Enhancing biopharmaceutical supply chains: Strategies for efficient drug formulary development in emerging markets

Oluchukwu Obinna Ogbuagu [1*], Akachukwu Obianuju Mbata [2], Obe Destiny Balogun [3], Olajumoke Oladapo [4], Opeyemi Olaoluawa Ojo [5], Muridzo Muonde [6]

[1] Sanofil, Nigeria
[2] Kaybat Pharmacy and Stores, Benin, Nigeria
[3] Independent Researcher, Lima Ohio, USA
[4] Health Mark Regional Medical Center Florida, USA
[5] Medical Statistician, University of Medical Science Teaching Hospital Ondo, Nigeria
[6] Africure Pharmaceuticals Namibia

* Corresponding Author: **Oluchukwu Obinna Ogbuagu**

Article Info

ISSN (online): 2582-8940
Volume: 03
Issue: 01
January-March 2022
Received: 12-01-2022
Accepted: 13-02-2022
Page No: 73-82

Abstract
Biopharmaceutical supply chains in emerging markets face numerous challenges that hinder the efficient development and distribution of essential medicines. These challenges include regulatory barriers, infrastructure deficiencies, logistical inefficiencies, and market volatility. This paper explores strategic approaches to optimizing drug formulary development within these contexts, highlighting the importance of data-driven decision-making, regulatory harmonization, and public-private partnerships. The research also discusses technological innovations, such as blockchain, IoT, and automation, which can enhance supply chain operations' transparency, traceability, and efficiency. By identifying these challenges and proposing actionable solutions, this paper offers recommendations for policymakers, industry leaders, and healthcare providers to strengthen supply chains and improve access to life-saving drugs. Future research directions are also outlined, focusing on the role of digital transformation, sustainable supply chain models, and regulatory advancements. Ultimately, this paper aims to contribute to the ongoing efforts to enhance drug formulary development and supply chain efficiency, ensuring equitable access to affordable medicines in emerging markets.

DOI: https://doi.org/10.54660/IJMBHR.2022.3.1.73-82

Keywords: Biopharmaceutical supply chains, drug formulary development, regulatory harmonization, public-private partnerships, technological innovations, sustainable procurement

1. Introduction

1.1 Overview of Biopharmaceutical Supply Chains

Biopharmaceutical supply chains are essential to ensuring that medicines, vaccines, and other therapeutic products reach their intended destinations promptly and efficiently. These supply chains are complex networks that involve numerous actors, including manufacturers, distributors, wholesalers, regulators, and healthcare providers (Myles & Church, 2022) [26]. Biopharmaceutical supply chains are particularly significant in emerging markets, where healthcare systems face unique challenges such as limited access to healthcare, poor infrastructure, and rising healthcare costs. Effective supply chains in these regions are crucial for addressing both public health needs and economic constraints (Ding, 2018) [12].

Emerging markets, often characterized by rapid economic growth and a burgeoning middle class, have seen a rise in demand for pharmaceutical products. This demand is driven by population growth, the increasing prevalence of chronic diseases, and improving healthcare awareness (Tusé, Nandi, McDonald, & Buyel, 2020) [45]. However, despite this growing need, many emerging markets lack the necessary infrastructure to support a robust biopharmaceutical supply chain.

Problems such as inadequate transportation networks, unreliable cold chain systems, and inefficient warehousing solutions hamper the availability of medicines and lead to supply disruptions.

Furthermore, biopharmaceutical supply chains must contend with regulatory, political, and financial challenges in these regions. Regulatory frameworks in emerging markets often lack the stability and uniformity found in developed economies. While some countries have made strides in developing comprehensive drug approval processes, others still struggle with inefficient, lengthy, and fragmented regulatory systems. This leads to delays in drug approval and distribution, which can hinder access to critical medicines, particularly in times of crisis, such as during an outbreak of infectious diseases or natural disasters (Ibrahim & Araujo, 2021) [19].

Effective biopharmaceutical supply chains are vital for improving healthcare in emerging markets, as they provide the logistical backbone for drug delivery, particularly in low-resource settings. For example, efficient drug distribution is seen in the success of immunization programs, where vaccines need to be transported and stored under specific temperature conditions. This is particularly important for biological drugs, which often require controlled environments throughout the supply chain. Thus, the significance of these supply chains cannot be overstated, as they are directly linked to the health outcomes of populations in emerging markets (Chung *et al*., 2022) [9].

1.2 The Role of Drug Formulary Development

Drug formulary development is an essential aspect of healthcare systems, particularly in emerging markets, as it governs the list of drugs made available within a given health system. A drug formulary outlines which drugs are considered necessary, safe, and effective for treatment, helping to guide clinicians in prescribing the most appropriate medications for their patients. Furthermore, formulary development is instrumental in ensuring cost efficiency and accessibility, as it determines which medications will be included in national health programs or insurance schemes (Koçkaya & Wertheimer, 2016) [20].

The role of drug formulary development extends beyond simply listing medications; it involves strategic decisions that balance clinical efficacy, safety, availability, and cost-effectiveness. In emerging markets, where healthcare budgets are often limited, formulary development is crucial in ensuring that the most cost-effective therapies are accessible to the greatest number of people (Organization, 2017) [29]. For example, formulary committees in these regions typically face the challenge of including essential medications while keeping within the constraints of limited resources. Formulary development can be a tool for controlling costs and reducing the financial burden of healthcare on governments, organizations, and patients (Yoo *et al*., 2019) [49].

In emerging markets, drug formularies are not always comprehensive or well-regulated. In many instances, formularies may be incomplete or fail to account for all necessary medicines, leading to gaps in access to critical treatments. For example, many emerging countries still face significant challenges in the availability of medicines for non-communicable diseases (NCDs) such as cancer, diabetes, and cardiovascular diseases. Without effective drug formularies that account for these emerging healthcare needs, patients may be left without access to the appropriate medications (Mello, 2017) [25].

