February 2026, Vol. 12, No. 1
ISSN 2163-758X

The Great Drug Regulation Divide: How Resource Imbalance Is Strangling Global Health Equity

Wenhan Jiao, Wanyu Zhang, and Shanshan Kang

China Pharmaceutical University, Nanjing, China

Abstract

This study investigates the global disparity in the allocation of pharmaceutical regulatory resources, focusing on the significant gap between high-income and low-income countries in terms of regulatory capacity, drug quality, safety, and accessibility. It highlights how differences in resources directly impact the ability of low-income countries to ensure the safety and availability of medicines, with high-income countries benefiting from more robust regulatory systems. The research utilizes a mixed-methods approach, combining quantitative data analysis of regulatory budgets and staffing levels, alongside qualitative case studies of countries with data gaps, such as Haiti and Papua New Guinea. The study also includes a detailed case analysis of China—the world's second-largest pharmaceutical market—to explore how regulatory capacity differences manifest within a large, middle-to-high-income economy. The findings reveal that the regulatory divide not only constitutes a technical challenge but also represents a fundamental issue of global health equity and public health security. To address this divide, the study proposes solutions including strengthening international cooperation, enhancing regulatory capacity in low-income countries, and implementing digital tools to improve regulatory efficiency. The study concludes with policy recommendations and identifies future research avenues, emphasizing the need for standardized data collection, cross-country comparisons, and the development of regulatory frameworks that suit the unique needs of different countries.

Keywords: drug regulation, China, country income levels, pharmaceutical industry,

Introduction

As a special commodity, pharmaceuticals are directly related to human health and life. Effective drug regulation, a cornerstone of modern health systems, plays a core role as a gatekeeper for global public health. Its critical importance is manifested in several key areas. First, by implementing rigorous review, approval, inspection, and post-market surveillance, regulatory authorities ensure that medicines entering the market are safe, effective, and of controlled quality—a fundamental prerequisite for ensuring public medication safety (Ratanawijitrasin & Wondemagegnehu, 2002). Second, a robust

February 2026, Vol. 12, No. 1
ISSN 2163-758X

regulatory system can foster pharmaceutical innovation by providing a clear and predictable pathway to market for new drugs of genuine clinical value while eliminating ineffective or high-risk products, thereby optimizing the allocation of healthcare resources (Kaplan & Laing, 2005). Furthermore, authoritative regulation effectively combats the production and circulation of substandard and falsified (SF) medicines, safeguarding the integrity of the pharmaceutical market and public trust in the healthcare system (WHO, 2017). In an era of globalization, where drug research, development, production, and supply chains are increasingly international, a regulatory failure in any single country or region can pose a potential threat to global public health. Consequently, a strong, science-based, and independent drug regulatory system is not merely an expression of national sovereignty but also an indispensable contribution to global health security.

Despite the critical importance of effective drug regulation, a significant "regulatory divide" exists globally. This gap is most pronounced between high-income countries and low- and middle-income countries (LMICs) (Roth et al., 2018). On one hand, regulatory agencies in developed nations—such as the United States Food and Drug Administration (FDA), the European Medicines Agency (EMA), and Japan's Pharmaceuticals and Medical Devices Agency (PMDA)—possess mature legal frameworks, sufficient financial resources, abundant professional expertise, and advanced information systems. These capabilities enable them to implement stringent oversight across the entire lifecycle of a pharmaceutical product, from development to post-market surveillance.

On the other hand, the National Regulatory Authorities (NRAs) in many LMICs, particularly in sub-Saharan Africa and parts of Southeast Asia, perennially face a multitude of challenges. These include scarce resources, weak technical capacity, personnel shortages, inadequate legal and regulatory frameworks, and deficient governance structures (Franzen et al., 2017; Ndomondo-Sigonda & Ambali, 2011). Furthermore, for many of the least-resourced NRAs, a systematic absence of critical data—such as separately reported budgets and precise staffing numbers—is observed. This lack of transparency and systemic data gaps is itself a finding that reflects institutional fragility and systemic inequity. This profound disparity in regulatory capacity directly contributes to severe global health inequities.

The negative consequences of this divide are threefold. First, regions with weak regulatory oversight have become epicenters for substandard and falsified medicines. The World Health Organization (WHO) estimates that approximately one in ten medical products in LMICs is substandard or falsified, leading not only to treatment failure and increased antimicrobial resistance but also to a substantial number of patient deaths (WHO, 2017). Second, the divide delays access to innovative medicines and high-quality

February 2026, Vol. 12, No. 1
ISSN 2163-758X

generic drugs in these nations. The absence of efficient review capacities and registration pathways prevents many essential, life-saving treatments from being timely introduced to local markets, depriving patients of therapeutic opportunities available in high-income countries (Ahonkhai et al., 2016; Ahonkhai et al., 2016). Third, it undermines the collective global response to public health emergencies, such as the COVID-19 pandemic. During the crisis, disparities in regulatory capacity led to inequalities in the approval, distribution, and quality monitoring of vaccines and therapeutics, exacerbating the global health crisis .

In summary, the global regulatory divide is not merely a technical or resource-allocation issue; it is a profound problem of global health equity. It infringes upon the fundamental right of the most vulnerable populations to access safe and effective medicines and impedes the achievement of the United Nations' Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all at all ages). Therefore, a thorough analysis of the causes, current state, and impact of this divide, along with the exploration of effective strategies to bridge it, holds significant theoretical value and practical importance.

Methodology

This study adopts a mixed-methods approach to analyze the imbalance in global pharmaceutical regulatory resource allocation and its impact on public health. The data used in this study are primarily derived from publicly available government reports, documents published by international organizations, and macroeconomic data from the World Bank and the International Monetary Fund, ensuring the reliability and international comparability of the research.

The study utilizes multiple data sources. First, the study collects data on the annual budgets and staffing of national regulatory authorities (NRAs) across different countries, specifically focusing on "total expenditure" or "program-level budgets" disclosed in the official reports of these regulatory agencies, along with the funding structure (e.g., government appropriations, user fees). Additionally, the study uses the World Health Organization's (WHO) Global Benchmarking Tool (GBT) reports to ensure consistency and comparability in evaluation standards.

Two core indicators are selected to measure the regulatory resource allocation of national pharmaceutical authorities: annual budget and full-time equivalent (FTE) staff numbers. To account for population size differences across countries, this study employs the standardized indicator of "regulatory personnel per one million population." This approach allows for a fair comparison across countries, especially when the disparity in regulatory resources is substantial.

February 2026, Vol. 12, No. 1
ISSN 2163-758X

For countries with missing data (e.g., Haiti and Papua New Guinea), this study follows the principle of "evidence first, conservative estimation." In cases of "data unavailable" or "budget not separately reported," the study treats these as significant findings and further analyzes the underlying systemic causes behind the missing data.

In addition to quantitative data analysis, the study incorporates qualitative analysis, particularly in exploring the institutional differences in pharmaceutical regulatory systems across countries of varying income levels. Through literature review and case studies, the research delves into the root causes of global pharmaceutical regulatory imbalances, including the disparities in regulatory capacity, legal frameworks, technological infrastructure, and staffing between high-income and low- and middle-income countries.

