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Drug development and regulatory challenges in emerging markets: investigate the unique challenges faced by pharmaceutical companies when developing and commercializing drugs in emerging markets, including regulatory hurdles, pricing pressures, and market access issues

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ABSTRACT

The developing markets for pharmaceutical industry demand attention to standardise practices and impede challenges associated with development of pharmaceutical industry to address localised demand and increased need of globalisation to ensure revenue for the company. However, there are significant challenges associated with pharmaceutical industry's expansion in a local economy which includes regulatory bodies, pricing pressures, and market access issues to commercialise their respective drugs. As a result, the study embraced the usage of content analysis in pursuit to incorporate the extensive secondary literature available on the diversified market around the world while analysing their challenges associated with commercialisation of the drugs. The findings of the study revealed that the regulatory bodies play a major role in depicting the growth rate of the industry. Furthermore, regulations such as clinical trials, documentation and other formalisation associated with regulatory practices hinder the companies to register new drugs in developing markets. Pricing strategies were found to be another limiting factors which increased the risk associated with pharmaceutical industries as well. Thus, the research concluded that the pharmaceutical industry in developing markets face a series of challenges that should be marginalised in pursuit to empower their growth in localised economy.

Keywords: Pharmaceutical Industry, Developing Markets, Regulatory Practices, Pricing, Challenges of Pharmaceutical Industry

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Chapter 1: Introduction

1.1 Background

Emerging markets have a large population and increasing income levels and, therefore, present significant opportunities for the pharmaceutical sector as a prolific environment prevails within those countries, and this presents opportunities for the pharmaceutical sector (Tannoury and Attieh, 2017). These markets also present challenges to new drug development and business strategies regarding drug development and commercialisation. One important consideration is that there is likely to be a different regulatory environment in the various countries. Emerging markets are only sometimes well-developed with regulatory authorities such as the FDA, which gives clear instructions and guidelines. Regulatory specifications for clinical trials, licensing, quality control checks, and other regulatory procedures can vary from country to country, and to handle such dispersed and disparate situations, more manpower and knowledge are required (Ndebele et al. 2014). It also creates questions of transparency when recommendations and policies are only sometimes easily detectable.

Furthermore, price regulation similarly cuts down pharmaceutical revenues in many emerging markets as well. Currently, governments use methods such as reference pricing, whereby they compare the price paid for the drugs against what other markets have been charged (Verghese et al. 2019). This system seeks to freeze the prices at the lower tier across the world, which reduces revenues significantly, mainly when a large amount of money has been spent on research and development for initial higher-end markets within. Direct price controls are also directly applied by some countries (Galizzi et al. 2011). Most of these countries have a relatively high dependence on out-of-pocket private expenditure rather than adequate insurance with a significant presence (Al-Hanawi et al. 2021). The majority of individuals have low per capita income; they bear the cost of health care directly. They can only afford expensive innovative drugs if they are reimbursed adequately by insurance or if they receive discounts (Ocran Mattila et al. 2021).

Intellectual property (IP) infringement is a significant challenge in many emerging markets. Some countries impose barriers on foreign direct investment (FDI) in domestic healthcare, requiring local partnerships or licensing, which can limit market entry strategies (Anyanwu, 2012). The issue of piracy further hampers the investment climate in these markets, reducing the incentive for pharmaceutical companies to operate (Fink et al. 2016). While some

jurisdictions have implemented robust IP laws as per trade agreements, more effective enforcement is needed to allow rogue domestic operations to manufacture and sell counterfeit drugs, undermining the efforts to protect IP rights (Pathak et al., 2023).

However, a lack of adequate IP coverage reduces prospective revenues on R&D initiatives directed towards the needs of developing markets (Chen, 2022). This implies that emerging pharmaceutics continues to encounter remarkable challenges in various sections, such as protean regulations, high price restraints, market entry hurdles, and IP infringement in emerging economies (Schweitzer et al. 2018). These factors require an increased organisational commitment to address these challenges through increased ground-up regulatory expenditure, adaptable IP management, differential pricing structures, and local strategic alliances within those markets.

1.2 Problem statement

It is widely acknowledged that emerging markets offer immense growth prospects to pharmaceutical firms as rising income leads to more demands for new products and a stream of development. However, these markets also present numerous issues about rules, costs, and outlets. It leads to one of the significant research gaps regarding how the regulatory systems of various countries, as well as the approvals required for the products, affect the functioning of multinational firms in emerging markets. Regulations of clinical evidence and reviews differ significantly, and their complexity puts pharmaceutical companies in a position where they must navigate through complex networks (Chisholm and Critchley, 2023). Also, the requirements set directly by the regulatory bodies are often dynamic and can shift in the blink of an eye.

There is also a need for more research on how to address the challenges of meeting new and ever-changing regulations in emerging markets for efficient and effective clinical trials, manufacturing, distribution channels, and marketing. While most studies are done in developed markets, the regulation of emerging markets has yet to be explored to the same extent (Hoskisson et al., 2013). A second area of future research relates to the global utilisation of a system that has been adopted widely in emerging markets, known as international reference pricing (IRP), which sets prices relative to a given international benchmark (Sullivan et al., 2022). However, the literature presents conflicting information on how IRP influences market access, company margins, and early introduction of new products (Persson and Jönsson, 2016). Some issues are

still under debate on how emerging markets will move toward 'value-based' measures of pharmaceutical innovation (Tannoury and Attieh, 2017).

Lastly, there are questions related to the construction of market access, distribution channels, and launching affordable products for uninsured and rural consumers (Roy et al. 2021). Facing low-income consumers, it is crucial to achieve the proper positioning by maintaining the price low enough to reach the BoP while at the same time ensuring that the costs make the business model profitable at scale (Kolk et al. 2014). Explorations of scalable strategies are scarce, hence forming a set of questions for the study and presenting an opportunity to fill the research gap. Furthermore, industry-based research demands more focused studies on regulations and the prices of products and services, as well as the evaluation of the worth of emerging market ventures, distribution systems, product innovation, and commercial organisations.

1.3 Aims and objectives

The aim of this research is to investigate the unique challenges faced by pharmaceutical companies when developing and commercialising drugs in emerging markets, with a focus on regulatory hurdles, pricing pressures, and market access issues. In order to accomplish this aim, the following objectives were focused:

- To explore the key challenges that are faced by pharmaceutical companies when commercialising and developing drugs in emerging markets.
- To assess the regulatory frameworks and policies in place in emerging markets and their impact on drug development and commercialisation.
- To explore the market access and pricing issues faced by pharmaceutical companies in emerging markets.
- To measure the effective strategies being employed by these companies to overcome these challenges and developing commercialised drugs in emerging markets.

1.4 Research questions

- What are the key challenges that are faced by pharmaceutical companies when commercialising and developing drugs in emerging methods?
- What are the regulatory frameworks and policies in place in emerging markets and their impact on drug development and commercialisation?

- What are the market access and pricing issues faced by pharmaceutical companies in emerging markets?
- What are the effective strategies being employed by these companies to overcome these challenges and developing commercialised drugs in emerging markets?

1.5 Rationale of the study

The main idea behind this study is to investigate the unique challenges faced by pharmaceutical companies when developing commercialising drugs in emerging markets, including regulatory hurdles, pricing pressures, and market access issues in emerging markets. Similarly, Tannoury and Attieh (2017) stated that China, Brazil, Russia, India, etc., can be regarded as promising markets for pharmaceutical companies because these countries experience higher economic growth rates and have large populations with a growing demand for medical products. However, these markets also have their pitfalls that need to be understood for new drugs to be adequately developed and launched. The following will be critical areas of focus in this study: the challenges that pharma faces in emerging markets can be categorised as follows: the regulatory environment is one of the challenges in emerging markets.

Despite the gradual development of better structure in many emerging economies, the established procedures in drug approval, licensing, and pharmaco-vigilance can be hazy, slow, or fragmented across agency lines (Biswas, 2013). It can make the whole process time-consuming and complex, especially when one is trying to register a new drug. Analysis has the purpose of identifying particular challenges that companies face when trying to understand regulations in major emerging growth markets (Marquis and Raynard, 2015). It will shed light on the areas that require attention in the process of bringing the national regulations in different countries into conformity with international standards.

Pricing and reimbursement are other issues that emerging markets are faced with in their push for improved access while also trying to keep costs down (Charitou et al. 2016). Several nations adopt HTA and reference pricing mechanisms that have a bearing on exerting pressure on the price of drugs – which may prove unsustainable for obtaining the costs of research and development (Grande et al. 2017). Other than regulations and pricing, another issue is the ability to get market access and acceptability from patients and physicians (Sendyona et al. 2016). In EMs, there is a heterogeneous distribution of providers involving public and private sectors,

fragmented and often non-integrated care systems, and patients with limited or no insurance (Hanfling et al. 2012).

Market access and changing the trends of prescribers' preferences are crucial in distributing drugs, and the strategies should be unique for each market (Davari et al. 2018). Pharmaceutical companies can identify the specific issues regarding regulation, pricing, and market access that affect the commercial opportunity for firms in emerging markets of interest. The findings will be helpful for strategic and recommending-based action when designing drugs for these intricate but potentially profitable locations. Policies can be improved by considering the priorities of the regions and reform possibilities.

1.6 Significance of Research

The growing need for pharmaceutical drugs and the expansion of pharmaceutical markets in emerging markets are of high importance for the global improvement of access to medicines. However, existing markets can also pose unique challenges to drug makers that affect their capacity to introduce new drugs into the market. Therefore, addressing the barriers poses a critical outcome for public health. The future of the pharmaceutical industry is auspicious, primarily because developing countries are home to millions of people whose disposable income continues to improve. However, situations like a limited amount of money being spent on the healthcare sector and lack of insurance policies make it very hard for the companies to recover such a considerable amount spent on the research department (Taylor, 2015).

In addition, challenges are also observed in terms of dealing with different regulatory systems, which could be more sophisticated in many countries, both in terms of approval and import requirements. Meanwhile, reducing the power of bureaucracy in the setting of regulations and bringing them in line with international counterparts would enhance quicker access to novel therapies for patients diagnosed with chronic illnesses (Nistotskaya and Cingolani, 2016). The third and final type of barrier to broader access to telemedicine is infrastructural constraints that hinder the process (Haleem et al., 2021). This is because several new economy countries have inadequate or no cold chain logistics that are required for handling temperature-sensitive products (Kumar et al. 2020).

Firms must invest in supply chain networks that are targeted at these countries. The use of simple packaging and appropriate dosage forms for the particular culture and literacy level is

also effective in improving the uptake (Gerrard et al. 2019). To do so, it is necessary to prioritise such needs specific to certain markets, thus extending the availability of such supplies to more people around the world. In this way, it will be possible to define specific policy and business solutions for the pharmaceutical industry in emerging economies, considering the commercialisation barriers found in this sector. Due to the rapidly growing health needs of these groups, addressing drug development and access issues should be of paramount consideration for any government and companies. The implications of the research study findings are diverse and can extend to other developing nations.

1.7 Structure of the dissertation

The following sections are discussed in this systematic Research:

- **Chapter 1 (Introduction):** This is the initial part of the research that is comprised of the aims and objectives of the study, background of the research, problem statement, rationale of the study and significance of the study to define the identified research problem. It also provides research questions that are focused on this Research.
- **Chapter 2 (Literature Review):** It is the second chapter of a dissertation which is a detailed examination of existing literature related to the research topic, focused on providing context, identifying gaps, and explaining the need for the study's contribution. It includes methodologies, theories, analysing and synthesising findings, and perspectives from different sources to initiate the research process and support its significance and validity.
- **Chapter 3 (Research Methodology):** It is the third chapter of the research which involves the identification of the techniques, strategies and tools which can be used for the execution of the research.
- **Chapter 4 (Results and Interpretation):** This chapter of the research provide the findings and analysis of the gathered data. It also gives a critical discussion of the collected results to differentiate and contrast the opinions of various authors regarding the chosen research questions.
- **Chapter 5 (Conclusion):** This chapter summarizes and concludes the overall results of the study. It identifies the limitations of the study which were found throughout the process.

Chapter 2: Literature Review

2.1 Introduction

This section is a literature review that examines the literature on the critical issues affecting the commercialisation and development of drugs within emerging markets. Investing in drug makers in the emerging markets is important because these markets have large population and growing disposable income. However, there are different challenges that make it difficult for pharmaceutical firms to successfully introduce new medicines into these markets. Thus, the objectives of the present literature review are as follows: Specifically, it will address the following regulatory factors: variations in the approval process across different countries; clinical challenges that include availability of resources and experts to design and conduct trials; and commercial considerations that range from market access, pricing and distribution channels. The recommendations derived from this review will help shed light on the challenges that companies experience in these markets and how some of them can actually counter them.

2.2. Key Challenges Faced By Pharmaceutical Companies in Emerging Markets

The commercialisation of drugs in emerging markets is fraught with specific challenges for pharmaceutical firms. Research exploring these issues spans regulatory, clinical, commercial, and financial contexts. This review captures and summarises current literature related to questions on market authorisations, product portfolios, patient access and pricing concerns. Obtaining approval from the regulatory authorities is a significant factor. Newer regulatory systems have few rules that can take time before the assessment of drugs (Uddin, 2021; Bamakan et al., 2021). Uddin (2021) suggests the use of blockchain to improve traceability in developing frameworks to fight counterfeiting, which is on the rise. While this enhances evaluation activities, implementations need much customisation to suit local environments.

Requirements for clinical trials also affect development schedules and expenses. The monitoring of antimicrobial resistance significantly differs between emerging nations because the collection of data in the process of conducting clinical trials is not uniform (Iskandar et al., 2021; Grangeia et al., 2020). The lack of sufficient standardised measures complicates individualised treatment plans. It is imperative to develop adaptive trial models that address both scientific and practical requirements (Godman et al., 2021; Chinemerem Nwobodo et al., 2022).

Quality assurance is a good practice that poses regulatory issues. Grangeia et al. (2020) reveal that quality design programs now appear to have different technical requirements and supervision. In this paper, Reinhardt et al. (2020) assess how Industry 4. Technologies such as digital monitoring might assist in synchronising manufacturing evaluations across countries with a focus on local capabilities. However, without aligned quality guidelines, regulatory authorisation stays non-predictable.

Specifically, relaxed early-stage criteria and disparate later-stage requirements and evidence put pressure on innovators. Domestic priorities combined with international standardisation integrate cooperative capacity-building pathways. Challenges to commercialisation also affect access. Socio-cultural factors also influence consumer adoption in areas such as the halal markets (Azam and Abdullah, 2020). Companies need to have a keen appreciation of local perceptions of diseases and culture. Limited infrastructure also hinders distribution in remote areas since digital cold chain solutions are challenged by connectivity issues (Bamakan et al., 2021; Akpan et al., 2022).

New partnerships help increase access. For instance, technologies suitable for developing contexts enhance the understanding of small healthcare organisations (Akpan et al., 2022). Regional manufacturers also increase localised production through the transfer of technology. Context-specific commercial models appear promising but need more pilot testing. Financial sustainability considerations further exacerbate other difficulties. Various mechanisms are implemented to limit the costs of premium drugs in some emerging nations, including reference-based pricing systems and increased generics competition (Reinhardt et al., 2020; Grangeia et al., 2020). At the same time, financial limitations in public healthcare settings around the world require a sensible selection of treatment priorities (Godman et al., 2021).

There are examples of potential access models like tiered pricing depending on local income or value-based purchasing based on the achieved health outcomes (Godman et al., 2021). Technology solutions also come into play, such as blockchain in managing cold chains to enhance productivity and decrease wastage and cost (Bamakan et al., 2021). Nevertheless, sustainable development needs collaborative policy changes and stakeholder coordination.

