling rapid adoption of new technologies [29]. Bangladesh likewise leveraged TRIPS flexibilities to accelerate generic innovation through streamlined technology acquisition [30]. Strengthening RandD ecosystems in Nigeria is therefore essential for reducing dependency on external suppliers and cultivating a skilled workforce capable of driving local pharmaceutical innovation and modernization [27].

Table 1 Comparison of Pharmaceutical Manufacturing Constraints in Nigeria, India, and Bangladesh

Constraint Category	Nigeria	India	Bangladesh
Regulatory and Quality Systems	Regulatory processes often slow; inconsistent enforcement; limited GMP-compliant facilities; capacity gaps in inspection and post-market surveillance.	Mature regulatory environment; strong GMP enforcement; globally recognized authorities; extensive export-certified infrastructure.	Rapidly improving regulation; strong government push to meet WHO prequalification; increasing GMP compliance, though still evolving.
Production Costs and Industrial Inputs	High production costs driven by unreliable power, expensive logistics, imported APIs, and weak industrial clusters; limited economies of scale.	Large-scale industrial zones reduce production costs; established API parks; strong supply chain integration; competitive electricity and logistics systems.	Lower production costs due to government subsidies, API park initiatives, and well-integrated manufacturing clusters; cost-effective labor market.
Infrastructure (Power, Logistics, Industrial Parks)	Chronic power shortages; fragmented logistics networks; few functional pharmaceutical industrial parks.	Robust industrial parks; efficient logistics corridors; stable power supply enabling large-scale manufacturing.	Strengthening industrial zones; dedicated pharma parks; improving logistics through export-oriented infrastructure investments.
RandD, Technology Transfer and Innovation Capacity	Limited RandD funding; minimal technology transfer partnerships; weak linkage between universities, research institutes, and industry.	Strong global partnerships; advanced formulation development; thriving biotech and generics innovation landscape.	Growing RandD capabilities supported by state incentives; strong generic formulation capacity; increasing partnerships with foreign firms.
Human Capital and Technical Workforce	Shortage of pharmaceutical engineers, industrial pharmacists, and regulatory scientists; limited specialized training programs.	Strong technical workforce; established educational pipelines for pharmaceutical sciences and industrial engineering.	Competitive workforce strengthened by targeted training programs and industry-led skill development initiatives.
Market Structure and Export Capacity	Highly import-dependent market; limited export competitiveness; weak regional penetration.	One of world's largest exporters of generics; diversified global markets; strong reputation for affordable, high-quality medicines.	Major exporter to developing countries; competitive in low-cost generics; benefitting from TRIPS flexibilities.

4.3. Nigeria vs India/Bangladesh: structural differences

Nigeria differs significantly from India and Bangladesh in terms of API production depth, regulatory maturity, industrial infrastructure, and export capacity [24]. While India built robust upstream API clusters and secured global regulatory approvals, Nigeria remains dependent on imported inputs and has limited international market reach [26]. Bangladesh, supported by TRIPS flexibilities and coordinated industrial incentives, developed competitive export-oriented industries, whereas Nigeria's manufacturing ecosystem remains inward-looking with minimal integration into global value chains [28]. Market fragmentation, variable enforcement of quality standards, and high operating costs further widen the structural gap [23]. Additionally, Nigeria's financial environment offers fewer long-term industrial loans and

weaker policy consistency compared with the aggressive state-led industrialization seen in India and Bangladesh [30]. These structural differences highlight the need for Nigeria to prioritize regulatory strengthening, infrastructure investment, and targeted industrial policies that can bridge existing competitiveness gaps and support sustained local production growth [27].

5. Policy and regulatory reforms in India and Bangladesh

5.1. Regulatory strengthening and quality assurance systems

Strengthening regulatory systems is foundational to developing a competitive pharmaceutical manufacturing ecosystem, particularly for countries seeking to reduce import dependence and enhance domestic production [29]. Effective regulation ensures that products meet consistent quality, safety, and efficacy standards, thereby boosting public confidence and enabling manufacturers to pursue both domestic and export markets [31]. India's transformation was accelerated by major reforms within its regulatory authority, which streamlined registration timelines, improved inspection standards, and expanded laboratory testing capabilities [34]. Bangladesh adopted a similar strategy by upgrading quality assurance systems and enhancing surveillance mechanisms that supported expansion into regional markets [28]. For Nigeria, regulatory strengthening must include predictable approval processes, continuous GMP enforcement, and improved coordination between federal oversight agencies and state-level authorities [33]. Investments in digital regulatory systems, pharmacovigilance infrastructure, and staff capacity development are equally essential. Without these improvements, local firms face significant barriers achieving international certification and cannot compete with established producers across Asia. Regulatory reform therefore represents a cornerstone of Nigeria's long-term pharmaceutical development, enabling the country to attract investment, encourage technology transfer, and ensure that manufacturers consistently meet global standards that establish credibility in regional and international markets [35].