This study adopts the World Bank's income classification system, categorizing countries into four groups: high-income, upper-middle-income, lower-middle-income, and low-income. The study then analyzes the allocation of pharmaceutical regulatory resources in each group and evaluates the potential impact of these disparities on public health.

The safety of global pharmaceutical and medical products is highly dependent on the functional capacity of National Regulatory Authorities (NRAs). Globally, however, the capacity of these institutions exhibits a distinct and unbalanced pyramidal structure. At the apex of this pyramid are a small number of mature, well-resourced regulatory agencies. In contrast, the broad base is composed of a vast majority of authorities whose capacities are still at a foundational or developing stage, a reality that directly impacts medication safety for billions of people worldwide.

The WHO Global Benchmarking Tool (GBT) and Maturity Level Criteria

To scientifically evaluate the effectiveness and maturity of national regulatory systems, the World Health Organization (WHO) developed the Global Benchmarking Tool (GBT), the internationally recognized gold standard for assessment. Through a systematic evaluation of core regulatory functions, the GBT classifies a regulatory system into four Maturity Levels (ML), defined as follows (World Health Organization, 2021):

ML1 (Foundational Level): Some elements of a regulatory system exist.

ML2 (Developing Level): An evolving regulatory system that is not yet fully functioning or integrated.

ML3 (Stable, Well-Functioning, and Integrated Level): A stable, well-functioning, and integrated regulatory system is in place.For example, the World Health Organization

February 2026, Vol. 12, No. 1
ISSN 2163-758X

(WHO) has recognized China's vaccine regulatory authority as meeting Maturity Level 3 (ML3), positioning it as a capable regional regulatory authority(WHO, 2014).

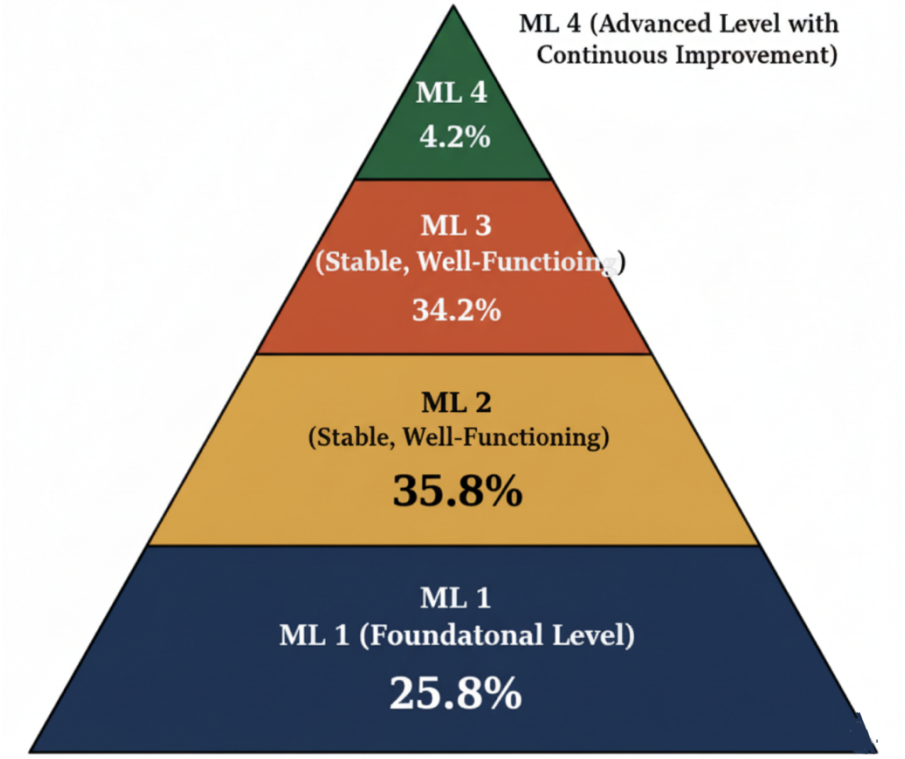
ML4 (Advanced Level with Continuous Improvement): The regulatory system is operating at an advanced level of performance and is continuously improving.

A national or regional regulatory authority must achieve at least ML3 to be considered capable of reliably ensuring the quality, safety, and efficacy of medical products in its market (World Health Organization, 2021).

The Current State of Global Regulatory Maturity Distribution

Periodic assessment reports from the WHO reveal the true landscape of global regulatory capacity. According to the most recent report submitted to the 77th World Health Assembly in May 2024, the distribution of capabilities among the 120 national drug regulatory authorities that had undergone a formal evaluation shows a pronounced bottom-heavy, top-narrow structure (World Health Organization, 2024).

Figure 1:
Distribution of Global NRA Maturity Levels



February 2026, Vol. 12, No. 1
ISSN 2163-758X

Analysis and Impact: The Public Health Crisis Behind the Data

The pyramidal structure revealed by these data is not merely a statistical representation; it is directly linked to global public health risks.

First, weak regulatory capacity is a direct cause of the proliferation of Substandard and Falsified (SF) medical products. In a seminal 2017 study, the WHO reported that approximately one in ten medical products in low- and middle-income countries is either substandard or falsified (World Health Organization, 2017). When a country's NRA is at ML1 or ML2, it often lacks the capacity to conduct effective market surveillance and product testing, creating opportunities for illicit actors to manufacture and distribute SF medicines.

Second, NRAs at the developing stage exhibit common deficiencies in critical regulatory functions. A 2018 study published in BMJ Global Health that assessed the regulatory capacity of 27 African nations found that, despite progress, significant gaps remained in several core areas, including clinical trial oversight, safety monitoring (pharmacovigilance), and post-market control (Roth et al., 2018). Many agencies lack the necessary processes, specialized personnel, and technical tools to effectively track adverse drug reactions after a product is marketed. This means potential safety risks cannot be promptly identified and addressed (Roth et al., 2018). Such functional deficits can render even authentic medicines harmful due to unmonitored risks.

Finally, achieving a mature level (ML3/ML4) is not only a reflection of technical competence but also a prerequisite for participating in global cooperation and ensuring a nation's population has access to advanced therapies. Regional international bodies, such as the Pan American Health Organization (PAHO), stipulate that a high maturity level is a precondition for an NRA to be designated as a "National Regulatory Authority of Regional Reference" (NRAr) (Pan American Health Organization, 2021). Only by meeting this standard can an authority's review decisions and inspection reports form the basis for regional or international recognition, thereby accelerating the market entry of new drugs, vaccines, and advanced medical technologies through "Reliance Pathways" (Pan American Health Organization, 2021). Conversely, NRAs that remain at the ML1/ML2 level cannot earn international trust for their review capacity, leading to longer waiting times and greater uncertainty for their citizens in accessing life-saving, innovative medicines from the global pipeline.

