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Biopharmaceutical Innovation and Regulatory Harmonisation in Emerging Economies: A Comprehensive Analysis of Brazil, China, India, and South Africa

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Abstract

Introduction: Emerging economies are changing the playing field of global biopharmaceutical innovation and international review mechanisms should be adjusted accordingly. However, heterogenous regulatory frameworks and innovation potential prevent sustainable global market access with truly affordable health care. Analyses of biopharmaceutical innovation trajectories, regulatory environments and policy ecosystems in these four market-pairs can inform opportunities for improved collaboration and patient access. **Methods:** We performed an in-depth analysis of the innovation pipelines and biopharmaceutical industries in Brazil, China, India, and South Africa. Information was retrieved from regulatory databases, company reports, clinical trial registries and peer-reviewed sources (2018-2024). We examined 376 drug candidates from 66 companies, analysing their innovation attributes, regulatory approval methods, and policy environments. Other information about trends in clinical trials, timelines for regulatory approval and recent policy developments were abstracted in a systematic manner. **Results and Discussion:** Analysis showed 376 biopharmaceutical candidates in development, about 60% of which were new chemical or molecular entities. China still had the highest number of New Molecular Entity (NME) at 46 in 2024 and India's biopharmaceutical sector accounted for 49% of the country's total biopharmaceutical output. Regulatory timelines varied significantly—from 21 days under China's pilot programme, to 10–14 months in Brazil, and up to approximately four years historically in South Africa. The gap in clinical research activity between BRICS and G7 countries decreased by 68.6% between 2018 and 2022. Challenges included limited resources, regulatory complexity, and low levels of harmonisation, while progress was driven by government support, attention to local health needs, and international collaboration. **Conclusion:** There is great potential in biopharmaceutical innovation in BRICS, but there is a requirement for regulatory harmonisation to obtain global impact. Policy recommendations include risk-based assessments, installation of reliance mechanisms, public-private partnerships and establishment of regional harmonisation platforms. These measures could accelerate the arrival of new treatments while maintaining safety standards and supporting the growth of a viable business environment.

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Introduction

The global biopharmaceutical landscape is undergoing a significant shift, with emerging economies playing an increasingly central role. Countries like Brazil, China, India, and South Africa are transitioning from their historic roles as low-cost manufacturers to becoming sources of pharmaceutical innovation and regulatory reform (Rezaie et al., 2008; Thorsteinsdóttir et al., 2004). These countries collectively hold more than 40% of the world's population and bear a disproportionate burden of global disease. This demographic and epidemiological pressure positions them to meet critical global health needs and play a leadership role in drug research and development (Chaturvedi & Thorsteinsdóttir, 2011; Manoharan et al., 2024).

However, their potential is undermined by highly fragmented regulatory frameworks, inconsistent approval processes, and underdeveloped harmonisation mechanisms. These barriers slow down the development, review, and delivery of new therapies, limiting patient access and investor confidence. As a result, despite a growing pipeline of innovative products, BRICS countries often face delayed integration into global pharmaceutical markets. In this review, novel biopharmaceutical products (NBPs) refer to innovative biological medicines and advanced therapeutic products developed within emerging economies.

There is a fresh opportunity to move beyond generic production toward the development of novel therapies. But to fully realise this potential, coherent regulatory systems, aligned with international standards, are urgently needed. Without this alignment, innovation efforts may remain constrained by bureaucratic inefficiencies and inconsistent evaluation criteria across markets.

Historical Context and Evolution

Novel biopharmaceutical products (NBPs) and the biopharmaceutical industry in these developing countries have evolved significantly over the last twenty years. India's pharmaceutical sector, which includes generic drug manufacturing and biopharmaceutical products, accounts for 49% of the country's biopharmaceutical output as of 2024 with India emerging as a major global producer of biopharmaceutical products and biosimilars (Cactus Communications, 2024). The fast-paced regulatory modernization of China's drug regulation agency, the National Medical Products Administration (NMPA), led to 46 new drugs approvals in 2024 including 39 domestically-developed innovations—new high in pharmaceutical innovation in the country (*Wu et al., 2025a*). Strong research capacity in Brazil has supported biosimilar development and innovative product discovery, while the move from the Medicines Control Council to the South African Health Products Regulatory Authority (SAHPRA) is part of efforts to modernise regulations (Keyter et al., 2018).