5.2. Harmonized industrial and health-sector policies

Pharmaceutical sector growth depends heavily on alignment between industrial policy and national health objectives, ensuring that production incentives match public health priorities [30]. Countries that successfully expanded their pharmaceutical industries such as India implemented policy frameworks that synchronized industrial development, health financing, and regulatory modernization [32]. Bangladesh, similarly, coordinated industrial incentives with national health policies, enabling simultaneous improvement in medicine affordability and manufacturing competitiveness [28]. Nigeria's policy environment, however, remains fragmented, with industrial, trade, and health-sector policies often operating in silos that reduce overall effectiveness [34]. Harmonization is necessary to create a unified direction across ministries, streamline resource allocation, and eliminate conflicting regulatory or fiscal requirements. Coordinated policy design enables structured procurement planning that supports domestic manufacturers while ensuring affordability and uninterrupted supply of essential medicines [29]. Ensuring clear linkages between policy domains also strengthens long-term investment certainty, enabling manufacturers to expand capacity and integrate more deeply into regional value chains. Nigeria can benefit significantly from institutionalizing inter-ministerial coordination mechanisms, aligning pharmaceutical industrialization with public health goals, and implementing coordinated quality benchmarks and incentives that support sector-wide modernization [33].

5.3. Incentives supporting local and foreign investment

Investment incentives form a critical pillar of pharmaceutical sector expansion, helping manufacturers manage high upfront capital costs and long-term operational expenses [28]. India expanded rapidly by offering tax holidays, subsidized industrial land, and RandD incentives that attracted large-scale domestic and foreign investors [35]. Bangladesh followed a similar pathway through duty waivers on raw materials, tax reductions, and targeted credit programs for technologically advanced production facilities [31]. Nigeria's current incentive landscape is less structured and often inconsistently implemented, reducing its ability to attract stable investment or encourage major technology upgrades [30]. Strengthening incentive schemes requires the creation of predictable fiscal policies, subsidized credit facilities, and targeted support for API manufacturing, packaging, and quality assurance infrastructure [32]. Investment promotion should also be linked to performance benchmarks such as GMP certification and local workforce development, ensuring that incentives produce measurable industrial outcomes. In addition, special economic zones dedicated to pharmaceuticals could help reduce utility costs, streamline customs processes, and improve production efficiency. By adopting a unified and transparent incentive framework, Nigeria can stimulate investor confidence, accelerate modernization, and position the pharmaceutical sector to capture domestic and regional market opportunities [34].

5.4. Export orientation, TRIPS flexibilities, and market expansion

Export orientation was a defining feature of India's pharmaceutical success, enabling rapid scale-up and global competitiveness supported by strong API capacity and international regulatory approvals [29]. Bangladesh also leveraged TRIPS flexibilities to manufacture a wide range of generics without patent restrictions, accelerating expansion into regional markets and strengthening its industrial base [33]. These strategies highlight the importance of enabling manufacturers to access global markets, drive economies of scale, and reinvest earnings into RandD and technology upgrades [35]. Nigeria has yet to build significant export capacity due to regulatory fragmentation, limited API production, and infrastructural bottlenecks [28]. However, strategic use of TRIPS-compliant flexibilities, combined with streamlined export certification processes, could help stimulate growth in regionally competitive product segments. Supporting export readiness requires investments in quality infrastructure, harmonization with regional regulatory systems, and targeted industrial incentives that promote scale and competitiveness [32]. Market expansion efforts must also prioritize West African regional demand, leveraging Nigeria's unique geographic and economic position. An export-oriented industrial strategy would therefore create stronger economies of scale, stimulate RandD investments, and enhance Nigeria's long-term pharmaceutical resilience [31].