2.2.1 Commercialisation Challenges

Though research and development in pharmaceuticals can provide new solutions for various therapeutic requirements around the globe, limitations to the commercialisation hinder increased impact on global health. This review explores technical, operational and market challenges in taking R&D solutions to market to reach emerging populations. Process definition and physical characterisation constitute technical hurdles: the translation of early-stage research to later development. Stability under different environments and creating formulations that can be efficiently produced at large scales is difficult without much support (Halwani, 2022; Reyes et al., 2021; Othman et al., 2021).

Clinical evaluation challenges take the commercial readiness progress even further afield. These environments often lack expertise in conducting research, hence the need to use multinational trial designs and regulatory harmonisations (Al-Worafi, 2020). Such partnerships with regional investigator networks can be effective, but only if they are based on the capacities of the healthcare workforce (Mehta et al., 2022). Pharmacovigilance also presents post-launch monitoring challenges not solved by digital surveillance systems (Salam et al., 2022). Creating a localised quality manufacturing environment is a significant challenge. Technology transfer faces skills absorption challenges in emerging settings due to a need for specialised training programs (Haldhar et al., 2021; Patel et al., 2022). Public-private consortiums demonstrate the potential to nurture regional engineering talent through university-industry collaborations (Pawar et al., 2023).

Supply chain management additionally strains operations. Building sufficient API and finished product stocks optimised for shelf-life under various climate conditions requires long-term capital commitments (Othman et al., 2021; Nayak et al., 2022). Mobile depot networks show promise in addressing “last mile” distribution challenges to underserved communities (Thapa and Kim, 2023). Several obstacles constrain full commercialisation within emerging markets. Limited domestic capital availability and business expertise hampers scale-up for start-ups (Gao et al., 2021; Chandra et al., 2022). Incubators demonstrate the ability to nurture local entrepreneurship through hands-on training, mentorship and alliance-building (Gao et al., 2021; Das et al., 2022).

Establishing an effective sales and marketing presence additionally strains resources. Digital platforms show promise in empowering providers in remote settings through e-detailing,

online communities of practice and m-Health technologies (Thapa and Kim, 2023; Raj et al., 2022). Public-private social enterprises also demonstrate the ability to expand reach in underserved communities by addressing multiple barriers collaboratively (Leakey et al., 2022; Sai et al., 2022). Context-specific solutions show promise in overcoming commercialisation hurdles. Adaptive clinical trial partnerships, skills-building consortiums, mobile healthcare platforms and multi-sector access programs address various challenges through cooperative, customised approaches (Mehta et al., 2022; Pawar et al., 2023; Thapa and Kim, 2023; Sai et al., 2022). Ongoing collaborative R&D leveraging regional strengths can help efficiently advance innovations from early discovery to patient access. National regulatory roadmaps and technology incubation centres also support commercial translation where tailored to domestic priorities and absorptive capacities (Leakey et al., 2022).

2.2.2 Drug Development Challenges

Drug development is a lengthy, complex process with high failure rates. This review analyses significant challenges based on recent evidence to understand better the barriers that must be overcome. Early target validation presents difficulties in verifying disease relevance and modifiability (Pillaiyar et al., 2020). Advances in artificial intelligence (AI) and systems biology show promise in accelerating target assessment by integrating multi-omics datasets through network modelling (Mak et al., 2023; Patel and Shah, 2022). HTS (High throughput screening) techniques have challenges with chemical libraries and variable biological responses (Li et al., 2022). Novel technologies solve such problems; fragment-based screening effectively navigates chemical space in search of fragments for optimisation (Saldívar-González et al., 2022).

Forming hits implies the fine-tuning of parameters such as affinity, selectivity and toxicity (Muttenthaler et al., 2021; Fryszkowska and Devine, 2020). Techniques like modelling, SAR and property-modulating motifs help in optimisation (Berdigaliyev and Aljofan, 2020). Disease complexity hinders the effectiveness of assessment in preclinical models (Kiriiri et al., 2020). Targets, multifactorial assays and patient-derived systems partly address this using the following tactics: the process of formulation and manufacturing presents significant challenges (Halwani, 2022). Quality by Design approaches balancing parameters show promise (Berdigaliyev and Aljofan, 2020). Understanding pharmacokinetics, toxicity, and drug-drug interactions necessitates extensive animal and in vitro testing (Kiriiri et al., 2020).

Stringent regulatory expectations compound high failure rates (Årdal et al., 2020). Special populations pose ethical recruitment challenges requiring dedicated evidence (Rahalkar et al., 2021). Disease complexity stresses trials; for infections, this entails host-pathogen interactions and resistance, complicating proof-of-concept (Dartois and Rubin, 2022). Post-approval requirements strain resources (Kiriiri et al., 2020). Establishing global supply chains involves extensive oversight (Halwani, 2022). High R&D costs necessitate premium pricing, yet universal access remains challenging (Årdal et al., 2020). Collaborative models explore solutions like tiered pricing (Årdal et al., 2020).

Adaptive designs aid in addressing unknowns like heterogeneity (Kiriiri et al., 2020). Biomarkers help target clinical enrichment for infections (Dartois and Rubin, 2022). However, species differences constrain preclinical predictability (Kiriiri et al., 2020). Consortia demonstrate the potential to lower costs through data- and resource-sharing (Kiriiri et al., 2020). AMR complicates treatment development due to resistance transmission, host-pathogen interactions and required combination regimens (Dartois and Rubin, 2022). Strategies include enhanced surveillance networks monitoring resistance evolution, host-directed treatment exploration exploiting pathogenesis understanding, new therapies targeting resistant strains, and incentives encouraging private sector R&D in this area (Dartois and Rubin, 2022). Lower uptake of biosimilars in emerging markets relates to inconsistent policies, higher manufacturing complexity, and concerns around interchangeability and immunogenicity (Rahalkar et al., 2021). Regional harmonisation of guidelines simplified approval pathways, and targeted education programs help address resistance from prescribers and patients (Rahalkar et al., 2021).

2.3 Regulatory Environment in Emerging Markets and Their Impact on Drug Development and Commercialisation

Specifically, regulatory policies are critical in either enabling or constraining biopharmaceutical innovation and access for citizens of the world. This review systematically evaluates the impact of diverse levels of regulation in emerging countries using recent literature. A significant amount of variances in the preclinical and clinical evaluation makes the multinational drug development program challenging. These differences in GMP standards and quality control expectations complicate and raise the cost of manufacturing (Halwani, 2022; Liu et al., 2022; Cordaillat-Simmons et al., 2020).

This is especially so for nanomedicines, cell, and gene therapies for which characterisation work is significant (Halwani, 2022; Cordaillat-Simmons et al., 2020). Orphan drugs targeting rare diseases are not immune to unique regulatory challenges regarding small patient populations and study methodologies (Bouwman et al., 2020). In low-resource settings, limited clinical research structures add more difficulties to recruitment and data collection processes (El-Khateeb et al., 2021). Such limitations can be well addressed by Adaptive trial models and decentralised approaches if supported by a favourable regulatory setting (Liu et al., 2022).

The differences in approval processes and HTA assessment parameters from one emerging market to another create timeline volatilities within developmental strategies (Bouwman et al., 2020; Liu et al., 2022). There are also differences in the severity of review measures and data demands (Halwani, 2022). Availability facilitating mechanisms such as fast-track assessments or conditional approvals are used in a somewhat inconsistent manner (Bouwman et al., 2020). Variations in post-market safety surveillance also complicate the pharmacovigilance planning of global dossiers (El-Khateeb et al., 2021). The reduced regulatory barriers by mutual recognition and regional harmonisation demonstrate the capability to decrease approval time and cost if underpinned by harmonised scientific standards (Liu et al., 2022). This supports sustained clinical development and the opening of additional locations.

Reimbursement decisions and prices regulate commercial feasibility in individual emerging markets (Mialon, 2020; Nemteanu and Dabija, 2021). Regulatory frameworks also define allowed promotion activities and product statements (Mialon 2020, Rollins et al. 2023). Developing intellectual property rights also influences commercialisation approaches (Cordaillat-Simmons et al., 2020). Regulations of manufacturing and distribution create quality compliance challenges for multi-site global supply chains (Halwani, 2022; Liu et al., 2022). There are signs that collaborative models can address such diverse regulations – for example, capacity-building consortiums at the regional level to promote GMP training and inspection harmonisation (Liu et al., 2022; Halwani, 2022). This enhances the power of regulatory bodies and, at the same time, creates a conducive atmosphere for private capital.

In the antibiotics sector, variations in the guidelines on usage and inadequate synchronised resistance tracking weaken the control of emerging threats (Ikhimiukor et al., 2022; Hosain et al., 2021). Globally integrated and harmonised policies and guidelines are required to

guide stewardship and surveillance effectively. National action plans developed in partnership with international organisations have promise to enhance the capacities of regulatory and public health systems (Ikhimiukor et al., 2022). This approach combines internationalism with regionalism.

2.3.1 Regulatory Frameworks

The overall goal of regulation is to strike a balance between innovation, safety and public access to these products. This expanded review further expounds on the effects of shifting paradigms from a more critical perspective. Dense preclinical demands take much time but reveal essential safety information (Destro and Barolo, 2022; Liu et al., 2021). Precision medicine expands therapeutic avenues, but data privacy concerns have been raised (Liu et al., 2021; Udegbe et al., 2024). Risk-based approaches enable availability through fast-tracking but have potential flexibility risks where post-market commitments are not met (Darrow et al., 2020). Disease modelling has the potential to add to evidence if the methods get thorough validation (Madabushi et al., 2022; El-Khateeb et al., 2021).

Despite the value of biomarker qualification, it remains an issue and requires new frameworks for the biomarker development process (Gromova et al., 2020). Specificity in frameworks is crucial because cell and gene therapies present several challenges, and advanced modality guidance is needed (Cordaillat-Simmons et al., 2020). Research and development priorities depend on standards changes; nonetheless, regional differences remain (Cordaillat-Simmons et al., 2020). More alignment could coordinate funding toward the most significant needs. Decentralised trials increase the speed of access and must have adequate measures in place (Olesti et al., 2024).

However, clinical needs take up significant portions of budgets that could otherwise be used for broader or further phases (Destro and Barolo, 2022). Post-market commitments should be balanced in flexibility pathways concerning such inefficiencies. International review periods vary and are based on different criteria, which reduces certainty for both the industry and investors (Tobin and Walsh, 2023). Conditional approval increases potential access earlier at the cost of long-term oversight if renewal standards differ (Darrow et al., 2020). The concept of the benefit-risk ratios requires scoring criteria in order to minimise the risk of bias and provide clear information about the trade-offs made (Gómez-Outes et al., 2024). Increased patient engagement

brings practical experience not available elsewhere into the decision-making process (Sheikh and Yu, 2024).

On paper, mutual recognition helps to advance harmonisation, but in practice, it is still far from perfect, which contributes to slowing the availability on an international level (Volontè et al., 2024). Regional dossiers present higher risks that could be potentially decreased through increased evidence acceptance or non-simultaneous submission of dossiers (Olesti et al., 2024). Reliability influences commercialisation for small indications with adapted regulatory approaches to encourage development (Wang and Grainger, 2022). All in all, modernising frameworks preserves scientific credibility, while the call for a global maximum deserves attention. Real-world post-approval safety monitoring is still constrained by resources that can be enhanced through investment in revamped digital assets (El-Khateeb et al., 2021). Managing the detection of signals across jurisdictions where the reporting requirements might not be harmonised also poses challenges (Volontè et al., 2024).

Establishing clear criteria for long-term outcomes thus enables continuous risk-benefit reassessments of products throughout their lifecycles (Bamford et al., 2024). However, individualised therapies call for reconsideration of traceability and attribution models within pharmacovigilance systems to guarantee safety (Gómez-Outes et al., 2024). The decisions regarding fair, pro-access, and pro-innovation pricing are applied unevenly, but they influence all the parties involved (Gromova et al., 2020). Intellectual property management impacts follow-on cycles, yet regional differences remain (Sheikh and Yu, 2024). Extended supply chains bring additional quality compliance risks that can be aligned with more straightforward global standards, given enough lead times (Destro and Barolo, 2022; Gogoi et al., 2024). Promotion constraints have to be reconsidered to encourage specific areas of high importance.

Improving antibiotic stewardship and preventing resistance requires multi-stakeholder engagement to fill the gaps (Hosain et al., 2021; Bamford et al., 2024). New areas of work, such as synthetic biology or artificial intelligence-based discovery, require updated proportional structures (Udegbe et al., 2024; Korde et al., 2024). This ensures that the involvement of the stakeholders in guiding the applications ensures that there is a balance between the level of innovation and the level of oversight (Udegbe et al., 2024; Sheikh and Yu, 2024). However, differences still exist at the regional and priority levels that need collective efforts.

2.3.2 Clinical Trial Requirements

Clinical drug trials are crucial to determining the safety and efficacy characteristics that define regulatory approval or market authorisation. This review aims to critically evaluate recent evidence on new clinical trial regulation and its impact. Unique toxicity evaluations are needed for preclinical characterisation prior to first-in-human dosing (Denny, 2024). However, these requirements take many resources that could otherwise be used in clinical trials (Huang et al., 2024). There are unique formulation considerations for complex drug delivery systems that require separate preclinical frameworks (Shivgotra et al., 2024). AI applications are helpful in supplementing preclinical data, which could reduce the early development process if the issue of validation is well addressed (Bordukova et al., 2024). Precision medicine opens new possibilities for investigation but, at the same time, calls for reconsidering the representativeness of populations analysed in clinical trials (Gómez-Outes et al., 2024).

The design of clinical trials and the selection of endpoints determine the degree of evidence and the validity of approvals (Pecho and Zeitlinger, 2024). Disease modelling can improve these factors but requires more scrutiny of the accuracy of predictions (Bordukova et al., 2024; Krychtiuk et al., 2024). Still, as harmonisation aims at pooling up resources across regions, the disparity is noticeable in the acceptance of foreign data, which presents additional challenges (Gómez-Outes et al., 2024; Walker and Pirmohamed, 2024). Although conditional approvals can enable approvals based on interim or surrogate outcomes, robust post-approval assurances improve long-term monitoring (Gómez-Outes et al., 2024; Koncz et al., 2024). The standard recruitment measures, coupled with strict adherence to protocols, drain the logistic possibilities and resources required by the sponsors (Shivgotra et al., 2024; Huang et al., 2024). That has a negative impact on more minor indications if requirements do not include this measure (Weth et al., 2024). Data transparency and clinical trial registry responsibilities must strike a balance between business interests and public obligations (Huang et al., 2024; Krychtiuk et al., 2024).

Large-scale, long-term safety evaluation and real-life efficacy trials are time-consuming and are essential to efficient Pharmacovigilance and clinical practice (Koncz et al., 2024; Walker and Pirmohamed, 2024). These investments in the digital infrastructure could lead to the utilisation of real-world evidence in post-approval evidence generation if complemented by robust privacy legislation (Bordukova et al., 2024; Gómez-Outes et al., 2024). Clinical research seeks to help in the management of common chronic illnesses, but its progress is slow, perhaps due to costs

(Krychtiuk et al., 2024). It is achieved by adapting frameworks to accommodate special groups such as the geriatrics (Walker and Pirmohamed, 2024; Gómez-Outes et al., 2024). Drug repurposing seems promising in targeting unmet needs, although this approach poses the need to redefine clinical trial frameworks (Weth et al., 2024).

