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A Market Access Optimization Model for New Drug Indications in Emerging Pharmaceutical Markets

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Abstract
Expanding market access for new drug indications in emerging pharmaceutical markets presents a multifaceted challenge that spans regulatory, economic, and health system dimensions. These markets—characterized by diverse health policies, limited healthcare budgets, and heterogeneous regulatory environments—require tailored strategies to ensure timely and equitable access to therapeutic innovations. This proposes a Market Access Optimization Model designed to facilitate the strategic introduction of new drug indications within such complex and evolving landscapes. The model integrates key components of market access strategy, including regulatory alignment, value-based evidence generation, stakeholder engagement, and adaptable pricing frameworks. Using a data-driven and modular approach, it combines health technology assessment (HTA) principles with multi-criteria decision analysis (MCDA), epidemiological modeling, and budget impact simulations to optimize launch sequencing and market entry strategies. The model is designed to be context-sensitive, incorporating country-specific health infrastructure, disease burden, payer priorities, and socio-economic indicators to guide decision-making. Application scenarios across oncology, infectious diseases, and rare diseases in Latin America, Southeast Asia, and Sub-Saharan Africa demonstrate how the model supports pharmaceutical firms in prioritizing markets, customizing value propositions, and navigating reimbursement negotiations. Additionally, the framework provides policy makers and regulators with a structured approach to evaluate and accelerate the introduction of clinically relevant indications while safeguarding health system sustainability. By addressing key challenges—such as data fragmentation, pricing uncertainty, and regulatory heterogeneity—this model advances a pragmatic and scalable solution for improving access to medicines in low- and middle-income countries. This concludes with recommendations for cross-sector collaboration, digital innovation, and the use of real-world evidence to enhance adaptive decision-making. Ultimately, the Market Access Optimization Model serves as a strategic tool for aligning industry goals with public health objectives, fostering more inclusive and efficient access to innovative therapies in emerging pharmaceutical markets.

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Keywords: Market access, Optimization model, New drug, Indications, Emerging pharmaceutical markets

1. Introduction

Emerging pharmaceutical markets—comprising regions such as the BRICS (Brazil, Russia, India, China, South Africa), the Middle East and North Africa (MENA), and Sub-Saharan Africa—are experiencing substantial growth in both pharmaceutical demand and healthcare infrastructure development (Otokiti *et al*., 2022; Ibidunni *et al*., 2022). These markets collectively represent a significant share of the global population and an increasing burden of non-communicable and infectious diseases (Onalaja and Otokiti, 2022; OLUDARE *et al*., 2022).

As access to healthcare services improves and the demand for innovative therapies rises, emerging markets are becoming increasingly attractive to multinational pharmaceutical companies seeking to expand their global reach (Ogeawuchi *et al*., 2022; Ogeawuchi *et al*., 2022).

However, while the initial approval and commercialization of new drugs in these regions is often prioritized, the introduction of new indications for already approved drugs presents unique challenges (Agboola *et al*., 2022; Fagbore *et al*., 2022). These challenges stem from a combination of scientific, regulatory, economic, and infrastructural factors. Unlike high-income countries where health technology assessment (HTA) systems and centralized reimbursement frameworks guide the uptake of new indications, many emerging markets lack streamlined processes (Fagbore *et al*., 2022; Ogeawuchi *et al*., 2022). This results in delays or inconsistencies in access to potentially life-saving therapies for expanded patient populations.

Furthermore, the value of new indications—particularly those that address niche or chronic conditions—is often difficult to communicate effectively in environments with limited real-world data collection, low health literacy, or underdeveloped pharmacoeconomic frameworks (Adewuyi *et al*., 2022; Nwangele *et al*., 2022). As a result, even when regulatory approval is granted, uptake remains slow or highly variable across regions, impeding both public health outcomes and commercial sustainability.

The successful launch of new drug indications in emerging markets is hindered by several structural and systemic obstacles. Regulatory barriers include prolonged approval timelines, lack of harmonization across countries, and limited pathways for accelerated or conditional approvals for expanded indications. Even when approvals are secured, pricing and reimbursement challenges often prevent timely access (Esan *et al*., 2022; Ubamadu *et al*., 2022). Many governments and insurers are reluctant to cover new indications without clear cost-effectiveness data, which may be difficult to generate locally due to data scarcity or methodological limitations (Oluoha *et al*., 2022; Kisina *et al*., 2022).

Moreover, emerging markets exhibit fragmented market environments. Health systems in these regions are characterized by heterogeneity in terms of financing models, coverage schemes, provider capacities, and patient access. In countries like Nigeria or India, for example, public-private healthcare dichotomies create disparate access realities, with patients in rural or low-income settings remaining underserved despite national policy efforts (Oluoha *et al*., 2022; Akpe *et al*., 2022). This fragmentation complicates market access strategies that depend on uniform pricing, centralized decision-making, or nationwide promotional campaigns.

These challenges collectively constrain the ability of pharmaceutical firms to maximize the reach and impact of new indications, while also limiting patient access to potentially transformative treatments. There is thus an urgent need for a structured, evidence-informed, and adaptable framework that can guide access decisions in the face of regulatory complexity, economic constraints, and health system diversity (Oluoha *et al*., 2022; Ogeawuchi *et al*., 2022).