February 2026, Vol. 12, No. 1
ISSN 2163-758X

Comparative Analysis of Regulatory Resources by Income Level

To ensure objectivity and consistency in comparison, this report adopts the World Bank's FY2025 income classification standard, which divides global economies into four categories: High Income, Upper-Middle Income, Lower-Middle Income, and Low Income. In this study, two core indicators are selected to measure the regulatory resources of national pharmaceutical authorities: Annual Budget and Regulatory Personnel (FTE). The annual budget is primarily drawn from the "total annual expenditure" or "program-level budget" disclosed in regulatory agencies' official annual reports, with, whenever possible, details on the funding structure (e.g., government appropriations, user fees). Regulatory personnel are measured using the number of full-time equivalents (FTEs) reported in official annual or audit reports. To account for differences in population size across countries, this study employs the standardized indicator of "regulatory personnel per one million population." For countries with missing data (e.g., Haiti and Papua New Guinea), this study adheres to the principle of "evidence first, conservative estimation." Cases of "data unavailable" or "budget not separately reported" are treated as findings in themselves and are further analyzed for the underlying systemic causes.

Haiti and Papua New Guinea were selected not because they are the sole countries lacking data, but because they represent distinct, severe examples where the absence of quantitative metrics (budget and FTE staff) serves as a clear signal of underlying systemic weakness. Haiti epitomizes "institutional presence without functional capacity," where political instability and extreme resource scarcity prevent the agency from executing its mandate effectively. Papua New Guinea is illustrative of "institutional subordination," where regulatory functions are subsumed within the National Department of Health, with no budget transparency or institutional independence . Analyzing these two cases allows us to interpret the data gap itself as evidence of fragile governance and a fundamental crisis of capacity.

High-Income Countries

The United States Food and Drug Administration (FDA) represents the benchmark among high-income countries. In fiscal year 2023, the FDA's budget reached USD 8.4 billion, with more than 18,000 full-time employees. Standardized by population, this translates into approximately 54 regulatory staff per million people—arguably the global "ceiling" of regulatory resource allocation. Such abundant resources not only ensure comprehensive coverage of the large domestic market but also enable the FDA to set and influence global regulatory science standards. Furthermore, the significant share of user fees in its budget

February 2026, Vol. 12, No. 1
ISSN 2163-758X

reflects a mature “government–industry” funding model.

The European Medicines Agency (EMA) provides a contrasting example. Unlike a centralized “super NRA,” the EMA operates as a regional coordinating platform, with 982 employees in 2023. Its primary mandate lies in coordinating centralized review procedures and offering scientific guidance, while actual enforcement remains the responsibility of member states’ national competent authorities (NCAs). This illustrates two different modes of resource allocation in high-income contexts: the centralized national model represented by the FDA, and the distributed regional network model of the European Union. Although the latter is more fragmented, the combined resources of the EMA and national agencies also constitute a substantial investment in regulatory oversight.

Upper-Middle-Income Countries

Brazil’s National Health Surveillance Agency (ANVISA) exemplifies this category. In 2022, its budget amounted to approximately 2.7 billion Brazilian reais, with a workforce of around 2,000 staff. ANVISA’s centralized oversight spans multiple sectors—including pharmaceuticals, medical devices, food, and cosmetics—while its financing combines government appropriations and user fees. This reflects an effort by upper-middle-income countries to build comprehensive and independent regulatory systems capable of supporting their expanding pharmaceutical markets.

Turkey’s Medicines and Medical Devices Agency (TİTCK) had 961 employees at the end of 2023. Although smaller in size than ANVISA, TİTCK has actively aligned its regulatory practices with international standards, particularly in the field of clinical trial approvals. This demonstrates a “catch-up” trajectory, highlighting the ambition of upper-middle-income countries to modernize their systems rapidly.

Lower-Middle-Income Countries

The Food and Drugs Authority (FDA) of Ghana reported a budget in the range of several million USD in its 2020 annual report, with a staff size in the hundreds. Compared with high-income countries, this represents a stark quantitative gap. Despite limited resources, Ghana’s FDA has sought to expand organizational capacity and strengthen laboratory testing. Nevertheless, its staff density remains low after population standardization, directly constraining its regulatory reach and effectiveness.

Papua New Guinea (PNG) illustrates additional systemic weaknesses. Its regulatory

February 2026, Vol. 12, No. 1
ISSN 2163-758X

functions are embedded within the National Department of Health (NDoH), and no separate budget line is disclosed in the national accounts. This lack of transparency and institutional independence is itself symptomatic of fragile regulatory capacity. PNG's case highlights how the absence of data is itself a finding: opaque budgetary structures and institutional subordination are both causes and consequences of weak regulatory systems.

Low-Income Countries

The Rwanda FDA reported a budget of 4.16 billion Rwandan francs (equivalent to several million USD) in fiscal year 2020/21, with a budget execution rate of 96%. This example demonstrates that even in low-income contexts, it is possible to establish an independent agency with a formal budget. Nevertheless, the absolute volume of resources remains extremely limited, restricting the agency to core functions such as registration and approvals, while leaving little capacity for broader market surveillance or pharmacovigilance.

Haiti's Directorate of Pharmacy and Medicines/Medical Technology (DPM/MT) presents a more extreme case. While an agency formally exists within the Ministry of Health, no comparable data on budget or staffing are available. Information on its operations is instead derived largely from international organizations such as the Pan American Health Organization (PAHO). Haiti epitomizes an "institutional presence without functional capacity": although the agency exists in name, political instability and severe resource scarcity prevent it from carrying out its regulatory mandate effectively. In such cases, "data not available" must be explicitly reported as "not comparable," with institutional evidence used as a substitute for quantitative indicators.

Key Data Comparison

Income Group	Representative Country / Region	Agency	Year	Budget (Approx.)	Staff (Approx.)	Per Capita Staffing (per million people)	Data Source / Notes
High-	United States	FDA	FY2023	USD 8.4	18,000	~54	Official Budget Summary

February 2026, Vol. 12, No. 1
ISSN 2163-758X

Income Group	Representative Country / Region	Agency	Year	Budget (Approx.)	Staff (Approx.)	Per Capita Staffing (per million people)	Data Source / Notes
Income				billion			
High-Income	European Union (Coordination Level)	EMA	2023	See Annual Report	982	N/A	EMA Annual Report (Not a national-level agency, not comparable)
Upper-Middle Income	Brazil	ANVISA	2022	BRL 2.7 billion	~2,000	~9.4	ANVISA Annual Report
Upper-Middle Income	Turkey	TİTCK	2023	Not uniformly disclosed	961	~11.2	Official Activity Report
Lower-Middle Income	Ghana	FDA	2020	Millions of USD	Hundreds	Low	FDA Ghana Annual Report
Lower-Middle Income	Papua New Guinea	NDoH	-	Budget not listed separately	Unknown	N/A	National Budget Volumes (Systemic absence)
Low-Income	Rwanda	FDA	FY20/21	RWF 4.16 billion	Unknown	Low	Rwanda FDA Annual Report
Low-Income	Haiti	DPM/MT	-	Data unavailable	Unknown	N/A	PAHO/GHS Index (Systemic absence)

February 2026, Vol. 12, No. 1
ISSN 2163-758X

There is a gap of several orders of magnitude, from the "billion-dollar club" in high-income countries to the "million-dollar survival line" in low-income nations; the disparity in budget and personnel can be a hundredfold or even a thousandfold. This also reflects the value of transparency; whether a budget is listed separately and whether an annual report is publicly available are key indicators for measuring the maturity of a country's regulatory system. The data gap itself is a "soft underbelly" that limits the precision and effectiveness of international aid.