On the other hand, efficient formulary development can also contribute to the financial sustainability of healthcare systems. By integrating cost-effectiveness analyses into formulary decisions, healthcare providers can prioritize treatments that offer the greatest value for money. This approach allows for the inclusion of newer and more expensive treatments without overburdening healthcare budgets, thus ensuring the equitable distribution of resources. Developing a well-balanced formulary is a cornerstone for equitable access to medicines in emerging markets.

1.3 Key Challenges Faced in Supply Chain Optimization

The optimization of biopharmaceutical supply chains in emerging markets is hindered by several key challenges that vary across different regions. One of the most significant hurdles is the regulatory environment. While many countries have established regulatory agencies to oversee drug approvals, the regulatory landscape is often fragmented and inconsistent. In some markets, the approval process is slow and complex, involving multiple agencies that may have differing standards (Edoh, Ukpabi, & Igol, 2021) [14]. This lack of harmonization can result in delayed drug availability and create confusion in the supply chain, particularly for global pharmaceutical companies seeking to enter new markets. Furthermore, regulatory uncertainty and the lack of intellectual property protections can discourage investment in local manufacturing and distribution, further exacerbating supply chain inefficiencies.

Infrastructure gaps present another major challenge. Emerging markets often face limitations in basic infrastructure such as reliable transportation networks, electricity supply, and cold chain systems. The absence of efficient transportation infrastructure not only delays the delivery of medications but also increases the risk of product spoilage or damage. Cold chain logistics, vital for transporting temperature-sensitive medications like vaccines and biologics, is particularly affected. Inadequate or unreliable cold chain systems can result in significant financial losses and, more importantly, the distribution of compromised products to patients. The lack of warehouse facilities with adequate storage conditions also contributes to inefficiencies in the supply chain.

Market volatility further complicates supply chain optimization efforts. The prices of pharmaceuticals can fluctuate due to various factors, including currency instability, inflation, and supply-demand imbalances. In some regions, biopharmaceutical companies face difficulties with pricing strategies, as governments and insurers may impose price controls or limit reimbursements for certain drugs. These factors make it difficult to maintain a stable and predictable supply of medicines, which can lead to shortages or the diversion of drugs to higher-paying markets (Edoh, Ukpabi, & Igoli, 2021) [14].

1.4 Purpose of the Paper and Key Research Questions

This paper aims to explore strategies for enhancing biopharmaceutical supply chains in emerging markets, with a particular focus on improving drug formulary development. The paper aims to identify key barriers to supply chain optimization and propose actionable solutions that can improve the availability, affordability, and accessibility of medicines. It will investigate the role of technology,

regulatory reforms, and public-private partnerships in overcoming these barriers and creating more efficient and resilient supply chains.

The key research questions that will guide this investigation are:

- What are the most significant challenges to biopharmaceutical supply chain optimization in emerging markets, and how do they affect drug formulary development?
- How can emerging markets address regulatory and infrastructure challenges to improve the efficiency and effectiveness of drug formulary development?
- What strategies and technological innovations can be adopted to optimize biopharmaceutical supply chains, and how can these contribute to the development of more equitable drug formularies?

By addressing these questions, this paper seeks to provide a comprehensive framework for improving biopharmaceutical supply chains in emerging markets, ultimately enhancing access to essential medicines and improving health outcomes.

2. Challenges in Biopharmaceutical Supply Chains in Emerging Markets

2.1 Regulatory and Compliance Barriers

One of the primary challenges biopharmaceutical supply chains face in emerging markets is navigating the complex regulatory and compliance landscape. These barriers delay the entry of essential medicines into the market and hinder the development of a reliable and resilient supply chain. Regulatory frameworks vary significantly across countries, with each nation having its own set of approval processes, standards, and agencies responsible for the oversight of drug safety and efficacy. In many emerging markets, regulatory systems are fragmented, inefficient, and lack harmonization with international guidelines, which results in inconsistent drug approvals and delays in drug availability (Algorri *et al*., 2022) [3]. For instance, while some countries in emerging markets have relatively well-established regulatory agencies that follow standards similar to the World Health Organization (WHO) or the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), others may still rely on outdated or ambiguous regulatory processes. These inefficiencies slow down the approval of new drugs and increase the risk of counterfeit or substandard medications entering the market, which could compromise public health.

The intellectual property (IP) landscape in emerging markets presents another set of challenges. Although patents are supposed to protect pharmaceutical companies' rights, enforcing IP laws is often weak or inconsistent. This creates an environment in which counterfeit drugs and generic substitutes flood the market, undermining the profitability of legitimate manufacturers and delaying the entry of new, life-saving treatments. Furthermore, some emerging markets may engage in parallel importing, where drugs are purchased from countries with lower prices and reintroduced into local markets at a profit. While this practice can increase access to medicines, it can also create a situation where manufacturers are unable to control pricing or maintain consistent supply chains, as these drugs often bypass regulated distribution channels (Sople, 2016) [43].

Regulatory compliance is further complicated by the requirement to meet international standards. Many emerging markets are subject to multiple international frameworks, including the European Medicines Agency (EMA) or the U.S. Food and Drug Administration (FDA) standards for drug imports. To comply with these regulations, biopharmaceutical companies must ensure that their products meet rigorous quality and safety standards, which may require production, labeling, or packaging modifications (Abbott & Snidal, 2021) [1]. This increases the complexity and cost of introducing drugs into these markets, especially if local regulatory agencies do not align with international standards. The resulting delays and cost overruns significantly impact the efficiency and affordability of biopharmaceutical supply chains in emerging markets (Ragavan & Vanni, 2021) [35].

2.2 Logistical and Infrastructure Constraints

Logistical challenges, particularly related to infrastructure, present significant obstacles for the effective functioning of biopharmaceutical supply chains in emerging markets. A reliable infrastructure network is essential for ensuring that drugs are delivered safely and efficiently from manufacturers to end-users. In many emerging markets, however, infrastructure limitations significantly hamper the effectiveness of supply chains. Poor road networks, inadequate port facilities, and inefficient transportation systems delay the delivery of medications, increase costs, and introduce significant risks to drug safety, especially for temperature-sensitive products (Ibrahim & Araujo, 2021) [19].