The primary objective of this review is to propose and detail a Market Access Optimization Model tailored to the introduction of new drug indications in emerging pharmaceutical markets. The model is designed to assist pharmaceutical companies, payers, and policymakers in identifying the most efficient and equitable strategies for launching new indications in diverse and resource-constrained settings. It integrates data-driven methodologies—such as multi-criteria decision analysis (MCDA), cost-effectiveness modeling, and epidemiological mapping—with context-sensitive approaches to pricing, stakeholder engagement, and value demonstration.

Rather than offering a one-size-fits-all solution, the model provides a modular and adaptable framework that accommodates local variability in regulatory maturity, healthcare financing, disease burden, and economic capacity (Ogeawuchi *et al*., 2022; Uzozie *et al*., 2022). It also includes strategic tools for prioritizing countries or regions based on readiness and potential impact, enabling companies to sequence launches effectively and allocate resources judiciously.

The significance of this model lies in its ability to address a major gap in current pharmaceutical access strategies: the lack of tailored approaches for new indication launches in low- and middle-income settings. For pharmaceutical companies, the model offers a pathway to optimize global development strategies, improve lifecycle management of existing products, and realize commercial returns in underutilized markets. For payers and policymakers, it provides a structured methodology for evaluating the clinical, economic, and societal value of new indications and supports informed resource allocation within constrained budgets.

More broadly, the model advances the global health equity agenda by promoting timely, affordable, and data-informed access to medical innovations. It empowers stakeholders in emerging markets to move beyond reactive, fragmented decision-making toward proactive, strategic, and evidence-based planning for indication-specific access (Esan *et al*., 2022; Ojika *et al*., 2022). By aligning market access strategies with local realities and stakeholder needs, this framework fosters sustainable health system strengthening and contributes to universal health coverage goals.

2. Methodology

This systematic review followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) methodology to ensure a transparent and replicable process for identifying, selecting, and synthesizing relevant literature concerning market access optimization models for new drug indications in emerging pharmaceutical markets. The aim was to consolidate multidisciplinary evidence that informs strategies to enhance access, affordability, and uptake of novel therapies within regulatory, economic, and healthcare delivery contexts unique to emerging economies.

A comprehensive literature search was conducted across multiple databases including PubMed, Scopus, Web of Science, and Embase, covering the period from 2000 to 2024. Search terms included combinations of keywords such as “market access,” “drug indication expansion,” “pricing strategies,” “regulatory approval,” “HTA in emerging markets,” and “pharmaceutical access models.” Boolean operators and controlled vocabulary (e.g., MeSH terms) were used to refine search precision. Additional grey literature, including WHO reports, policy briefs, and regional regulatory documents, was also reviewed to ensure inclusion of practical and region-specific insights.

The identification process yielded 536 records. After

removing 112 duplicates, 424 articles remained for screening. Titles and abstracts were reviewed independently by two researchers using predefined inclusion criteria. Studies were retained if they addressed: (1) market access or commercialization strategies for new drug indications, (2) pricing and reimbursement mechanisms in low- and middle-income countries (LMICs), (3) regulatory pathways for drug expansion, or (4) cross-sectoral collaborations and health technology assessment (HTA) practices relevant to emerging markets. Articles were excluded if they focused exclusively on high-income countries, discussed only clinical efficacy without access components, or lacked empirical or conceptual depth.

This screening process resulted in 147 full-text articles selected for eligibility assessment. Each article was thoroughly reviewed to determine its methodological rigor, contextual relevance, and applicability to emerging market conditions. During this phase, an additional 71 articles were excluded for reasons such as lack of market access relevance, narrow therapeutic scope, or insufficient methodological clarity. Disagreements between reviewers were resolved through consensus discussions or adjudicated by a third reviewer to maintain consistency and objectivity.

Ultimately, 76 studies were included in the final synthesis. These articles were analyzed using a narrative synthesis approach and organized thematically into key domains: regulatory alignment and indication-specific approval pathways; innovative pricing strategies (e.g., value-based pricing, risk-sharing agreements); stakeholder engagement models involving payers, providers, and manufacturers; and frameworks for adaptive HTA in resource-constrained settings. The synthesis highlighted critical success factors such as early dialogue with regulators, local burden-of-disease evidence generation, and dynamic pricing models linked to real-world outcomes.

The PRISMA-guided review enabled a rigorous and comprehensive examination of the multifaceted elements influencing market access for new drug indications in emerging markets. It underscored the importance of aligning regulatory science, economic evaluation, and stakeholder collaboration to overcome access barriers. This evidence base supports the design of a market access optimization model that is context-sensitive, data-informed, and capable of accelerating the equitable delivery of new therapies in underserved regions.

2.1 Literature Review

The globalization of pharmaceutical innovation has intensified the need for efficient and equitable market access strategies, especially as new drug indications are developed and expanded beyond their original scope. While developed markets have well-defined regulatory and reimbursement infrastructures that support streamlined access for new indications, emerging markets present a more fragmented and resource-constrained landscape (Ojika *et al*., 2022; Adelusi *et al*., 2022). This literature review synthesizes existing research on market access pathways, highlights specific challenges facing emerging economies, and evaluates optimization approaches including health technology assessment (HTA), adaptive pricing models, and data-driven strategies to enhance uptake of novel therapies.