Regulatory Harmonisation Imperative

The significant regulatory standard disparities across these two markets constitute key barriers to global drug innovation and patient availability. Despite a 68.6% reduction in the distance across BRICS and G7 nations for clinical trials from year 2018 to 2022, convergence of regulation remains relevant when making efforts to optimise the potential of innovation (Manoharan *et al.,* 2024). The ICH comprises members from all five continents. Illustrating the growing acceptance of global regulatory harmonisation, ANVISA became a member after 2016 (International Council for Harmonization, 2024).

Contemporary Challenges and Opportunities

Outstanding challenges include significant variation in regulatory clearance timelines—ranging from 21 days under China's pilot programme to delays of up to four years in South Africa (Moeti et al., 2023; RegASK, 2024). However, recent developments, such as the meeting of the BRICS Working Group on Pharmaceutical Markets and ongoing efforts to draft simplified biosimilar guidelines, indicate that these challenges are being

actively addressed (BRICS Competition Centre, 2025). The COVID-19 pandemic has also served as a critical lesson for pharmaceutical industries in developing countries, underscoring the urgent need to accelerate and strengthen regulatory reforms globally (Arlett et al., 2025).

Study Rationale and Objectives

This review addresses the following topics: (1) the current state of biopharmaceutical innovation in South Africa, China, India, and Brazil; (2) the regulatory approach to fostering innovation and facilitating market access; (3) the ratio of successful to unsuccessful applications and the policy rationale behind these outcomes; and (4) evidence-based options for regulatory adjustments to support global health cooperation.

It is essential for policymakers and businesses of all sizes to understand their roles within these evolving systems. The ongoing tension between the push for innovation and the imperative of affordability presents a significant challenge for public health authorities striving to maintain access to potentially life-saving medicines. Understanding the foundations of these dynamics is critical for informed decision-making and strategic alignment.

Materials and methods

Study Design and Scope

This review analysis included both quantitative and qualitative evaluations of biopharmaceutical pipelines and regulatory policy contexts. The quantitative data were derived from secondary sources, such as regulatory databases, company reports, and clinical trial registries. The qualitative component involved thematic categorization of policy trends and regulatory frameworks. The research, conducted from 2018 to 2024, aimed to summarize recent progress in regulatory modernization and innovative patient care pathways (PMA) in Brazil, China, India, and South Africa.

Data Collection Framework

Company and Product Analysis: All Biopharmaceutical companies in the four focus countries were systematically screened based on various sources such as national regulatory databases, industry reports or company announcements. A total of 66 companies were identified and investigated, representing a broad spectrum of indigenous biopharmaceutical innovation in the region. We gathered data for every company on their development pipelines, including 376 specific drug candidates and vaccines in development.

Table 1: Biopharmaceutical Companies Analysed by Country

Country	Number of Companies
India	26
China	28
Brazil	19
South Africa	17
Total	66 Companies with 376 drug candidates

Assessment of regulatory context: We conducted a review of national laws, regulatory approval processes, and regional policy developments. Data sources included the official websites of regulatory authorities, policy submissions, industry documents, and peer-reviewed academic publications. Key developments—such as reforms by China's National Medical Products Administration (NMPA), regulatory modernisation by Brazil's ANVISA, enhancements within India's Central Drugs Standard Control Organisation (CDSCO), and the transition to SAHPRA in South Africa—were examined in detail.

Data Sources: Clinical trial data were obtained from the World Health Organization's International Clinical Trials Registry Platform (ICTRP) and relevant national registries. We evaluated innovation activity and regulatory impact by analysing trial distribution across therapeutic areas, sponsorship categories, and temporal trends.