One of the most critical components of biopharmaceutical supply chains is the management of cold chains. Certain medications, including vaccines, biologics, and insulin, require strict temperature controls throughout the supply chain to maintain their efficacy and safety. However, cold chain infrastructure in emerging markets is often inadequate or poorly maintained (Sarkis, Bernardi, Shah, & Papathanasiou, 2021) [36]. The lack of refrigerated transport, insufficient storage facilities, and inconsistent temperature monitoring systems all contribute to potential spoilage and wastage. In the worst cases, this can lead to the distribution of compromised or ineffective products, further exacerbating health crises and eroding trust in the pharmaceutical system (Singh, Kumar, & Kumar, 2016) [41].

Transportation inefficiencies are another major problem. In many emerging markets, road infrastructure is underdeveloped, leading to delays in transporting goods from manufacturing sites to distribution hubs and, ultimately, to healthcare providers. These inefficiencies are often compounded by unreliable electricity grids and lack of communication systems that help coordinate the movement of goods. In remote or rural areas, where healthcare access is often limited, the inability to transport drugs quickly can be particularly damaging, leading to shortages or delays in the availability of essential medicines (Pojani & Stead, 2017) [34].

In emerging markets, inventory control is another area where logistical issues are prevalent in biopharmaceutical supply chains. Inadequate warehousing facilities, poor stock management practices, and inaccurate inventory tracking can result in overstocking, stockouts, or expiration of drugs. Pharmaceutical products are sometimes stored in warehouses that lack the necessary environmental conditions to preserve their quality (Pojani & Stead, 2015) [33]. The absence of automated inventory tracking systems and real-time data also contributes to inefficiencies, making it difficult to predict

demand, manage stock levels, and avoid waste. Addressing these issues requires investment in infrastructure and modern technologies that can enhance supply chain visibility and operational efficiency.

2.3 Market Dynamics and Pricing Volatility

Market dynamics and pricing volatility are major challenges in emerging markets that impact the affordability and accessibility of biopharmaceutical products. High drug prices are a significant barrier in many emerging economies, where a large portion of the population may not have the financial means to afford essential medications (Winegarden, 2020) [48]. Prices for branded drugs are often prohibitively high, making access to life-saving therapies difficult for those in lower-income groups. Governments and healthcare organizations must carefully balance the need for equitable access to medicines with the reality of limited financial resources.

One of the key factors contributing to pricing volatility is the prevalence of parallel trade. While parallel importing can help lower drug prices by bringing medicines from countries sold at lower prices, it can also create inefficiencies in the supply chain. Parallel traders often bypass official distribution channels, which can result in the distribution of substandard drugs or unauthorized imports. This reduces manufacturers' ability to control product pricing and distribution, leading to price fluctuations and market instability. This volatility can create challenges for formulary developers, as they must navigate unpredictable pricing in an environment where price sensitivity is high (Organization, 2018) [30].

Procurement inefficiencies also play a significant role in driving up drug prices in emerging markets. In many of these countries, procurement processes are often marked by inefficiency, corruption, and lack of transparency, resulting in inflated prices. The involvement of intermediaries and non-competitive bidding can drive up the costs of pharmaceuticals. These inefficiencies contribute to supply chain bottlenecks, increasing the overall cost of medicines and reducing the ability of governments to purchase essential drugs for public health programs (Kohler, Martinez, Petkov, & Sale, 2016) [21]. In addition, the lack of standardized procurement processes and price negotiation strategies means that countries may be paying higher prices for drugs than necessary. Without centralized procurement mechanisms or price agreements with pharmaceutical manufacturers, the cost of acquiring medicines can vary widely, leading to inconsistencies in drug availability and financial strain on public health systems. (Berdud *et al*., 2019) [5]

2.4 Data Gaps and Digitalization Challenges

Adopting advanced digital technologies is another area where many emerging markets lag. Data gaps and a lack of digital infrastructure impede the optimization of biopharmaceutical supply chains. Advanced technologies such as artificial intelligence (AI), blockchain, and predictive analytics offer significant potential for improving supply chain operations, but their integration in emerging markets has been slow and inconsistent.

AI and predictive analytics can enhance supply chain forecasting, demand planning, and inventory management. By analyzing historical data, these technologies can predict fluctuations in demand, optimize stock levels, and improve order fulfillment. However, many emerging markets still rely on outdated manual systems or basic software for these processes, which limits their ability to improve efficiency and reduce wastage (Seyedan & Mafakheri, 2020) [37].

Blockchain technology holds promise for improving transparency and traceability in biopharmaceutical supply chains. It can enable real-time tracking of products, ensuring that they remain within regulatory standards throughout the entire supply chain. Blockchain can also help address the issue of counterfeit drugs, as it provides a secure and immutable record of product movements. Despite these benefits, the adoption of blockchain has been limited in many emerging markets due to the high upfront costs, technical complexity, and lack of skilled workforce to implement and manage these systems (Sun & Ali, 2022) [44].

Finally, limited access to data and underdeveloped digital infrastructure make it challenging for supply chain actors to understand product availability, safety, and efficacy in real-time. Without robust data systems, it is difficult to coordinate activities across various stages of the supply chain, monitor performance, or respond rapidly to disruptions. Addressing these challenges requires investment in both technological infrastructure and human capital, as well as a concerted effort from both public and private sectors to adopt digital solutions.

3. Strategic Approaches to Optimizing Drug Formulary Development

3.1 Data-Driven Decision-Making

Data-driven decision-making has become one of the most effective strategies for optimizing drug formulary development and ensuring efficient supply chains, particularly in emerging markets. By leveraging artificial intelligence (AI), machine learning, and big data, biopharmaceutical companies can enhance demand forecasting, improve inventory management, and reduce operational inefficiencies. These technologies enable more precise predictions of future drug requirements, mitigating stockouts and overstocking issues plaguing many emerging markets (Nguyen, Lamouri, Pellerin, Tamayo, & Lekens, 2022) [28].