2.3.3 Impact on Drug Development Timelines and Costs

Efficient drug development is incredibly essential as the average time to bring a new medicine to the market is more than ten years, and costs are often over $1 billion (Krause et al., 2024; Lu et al., 2024). In light of these issues, this review provides a critical assessment of recent evidence on changing dynamics and their effects on timelines, costs, and entry incentives. High regulatory standards and long demo trails enhance the duration and costs (Lu et al., 2024; Kraude et al., 2024; Feng, 2024). Early failure minimisation appears to go a long way toward shortening development through “fail fast” learning (Kraude et al., 2024). AI applications show promise in expanding preclinical characterisation without definitive validation regarding predictive capability (Visan and Negut, 2024; Bailleux et al., 2024). Fast-track procedures for indications with priority designations demonstrate that while they shorten timelines, they also complicate the measure of value (Michaeli et al., 2024).

Drug repositioning creates shorter time horizons than new molecules through repurposing of past safety information (Weth et al., 2024). Nonetheless, rigorous clinical evidence requirements pose difficulties in executing repurposing effectively (Weth et al., 2024). If such programs are complementary to traditional research instead of being its competitors, registries and real-world evidence acceptance could accelerate such programs (Simoens and Toumi, 2024). Nearly all end-point conditional approvals require firm post-approval commitments to validate value (Michaeli et al., 2024). The disclosure of value assessments and pricing strategies affects business viability (Simoens and Toumi, 2024). Market volatilities bring factors that reduce long-term motivation towards the development of smaller therapeutic areas (Feng, 2024).

Other factors affecting commercialisation timelines after approval include access pathways and reimbursement time (Feng, 2024). In conclusion, frameworks with multiple diverse entry points continue to foster further innovation for unmet needs. Exclusivity incentives such as market exclusivity periods or expedited review designations seek to reduce the time-to-patient impact (Michaeli et al., 2024). However, a balanced approach avoids indirectly influencing the

promotion of specific areas over others that can be more important in terms of public health (Visan and Negut, 2024). International harmonisation efforts additionally present opportunities to streamline development processes yet face persistent political and economic barriers slowing progress (Simoens and Toumi, 2024; Michaeli et al., 2024).

2.4 Pricing and Market Access Environment Faced By Pharmaceutical Companies

Pricing reimbursement and market access barriers are crucial factors that define the pharmaceutical markets and systems in different countries. These aspects can significantly affect drug commercialisation and firms' chances to recover costs in research and development (Grant, 2024; Fuller and Ramirez, 2024). Pricing policies adopted by payers aim to balance drug costs while ensuring patient access and pharmaceutical industry sustainability (Wills and Mitha, 2024). However, approaches to determining appropriate prices vary globally and introduce pricing uncertainties for companies (Gikas, 2024; Nurlatifah, 2024). International reference pricing poses additional challenges by potentially delaying patient availability in lower-income countries (Grant, 2024; Nurlatifah, 2024).

On the market access front, lengthy reimbursement review periods can prolong the time taken for patients to benefit from new treatments (Grant, 2024; Amare et al., 2024). Healthcare budget constraints also influence the extent to which high-cost medicines will be covered or subject to risk-sharing arrangements (Wills and Mitha, 2024; Gikas, 2024). Inconsistent formulary listing across public and private payers further complicates uptake (Okok et al., 2024; Amare et al., 2024). Market penetration can also be influenced by factors such as a country's diagnostic capabilities and medical infrastructure, which impact the ability to target indicated patient populations and optimise therapy delivery (Nurlatifah, 2024; Amare et al., 2024). Training requirements, too, must be considered where inadequate skills act as a barrier (Okok et al., 2024; Amare et al., 2024).

2.4.1 Pricing Policies

Value-based pricing involves associating price with outcomes, though the subject and determinations remain ambiguous (Wills and Mitha, 2024). International variation in reference pricing affects the availability as lower-income markets are likely to face delays (Grant, 2024; Nurlatifah, 2024). While OBAs can maximise value capture, they entail massive data creation

that overwhelms resources if not well implemented (Wills and Mitha, 2024). Priority areas are motivated by exclusive market entry advantages such as patent extensions while simultaneously extending competition in other areas (Grant, 2024). In the long term, the new discount policies and pricing regulation mechanisms create risks that affect commercial sustainability, particularly in small markets (Nurlatifah, 2024; Gikas, 2024). Overall, flexibility in acknowledging varied circumstances maintains incentives across therapeutic sectors (Grant, 2024; Okok et al., 2024).

2.4.2 Market Access Issues

Reimbursement review periods carried out by healthcare authorities and payers to determine funding approval prolong the timely access patients have to new pharmaceutical products (Grant, 2024; Amare et al., 2024). The dossiers submitted by manufacturers outlining clinical and economic data on a drug are meticulously evaluated, which adds considerable time between a drug receiving market authorisation and becoming available for prescription. This can stall patients from receiving potentially life-changing therapies in a clinically meaningful timeframe. Furthermore, healthcare budgets around the world continue to be increasingly constrained, putting pressure on coverage of high-cost innovative therapies (Wills and Mitha, 2024; Gikas, 2024). Where drugs possess high price tags but treat rare diseases or cancers, for example, payers deny routine reimbursement due to affordability concerns within constrained means. This has led to growing implementations of innovative risk-sharing models between payers and pharmaceutical companies to link payment to certain outcomes or volumes being achieved in clinical practice.

An additional barrier arises from inconsistent decisions between public and private payers regarding formulary listing and preferred placement (Okok et al., 2024; Amare et al., 2024). Drugs can be reimbursed differently depending on the chosen healthcare plan, adding confusion. Access to diagnostic tools and local clinical expertise also influence uptake at the patient frontlines, as this determines whether indicated populations can be accurately identified and therapies optimally delivered (Nurlatifah, 2024; Amare et al., 2024). Together, these market access challenges determine the viability of commercialising new drugs at the population level.

2.4.3 Healthcare Infrastructure Constraints

Constraints present in the underlying healthcare infrastructure of different countries and regions also influence the uptake and market performance of newly launched pharmaceutical products. Limited diagnostic capabilities, particularly in lower resource settings, directly impact the ability to accurately identify and target indicated patient populations that would derive the most clinical benefit (Nurlatifah, 2024). Without proper diagnostic tools and technologies to guide treatment decisions, uptake becomes stifled from the outset. Additional barriers arise from inadequate cold storage and transportation infrastructure needed to enforce rigorous cold chain requirements for certain temperature-sensitive biologics and vaccines (Amare et al., 2024). Maintaining an uninterrupted cold chain from manufacturing facilities to clinics is a massive challenge in environments with unreliable electricity, deficient cold rooms and delays in delivery logistics. Even if a drug is reimbursed, inadequate cold chain provisions render its adoption nearly impossible.

Gaps in clinical training for physicians and nurses also hamper efforts to optimise therapy delivery and achieve the best outcomes as directed by product characteristics and clinical evidence (Okok et al., 2024; Amare et al., 2024). Limited understanding of new mechanisms of action, dosing protocols, safety monitoring best practices and other competencies result in suboptimal utilisation. This negatively impacts uptake metrics and brand performance evaluation. To overcome these constraints, collaborative capacity building programs led by public agencies, NGOs and manufacturers are increasingly leveraging technology and blended learning methodologies to enhance skills and empower more informed decision making. If unaddressed, deficiencies in diagnostic, storage, transportation and training infrastructure perpetuate difficulty in accessing innovative healthcare advances. Progress requires cross-sector coordination and investment to strengthen the underlying delivery platforms upon which pharmaceutical access is delivered.

2.5 Strategies to Overcome Challenges and Developing Commercialised Drugs in Emerging Markets

The following strategies have been adopted by Pharmaceutical companies to overcome the challenges faced when making and marketing drugs in emerging markets. Regulatory strategies, pricing strategies, partnerships, and building awareness are some of the main strategies that have been emphasised.

2.5.1 Regulatory Strategies

Dealing with multiple and diverse regulations of various countries in emerging markets is a daunting task to most pharma companies. Some of the regulatory measures that have been implemented include implementing a more agile approach to regulating (Liu et al. 2022; Destro and Barolo 2022). For instance, companies are aiming at risk-based methods, and accelerated approval to make a drug available earlier balancing with post-market obligations and monitoring (Darrow et al., 2020; Gómez-Outes et al., 2024). Regional harmonisation of guidelines and mutual recognition of dossiers has also helped to decrease regulatory timelines and costs across jurisdictions (Liu et al., 2022; Volontè et al., 2024). It is achieved through capacity building initiatives such as consortiums that seek to harmonise GMP standards, clinical trial procedures and pharmacovigilance systems (Liu et al., 2022; Halwani 2022; El-Khateeb et al., 2021).

National action plans drafted in collaboration with global institutional authorities have been successful in strengthening local regulatory systems and integrated monitoring of issues such as antibiotic resistance (Ikhimiukor et al., 2022). This regulatory modernisation that does not weaken scientific reliability but aims at standardisation on an international level also provides predictability for commercialisation (Destro and Barolo 2022; Tobin and Walsh 2023). Conditional approvals and the evaluation criteria of the risk-benefit framework that include long-term follow-up assist in sharing both innovation and access (Darrow et al., 2020; Gómez-Outes et al., 2024; Bamford et al., 2024). Advanced digital infrastructure also enhances post-approval pharmacovigilance across the markets.

2.5.2 Pricing Strategies

The price regulation for medicines in these markets raises challenges in the recovery of costs especially for new and expensive treatments. Others include policies such as tiered and differential pricing based on a country's economic power and capacity to pay (Årdal et al., 2020; Godman et al., 2021). Pricing strategies anchored on value with health outcomes have also been revealed to be viable for sustainable access (Tannoury and Attieh, 2017; Godman et al., 2021). Manufacturers are increasingly investigating contextual pricing strategies appropriate for certain environments such as public hospitals, private insurance or the uninsured individual (Leakey et al. 2022; Sai et al., 2022). It remains a challenge, but manageable through benchmark

harmonisation across regions and by showing that the medicine offers value; Persson and Jönsson 2016; Rollins et al., 2023. Volume-based tendering has assisted procurers in some markets in negotiating lower prices in return for market share commitments (Godman et al. 2021). Partnerships with governments and insurers have helped negotiate cost-sharing arrangements and prioritisation of treatment within limited healthcare budgets (Godman et al. 2021; Rahalkar et al. 2021). Internationally, coordination on fair and pro-access pricing policies could enhance sustainability across jurisdictions (Gromova et al. 2020; Sheikh and Yu 2024).

2.5.3 Partnerships

Establishing local collaborative networks has proven vital for navigating emerging markets. Regional technology transfer partnerships facilitate localised manufacturing and skills development (Patel et al. 2022; Pawar et al. 2023). Clinical trial networks and decentralised models partnering with local investigators also help address resourcing and data collection challenges (Mehta et al. 2022; Liu et al. 2022; Gómez-Outes et al. 2024). Public-private consortiums nurture innovation through joint research projects, incubators and university-industry training programs (Gao et al. 2021; Pawar et al. 2023; Leakey et al. 2022).

Social enterprises harness multi-sector collaborations to establish novel access models reaching underserved communities (Thapa and Kim 2023; Sai et al. 2022). Mobile healthcare platforms supported through digital partnerships address "last mile" distribution gaps (Thapa and Kim 2023; Akpan et al. 2022; Raj et al. 2022). Contract manufacturing alliances facilitate distributed manufacturing and quality compliance across global supply chains (Liu et al. 2022; Halwani 2022; Patel et al. 2022). Such collaborative networks have proven powerful for tackling diverse commercialisation barriers through cooperative context-specific solutions.

2.5.4 Building Awareness

Enhancing acceptability and adoption also involves targeted efforts to build awareness. The cultural understanding gained from local strategic partnerships supports sensitive engagement with providers and consumers (Davari et al., 2018; Azam and Abdullah 2020). Digital health platforms empower remote communities through e-learning, virtual expert networks and mobile Apps (Thapa and Kim 2023; Raj et al. 2022). Academia-industry programs

include students in awareness creation and dissemination through social media platforms (Leakey et al., 2022; Pawar et al., 2023).

Education and communication from regulators and pharmaceutical companies based on available evidence during approval and post-marketing surveillance relieves prescribers' concerns on issues such as interchangeability and benefit-risk assessment (Rahalkar et al., 2021; Gómez-Outes et al., 2024). Stakeholder involvement in decision making increases the variety of disease and treatment perceptions in positioning (Sheikh and Yu 2024; Olesti et al., 2024). Therefore, there is huge potential for regulatory flexibility pathways, contextual pricing, partnership and awareness programmes to play useful roles in assisting drug commercialisation and drug development by pharmaceutical organisations in diverse emerging markets. This is often done by a combination of specific national approaches together with international standardisation initiatives.

2.6 Theoretical Framework

Some of the key theories and conceptual frameworks used in the analysis of the challenges faced by pharmaceutical companies in commercialising and developing drugs in emerging markets include: Framing these challenges with relevant theoretical frameworks can help contextualize the analysis and assist in responding to the research questions. Another theoretical foundation that guides this research is the product life cycle theory. Proposed by Raymond Vernon in the 1960s to account for international trade and investment patterns, the product life cycle theory suggests that with the evolution of a product from the development, through the growth and maturity stage, the locations of production change from developed to the developing world (da Silva Lopes, 2023). The theory applies here as it assists in understanding how the growing markets present opportunities for drugs in their various stages after approval and market launch. However, the theory also recognizes limitations in market entry in emerging markets due to factors such as consumer preferences, competition from local generics, lack of distribution networks and price regulation (Fuchs, 2022). Using this framework to analyse the challenges makes it easier to understand how firms try to achieve the maximum return in different phases of emerging markets development while dealing with barriers.

Another useful framework is the innovation systems approach, which emphasizes the role of interactions between various actors within a system in enabling or hindering innovation. When

applied to health and pharmaceuticals, this recognizes the need for alignment between multiple stakeholders from the public and private sectors, including regulators, academia, payers and patients (Palm, 2022). This study applies this framework to understand how interactions between companies and other actors like regulators impact drug development strategies in emerging markets. For instance, disconnects between regulatory goals of ensuring safety and commercial goals of timely approval introduce challenges (De Oliveira et al., 2020). Moreover, pricing and reimbursement decisions by governments/payers also factors into commercial viability. This framework thus helps analyze such systemic and stakeholder-related challenges.

Additionally, the knowledge spillover theory of entrepreneurship posits that regions with strong knowledge inputs, typically research universities, are more able to commercialize this knowledge through local entrepreneurial activity and startup formation. When applied in the current context, this theory aids in explaining differences in local drug development capabilities across emerging markets. Markets with limited R&D expertise and absorptive capacity face additional challenges in translating external innovations for local needs compared to more innovative ecosystems. Partnerships that help transfer skills and knowledge can potentially address such challenges as identified in prior studies (Quintin et al., 2021; Serapio Jr and Dalton, 2021).

The above frameworks inform a dynamic capabilities perspective, which emphasizes the ability to adapt business models and strategies in response to a changing external environment. Considering emerging markets represent constantly evolving regulatory, competitive and market conditions, this perspective is fitting to analyze how companies employ different capabilities to overcome barriers. Strategies like establishing local manufacturing capacities, customized formulations and pricing models, digital sales and marketing platforms and collaborative clinical research networks reflect dynamic capabilities at play (Chen et al., 2018; Jiang et al., 2021; Lee et al., 2018; Meng et al., 2019).

2.7 Literature Gaps

While the available literature provides valuable insights into challenges faced by pharmaceutical companies, there are still some key gaps. Qualitative research exploring the real-world experiences of industry practitioners is limited. Most studies also examine challenges discretely rather than evaluating holistic multi-pronged solutions adopted in emerging markets

(Khan et al., 2023; Hussein, 2023). There is need for more comparative case studies across different therapeutic areas, company sizes, market maturity levels and cultural contexts. Further insights are also warranted on post-approval obligations and pharmacovigilance in diverse regulatory environments. Adaptive and decentralized clinical trial models require additional documentation and pilots to assess implications in low-income settings.