Table 2: Regulatory Timeline Comparison (2024)

Country	Regulatory Authority	Typical Review Time	Recent Improvements	Key Challenges
China	NMPA	21 days (pilot programme)	Priority review pathways, conditional approvals	Resource allocation, international harmonisation
India	CDSCO	Variable (6–18 months)	Fast-track approvals, orphan drug pathways	Capacity constraints, predictability
Brazil	ANVISA	10–14 months	Electronic submissions, ICH participation	Timeline predictability, local requirements
South Africa	SAHPRA	2–4 years (improving)	Risk-based assessment, backlog clearance	Resource constraints, historical backlogs

Note: China's 21-day timeline reflects select pilot programme cases and is not representative of standard review durations across all product categories. (Zhang et al., 2022).

Policy and market survey: Market data, policy objectives, and international cooperation frameworks were analysed using government reports, publications from international organizations, and industry sources. The review also included an assessment of intellectual property structures, public–private collaborations, and efforts toward international regulatory alignment.

Innovation Classification System

Drug candidates were categorized based on: (1) novelty status—whether they were new chemical or molecular entities, or modifications of existing compounds; (2) stage of development, including discovery, preclinical, clinical phases I–III, regulatory review, and market approval; (3) therapeutic area of focus; and (4) for finished dosage forms (FDs) and finished medicines (FMs), their market registration status with major regulatory bodies such as the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and China's National Medical Products Administration (NMPA).

Regulatory Analysis Framework

Regulatory systems were reviewed with respect to the following dimensions: organizational structure and capacity; approval processes and timelines; participation in international harmonisation initiatives; implementation of risk-based assessments; use of reliance mechanisms and recognition agreements; and post-market surveillance practices.

Data Analysis Methods

The quantitative analysis included descriptive statistics on pipeline characteristics, regulatory timelines, and clinical trial distribution. Differences between countries and temporal trends were assessed using comparative analyses. The qualitative component involved thematic coding of policy and regulatory frameworks to identify similarities and differences, highlight best practices, explore opportunities for harmonisation, and examine common challenges.

Quality Assurance and Limitations

The quality of the data was ensured by cross-checking official regulatory databases and triangulating findings across multiple sources. Limitations include potential variation in reporting standards across countries, differences in data availability and transparency—particularly between PHEIC-related regimens or therapies and those outside that scope—and the rapidly evolving regulatory environment. It should be noted that

Table 3: Innovation Pipeline Distribution

Development Stage	Number of Candidates	Percentage	Key Characteristics
Discovery/Preclinical	252	67%	Strong early-stage research activity
Phase I Clinical	56	15%	Increasing clinical development
Phase II Clinical	45	12%	Advanced development programmes
Phase III Clinical	30	8%	Late-stage development
Market Approved	11	3%	Global market success
Total Novel Entities	226	60%	Genuine innovation focus
Known Compound Extensions	150	40%	Incremental improvements

the analysis is based on conditions as of the end of 2024 and therefore may not reflect the most recent policy changes or market developments.

Results and discussion

Innovation Pipeline Characteristics

Our study of 66 biopharmaceutical firms across Brazil, China, India, and South Africa identified a vibrant innovation landscape, with 376 drug candidates and vaccines in the pipeline. Of these, 60% (226) were classified as new chemical and molecular entities—including both small-molecule drugs (NCEs) and biologics developed as global firsts or for novel indications—while the remaining 40% (150) were modifications or extensions of existing compounds. This distribution reflects a shift beyond traditional generic manufacturing toward a more innovation-driven approach that encompasses both chemical and biologic product development. Analysis by development stage revealed that more than two-thirds of candidates (252; 67%) remain in the preclinical or discovery phases—reflecting both strong early-stage research activity and the ongoing challenge of advancing projects into later development stages. Representation in clinical development was highly variable: 15% of candidates were in Phase I trials (56 candidates), while 12% and 8% were in Phase II and Phase III trials, respectively (45 and 30 candidates). Only a small proportion (3%, or 11 drugs) reached the U.S. market, underscoring the significant barriers to achieving global marketing approval.

Country-Specific Innovation Patterns

China showed the strongest innovation trend, with 46 drugs approved by the National Medical Products Administration (NMPA) in 2024—marking a new high in national pharmaceutical innovation (National Medical Products Administration, 2024). Of these, 39 were developed domestically, reflecting an 85% domestic innovation rate. Oncology dominated the therapeutic focus, accounting for 50% of approvals (23 drugs), followed by gastrointestinal and metabolic drugs at 13% (6 drugs).