Market access refers to the set of activities undertaken by pharmaceutical companies to ensure that patients can obtain new treatments under sustainable pricing and reimbursement conditions. In developed markets such as the United States, United Kingdom, Germany, and Japan, regulatory pathways for label expansions are well-structured. New indications for approved drugs often follow established routes such as supplemental new drug applications (sNDAs) or Type II variations, and are supported by mature health technology assessment bodies like NICE (UK), IQWiG (Germany), and ICER (US). These agencies evaluate clinical effectiveness, cost-effectiveness, and budget impact to inform pricing and reimbursement decisions. Access in these settings is further facilitated by robust payer frameworks, early scientific advice procedures, and post-marketing evidence generation protocols.

In contrast, emerging markets, including those in sub-Saharan Africa, Southeast Asia, and parts of Latin America, are characterized by heterogeneous regulatory systems and limited HTA capacity. Market access for new drug indications in these regions often depends on fragmented approval processes, variable data requirements, and less transparent pricing mechanisms. While some middle-income countries (e.g., Brazil, China, and South Africa) have begun integrating HTA into decision-making, many others continue to rely on basic pharmacoeconomic analyses or reference pricing benchmarks without formalized frameworks (Ojika *et al*., 2022; Adelusi *et al*., 2022). Consequently, the time lag between global approval of new indications and their availability in emerging markets can be extensive, contributing to inequitable health outcomes.

A major challenge in emerging pharmaceutical markets is the inconsistency and unpredictability of regulatory pathways for new indications. Unlike mature regulatory environments with harmonized standards and mutual recognition procedures, emerging markets often operate under country-specific rules that complicate multi-country submissions. For example, while the World Health Organization's Collaborative Registration Procedure aims to accelerate access by leveraging prior approvals, uptake remains limited in many regions due to bureaucratic inertia, limited capacity, and sovereignty concerns.

Budget impact constraints further complicate market access efforts. Payers in emerging economies often face significant financial limitations, forcing them to prioritize access based on short-term cost containment rather than long-term value. New indications—particularly those involving oncology, rare diseases, or biologics—are often deprioritized unless subsidized by external programs or donor funding. Additionally, the lack of dedicated funds for innovative therapies means that even when regulatory approval is granted, reimbursement may be delayed or denied due to affordability concerns (Olajide *et al*., 2022; Olawale *et al*., 2022).

Another critical barrier is the growing expectation for local clinical evidence. Health authorities in several emerging countries increasingly demand local real-world evidence (RWE), pharmacovigilance data, or subpopulation-specific clinical trials before approving new indications. This requirement can be particularly burdensome for manufacturers, as conducting localized studies adds time and cost, and may not be scientifically necessary in the context of global evidence. Yet, from the perspective of local regulators, such data are crucial for ensuring clinical relevance, public trust, and optimal resource utilization. The lack of centralized infrastructure for data collection further exacerbates these challenges, hindering evidence-based policy formulation and

delaying patient access.

To address these challenges, several optimization strategies have been proposed and, in some cases, piloted across emerging markets. One of the most significant advancements is the incorporation of health technology assessment (HTA) into national decision-making processes. HTA provides a structured approach for evaluating the clinical, economic, and social value of new therapies. Countries such as Thailand, Colombia, and Egypt have begun institutionalizing HTA units to guide pricing and reimbursement decisions for new indications. While institutional capacity remains variable, HTA offers a promising platform for balancing innovation and affordability (Olajide *et al*., 2022; Olawale *et al*., 2022).

Adaptive and risk-sharing pricing models are also gaining traction. These include value-based pricing, where reimbursement is tied to patient outcomes, and managed entry agreements (MEAs), which allow for conditional reimbursement while additional data are collected. For instance, outcome-based agreements for oncology drugs have been tested in South Africa and Turkey, providing precedent for broader application. Such models require robust data infrastructure and strong payer-manufacturer collaboration, but they represent a pragmatic way to reduce uncertainty and enable early access.

Data-driven decision-making is another critical enabler. Emerging markets are increasingly investing in electronic health record systems, centralized procurement platforms, and real-world data analytics to support regulatory and access decisions. These tools enable better forecasting of budget impact, population-level disease burden analysis, and monitoring of post-launch drug performance. Machine learning models, for example, are being explored to predict utilization patterns and guide pricing negotiations for new indications. Furthermore, regional platforms like the African Medicines Agency (AMA) and the ASEAN Pharmaceutical Regulatory Framework hold potential for harmonizing access protocols, pooling clinical data, and fostering collaborative market entry strategies.

The literature highlights that market access for new drug indications in emerging markets is shaped by a confluence of regulatory complexity, economic constraints, and data availability. While structural limitations persist, the adoption of HTA, innovative pricing models, and analytics-based decision-making offers a pathway to optimize access and reduce inequities (Onukwulu *et al*., 2022; Olajide *et al*., 2022). Future policy and research should prioritize capacity-building in HTA, investment in digital infrastructure, and regional harmonization to enhance the timely availability of new therapies in underserved regions.

2.2 Conceptual Framework

The Market Access Optimization Model for new drug indications in emerging pharmaceutical markets is grounded in the intersection of evidence-based strategy, stakeholder coordination, and adaptive implementation. Recognizing the diverse challenges across low- and middle-income countries (LMICs), the model incorporates both core structural components and mechanisms for dynamic integration with local market realities as shown in figure 1(Okon *et al*., 2022; Agboola *et al*., 2022). This framework offers a holistic, modular, and context-sensitive approach for improving the uptake, affordability, and sustainability of new indications, particularly where health systems are fragmented or under-resourced.