Policy differences severely impact the data retrieval for this report[13]. Therefore, it is recommended to promote the establishment of a simplified, internationally accepted template for NRA annual reports to encourage countries (especially low- and middle-income countries) to enhance transparency. The international community should prioritize "regulatory system strengthening" as a key area of public health assistance, with a focus on supporting human resource training and the construction of quality control infrastructure.

A direct and profound positive correlation exists between a nation's income level and its investment in pharmaceutical regulatory resources. This vast disparity in resource allocation directly affects the stability of the global pharmaceutical safety net. Bridging this gap requires not only the internal efforts of low- and middle-income countries but also a global collaborative framework to support the development of transparent, effective, and sustainable regulatory capacity.

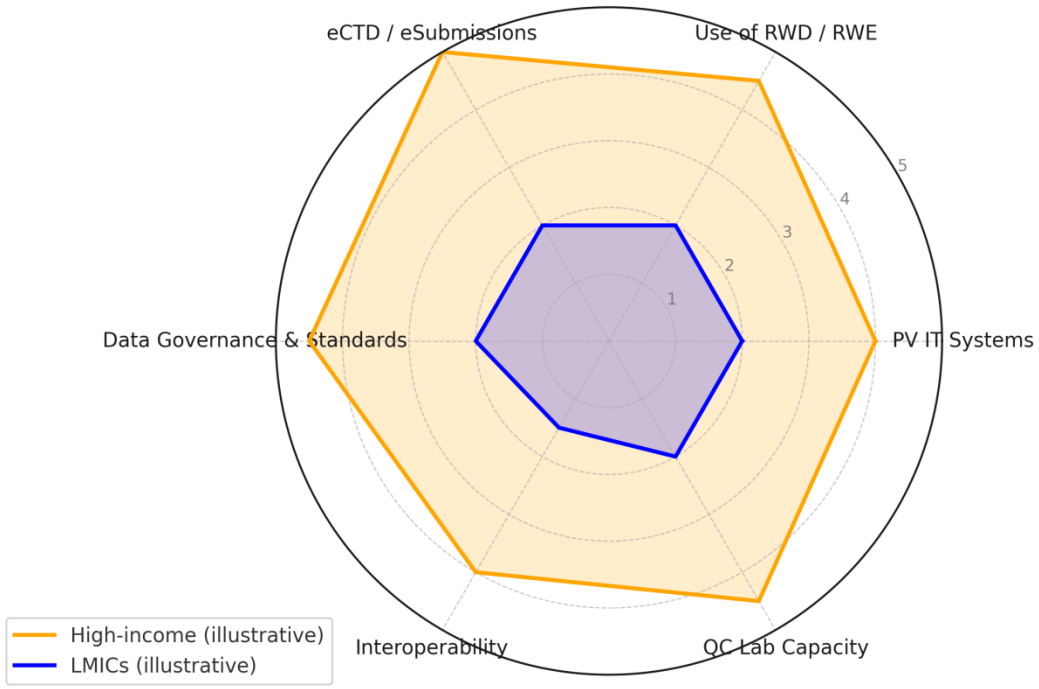
In the field of pharmaceutical regulation, generational differences in technological tools and infrastructure also constitute a major factor shaping the regulatory capacity of different countries. High-income economies generally adopt the internationally recognized electronic common technical document (eCTD) standard, enabling highly integrated electronic submission systems that facilitate cross-departmental and cross-agency data sharing and coordinated review. At the same time, these countries actively employ advanced tools such as real-world data (RWD) and real-world evidence (RWE) to support indication expansion, post-marketing reassessment, and risk management decision-making. For example, the U.S. Food and Drug Administration (FDA) has developed the Sentinel system, and the European Medicines Agency (EMA) has established the DARWIN EU platform, both of which strengthen the real-time and scientific basis of regulatory oversight throughout the entire life cycle of medicines.

By contrast, many low- and middle-income countries (LMICs) still rely on paper-based submissions, and their application documents often lack standardized formats. This results in inefficient reviews and delayed information transmission. Moreover, deficiencies

February 2026, Vol. 12, No. 1
ISSN 2163-758X

in laboratory quality control infrastructure significantly constrain their capacity for product testing, making it difficult to promptly detect and address market risks. In some countries, regulatory information systems remain underdeveloped, with data confined to paper records or fragmented Excel spreadsheets. Such limitations hinder the establishment of effective risk-warning mechanisms and evidence-based decision support.

To more clearly illustrate this disparity, the following “Tech & Infrastructure Readiness (Illustrative) for High-Income vs LMICs.” radar chart provides an explanatory assessment of regulatory capacity across six key dimensions, comparing high-income countries with LMICs.



Tech & Infrastructure Readiness (Illustrative) for High-Income vs LMICs.

Note. RWD = Real World Data; RWE = Real World Evidence; eCTD = electronic Common Technical Document; PV = Pharmacovigilance. Scores are illustrative (1–5 scale).

This figure evaluates six core competency domains: the application of real-world data and evidence (RWD/RWE), electronic common technical document and electronic submissions (eCTD/e-Submissions), data governance and standards, system

February 2026, Vol. 12, No. 1
ISSN 2163-758X

interoperability, quality control laboratory capacity (QC Lab Capacity), and pharmacovigilance information technology systems (PV IT Systems).

The figure clearly demonstrates that high-income countries (orange line) consistently achieve higher levels of maturity across all six dimensions, with scores approaching 4–5. This forms a full and outwardly expanded polygon, representing a comprehensive and robust technological and infrastructural system. By contrast, low- and middle-income countries (blue line) generally score lower, concentrated in the 2–3 range. Their polygon is visibly smaller and contracted, highlighting significant weaknesses across key domains. The most pronounced disparities occur in the application of RWD/RWE and electronic submissions (eCTD), which directly correspond to the previously noted reality that high-income countries have widely adopted RWE while LMICs continue to rely on paper-based submissions. Additionally, the low scores of LMICs in quality control laboratory capacity and system interoperability confirm their fragile infrastructure and the prevalence of data silos.

This technology- and infrastructure-based "digital divide" has dual implications. On the one hand, it delays the accessibility of innovative medicines in low- and middle-income countries. On the other, it creates risk exposures that facilitate the circulation of falsified and substandard medicines in the global market. Therefore, international capacity-building and aid initiatives should precisely target narrowing this divide. Policy priorities should include supporting LMICs in developing unified electronic submission platforms, strengthening the hardware and personnel capacities of quality control laboratories, and promoting the standardization and interoperability of regulatory information systems. Only through such targeted measures can the overall effectiveness and equity of the global pharmaceutical regulatory system be systematically enhanced.