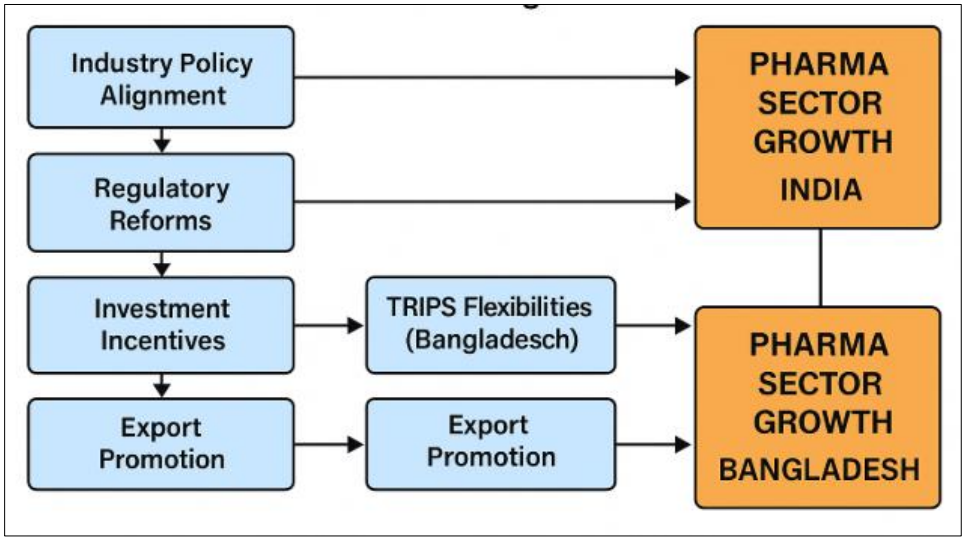

Figure 2 Policy Evolution Pathways Leading to Pharma Sector Growth in India and Bangladesh

6. Nigeria's reform priorities: evidence-based policy pathways

6.1. Strengthening the National Agency for Food and Drug Administration and Control (NAFDAC)

Strengthening NAFDAC is essential for building a resilient pharmaceutical manufacturing ecosystem capable of meeting domestic and regional demand [35]. As the national regulatory authority, NAFDAC's effectiveness directly influences product quality, investor confidence, and Nigeria's ability to expand into broader African markets. Although significant progress has been recorded in inspection capacity and laboratory upgrades, gaps remain in digital surveillance systems, regulatory predictability, and post-market monitoring—limitations that constrain manufacturers seeking international certifications [33]. Enhancing NAFDAC's operational efficiency requires investment in workforce skills, expansion of laboratory infrastructure, and adoption of real-time monitoring technologies that support proactive risk detection [38]. Furthermore, NAFDAC should streamline quality audits, integrate electronic dossier management, and strengthen coordination with customs authorities to reduce counterfeit products entering the retail market. Countries such as India benefitted greatly from early regulatory modernization, enabling faster approvals and international recognition of local products [36]. To replicate similar outcomes, Nigeria must ensure sustained funding, strengthen institutional independence, and accelerate harmonization with regional regulatory frameworks. These reforms will enhance transparency, improve processing timelines, and reduce compliance burdens that currently limit manufacturing growth [40].

6.2. Streamlined regulatory pathways and accelerated drug registration

A major constraint for Nigerian manufacturers is the lengthy and unpredictable drug registration process, which leads to delays in market entry and discourages investment [37]. Establishing streamlined regulatory pathways such as fast-

track approvals for essential medicines and reliance procedures for products already approved by recognized regulatory authorities would significantly reduce administrative burdens [33]. Accelerated pathways should integrate risk-based classification, enabling NAFDAC to focus resources on high-risk categories while expediting low-risk applications. Bangladesh and India achieved substantial efficiency gains by adopting digital submission platforms and transparent review timelines, practices that Nigeria can adapt to strengthen regulatory consistency [39]. Improved predictability reduces uncertainty for manufacturers, supports rapid product rollout, and enhances competitiveness relative to imported medicines. Ultimately, streamlined processes contribute to lower production costs, quicker market response, and stronger investor confidence [35].