Regulatory heterogeneity is one of the most significant barriers to new indication access in emerging markets. The optimization model emphasizes early and strategic regulatory alignment, ensuring that approval processes for new indications are planned in parallel with development milestones. This involves mapping out regional and national regulatory frameworks and identifying opportunities for accelerated pathways such as conditional approvals, fast-track reviews, or reliance on approvals from trusted reference authorities (e.g., EMA, FDA).

Moreover, the model encourages regulatory harmonization efforts, such as participation in regional initiatives like the African Medicines Agency (AMA) or ASEAN Joint Assessment procedures. By aligning regulatory strategies across multiple markets, companies can reduce time-to-market and duplication of effort. Simultaneously, early dialogue with regulators allows for the tailoring of evidence packages—such as local subpopulation data or real-world evidence—to meet market-specific requirements.

A central pillar of the framework is robust and localized value demonstration. This includes clinical evidence (efficacy, safety, and comparative effectiveness), pharmacoeconomic data (cost-effectiveness, budget impact), and broader societal contributions (productivity gains, public health externalities, equity improvements).

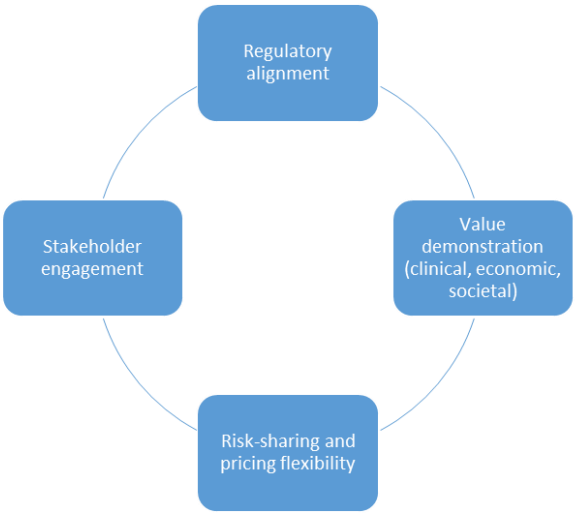

Fig 1: Core Components of the Optimization Model

In markets with nascent or non-existent HTA bodies, the model advocates for early scientific advice or collaborative HTA development with local institutions or academic partners. Where formal HTA is not yet feasible, simplified decision-support tools, such as cost-consequence matrices or disease burden overlays, can be applied to frame discussions with payers and policymakers (Onifade *et al*., 2022; Kufile *et al*., 2022). The model also promotes the use of adaptive evidence generation, incorporating real-world data (RWD) and observational studies post-launch to refine the value proposition over time.

Stakeholder engagement is critical to the success of new indication launches in emerging markets, where decision-making often involves a wide range of actors including regulators, health ministries, payer agencies, healthcare providers, patient advocacy groups, and non-governmental organizations. The model includes structured mechanisms for multi-stakeholder engagement, beginning with stakeholder mapping and segmentation to understand influence dynamics

and decision-making processes.

Engagement strategies should be inclusive, culturally attuned, and sustained throughout the product lifecycle. Early interactions with national formulary committees, budget holders, and health insurance schemes can identify barriers to inclusion and unlock co-development opportunities. Additionally, patient advocacy involvement can help shape value narratives and ensure that access strategies resonate with end-user concerns and cultural preferences.

The model supports the creation of local advisory boards or access coalitions to provide ongoing input, disseminate evidence, and foster collaborative problem-solving (Kufile *et al*., 2022; Onifade *et al*., 2022). These structures enhance transparency, trust, and alignment around shared access goals.

Given the budget constraints in many emerging markets, the optimization model emphasizes the need for flexible and equitable pricing strategies, including risk-sharing arrangements, tiered pricing, volume-based discounts, and outcomes-based contracts.

Risk-sharing mechanisms—such as pay-for-performance or indication-specific pricing—can align incentives between manufacturers and payers by linking reimbursement to demonstrated clinical or economic outcomes. In countries with limited HTA capacity, managed entry agreements (MEAs) can offer a pragmatic interim solution, allowing conditional access while further data is gathered.

To ensure affordability and avoid access disparities, the model encourages GDP-indexed pricing models and differential access frameworks that reflect both the country's economic status and disease burden. These approaches must be underpinned by transparent methodologies to build trust with governments and civil society (Kufile *et al*., 2022; Ogunnowo *et al*., 2022).

Emerging pharmaceutical markets are marked by high heterogeneity in terms of health system maturity, fiscal capacity, and epidemiological profiles. The Market Access Optimization Model is designed to adapt to these conditions by embedding local data, priorities, and capabilities into decision-making.

The model first assesses health system readiness, including infrastructure for diagnosis, treatment delivery, pharmacovigilance, and data collection. For example, if a new oncology indication requires biomarker testing, the model identifies whether diagnostic platforms are available and, if not, recommends partnerships or investment plans to bridge capacity gaps.

Capacity assessments inform the sequencing of market entry, prioritizing countries or regions with sufficient delivery systems to support clinical and economic success. In low-capacity environments, the model may support staged launches or pilot programs that generate local evidence and build system readiness in phases.

Economic feasibility is essential for access sustainability. The model incorporates macroeconomic indicators, such as GDP per capita, health expenditure as a percentage of GDP, and out-of-pocket spending rates, to inform pricing, affordability thresholds, and payer negotiation strategies. Tools like affordability indexes or willingness-to-pay analyses can help tailor the economic component of the value proposition to national contexts (Kufile *et al*., 2022; Ogunnowo *et al*., 2022).

