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The Impact of Generic Drug Entry in the South African Market

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360328

A research dissertation submitted to the Faculty of Commerce, Law, and Management, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Master of Business Administration

Supervisor

Dr. Thubelihle Ndlela

Johannesburg, 2024

DECLARATION

I, Tshepiso Leballo, hereby declare that this thesis is my own work. This research paper (thesis) is submitted in fulfilment of the requirements for the Master of Business Administration in the Faculty of Commerce, Law and Management at the University of the Witwatersrand, Johannesburg South Africa. In addition, I declare that:

1. I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is an academic offence.

2. Where external sources have been used, all have been acknowledged by means of appropriate in-text citation and added to the list of references.

3. This thesis has not been submitted before for any degree or examination at this or any other university.

4. I recognize that it was my responsibility to conduct this research in an ethical manner and according to the guidelines of the University of the Witwatersrand.

ACKNOWLEDGEMENTS

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I am truly thankful to my husband (Norman Mhlanga) and children for their unwavering love, patience, and understanding during this demanding period. Thank you for believing in my dreams, providing the support I needed while planning a wedding in my first year of study, and welcoming our beautiful daughter during my final year.

Lastly, I wish to express my gratitude to my parents and siblings for their encouragement and support. Thank you for motivating me to excel in all my endeavours and for stepping in for my family on days when my academic commitments required my absence. This thesis would not have been possible without the collective efforts of everyone who has been part of this journey.

DEDICATION

This master's thesis is dedicated to my children, Oratilwe (7) and Onthatile (2 months). I wrote this thesis while pregnant with Onthatile and submitted it with her in my arms. Follow your dreams and always remember that education is the key to success.

ABSTRACT

This study explores the impact of generic drug entry into the South African pharmaceutical market, focusing on pricing strategies, market competition, patient access, and regulatory dynamics. Using a qualitative approach, semi-structured interviews with pharmaceutical marketers revealed that the introduction of generics substantially lowers medicine costs, increases affordability, and places downward pressure on originator drug prices. Thematic analysis showed that medical aid reimbursements, regulatory price controls, and market competition shape pricing decisions. However, resistance persists among some healthcare professionals and patients due to lingering concerns over generic drug efficacy and quality. To address this, educational campaigns and rigorous bioequivalence testing were identified as crucial enablers of acceptance. The study further found that generics improve healthcare accessibility, especially in rural and underserved areas where affordability significantly influences treatment adherence. Despite these gains, regulatory hurdles such as patent laws and delayed approval timelines impede timely market entry of generics. The research recommends that policymakers expedite regulatory approvals and implement targeted awareness strategies to build public trust in generics. This study contributes new insights into the strategic perspectives of pharmaceutical marketers and offers actionable recommendations to improve generic medicine uptake. It lays a foundation for future research using quantitative methods to measure economic and health outcomes more precisely. Overall, the findings support broader policy objectives aimed at promoting equitable access to essential medicines and reducing healthcare system costs through increased use of generics in South Africa.

Keywords

Price erosion, Originator medicines, Generic medicines, Prices

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Chapter 1: Overview of the study

1.1. Introduction and Background to the Study

The South African pharmaceutical market has recently experienced an increase in the launch of new generic medications following SAHPRA's announcement in 2019 to reduce registration timelines from over five years to approximately two to three years (SAHPRA, 2023). This change indicates that a more significant number of registrations will occur in a short period, thereby enabling patients to access more affordable medicines more quickly. Research indicates that 64% of all prescription medications sold in South Africa are generic, while only 36% are innovative (Bangalee & Suleman, 2019). Despite the higher volume of generic medication sales, a significant amount of money continues to be spent on innovative medicines. Among the 64% of generic drugs sold, many are derived from the same originator molecule, with some having up to 13 generics emerging from one original compound (Inseng & Chuma, 2020). These generics are offered at competitive prices lower than the originator product and recently launched predecessor generics. Notably, the price difference can reach as high as 60% compared to the originator's (Inseng & Chuma, 2020).

With a life expectancy of 65 years and a Gini index of 0.63, South Africa holds the highest income inequality in the world (Stats SA, 2024). This disparity significantly influences patients' decisions regarding purchasing either originator or generic medications, depending on their affordability. Life expectancy has also been adversely affected due to reduced access to optimal treatment options caused by financial constraints (Xinxi & Yabing, 2020) .

What impact does the availability of generic medications priced 60% lower than their originator counterparts have on patients and the pricing of the originator's medication?

1.2. Problem Statement and Research Gap

The escalating cost of pharmaceutical treatments globally has become a significant barrier to equitable healthcare access, particularly in low- and middle-income countries (LMICs). A considerable body of international research has explored the pricing dynamics between branded originator drugs and their generic counterparts, highlighting stark disparities in affordability and accessibility (Avik, Anuj, Abhishek, Ghosh, 2020). For instance, a study conducted in India on medications for thromboembolic conditions found wide cost variations among anticoagulants, fibrinolytics, and antiplatelets (Avik et al., 2020; Godman et al., 2021). These findings underscore the critical role of prescribers in considering patients' financial capabilities when selecting therapies, especially in resource-constrained settings.

Globally, the pricing of life-saving medications—particularly cancer treatments—remains a growing concern. Cancer drugs introduced between 2009 and 2014 averaged over USD 100,000 annually, with some newer therapies nearing USD 500,000 per year (Leighl, Fernandez, Caissie., 2021). Such exorbitant pricing severely limits access for most households, even in high-income countries like the United States. In LMICs such as Thailand, patients often face catastrophic health expenditures, sometimes resorting to borrowing or selling assets to afford treatment (Leighl et al., 2021). The introduction of generic and biosimilar medicines has been shown to mitigate these costs by reducing originator prices, improving affordability benchmarks for insurers, and expanding treatment options (Tore, Kaya, Dedeoglu., 2022; Godman et al., 2021).

In the South African context, the dynamics of generic drug entry and its implications for access, pricing, and market behaviour remain underexplored. Research by van der Merwe and Smit (2013) found that as generics enter the local market, originator prices tend to decline to preserve competitiveness. This price erosion has significant implications for market share and patient access. However, the strategic responses by pharmaceutical companies—including marketing approaches, promotional practices, and pricing strategies—after patent expiry remain insufficiently interrogated, particularly in the context of South Africa’s dual public-private healthcare system (Gray & Suleman, 2015).

Efforts by regulatory bodies such as the South African Health Products Regulatory Authority (SAHPRA) to streamline the registration process for both originator and generic medicines have

further shifted the market landscape. Recent regulatory reforms have reduced approval timelines by 68% for both innovative and generic products, thereby accelerating access to potentially more affordable therapies (Keyter et al., 2021). Yet, the extent to which this regulatory agility has translated into meaningful improvements in patient access, cost savings, and market competitiveness in South Africa is not well documented.

Interpretation of Management Theories

Moreover, while literature has acknowledged the macroeconomic and supply-side benefits of generic entry (Godman et al., 2021), there remains a paucity of research focused on its patient-level impact within the South African healthcare system. Specifically, there is limited understanding of how the introduction of generic medicines influences treatment choices, access disparities, or financial burden among South African patients. Additionally, the strategies employed by pharmaceutical marketers in introducing generic alternatives—particularly post-patent expiry—have not been thoroughly examined in the local context.

The competitive dynamics surrounding generic drug entry in South Africa can be meaningfully interpreted through established management theories. Porter's Five Forces framework, for instance, highlights how generics intensify competition and increase the bargaining power of buyers, forcing originator firms to adjust their pricing strategies or risk losing market share (Porter, 1980; Van der Merwe & Smit, 2013). The presence of cheaper alternatives also raises the threat of substitutes, prompting firms to employ defensive tactics such as introducing pseudo-generics (Gray & Suleman, 2015).

The Resource-Based View (RBV) explains how firms leverage internal capabilities to achieve competitive advantage (Barney, 1991). While originator companies historically depended on R&D and brand equity, these resources become less effective post-patent. In contrast, generic manufacturers utilise operational efficiency and regulatory responsiveness as key strategic assets. The South African Health Products Regulatory Authority's (SAHPRA) accelerated approval reforms further empower generics by reducing structural entry barriers (Keyter, Meyer, & Summers, 2021).

Institutional theory adds a sociological dimension, suggesting that firms are shaped by external pressures. Regulatory mandates (coercive), professional norms (normative), and imitation of

successful market practices (mimetic) all influence the adoption of generic strategies (DiMaggio & Powell, 1983). The state's push for affordable medicines and the global call for equitable access create an institutional environment that favours generics (Godman et al., 2021).