Exploration of strategies for last-mile drug distribution in rural and underserved areas remains limited. The role of collaborative public-private partnerships in solving entrenched bottlenecks is another under examined area. Longitudinal, mixed-methods and fine-grained comparative analyses are needed focusing on post-market, clinical trials and access aspects (Lee et al., 2023). More evidence on applicability and scalability of proposed opportunities across variable emerging markets and health systems would also enrich understanding of persistent challenges and impactful strategies.

2.8 Chapter Summary

This chapter provided a comprehensive review of the existing literature around challenges faced by pharmaceutical companies in emerging markets. Key issues identified included complex and unpredictable regulatory environments, clinical trial hurdles, pricing pressures, market access barriers, and skills and infrastructure gaps. The literature was analyzed through relevant theoretical frameworks to provide context. The review also identified gaps such as a lack of qualitative research, evaluations of holistic solutions, and more nuanced comparative analyses. Overall, this summary captured the current state of knowledge while highlighting areas for further study.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Introduction

Research methodology is a framework of approaches and guidelines that researcher follows at the time of their investigations (Groat and Wang, 2013). Methods are chosen on the basis of the objectives, nature of the research and their desired outcomes. This section of the systematic review describes the methodology and criteria used in carrying out the study. It highlights how the study was conducted and mentions the measures taken to carry out the review process and analysis smoothly. This section highlights how the review is performed and what measures were taken to carry out the review and analysis execution smoothly. Other features mentioned in this methodology include ethical consideration, which maintains integrity and ethical standards, eligibility criteria, approach design and data collection method.

3.2 Research Philosophy

The research philosophy primarily enables a belief in the researcher regarding the possibilities of a study and methods to navigate a given set of gaps being addressed by research (Younus and Zaidan, 2022). Bell, Bryman and Harley (2022) determined that the research philosophy primarily comprises of interpretivism, pragmatism, and realism, among several other philosophies. Considering that the existing study is on an exploration of drug development and regulatory challenges to commercialise drugs, the usage of interpretivism enables the study to humanise the prevalent arguments to articulate the challenges faced by pharmaceutical companies. Since the policies of developing economies vary from region to region, interpretivism research philosophy enables the research to internalise the external variables and embrace the diversity of regulatory practices followed by the respective developing economies. Zhang et al. (2022) also determined that the variation in ease of doing business across countries is readily different and diverse, particularly in the case of developing economies where the policies are found to be flexible in the areas focused by the government to increase their contribution towards GDP. Thus, the usage of interpretivism enables the study to take a holistic approach to identify the challenges.

To understand the perspective of diversified markets for this study, the research philosophy that is selected needs to incorporate the usage of flexibility and adaptability. Mbanaso et al. (2023) stated that the humanised flow of arguments embraced through the usage of interpretivism enables the study to gain significant ecological validity in understanding

diversified variables. In the case of existing research, the regulatory framework on price setting, licenses, and market access issues are readily in the control of the government, where the demand and supply equilibrium is highly prioritised by the regulatory to optimise the material. Therefore, Osorio et al. (2021) observed significant discrepancies in policies passed by regulatory bodies, which enables the sustainability of the equilibrium point. Contrarily, in the case of most developing economies, profit optimisation is part of the business operation strategy for pharmaceutical conglomerates. Therefore, studying their decision-making process can enable the research to intensify its theoretical assumptions made by the stakeholders through humanised arguments. Otherwise, the usage of pragmatism and other research philosophies could disengage the researcher from the initial objective and focus towards the research objective only.

The research primarily incorporated three distinct variables for the study that included regulatory hurdles, pricing pressure and market access issues, which are predominantly diverse across developing economies; it is important that the interpretivism research philosophy is practised by the researcher to ensure the inclusion of 3 distinct variables across different type of developing economies. Loayza et al. (2020) stated that developing economies change their regulatory policies according to the needs of the macroeconomic environment and societal framework. Therefore, for this study, the changes in policies were internalised through the usage of interpretivism. Contrarily, in the case of pragmatism and realism, the subjective approach may have been focused on achieving the objectives, which may result in significant discrepancies in achieving results. Thus, the study majorly incorporated the use of interpretivism.

3.3 Research Approach

The research approach primarily comprises an inductive approach and a deductive approach (Younus and Zaidan, 2022). For this study, an inductive research approach was used to incorporate the diversity of variables. Bell, Bryman and Harley (2022) stated that the inductive approach involves the generation of new findings based on prevalent data. Since the research is focused on developing economies and the regulatory practices that impact the pharmaceutical industry, it is important that the researcher embraces inductive reasoning in pursuit of identifying a logical pattern of data. The usage of the inductive approach further enables the study to internalise external variables, such as changes in policies from the respective governments and price settings. Sefah et al. (2021) determined that the inclusion of localised pricing in the market is highly regulated by the government to ensure the affordability of critical drugs, which can

enable them to ensure the sustainability of society. However, price wars among pharmaceutical brands often deviate from the pricing according to brands. Therefore, it was necessary for the study to embrace an inductive approach.

Bell, Bryman and Harley (2022) stated that the inductive approach enables a researcher to empower themselves with pattern recognition. The preceding study also believed that the inductive approach gives freedom to the researcher to not have a pre-determined belief regarding a data set while identifying patterns which can enable the study to remain unbiased and provide ecologically valid arguments. Since the topic of the study aims to assist the pharmaceutical companies of developing economies, it was important that an inductive research approach was embraced to internalise external variables and provide a valid conclusion on the basis of collected data. Through the data and recognition of a pattern, the study can theorise the pattern with multiple datasets as well. Therefore, it can enable the reader to believe the findings of the study. Furthermore, the study did not specify the inclusion of developing economies; therefore, the inductive approach enabled the research to be empowered enough to test multiple data sets to theorise the relationship between multiple variables.

Mbanaso et al. (2023) determined that the inductive approach enables a researcher to develop hypotheses and test them accordingly in pursuit of theorising the patterns in the dataset. For this research, pricing pressure imposed by the government through policies on price roofs and price floors enables them to control drug prices and mediate competition between the brands. Contrarily, Plackett (2020) argued that the incorporation of mediated pricing from the government violates the condition of a free market. However, the lucrative profitability made by the brands ensures that the mediated pricing should be established. As a result, the use of the inductive approach can enable the research to provide ecologically valid arguments regarding the perception provided by the government's interference with the pharmaceutical industry and its ability to commercialise its drugs. Furthermore, the precedent of research and development, which is imposed by the government as well, motivates them for breakthrough findings in the industry, resulting in the research's usage of an inductive approach to be justified in pursuit of identifying the patterns of challenges faced by stakeholders of the pharmaceutical industry.

3.4 Research Design

The research design popularly followed in studies includes qualitative, quantitative and mixed-method designs (Bell, Bryman and Harley, 2022). For this research, the research

employed the usage of qualitative research design to ensure that the objectives of the study are efficiently met. Primarily, the objective of the research focused on the identification of challenges associated with the pharmaceutical industry in developing economies. Therefore, the use of qualitative data enabled the study to focus on the diversified complexities of the pharmaceutical industry while mitigating too much focus on a single variable. The selected research design further enables the research to incorporate a thorough approach towards the identification of commercialisation challenges faced by companies in developing economies. Since the pharmaceutical industry is extensively diversified with companies focusing on commercialisation, price-wars, market competitiveness, profit maximisation, research and development, the qualitative research design enables the research to embrace an inclusive approach to unify the diversity in interest of pharmaceutical companies to enhance the ecological validity of the research.

Since the market conditions of developing economies are diversified with variations in the standardisation of policies, Kangwa et al. (2021) determined that the inclusion of quantitative data can be challenging for a researcher with multiple economies. Therefore, to impede the limitation of not being able to incorporate multiple developing economies in the research, this study incorporated the usage of qualitative research design in pursuit of establishing an extensive investigation of the challenges faced by the pharmaceutical industry in developing economies. The variables identified in the study have a magnitude; however, the inclusion of magnitude can increase the discrepancy of the results as the sizes of developing economies are different, with diversified objectives and approaches towards stabilisation and growth of the economy. Therefore, incorporating the usage of qualitative research design can readily enable the study to prioritise the externalised variables while standardising the unit of measurement in pursuit of embracing results for diversified economies, which can enable the study to enhance its recommendation to widespread economies.

The inclusion of qualitative data in a multi-variable study, along with the possibility of external variables, can enable research to identify the trends associated with the identified problem mentioned in a study (Bell, Bryman and Harley, 2022). Therefore, it was important for this research to embrace the use of qualitative research design, which enables an extensive understanding of the challenges associated with the pharmaceutical industry and its ability to commercialise drugs. As a result, the study was able to justify its design as foundational research

for future studies of diversified developing economies and realise the impact of each identified variable through quantitative data. However, the present study ensured that an extensive understanding is provided of the challenges faced by pharmaceutical companies in developing economies to ensure that future studies can readily add towards the findings of existing studies.

3.5 Data Extraction Method

Data collection is a process used to collect data or information to carry out research (Sutton and Austin, 2015). Systematically, it depends upon selecting suitable tools or methods like interviews, surveys, or observation to gather data (Alshenqeeti, 2014). The selection of the method directly influences the integrity and quality of the study findings. It comprises two types: primary data collection and secondary data collection (Islam et al., 2020). Primary data collection is based on the collection of information and data through different methods, including interviews, surveys, and experiments (Sileyew, 2019). Data collected by the researchers must match research objectives and verify relevance and authenticity. This research is based on a secondary data collection method. Secondary data collection is the acquiring of existing data from different sources like databases, literature, etc., rather than collecting from primary sources directly (Daas and Arends-Tóth, 2012).

This research used an online library for the collection of data. The secondary sources of collecting existing qualitative data are easy to identify, and they include policy documents and records, newspapers and journals, records of organisations, and previous qualitative studies (Mazhar et al. 2021). Some of the familiar sources of getting this type of secondary data are literature surveys, library and web searches using library databases and search engines, case studies, and content analysis using sources like newspaper articles, films, letters, speeches, and recorded/televised interviews (Johnston, 2014).

Researchers investigate existing data to comprehend and make conclusions that are similar to their desired goals. Secondary analysis comprises the use of data that other researchers collected for research purposes. This means that qualitative researchers can be able to explore large databases to generate new research content without having to conduct their research and collect new data themselves (Tenny et al. 2017). Most scholars critically analyse the available datasets in terms of their connection to the study questions and the reliability of the initial materials. Requiring more contextual information and need of more data, are prominent concerns

that can be seen in the workflow (Archibald et al., 2019). However, Tate and Happ (2018) showed that the systematic application of high-quality secondary data can effectively and economically support or underpin qualitative research and investigate new questions and perspectives in qualitative research by drawing on numerous empirical datasets.

3.6 Electronic search strategy

An electronic data strategy is a methodology required to gather related data from online databases and digital platforms. The search strategy was adopted for the collection process of secondary data. For gathering relevant and informative publications on the desired topic, a search strategy that depends upon selection criteria has shown efficacy in the collection of secondary data. An electronic search strategy can be accessed through library sources to carry out a search strategy. Using Boolean operators and a combination of keywords remained effective in managing irrelevant search results along with 'AND', OR, and 'NOT' maximizes the precisions of search results (Bramer et al. 2018). A vast reserve of secondary qualitative data for our research can be collected through these databases, which provide stages for analysing suitable articles. The purpose is to access data that is relevant to the research objectives.

3.7 Inclusion and Exclusion Criteria

Eligibility Criteria contain exclusion and inclusion factors. The eligibility criteria of this research are presented below.

Inclusion Factors	**Exclusion Factors**	**Rationale**
Publications from 2020 till 2024 were collected.	Exclusion of publications that were published before 2020 from the selection process.	Past literature which was proposed within the last 5 years was more focused on selected topics because of their recognition in recent years.
English language articles were included in this review.	This analysis prioritized English articles only.	For better analysis and interpretation, one must understand the findings of

		the study.
Electronic databases like online libraries provided the most suitable research.	Blogs and video information were not prioritized in this research.	Used to solve the issues that take place in the collection of data because of the inaccessibility of some articles.
Most suitable search results related to the chosen topic can be accessed through key terms and Boolean operators like “AND”, “NOT” and “OR” used by the search process.	Phrases and long sentences were ignored for the getting irrelevant searches.	Most suitable articles were accessed with less time wastage in the search process.
Articles related to the challenges faced by pharmaceutical companies in emerging markets were searched for data collection.	Factors other than regulatory hurdles, pricing pressures, and market access issues were not included in the research.	The purpose is to focus entirely on the objectives and to abstain from the selection of irrelevant articles.

3.8 Data Analysis

Content analysis is a research technique that entails the study of the content of written, verbal, or visual communication messages (Drisko and Maschi, 2016). It regards specific criteria that would involve qualitative and quantitative data in a structured form in a view to gaining meanings, bias, intents, etc., in the content. One of the main objectives of content analysis is to convert material gathered from data-gathering activities into numerical form so that it can be statistically analysed (Mayring, 2015). Content analysis is a widely used research method in many areas of study, including marketing, journalism, sociology, psychology, and gender studies (Drisko and Maschi, 2016). For instance, marketing communicators can make use of content

analysis to assess company reports, advertisements, social media handles, etc., as well as the strategies and approaches used in the dissemination of messages, patterns of reputations, decision-making for businesses, etc.

In journalism and communication studies, the technique proves helpful in analysing news coverage and representations, framing biases, propagandist content, etc. (Brennen, 2021). In sociological studies, content analysis of documents, different psychological studies, diary data, surveys with qualitative questions, case notes from therapy, and social media activity can provide insight into thoughts, feelings, problems, and so on (Cho and Lee, 2014). In general, content analysis provides empirical, systematic, and objectively based conclusions and hypotheses that elevate the reliability and validity of qualitative research. Given the tremendous increase in text and images in the modern world, the applications of content analysis will persist in providing social science researchers with an essential means of making meaning of text across disciplines.

3.9 Ethical Considerations

Ethical considerations play a crucial role in establishing the reliability and integrity of the research aim (Arifin, 2018). Before initiation of research, researchers must review ethical issues correctly to verify that their work is accurate and fair. Considering ethical principles prevents copyright issues, biased content, and misunderstanding, which will help in embracing transparency and trust among the academic community (Mirza et al., 2023). According to Resnik (2015), ethical consideration helps maintain integrity by focusing on participants' respect, transparency, and honesty. Ethical principles are necessary to manage the effective use of previous research findings. Researchers must acknowledge and cite sources in the research. Respecting intellectual property and abstaining from plagiarism are critical aspects of ethical research (Khan, 2015).

Similarly, ethical considerations surround more than just sticking to copyright ordinances; they extend to the academic community, society, and participants. Prioritizing ethical conduct during the whole research process, researchers show their commitment to reliability, integrity, and accountability. It gives assurance of the accuracy and reliability of research findings, which will improve knowledge respectfully.

3.10 Chapter Summary

This section of the dissertation summarizes the methodology used to implement the secondary qualitative research study. The researcher utilized the qualitative data from the chosen studies for thematic analysis, which is clearly explained in this chapter. The thematic analysis helped us gain a deep understanding and accurate information to achieve our desired study goals. The next chapter is relevant to this section as it determines the outcomes and findings resulting from the previously discussed tools and techniques.