6.3. Fiscal and industrial incentives for local manufacturing

6.3.1. Tax holidays, import duty waivers, preferential financing

Fiscal incentives remain one of the strongest tools for stimulating pharmaceutical investment in emerging markets [36]. Nigeria can accelerate industrial growth by offering targeted tax holidays, reduced corporate taxes for GMP-compliant manufacturers, and duty waivers on essential raw materials and production equipment [38]. Preferential financing including low-interest loans, credit guarantees, and long-tenor development funds would help manufacturers upgrade facilities, adopt new technologies, and expand capacity [33]. India and Bangladesh increased sector competitiveness by aligning incentives with RandD commitments, quality improvements, and export readiness criteria, creating predictable environments that encouraged large-scale investments [40]. Nigeria's fragmented incentive landscape limits its impact, making policy clarity and consistency crucial for long-term success. Well-structured incentives would lower operational costs, increase production scale, and improve affordability of locally manufactured medicines [35].

6.3.2. Incentives for API production and backward integration

Table 2 Recommended Policy Incentives and Expected Impact on Nigeria's Pharma Manufacturing Ecosystem

Policy Incentive	**Description of Intervention**	**Expected Impact on Manufacturing Ecosystem**
Tax Holidays for Pharmaceutical Manufacturers	Provide 5–10-year corporate tax exemptions for new or expanding pharmaceutical facilities.	Reduces operational costs; attracts new investors; increases local production capacity.
Import Duty Waivers on APIs, Excipients, and Machinery	Remove or reduce tariffs on raw materials, packaging, and specialized manufacturing equipment.	Lowers cost of production; improves competitiveness with imported products; encourages backward integration.
Preferential Financing and Low-Interest Credit Schemes	Create dedicated pharma financing windows through development banks, offering single-digit interest rates.	Expands access to capital; supports factory upgrades; facilitates scale-up of GMP-compliant facilities.
Incentives for API Production and Backward Integration	Establish API parks; provide subsidies for utilities, land acquisition, and RandD for active ingredient synthesis.	Reduces import dependency; builds resilience to global supply disruptions; enhances value chain depth.
Export Expansion Grants and TRIPS Flexibility Utilization	Offer export rebates, certification support, and legal facilitation to maximize TRIPS flexibilities before expiration.	Boosts global market entry; strengthens competitiveness; promotes large-scale generic production.
Accelerated Drug Registration Pathways	Introduce fast-track approvals for locally manufactured essential medicines meeting quality criteria.	Improves market entry speed; increases domestic supply; incentivizes high-standard local production.
Public Procurement Preferences for Local Manufacturers	Mandate a percentage of federal and state health commodity procurement from certified local producers.	Ensures stable demand; improves financial sustainability; encourages investment in quality upgrades.
RandD Grants, Innovation Funds and University–Industry Collaboration	Provide grants for formulation development, bioequivalence studies, and joint research projects.	Expands innovation ecosystem; builds domestic technical expertise; supports long-term industrial competitiveness.

Infrastructure Support in Industrial Zones	Subsidize electricity, water, and quality-testing laboratories within pharma industrial zones.	Strengthens production reliability; reduces overhead costs; improves GMP compliance rates.
Technology Transfer Incentives for Foreign Partners	Offer tax credits and regulatory incentives for multinational companies that transfer manufacturing know-how.	Accelerates capability development; improves quality assurance; enhances export readiness.

Backward integration is essential for reducing Nigeria's heavy reliance on imported APIs, which exposes manufacturers to global supply disruptions and currency instability [37]. To encourage API production, Nigeria should introduce targeted incentives such as specialized industrial zones, subsidized energy schemes, and grants supporting process technology acquisition [39]. Bangladesh achieved significant progress by coupling its TRIPS benefits with API parks that offered shared utilities and centralized effluent treatment models Nigeria could adapt to scale local API output [33]. India's API industrial clusters also demonstrate how infrastructure-heavy incentives can reduce production costs and enhance competitiveness [40]. Encouraging joint ventures with foreign API producers, providing RandD tax credits, and supporting technology transfer programs would further accelerate backward integration. Strengthening API capacity will ultimately improve medicine availability, reduce import bills, and support export-oriented growth [36].