Stakeholder theory reinforces the ethical obligation of pharmaceutical companies to balance profitability with public health outcomes (Freeman, 1984). Key stakeholders—including patients, insurers, and the state—demand greater affordability and access. The high cost of originator drugs, particularly in oncology and HIV/AIDS treatment, often excludes vulnerable populations from care (Leighl et al., 2021; Park, 2002), underscoring the societal value of generic entry.

Lastly, Rogers' Diffusion of Innovation theory explains adoption patterns of generics as a form of disruptive innovation. Uptake depends on awareness, perceived efficacy, and trust among prescribers and patients (Rogers, 1962; Godman et al., 2021). Resistance to generic substitution—especially in hospital settings—suggests that more education and confidence-building measures are needed (Chu, Li, & Zhang, 2023).

Together, these theories offer a comprehensive lens through which to examine the strategic, regulatory, and ethical complexities of generic drug entry in the South African pharmaceutical market.

This research seeks to fill this gap by critically analysing the impact of generic drug entry in South Africa, with specific attention to pricing behaviour, regulatory dynamics, market strategies, and patient outcomes. It will also evaluate the interplay between policy reform, market competition, and affordability to determine the extent to which generic medicines contribute to equitable healthcare access in the country

Purpose/Objective of the study

This research aims to investigate the multifaceted consequences of generic drug entry in South Africa, considering factors such as pricing dynamics, healthcare accessibility, market competition, and patient outcomes. By comprehensively analysing these dimensions, the study seeks to provide valuable insights for healthcare providers that can empower pharmaceutical marketers to make informed decisions, refine their strategies, and effectively navigate the evolving landscape of the South African pharmaceutical market.

1.3. Research Questions

The research paper aims to answer the key questions below:

1. What are the key factors influencing healthcare professionals' perceptions and acceptance of generic drugs in South Africa, and how can marketers leverage these insights in promotional strategies
2. How do pricing strategies for generic drugs compare to those for branded medications in South Africa, and what market factors drive these pricing decisions?
3. What are the healthcare accessibility implications of generic drug entry in South Africa, particularly in underserved or rural areas?
4. What regulatory challenges and opportunities exist for marketers in promoting generic drugs in South Africa, and how can companies navigate these effectively?

1.4. Delimitations of Study

Delimitations in a research study refer to specific boundaries and limits that the researcher will establish during their research (Theofandis & Fountouki, 2018). Delimitations help to narrow the focus and scope of the research, making it more precise regarding the point the researcher aims to prove (Theofandis & Fountouki, 2018). The study will not examine the effects of the price erosion of generic medicines on the pharmacy chain business model. Additionally, the study will not investigate the effects that generic entrants have on medical aid scheme benchmarks.

1.5. Definition of Terms

1.5.1. Price Erosion

Price erosion is defined as the gradual decline in medication prices over time (Neumann et al., 2021). The entrants of new generic medications drive a decline in price because manufacturers start engaging in price wars to ensure they maintain or capture market shares (Neumann et al., 2021). Price erosion could also be due to the loss of exclusivity of originator brands once their patent expires, which opens doors to generic entrants in the market. Price erosion could also be accounted for by regulatory changes in a country that could impact medicine pricing (Neumann et al., 2021).

1.5.2. Originator Medicines

An originator medicine is an innovative product whose approved indications by SAHPRA were granted based on safety, quality, and efficacy data and, therefore, holds the patent for the registration of the dossier (Hela, 2014). The patent protection enables the innovator company to become a monopoly and have high prices due to the high cost of bringing the medicine to market (Rong & Jayashree, 2021). Patents usually last for 20 years, but a company can have 10 years in the market due to the many timeous processes that occur before the product is brought to the market.

1.5.3. Generic Medicines

Generic medicines are a copy of the originator medicines, with the same active ingredients, which are launched once the patent of the originator molecule has expired (Al-Worafi & Mohammed, 2020). Generic medicines are launched at much lower prices, which can go down to as low as 85 per cent of the originator medicine. Generic medication also needs to meet the same safety, effectiveness, and quality standards as the originator medicine (Al-Worafi & Mohammed, 2020).

1.6. Chapter Outline

This research paper will consist of six chapters. The first chapter will provide an overview of the study, outlining the problem statement, research questions, objectives, and definitions. The second chapter will be a literature review of existing research on this topic, examining research from both local and global perspectives. Chapter three will detail the research methodology, which will lead to the research findings regarding the hypothesis. This research paper will elucidate how the research will contribute to the current literature and the marketing field. Furthermore, chapter four will present the research findings and analysis, followed by chapter five, which discusses the findings. The research will conclude with chapter six, highlighting the recommendations and conclusions for future researchers.

Chapter 2: Literature Review

2.1. Introduction

The literature review will examine existing research on this topic globally and locally. It will also examine the research gap regarding the price erosion effects of generic medications on patients and originator medicines and prices. It has been emphasized that the increased availability of generic and biosimilar drugs is pivotal for maintaining quality healthcare amidst resource constraints (Godman, Haque, McKimm, Kurdi., 2021). It's argued that generics can reduce patient co-payments and enhance medication access globally. However, it’s also noted that for generics to be a viable alternative, patients must trust their efficacy and safety, which is often influenced by perceptions and regulatory assurances.

The dynamics of generic competition have been extensively studied. An analysis on the impact of generic entrants post-patent expiry was conducted and it was found that medicine prices dropped by 20% in markets with approximately three generic competitors, and up to 80% in markets with ten or more competitors (Xuan, Tran, Le., 2022). This price erosion significantly influences the reimbursement strategies of medical aids and insurance companies. In China, the implementation of the Zero-Markup Drug Policy (ZMDP) in 2009 aimed to curb the rapid growth of drug expenditures. An observation was noted that while the policy effectively reduced outpatient treatment costs, its impact on inpatient care was limited (Chu, Li, Zhang., 2023). This discrepancy was attributed to healthcare practitioners' prescribing behaviours, where there was a preference for originator brands for critically ill patients, highlighting the complexities in shifting prescriber habits towards generics.

The global HIV/AIDS crisis underscores the critical role of generics in enhancing drug accessibility. Park (2002) discusses how the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement's stringent patent protections led to increased medicine prices, adversely affecting LMICs with high HIV prevalence. In response, Aspen Pharmacare launched Aspen-Stavudine in 2003, Africa's first generic antiretroviral (ARV), resulting in a 41% cost saving compared to the originator brand and significantly improving patient access and compliance (Pharmacare, 2003). In the South African context, the interplay between generic entry and drug pricing presents a complex picture. Van der Merwe and Smit (2013) found that the introduction of

generics leads to a decline in originator prices as companies strive to maintain market share. However, the extent of this price erosion varies across therapeutic classes and is influenced by factors such as market competition and regulatory policies. Moreover, the presence of pseudo-generics—originator companies' own generic versions—can complicate the market dynamics, potentially limiting the intended price reductions (Gray & Suleman, 2015).

Regulatory frameworks play a crucial role in facilitating or hindering generic drug entry. It's been highlighted that efforts have been made by the South African Health Products Regulatory Authority (SAHPRA) to streamline the registration process for both originator and generic medicines, reducing approval timelines by 68% (Keyter, Meyer, Summers., 2021). While this initiative aims to enhance medicine accessibility, the actual impact on patient outcomes and market competitiveness requires further empirical investigation. Despite these developments, challenges persist. Godman et al. (2021) note that while the macroeconomic benefits of generics are well-documented, there is a lack of research on their patient-level impact in South Africa. Specifically, understanding how generic medicines influence treatment choices, access disparities, and financial burdens remains underexplored. Additionally, the marketing strategies employed by pharmaceutical companies post-patent expiry, including pricing and promotional practices, warrant closer scrutiny to assess their effects on generic uptake and healthcare equity.

Empirical Literature Review

This report will contribute to academic and practitioners' literature by contributing to consumer marketing. The study will look at the impact that the entry of generic medicines has on people's lives in terms of opening access to medication as well the impact that is seen on the market share of originator brands and how the generic medicines drive down the price of originator medicines since SAHPRA decided to shorten the time of registering new generic medicines once the patent of the originator brand has expired.

The review will examine the practical and theoretical aspects of generic medicine's price erosion effects. By examining the market share and price effects of new generic entrants, marketers and businesses can guide their strategies on whether it is profitable short—and long-term to launch originator or generic medicine.