The imbalance of regulatory resources is not merely a technical issue but also a critical challenge for the global public health system. Insufficient regulatory resources directly affect drug review and approval, post-marketing surveillance, and market inspections. Consequently, they reduce medicine accessibility, contribute to drug shortages, enable the proliferation of falsified medicines, and exacerbate antimicrobial resistance (AMR). Collectively, these issues pose severe threats to patients, national health systems, and global public health security.

Direct Impacts on Patients: Dual Threats to Life and Health

The absence of effective regulatory capacity manifests in two fundamental harms to patients: inaccessibility and insecurity.

February 2026, Vol. 12, No. 1
ISSN 2163-758X

"Access Deficit" for Life-Saving Medicines

In resource-constrained regulatory systems, the drug review and approval processes are often inefficient and prolonged, which directly delays the introduction of innovative and urgent treatments into the market. For patients, this means that potentially beneficial therapies may be postponed indefinitely. Globally, the availability of essential medicines for children (EMC) between 2016–2020 was only 43.1%, far below ideal levels (WHO Model List of Essential Medicines for Children - 8th List, 2021, n.d.). This cold statistic hides behind it the countless children who lost their lives due to the inability to receive timely treatment, forming a serious "access deficit."

For example, in the late 1990s, highly active antiretroviral therapy (HAART, colloquially "cocktail therapy") became widespread in high-income regions, transforming HIV/AIDS from a fatal disease into a manageable chronic condition. However, in sub-Saharan Africa, where the epidemic was most severe, national regulatory authorities (NRAs) lacked the ability to independently review complex new drugs, resulting in significant approval backlogs. Moreover, patent and pricing issues delayed the widespread adoption of these life-saving therapies for years. During these years of "regulatory and access delay," millions of patients died due to their inability to access effective treatment . This has become a tragic global health lesson on the consequences of delayed medicine access.

"Secondary Harm" from Substandard and Falsified (SF) Medicines

A dysfunctional regulatory system cannot adequately monitor the post-market pharmaceutical supply, creating opportunities for the production and circulation of SF medical products. These medicines may contain insufficient active ingredients or harmful contaminants, leading to "secondary harm" rather than healing. In sub-Saharan Africa, approximately 19% of antimalarials have been confirmed to be falsified or substandard, directly correlating with increased treatment failure rates and deaths (Mengesha et al., 2024).

The proliferation of fake medicines not only deprives patients of recovery opportunities but also severely undermines public trust in the formal healthcare system. In 2008, Nigeria experienced a public health tragedy with the counterfeit teething syrup My Pikin, which contained diethylene glycol, a toxic industrial solvent. This resulted in the deaths of at least 84 infants due to acute renal failure (Fatal Poisoning among Young Children from Diethylene Glycol-Contaminated Acetaminophen --- Nigeria, 2008--2009, 2009). Subsequent investigations revealed significant regulatory gaps in GMP inspection and

February 2026, Vol. 12, No. 1
ISSN 2163-758X

post-market surveillance. This real event serves as stark evidence of how regulatory failure can lead directly to mass casualties.

Systemic Erosion of National Health Systems

The negative effects of the regulatory divide extend beyond individual patients and erode the very foundation of national health systems.

Unnecessary Increase in Medical Costs

Failures in regulation lead to therapeutic failure and adverse drug reactions, forcing patients to seek additional, more complex treatments or prolonged hospitalization. For health systems, this results in strained budgets and inefficient resource utilization. These avoidable costs impose an enormous burden on limited health insurance and national healthcare financing systems.

Loss of Public Trust

Frequent drug safety incidents gradually erode public trust in regulatory bodies, hospitals, and pharmacies. Once trust is broken, the consequences are disastrous: citizens may refuse to follow medical advice, decline vaccination, or turn to unregulated informal channels for medicines—further exacerbating health risks. A system that loses legitimacy faces increasing difficulty in implementing any public health policy.

Long-Term Threats to Global Health Security

In an interconnected world, a regulatory weakness in one country can become a global vulnerability.

Accelerating the Spread of Antimicrobial Resistance (AMR)

Poor regulatory oversight is a key driver of AMR: subtherapeutic doses in substandard antibiotics fail to eliminate pathogens, while weak governance over prescription and sales allows misuse. In the Greater Mekong Subregion (Cambodia, Laos, Myanmar, Thailand, Vietnam), widespread distribution of subpar antimalarials—often lacking effective doses—has significantly contributed to artemisinin resistance, threatening decades of global malaria control efforts.

Weakening Pandemic Response Capacity

February 2026, Vol. 12, No. 1
ISSN 2163-758X

The COVID-19 pandemic demonstrated that efficient, agile regulatory systems are critical in public health emergencies, a step seen as crucial for global preparedness (Mukherjee & Goodman, 2023). During the COVID-19 pandemic, countries with strong regulatory capacities such as the U.S. FDA and EMA were able to conduct rolling reviews and authorize vaccines within weeks, establishing immunity barriers for their populations. In contrast, many lower-capacity countries struggled to independently assess the safety and efficacy of novel vaccines and therapeutics, relying on WHO's Emergency Use Listing or donations(Massard da Fonseca et al., 2024; Khadem Broojerdi et al., 2021). This "vaccine divide" not only exacerbated inequities in global pandemic control but also left room for viral mutation and spread

China’s Drug Regulatory Landscape

Building on the previous discussion of the global disparity in drug regulatory systems and the significant gaps between high-income and low- and middle-income countries, it is crucial to examine China’s unique position and efforts in bridging these regulatory divides. As the world’s second-largest pharmaceutical market, China faces distinct challenges as it navigates the growing complexities of globalized pharmaceutical supply chains. These challenges include aligning with international regulatory standards and ensuring the efficacy of its domestic regulatory system.

Internationalization of China’s Drug Regulatory System

With globalization intensifying, the pharmaceutical supply chain is becoming increasingly transnational and multifaceted. This trend has made it an inevitable necessity for China to internationalize its drug regulatory framework. Accelerating the alignment of China’s drug regulatory system with international standards not only enhances the scientific rigor and authority of its regulation but also serves as a critical strategic pathway for China to transition from being a major pharmaceutical manufacturing nation to an innovation-driven powerhouse.

Relevant policies have outlined clear expectations for the National Medical Products Administration (NMPA) in advancing its internationalization efforts. On one hand, China is committed to continuously translating and implementing globally accepted regulatory guidelines, particularly in the field of drug evaluation. This includes gradually aligning with the standards of the International Council for Harmonisation (ICH), which will enhance China’s clinical trial institutions' participation in international multi-center studies and promote the synchronized development and market launch of innovative medicines worldwide. On the other hand, China is accelerating its integration into

February 2026, Vol. 12, No. 1
ISSN 2163-758X

international pharmaceutical inspection cooperation mechanisms. By adhering to internationally recognized Good Manufacturing Practice (GMP) standards, China is expanding the scope of export certifications to cover all enterprises and products that meet regulatory requirements, providing institutional support for the global expansion of Chinese pharmaceuticals and medical devices (Wang, 2025).