6.4. Expanding domestic RandD, innovation ecosystems, and technology transfer

Nigeria's pharmaceutical sector suffers from limited RandD capability, weak academic–industry linkages, and insufficient investments in innovation infrastructure [34]. Expanding domestic RandD requires establishing innovation hubs, strengthening university partnerships, and incentivizing collaborative research programs focused on drug formulation, API synthesis, and quality enhancement technologies [36]. India's RandD ecosystem developed rapidly due to strong public funding, industry-driven consortia, and policy frameworks that rewarded innovation through tax incentives and competitive grants [38]. Bangladesh also leveraged university partnerships and foreign collaborations to build technical capacity across its expanding manufacturing base [33]. Nigeria can adopt similar strategies by creating dedicated pharmaceutical research funds, improving access to pilot-scale production facilities, and supporting technology transfer agreements with established international firms. Strengthening RandD capacity will diversify Nigeria's pharmaceutical portfolio, encourage bioequivalence research, and support greater self-sufficiency in essential medicines [39].

6.5. Stimulating domestic market demand via procurement reforms

Public procurement reforms can significantly increase demand for locally manufactured products, creating stable markets that encourage investment [35]. Nigeria's procurement policies should prioritize domestically produced medicines that meet quality standards, supported by long-term framework contracts and timely payment systems [40]. India's procurement incentives, combined with price controls, helped manufacturers achieve scale while ensuring affordability for public health programs [37]. Nigeria can replicate these gains by creating transparent tendering processes, incorporating quality-based selection, and establishing guaranteed purchase agreements for essential medicines. Stronger demand signals will stimulate production expansion and reinforce industry confidence [33].

7. Strengthening infrastructure, skills, and production enablers

7.1. Power, logistics, industrial zones, and manufacturing clusters

Reliable infrastructure is essential for a competitive pharmaceutical sector, and Nigeria's current deficits in electricity, transportation, and logistics significantly elevate production costs [42]. Frequent power interruptions compel manufacturers to rely on diesel generators, raising operational expenses and reducing global competitiveness [39]. Strengthening the national grid, expanding gas-powered industrial corridors, and providing stable electricity within designated pharmaceutical zones would greatly enhance cost efficiency. Logistics remain another bottleneck, with delays at ports and poor road networks contributing to prolonged import timelines for APIs and packaging materials [44]. Establishing specialized pharmaceutical industrial zones with centralized utilities, shared quality infrastructure, and efficient customs mechanisms would replicate the cluster-driven efficiencies achieved in India and Bangladesh [40]. Such clusters promote shared services, attract foreign partners, and stimulate technology diffusion across firms. Improved warehousing, cold-chain capacity, and bonded logistics facilities would further enable predictable supply flows and reduce manufacturing downtime [45]. Without coordinated infrastructure investment, policy reforms alone cannot deliver a competitive environment for local production. Therefore, prioritizing industrial zones and logistics modernization is fundamental to Nigeria's long-term pharmaceutical transformation [41].

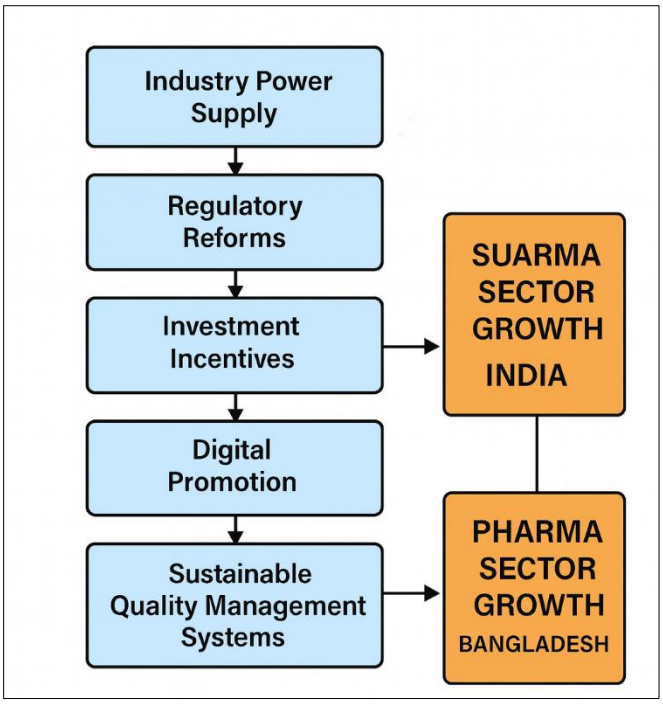

Figure 3 Infrastructure and Workforce Enablers Required for Sustainable Local Manufacturing in Nigeria