Benefits of marketing managers launching new generics to the market.

The total number of people living with HIV in South Africa as of 2022 is approximately 8,45 million, and HIV/AIDS is seen as one of the leading causes of mortality (Stats SA, 2024) with approximately 85 769 vs approximately 191 210 deaths as observed in 2002 (Cowling, 2024).

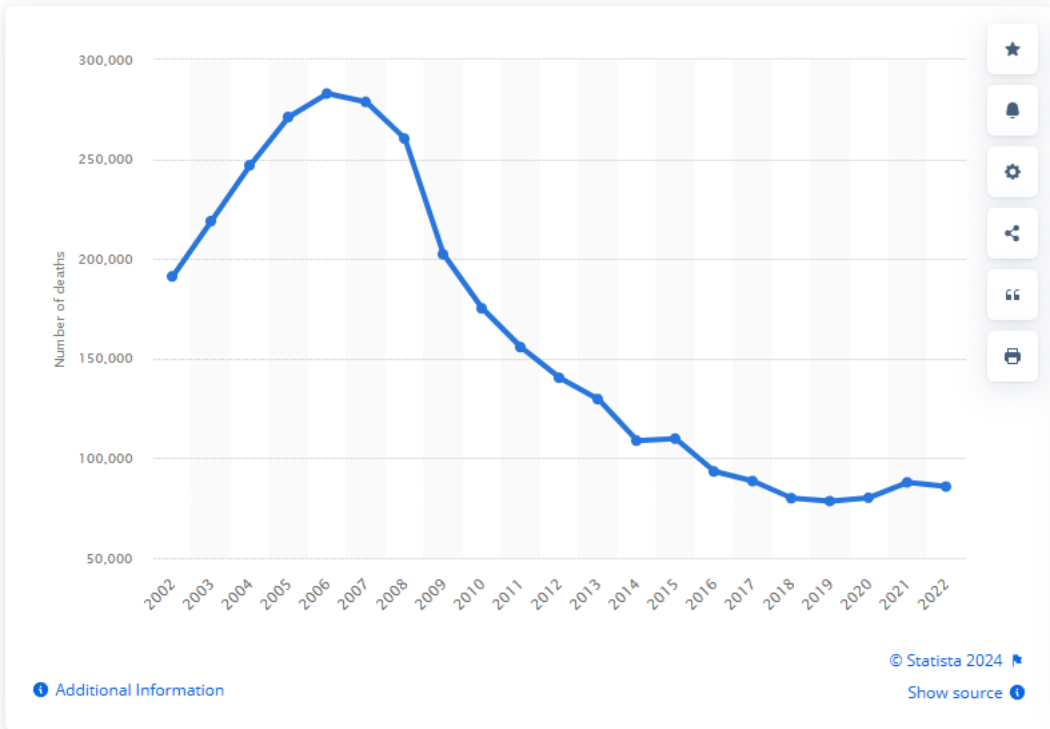


Figure 1: *Number of deaths from HIV/AIDS in South Africa from 2002 to 2022*

Research has shown that the generic entrants of HIV medicines have contributed to the decline in mortality rates as these cost-effective medicines provide access to medication to a broader group of patients, especially in the public sector (Capobiancao, 2018). Seeing that the market size of ARVs is worth R 43 854 098 in value (Parekh, 2023). Marketers can benefit from gaining market share from the originator or higher priced generics by adjusting their price points to service a portion of the 8,45 million patients living with HIV/AIDs in South Africa. Marketing managers continually seek to launch attractive brands to their consumers from a price and accessibility perspective to ensure growth or maintain brand profitability. It is also seen with such chronic medications that once a patient starts using a particular brand and it works for them, they tend to stick to it for more extended periods, and this phenomenon is known as brand love or brand loyalty (Capobiancao, 2018).

2.2. Theoretical Framework

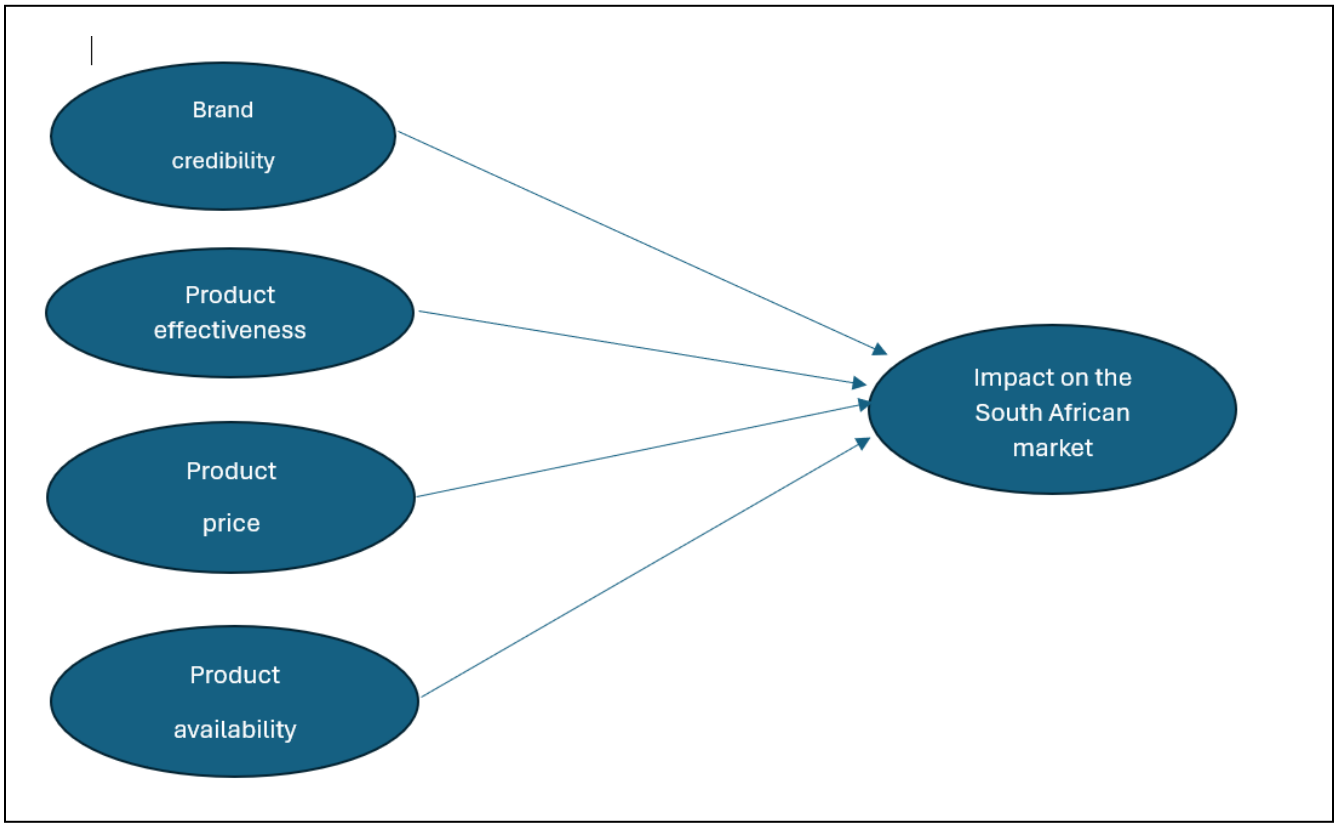


Figure 2: Perceptive value framework

Perceptive value theory

The perceptive value theory is a theory of marketing contribution to customers' perceived value (Shakhar et al., 2022). How a consumer perceives value is imperative for the success and survival of an organisation. An organisation's marketing department is responsible for driving the customers' perceived value by reducing or eliminating marketplace imperfections of their products (Shakhar et al., 2022). The theoretical framework will investigate what drives patients' choices to choose either an originator or generic medicine for their chronic medicine treatment. The constituents of value are product effectiveness, price, and availability.

One of the most significant criticisms of the perspective value theory is its inherent subjectivity. Since value is derived from individual perception, it varies significantly across different people and situations (Salehabadi, 2022). This leads to difficulties in establishing objective standards of value, especially in areas such as ethics and morality, where shared values are often necessary.

Critics of Perspective value theory argue that it leads to relativism, which holds that all values are valid simply because they are perceived by someone (Meltzer et al., 2020). This undermines the possibility of universal moral or ethical standards. For instance, different cultural or individual perceptions of actions could result in conflicting value judgements that cannot be reconciled, complicating ethical discussions.