Achievements of China's Drug Regulatory System

China has made significant strides in reforming and innovating its drug regulatory landscape. The advancements are largely evident in the following seven areas:

Upgraded Legal and Regulatory Framework

China has comprehensively upgraded its legal and regulatory framework, guided by an international perspective, problem-oriented thinking, and a commitment to scientific development. Key principles, such as risk management, full lifecycle control, scientific regulation, and social governance, have been established. The implementation of systems such as drug marketing authorization holders (MAHs) and professional inspectors reflects the modernization of China's regulatory law (Wang, 2025).

Reforms in Drug Review and Approval Processes

In response to growing demand for innovation, quality, efficiency, and capacity-building, China has deepened its reforms in drug review and approval. The introduction of systems like prioritized approval and conditional market entry has helped China approve 106 innovative drugs and 191 medical devices. To further support this, 426 technical guidance documents for drug evaluation and 529 for medical devices have been established, providing robust support for pharmaceutical R&D (Ma, 2023).

Contributions to the Global Pandemic Response

During the COVID-19 pandemic, the NMPA swiftly approved five COVID-19 vaccines under conditional approval and authorized 136 COVID-19 diagnostic kits. This rapid approval and regulatory oversight showcased the regulatory body's commitment to public health during a global crisis (Ma, 2023).

Traditional Chinese Medicine (TCM) Innovation

China has made notable progress in the registration and regulation of TCM, facilitating the international recognition of Chinese medicine standards. The approval of 22

February 2026, Vol. 12, No. 1
ISSN 2163-758X

innovative TCM drugs highlights the country's commitment to integrating traditional medicine into modern regulatory frameworks (Wang, 2025).

Strengthening Full Lifecycle Quality Control

China has also emphasized strengthening quality control over the full lifecycle of pharmaceutical products. With the country's vaccine regulatory system passing WHO evaluations, the overall drug inspection pass rate has increased to 99.4%, ensuring drug safety (Ma, 2023).

Building Regulatory Capacity

The establishment of regional evaluation and inspection centers in the Guangdong-Hong Kong-Macao Greater Bay Area and Yangtze River Delta has improved China's ability to handle large-scale evaluations. Furthermore, China has launched 19 regulatory science projects and established 117 key laboratories, accelerating the modernization of its regulatory system (Wang, 2025).

Enhancing International Cooperation

China has deepened its international regulatory cooperation, engaging with organizations like WHO, ICH, and the International Medical Device Regulators Forum (IMDRF). By becoming a member of these international bodies, China has expanded its regulatory reach and influence (Ma, 2023).

Regional Imbalances and Challenges

Despite the vertical clarity of the regulatory structure, there are significant horizontal disparities in resource allocation across different regions within China. According to a quantitative assessment study released in June 2025(Fu et al., 2025), China's pharmaceutical regulatory capacity varies considerably between regions due to differences in local economic development, resource investment, and policy enforcement. These imbalances manifest in several ways:

Economic Disparities

Developed regions such as the coastal provinces have greater financial resources, enabling them to invest more in regulatory infrastructure, personnel training, and technological advancements, which enhances regulatory efficiency. In contrast,

February 2026, Vol. 12, No. 1
ISSN 2163-758X

underdeveloped regions in the central and western parts of China face challenges such as limited funding, talent shortages, and outdated technology (Wang, 2025).

Talent Mobility Issues

Highly skilled professionals, including drug inspectors and evaluators, tend to migrate toward more developed areas like Beijing, Shanghai, and the Pearl River Delta, leaving the central and western regions with a shortage of qualified personnel. This has led to challenges in staffing and retention at the local level, affecting regulatory effectiveness.

Weakened Local Regulatory Bodies

At the municipal and county levels, regulatory bodies face staffing and funding shortages that prevent them from adequately fulfilling their responsibilities, impacting the breadth and depth of market supervision (Ma, 2023).

Globalization of China's Drug Regulation

China's increasing participation in international drug regulation highlights both the progress and the challenges of its regulatory system. China's regulatory framework is transitioning from a domestic focus to an internationally recognized system. However, there are several ongoing challenges:

Insufficient Global Outreach

Due to limited resources, China's international regulatory influence remains modest. Further strengthening of regulatory outreach and global partnerships is necessary (Wang, 2025).

Need for Regulatory Science Advancement

China must continue to expand its involvement in international regulatory science research to ensure that its regulatory cooperation remains robust and comprehensive (Ma, 2023).

Building a Qualified International Regulatory Workforce

China faces a shortage of highly skilled regulatory personnel capable of representing the country in international discussions and decision-making. This limits China's ability to fully engage in global regulatory governance (Ma, 2023).

February 2026, Vol. 12, No. 1
ISSN 2163-758X

Bridging the Regulatory Gap: Global Solutions and Future Perspectives

In the previous sections, we discussed the imbalance in pharmaceutical regulatory resources and its impact on drug accessibility and public health. Bridging this gap requires a multi-dimensional and systematic solution. This section will explore feasible paths to narrow the regulatory gap from three perspectives: reviewing existing international cooperation mechanisms, exploring future innovative pathways, and redefining the responsibilities of high-income countries.

Review of Existing International and Regional Cooperation Mechanisms

In recent years, the international community has implemented various cooperation mechanisms to address regulatory capacity challenges (Narsai et al., 2025). The core strategies include regulatory convergence, mutual recognition, and reliance, which aim to reduce redundant reviews and accelerate drug approval through unified standards and shared review data. These mechanisms are especially important for countries with limited regulatory resources.

For example, a study by Danks et al. (2023) demonstrated that the reliance review mechanism can effectively shorten drug approval timelines, particularly in resource-scarce countries. Additionally, Fonseca et al. (2024) noted that some middle-income countries temporarily address their regulatory gaps by borrowing decisions from mature regulatory agencies when they lack capital and human resources.

At the regional level, many African countries, such as Ghana, Nigeria, and Rwanda, have signed memoranda of understanding to deepen cooperation in drug approval, data sharing, and mutual recognition of evaluation reports. This collaboration helps share the regulatory burden and improves regional approval efficiency and consistency. The establishment of the African Medicines Agency (AMA) is aimed at promoting regulatory convergence and unified standards across Africa. Although AMA’s progress has been slow, once operational, it will significantly speed up the entry of new drugs and vaccines into the African market and provide crucial support in drug safety regulation and combating counterfeit drugs(Wairagkar et al., 2025).

Future Innovative Pathways and Regulatory Model Exploration

In addition to improving existing cooperation mechanisms, exploring innovative regulatory models is crucial for countries with limited resources to achieve accelerated capacity building. Digital regulatory mechanisms offer great potential to enhance efficiency. By utilizing big data, artificial intelligence, and remote monitoring

February 2026, Vol. 12, No. 1
ISSN 2163-758X

technologies, post-market surveillance of adverse events can be optimized, improving the accuracy of risk warnings. However, the promotion of digital health platforms also faces challenges such as lagging regulatory frameworks, insufficient infrastructure, and data standardization issues. To overcome these challenges, introducing "regulatory sandboxes" is recommended, as they allow for the testing and application of new data-driven tools in controlled environments, thus fostering the development of regulatory science.