In addition, the model considers financial risk protection mechanisms, such as public insurance schemes or donor-funded programs, to estimate how much of the target population can realistically access the new indication without incurring catastrophic health expenditure.

To ensure alignment with national health priorities, the optimization model integrates burden-of-disease metrics, including DALYs, incidence/prevalence rates, and unmet need assessments. By mapping the local epidemiological landscape, the model can demonstrate public health relevance, justify resource allocation, and strengthen the case for prioritization of the new indication.

In countries with limited surveillance data, the model recommends collaboration with local academic institutions, public health authorities, or international agencies (e.g., WHO, IHME) to derive estimates or conduct gap-filling studies. Prioritizing indications that align with national disease control strategies or essential medicines lists enhances policy receptiveness and accelerates uptake (Kufile *et al*., 2022; Ogunnowo *et al*., 2021).

The Market Access Optimization Model synthesizes regulatory planning, stakeholder engagement, tailored value communication, and adaptive pricing into a unified strategic framework. Its ability to integrate with local market realities ensures relevance and sustainability, supporting pharmaceutical firms and health authorities alike in expanding timely and equitable access to new drug indications in emerging markets.

2.3 Case Studies and Application Scenarios

The successful application of the Market Access Optimization Model can be illustrated through real-world and hypothetical case studies across diverse emerging markets (Gbabo *et al*., 2022; Ezeilo *et al*., 2022). These cases highlight the strategic customization of value communication, pricing, and stakeholder engagement to suit local market contexts, showcasing the model's flexibility and practical utility.

Latin American countries, including Brazil, Mexico, Argentina, and Colombia, have witnessed a steady rise in cancer prevalence, prompting increased demand for advanced oncology therapeutics. However, the high cost of biologics and targeted therapies presents significant access challenges, particularly for new indications of existing oncology drugs. Fragmented health systems—with public, private, and social security institutions operating independently—further complicate reimbursement and distribution strategies.

In this context, pharmaceutical companies have employed access sequencing based on regulatory readiness, payer openness, and institutional demand. For example, a company launching a new breast cancer indication for an existing HER2-targeted therapy may prioritize markets like Brazil and Mexico due to more mature regulatory pathways and HTA mechanisms. Simultaneously, in countries with less formalized assessment systems, early scientific advice and value communication tools such as budget impact models, patient case studies, and real-world evidence can help support inclusion in formularies.

Additionally, oncology access programs in Latin America benefit from collaboration with medical societies and patient advocacy organizations, which amplify demand and support policy engagement. Tailored value communication strategies, which emphasize not only survival benefits but also productivity gains and family burden reduction, have proven effective in securing reimbursement and broadening

access (Gbabo *et al*., 2022; Chima *et al*., 2022).

Southeast Asia faces a dual burden of infectious and non-communicable diseases, with antimicrobial resistance (AMR) presenting a growing threat. The introduction of new indications for broad-spectrum or last-line anti-infectives (e.g., carbapenems or novel cephalosporins) requires a nuanced approach due to extreme pricing sensitivity and high public-sector procurement dependence.

In countries like Indonesia, the Philippines, and Vietnam, pharmaceutical companies must work within constrained public budgets and tender-based pricing systems. Here, the optimization model supports the use of tiered pricing strategies and value-based procurement frameworks, ensuring affordability without undermining long-term sustainability.

Reimbursement negotiations are strengthened by presenting local AMR surveillance data and scenario-based cost avoidance analyses (e.g., avoided ICU admissions, reduced length of hospital stay). In Indonesia, for example, collaborative efforts between local hospitals, academic institutions, and manufacturers have led to the incorporation of new indication therapies into national guidelines through risk-sharing agreements and targeted volume guarantees (Gbabo *et al*., 2022; Ezeilo *et al*., 2022).

Moreover, co-development of diagnostic stewardship tools and training programs enhances prescriber confidence, mitigates misuse, and strengthens the rationale for public funding, particularly for restricted-use antibiotics.

Sub-Saharan Africa faces considerable challenges in accessing treatments for rare diseases, including limited diagnostics, low awareness, and absent reimbursement frameworks. Nonetheless, rising interest in health equity, donor engagement, and the establishment of regional health institutions provide a foundation for introducing access equity models for new indications.

A notable example is the expansion of enzyme replacement therapies for lysosomal storage disorders in countries like Kenya, Nigeria, and Ghana. Pharmaceutical firms have employed the optimization model by forming public-private partnerships (PPPs) with ministries of health, donor organizations, and non-governmental groups to finance treatment access and build diagnostic infrastructure.

Through access equity modeling, these programs identify the most vulnerable patient populations, assess service delivery readiness, and allocate resources using a burden-weighted index. Real-world evidence generated via regional centers of excellence supports ongoing value assessment and helps secure long-term public financing commitments (Gbabo *et al*., 2022; Chima *et al*., 2022).

Ultimately, these scenarios demonstrate how adaptive application of the Market Access Optimization Model can bridge systemic gaps, align stakeholder incentives, and sustainably expand access to new drug indications in highly variable emerging market settings.

2.4 Policy and Strategic Implications

The expansion of new drug indications into emerging markets presents both a growth opportunity for multinational pharmaceutical firms and a policy challenge for regulators aiming to ensure equitable access to innovative therapies. Market access optimization, particularly in resource-limited settings, requires strategic alignment between private sector objectives and public health goals as shown in figure 2(Chima *et al*., 2022; Ezeilo *et al*., 2022). This outlines the policy and strategic implications for key stakeholders—including pharmaceutical firms, regulatory agencies, and health technology assessment (HTA) bodies—emphasizing the critical role of digital tools and real-world evidence (RWE) in driving informed, adaptive, and sustainable access strategies.