AI and machine learning models can analyze vast quantities of historical data to identify trends and patterns in drug demand. By incorporating seasonal fluctuations, regional health trends, and socioeconomic variables, AI can provide real-time insights into the demand for specific drugs across different geographic locations. This allows pharmaceutical companies to adjust their manufacturing and distribution strategies in response to anticipated shifts in demand, ensuring that the right drugs are available in the right quantities at the right time (Zhu, Ninh, Zhao, & Liu, 2021).

Big data analytics can further improve decision-making by integrating data from various sources, such as healthcare providers, government reports, and pharmaceutical distribution networks. By consolidating information from these disparate channels, companies gain a comprehensive understanding of current market dynamics, helping prevent supply chain disruptions. For instance, predictive analytics can assist in identifying potential shortages or surpluses early, enabling proactive interventions, such as reallocating stock, adjusting manufacturing schedules, or increasing imports (Wang, Kung, Wang, & Cegielski, 2018) [47].

In terms of inventory management, AI algorithms can automate the process of stock tracking, enabling real-time monitoring of drug stocks in warehouses and distribution

centers. This is particularly crucial for temperature-sensitive drugs that require cold chain management. Through the use of sensors and IoT devices, AI systems can track environmental conditions and product movement, ensuring that drugs are stored and transported in optimal conditions. AI-driven systems can also improve stock turnover by reducing lead times and enhancing supplier relationships through automated ordering processes, leading to a more efficient supply chain (Dinh, 2020) [13].

3.2 Regulatory Harmonization and Policy Innovations

Regulatory barriers are a significant challenge to biopharmaceutical supply chains in emerging markets. One of the most promising approaches to overcoming these barriers is regulatory harmonization, which involves the alignment of regulatory standards and approval processes across countries or regions. Standardized approval pathways and international collaborations between regulatory agencies can streamline the drug approval process and facilitate faster and more consistent access to medicines (Dhiman, Gummadi, & Dureja, 2019) [11].

The World Health Organization (WHO) and other international regulatory bodies have been at the forefront of promoting harmonized regulatory standards. By adopting global guidelines, emerging markets can reduce the complexity and cost of obtaining drug approvals. For example, aligning with the International Council for Harmonisation (ICH) standards enables manufacturers to produce drugs that meet the stringent quality and safety requirements of both local and international markets, thereby improving the efficiency of the drug approval process (Burns *et al*., 2022) [6].

Countries that engage in international collaborations, such as the African Medicines Regulatory Harmonization initiative (AMRH) or the Asia-Pacific Economic Cooperation (APEC), benefit from shared knowledge, resources, and expertise. These collaborations allow for more efficient drug registration procedures, mutual recognition of clinical trial data, and improved information sharing. Such efforts foster a greater exchange of regulatory best practices and reduce the regulatory burden on manufacturers, which can lead to faster market entry for essential medicines (Calder, 2016) [8].

Adaptive regulatory frameworks are another important aspect of optimizing drug formulary development. In dynamic healthcare environments, regulatory systems must be flexible and able to respond to emerging health threats, such as pandemics or public health crises. An adaptive regulatory approach allows for quicker approvals for urgent drugs, facilitates real-time monitoring of drug safety, and provides mechanisms for fast-tracking new treatments without compromising safety. Regulatory bodies must be proactive in adopting such frameworks, ensuring that they can respond quickly to changes in disease epidemiology and technological advancements in drug development (Hirsch *et al*., 2016) [18].

3.3 Public-Private Partnerships (PPPs)

Public-private partnerships (PPPs) have emerged as a key strategy for enhancing the resilience and efficiency of biopharmaceutical supply chains in emerging markets. These partnerships leverage the strengths of both public and private sectors to address the critical challenges faced in drug formulary development and distribution.

Governments in emerging markets often struggle with limited financial resources, outdated infrastructure, and regulatory inefficiencies. By collaborating with multinational pharmaceutical companies, local manufacturers, and non-governmental organizations, governments can access the technical expertise, funding, and supply chain networks required to improve healthcare access. In turn, pharmaceutical companies gain entry into new markets, enhancing their growth potential while fulfilling corporate social responsibility goals (Smyth, Webb, & Phillips, 2021) [42].

One of the key advantages of PPPs is the ability to scale up production of essential medicines. For instance, through collaborations with local manufacturers, multinational companies can transfer technology, share knowledge, and provide technical assistance to improve local production capabilities. This helps to reduce dependency on imports, lower costs, and increase the availability of medicines within the country. In countries with high disease burdens, such as sub-Saharan Africa, PPPs have proven particularly successful in expanding the reach of vaccines, antiretroviral therapies, and other critical treatments.

PPPs can also support infrastructure development, such as establishing distribution networks, cold chain logistics, and healthcare facilities. Joint investments in such areas can improve the reliability of drug delivery systems and reduce inefficiencies in transportation and storage. Additionally, these collaborations can facilitate bulk purchasing agreements, allowing governments to negotiate better prices and improve the affordability of medicines (Gillespie, Privitera, & Gaspero, 2019) [16].

By fostering strong relationships between governments, private industry, and other stakeholders, PPPs can also enhance the agility and responsiveness of the supply chain, enabling quicker responses to emerging health crises, such as pandemics or localized outbreaks.

3.4 Decentralized Manufacturing Models

Decentralized manufacturing models are gaining traction as a strategy to optimize drug formulary development and reduce supply chain vulnerabilities in emerging markets. Traditionally, many countries have relied on importing drugs from multinational companies, which creates a dependency on foreign suppliers and exposes markets to global disruptions. By establishing local manufacturing capabilities, emerging markets can ensure a more stable and reliable supply of essential medicines (Buxton & Bingham, 2015).