The paradigm of capacity building needs to shift from traditional material aid to "empowerment-based" assistance, focusing on helping recipient countries build robust regulatory frameworks, information systems, and professional talent. Empowerment assistance should adopt a tiered support approach, providing differentiated support for countries at different levels of regulatory capacity, while including strict performance evaluation and feedback mechanisms to ensure the sustainability of projects and the efficient use of resources.

Another key innovative pathway is the establishment of resilient emergency regulatory mechanisms. During global public health emergencies, many countries lack the capacity to conduct rapid approvals and regulatory adjustments. Therefore, regulatory systems must be equipped with a dual-track mechanism, where emergency procedures are set up alongside standard processes, and cross-border emergency approval platforms should be established in advance. This would allow for rapid sharing of review data and mutual recognition of approvals, thereby saving valuable time for global public health during crises.

Redefining the Responsibility of High-Income Countries: From "Aid" to "Empowerment"

In global public health governance, the role of high-income countries (HICs) must fundamentally shift from "donors" to "empowerers." This means that high-income countries should not only provide financial support but also establish deep, long-term partnerships by sharing mature regulatory systems, standard templates, and information systems.

High-income countries should actively advocate for more equitable regulatory recognition and resource-sharing mechanisms on international platforms, such as the WHO and ICH, ensuring that resource-poor countries have a greater voice in the global regulatory framework. Furthermore, all empowerment projects should include transparent performance monitoring and accountability mechanisms to ensure the

February 2026, Vol. 12, No. 1
ISSN 2163-758X

effective use of resources. The ultimate goal is to establish a fair global benefit-sharing system, where middle- and low-income countries are no longer simply recipients of aid but become active participants and contributors to global public health governance.

Conclusion

This study analyzes the imbalance in the allocation of global pharmaceutical regulatory resources, highlighting the significant gap in regulatory capacities between high-income and low-income countries, particularly in terms of drug quality, safety, and accessibility. The research shows that the disparity in global pharmaceutical regulatory resources directly impacts the safety and accessibility of medicines in low-income countries. High-income countries, with their ample resources and well-established regulatory systems, are able to ensure drug quality and safety, whereas low-income countries, due to insufficient regulatory capacity, face issues such as poor drug quality, delayed market access, and public health risks.

The regulatory divide in pharmaceutical governance is not merely a technical issue; it is also a matter of global health equity and social justice, which affects global public health security. Bridging this divide requires a multi-dimensional approach, including strengthening international cooperation, advancing regulatory capacity building, and implementing digital regulatory tools.

The study finds that the disparity in the allocation of pharmaceutical regulatory resources directly affects the safety and accessibility of medicines in low-income countries. High-income countries can ensure drug quality and safety through sufficient resources and well-developed regulatory systems, while low-income countries face challenges due to inadequate regulatory capacity, limited resources, and delayed market access, leading to worsened drug quality issues and public health risks.

Furthermore, the regulatory divide is not only a technical issue but also a fundamental problem related to global health equity and public health safety, particularly in low-income countries, where drug quality problems are prevalent. Bridging this divide requires the implementation of a range of solutions, including strengthening international cooperation, advancing regulatory capacity in low-income countries, and introducing digital tools to improve regulatory efficiency.

Based on the findings of this study, we propose three key measures: First, strengthening international cooperation by promoting the unification of global pharmaceutical regulatory standards and adopting mutual recognition and reliance review mechanisms to accelerate drug market entry. Second, high-income countries

February 2026, Vol. 12, No. 1
ISSN 2163-758X

should support low-income countries in building modern pharmaceutical regulatory systems through technical assistance, capacity-building programs, and training. Finally, it is essential to promote digital regulation, encouraging low-income countries to adopt digital platforms to enhance regulatory efficiency, particularly in drug approval, market supervision, and drug safety monitoring.

Future Research Directions: This study faces data gaps and comparability issues, and future research could explore solutions to the challenges of cross-national data collection, promoting the establishment of standardized global pharmaceutical regulatory data collection practices to fill these gaps. Future research should also expand on case studies to explore the specific practices and successful experiences of pharmaceutical regulatory system development in different countries, with particular attention to the roles and contributions of low-income countries in global regulatory cooperation. Additionally, future research should focus on data standardization, improving the accuracy of cross-country comparisons, and fostering multi-level international cooperation to develop pharmaceutical regulatory frameworks tailored to the needs of each country, thereby optimizing the global allocation of pharmaceutical regulatory resources.

References

Agência Nacional de Vigilância Sanitária. (2023). Relatório de gestão 2022.

Ahonkhai, V., Martins, S. F., Portet, A., Lumpkin, M., & Hartman, D. (2016). Speeding Access to Vaccines and Medicines in Low- and Middle-Income Countries: A Case for Change and a Framework for Optimized Product Market Authorization. PLOS ONE, 11(11), e0166515.

Alireza Khadem Broojerdi, Alfonso, C., Dehaghi, A., Refaat, M., & Hiiti Sillo. (2021). Worldwide Assessment of Low- and Middle-Income Countries' Regulatory Preparedness to Approve Medical Products During Public Health Emergencies. Frontiers in Medicine, 8(722872).

Danks, L., Boitumelo Semete-Makokotlela, Kennedy Otwombe, Parag, Y., Walker, S., & Salek, S. (2023a). Evaluation of the impact of reliance on the regulatory performance in the South African Health Products Regulatory Authority: implications for African regulatory authorities. Frontiers in Medicine, 10(1265058). https://doi.org/10.3389/fmed.2023.1265058

European Medicines Agency. (2024). Annual accounts: Financial year 2023.

February 2026, Vol. 12, No. 1
ISSN 2163-758X

European Medicines Agency. (2024). Annual report 2023.

Fatal Poisoning Among Young Children from Diethylene Glycol-Contaminated Acetaminophen --- Nigeria, 2008--2009. (2009). Www.cdc.gov.

Food and Drugs Authority, Ghana. (2021). 2020 annual report.

Franzen, S. R. P., Chandler, C., & Lang, T. (2017). Health research capacity development in low and middle income countries: reality or rhetoric? A systematic meta-narrative review of the qualitative literature. BMJ Open, 7(1), e012332.

Fu, L., Jia, G., Wei, M., & Cui, Y. (2025). Key regulatory challenges in developing modified new chemical drugs in China: a national survey study. Frontiers in Pharmacology, 16(16). https://doi.org/10.3389/fphar.2025.1576013

Garg, R., Bhargava, A., & Singh, S. K. (2024). Capacity Building in Public Health Emergency Management: A Crucial Pillar for Global Health Security. NMO Journal, 18(1), 28–32.

Kaplan, W., & Laing, R. (2005). Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines An Overview of Key Concepts, Issues and Opportunities for Future Research.

Ma, F. (2023). Xu Jinghe: Leading Innovation and Advancing China's Pharmaceutical Regulatory Modernization. Pharmaceutical Economic Report, 2023-02-23(001). https://doi.org/10.38275/n.cnki.nyyjj.2023.000189.

Massard da Fonseca, E., Nachlis, H. S., Thomson, K., & Jarman, H. (2024). Borrowing Regulatory Capacity in Middle-Income Countries during Public Health Crises: Brazil, Regulatory Reliance, and the Politics of COVD-19 Vaccine Regulation. Social Science & Medicine, 117563(365), 117563.