Multinational pharmaceutical companies entering or expanding in emerging markets must adopt nuanced market access strategies grounded in segmentation, launch prioritization, and contextual adaptability. Market segmentation is essential for identifying high-priority regions based on disease burden, market potential, healthcare infrastructure, and regulatory maturity. Rather than adopting a one-size-fits-all approach, firms must classify emerging markets into clusters—such as innovation-ready (e.g., Brazil, Thailand), price-sensitive (e.g., Nigeria, Bangladesh), or donor-reliant (e.g., DRC, Haiti)—to tailor their market access strategies accordingly.

Launch prioritization should focus on balancing commercial viability with public health impact. In cases where global clinical trials demonstrate strong efficacy across diverse populations, companies can prioritize rapid entry into high-burden emerging markets using existing data. However, when significant variations in population genetics, health system capacity, or co-morbidities exist, firms may need to delay entry until local data or infrastructure supports safe and effective use. An adaptive launch sequence, coordinated with regional or sub-regional platforms, enables firms to manage risk while maximizing access.

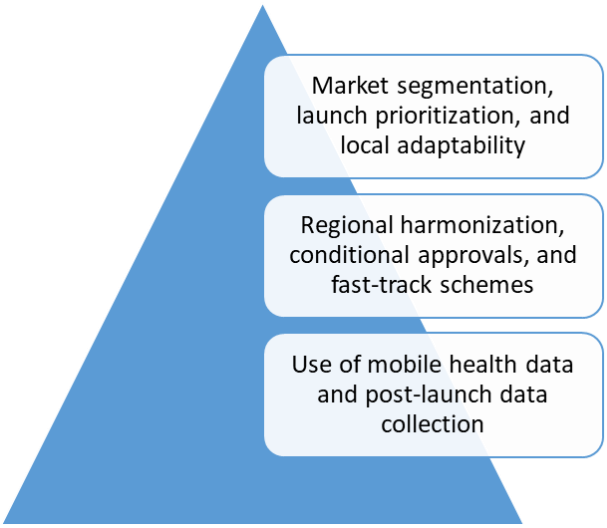

Fig 2: Policy and Strategic Implications

Local adaptability remains a cornerstone of successful market access. This involves customizing pricing models, regulatory engagement, and commercialization strategies based on country-specific needs. For instance, differential pricing or tiered cost structures—anchored in value-based metrics—can increase affordability without eroding global pricing integrity. Local partnerships with providers, public procurement agencies, and community health organizations are also vital in improving distribution, education, and uptake (Komi *et al*., 2022; Mustapha *et al*., 2022). Furthermore, building local capacity through technology transfer or clinical research investments can enhance legitimacy and long-term market presence.

For regulators and HTA agencies in emerging markets,

enabling timely and evidence-based access to new drug indications requires targeted reforms and international collaboration. One key recommendation is the harmonization of regulatory processes across regions. Platforms such as the African Medicines Agency (AMA), ASEAN Joint Assessment, and the Pan American Network for Drug Regulatory Harmonization (PANDRH) offer opportunities for shared dossier evaluations, reliance mechanisms, and common review templates. Harmonization reduces duplication, accelerates review timelines, and fosters trust in regulatory decisions.

Conditional approvals and fast-track mechanisms are also essential tools for bridging access gaps. Conditional market authorizations—where drugs receive temporary approval based on strong surrogate endpoints or preliminary evidence—can facilitate early access while additional data is gathered. Fast-track pathways, including priority review or rolling submission formats, can be particularly useful for drugs addressing high-burden or neglected diseases (Komi *et al*., 2022; Forkuo *et al*., 2022). Regulators should develop criteria to govern such pathways transparently, including post-marketing surveillance requirements and exit conditions if therapeutic benefits are not confirmed.

HTA bodies must evolve toward greater methodological flexibility and stakeholder engagement. In many emerging markets, rigid cost-effectiveness thresholds or limited local data constrain HTA effectiveness. Context-sensitive methods—such as budget impact analysis, multi-criteria decision analysis (MCDA), and deliberative processes—can offer more inclusive evaluations. HTA agencies should also build formal frameworks for early dialogue with industry, allowing for joint planning of evidence generation and risk-sharing schemes. Technical partnerships with established HTA bodies in high-income countries can support capacity-building and knowledge exchange.

Digital health technologies and real-world data are increasingly indispensable in optimizing market access, particularly in settings where traditional clinical infrastructure is lacking. Mobile health (mHealth) platforms offer a scalable solution for both data collection and patient engagement. In countries with high mobile phone penetration, apps and SMS-based systems can capture medication usage, adverse events, and treatment outcomes. These platforms provide a cost-effective way to generate real-time, patient-level data that can inform post-launch evaluations and pricing negotiations.

Post-launch data collection through electronic health records (EHRs), insurance claims, and pharmacovigilance platforms enhances the regulatory and payer landscape. RWE enables dynamic assessment of drug effectiveness in routine clinical settings, offering critical insights into adherence, therapeutic variability, and population-specific outcomes. For regulators, this information supports adaptive licensing and ongoing benefit-risk assessments. For HTA bodies, RWE augments traditional trial data, helping to evaluate long-term value and refine coverage decisions.