Perspective value theory is also relevant in psychology, particularly when studying how individuals' subjective perceptions shape their preferences and behaviours (Li, 2019). Perception-based theories can help explain why people value experiences or goods in ways inconsistent with objective standards. In environmental studies, PVT can be used to discuss how individuals or societies perceive the value of ecosystems or natural resources (Li, 2019). However, as some critics point out, the theory may neglect broader ecological values independently of human perception.

The marketer must educate the consumers that generic medicines are not inferior to originator brands. These can be done by doing non-inferiority studies comparing the bioequivalence of generic and originator brands. For a consumer to switch from an originator brand, there needs to be a price benefit to motivate patients to make the switch. Another important element is product availability; marketers must ensure through their forecasting that they have enough stock to supply the patients' monthly treatment needs.

The first component of the framework, brand credibility, encompasses internal and external influences that can impact consumer behaviour. In the context of generic medication, brand credibility refers to the trustworthiness and reliability a generic drug manufacturer establishes with consumers, healthcare professionals, and regulatory bodies. This credibility is built on several key factors, such as transparency and quality assurance (Inseng & Chuma, 2020). Looking at transparency, brand credibility is reinforced by clear communication about the sourcing, manufacturing, and testing processes behind the generic medication. A transparent approach helps consumers and healthcare providers understand the product's origins and the steps taken to ensure quality (Shah & Rajan, 2021). Looking at quality assurance, Generic medications are required to meet the same rigorous standards as brand-name drugs in terms of active ingredients, strength, dosage form, and route of administration. A credible generic manufacturer ensures that its products are manufactured in accordance with Good Manufacturing Practices (GMP) and pass strict quality control tests (Inseng & Chuma, 2020).

The second component of the framework focuses on product effectiveness. Product effectiveness in the context of generic medication refers to how well a generic drug performs compared to its brand-name counterpart regarding safety, efficacy, and overall therapeutic outcomes. Generic medications are designed to be bioequivalent to their brand-name versions, meaning they contain the same active ingredients, work similarly, and are taken in the same dosage form. This bioequivalence ensures that the generic drug delivers the same therapeutic benefits to patients as the brand-name drug as long as it meets regulatory standards (Musazzi et al., 2020).

The third component of the framework focuses on product price. Product price in the context of generic medications refers to the cost of these drugs compared to their brand-name counterparts. Generally, generic medications are significantly less expensive than branded drugs. This price difference primarily stems from the lower costs associated with generics' development, marketing, and regulatory approval processes. While brand-name drugs require extensive clinical trials and extended research and development periods to bring them to market, generic drugs are typically introduced after the brand-name drug's patent has expired. This allows generic manufacturers to bypass many initial costs associated with drug development, resulting in lower consumer prices (Terman et al., 2022).

The final component of the framework encompasses product availability. Product availability in the context of generic medications refers to how these drugs are accessible to patients in various markets. Factors such as regulatory approval processes, market competition, and distribution channels influence the availability of generic medications. Once a brand-name drug's patent expires, multiple generic manufacturers are typically able to produce and distribute the same drug, increasing its availability and ensuring that patients have access to a lower-cost alternative (Hussain et al., 2024).

Chapter summary

The literature review highlights the critical role that generic medicines play in enhancing affordability, improving patient access, and exerting downward pressure on originator drug prices. South Africa’s evolving regulatory framework, particularly reforms by SAHPRA, has accelerated generic entry, although challenges such as patient scepticism and delayed approvals persist. Empirical and theoretical insights suggest that trust in generic efficacy, pricing strategies, and product availability are central to shaping market outcomes. The perceptive value theory reinforces

the importance of how consumers evaluate price, credibility, and effectiveness in choosing between originator and generic medicines. This chapter establishes a foundation for understanding the strategic and behavioural dynamics of generic drug adoption, providing context for the study's focus on how marketers navigate these forces to influence access and affordability within the South African healthcare system.

Chapter 3: Research Methodology

3.1. Introduction

This chapter will outline the methodology used for the current study to support the proposed conceptual model. Answering the study questions and interpreting the data from which the conclusions are derived depend on the data employed. This chapter will provide an overview of the research design, data collection and analysis techniques, research tools, limits, and sampling processes.

3.2. Research design

For the objectives of this study to be realised, qualitative research was conducted using semi-structured interviews. The semi-structured interviews assisted the researcher in gathering information on participants' experiences, thoughts, and perceptions regarding the use of generic medicines. Mark Saunders categorises several research strategies based on the type of research problem. In this research, grounded theory was used, an inductive approach where the researcher collected data and developed theories or concepts based on patterns observed in the data (Saunders et al., 2019). Mark Saunders also discusses different research philosophies that underpin the strategies researchers choose. In this research, realism was used. Realism posits that an objective reality exists independent of human perception. However, it recognises that our experiences and social contexts always mediate our understanding of this reality (Saunders et al., 2019). This approach combines elements of both positivism and interpretivism and often uses both qualitative and quantitative methods (Saunders et al., 2019).

Research Paradigm

Given the complex and multifaceted nature of pharmaceutical market dynamics, this study adopts a constructivist research paradigm. The constructivist worldview holds that reality is socially constructed and that individuals interpret phenomena based on context, experience, and subjective meanings (Creswell & Poth, 2018). This is particularly relevant to the current study, which seeks to understand the perceptions, strategies, and contextual challenges faced by pharmaceutical marketers and other key stakeholders in the context of generic drug entry in South Africa.

Constructivism is appropriate because this research does not aim to quantify the prevalence of generic usage or statistically predict market trends. Instead, it seeks to explore and interpret how decision-makers and market participants *perceive*, *respond to*, and *strategically manage* the entry of generic medicines in a highly regulated and price-sensitive environment. These meanings are best uncovered through qualitative inquiry, which allows for depth, flexibility, and the emergence of context-specific insights (Lincoln & Guba, 1985).

Accordingly, this study employs a qualitative research methodology, which aligns with the constructivist paradigm and is widely used in health systems research to explore the "how" and "why" behind behaviours, decisions, and institutional practices (Denzin & Lincoln, 2011). In this context, qualitative methods allow the researcher to gather detailed narratives from pharmaceutical marketers, policy influencers, and industry experts regarding pricing strategies, market adaptation, and perceptions of regulatory reform and patient trust.

The use of semi-structured interviews as a primary data collection tool is deliberate. This method provides a balance between guiding the conversation toward specific thematic areas (e.g., post-patent strategies, market erosion, brand trust) and allowing participants to elaborate freely on their lived experiences and organisational contexts (Gill et al., 2008). It also facilitates the identification of shared themes as well as divergent perspectives among participants with varied roles in the pharmaceutical value chain.

This qualitative approach is especially suited to a phenomenon like generic drug entry, which is influenced not only by market economics but also by socio-political dynamics, regulatory environments, and professional ideologies. A positivist or purely quantitative approach would fail to capture these nuanced, interpretive layers that shape market behaviours and policy implementation in practice.

3.3. Data collection and analysis methods

3.3.1 Data collection methods

Population

This study consisted of a population sample from South African pharmaceutical industry marketers who manage, launch, and create daily marketing strategies for chronic generic medicines. Generic company marketers are involved in launching new generic medicines and are decision-makers regarding the price of the new product.

Sample Selection

This study employed convenience sampling, a non-probability sampling technique commonly used in qualitative research (Andrade, 2020). Convenience sampling allows researchers to select participants based on ease of access, availability, and willingness to participate, especially when a defined sampling frame is absent (Andrade, 2020). This approach was particularly appropriate given the exploratory nature of this study and the logistical constraints, such as time and geographic accessibility. Participants were selected due to their proximity to the researcher and their relevance to the research objective—specifically, marketing professionals in the pharmaceutical sector who possess insights into the launch and positioning of generic medicines in South Africa. Convenient access channels were utilised to identify participants, including professional colleagues and industry networks familiar to the researcher. Individuals who met the inclusion criteria and expressed interest were formally invited to participate.

A total of twelve (12) respondents were selected for this study. This sample size is consistent with best practices in qualitative research, where smaller, focused samples are sufficient to achieve data saturation—the point at which no new themes emerge from the data (Guest, Bunce, & Johnson, 2006). Studies have shown that data saturation in homogeneous groups can often be reached with as few as 6–12 interviews, depending on the depth of inquiry and complexity of the topic (Guest et al., 2006; Malterud, Siersma, & Guassora, 2016). Given the relatively focused scope of this research—exploring marketing strategies and perceptions around generic drug entry—twelve participants were deemed adequate to provide rich, meaningful data.