The NMPA has implemented extensive regulatory reforms, including the introduction of fast-track mechanisms. Notably, review times for certain innovative treatments were reduced to 21 days under specific pilot programmes. These timelines reflect exceptional cases and should not be viewed as equivalent to standard review durations in other jurisdictions (China FDA Approval Monitor, 2024).

India (n = 26) represented the largest number of companies included in our analysis, and its biopharmaceutical industry reported particular strength, accounting for 49% of its $151 billion biopharmaceutical output value (Salter et al., 2007). Indian firms demonstrated strong performance in vaccine development and biosimilars production. Many Indian companies have successfully obtained U.S. FDA approvals for products marketed globally.

Brazil accounted for 19 companies in our study, demonstrating particular strengths in infectious

disease research and applications related to tropical medicine. Brazilian firms have benefited from strong links with academic institutions and government agencies—particularly through organisations like Bio-Mangino's—to develop products tailored to domestic health needs. The national regulator, ANVISA, has undertaken modernisation efforts, including the implementation of the electronic Common Technical Document (eCTD) and participation in ICH harmonisation initiatives (Brazilian Health Regulatory Agency, 2024).

Seventeen South African companies were included in the analysis, reflecting relatively limited local pharmaceutical manufacturing capacity compared to other BRICS nations. While South African firms have shown strong performance in HIV/AIDS research and vaccine development—key national health priorities—they appeared less active in other therapeutic areas. The transition from the Medicines Control Council (MCC) to the South African Health Products Regulatory Authority (SAHPRA) represents an ongoing effort to reform outdated regulatory systems and reduce approval timelines (South African Health Products Regulatory Authority, 2024).

Regulatory Environment Assessment

Regulatory timelines varied significantly across the four countries, reflecting differences in their systems and institutional capacities. The most notable progress has been made by China's National Medical Products Administration (NMPA), where pilot programmes have reduced review times to as little as 21 days for innovative products, largely due to enhanced collaboration between evaluation authorities and sponsors (RegASK, 2024). Brazil's ANVISA currently takes between 10 and 14 months to approve new drugs—a notable improvement over previous years, although still slower than leading global regulators (Artixio, 2025).

India's Central Drugs Standard Control Organisation (CDSCO) reports highly variable approval timelines, which depend on the drug category and regulatory complexity. Ongoing reforms aim to improve predictability and efficiency (Central Drugs Standard Control Organisation, 2024). South Africa has historically experienced the longest delays, with approval times often exceeding four years; however, the South African Health Products Regulatory Authority (SAHPRA) is actively working to address these issues through the introduction of risk-based assessments and backlog elimination strategies (Keyter et al., 2018).

Clinical Trial Landscape Evolution

Between 2018 and 2022, clinical trial trends in the G7 and BRICS nations showed a striking convergence. The gap in total clinical trial numbers between the two blocs narrowed significantly, with the difference in MAX priority trials decreasing by 68.6%—from 12,199 in 2018 to 3,834 in 2022 (Manoharan et al., 2023). China emerged as a key driver of this shift, now leading the world in clinical trial registrations and surpassing even the United States in total volume.

Oncology was the most prominent therapeutic area for clinical trials in BRICS nations, aligning with both the global disease burden and the growing capacity of these countries to support cancer research. Most clinical trial interventions were drug trials (60%), followed by vaccine trials (15%) and other interventions such as biologics and medical devices (25%). Approximately 40% of all registered trials were sponsor-funded, indicating strong investment from international pharmaceutical companies in the BRICS region.

Regulatory Modernization Initiatives

All four countries introduced major regulatory reforms during the study period. China's National Medical Products Administration (NMPA) overhauled its regulatory system by implementing priority review pathways, conditional approval processes, and breakthrough therapy designations—resulting in 18 products (39% of all approvals in 2024) being granted fast-track status (Wu et al., 2025). Brazil's ANVISA became a member of the International Council for Harmonisation (ICH) in 2016 and has since adopted electronic submission systems to support its risk-based inspection programmes (Brazilian Health Regulatory Agency, 2024).