Artificial intelligence (AI) and machine learning tools further amplify the utility of digital data by identifying usage patterns, risk profiles, and predictive outcomes (Oladuji *et al*., 2022; Ajuwon *et al*., 2022). For example, predictive models can forecast the budget impact of indication expansion, simulate treatment pathways, and support scenario planning for policy interventions. Cloud-based dashboards integrating RWE, market analytics, and regulatory timelines can streamline decision-making across stakeholder groups.

To maximize the impact of digital and RWE tools, governments and industry must invest in data infrastructure, governance protocols, and workforce training. Interoperability standards, ethical data use policies, and patient consent mechanisms are critical to ensure data quality and public trust. Furthermore, global health organizations and development partners can play a catalytic role by funding pilot projects, supporting open-source tools, and disseminating best practices.

The strategic and policy implications of optimizing market access for new drug indications in emerging pharmaceutical markets are multifaceted. For pharmaceutical firms, success hinges on granular market segmentation, evidence-informed launch planning, and deep local engagement. Regulators and HTA bodies must embrace regulatory convergence, conditional approval pathways, and flexible evaluation frameworks to foster timely access. Simultaneously, digital health technologies and real-world evidence collection stand as powerful enablers of agile, data-driven decision-making (Oladuji *et al*., 2022; Ajuwon *et al*., 2022). A coordinated, cross-sectoral approach—rooted in innovation, transparency, and equity—will be essential to ensure that life-saving therapies reach those who need them most, regardless of geography or income.

2.5 Challenges and Limitations

While the Market Access Optimization Model for new drug indications in emerging pharmaceutical markets presents a structured and adaptive approach to expanding therapeutic reach, several challenges and limitations must be acknowledged (Oyedele *et al*., 2022; Ajayi and Akanji, 2022). These constraints impact model implementation, reliability, scalability, and long-term sustainability as shown in figure 3. The most critical issues include data gaps and uncertainty, political and economic volatility, and ethical and equity considerations.

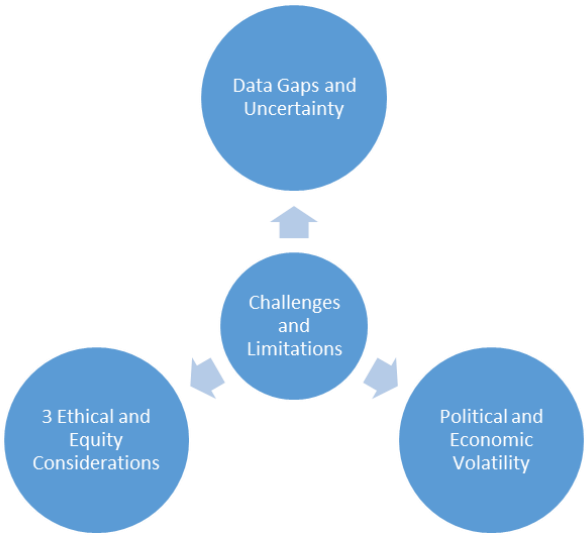

Fig 3: Challenges and Limitations

One of the most persistent limitations in emerging markets is the scarcity of real-world data (RWD) and local economic evidence. The model relies heavily on robust epidemiological, clinical, utilization, and cost-effectiveness data to support decision-making and value demonstration.

However, many low- and middle-income countries (LMICs) lack systematic data collection systems such as electronic health records (EHRs), integrated claims databases, or national health registries. This data deficiency impedes the generation of context-specific health technology assessments (HTAs), budget impact analyses, and comparative effectiveness studies that are essential for informed pricing and reimbursement decisions.

Additionally, available data are often fragmented across public and private sectors, outdated, or incomplete, leading to significant uncertainty in model outputs. For example, estimating the incidence of a rare disease or the treatment pathway of a newly indicated oncology drug may require assumptions based on global averages or surrogate populations, potentially reducing the accuracy and local relevance of the model. Similarly, patient adherence rates, treatment switching patterns, and healthcare resource utilization are often untracked, limiting the ability to simulate real-world performance and cost-effectiveness accurately.

To address these gaps, the model must incorporate uncertainty ranges and adopt probabilistic sensitivity analyses to test different assumptions. Moreover, partnerships with academic institutions, health ministries, and multilateral organizations can support capacity building in health data infrastructure, enabling more reliable and timely evidence generation in the future (Ajayi and Akanji, 2022; Matthew *et al*., 2022).

Emerging markets are frequently subject to political instability and macroeconomic shocks, which pose significant risks to the consistent implementation of access strategies. Fluctuating currencies, inflation, civil unrest, and sudden policy changes can derail even well-planned market access initiatives. For instance, currency depreciation may make imported medicines unaffordable overnight, while sudden healthcare budget reallocations due to pandemics or natural disasters can lead to reimbursement delays or cancellations.

Additionally, healthcare budgets in LMICs are often limited and vulnerable to external economic pressures, such as debt crises or shifts in donor funding priorities. As a result, ministries of health and insurance providers may deprioritize funding for new drug indications perceived as costly or non-essential, regardless of their clinical value. In highly volatile environments, governments may impose price controls, increase import tariffs, or suspend regulatory approvals, disrupting long-term planning for pharmaceutical companies. The optimization model must therefore include scenario planning tools to account for political and economic contingencies. Flexible pricing mechanisms, such as tiered pricing or managed entry agreements, can help absorb some of the financial risk for both manufacturers and governments. Furthermore, strong engagement with local policymakers and regional bodies can facilitate more stable, resilient access frameworks.