Inclusion Criteria

The criteria below were utilised in the selection process of the participants.

1. Marketers between the ages of 30 and 55. This age group was selected because these marketers would have had experience launching generic medicines and are most likely to have worked for both originator and generic companies in their work experience.
2. Marketers who understood the difference between generic and originator medicines.
3. Marketers who were willing to participate in this research voluntarily.
4. Marketers who currently worked for generic pharmaceutical companies

3.3.2 Data analysis

In qualitative research, Atlas.ti (often called Atlas) is a software tool used for data analysis, especially when handling large amounts of qualitative data such as interviews, focus groups and textual documents. It helps researchers organise, code, and analyse qualitative data more systematically (Sorratto et al., 2019). Researchers can look for patterns and trends across the data as codes are applied, helping them identify key themes, relationships, or categories. Atlas allows for the visual representation of these themes through network diagrams or charts, helping to map out the connections between various pieces of data (Sorratto et al., 2019).

Thematic analysis was used to analyse the data collected from the semi-structured interviews. Thematic analysis is a technique used to analyse qualitative data. This technique helped identify patterns and categories of the participant's views (Caulfield, 2023). Data analysis included reviewing the data received from the industry experts' interviews. The thematic analysis was valued because of its adaptability to a wider range of qualitative data.

3.4. Research instrument

Seeing that this is a qualitative study, the research instrument that was chosen was aimed at getting rich and in-depth insights into the participant's preferences and perceptions related to generic medicines. The interviews allowed participants to give their insights on the impact of generic entry in the South African market. A semi-structured interview model was used to ensure that consistency is applied while also allowing for flexibility in acquiring emerging themes. The interview questions consisted of open and closed-ended questions. Open-ended questions are

helpful when one wants the participants to elaborate on their responses and get them engaged (Cullen, 2023).

3.5. Limitations

The study acknowledges certain limitations that can impact the scope of the findings. Since this research paper follows a qualitative approach, the research findings may not represent the entire South African market in the generic pharmaceutical industry. The small sample size and the demographic factors may limit the results' generalisability to a larger population. The short timeframe for the study may impact the depth and breadth of the data collected. This might restrict the exploration of specific aspects related to the impact of generic drug entry in the South African market. External factors such as socio-cultural issues and inflation were beyond the researcher's control. The interviews were conducted only in English, which could have been a limitation in people fully expressing their views.

3.6. Quality assurance

Quality assurance in qualitative research can be measured using reliability and validity, which in the qualitative paradigm is seen as the rigour and trustworthiness of the study (Golafshani, 2003). Triangulation was used to increase the researcher's truthfulness and eliminate bias and thus a way of achieving reliability and credibility (Golafshani, 2003).

Validity

Extensive literature reviews on the validity of the impact of generic drug entry were conducted to ensure the validity of this study. The literature review has aided in shaping the theoretical concept, which, in turn, assisted with the emergence of research questions that helped answer the research objective. Semi-structured interviews were conducted as part of the research instrument to gather a holistic and comprehensive understanding of the research objective. The triangulation of data sources is critical in establishing the credibility of the results and thus validating the gathered information. The emerging themes, transcripts, and recordings were revisited to ensure the participant's viewpoints were represented accurately.

The triangulation in this research was achieved by combining the following sources of data:

Primary Data: Semi-structured interviews with 12 pharmaceutical marketers based in South Africa. These marketers are responsible for launching and marketing generic drugs. The interviews were used to gather in-depth insights into their experiences, perceptions, and strategies.
Secondary Data: Extensive literature review from both global and local sources. This included academic articles, policy documents, and industry reports related to generic drugs, pricing strategies, healthcare access, and regulatory frameworks in South Africa and internationally.
Thematic Analysis: Performed using Atlas.ti software, which helped identify recurring themes across the interviews, such as pricing dynamics, perceptions of generics, accessibility issues, and regulatory challenges. These multiple data sources were cross-referenced to increase credibility, reduce bias, and enhance the reliability and validity of the findings, as explicitly stated in the "Quality Assurance" and "Validity" sections of the methodology chapter.

Reliability

Quality is the most important test of qualitative research because it measures reliability. It aids in understanding a situation that would generally be confusing or enigmatic (Golafshani, 2003). Reliability has the purpose of creating understanding. This research has a documented research design which was part of the audit trail. The audit trail ensured that high-quality data collection procedures as well as data analysis are adhered to ensure the reliability of the study.

3.7. Ethical considerations

An ethics approval application was submitted to the University of the Witwatersrand. Ethical considerations were adhered to after approval was received. Informed consent was obtained from the participants, highlighting that the study would protect their responses' confidentiality by ensuring they were captured anonymously. The fact that they could leave the study at any moment was also disclosed to participants. The researcher and supervisor will only have access to anonymised transcripts and other data on request, as they will be kept on a password-protected computer.

Chapter summary

This chapter detailed the methodological approach employed to investigate the impact of generic drug entry in South Africa's pharmaceutical market. Guided by a constructivist paradigm, a qualitative research design was adopted to explore the perceptions, strategies, and experiences of

pharmaceutical marketers involved in the commercialisation of generic medicines. The use of semi-structured interviews allowed for the collection of rich, context-specific data, while convenience sampling enabled access to knowledgeable participants within industry networks. Data were analysed thematically using Atlas.ti software, which supported the identification of recurring patterns and insights relevant to pricing strategies, brand positioning, and regulatory dynamics. Measures to ensure quality and trustworthiness—including triangulation, audit trails, and rigorous validity checks—strengthened the reliability of findings. Ethical protocols were also rigorously followed, ensuring the confidentiality and voluntary participation of all respondents. While limitations such as sample size and scope are acknowledged, the chosen methodology provides a solid foundation for understanding how market participants navigate the complexities of generic medicine entry, thereby supporting the study's broader aim of promoting equitable healthcare access and sustainable pharmaceutical strategies in South Africa.

Chapter 4: Research findings and analysis

4.1. Introduction

The findings and analysis presented in this research report offer a comprehensive exploration of the impact of generic drug entry in the South African market from qualitative research. Through rigorous data collection methods such as interviews, valuable insights were gathered from marketers who are industry experts in generic pharmaceuticals. Cleaning procedures through data screening were imperative in ensuring the validity of the qualitative research conducted (Berg, 2001). These findings will be critically examined and interpreted in the following sections, considering existing literature and theoretical frameworks. This analysis aims to elucidate the complexities and nuances uncovered during the research process, shedding light on the impact of generic drug entry in South Africa. The research topics that shaped the focus and direction of data gathering and analysis are explained in this chapter. Apart from fulfilling the study's main goals, several other discoveries were made throughout the qualitative investigation, which will be uncovered in this research report. This chapter will outline data cleaning through screening; it will also highlight the participants' demographics and the research questions they will be asked. The different themes that emerged from the research will then be unpacked.

4.2. Data cleaning through screening

Data screening and cleaning are crucial in ensuring the validity and reliability of qualitative research findings derived from interview questions. As highlighted by Smith and Jones (2020), meticulous data screening involves initial checks for completeness, accuracy, and consistency across transcripts and field notes, ensuring that all data points are accounted for and any discrepancies are addressed promptly. This process not only enhances the trustworthiness of the data but also allows researchers to identify and rectify any errors or inconsistencies that could skew the analysis (Pilowsky et al., 2024). Moreover, according to Miles and Huberman (2019), rigorous data cleaning procedures, such as identifying and removing duplicate or irrelevant information, help streamline the analysis process and facilitate a focused exploration of themes and patterns within the qualitative data. By adhering to these practises, researchers can maintain the integrity of their findings, ensuring that interpretations are grounded in accurate and reliable data, thus bolstering the overall robustness and credibility of the qualitative research outcomes.

4.3. Demographics of Participants

A total of 12 participants were interviewed, including marketers who work for generic companies in the pharmaceutical industry. The participant group was a heterogeneous combination of 6 female and 6 male marketers aged between 30 and 55. Industry professionals contributed expertise in sales and experimental marketing by providing responses that exhibited an extensive skill set of practical knowledge. The diversity in disease area backgrounds offered a nuanced perspective on the interplay between pricing strategies and consumer decision-making processes across various therapeutic areas.

The core objective of this study was to comprehend the results of the impact of generic drug entry on the South African market.

4.4. Research Questions

The four main questions that directed this investigation are listed below to contextualise the presented analysis.