Local production reduces the risks associated with long supply chains, such as transportation delays, currency fluctuations, and political instability in the source country. It also mitigates the impact of trade barriers or tariffs that may affect the affordability and accessibility of medicines. Establishing manufacturing plants locally allows for faster delivery times and lower transportation costs, improving the overall efficiency of the supply chain.

Technology transfer is a crucial component of decentralized manufacturing. Through partnerships with multinational pharmaceutical companies, local manufacturers can access the necessary technologies, expertise, and intellectual property required to produce high-quality medicines. This collaboration can also involve capacity building through training programs, which enhances the local workforce's skills and strengthens the domestic pharmaceutical sector (Harrison, Ruck, Medcalf, & Rafiq, 2017) [17].

A strong local manufacturing base also enables better control over drug quality and regulatory compliance. By adhering to

international manufacturing standards, local plants can produce drugs that meet local and global markets' safety and efficacy requirements. Moreover, local production contributes to economic growth by creating jobs and stimulating the domestic economy.

3.5 Sustainable Procurement Strategies

Sustainable procurement strategies are essential for ensuring drug formulary development's long-term viability and affordability in emerging markets. Bulk purchasing, value-based pricing, and risk-sharing agreements are key approaches that can optimize procurement processes and reduce costs. Bulk purchasing allows governments and large institutions to negotiate better prices by buying drugs in large quantities. This strategy can help address affordability issues, particularly for life-saving medicines, and ensure that countries can meet their healthcare needs without overspending. Bulk purchasing programs also benefit from economies of scale, reducing the per-unit cost of drugs and making them more affordable for the public health system (Vogler *et al*., 2019) [46].

On the other hand, value-based pricing ties a drug's price to its clinical effectiveness and the value it delivers to patients. This pricing model aligns the interests of both healthcare providers and pharmaceutical manufacturers, ensuring that drugs are priced to reflect their real-world impact on patient outcomes. By focusing on value rather than volume, value-based pricing encourages the development of treatments that offer significant health benefits and helps reduce the overall cost burden on healthcare systems (Neumann, Cohen, & Ollendorf, 2021) [27].

Risk-sharing agreements offer another innovative approach to procurement in biopharmaceutical supply chains. In these agreements, pharmaceutical companies and healthcare providers share the financial risks associated with the price and efficacy of a drug. For example, suppose a drug does not achieve the expected clinical outcomes. In that case, the manufacturer may agree to reduce the price or offer a refund. This model incentivizes pharmaceutical companies to invest in effective therapies while ensuring that governments and healthcare providers are not burdened with the financial risks of suboptimal treatments.

Together, these sustainable procurement strategies contribute to more efficient, affordable, and resilient drug formulary development, ensuring that emerging markets can provide access to life-saving medicines while managing costs.

4. Technological and Operational Innovations for Supply Chain Resilience

4.1 Blockchain for Transparency and Traceability

Blockchain technology has emerged as a transformative force in enhancing transparency, traceability, and accountability within biopharmaceutical supply chains. As counterfeit drugs become an increasing concern in emerging markets, blockchain provides a secure, immutable ledger to track pharmaceutical products' origin, manufacturing, and distribution, ensuring that drugs are authentic and compliant with regulatory standards.

One of the key advantages of blockchain technology is its ability to provide end-to-end visibility in the supply chain. Each transaction—from manufacturing to distribution to the point of sale—can be securely recorded and verified using distributed ledger systems. This transparency allows stakeholders to track the drug's journey at every stage, reducing the risk of counterfeit drugs entering the supply chain. In emerging markets, where enforcing intellectual property rights and drug quality control can be challenging, blockchain provides an effective solution to ensure that drugs are sourced from reputable manufacturers and have not been tampered with during transit (Ma, Shi, & Kang, 2022) [22].

Blockchain also facilitates compliance with regulatory requirements by ensuring that all data regarding drug manufacturing, storage, and distribution is recorded accurately and cannot be altered. In regions where regulatory oversight may be limited or inconsistent, blockchain provides a mechanism to ensure that pharmaceutical companies, distributors, and retailers comply with the required standards and protocols. For example, by linking blockchain technology with regulatory databases, authorities can easily verify whether drugs have passed clinical trials, met safety standards, and are licensed for sale in the local market. This also simplifies auditing processes, reducing administrative costs and time spent on manual checks (Mackey & Nayyar, 2017) [23].

Moreover, blockchain enables improved collaboration between stakeholders, including manufacturers, distributors, retailers, and regulators. With real-time access to shared data, stakeholders can quickly identify discrepancies in the supply chain and address any issues before they escalate. This strengthens the supply chain's resilience and enhances the efficiency of drug formulary development, ensuring timely access to quality medications (Panda & Satapathy, 2021) [32].

4.2 Internet of Things (IoT) in Cold Chain Logistics

The Internet of Things (IoT) is playing a crucial role in enhancing the resilience of supply chains by improving the monitoring and management of temperature-sensitive products, such as biologics, vaccines, and insulin. These products require strict temperature controls during transportation and storage to maintain efficacy. Failure to maintain the required conditions can lead to product degradation, posing significant risks to patient safety and increasing costs due to product waste.

IoT devices equipped with temperature and humidity sensors are increasingly being used in cold chain logistics to provide real-time monitoring of drugs during transport and storage. These devices can be embedded into packaging or attached to shipping containers to continuously track the temperature and other environmental conditions throughout the supply chain journey. By collecting this data, IoT solutions help supply chain managers ensure that drugs are kept within the specified temperature range and that any deviations are promptly detected and addressed (Sharma & Gupta, 2020).