7.2. Skilled workforce development and pharmaceutical engineering capacity

A skilled workforce forms the backbone of pharmaceutical manufacturing, and Nigeria faces substantial gaps in pharmaceutical engineering, quality assurance, and advanced production technologies [43]. Limited academic specialization in areas such as process engineering, API synthesis, and industrial biotechnology restricts the technical depth needed to support high-value manufacturing [40]. India and Bangladesh expanded their industrial talent pools through strong university–industry partnerships, specialized training institutes, and government-funded skills programs aligned with industrial policy objectives [39]. For Nigeria, developing a similar workforce pipeline will require curriculum modernization, investment in pharmaceutical engineering programs, and long-term collaboration with global research institutions. Structured apprenticeships, GMP-focused certification programs, and in-plant training schemes would also equip local workers with practical skills relevant to modern production lines [44]. Supporting professional development for regulators, quality auditors, and laboratory scientists is equally essential for strengthening compliance frameworks. Enhancing workforce capability not only improves production quality but also attracts foreign investors seeking consistent technical standards. A comprehensive, skills-focused development agenda is therefore central to accelerating Nigeria's transition toward competitive, innovation-oriented pharmaceutical manufacturing [41].

7.3. Digital supply chain systems and quality management infrastructure

Digitalization is now a cornerstone of modern pharmaceutical production, enabling real-time monitoring, quality assurance, and predictive supply chain management [42]. Implementing digital batch record systems, serialization technologies, and automated deviation reporting strengthens regulatory compliance and reduces production errors. Nigeria's current digital infrastructure remains uneven, with many firms relying on manual documentation and outdated processes that hinder efficiency [45]. India's digitization of production monitoring and Bangladesh's adoption of electronic quality management systems offer practical models for Nigeria to emulate [39]. Investing in digital traceability, warehouse automation, and integrated ERP platforms would enhance supply chain visibility and reduce risks of counterfeits entering distribution channels. These digital upgrades are critical for achieving GMP consistency and preparing firms for regional and international market expansion [43].

7.4. Local investment mobilization and private sector participation

Mobilizing domestic investment is crucial for scaling Nigeria's pharmaceutical manufacturing capacity, particularly in a sector where foreign investors often seek stable regulatory and infrastructural environments before committing long-term capital [41]. Encouraging local participation through tax incentives, public–private financing vehicles, and sector-focused investment funds would enhance capital availability [44]. Strengthening Nigeria's financial markets to support

pharmaceutical bonds, innovation grants, and equity financing would further catalyze industrial growth [42]. Engaging private sector associations in policy design ensures that incentives align with real-world industry needs, thereby improving uptake and fostering a supportive business environment for sustained manufacturing expansion [40].

8. Regional and global market integration

8.1. Leveraging ECOWAS and African Continental Free Trade Area (AfCFTA) markets

Regional trade frameworks such as ECOWAS and the AfCFTA present major opportunities for Nigeria to expand pharmaceutical exports and achieve economies of scale [36]. With a large and growing West African population, regional demand for affordable, quality-assured generics continues to increase, creating commercial potential for domestic manufacturers seeking to diversify beyond the national market [34]. However, realizing these opportunities requires deeper regulatory cooperation, efficient customs processes, and improved trade logistics to reduce border delays that undermine competitiveness [37]. AfCFTA's rules of origin also provide incentives for localized production, encouraging member states to prioritize regional value chains in pharmaceuticals. Nigeria can leverage its geographic centrality and industrial potential to position itself as a leading supplier of essential medicines within West Africa, provided quality standards are consistently maintained [39]. Strengthening regional supply chains would also reduce collective dependency on distant manufacturing hubs and improve health security across the continent [40].

8.2. Export readiness, certification pathways, and quality harmonization

Achieving export readiness requires Nigerian manufacturers to meet stringent quality standards, obtain internationally recognized certifications, and align production processes with harmonized regulatory frameworks across Africa [35]. Countries like India secured global market share by ensuring that firms met WHO prequalification standards early in their industrial expansion, enabling access to donor-funded procurement markets [38]. For Nigeria, targeted investment in GMP compliance, upgraded laboratories, and digital quality management systems is critical for reducing certification barriers [34]. Harmonizing national regulations with regional frameworks such as the African Medicines Regulatory Harmonization (AMRH) initiative would streamline cross-border movement of medicines and simplify export licensing [36]. Furthermore, consistent product documentation, bioequivalence studies, and strong pharmacovigilance systems strengthen market credibility and reduce rejection risks in importing countries [39]. With these improvements, Nigerian manufacturers can expand into ECOWAS and AfCFTA markets, positioning the country as a competitive regional pharmaceutical hub [40].