Mengesha, A., Bastiaens, H., Ravinetto, R., Gibson, L., & Dingwall, R. (2024). Substandard and falsified medicines in African pharmaceutical markets: A case study from Ethiopia. Social Science & Medicine (1982), 349(116882), 116882.

Mukherjee, S., & Goodman, L. (2023). Strengthening regulatory systems globally: a crucial step towards pandemic preparedness and response. BMJ Global Health, 8(8), e012883.

Narsai, K., Leufkens, H. G. M., Brinkhuis, F., Mantel-Teeuwisse, A. K., & van den Ham, H. A. (2025). Transitioning to regulatory harmonisation for medicines: a comparison

February 2026, Vol. 12, No. 1
ISSN 2163-758X

between Africa and Europe. Drug Discovery Today, 30(8), 104416.

Ndomondo-Sigonda, M., & Ambali, A. (2011). The African Medicines Regulatory Harmonization Initiative: Rationale and Benefits. Clinical Pharmacology & Therapeutics, 89(2), 176–178. https://doi.org/10.1038/clpt.2010.299

Pan American Health Organization. (2021). Procedure for the qualification of national regulatory authorities of regional reference for medicines and biological products.

Pan American Health Organization. (n.d.). Reports on Haiti. Pan American Health Organization.

Papua New Guinea National Department of Health. (n.d.). Policies& Standard.

Ratanawijitrasin, & Eshetu Wondemagegnehu (2002). Details for: Effective drug regulation : › WHO HQ Library catalog. Who.int.

Riviere, J. E., & Buckley, G. J. (2012). Ensuring Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad. In National Academies Press eBooks. The National Academies Press, Washington, D.C.

Roth, L., Bempong, D., Babigumira, J. B., Banoo, S., Cooke, E., Jeffreys, D., Kasonde, L., Leufkens, H. G. M., Lim, J. C. W., Lumpkin, M., Mahlangu, G., Peeling, R. W., Rees, H., Ndomondo-Sigonda, M., Stergachis, A., Ward, M., & Nwokike, J. (2018). Expanding global access to essential medicines: investment priorities for sustainably strengthening medical product regulatory systems. Globalization and Health, 14(1). https://doi.org/10.1186/s12992-018-0421-2

Rwanda Food and Drugs Authority. (2022). Rwanda Food and Drugs Authority annual report FY 2020 - 2021.

Türkiye İlaç ve Tıbbi Cihaz Kurumu. (2024). 2023 yılı idare faaliyet raporu. https://www.sayistay.gov.tr/reports/download/24obn2ao6O-turkiye-ilac-ve-tibbi-cihaz-kurumu

U.S. Food and Drug Administration. (2022). FY 2023 budget summary fact sheet. U.S. Department of Health and Human Services.

Wairagkar, N., Djoudalbaye, B., Moubarak, I., Zakari, M., Shaffer, D. N., Ismail, A. J., Abouhussein, D. M. N., Adeyeye, M. C., Darko, D. M., Fimbo, A. M., Rukwata, R. T., Semete-Makokotlela, B., Bienvenu, E., Rakotonirina, J., Sidibe, M., Kim, J. H., Samate, M. C., & Ndembi, N. (2025). The African Medicines Agency - A potential gamechanger

February 2026, Vol. 12, No. 1
ISSN 2163-758X

that requires strategic focus. PLOS Global Public Health, 5(2), e0004276.

Wang, X. (2025). Current State and Reflections on the Internationalization of China's Pharmaceutical Regulation. Chinese Pharmaceutical Guide, 27(06), 539–542. http://drc.hznet.com.cn/DRCNet.Mirror.Documents.Web/DocSummary.aspx?DocID=8016807&leafID=70

WHO Model List of Essential Medicines for Children - 8th list, 2021. (n.d.). Www.who.int. https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.03

World Bank. (2024). World Bank country classifications by income level for 2024–2025.

World Health Organization. (2014, July 4). WHO assessment of China's national drug regulatory authority for vaccines. https://www.who.int/director-general/speeches/detail/who-assessment-of-china-s-national-drug-regulatory-authority-for-vaccines

World Health Organization. (2017). A study on the public health and socioeconomic impact of substandard and falsified medical products (WHO/EMP/RPS/2017.1).

World Health Organization. (2017). A study on the public health and socioeconomic impact of substandard and falsified medical products (WHO/EMP/RPS/2017.1).

World Health Organization. (2017). A study on the public health and socioeconomic impact of substandard and falsified medical products (WHO/EMP/RPS/2017.1).

World Health Organization. (2019). WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products: Revision VI (WHO/EMP/RPS/2019.2).

World Health Organization. (2021). WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory system of medical products: Revision VI (WHO/REG/2021.1).

World Health Organization. (2024, May 10). Update on the assessment of national regulatory authorities: Report by the Director-General to the Seventy-seventh World Health Assembly (A77/9).

Author Notes

Wenhan Jiao is an undergraduate student at the International Pharmaceutical Business School, China Pharmaceutical University, majoring in Pharmaceutical Administration. Her main areas of study focus on pharmaceutical regulation and global public health. During her studies, she has participated in introductory research related to the World Health

February 2026, Vol. 12, No. 1
ISSN 2163-758X

Organization's Global Benchmarking Tool (GBT) and has maintained an interest in the allocation of regulatory resources across countries. Through coursework, she has gradually developed skills in literature review, data organization, and basic analytical methods. In addition to academic learning, she actively participates in academic activities and volunteer services to broaden her perspective and gain practical experience. Looking ahead, she hopes to continue her studies and further explore the connections between pharmaceutical policy and public health.

Wanyu Zhang is an undergraduate student majoring in International Trade at the International School of Pharmacy and Business, China Pharmaceutical University. Her academic interests center on pharmaceutical trade and global regulatory policy. Beyond classroom learning, she actively explores international pharmaceutical policy trends, such as comparing approval processes across countries and examining the distribution of pharmaceutical resources in cross-border trade. These explorations have provided her with a clearer understanding of the relationship between regulation and resource flows. In addition to academic studies, she values opportunities for international exchange, where she hopes to broaden her perspectives and gain practical experience. She is motivated to learn from diverse viewpoints, enhance her knowledge, and contribute actively in collaborative environments. Wanyu is enthusiastic about pursuing further studies and professional development in the pharmaceutical field.

Shanshan Kang is an Associate Professor of Economics and International Trade at the China Pharmaceutical University, School of International Pharmaceutical Business. With decades of experience in teaching Business English and cross-cultural communication, she has also served as a coordinator and instructor for the Global Partnership in Education. Prof. Kang's research focuses on treaties and conventions governing the international sale of goods, as well as regulations related to drug import and export. She has led and participated in multiple research projects, including a study on the regulatory system for market access of herbal medicines in the European Union. She has published several academic papers and acted as chief editor for a number of textbooks. Her recent publications include *FDA Current Good Manufacturing Practice (CGMP) for Medical Products in the United States* and *Compilation of FDA Guidelines on Current Good Manufacturing Practice for Medical Products.*