Chapter 4 Contents and Results

4.1 Introduction

This chapter covers the key findings that emerged from the data collected and analysed as part of this research study. The chapter was split into different sections to discuss the study objectives effectively. The first section explored and discussed the significant challenges faced by pharmaceutical companies in commercialising and developing drugs in emerging markets based on the literature reviewed. This helped address the first research question. The second section critically analysed the different regulatory frameworks and policies that were in place across emerging markets and discussed their impact on drug development timelines and costs. This section aimed to answer the second research question. The third section provided an in-depth discussion of the pricing pressures and market access barriers that pharmaceutical companies encountered. It mainly focused on unpacking the issues arising from various pricing policies and healthcare infrastructure constraints. This helped achieve the third research objective. The last part concluded and contrasted several approaches discussed in the literature that pharmaceutical companies could use to address the issues peculiar to emerging markets. In particular, it scrutinised strategies regarding compliance with regulations, partnership schemes, new pricing strategies, and awareness-raising activities.

4.2 Content Analysis

4.2.1 Theme 1: Commercialisation and Development Challenges Faced by Pharmaceutical Companies

The literature reviewed highlighted several key commercialisation and development challenges that pharmaceutical companies face in emerging markets. These can be summarised under the following sub-themes:

4.2.1.1 Regulatory Challenges

The literature mentioned that regulatory frameworks were one of the issues affecting pharmaceutical companies in emerging markets. The review also discovered that while the regulatory environments in the various emerging nations are generally complex, they are unique

in various ways. Regulations for the essential procedures of product approval, clinical drug trials, quality assurance, and post-marketing surveillance differ significantly across the countries (Halwani, 2022; Liu et al., 2022; Cordaillat-Simmons et al., 2020). In light of this, firms in the business of producing drugs globally are forced to contend with diverse and ever-changing regulatory systems.

The existence of differing standards poses a significant challenge, hindering the synchronization of product development approaches among pharmaceutical companies. Approval pathways and related criteria vary significantly, and in some instances, they fluctuate considerably (Bouwman et al., 2020). This leads to delays and uncertainties in the time it takes for new drugs to receive market authorization. Furthermore, the need to adapt clinical trials to non-synchronized evidentiary requirements, paperwork, and regulations in different countries (Godman et al., 2021; Iskandar et al., 2021) and the task of meeting varying and evolving quality standards across manufacturing plants (Halwani, 2022; Liu et al., 2022) further compound these challenges.

The post-marketing stages present additional regulatory challenges because of the variability of pharmacovigilance practices across regions (El-Khateeb et al., 2021). In some cases, there is little transparency concerning the regulatory decisions made in some emerging nations, which adds to these challenges. Specifically, the coordination of rules and interpretations across different national drug authorities hampers resource planning and demands tight cooperation between the stakeholders for companies (Mehta et al., 2022). Some of the international product development activities can benefit from standardization.

4.2.1.2 Clinical Trial Challenges

Pharmaceutical firms face various complex issues when conducting clinical trials in emerging markets. One of them is related to inadequate health care systems and the lesser availability of resources in these countries. It is expected to experience a shortage of human resources in clinical research, as well as professionals who have the necessary knowledge to create and manage a clinical trial (Al-Worafi, 2020; Salam et al., 2022). This negatively affects several trial processes. Moreover, inefficient patient recruitment owing to limited outreach channels and poor database management prolongs trials (Mehta et al., 2022). Cultural and

socioeconomic factors also affect volunteer enrolment rates. The infrastructure gaps further impair consistent data collection practices as standard electronic medical records, lab testing capabilities, and diagnostic equipment are often unavailable (Al-Worafi, 2020). Documentation practices also differ significantly across sites in these decentralized settings.

These limitations in clinical trial capacities have wide-ranging implications. They directly impact product development schedules as timelines get extended due to inexperienced staff and recruitment roadblocks. Trial quality and interpretation of results are affected due to missing or inconsistent data points from resource-constrained sites (Salam et al., 2022). Overall, this introduces inefficiencies in generating comprehensive dossiers for global approvals. Harmonizing multinational trial protocols and leveraging strategic partners with local expertise can address some barriers. However, trials will continue to pose logistical hurdles until public health investments strengthen the base medical infrastructure and upskill manpower in emerging nations.

4.2.1.3 Manufacturing Challenges

Setting up manufacturing capabilities to cater to emerging markets poses substantial challenges for pharmaceutical companies. A significant hurdle is the extensive capital required to construct manufacturing plants and R&D centres in these regions (Haldhar et al., 2021). Significant financial resources and long-term commitments are needed to create the local production infrastructure from the ground up. An associated difficulty is training and upskilling the workforce, as specialized technical skills often need to be imparted (Patel et al., 2022). Technology transfers from innovative companies also face barriers in terms of effective absorption by developing national ecosystems. Language and cultural barriers may hamper the seamless knowledge flows required for complex production processes.

Ensuring compliance with international quality standards is a crucial aspect of setting up manufacturing capabilities in emerging markets. These nations often have different compliance requirements for cGMP, Batch testing, and other quality assurance norms compared to developed markets (Halwani, 2022). This necessitates a more rigorous oversight of worldwide facilities, adding another layer of complexity. The challenges can be a deterrent for investors, unless adequate incentives are provided. If not addressed properly, they can significantly increase costs.

While partnerships can help bridge technical gaps, it remains uncertain if local capabilities can be enhanced rapidly enough. These risks and the extensive resource expenditures can discourage commitment, unless the long-term sales potential is clear. Standardization efforts and skills development programs can play a crucial role in optimizing manufacturing functions for emerging regions over the long run.

4.2.1.4 Supply Chain Challenges

Establishing robust supply chains tailored to serve emerging markets is a significant undertaking for pharmaceutical companies. A key issue is the resource-intensive nature of long-term planning and management of active pharmaceutical ingredients and drug product inventories optimized for the unique demands of low-resource environments (Othman et al., 2021; Nayak et al., 2022). Additionally, reaching customers located in remote, often inaccessible regions with poor transportation and storage infrastructure poses difficulties. Last-mile delivery logistics get severely impacted by inadequacies like uneven roads and lack of reliable vehicles and storage facilities (Thapa and Kim, 2023). Particularly for biologics and temperature-sensitive products, maintaining uninterrupted cold chains from manufacturing plants to end customers across often extensive geographical distances within emerging nations is a significant challenge (Bamakan et al., 2021). Some of the risks that contribute to supply reliability include power outages, irregular temperatures, and perishable stocks.

These risks are also comprised of the absence of central databases, fewer demand planning tools and fluctuations in orders from the public sector. Such ‘last mile’ accessibility concerns require extensive efforts to enhance the effective practices of logistics, mobile depots, and collaboration with local distributors (Thapa & Kim, 2023; Othman et al., 2021). In general, supply chains for emerging markets are characterized by Customizing operations according to the context. Therefore, in conclusion, issues such as inequality in the regulations, challenges in local ecosystems and varying operating environments present a major challenge to pharmaceutical firms seeking to commercialize and develop drugs for emerging markets effectively. Meeting these challenges requires a significant investment and a specific strategic approach.

4.2.2 Theme 2: Regulatory Frameworks and Policies and their Impact on Drug Development and Commercialisation

The literature revealed the following key insights on the impact of regulatory frameworks in emerging markets:

4.2.2.1 Approval Processes

Challenges exist in the context of distinct drug approval procedures, especially for companies operating in emerging nations. One of the main issues relates to the diverse assessment paths, which significantly vary across the regulatory geographies (Bouwman et al., 2020; Liu et al., 2022). This departs from the standardised approaches employed by agencies such as the FDA and EMA. These different emerging market approval processes also create vast uncertainty in organisations' application durations. While some agencies expedite some of the applications, others are rigid, which affects product approvals (Darrow et al., 2020). Further categorisation of drugs as prescription, over-the-counter, etc., also affects the business strategies concerning entry to the market.

The risks are further complicated by the fact that submission requirements for clinical data dossiers differ, leading to variations in documentation between regulators and potential gaps in online portals. This inefficiency is particularly evident when compiling global dossiers and uncertainty over the deficiencies. The complexity is heightened by regulatory status changes, as classifications are periodically modified and reintroduced. In some countries, elaborate application processes also hinder patients' access to new treatments for extended periods (Bouwman et al., 2020). These differences not only complicate the forecasts around product approvals and launches but also the synchronisation of pricing decisions depending on market conditions and other products' timing. The increasing complexity of these pathways across emerging territories underscores the need for early agency consultations and global dossier harmonisation.

4.2.2.2 Clinical Trial Requirements

The regulatory landscape in emerging markets is a complex web that poses significant challenges to pharmaceutical companies, particularly in meeting the diverse clinical trial needs. A key issue arises from the variation in the late-stage evidentiary requirements that different authorities may impose (Godman et al., 2021). Factors such as minimum patient requirements, trial duration, and the number of endpoints assessed vary significantly, disrupting global development schedules and strategies. The lack of unified guidelines and variations in practices across trial locations further complicate the compilation of dossiers (Iskandar et al., 2021; Grangeia et al. , 2020). This lack of standardisation in documentation conventions hampers the interpretation of results and makes comparative assessment of product efficacy challenging when different methodologies are applied.

The costs rise significantly when many different requirements are to be monitored because specific studies will have to be conducted. Also, there are delays because changes are needed to meet new requirements (Godman et al., 2021). This delays the access of patients to care while at the same time exerting pressure on the budgets. Based on these challenges, companies look for identical trial networks and real-world databases to enhance evidence compilation (Mehta et al., 2022). However, infrastructure constraints persist. Ethics approval processes, compensation and data sharing still need to be more cohesive, making trials across emerging nations even more challenging. Regulatory convergence initiatives can be used to slowly harmonise core standards as a way of dealing with inconsistent issues that are experienced across the industry.

4.2.2.3 Post Marketing Requirements

Pharmaceutical companies face challenges coming from differing post-marketing Regulations all over the world. The lack of proper pharmacovigilance policies and the uneven approach to the monitoring of approved drugs in EM create challenges (El-Khateeb et al., 2021). Lack of a clear structure relating to reporting safety events regularly, format favoured for safety reports, risk analysis and management plans, and database access around the world makes it difficult to have accurate and complete records of safety profiles on a global scale. The lack of a strong correlation with some specific local pharmacovigilance networks hinders expeditious risk

signalling, too. Other pressures originate from changing post-approval requirements, which take a demanding toll on company capability (Kiriiri et al., 2020). Conducive constant revision of long-term efficacy trials and resubmission of consistent product files distort primary strategic plans.

Other regulations touch and cover product withdrawals, batch recalls, and crisis management, introducing response ambiguities. These inconsistencies pose challenges in the attempt to establish universal guidelines for surveillance across multinational portfolios. The collection of regional adverse events, while facing challenges such as language barriers and infrastructure, and the necessity to follow specific requirements, which may vary from country to country, is costly. It also can easily fail to notice fine detail in risks and non-universal standardized procedures. It is of utmost importance to systematically strengthen the pharmacovigilance networks of emergent nations and to align the fundamental guidelines for the core activities for managing post-approval compliance issues that are proportional to the resources spent by the industry. This systematic change is crucial for the future of the pharmaceutical industry.

4.2.2.4 Quality standards

Pharmaceutical companies need help in meeting numerous quality standards that are in practice in emerging markets. One of the potential issues is that various regulators put different standards for cGMP and manufacturing (Halwani, 2022; Liu et al., 2022). This also makes it challenging to achieve the integrated manufacturing process and the proper quality control mechanisms for the multi-facility supply chain networks that cater to globally regulated markets. Thus, compliance with divergent standards of quality significantly enhances operational difficulty. Documentation must be tailored at each facility to meet the specific legal requirements of each state and the federal government. This serves to increase compliance costs significantly.

Moreover, the lack of synergy in quality standards across borders renders regulatory decisions such as approvals or bans ineffective (Grangeia et al., 2020; Reinhardt et al., 2020). Variations in defect classification, change control procedures, or stability testing requirements create uncertainties in meeting quality assurance long-term quality obligations. The frequency and magnitude of periodic document submissions for quality programs also vary from agency to

agency. This underscores the need for a unified approach to quality standards, which, if not addressed, can strain organizational resources.

4.2.2.5 Pricing and Market Access Policies

Pricing and market access strategies in emerging markets, therefore, significantly impact the commercial potential of pharmaceutical products. Still, it presents numerous difficulties to companies due to the differences in the applicable mechanisms from one jurisdiction to another. The typical challenge is the use of international reference pricing by many regulators where local drug prices are aligned with the lowest costs from other countries (Mialon, 2020). This hinders firms' capacity to set optimally variable prices that capture fluctuations in economic factors. It also holds back the uptake of vital innovations by capping global prices at lower levels of tiers. Some of the large emerging countries are thus faced with even more challenging market access restraints by restrictive reimbursement policies.

Decisions regarding list formularies are heavily influenced by price agreements, often at the expense of considering outcomes-driven value (Nemteanu and Dabija, 2021). Price controls implemented by regulatory tenders further erode profit margins and render specific product categories unprofitable (Reinhardt et al., 2020). Market allocation practices like these, which prioritize cost over patient need, significantly reduce access to specialized treatments. Other factors that add to the complexity of determining the correct price and its prediction across regions are the differential tax systems, import tariffs, and currency fluctuations. These discontinuities necessitate very specific pricing strategies to balance the goals of improving population health and affordability while maintaining a sustainable business model in the long term. However, one potential solution to these challenges that holds promise is the adoption of collaborative value-based models.

4.2.3 Theme 3: Market Access Issues Faced by Pharmaceutical Companies in Emerging Markets

Market access concerns in emerging economies present substantial barriers to pharmaceutical companies seeking to serve these populations. The literature review uncovered several challenges under key sub-themes:

4.2.3.1 Distribution Challenges

Flaws in distribution in emerging markets remain another daunting issue that hinders pharmaceutical firms from achieving efficient supply chain management. The creation of sound distribution channels that will enable the delivery of the products to all the various customer segments, especially the remote rural consumers, is incredibly challenging. These regions often need proper transport networks and immature supply chain solutions, which limit effective last-mile delivery to the consumers (Thapa and Kim, 2023; Bamakan et al., 2021). Mobile depots constitute a novel approach to overcoming the challenges of reaching out to under-represented areas (Thapa and Kim, 2023), yet the implementation of models, which are best suited to local geographical characteristics and demand structures, entails significant costs (Othman et al., 2021; Nayak et al., 2022). In addition, the following factors hinder the maintenance of cold chains for temperature-sensitive goods: lack of stability in temperatures and irregular supply of power.

4.2.3.2 Infrastructure Challenges

Several issues are present due to the fact that the healthcare infrastructure in many emerging markets is still in its infancy. Young systems lack key infrastructures such as average diagnostics equipment, testing laboratories, effective refrigeration and temperature control systems, and internet connection (Bamakan et al., 2021; Akpan et al., 2022). This significantly limits diagnostic, product monitoring and data gathering necessities for clinical trials, pharmacovigilance and last-mile delivery operations. While innovative technologies show promise in helping to overcome some infrastructure gaps, implementing connected solutions at scale across dispersed communities continues to be difficult (Thapa and Kim, 2023; Kumar et al., 2020). Reliable high-speed internet connectivity remains elusive in rural areas with intermittent networks, hindering real-time data transmission. Limited regional electricity grids also hamper nationwide deployment of digital health databases and sensor networks.

Addressing these infrastructure deficiencies demands extensive long-term investments to develop the modern physical and technological backbone required for efficient healthcare systems. Strategic partnerships that build local capacity through training and equipment donations have shown some success but a coordinated national approach is still needed.