IoT-based systems offer several advantages over traditional monitoring methods. First, they provide continuous, real-time data, which means that any issues related to temperature fluctuations can be identified immediately, rather than only at the destination. This real-time feedback allows supply chain managers to take corrective actions, such as rerouting shipments or adjusting storage conditions, to ensure product integrity. Second, IoT devices can transmit data to cloud-based platforms, allowing stakeholders from various parts of the supply chain—manufacturers, distributors, and healthcare providers—to access the information simultaneously. This collaborative approach enables quick decision-making and enhances the overall efficiency of the supply chain (Abdulmalek *et al*., 2022) [2].

IoT in cold chain logistics also helps ensure compliance with

regulatory requirements for temperature-sensitive drugs. Many regulatory bodies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), require pharmaceutical companies to monitor and maintain specific storage conditions for biologics and vaccines. IoT technology facilitates compliance by automatically recording and storing temperature data, which can be used as proof during audits and inspections.

Furthermore, integrating IoT systems with blockchain technology can enhance data security and traceability. IoT devices can generate data that is recorded on a blockchain ledger, ensuring that the data is immutable and can be easily verified by all stakeholders in the supply chain. This combination of IoT and blockchain technology enhances the supply chain's resilience and ensures that temperature-sensitive products reach their destination safely and efficiently (Bamakan, Moghaddam, & Manshadi, 2021) [4].

4.3 Automation and Smart Warehousing

Automation in warehousing and inventory management is revolutionizing the efficiency and resilience of biopharmaceutical supply chains. Companies can streamline warehouse operations, reduce human error, and improve inventory control by incorporating automated systems such as robotic process automation (RPA), automated guided vehicles (AGVs), and drones.

Smart warehousing involves using technologies such as sensors, RFID tags, and advanced software systems to automate inventory storage, retrieval, and management. These systems can track the location, quantity, and status of every product in the warehouse, providing real-time visibility and enabling better decision-making. For example, RFID tags allow for tracking individual drug products, reducing the chances of stockouts, overstocking, or misplaced inventory. This automated tracking helps optimize stock levels, ensuring that drugs are available when needed and minimizing the risk of waste due to expired or obsolete products (Shashi, 2022) [40].

One of the significant advantages of warehouse automation is the ability to improve operational efficiency. Automated systems can speed up receiving, sorting, and dispatching drugs, reducing the time it takes to process orders and increasing throughput. This results in faster delivery times, which is especially critical in emergencies where access to life-saving medications must be prioritized.

Moreover, automated systems can help minimize waste by improving the accuracy of inventory management. By providing real-time data on stock levels and expiration dates, smart warehousing systems can help ensure drugs are used before expiration, reducing the financial losses associated with unsellable inventory. This is particularly important in emerging markets, where the cost of wasted drugs can be significant, and the availability of medications is often limited.

Automation also enhances distribution efficiency by improving the coordination of orders and shipments. Advanced software systems can optimize the picking and packing process, reducing the risk of errors and ensuring that the correct drugs are sent to the right locations. Automated warehouses can also integrate with other supply chain systems, such as transportation management and demand forecasting platforms, creating a seamless flow of information across the entire supply chain. This integration ensures that inventory levels are aligned with real-time demand, improving the overall responsiveness of the supply chain (Dhaliwal, 2020) [10].

4.4 Digital Marketplaces and E-Procurement Systems

Digital marketplaces and e-procurement systems are transforming how pharmaceutical companies and healthcare providers engage with suppliers, making the procurement process more efficient, transparent, and cost-effective. These platforms allow stakeholders to interact, negotiate, and complete transactions digitally, eliminating the need for time-consuming paperwork and reducing the risk of procurement inefficiencies.

E-procurement systems automate the entire procurement process, from supplier selection and contract negotiation to order fulfillment and payment. Using digital platforms, companies can access various suppliers, compare prices, and ensure they purchase drugs at the most competitive rates. This reduces costs and enhances transparency by providing a clear record of all transactions and interactions (Masheti, 2016) [24].

Digital marketplaces enhance supplier engagement by providing a centralized platform where buyers and suppliers can communicate directly. These platforms allow suppliers to showcase their products, highlight their certifications, and share information about their manufacturing capabilities. Buyers can easily assess the quality of the suppliers' offerings and choose the best option based on price, quality, and delivery times.

E-procurement systems can also integrate with other supply chain management tools, such as inventory management, demand forecasting, and payment processing systems, creating a seamless flow of information throughout the procurement process. This integration helps improve data accuracy, reduce lead times, and optimize stock levels, leading to better decision-making and a more efficient supply chain (Shankar *et al*., 2022) [38].

In emerging markets, where the procurement process is often fragmented and lacks transparency, digital marketplaces can provide much-needed visibility and efficiency. By facilitating direct communication between buyers and suppliers, these platforms reduce the reliance on intermediaries, making the procurement process more cost-effective and less prone to delays. Additionally, digital platforms can help ensure compliance with regulatory standards by providing clear records of all transactions and ensuring suppliers meet the necessary certifications and quality standards (Ozkan, 2020) [31].

5. Conclusion and Recommendations

5.1 Summary

This paper highlights several key challenges and strategic opportunities that affect biopharmaceutical supply chains in emerging markets, particularly concerning drug formulary development. The findings underscore the importance of enhancing supply chain efficiency through technological innovations, regulatory harmonization, and improved stakeholder collaboration.

One of the primary findings is that regulatory barriers, including the variability of approval processes and intellectual property concerns, significantly hinder the timely introduction of drugs into emerging markets. Policymakers need to focus on harmonizing regulatory frameworks to expedite drug approval processes and facilitate cross-border trade. This will not only improve access to essential

medicines but also enhance the cost-efficiency of healthcare systems.

Another key finding is the logistical and infrastructure constraints that plague these regions. Inefficiencies in transportation, cold chain management, and inventory control can lead to product wastage, delays, and increased costs. The application of technologies such as IoT for real-time monitoring of temperature-sensitive products, as well as automation in warehousing and logistics, can mitigate these challenges and improve the overall efficiency of the supply chain.