1. In South Africa, how do generic drug pricing tactics differ from branded drug pricing strategies, and what market considerations influence these pricing decisions?
2. What are the main determinants of generic medicine adoption and perception among South African patients and medical professionals, and how can marketers use these findings to inform their promotional strategies?
3. What are the healthcare accessibility implications of generic drug entry in South Africa, particularly in underserved or rural areas?
4. What regulatory challenges and opportunities exist for marketers in promoting generic drugs in South Africa, and how can companies navigate these effectively?

4.5. Thematic Analysis of the marketer's interviews

The objective of the thematic analysis was to discern discernible trends and motifs in the information collected from the viewpoints of marketers (Finlay, 2021). Through thematic analysis, observable themes emerged, including patient attitudes towards generic medications, the influence

of the healthcare professional in the decision-making processes, and the pivotal role that generics play in the South African population.

The first two themes emerged from trying to answer the first research question: “How do pricing strategies for generic drugs compare to those for branded medications in South Africa, and what market factors drive these pricing decisions?”

4.5.1. Theme 1.1: The Influence of Health Insurance and Public Health Programs on Drug Pricing

In South Africa, as in many other countries, the pricing of pharmaceutical products, including generic and branded medications, is deeply influenced by the structure of health insurance and public health programs. These factors affect the ability of both individuals and the government to negotiate drug prices, manage healthcare costs, and ensure access to necessary treatments.

1. Role of Health Insurance in Drug Pricing

Health insurance providers secure discounted rates for branded and generic drugs through negotiated contracts with pharmaceutical companies and distributors. Insurers may leverage their membership base's volume to negotiate lower medicines prices. This is especially true for generics, where insurance companies may encourage the use of cheaper alternatives to branded drugs to reduce overall healthcare costs. Insurers often create formularies (lists of covered drugs), prioritising generics over branded drugs due to their lower cost. They may also implement generic substitution policies, where doctors are encouraged to prescribe generic versions of drugs rather than branded ones. This influences the pricing strategy for generic drugs, as they are positioned as more cost-effective options within the insurance framework.

4.5.2. Theme 1.2: Pricing and Market Dynamics

Participants shared a standard view regarding how generic medications are priced vs the originator medicines. They articulated that generic drugs are priced lower than branded medications due to reduced development costs and competitive pressures. One of the respondents said, “As a marketer, the things that I look at when deciding the price of the new generic that I am going to launch include the following: Is my product the first generic on the market? This question helps me determine the percentage price difference I need to launch, which normally ranges between

20-30% compared to the originator brand. If other competitor generics are in the market, the new generic must benchmark themselves against the cheapest generic available". Market dynamics include production costs, regulatory requirements, competition, and government tenders impacting pricing strategies. The finding of this theme is supported by an article in the Management Science journal, which highlights that generic drugs typically do not incur the same R&D expenses because they rely on the existing scientific knowledge and data from the originator drug, which has already been developed and tested. As a result, the upfront cost to develop generics is much lower, often focused on meeting regulatory standards for bioequivalence (Wang et al., 2022).

The second theme emerged from trying to answer the second research question: "What are the key factors influencing patients' and healthcare professionals' perceptions and acceptance of generic drugs in South Africa, and how can marketers leverage these insights in promotional strategies?"

4.5.3. Theme 2: Perceptions and Acceptance

These participants, who are industry professionals, shared the same sentiment that perceptions of efficacy, safety, and reliability influence healthcare professionals' acceptance of generic medicines. Marketers can provide healthcare professionals with robust clinical evidence, educational efforts, and partnerships with healthcare organisations to improve acceptance of their marketing strategies. Most patients are unaware of the difference between generic and originator medicines; their main concern is getting an effective medicine that will improve the patient's life and slow down the progression of the disease. Patients are happy if they get a cost-effective medication that works because that would mean they do not need to pay a co-payment, and if they are on medical aid, their savings will take longer to become depleted. Marketers must conduct educational campaigns to educate patients that generic drugs generally have efficacy and safety profiles similar to branded medications.

Furthermore, the study revealed that some patients are still not educated about the difference between generic and branded medicines, and this is supported by a research article that can be found in the Journal of Pharmacy and Community Medicine, which shows in the results section that 14% of patients believed that generic medicines are not as effective as originator medicines because they take longer to have an effect (Al-Watafi et al., 2020). This causes a burden on the

health status of the country's citizens because as medical aid funds run out at the cause of the year, some people who are on originator medicines default on their medications due to affordability.

The theme of perceptions and acceptance of patients regarding the use of generic medicines aligns closely with the theory of marketing's contribution to customers' perceived value (Misra et al., 2022). This theory suggests that customer perceptions are shaped by the benefits they believe they will receive relative to the costs incurred. In generic medicines, patients may have preconceived notions about quality and effectiveness compared to branded drugs, influenced by marketing messages, societal perceptions, and personal experiences. If patients perceive generics as equally effective but more affordable, they may view them as a higher-value choice, enhancing their acceptance. On the other hand, negative perceptions about generics' quality could diminish their perceived value despite their lower cost. Thus, marketing strategies that emphasise the quality, safety, and efficacy of generics can help shift patient perceptions, increasing acceptance and enhancing the perceived value of these medicines.

The third theme emerged from trying to answer the third research question: What are the healthcare accessibility implications of generic drug entry in South Africa, particularly in underserved or rural areas?

4.5.4. Theme 3: Healthcare Accessibility

Insights from industry professionals revealed that generic drugs can enhance accessibility, particularly in underserved or rural areas, by providing more affordable treatment options. Patient adherence can be affected by drug costs, availability, and education about generics. Increased availability of affordable medications can lead to better adherence and health outcomes in remote areas. Generics often become available sooner than brand-name drugs once the patent expires. This means that essential medications can reach underserved areas more quickly, addressing gaps in treatment availability. Overall, the availability and use of generic medicines in underserved areas can help bridge gaps in healthcare access, improve treatment outcomes, and support broader public health goals.

In addition to the above results received from the participants, a research article by Kirsi Kvarnstrom suggests that the availability of generics contributes to increased access and improved adherence to treatment, particularly in chronic conditions like hypertension and diabetes, which

are prevalent in rural populations (Kvarnstrom et al., 2021). Furthermore, improved adherence leads to better disease management and reduced hospitalisations, further alleviating the burden on healthcare systems in these areas.

The fourth theme emerged from trying to answer the fourth research question: What regulatory challenges and opportunities exist for marketers in promoting generic drugs in South Africa, and how can companies navigate these effectively?

4.5.5. Theme 4: Regulatory Landscape

Industry professionals agreed that the regulatory landscape in South Africa plays a crucial role in shaping the entry and availability of generic medicines. South Africa's regulatory framework, overseen primarily by the South African Health Products Regulatory Authority (SAHPRA), has several key features that impact the entry of generics into the market:

Regulatory Approval: Generic medicines must receive approval from SAHPRA before being marketed in South Africa. This process involves submitting evidence demonstrating that the generic is therapeutically equivalent to the reference brand-name drug. Streamlined regulatory procedures can facilitate faster market entry for generics.

Patent and Intellectual Property Laws: South Africa's intellectual property laws, including patent protections, can affect the timing of generic entry. Generic manufacturers must navigate patent laws and may need to wait until patents on brand-name drugs expire.

Pricing Regulations: South Africa has a regulatory framework that influences drug pricing, including mechanisms to control the cost of medicines. Policies like pricing negotiations and caps can impact generic drugs' affordability and market dynamics. Regulators may set price ceilings to ensure that generics are priced competitively and remain affordable for the public.

Chapter summary

The findings presented in this chapter highlight the multidimensional impact of generic drug entry in the South African pharmaceutical sector. Drawing from marketers' perspectives, the analysis revealed that pricing strategies are heavily influenced by health insurance structures, market positioning, and public sector dynamics, with generics offering a cost-effective alternative to originator brands. However, the uptake of generics continues to be shaped by perceptions of

efficacy and quality among both patients and healthcare professionals. Marketers are therefore required to adopt evidence-based communication strategies and engage in educational initiatives to build trust. Importantly, the findings emphasise the role of generics in improving healthcare access, particularly in underserved and rural communities, where affordability is a key determinant of adherence. Regulatory delays and patent protections remain significant barriers, although recent reforms by SAHPRA offer a promising avenue for more timely market access. Overall, this chapter affirms that while generics hold substantial potential for advancing equitable healthcare, their success is dependent on a combination of regulatory efficiency, strategic pricing, and stakeholder education.