India's Central Drugs Standard Control

Organisation (CDSCO) has streamlined clinical trial oversight and introduced fast-track pathways for orphan drugs and novel therapies (Central Drugs Standard Control Organisation, 2019). South Africa's SAHPRA has implemented a formal quality management system, electronic document management, and risk-based evaluation within its regulatory framework (South African Health Products Regulatory Authority, 2024).

Barriers and Challenges

Although there has been considerable improvement, barriers are common across all four countries. Resource constraints limit regulatory capacity because too few trained reviewers and outdated infrastructure reduce review efficiency. A spectrum of increasingly complex and unstable regulatory environments continues to challenge industries in planning future investments. Variability in intellectual property enforcement across countries significantly affects innovation incentives and the potential for international collaboration. Additionally, local language requirements in jurisdictions such as South Africa, China, and Brazil may impose further administrative burdens on global pharmaceutical companies. Infrastructure limitations are further exacerbated when supporting advanced biopharmaceutical applications and clinical development activities. Concerns around quality control, corruption, and population vulnerability present significant barriers for international pharmaceutical companies considering investment in certain markets. Furthermore, limited regional harmonisation mechanisms restrict the potential efficiency gains that could be achieved through greater regulatory coordination.

Success Factors and Enablers

Regulatory and innovation successes across the study countries can be attributed to several key factors. Strong government support—through targeted funding programmes, fiscal incentives, and strategic planning initiatives—emerged as a critical enabler. A focus on local health needs and population-specific therapeutic demands has helped identify the most effective product development and market access strategies. Public–private collaboration models have facilitated knowledge transfer, shared risk, and capacity building.

International collaboration—such as participation in the International Council for Harmonisation (ICH), bilateral recognition agreements, and strategic partnerships with global pharmaceutical firms—has further enabled access to technology, expertise, and international markets, significantly advancing the development of local capabilities.

Discussion

Innovation Ecosystem Evolution

As the BRICS nations shift from manufacturing-based roles to becoming sources of innovation, the global pharmaceutical landscape is undergoing a major transformation. Our study demonstrates that these countries are emerging as genuine innovators, moving beyond reverse engineering and replication. With 60% of candidate compounds in the pipeline classified as novel, BRICS countries are positioning themselves as strong contenders in global innovation competitiveness.

However, the relatively low success rates and high attrition of candidates highlight persistent challenges in translating early-stage research into market-ready products. This trend underscores the need for continued government focus on regulatory reform, improved market access, and support for late-stage development—even as significant progress is being made in early-stage research and discovery.

Regulatory Convergence and Harmonisation

The substantial narrowing of the clinical trial gap between BRICS and G7 countries—a 69% reduction—reflects evolving regulatory frameworks, improvements in national evaluation procedures, and growing international confidence in the research capabilities of emerging economies. China's emergence as the global leader in clinical trial registrations exemplifies how swiftly a regulatory landscape can advance when supported

by targeted policy attention and sustained resource allocation.

The broad disparity in approval timelines—from China's 21-day pilot reviews to the protracted four-year delays historically experienced in South Africa—highlights systemic inefficiencies and the urgent need to strengthen regulatory capacity. The positive outcomes associated with China's NMPA reforms should serve as a model for other emerging markets, reinforcing the importance of regulatory modernisation and digital integration. Without the consistent dissemination of regulatory standards and safety protocols, no framework can align fully with international expectations.

Policy Framework Implications

The evolution of intellectual property (IP) regimes among BRICS nations highlights the ongoing tension between incentivising innovation and ensuring equitable access. India and Brazil's earlier reliance on more flexible patent systems facilitated the growth of strong generic industries, which later laid the foundation for their emerging innovative capabilities. However, as these countries shift towards stronger IP protection to support innovation, new challenges arise regarding maintaining affordability and access while continuing to stimulate research and development.

Public–private partnership (PPP) models have proven effective across all four countries, demonstrating the potential of collaborative approaches to address resource limitations and build sustainable innovation ecosystems. Examples include Bio-Manguinhos in Brazil, India's biopharmaceutical clusters, China's national innovation programmes, and disease-specific research initiatives in South Africa—all representing distinct but successful models for leveraging public resources to advance pharmaceutical innovation.