Furthermore, the research highlights the importance of data-driven decision-making in optimizing drug formulary development. Healthcare providers can better forecast demand, manage inventory, and minimize waste by leveraging AI, machine learning, and big data analytics. This technological adoption can also enable more personalized care and the efficient allocation of resources, ensuring that drugs are available when and where they are needed most.

For industry leaders, adopting decentralized manufacturing models and forming public-private partnerships are crucial strategies for strengthening supply chain resilience. By localizing production and collaborating with local manufacturers, the reliance on imports can be reduced, and the cost of drugs can be minimized. Industry leaders must prioritize sustainability in procurement practices, such as engaging in bulk purchasing and value-based pricing models that align incentives and reduce procurement inefficiencies.

The implications of these findings extend to healthcare providers, who are at the frontlines of ensuring equitable access to medicines. Implementing efficient supply chain systems and integrating technology into daily operations will allow providers to offer better care, minimize stockouts, and ensure the availability of essential medications at affordable prices.

5.2 Policy Recommendations

To address the identified challenges, this paper recommends a set of policy actions to improve drug formulary development and enhance supply chain efficiency in emerging markets.

First, policymakers should focus on regulatory harmonization and adopting standardized approval pathways for pharmaceutical products. Establishing regional regulatory bodies or enhancing cooperation between national and international regulatory agencies can reduce the time and cost associated with drug approvals, ensuring that drugs are available to patients more quickly and affordably. These efforts should include creating adaptive regulatory frameworks that can keep pace with technological advancements, such as personalized medicine, gene therapies, and biologics, which require specialized regulatory oversight.

Second, governments should incentivize the adoption of digital technologies and innovations within the supply chain. This could include offering financial incentives for companies to invest in blockchain for enhanced transparency, IoT solutions for cold chain logistics, and warehouse automation. Policymakers should also invest in infrastructure improvements, such as reliable transportation networks and data centers, to ensure that technological solutions can be effectively implemented.

Additionally, policies promoting collaboration between public and private sectors—through public-private partnerships (PPPs)—should be prioritized. These partnerships can facilitate knowledge transfer, improve access to capital for local manufacturers, and create more resilient supply chains. Governments should also provide incentives for local production of essential medicines, which can help mitigate supply chain risks and reduce dependence on imports, particularly during geopolitical instability or economic crises.

Lastly, policymakers should consider implementing frameworks for sustainable procurement strategies. Bulk purchasing agreements, risk-sharing mechanisms, and value-based pricing models should be promoted to improve procurement efficiency and reduce costs. These strategies would help ensure that high-quality drugs are affordable, benefiting both healthcare providers and patients.

References

1. Abbott KW, Snidal D. The governance triangle: Regulatory standards institutions and the shadow of the state. In: The spectrum of international institutions. Routledge; c2021. p. 52-91.
2. Abdulmalek S, Nasir A, Jabbar WA, Almuhaya MA, Bairagi AK, Khan MA-M, *et al*. IoT-based healthcare-monitoring system towards improving quality of life: A review. Paper presented at: Healthcare; c2022.
3. Algorri M, Abernathy MJ, Cauchon NS, Christian TR, Lamm CF, Moore CM. Re-envisioning pharmaceutical manufacturing: increasing agility for global patient access. J Pharm Sci. 2022;111(3):593-607.
4. Bamakan SMH, Moghaddam SG, Manshadi SD. Blockchain-enabled pharmaceutical cold chain: Applications, key challenges, and future trends. J Clean Prod. 2021;302:127021.
5. Berdud M, Chalkidou K, Dean EB, Ferraro J, Garrison L, Nemzoff C, *et al*. The future of global health procurement: issues around pricing transparency.
6. Burns L, Le Roux N, Kalesnik-Orszulak R, Christian J, Hukkelhoven M, Rockhold F, *et al*. Real-world evidence for regulatory decision-making: guidance from around the world. Clin Ther. 2022;44(3):420-437.
7. Buxton J, Bingham T. The rise and challenge of dark net drug markets. Policy brief. 2015;7(2):1-24.
8. Calder A. Assessment of potential barriers to medicines regulatory harmonization in the Southern African Development Community (SADC) region. 2016.
9. Chung YH, Church D, Koellhoffer EC, Osota E, Shukla S, Rybicki EP, *et al*. Integrating plant molecular farming and materials research for next-generation vaccines. Nat Rev Mater. 2022;7(5):372-388.
10. Dhaliwal A. The rise of automation and robotics in warehouse management. In: Transforming Management Using Artificial Intelligence Techniques. CRC Press; c2020. p. 63-72.
11. Dhiman SK, Gummadi V, Dureja H. Partnership efforts–Their potential to reduce the challenges that confront regulators and pharmaceutical industry. Appl Clin Res Clin Trials Regul Aff. 2019;6(1):7-17.
12. Ding B. Pharma Industry 4.0: Literature review and research opportunities in sustainable pharmaceutical supply chains. Process Saf Environ Prot. 2018;119:115-130.
13. Dinh H. The Revolution of Warehouse Inventory Management by Using Artificial Intelligence: Case Warehouse of Company X. 2020.