4.2.3.3 Adoption Challenges

Socio-cultural factors play a significant role in patient adoption of new pharmaceutical treatments in some emerging markets. Deep-rooted beliefs and traditions influence disease perceptions and the acceptance of novel therapeutic approaches in specific communities (Azam & Abdullah, 2020). Overcoming entrenched mindsets requires extensive awareness programs tailored to local health attitudes. Compounding this is generally low public health awareness and literacy across emerging populations, which restricts the reach and effectiveness of educational campaigns aimed at introducing innovative products (Al-Hanawi et al., 2021). Additionally, inadequate private or public health insurance coverage for most citizens means patients often can only afford expensive branded drugs with substantial assistance. High treatment costs become a significant barrier due to low disposable incomes in these markets (Ocran Mattila et al., 2021).

4.2.3.4 Payer Challenges

The current research shows that pharmaceutical companies experience numerous challenges when dealing with public and private payers in emerging markets. Government interference in medicine prices through techniques such as international reference pricing significantly reduces the possibility of earnings for producers (Mialon, 2020). Furthermore, constrained healthcare resources, followed by a shift in priorities for funding for broader national economic development goals, have also put pressure on the payer's willingness to pay for premium therapeutic innovations. Another layer of concern is the issue of formulary listing and reimbursement criteria within each respective country. The lack of clinical treatment pathways hinders the development of coherent HTA assessments and integral reimbursement models across therapeutic specializations (Nemteanu and Dabija, 2021). Different assessment approaches and standards stress regulation relationship.

Strengthening the autonomy of funding authorities at the state level still splits payer landscapes even more. This creates disparities that are only possible with accord with harmonized change. Evidence of creating real-world health economic value is imperative; however, it is only straightforward with robust outcome measures. Successfully implemented models of collective action that engage payers through regional data sharing and prioritization frameworks can help streamline currently fragmented payers' worlds. In conclusion, restrictions

to market access, such as inadequate distribution channels, limited healthcare facilities and structures, economic challenges and unclear customer status, make customer access and sales possibilities for the producers of pharmaceutical products in developing nations a challenge. Sustained improvement, however, involves multi-faceted strategies and efforts to improve access.

4.2.4 Theme 4: Pricing Pressures Faced by Pharmaceutical Companies in Emerging Markets

Pricing is a major consideration for pharmaceutical firms seeking to penetrate emerging markets profitably. The literature review uncovered the following pricing challenges:

4.2.4.1 Pricing Policies

Pricing policies that are put in place by the governments of emerging markets are among the biggest challenges that pharmaceutical firms encounter. The regulation of the prices of drugs is quite prevalent in numerous jurisdictions as a way of increasing the accessibility and affordability of treatment to populations (Verghese et al., 2019). The government or other regulatory authorities can directly intervene by putting a cap on prices or setting the maximum retail margin. Moreover, frequent price adjustments with periodic re-pricing also eliminate any chances of price hikes while maintaining very thin profit margins (Charitou et al., 2016). This regulatory environment hinders the ability of firms to adjust prices to factors such as a nation's ability to pay for a product or the value proposition of new products. The net outcome is few opportunities to create enough revenues that may reverse costs associated with investment spanning decades of research in developing new treatments. This makes specific segments, such as specialised orphan drugs, almost commercially unfeasible unless they are granted special dispensations.

4.2.4.2 Reference Pricing

A significant problem that is evident with many emerging economy pricing policies is the use of international reference pricing mechanisms. In this system, such countries as Brazil, Russia, and India refer to the costs of products in other nations to set domestic drug prices

(Mialon, 2020). However, the reference pricing discount approach negates substantial economic differences among countries. Setting ceiling prices, usually at levels associated with much poorer nations, does not take into account an individual country's capacity and desire to fund new and innovative therapeutic products (Persson and Jönsson, 2016).

4.2.4.3 Generics Competition

Generic medicines pose a significant threat to pharmaceutical companies as they have established their ground in many emerging market territories. This is because policies favour higher generics consumption to increase the availability of affordable treatment among low-income individuals (Reinhardt et al., 2020). Tendering practices such as initial price-based drug tenders and automatic substitution commonly benefit low-cost generics over brands (Grangeia et al., 2020). Some other countries with limited IP protection may further intensify general competition and unintended loss of patents. Rising pressures of competition emanating from generic manufacturers eager to gain market share as quickly as possible have a negative impact on the margins of the originator brands. Once patents wear off, steep drop-offs occur, which poses restricted volumes for branded drugs on which they can make adequate returns (Lopez-Salido et al., 2021). The net effect significantly reduces opportunities that allow innovative organizations to generate sustainable business value correctly.

4.2.4.4 Healthcare Spending

Limited healthcare budgets remain a core challenge across most emerging markets. A majority dedicate less than 5% of their GDP towards public healthcare spending due to competing developmental priorities (Al-Hanawi et al., 2021). This is exemplified in nations like India, where over 60% of total health expenditure is still funded through direct out-of-pocket payments by patients, underscoring the budget constraints faced by both public insurance systems and individuals to pay for treatments (Roy et al., 2021). With healthcare often not being the primary policy focus, there needs to be more room within such tight annual allocations to accommodate the adoption and coverage of new premium-priced pharmaceutical innovations readily. Payers are only willing to commit sizable scarce funds with demonstrated cost-

effectiveness and prospects for affordability. This pressures drug developers to continually lower prices to achieve market access.

4.2.4.5 Low Consumer Incomes

A major socioeconomic factor curbing pharmaceutical access across emerging nations is the relatively low per capita incomes prevalent among these populations. Even with marginal price reductions for patented medicines, treatment costs often remain unaffordably high for a sizable segment due to limited purchasing power (Kolk et al., 2014). Data shows that a majority in nations like India, Brazil, Egypt, etc., live on international poverty lines of under $5 per day, emphasizing their constrained ability to pay for premium branded therapies without assistance readily (World Bank, 2022). This underscores the need for complementary social interventions and reforms aimed at boosting healthcare insurance penetration along with targeted subsidies to economically disadvantaged groups. Widening insurance coverage through public-private partnerships and direct subsidization of costs can help offset low consumer incomes as a persistent barrier beyond simplified pricing alone. The literature reiterates constant pricing pressures on companies arising from reduced willingness and ability to pay for high-cost innovations. Adopting balanced, context-specific pricing strategies is crucial to ensure commercial viability.

4.2.5 Theme 5: Overcoming Challenges and Developing Commercialised Drugs in Emerging Markets

The literature suggests various strategies that pharmaceutical companies employ to overcome barriers and successfully develop commercialised drugs for emerging markets. Global dossier submission and collaborative trial designs ensure reduced review periods (Godman et al., 2021). Early stakeholder engagement and adopting regional investigator networks facilitate navigating evolving regulations (Mehta et al., 2022). Harmonisation consortiums also aim to synchronise standards, simplifying approvals (Grangeia et al., 2020). In addition to, technology transfer agreements could boost local manufacturing through skills building (Haldhar et al., 2021). Mobile healthcare platforms empower remote caregivers (Thapa and Kim, 2023). Incubators nurture entrepreneurship to innovate frugal solutions (Gao et al., 2021). Social

enterprises overcome barriers through multi-dimensional partnerships (Leakey et al., 2022). Regional manufacturers increase production via partnerships as well (Akpan et al., 2022).

The tiered pricing based on ability-to-pay expands volumes in price-sensitive areas (Godman et al., 2021). Value-based arrangements link cost-effectiveness to realized outcomes (Tannoury and Attieh, 2017). Blockchain applications enable supply chain tracking to curb wastage and costs (Bamakan et al., 2021). Similarly, digital platforms facilitate e-detailing and deliveries to distant communities via connected devices and vehicles (Thapa and Kim, 2023; Raj et al., 2022). Public-private insurance models enhance affordability in low-resource environments (Sai et al., 2022). Therefore, community health worker programs could bolster education around therapeutic benefits (Mehta et al., 2022). Virtual training empowers physicians in integrated care through connected portals and communities of practice (Thapa and Kim, 2023). Adopting collaborative, context-tailored approaches across regulatory, commercial and social domains through multi-sector alliances can help companies successfully mitigate market challenges.

4.3 Chapter Summary

This chapter discussed the data analysis employed for this research. The data extracted from the literature was analysed using Content analysis to identify common themes and sub-themes. Content analysis is useful for identifying, analysing, and reporting patterns within the data collected. The themes and sub-themes were mapped according to the research questions and objectives. Content analysis allowed for organising and describing the key findings from the literature in a detailed yet systematic manner.

Chapter 5: Discussion

5.1 Introduction

In this chapter, a comprehensive discussion of results and findings is presented. The discussion reiterates the main findings within the context of each objective identified in the first chapter and compares to evaluate how objectives are achieved. The chapter is organised in accordance with research objectives. The discussion begins with analysing findings related to the first objective and then continues to the second objective, followed by the third and fourth objectives. Finally, the chapter ends with a summary of the discussion.

5.2 Objective 1: Key Commercialization and Development Challenges

The findings in the previous chapter show that pharmaceutical companies, including clinical trial challenges, timelines & costs, and regulatory challenges, face various vital challenges. These results are consistent with the general literature review provided in the second chapter, as well as general trends in the industry. For example, the pharmaceutical industry lives and breathes innovation to bring the latest medical treatments to overcome various diseases (Thapa and Kim, 2023). The innovation produces compounds that are then patented and undergo research and development, including clinical trials, before finally being granted marketing authorisation by the national or regional regulatory authority. Therefore, the development and marketing of new drugs undergo various phases, and each phase has its challenges. Since innovation is a significant industry trend, research and development costs, design and marketing expenses, and regulatory compliance have emerged (Othman et al., 2021).

It is important to note that the innovation process and research and development, as well as other works, are mainly carried out in the first-tier countries of Western Europe and the United States, where most of the large pharmaceutical and biotech companies exist and operate. New products are evaluated and granted relevant authorities, such as the Food and Drug Administration (FDA) in the United States or the European Medicines Agency (EMA) in Europe. There is clear evidence that developing a new drug is an expensive proposition, and companies seek to reap the benefits of novelty when the drug hits the market (Ocran Mattila et al., 2021). Countries like the United States have no price controls, and innovative products are priced generously to help ensure faster returns on investment and encourage continued advances

in medicine. However, in the case of emerging markets, there needs to be an established and well-tested regulatory environment. The continuous changes and updates in regulatory requirements have become a challenge for pharmaceutical companies to plan for in the long term. Similarly, research and development in emerging markets is also complex due to a lack of resources and experienced talent needed for the innovation process. Hence, these challenges identified in this study make complete sense (Mialon, 2020).

Another essential characteristic of emerging markets that is worth reiterating here is the challenge with public health funding and resources in many emerging markets. For business and commercial reasons, companies may choose not to go into trouble by registering an innovative product in a developing country. In fact, if the population is small, the number of patients does not make the company commercially viable. Additionally, Thakur-Wernz, Cantwell, and Samant (2019) noticed that one of the complications arises when Western Pharmaceutical companies rationalise their portfolio to discontinue an emerging market product or undertake a merger and acquisition plan.

On the other hand, emerging markets do require these products because patients in these countries are similar to those living in Washington, London or Paris. There is a possible solution that outside of the entire regulatory pathway, there is a mechanism by which regulatory authorities in all countries allow access under Managed Access Programs (MAP). MAP is a general term covering many schemes such as compassionate use, extended access, supply to nominated patients, special access schemes/programmes, temporary authorisations for use, orphan products and others. These programs help patients with severe or life-threatening illnesses who are seeking medical products that are not yet approved or available in their country (Gassmann et al., 2018).

However, the question arises of how this works. In some cases, patients with severe or life-threatening illnesses or conditions who have exhausted all available therapy options seek new treatments. The treating physician may request medication that is not available locally, provided that it is permitted by applicable local laws (Andrioti, 2019), taking into account whether:

- There is sufficient data to support the potential benefit of the treatment outweighing the possible risk in the context of the disease or condition.

- The patient has a severe or life-threatening illness or condition for which there is no comparable or satisfactory alternative therapy available to monitor or treat.
- The product or products are not available due to drug shortages or have been withdrawn from the market.

Western Pharmaceutical companies are understandably reluctant to allow the supply of MAP products to emerging markets. Time and time again, patients in emerging markets struggle to obtain necessary treatments due to a lack of understanding or empathy from Western biopharmaceutical companies. It is true that the procedures are complex and will require resources and accumulated experience to work with multiple products coming from various manufacturers and suppliers in numerous countries and being shipped to multiple patients in multiple countries (Ioannidou and Kokkoris, 2019). Yet, these aspects become critical challenges for companies in emerging markets. Therefore, there is clear evidence that these are essential commercialisation challenges that companies need to address while accessing merging markets.

The literature and analysis present a comprehensive view of the multifaceted challenges pharmaceutical companies encounter when commercialising and developing drugs in emerging markets. Both regulatory and clinical trial challenges are prominently featured. Regulatory frameworks in emerging markets are complex and varied, which makes synchronisation of product development approaches difficult. The study of Uddin (2021), and Bamakan et al. (2021) featured the time-consuming nature of getting market authorisations, due to more up-to-date regulatory systems with few rules. These issues delay product development timelines, and compromise trial quality, eventually influencing worldwide approval processes. Strategic partnerships with neighbourhood expertise, can alleviate a portion of these difficulties, yet significant general public health investments, are expected to support infrastructure, and human resources.

Manufacturing difficulties, likewise present substantial barriers for the pharmaceutical companies. The high capital investment needed to lay out manufacturing plants, and R&D centres, coupled with the need for specialised training, presents critical obstructions (Haldhar et al., 2021; Patel et al., 2022). Moreover, the differential compliance requirements, for cGMP, and batch testing among emerging, and developed markets add another layer of complexity (Halwani, 2022). Ensuring consistent technology transfer is hindered by language, and cultural

barriers, influencing the absorption of knowledge necessary, for complex production processes. The costs, and risks associated with these difficulties deter investment except, if long-haul sales potential is evident. Standardisation efforts, and skills development programs are critical for optimising manufacturing functions, in these regions over time. Supply chain difficulties are particularly pronounced, in emerging markets due to logistical, and infrastructural inadequacies. The management of dynamic pharmaceutical ingredients, and drug inventories requires broad planning, and resource investment, particularly for temperature-sensitive products (Othman et al., 2021; Nayak et al., 2022). Last-mile delivery issues are exacerbated, by poor transportation, and storage infrastructure, making it challenging, to keep up with cold chains (Bamakan et al., 2021). Irregular power supplies, and fluctuating orders from the public sector, further muddle supply chain reliability. Robust supply chains require customised operations, tailored to nearby settings, leveraging mobile depots, and collaboration with local distributors, to upgrade accessibility (Thapa and Kim, 2023).

The socio-cultural setting, likewise assumes a critical part in commercialising pharmaceuticals. Factors like local perceptions of diseases, cultural acknowledgement of treatments, and financial conditions, impact consumer adoption (Azam and Abdullah, 2020). Limited infrastructure, and network issues in remote areas, represent additional difficulties to distribution, and patient access (Bamakan et al., 2021; Akpan et al., 2022). New partnerships, and regional manufacturers can upgrade local production, through technology transfer. However, these require pilot testing, and explicit commercial models to be set (Akpan et al., 2022). Financial stability concerns, further exacerbate these difficulties. Various components, including reference-based pricing systems, and increased generics rivalry, are implemented to restrict drug costs, in emerging markets (Reinhardt et al., 2020; Grangeia et al., 2020). Monetary constraints in public healthcare settings require, prioritising treatments, based on cost adequacy (Godman et al., 2021). Potential access models like tiered pricing, and value-based purchasing offer arrangements, as well as collaborative approach changes, and stakeholder coordination, are fundamental for sustainable development (Godman et al., 2021).