Global Health Impact and Access

BRICS nations have prioritised pharmaceutical innovation in disease areas of local relevance—such as cancer, infectious diseases, and metabolic disorders—aligning both with global health priorities and national disease burdens. However, the concentration of successful global approvals among established multinational companies underscores the persistent challenges that firms from emerging economies face in accessing high-income pharmaceutical markets.

The initiative by the BRICS Working Group on Pharmaceutical Markets to develop harmonised, not-for-profit requirements for biosimilars presents a valuable opportunity to enhance regional integration, improve access to biological medicines, and stimulate regional market development. This model could serve as a foundation for broader harmonisation efforts that balance the dual objectives of fostering innovation and expanding equitable access.

Regulatory Capacity and Resource Challenges

Despite significant modernisation efforts, resource limitations remain a major challenge across all BRICS regulatory systems. The reliance on third-party evaluators in some jurisdictions, along with persistent application backlogs, underscores the ongoing need for investment in regulatory infrastructure and capacity-building initiatives.

International Collaboration and Competition

The increasing engagement of BRICS countries (Brazil, Russia, India, China, and South Africa) in international harmonisation efforts—including their participation in the International Council for Harmonisation (ICH) and the signing of memoranda of understanding (MOUs)—demonstrates growing state-level attention to global pharmaceutical governance. However, geopolitical tensions and trade-related uncertainties may pose challenges to future cooperation and sustained market access.

The rise of pharmaceutical innovation within the BRICS also signals a shift in global market dynamics. These countries must navigate a complex landscape that requires balancing collaboration and competition—as both suppliers and consumers. As a result, transnational pharmaceutical companies

(TPCs) will need to develop nuanced strategies to engage effectively with these emerging economic players, who may simultaneously act as partners, buyers, and competitors.

Future Opportunities and Risks

The COVID-19 pandemic highlighted the potential and capability of pharmaceutical markets in BRICS countries. India and China were among the first to develop vaccines—providing a rare test of their crisis response capacity. However, the pandemic also exposed key weaknesses, including fragile supply chains and the regulatory hurdles associated with rapid mobilisation. Regional health networks (RHNs) will play a critical role in strengthening preparedness and response to future health crises.

In addition to aligning with disease burden, BRICS nations are likely to be better positioned to respond to emerging epidemiological challenges driven by climate change, demographic transitions, and novel disease patterns requiring innovative treatments. Realising this potential, however, will require increased investment in regulatory infrastructure, enhanced international collaboration, and the establishment of sustainable financing mechanisms.

Conclusion

Our findings highlight clear progress: 376 drug and vaccine candidates were identified across 66 firms, with 60% representing novel entities. Regulatory agencies in all four countries have introduced modernization initiatives, with varying timelines and degrees of harmonisation. Notably, China has implemented pilot fast-track reviews, and South Africa has taken steps to reduce historical backlogs.

Despite this momentum, key barriers remain. Fragmented regulatory systems, capacity limitations, and inconsistent recognition frameworks continue to hinder efficient market access and regional alignment.

Policy Implications

To maximise innovation and patient access, coordinated efforts are essential. Policymakers should:

- Strengthen regulatory harmonisation through mutual recognition and shared standards.
- Invest in regulatory capacity building and workforce development.
- Expand public–private partnerships to support late-stage development.
- Align innovation incentives with access goals through flexible IP and pricing mechanisms.

Future Outlook

Continued monitoring of policy outcomes, regulatory timelines, and access indicators will be critical. Collaborative models and harmonized frameworks can drive both innovation and equity, positioning BRICS nations as influential contributors to global pharmaceutical progress.

Authors contributions

All authors contributed to study design, data collection, analysis, and manuscript preparation. All authors read and approved the final manuscript

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Ethical approval statement

Not applicable. This study involved analysis of publicly available data and did not involve human participants or require ethics approval.

Conflict of interest

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Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this manuscript, generative AI tools were used solely to improve the readability and language. After using these tools, the authors carefully reviewed, edited, and revised the content as required. The authors take full responsibility for the content of the publication.

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