14. Edoh NL, Ukpabi UJ, Igol JO. Untargeted metabolomics profiling of high beta carotene cassava with respect to postharvest physiological deterioration. 2021.
15. Edoh NL, Ukpabi UJ, Igoli JO. Effect of scopoletin and carotenoids on postharvest physiological deterioration (PPD) of transgenic high beta carotene cassava. J Food Res. 2021;10(4):1-9.
16. Gillespie JJ, Privitera GJ, Gaspero J. Biopharmaceutical entrepreneurship, open innovation, and the knowledge economy. J Innov Manag. 2019;7(2):59-77.
17. Harrison RP, Ruck S, Medcalf N, Rafiq QA. Decentralized manufacturing of cell and gene therapies: Overcoming challenges and identifying opportunities. Cytotherapy. 2017;19(10):1140-1151.
18. Hirsch G, Trusheim M, Cobbs E, Bala M, Garner S, Hartman D, *et al*. Adaptive biomedical innovation: evolving our global system to sustainably and safely bring new medicines to patients in need. Clin Pharmacol Ther. 2016;100(6):685-698.
19. Ibrahim T, Araujo CA. Biopharmaceutical supply chain challenges in developing countries: an exploratory analysis. Paper presented at: Supply Chain Forum: An Int J; c2021.
20. Koçkaya G, Wertheimer A. Pharmaceutical market access in emerging markets: SEEd. 2016.
21. Kohler JC, Martinez MG, Petkov M, Sale J. Corruption in the pharmaceutical sector: diagnosing the challenges. 2016.
22. Ma J-Y, Shi L, Kang T-W. The effect of digital transformation on the pharmaceutical sustainable supply chain performance: The mediating role of information sharing and traceability using structural equation modeling. Sustainability. 2022;15(1):649.
23. Mackey TK, Nayyar G. A review of existing and emerging digital technologies to combat the global trade in fake medicines. Expert Opin Drug Saf. 2017;16(5):587-602.
24. Masheti C. E-procurement practices and operational performance of pharmaceutical manufacturing firms in Nairobi. University of Nairobi; c2016.
25. Mello MM. What makes ensuring access to affordable prescription drugs the hardest problem in health policy. Minn L Rev. 2017;102:2273.
26. Myles L, Church TD. An industry survey of implementation strategies for clinical supply chain management of cell and gene therapies. Cytotherapy. 2022;24(3):344-355.
27. Neumann PJ, Cohen JT, Ollendorf DA. The right price: a value-based prescription for drug costs. Oxford University Press; c2021.
28. Nguyen A, Lamouri S, Pellerin R, Tamayo S, Lekens B. Data analytics in pharmaceutical supply chains: state of the art, opportunities, and challenges. Int J Prod Res. 2022;60(22):6888-6907.
29. Organization WH. China policies to promote local production of pharmaceutical products and protect public health. World Health Organization; c2017.
30. Organization WH. Technical report: pricing of cancer medicines and its impacts: a comprehensive technical report for the World Health Assembly Resolution 70.12: operative paragraph 2.9 on pricing approaches and their impacts on availability and affordability of medicines for the prevention and treatment of cancer. 2018.
31. Ozkan N. Fostering Digital Marketplaces in Logistics and Supply Chain: Trends and Opportunities. Politecnico di Torino; c2020.
32. Panda SK, Satapathy SC. Drug traceability and transparency in medical supply chain using blockchain for easing the process and creating trust between stakeholders and consumers. Pers Ubiquitous Comput. 2021;1-17.
33. Pojani D, Stead D. Sustainable urban transport in the developing world: beyond megacities. Sustainability. 2015;7(6):7784-7805.
34. Pojani D, Stead D. The urban transport crisis in emerging economies: An introduction. Springer; c2017.
35. Ragavan S, Vanni A. Intellectual property law and access to medicines: TRIPS agreement, health, and pharmaceuticals. Taylor & Francis; c2021.
36. Sarkis M, Bernardi A, Shah N, Papathanasiou MM. Emerging challenges and opportunities in pharmaceutical manufacturing and distribution. Processes. 2021;9(3):457.
37. Seyedan M, Mafakheri F. Predictive big data analytics for supply chain demand forecasting: methods, applications, and research opportunities. J Big Data. 2020;7(1):53.
38. Shankar V, Grewal D, Sunder S, Fossen B, Peters K, Agarwal A. Digital marketing communication in global marketplaces: A review of extant research, future directions, and potential approaches. Int J Res Mark. 2022;39(2):541-565.
39. Sharma DK, Gupta P. Internet of Things: The new Rx for pharmaceutical manufacturing and supply chains. In: An Industrial IoT Approach for Pharmaceutical Industry Growth. Elsevier; c2020. p. 257-288.
40. Shashi M. Digital Strategies to improve the performance of pharmaceutical supply chains. Walden University; c2022.
41. Singh RK, Kumar R, Kumar P. Strategic issues in pharmaceutical supply chains: a review. Int J Pharm Healthcare Mark. 2016;10(3):234-257.
42. Smyth SJ, Webb SR, Phillips PW. The role of public-private partnerships in improving global food security. Global Food Sec. 2021;31:100588.
43. Sople VV. Managing intellectual property: The strategic imperative. PHI Learning Pvt. Ltd.; c2016.
44. Sun Y, Ali SI. Internet of things (IoT) and blockchain applications in pharmaceutical supply chain provenance to achieve traceability, transparency, and authenticity. In: Advancing Smarter and More Secure Industrial Applications Using AI, IoT, and Blockchain Technology. IGI Global; c2022. p. 1-36.
45. Tusé D, Nandi S, McDonald KA, Buyel JF. The emergency response capacity of plant-based biopharmaceutical manufacturing-what it is and what it could be. Front Plant Sci. 2020;11:594019.
46. Vogler S, Zimmermann N, Haasis A, Babar-Ud-Din Z, Busse R, Espin Balbino J. Can pharmaceutical pricing and reimbursement policies make a difference in promoting equitable access to affordable medicines? From diagnosis to sustainable impact. Editorial. 2019.
47. Wang Y, Kung L, Wang WY-C, Cegielski CG. An integrated big data analytics-enabled transformation model: Application to health care. Inf Manag. 2018;55(1):64-79.
48. Winegarden W. Improving market efficiencies will promote greater drug affordability. Pacific Research

Institute; c2020. Available from: https://www.pacificresearch.org/wp.
49. Yoo S-L, Kim D-J, Lee S-M, Kang W-G, Kim S-Y, Lee JH, *et al*. Improving patient access to new drugs in South Korea: evaluation of the national drug formulary system. Int J Environ Res Public Health. 2019;16(2):288.
50. Zhu X, Ninh A, Zhao H, Liu Z. Demand forecasting with supply-chain information and machine learning: Evidence in the pharmaceutical industry. Prod Oper Manag. 2021;30(9):3231-3252.