Chapter 5: Discussion of Findings

5.1. Introduction

The study's findings' importance, ramifications, and constraints are made clear in the discussion of findings section. This conversation advances the field's understanding and provides ideas for future study. In addition, the study's findings have been compared with previous research and theoretical viewpoints in this section. The candidate was able to evaluate the results, pinpoint areas of convergence or divergence, and deepen theoretical understanding through the process of theoretical triangulation (Donkoh & Mensah, 2023).

5.2. Discussion

Thematic analysis was used to draw out themes from the interviews conducted with marketers in the pharmaceutical industry who are involved in launching new generic medicines in South Africa. The first theme that strongly emerged from this study is healthcare accessibility. The industry experts all agreed that the entrant of generic medicine entrants in South Africa aid the South African population with having more access to cost-effective treatment options of medications vs the originator brand medicines, seeing that the public sector services 85% of the South African population (Stats SA, 2022).

Furthermore, industry experts expressed their views that the pricing of generics is predominantly determined by their production costs and position in the market, such as the first or second generic to market after the originator patent has expired. A generic product could come in at a price difference of 20-30% below the originator brand if it is the 1st generic to market. One of the interviewees stated, “One of the other major factors that marketers consider when determining the price point of a generic entrant is the out-of-pocket amount that the patient would have to pay, seeing that their main aim is to provide access to high-quality, affordable medicines to patients” (Cronje, 2024). Medical aid reimbursements and benchmarks also play a major role in the marketer’s decision-making regarding price.

Moreover, the marketers interviewed acknowledged that it is their primary duty to educate health care professionals and patients about the efficacy of generic medications and the originator medicines. This will address their issues regarding perceptions and acceptance of generic

medicines. Marketers also need to partner with key opinion leaders who will assist in advocating for the quality of their products, and this education can be conducted by attending key congresses and getting patient-focused promotional materials for non-scheduled medications.

One of the participants made an interesting observation, stating that generics do not have the same efficacy as the originator brands and that it will take a while for some healthcare professionals and patients to believe otherwise. In addition to the above statement, the participant acknowledged that South Africa is going through tough financial times and suggested that patients can make use of generic medicines for acute illnesses. However, the participant would recommend originator brands for chronic illnesses since they have proven clinical research data on efficacy.

Chapter summary

This chapter analysed qualitative data from interviews with pharmaceutical marketers to explore the impact of generic drug entry in South Africa. The findings reveal that generics significantly enhance healthcare access, particularly within the public sector, by offering more affordable treatment options. Pricing strategies are influenced by market dynamics, including the timing of market entry, production costs, and medical aid reimbursement thresholds. However, generic uptake remains affected by patient and healthcare professional perceptions, especially concerning chronic conditions. The study underscores the critical role of marketers not only in pricing but also in education, advocacy, and collaboration with key stakeholders to promote confidence in generics. Overall, the findings affirm that successful generic integration into the healthcare system requires a multifaceted approach—balancing regulatory support, market competitiveness, and trust-building initiatives to ensure broader acceptance and equitable access.

Chapter 6: Recommendations and Conclusion

Given the complex results discussed in the above chapters, providing industry personnel with practical advice based on academic research and theoretical frameworks is essential. This section provides practical advice on managing the intricacies of the impact of generic medicine entrance in the South African market within the pharmaceutical marketing landscape based on the insights collected from thematic analysis. Drawing from influential studies in patient behaviour, marketing ethics, and the regulatory environment, the suggestions made here are meant to promote moral behaviour and well-informed decision-making in the field of pharmaceutical marketing.

6.1. Recommendations for Marketers

Industry professionals should prioritise developing robust strategies for new generic drug entries in the South African market by focusing on how new generic entrants disrupt the market. Companies can adapt and compete effectively by strategically analysing market dynamics, pricing, regulatory frameworks, and distribution methods. Developing robust strategies will allow companies to navigate the disruptive forces created by new generics while ensuring that they continue to serve the market's needs, improve access to affordable healthcare, and maintain profitability. Industry professionals should study how these drugs affect the pricing strategies of branded pharmaceuticals and the degree of competition that generics introduce. Pharmaceutical marketers should consider whether lower-priced generics shift consumer behaviour, such as increasing access to medicines for lower-income populations. Furthermore, they can analyse how generics influence the market shares of existing branded pharmaceutical companies or examine if generics are eroding sales or forcing the branded market to innovate or reduce prices.

6.2. Recommendations for Policymakers

To optimise the impact of generic drug entrants, it is recommended that policymakers implement robust strategies to enhance market access and streamline regulatory processes (Davis, 2022). Increased public education campaigns are also essential to raise awareness about the safety and efficacy of generic medicines (Chen & Patel, 2020). Also, fostering partnerships between the government, healthcare providers, and the pharmaceutical industry can further bolster the generic market, ensuring these vital medicines remain accessible to all South Africans (Nguyen T.

, 2023). By prioritising these initiatives, South Africa can continue to improve health outcomes and support sustainable healthcare practices.

6.3. Recommendations for Future Researchers

For future researchers interested in conducting quantitative research on the impact of generic drug entry in the South African market, the following recommendations can guide them in employing rigorous quantitative methodologies:

6.3.1 Surveys and Questionnaires

When deciding whom to survey, future researchers could design large-scale surveys targeting different stakeholders, such as consumers, healthcare professionals (doctors, pharmacists), and pharmaceutical companies. When deciding what to measure, the surveys could measure factors such as awareness and acceptance of generic drugs, price sensitivity, perceived efficacy, and satisfaction levels with generic medications versus branded alternatives. Questions could be structured using Likert scales to quantify responses. This is because surveys allow for the collection of standardised data from a large sample, enabling the researcher to generalise findings across the population and analyse trends in attitudes, behaviours, and practices related to generic drugs (Kumar, 2021).

6.3.2 Market Analysis and Pricing Models

When deciding what to analyse, researchers can collect data on drug prices, market shares, and sales volumes before and after the entry of generic drugs. Statistical tools like time-series analysis or regression models could be applied to study the effect of generic drug entry on the prices of branded drugs, market competition, and consumer choices (Miller & Adams, 2022). This approach provides an objective, quantitative analysis of market dynamics and can quantify generics' impact on pricing structures and competition. It also allows for the identification of patterns in generics' adoption across different sectors of the healthcare system (Patel et al., 2018).

6.3.3 Regression Analysis of Healthcare Costs

When deciding what to analyse, a regression analysis could examine how the entry of generic drugs affects overall healthcare costs. Variables like drug expenditures, hospitalisation rates, and the use of specific therapeutic classes can be modelled to estimate the cost-saving impact of generics (Nguyen & Roberts, 2021). This methodology allows researchers to isolate the specific influence of generics on healthcare costs while controlling other factors, such as inflation, demographic changes, and disease prevalence (Verma et al., 2020).

6.3.4 Health Outcome Data Analysis

When deciding what to measure, researchers can use patient-level data to analyse the impact of generic drug use on health outcomes, such as treatment adherence, recovery rates, or hospitalisation rates. Data can be collected from health records, clinical trials, or health insurance databases. By analysing health outcome data, researchers can measure whether the availability of generics affects patient health, treatment efficiency, or overall healthcare quality (Lee et al., 2022). Statistical comparisons between groups using generics versus branded drugs can provide concrete evidence of effectiveness.

6.3.5 Statistical Modelling of Drug Utilisation Patterns

When deciding what to analyse, researchers could develop statistical models to analyse drug utilisation patterns over time, comparing the consumption of generics versus branded drugs in different therapeutic areas or demographic groups (Johnson, 2021). Quantitative modelling can help identify trends in the adoption of generics and the factors that influence prescription behaviours. This could include examining differences in utilisation based on price, physician prescribing patterns, and patient demographics (Graham & Mitchell, 2019).

Future researchers can use these quantitative approaches to gather reliable, large-scale data on the effects of generic drug entry in South Africa. Whether through surveys, market analysis, econometric modelling, or health outcome tracking, quantitative research allows for measuring cause-and-effect relationships, identifying trends, and generalising findings to larger populations.

This will provide a more objective, numerical understanding of the market dynamics and healthcare impacts of generic drug entry.

6.4. Overall conclusion

This study's analysis provides insightful information about the complex dynamics behind the impact of generic drug entrants in the South African market. A thematic analysis of industry executives' interviews clarified the complex relationship between original and generic medications in South Africa, producing several important themes. This study contributes to the advancement of knowledge in the field of marketing by offering actionable insights and theoretical underpinnings for informed decision-making regarding the launch of new generic medicines in the South African market.