9. Implementation roadmap and risk mitigation

9.1. Phased implementation timeline

A phased implementation timeline allows Nigeria to sequence reforms logically, ensuring that regulatory, industrial, and infrastructural improvements evolve in parallel rather than in isolation [39]. The first phase focuses on strengthening regulatory systems, upgrading quality assurance laboratories, and supporting manufacturers' compliance with international standards. The second phase prioritizes scaling local production capacity, enhancing industrial zones, and expanding workforce development initiatives [42]. The third phase advances export readiness by aligning with regional certification pathways and deepening participation in ECOWAS and AfCFTA markets [38]. Implementing reforms gradually reduces systemic shocks and supports sustained institutional learning across the sector [44].

9.2. Institutional coordination mechanisms

Effective execution requires strong coordination mechanisms among key institutions, including NAFDAC, the Federal Ministry of Health, the Federal Ministry of Industry, Trade and Investment, and relevant economic planning agencies [41]. A central coordination platform can facilitate policy alignment, track progress, and identify emerging bottlenecks as reforms unfold [43]. Integrating private sector actors, research institutions, and financial regulators ensures that industrial policies are technically grounded and economically feasible [40]. Regular performance reviews, supported by transparent reporting systems, enable ongoing monitoring and course correction. Such structured coordination reduces duplication, promotes accountability, and ensures reforms are implemented cohesively across government and industry [44].

9.3. Risk identification and mitigation strategies

Risks associated with pharmaceutical sector reform include regulatory delays, funding gaps, quality failures, and market distortions driven by import competition [38]. Mitigation strategies must therefore prioritize predictable financing, strong inspection systems, and rapid response mechanisms to address non-compliance before it undermines market confidence [42]. Strengthening supply chain intelligence through digital tracking and pharmacovigilance improves early detection of substandard products and operational bottlenecks [41]. Additionally, clear incentives for local production reduce vulnerability to external shocks and ensure long-term viability [43]. Proactive risk management supports the resilience of reforms and promotes stable progress toward sustainable local manufacturing capacity [44].

10. Conclusion

Summary of key findings

This analysis demonstrates that Nigeria's pharmaceutical sector remains significantly constrained by regulatory bottlenecks, infrastructure gaps, high production costs, and limited technological capacity. Comparative assessment with India and Bangladesh shows that sustained investments in regulatory strengthening, export-oriented industrial strategies, and deliberate support for active pharmaceutical ingredient production were essential to their success. Nigeria's current system, while possessing substantial market potential, lacks the coordinated policy environment required for competitive local manufacturing. The review highlights several consistent themes: the need for harmonized industrial and health-sector policies, incentives that reduce operational costs, strengthened research and development ecosystems, and improved quality assurance infrastructure. It also emphasizes that scalable growth requires robust workforce development, digitalized supply chains, and strategic integration into regional and continental markets. Overall, the findings underline that Nigeria's pathway to pharmaceutical self-reliance depends on long-term policy consistency, institutional collaboration, and the creation of a business environment that can attract and sustain investment.

Strategic implications for Nigeria's health security and industrialization

The strategic implications of these findings are far-reaching for both national health security and broader industrial development. Strengthening local pharmaceutical manufacturing reduces Nigeria's vulnerability to global market shocks, supply chain disruptions, and foreign exchange volatility. Improved regulatory capacity enhances public health outcomes by ensuring higher-quality medicines, while strong industrial incentives can stimulate domestic investment, job creation, and technology transfer. By aligning industrial policy, procurement systems, and regulatory reform, Nigeria can gradually shift from dependence on imported medicines toward a resilient, self-sustaining pharmaceutical ecosystem. Furthermore, integration into ECOWAS and AfCFTA markets could enable Nigeria to expand its export base, positioning the country as a regional pharmaceutical hub. Achieving these outcomes requires coordinated long-term planning, predictable regulation, and targeted support for innovation. Ultimately, rebuilding the sector is not only an economic opportunity but a critical pillar for national security and public health resilience.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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