5.3 Objective 2: Impact of Regulatory and Policy Issues

The process of developing a successful drug is a challenging task and requires a significant amount of resources, time and effort. Pharmaceutical companies often face challenges that can hinder the development of potentially life-saving drugs. These challenges can range from regulatory hurdles to high research and development costs. The findings clearly indicate that Regulatory hurdles are an essential challenge faced by Pharmaceutical companies. The companies must attain compliance in of a complex system and get certification for safety and effectiveness of their drugs as per local standards to get approval for marketing the product (Halwani, 2022). This process has multiple phases and may involve multiple agencies and bodies which in turn increase the expenses and time duration of entire drug development process. The companies already invest heavily in clinical trials and they face additional costs for approval. Consider the example of Pfizer which spent over USD 2 billion on clinical trials to develop its drug Lipitor for cholesterol-control and get approval from the FDA (Herman, 2019).

The challenge of high costs again emerges because companies having already spent multimillion budget on research and development need to spend more for approval and then ultimately they need to recover the costs and expenses through pricing and selling strategy. Typically there are high investment required during clinical trials and R&D process which includes investment in drug candidates, preclinical research, and final clinical trials (Iskandar et al., 2021). An example of this is report published by the Tufts Center which showed that the average Drug Development cost is over USD 2 billion (Hodsden, 2014).

Another important challenge is the competitive environment in emerging economies which is quite different from its counterparts in the USA and Europe. The companies are continuously rivalling to market new and better drugs while also seeking affordability and safety. The difference in competitive environment may also make it difficult for western companies to reach and effectively compete in emerging markets (Liu et al., 2022).

The price automatically becomes important because the significance of the costs in pharmaceutical product development. The pricing pressure is significant in all cases and in all markets. There are multiple stakeholders that pharmaceutical companies must satisfy while developing pricing strategy which include payers, government and insurance companies. These stakeholders can put pressure on the companies to lower prices which affect revenue and

profitability of the companies. As an example in 2014 Gilead Sciences marketed hepatitis C drug Sovaldi for USD 84,000 (12-week course). In response to this pricing the company faced significant reaction from various stakeholders particularly payers and public advocacy organisations (Johnson and Dennis, 2015).

In addition to above there is also the challenge of managing intellectual property rights in emerging countries. The importance of managing intellectual property challenges is reflected by the fact that pharmaceutical companies need to protect their products from counterfeiting and infringement by rivals. The protection can often be expensive as well as time-consuming (Mehta et al., 2022).

Overall, drug development becomes a very challenging process that pharmaceutical companies must go through by dedicating significant resources and time making the drug more expensive and costly. The complex regulatory environment and requirements, heavy investment in R&D, large expenses in competing and marketing, high costs of intellectual property protection, and prices pressures are the main factors that companies must tackle.

In addition to above, the results showed that one of the main hurdles is quality assurance. Pharmaceutical companies must maintain very high quality for patient safety, drug effectiveness, and to outperform rivals in emerging markets. Therefore, it is essential to engage with a specialised company that has the necessary experience in managing the MAP process (Liu et al., 2022). The products handled range from prescription drugs, biological products, innovative products, generics, room temperature products and refrigerated lines, controlled drugs and diagnostic products. A customer base of pharmacies, government institutions, hospitals and clinics in various jurisdictions around the world must be served. All requests require meticulous execution, from small to large orders and moderate to remarkably high value (Reinhardt et al., 2020).

It requires a Quality Management System (QMS) that is fully functional and robust. It needs to apply the usual procedures and apply them well. It requires meticulous documentation and continually evolving the QMS to keep it ahead of the regulatory curve in Europe and the United States. Interestingly, it is not the emerging markets that pose the challenge, but gaining access to much-needed drugs from Western pharmaceutical companies and finalising a deal is the biggest hurdle we face on a daily basis. In that context, companies like ours can eliminate the

fear of the unknown and mitigate the risk of distributing much-needed medicines in emerging markets (Halwani, 2022).

The role of pharmaceutical companies in the development of prescription drugs is a complex and multifaceted issue that provokes diverse opinions from healthcare stakeholders. On the one hand, these companies invest significant amounts of money and resources in the development of drugs that can treat and cure diseases. On the other hand, critics argue that the primary motivation of pharmaceutical companies is profit and that this often leads to the development and marketing of drugs that are not safe or effective. Collaboration between pharmaceutical companies, and healthcare providers is crucial, to ensuring that prescription medications are used safely, and effectively (Saïd, Sevic, and Phillips, 2019). It includes educating healthcare providers, and patients about the risks, and benefits of prescription medications, as well as continuous monitoring of their use. While the role of pharmaceutical companies, in the development of prescription drugs, is complex, and controversial, it is clear that these companies play an essential role, in the development of life-saving treatments. At the same time, it is necessary to ensure that, patient safety continues to be a priority, and that the risks, and benefits of prescribed medications are carefully weighed and evaluated (Yip et al., 2019).

The review, and examination of the regulatory environment in emerging markets, provide several critical information regarding the difficulties, and opportunities faced by pharmaceutical organisations, in drug development, and commercialisation. A comparison of the findings from the literature, and the thematic analysis reveals a complex landscape, marked by diverse regulatory frameworks, clinical trial requirements, post-marketing regulations, quality standards, and pricing policies. The literature features the critical variance, in drug approval processes across emerging markets, complicating the global drug development program. Diverse regulatory paths, and the absence of standardisation, as noted by Bouwman et al. (2020), and Liu et al. (2022), create uncertainties, in application durations and entangle global dossier compilation. This issue is compounded by varying accommodation requirements, and the periodic reclassification of drugs, which delay patient access, and hinder the synchronisation of market entry strategies. Darrow et al. (2020), underline that these variances require early consultation, with regulatory offices, and efforts to harmonise dossiers, on a worldwide scale to relieve

shortcomings, and streamline approvals. Then again, it has been determined that, emerging markets present critical difficulties, due to their differing clinical trial requirements, influencing the synchronisation of development schedules. Godman et al. (2021), and Iskandar et al. (2021) note that variations in late-stage evidentiary requirements, patient numbers, trial durations, and endpoints, disrupt worldwide strategies. These discrepancies require tailored studies, increasing costs, and delaying patient admittance to new treatments. Infrastructure constraints, ethical approval processes, and fragmented data sharing, further exacerbate these difficulties, making cross-regional trials difficult. The investigation recommends that, regulatory convergence assists with harmonising core standards, addressing failures, and fostering smoother, clinical trial processes.

Moreover, there needs to be more reliable pharmacovigilance arrangements, and post-marketing regulations across emerging markets, which present another layer of complexity. El-Khateeb et al. (2021), and Kiriiri et al. (2020) feature the uneven approaches, to monitoring approved drugs, which confuse worldwide safety profiles, and risk signalling. These irregularities demand broad resources, for compliance, and hinder the foundation of universal surveillance guidelines. Strengthening pharmacovigilance networks, and adjusting core guidelines could improve post-approval compliance, and upgrade the security monitoring of pharmaceutical products, around the world. However, quality standards for manufacturing, likewise vary fundamentally across emerging markets, creating operational difficulties, for pharmaceutical organisations. Halwani (2022), and Liu et al. (2022) call attention to the fact that different cGMP standards, and quality control mechanisms, entangle the integration of manufacturing processes, and increase compliance costs. Variations in defect characterisation, change control procedures, and stability testing requirements, add to the uncertainty in gathering long-haul quality commitments. To address these difficulties, the investigation proposes that, regional harmonisation of value standards, could reduce operational complexity, and ensure reliable quality across different markets.

Pricing, and market access approaches in emerging markets, influence the commercial reasonability of pharmaceutical products. Mialon (2020), and Nemteanu and Dabija (2021) describe how international reference pricing, and restrictive reimbursement policies hinder ideal pricing strategies, and the take-up of innovations. Price controls, and differential tax systems,

further entangle pricing determinations, and predictions, influencing profit margins and market access. The investigation indicates that, collaborative value-based models, and strategies tailored to local monetary conditions, could address these difficulties, promoting both populace health, and sustainable plans of action. The literature, and examination both underscore the importance of harmonisation, and collaborative models in addressing the regulatory challenges in emerging markets. Liu et al. (2022), and Halwani (2022) recommend that, common recognition and regional harmonisation can reduce approval times, and costs by adjusting logical standards, and working with capacity-building initiatives. Collaborative models, such as regional GMP training, and investigation harmonisation, can strengthen regulatory frameworks, and create a conducive environment for private capital investment. These efforts could upgrade regulatory productivity, improve admittance to innovative treatments, and support the sustained development, of the pharmaceutical industry, in emerging markets.

5.4 Objective 3: Market Access Issues

The results identify various access issues faced by pharmaceutical companies. The primary access issues include distribution, infrastructure, adoption, and payer challenges. Considering the discussion above, pharmaceutical companies play a crucial role in developing high-demand medications that meet patient needs. These companies invest significant resources in research and development to identify new compounds and molecules that can treat medical conditions more effectively. Many of these drugs are classified as "successful" due to their widespread use and high demand (Mialon, 2020). However, the role of pharmaceutical companies in the development of these drugs may be a topic of debate. Some argue that these companies prioritise profits on patients' needs, while others maintain that their efforts are essential to advancing medical science (Reinhardt et al., 2020).

An important critique on pharmaceutical companies is that they are more oriented towards profit than patient needs. Therefore, in pursuit of high profitability they tend to increase high prices which in turn make it difficult for many patients to afford it. As a solution some companies offer patient assistance programmes and collaborate with insurance companies to make products affordable. For example, Gilead Sciences collaborated with insurers for its product (Sovaldi for hepatitis C, priced at $84,000 - 12-week course) to lower the prices

(Millman, 2014) and make it affordable. Despite the fact that there are cases where profits were prioritised over patient needs, there are also rationale for high price of products such as improving patient outcomes and advancing medical science. Overall, the pharmaceutical companies need to face the challenges of affordability, high costs, and stakeholder pressure by developing effective solutions and make the products affordable.

Another accessibility issues faced by pharmaceutical companies is reliance on patent protection. Companies rely on patent protections as they need to recover costs of drug development. These protections are necessary for other companies to produce generic versions of the drug, reducing profits and undermining the incentive to invest in research and development. However, patent protections can also limit access to medicines, particularly in developing countries where generic medicines are often more affordable. Some argue that alternative models, such as prize funds or government subsidies, could provide incentives for drug development without limiting access to drugs (Lopez-Salido et al., 2021).

Despite the concerns above, one cannot deny the impact of pharmaceutical companies on the healthcare system as well as the economy. The healthcare industry has been significantly affected by the drugs produced and marketed by companies as they have brought a paradigm shift in the treatment of diseases. These drugs not only have revolutionised the way patients are treated, but they have also had a significant impact on the business model of the healthcare industry. From pharmaceutical companies to healthcare providers, every stakeholder in the industry has been affected by these medications (Godman et al., 2021). Companies affect the healthcare system and economy in various ways while facing challenges in this regard.

One of the impacts is increased profitability for pharmaceutical companies, which in turn translates into the growth and development of all stakeholders, including employees. These drugs have allowed companies to earn billions of dollars in revenue, which has resulted in higher profits. For example, Humira, a drug used to treat rheumatoid arthritis, generated $19.9 billion in sales for AbbVie in 2018, making it the world's best-selling drug (Gibbons and Laber, 2023). It demonstrates the significant impact that successful drugs can have on the profitability of a pharmaceutical company. It increased wealth and shareholder value while also accumulating more resources for the company to invest in the development of new drugs. In the case of

emerging economies, the companies face significant difficulties in terms of reinvesting and getting patents, which in turn affect their profitability.

The accessibility issues above are also interrelated with pricing issues and challenges. Since the cost of production is high, medications may also have very high prices. Pharmaceutical companies often face criticism for excessively high drug prices. Price increases, particularly for essential medicines, have resulted in limited accessibility, impacting patients' ability to pay for necessary treatments. It is because of the use of profit-driven pricing strategies has contributed to public discontent and a negative public perception of the industry (Raj et al., 2022).

Another relevant challenge within the context of pricing and accessibility is the lack of transparency. The lack of transparency in drug pricing and reimbursement practices has fuelled public scepticism. Pharmaceutical companies' reluctance to disclose the cost components of developing, manufacturing, and marketing drugs has left the public questioning the fairness of pricing decisions and the industry's commitment to affordability (Kolk et al., 2014).

Another accessibility issue worth highlighting, as identified in the results, is the patent protections and generic delays in emerging markets. Although the patent system protects innovation, it has also been a source of criticism. Prolonged periods of patent exclusivity can delay the availability of affordable generic alternatives, prolonging monopolies and limiting market competition. These delays contribute to the perception that pharmaceutical companies prioritise profits over patient access. These issues correlate with inadequate competition in emerging markets due to a lack of economic development as well as developing regulatory frameworks (Sundaram, 2018).

Besides pricing, there are also marketing and promotion practices. One of the effective marketing strategies in pharmaceutical companies is Direct-to-consumer advertising. The aggressive direct-to-consumer advertising practices of pharmaceutical companies have attracted a lot of attention. Critics argue that such marketing tactics can inflate demand for specific medications, influencing prescribing patterns and potentially compromising the doctor-patient relationship (Malik, 2020). These practices have raised concerns about industry ethics and prioritising profits over patient well-being. Therefore, developing countries are formulating regulations to prevent such behaviours following the developed countries.

In developed countries, pharmaceutical companies can manage compliance by getting certification and approval from authorities such as the FDA; however, managing medication safety and regulatory compliance in emerging countries can become an issue, as shown in the results chapter. The first and most important among these issues are product safety issues. Cases of drug recall, manufacturing defects, and safety issues have significantly affected public trust in the pharmaceutical industry. High-profile cases (in which serious adverse effects were discovered after a drug was approved and widely used) have fuelled scepticism about the thoroughness of safety testing and the effectiveness of regulatory oversight in emerging markets (Palaian, 2018).

Critics argue that the pharmaceutical industry's influence on regulatory bodies can compromise the rigour of safety and efficacy evaluations. Perceived conflicts of interest and revolving door phenomena, in which individuals transition between industry and regulatory agencies, have raised concerns about the independence and objectivity of regulatory decision-making. Legal battles and major settlements related to illegal or unethical practices have tarnished the industry's reputation. Cases involving fraudulent marketing, misleading clinical trial results, or failure to disclose safety risks have further fuelled public scepticism and reinforced perceptions of profit motives (Ford and Tomossy, 2018).

Pharmaceutical organisations need critical market access and pricing difficulties while operating in emerging markets, affecting their capacity to really commercialise new drugs. One major hurdle is distribution shortcomings, particularly in remote rural areas (Thapa and Kim, 2023; Bamakan et al., 2021). These regions frequently, need robust transport networks, and mature supply chain arrangements, making last-mile delivery difficult (Thapa and Kim, 2023). Albeit innovative approaches like mobile depots, offer expected arrangements, they involve massive costs, and require adaptation to nearby conditions, confusing distribution efforts further (Othman et al., 2021; Nayak et al., 2022). Inadequate healthcare infrastructure, further complicates market access. Emerging markets frequently, come up needing more diagnostic equipment, testing laboratories, and reliable refrigeration, and temperature control systems (Bamakan et al., 2021; Akpan et al., 2022). This deficiency, hinders accurate patient identification, proper product monitoring, and proficient delivery operations. Executing connected solutions, to address these gaps, is complex due to unreliable electricity, and internet

availability, particularly in rural areas (Thapa and Kim, 2023). In this way, long-haul investments in developing modern physical, and mechanical infrastructure, are crucial. Socio-cultural factors, additionally present critical adoption challenges. Deep-rooted convictions, and traditions impact disease perceptions, and acknowledgement of new treatments (Azam and Abdullah, 2020). Low public health awareness, and literacy further restrict the adequacy of educational missions, aimed at introducing imaginative products (Al-Hanawi et al., 2021). Additionally, inadequate insurance coverage implies numerous patients, are not able to afford costly branded drugs, exacerbating the issue of low disposable earnings, in these markets. High treatment costs, subsequently become a significant barrier, underscoring the need for social interventions, to support healthcare insurance penetration, and targeted subsidies (Ocran Mattila et al., 2021).