In conclusion, the entry of generic drugs into the South African pharmaceutical market has significantly enhanced access to essential medications, improved affordability, and contributed to overall health outcomes in the population (Smith et al., 2022). This study underscores the critical role that generic medicines play in addressing the challenges posed by high drug costs and the burden of disease (Smith, 2022). However, while the benefits are clear, ongoing challenges such as market competition, regulatory frameworks, and public awareness must be addressed to realise the full potential of generics (Williams, 2021).

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Appendix





8.1 Interview Questions for Marketers

1. How do pricing strategies for generic drugs compare to those for branded medications in South Africa, and what market factors drive these pricing decisions?
2. What marketing tactics can be employed to communicate quality assurance measures for generic drugs and build trust among healthcare professionals and patients in South Africa?
3. What regulatory challenges and opportunities exist for marketers in promoting generic drugs in South Africa, and how can companies navigate these effectively?
4. What are the key factors influencing healthcare professionals' perceptions and acceptance of generic drugs in South Africa, and how can marketers leverage these insights in promotional strategies
5. What are the patient outcomes associated with the use of generic drugs compared to branded medications in South Africa, including efficacy, tolerability, and adherence?
6. How can pharmaceutical marketers collaborate with stakeholders to advocate for policies and initiatives that promote the integration of generic drugs and improve healthcare outcomes in South Africa?
7. What regulatory challenges and opportunities exist for marketers in promoting generic drugs in South Africa, and how can companies navigate these effectively?
8. How do patient preferences and experiences with generic drugs compare to those with branded medications, and how can marketers use this information to tailor messaging and educational campaigns?
9. What are the healthcare accessibility implications of generic drug entry in South Africa, particularly in underserved or rural areas?

10. What competitive strategies are most effective for pharmaceutical companies in navigating the competition between generic and branded medications in the South African market?

8.2 Consent for participation in Research





Consent Form for Participation in Research

Study Title: The Impact of Generic Drug Entry in the South African Market

Researcher: Tshepiso Leballo

Institution: Wits Business School

Introduction:

You are being invited to participate in a research study about The Impact of Generic Drug Entry in the South African Market. Before you decide whether or not to participate, it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully.

Purpose of the Study:

This research aims to investigate the multifaceted consequences of generic drug entry in South Africa, considering factors such as pricing dynamics, healthcare accessibility, market competition, and patient outcomes. By comprehensively analyzing these dimensions, the study seeks to provide valuable insights for healthcare providers and provides valuable insights that can empower pharmaceutical marketers to make informed decisions, refine their strategies, and effectively navigate the evolving landscape of the South African pharmaceutical market.

What Does Participation Involve?

If you agree to participate in this study, you will be asked to:

- Participate in a semi-structured interview lasting approximately 30 minutes.

- Discuss your experiences and perspectives related to the impact of generic drug entry in the South African market
- Allow the interview to be audio-recorded to ensure accurate capture of your responses.

Confidentiality:

Your privacy and the confidentiality of your data are paramount in this study. All personal identifiers will be removed from your responses during data analysis, and any

details that could potentially identify you will not be included in any reports, presentations, or publications resulting from this research.

Voluntary Participation:

Your participation in this study is entirely voluntary. It is up to you to decide whether or not to take part in this study. If you decide to participate, you will be given this consent form to sign. After signing it, you are still free to withdraw at any time and without giving a reason.

Right to Withdraw:

You have the right to withdraw from the study at any point without repercussion; your decision will not affect any current or future relationship with Wits Business School or its affiliates.

Consent:

I have read and understood the information provided above. I have had the opportunity to ask questions, and all my questions have been answered to my satisfaction. I consent to participate in this study under the conditions described.

Participant's Name: _____

Participant's Signature: _____ **Date:** _____

Researcher's Signature: _____ **Date:** _____

Please keep a copy of this form for your records.

8.3 Participant information sheet





Dear Sir/Madam,

Introduction:

My name is Tshepiso Leballo, and I am an MBA student at the University of the Witwatersrand, Johannesburg. Under the supervision of Dr. Thubelihle Ndlela, I am conducting a research study titled "The impact of generic drug entry in the South African market."

Invitation to Participate:
I am inviting you to take part in an online interview as part of this research. If you decide to participate, your involvement will last about 30-45 minutes. The interview will be conducted online at a time that is convenient for you.

Purpose of the Study:
This research aims to investigate the multifaceted consequences of generic drug entry in South Africa, considering factors such as pricing dynamics, healthcare accessibility, market competition, and patient outcomes. By comprehensively analyzing these dimensions, the study seeks to provide valuable insights for healthcare providers and provides valuable insights that can empower pharmaceutical marketers to make informed decisions, refine their strategies, and effectively navigate the evolving landscape of the South African pharmaceutical market.

Recording and Data Storage:
With your permission, I would like to audio record the interview. The recording will be stored on a secure hard drive and will be deleted after transcription. Only the researcher will have access to the data.

Personal Information:

During the interview, I will need to ask for some personal information about you, including your name, surname, and position at work. This information will help contextualize your responses.

Confidentiality and Anonymity:
Your participation in this study will be both confidential and anonymous. I will ensure that your name or any other identifying information is not included in any reports or publications resulting from this research. Any shared data will be anonymized to protect your identity.
Voluntary Participation:
Participation in this study is entirely voluntary. You are free to withdraw from the study at any time without any consequences. You do not have to answer any questions you are uncomfortable with. There are no direct benefits or compensation for participating in this study, but your insights will contribute significantly to the understanding of the impact of

Risks:
The risks associated with this study are minimal and are no more than what you encounter in everyday life. However, if any question makes you feel uncomfortable, we can pause or stop the interview and resume at another time if you wish.

Use of Study Results:
The findings of this research will be compiled into a research report, which will be available on the university library website. If you would like a summary of the report, I will be happy to send it to you upon request.

Contact Information:
If you have any questions or need further information, please feel free to contact me or my supervisor:
Researcher:
Tshepiso Leballo
Email: 360328@students.wits.ac.za
Phone: 0722658303
Supervisor:
Dr. Thubelihle Ndlela
Email: Thubelihle.ndlela@wits.ac.za

If you have any concerns or complaints about the ethical aspects of this research study, you are welcome to contact the University Human Research Ethics Committee (Non-Medical) at +27(0) 11 717 1408 or email hrecnon-medical@wits.ac.za.
Thank you for considering participation in this study.

Yours sincerely,
Tshepiso Leballo

8.4 Ethics Clearance Certificate

Graduate School of Business Administration
University of the Witwatersrand, Johannesburg

Wits Business School

Wits Business School Ethics Committee
Constituted under the University Human Research Ethics Committee (Non-Medical)

Ethics Clearance Certificate

Ethics protocol number: WBS/BA360328/813
This certificate is only valid with a legitimate ethics protocol number and signed by the Researcher (below).

Project title	The impact of generic drug entry in the South African market
Investigator / Researcher	Ms Tshepiso Leballo
Nature of Project	MBA (Research Article)
Decision of the Committee	Approved, provided stakeholders and participants are guaranteed anonymity and confidentiality.
Issue Date of Certificate	02/08/2024
Expiry date	Date of submission of the project / research report
Chairperson	Dr Ayanda Magida ☎ +27 11 717 3953 ✉ ayanda.magida@wits.ac.za

Declaration by Researcher

One copy must be signed by the Researcher and returned to the Chairperson of the Wits Business School Ethics Committee.

I fully understand the conditions under which I am authorized to carry out the abovementioned research and I guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I undertake to resubmit the protocol to the Committee.

Leballo Tshepiso
Signature

Date: 02/08/2024

8.5 Title approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Private Bag 3 Wits, 2050
Fax:
Tel:

Reference: Ms Jennifer Mgolodela
E-mail: jennifer.mgolodela@wits.ac.za

19 July 2024
Person No: 360328
TAA

Ms TN Leballo
27 Pierneef street
Birchleigh
1618
South Africa

Dear Ms Tshepiso Leballo

Master of Business Administration: Change of title of research

I am pleased to inform you that the following change in the title of your Research Report for the degree of **Master of Business Administration** has been approved:

From:	**Price erosion effects of generic medicines**
To:	**The impact of generic drug entry in the South African market**

Yours sincerely

Mrs Marike Bosman
Faculty Registrar
Faculty of Commerce, Law and Management