While the optimization model seeks to expand access efficiently, it also must confront ethical challenges related to fairness, inclusivity, and transparency. One major concern is the potential for access disparities, especially when companies prioritize wealthier or more urbanized segments of emerging markets to maximize return on investment. This selective approach may unintentionally exacerbate health inequities, leaving rural, low-income, or marginalized populations underserved.

In particular, the introduction of differential pricing strategies—though effective in enhancing affordability—must be carefully designed to avoid unintended consequences. For example, pricing drugs at different levels based on GDP or market size can lead to cross-border arbitrage or perceived discrimination, especially if transparency is lacking. Patients and civil society groups may question why the same treatment is priced differently across neighboring countries or even within the same country, undermining trust in pharmaceutical stakeholders (Ajonbadi *et al*., 2014; Otokiti *et al*., 2021).

Moreover, in the absence of strong regulatory oversight, risk-sharing agreements and outcomes-based pricing may favor better-resourced regions that can collect data and meet contract terms, leaving others behind. To ensure equitable impact, the model must include access equity metrics to monitor the distribution of benefits across populations. Engagement with local communities, patient groups, and public health advocates is critical for designing culturally appropriate and socially inclusive interventions.

Additionally, informed consent and data privacy remain key ethical issues when collecting RWD to support new indication access. Many LMICs have underdeveloped legal frameworks for data governance, raising concerns about exploitation or misuse of patient information. Companies must adhere to international standards and work with local authorities to build ethical data ecosystems that respect autonomy and confidentiality.

While the Market Access Optimization Model provides a promising pathway for expanding new drug indications in emerging markets, it must be applied with a clear-eyed understanding of its limitations. Addressing data scarcity, navigating economic instability, and embedding ethical safeguards are essential to realizing its full potential. Building trust, transparency, and local capacity will be key to sustaining access and achieving equitable health outcomes. Only through iterative refinement, collaborative governance, and shared accountability can the model evolve into a truly transformative tool for global pharmaceutical equity (Akinbola, O.A. and Otoki, 2012; Lawal *et al*., 2014).

Conclusion and Future Directions

This has proposed a market access optimization model designed to improve the entry of new drug indications into emerging pharmaceutical markets. Rooted in the principles of regulatory adaptability, stakeholder engagement, and data-driven decision-making, the model provides a flexible and scalable tool to streamline the often fragmented and delayed access pathways faced by new therapies in resource-limited settings. By incorporating health technology assessment (HTA), real-world evidence (RWE), and adaptive pricing frameworks, the model aligns pharmaceutical innovation with public health priorities, ensuring that medical advances are both clinically impactful and economically viable.

A key contribution of the model lies in its adaptability across different regulatory and economic environments. In contrast to rigid, one-size-fits-all approaches, this model supports customized market access strategies based on local infrastructure, disease burden, and policy capacity. Whether implemented in upper-middle-income countries with semi-mature HTA systems or low-income nations reliant on donor funding and parallel importation, the model facilitates an evidence-informed and context-sensitive pathway for the timely deployment of new drug indications. It also promotes a lifecycle view of access, incorporating early planning, launch sequencing, and post-market surveillance into a

unified operational framework.

To fully realize the potential of such a model, broad cross-sector collaboration is essential. Market access is not a siloed process but a convergence point for diverse actors, including multinational pharmaceutical firms, national regulatory authorities, payer organizations, and global health institutions. Industry actors bring innovation, technical expertise, and global evidence; governments contribute policy alignment and stewardship; while international agencies and NGOs provide the financial and technical resources necessary to bridge capacity gaps. The engagement of civil society, patient groups, and healthcare providers further ensures that access strategies are inclusive, equitable, and socially accountable. A coordinated approach among these stakeholders can accelerate harmonization, reduce duplication, and create shared value in the pursuit of public health goals.

Looking ahead, several research directions can enhance and extend the functionality of this market access optimization model. First, the integration of artificial intelligence (AI) and machine learning algorithms into forecasting processes can significantly improve the precision of demand estimation, budget impact analysis, and pricing simulations. AI-driven tools can identify optimal entry points and flag regions where early engagement may yield the greatest clinical and commercial returns. Second, decentralized and mobile-enabled data collection systems offer a promising means of gathering real-time evidence from diverse geographies, especially in settings where formal health information systems are underdeveloped. Leveraging mobile health (mHealth) platforms, wearable devices, and patient-reported outcomes can provide granular insights into treatment patterns and health outcomes.

Third, future research should focus on the design and evaluation of adaptive pricing strategies that account for uncertainty, local willingness to pay, and dynamic population needs. These may include risk-sharing agreements, indication-specific pricing, or volume-based discounts, which can make high-value therapies more accessible while safeguarding sustainability. Comparative case studies, randomized implementation trials, and collaborative modeling exercises will be essential in validating these strategies in diverse country contexts.

In conclusion, the proposed market access optimization model represents a forward-thinking approach to aligning drug development with global equity. Its flexible architecture, combined with a call for cross-sectoral collaboration and a robust research agenda, offers a pragmatic pathway for ensuring that new drug indications reach patients in emerging markets faster and more fairly. As pharmaceutical innovation accelerates, it is imperative that access models evolve in parallel—grounded in data, driven by partnership, and committed to health system resilience.

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