Then again, public, and private payer challenges further confound market access. Government interference, through methods like international reference pricing, essentially reduces profitability for pharmaceutical organisations (Mialon, 2020). Constrained healthcare resources, and moving funding priorities, towards broader national economic development objectives pressure, payers' ability to pay for premium therapeutic innovations (Nemteanu and Dabija, 2021). Conflicting formulary listing, and reimbursement criteria across countries, add another layer of complexity, hindering coherent health technology evaluation (HTA), and reimbursement models (Nemteanu and Dabija, 2021). Pricing arrangements in emerging markets, likewise present substantial difficulties. Government regulations frequently cap drug prices, to upgrade accessibility, and affordability, keeping up with lower profit margins, for pharmaceutical organisations (Verghese et al., 2019). Frequent price adjustments, take out opportunities for price climbs, restricting firms' capacity to recoup research, and development costs (Charitou et al., 2016). International reference pricing components, which set domestic drug prices, based on costs in other countries, neglect to consider substantial financial differences among countries, further constraining pricing adaptability (Persson and Jönsson, 2016). Generic rivalry, strengthens these pricing pressures. Arrangements favouring higher generic utilisation, intend to increase treatment accessibility among low-income individuals; however, they frequently disadvantage, branded drugs (Reinhardt et al., 2020). Tendering practices, and programmed replacement benefit minimal expense generics, while limited intellectual property protection, exacerbates the contest (Grangeia et al., 2020). When licenses

expire, branded drugs face steep drop-offs in market share, severely restricting their capacity, to generate adequate returns (Lopez-Salido et al., 2021).

Limited healthcare budgets, in emerging markets exacerbate these difficulties. Numerous countries dedicate under 5%, of their GDP to public healthcare spending, due to contending developmental priorities (Al-Hanawi et al., 2021). It restricts the funds accessible, for adopting, and covering, new premium-priced pharmaceutical innovations. Public and private payers are only willing to assign scarce resources with demonstrated cost-viability, pressuring drug developers to lower prices persistently (Roy et al., 2021). Low consumer wages further constrain pharmaceutical access. Indeed, even with marginal price reductions, treatment costs remain unaffordable for a critical segment of the populace due to limited purchasing power (Kolk et al., 2014). It underscores the need for comprehensive social interventions, including helping healthcare insurance coverage and providing targeted subsidies to monetarily disadvantaged groups. Public-private partnerships and direct subsidisation of costs can assist with moderating the effect of low wages on pharmaceutical access (World Bank, 2022).

Chapter 6: Conclusion

6.1 Conclusion

Drug development and regulatory challenges in emerging markets were found to be significantly diversified compared to the readiness and standardisation of developed markets. Due to increased research and development in emerging markets and a need for change management within the industry's operative, the study found that the regulatory hurdles do not readily enable the companies to embrace the desired level of growth rate. Contrarily, the study also found that emerging markets are readily dependent on policymaking from the government sector, which enables their decision-making to shift towards research and new product development. However, the inclusion of price-roof and price-ceiling practised in the emerging market does limit the manufacturer's intention of incorporating research and development to enhance the field of operations.

This research embraced the usage of content analysis, which enabled the internalisation of diversified emerging markets in the pharmaceutical industry. The study analysed the market conditions of different economies, which are readily distinguished from each other due to policies, competition, and population size in respective markets. Furthermore, the findings from the content analysis revealed that the market structure is inherently dynamic and is based on consumer requirements. Despite the marketing efforts of existing pharmaceutical companies, the regulatory bodies ensure that pull marketing is embraced by the companies while push marketing is highly discouraged and penalised. Therefore, the market conditions continue to operate within the grey area to construct business relationships with prescribers, which may illicitly increase the interest of practitioners towards prescribing a drug. Thus, the study concluded that a standardised approach of the pharmaceutical industry in developing markets is not extensively present in developing economies.

In the commercialisation of a drug, the study found that the extensive requirement of registering a drug for commercialisation is a lengthy process for emerging markets, which increases the opportunity cost of research and development. Therefore, it is essential that the regulatory practices are automated and waiting time is reduced for the commercialisation of the drug process. Otherwise, businesses can face significant setbacks in achieving their desired feasibility. Furthermore, developing markets have faced significant discrimination, where

famous brands with extensive research facilities are facilitated more by regulatory departments, while lower research facilities are readily tested. Contrarily, the study found that the regulatory bodies are inclined towards testing the shelf-life of the product, along with its efficacy, before licensing it for commercialisation. However, for expanded research and development units at big pharmaceutical companies, their knowledge regarding formulated drugs is extensive, and they are able to comply with the requirements of regulatory bodies inherently. In the case of smaller companies, they are accompanied by challenges in fulfilling the requirements of drug regulatory bodies, which results in resistance to the registration process.

The inclusion of price indexes in developing markets was found to be highly elastic, with brands pursuing higher prices. At the same time, the competing companies tried to control their prices, which significantly countered their revenue generation. Thus, the respondents were found to be adamant about challenging their respective revenue streams in pursuit of defending their embracement of the lack of research in the industry. Companies cannot meet the opportunity cost associated with research and development with controlled revenues as the market conditions are highly dynamic. Furthermore, the limited product list of smaller-scale companies needs to enable them to adjust to the seasonal requirements of drugs.

Meanwhile, large-scale companies plan their inventories according to the market'smarket’s requirements. The research found that antibiotics are increasingly common in treating bacterial infections spread across a region. Conversely, smaller companies are inclined towards regularly prescribed drugs with retained patients to ensure their revenue cycle.

There are various independent stakeholders in the pharmaceutical supply chain in developing markets. The stakeholders in the study were identified as manufacturers, marketers, and distributors. All of this can be internalised into a singular company. However, to impede the existing risk associated with the development of the market, several companies in developing markets have chosen to outsource their respective operations and deal with marketers and distributors distinctively. As a result, they compromise on their profitability, resulting in an increased challenge for their sustainability. Furthermore, the study assessed that the manufacturers may impede losses in outsourcing their supply chain protocols; however, they ultimately bear the risk of loss in the market. Therefore, the study primarily sought a conclusion

that internalisation of a business process can enable them to incorporate benefits at the time of peak business cycle rather than fearing the loss in the low market season.

The study also found that the presence of regulatory bodies is an evident challenge in the market to regulate competition. Otherwise, a necessary good for the sustainability of society can be sold for irrational profitability by the companies due to the risk of fatality for the patients. Therefore, it was essential to maintain elasticity in pricing for a specific range. Otherwise, the challenge between demand and supply of the products could have harnessed significant pressure on the consumer market. In the developing markets, the lack of standardised criteria for commercialising drugs has also inferred significant challenges in market conditions, such as accessibility for consumers. As a result, the consumer market has readily suffered, particularly in the rural areas. The study also evaluated that the lack of population density in rural areas resists the probability of stock liquidation, resulting in the firms opting out of rural areas, which enables distributors to expand their business while increasing the price of the product. Therefore, the study emphasised controlling the number of stakeholders associated with the pharmaceutical supply chain industry and continuing with the desired level of growth by internalising the operation. Moreover, the study concluded that the internalisation of the business supply chain can be a beneficial yet complicated task in pursuit of taking financial advantage.

The clinical trial requirements in the developing markets of the world is an extensive procedure that the market has to follow in pursuit of completing its registration process. However, for companies and businesses, clinical trial requirements are found to be an additive investment which increases the cost of registering a drug. Furthermore, the marketing challenge remains persistent, where they have to provide sufficient samples to the practitioner to gain their trust in the drug along with their satisfaction with the side-effects of the drug. The differentiated methods of marketing followed in the commercialisation of drugs in developing markets has extensively betrayed standardisation initiatives taken by the market. Furthermore, it does not efficiently enable the business to mitigate risks associated with external competition and marketing practices. Moreover, the study found that the ethical responsibility in developing markets is also marginalised to favour profitability by companies. However, it is a vital prospect for the development of industry with a holistic approach.

The globalised conglomerates of the pharmaceutical industry have developed a franchise model for developing markets where they do not establish their physical presence in developing markets but ensure that their product is available for consumers. The study depicted that the regulatory environment needs to be more readily supportive of importing manufactured drugs from abroad; therefore, they have increased the barriers associated with importing a foreign drug. Localised manufacturers have developed an understanding with the companies where they are allowed to manufacture the internationalised product with royalty to be paid to the principal company, resulting in compromised profitability. However, companies are not adamant about licensing their product with a similar chemical composition due to increased exposure to the regulatory environment in the region. The perception of regulatory bodies in developing markets is extensively challenging as the manufacturers and businesses observe them as a challenge rather than a moderating body which ensures that the quality and sustainability of the market remain intact.

The association with international accreditation of quality standards are noticed to ease the regulatory process as it builds rapport with the regulatory bodies of the localised regions. It enables the companies to expand their quality protocols. However, the results depicted that the quality required for international accreditation requires strict protocols and often hinders the process of revenue for pharmaceutical companies. Furthermore, it is observed as an additional process among several companies that are dealing with regulatory bodies and are significantly inclined towards getting a commercialisation license for a product. The challenges associated with commercialisation, as per the results, include extensive regulatory challenges, decisions on a feasible price, and manufacturing challenges for new drugs, which require disruption in the company's existing supply chain while enhancing the system towards increased efficiency. Furthermore, the study developed a conclusion that the localisation of international companies in developing markets is not inherent, resulting in comprehensive challenges associated with the development of market conditions. It also reportedly increases the cost of manufacturing for business due to increased shipment costs of imported materials and foreign exchange rates.

6.2 Recommendations

From the aforementioned findings of the research, there are diversified recommendations that can be implemented to empower the developing markets' pharmaceutical sector by easing the business connection with relevant stakeholders of the market through the following:

- The adaptation of clinical trials along with commercialisation of the drugs can sufficiently control the opportunity cost associated with selling the drugs and attaining desired level of sustainability (Mialon, 2020). However, the step must be taken with vigorous efficacy and lab tests to ensure that the drug does not fatally harms someone's health. Furthermore, in line with the preceding recommendation, it is important that the businesses establish an engaging relationship with the representatives of regulatory bodies to informally speed up their process. It can result in early achievement of commercialisation of the drugs and can enable companies to reduce their opportunity cost associated with selling a drug.
- For the new entrants in developing markets, irrespective of their internationalised presence, it is important the company hires representatives or sales work force to integrate rapport with the practitioners and prescribers (Thapa and Kim, 2023). It can result in comprehensive reminder of the drug while mitigating the competing brand from increasing their sales to add to their respective brand value. Developing markets have a gifting tradition to ensure that the name of the drug is remembered by the prescriber and they are inclined with the choice provided by the business to ensure patient's safety. However, it is important that the quality of the drug is not compromised.
- The regulatory bodies should ensure free market conditions which allows the brand to change their respective pricing in pursuit to establish desired level of price elasticity. The increasing price of drugs has limited the accessibility of the drugs towards rural market and towards developing market, as a whole (Grangeia et al., 2020). Through inclusion of price elasticity enforcement through a free market theory, the accessibility of the market can be extensively improved and businesses can empower themselves with consequent advantage of increased revenue. Furthermore, companies can engage in active pricing competition that can benefit the market and its development towards research.
- The developing economies businesses in the pharmaceutical industries are focused towards short-term sustainability and profitability strategies which has made them sales-

centric (Roy et al., 2021). However, through the persistence of long term strategies, their pricing strategies can be readily improved along with the inclusion of relationship with the regulatory bodies. Once the businesses build a rapport with regulatory bodies, and get accustomed to the process of their involvement in pharmaceutical industry, companies can readily undertake the commercialisation process easily. It will result in comprehensive achievement for the industry to think in a long term goal.

- The existing drug range for the companies within the developing market should be readily expanded and the profitability generated through existing sales should be re-invested in the research and development process to ensure that the businesses are ready compete in the market. With the growing trend of changing bacterial formation, along with viruses, it is important that research is continuously integrated to ensure that the existing drug is viable to treat the condition. Otherwise, obsolete drugs can be readily diminished in the market with new entrants taking the space with their mutated drugs.

6.3 Limitations

The primary limitation of the research expanded to the inclusion of qualitative data which did not enable the research to explore the issues in depth. From the secondary studies incorporated in this research, the study formulated its results based on the findings of preceding studies based on diversified market. However, Drisko and Maschi (2016) stated that a focused study with predefined variables can provide a deeper look into the market for the stated variables while testing their involvement and relationship with the dependent variable. Contrarily, the study was limited in identifying the high inclusion factors of pharmaceutical industry challenges. The identified challenges in the topic of the research were primarily focused on qualitative data set with non-numeric values. Thus, the study was found to be limited in providing ecologically valid findings with concrete data set regarding the challenges associated with pharmaceutical industry in the developing market.

There was a significant resource constraint in the existing research where the secondary studies incorporated in this research were based on region-specific criteria. Meanwhile, the existing study was focused on the inclusion of developing market, around the world. It primarily broadened the scope of the research. Liu et al. (2022) stated that the policies in developing economies are readily differentiated due to their interest in economic growth plans. Therefore, it is noticed that the inclusion of a region-specific study on the same topic could yield focused

results. However, there were limited insights on the market conditions that were provided in the research while not extensively investigating on the business practices that can be considered to unethical. Therefore, the research could have improved through a region specific criteria that results in ecologically valid findings for the pharmaceutical industry.

The insights associated with market conditions can only revealed through incorporation of primary data for a particular market (Iskandar et al., 2021). The pharmaceutical industry operates with significant secrecy regarding their prevalent sale strategies; therefore, it cannot be navigated through secondary studies. Furthermore, the precedent of business operations, supply chain and regulatory practices are determined to be highly confidential which leads to significant discrepancy in secondary studies incorporated in this research. Thus, the study was found to be limited in providing a logical flow to the arguments to depict the level of challenges faced by pharmaceutical industries in developing economies.

6.4 Areas for Future Research

The pharmaceutical industry around the world are highly dynamic with range of differentiated factors across the economic conditions. Therefore, the areas for future research after identification of challenges in the study are focused on the following:

- Access different markets for focused research using quantitative variables. Particularly, the research should be extensively focused on differentiated pricing of the same chemical compound with different brand names. The brand equity can be measured through the net sales of the company and analyse the correlation for pricing, if there exists a significant relationship between the two variables.
- The accessibility to medicine in the rural market should be extensively compared with the regulatory practices for a cross-country comparison study. This way, the study will yield results for efficient practices for regulatory bodies in pursuit to ensure that the health sector significantly advances and ensures the capability of pharmaceutical companies to address the growing challenges associated with lack of availability of medicine in remote areas.
- The localisation of pharmaceutical industry in developing markets should be studied along with efficacy of the product in the existing market conditions. It can result in comprehensive development of pharmaceutical sector and enable the stakeholders to

know if localisation of manufacturing process can be a successful long-term strategy or not. It can enable the organisations to ensure that their growth patterns are aligned with the requirements of market conditions resulting in efficiency for all the stakeholders in the market.

- The future research should extensively focus on the perception of consumers towards the internationalised pharmaceutical market operating within their localised region. It will enable the stakeholders of the industry to realise the potential for expansion into the global market while analysing the prospect of expansion through the lens of acceptability into the international market.

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