

Gordon Institute of Business Science

University of Pretoria

South Africa's National Health Reform: How leading R&D pharmaceutical companies are responding

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A research project submitted to the Gordon Institute of Business Science,
University of Pretoria, in partial fulfilment of the requirements for the degree of
Master of Business Administration.

07 November 2016

ABSTRACT

In December 2015, the South African government released the much anticipated White paper on the planned National Health Insurance (NHI) (Department of Health, 2015) raising more questions (“NHI White Paper”, 2016) amongst stakeholders. Frost and Sullivan (2011) have suggested that the planned cost containment of the NHI will benefit generic companies whilst research and development (R&D) companies, the biggest upstream providers in the private healthcare sector in South Africa, might consider pulling out of the country. In order to ensure long-term sustainable growth within the new NHI landscape, R&D pharmaceutical companies will have to align their strategic approach to meet several stakeholder demands in this changing environment. Therefore, this study’s primary objective was to investigate the behavioural tactics of R&D pharmaceutical companies in response to the NHI, viewed from their perspectives as the change recipients.

An in-depth exploratory qualitative research design was employed as the researcher was concerned not only with how these pharmaceutical companies are preparing for the NHI, but also with the rationale underpinning those selected change tactics employed by R&D pharmaceutical companies. A total of five, highly experienced senior executives, representing leading R&D pharmaceutical companies, were interviewed.

Findings from this research revealed several important themes, from the need for diversified pharmaceutical portfolios in order to address the country’s disease burden, to improved market access and public-private partnerships to overcome current challenges. However, throughout this research project, the importance of extensive stakeholder engagement, particularly from the government, was identified as both a barrier and enabler to the successful implementation of the NHI.



KEY WORDS

National Health Insurance

Pharmaceutical Operating Model

Stakeholder Theory

Organisational Change Theory

Complexity Theory

DECLARATION

I declare that this research project is my own work. It is submitted in partial fulfilment of the requirements for the degree of Master of Business Administration at the Gordon Institute of Business Science, University of Pretoria. It has not been submitted previously for any degree or examination in any other University. I further declare that I have obtained the necessary authorisation and consent to perform this research.

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07 November 2016

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1 INTRODUCTION TO THE RESEARCH PROBLEM

1.1 Introduction

According to McDermott, Fitzgerald, and Buchanan (2013), it is well known that any planned change, regardless of whether it is organisational, social, or policy change, is difficult. In most cases, the planned change initiatives result in very slow progress and may even fail to achieve full implementation of its originally desired mandate (By, Oswick & Burnes, 2014). The majority of organisational studies and political sciences have focused on change management from the instigators' perspective, with little to no acknowledgement of the response to change from the change recipient's perspective (Oreg, Michael & By, 2013).

Much has been written about the inequality that exists in South Africa's dysfunctional healthcare system, and it has been argued that the origin of this impaired system can be traced back to policies such as apartheid (Coovadia, Jewkes, Barron, Sanders & McIntyre, 2009). Furthermore, the failure of the post-apartheid government to overcome the health system challenges that it faced in 1994, has resulted in the persistence of a dysfunctional healthcare system (Coovadia et al, 2009).

The introduction of the National Health Insurance (NHI) in South Africa has brought about a major healthcare policy reform process, with the implementation of reforms having progressed much slower than planned, if not completely ceased. Human (2010) pronounces South Africa's current healthcare system as "a two-tiered system that exposes the class inequality that continues to linger after the demise of the Apartheid regime".

In December 2015, the South African government released the much anticipated White paper on the planned NHI (Department of Health, 2015), raising more questions ("NHI White Paper", 2016) amongst stakeholders, who anticipated clarity on queries raised after the release of the Green paper in 2011 (Department of Health, 2011). The biggest criticism from the private sector has been the lack of detail on what the role of the private healthcare sector will be in this new landscape. The expected impact of the NHI will extend beyond patients and role players directly involved in the provision of private health services (Econex, 2013).

Effective policy change requires change recipients (those whom the change is primarily meant to influence) to translate the policy mandates into their local contexts as they interpret, tailor and adapt policy mandates to fit their local contexts (McDermott, Fitzgerald & Buchanan, 2013). This perspective brings the role of the recipients to the forefront, not as victims of the change, but as active participants in an evolving business environment. Organisations have an unavoidable responsibility towards their stakeholders, as they may wield significant power and are representative of the public society (Buccholtz & Carroll, 2012).

Healthcare systems are considered complex adaptive systems (CASs) and as such, defined as systems in which the components comprising it “interact and mutually affect each other to generate new behaviours”. Therefore, even by changing only one element in this system, the behaviour of the entire system can be significantly and drastically impacted (Lowell, 2016). In order to effectively implement health and development strategies, there is a need for capacity- and systems building, in relation to structures, processes and resources required for policy advocacy, development, implementation and evaluation. Pharmaceutical companies are frequently placed in the role of policy entrepreneurs and champions of change in diverse settings like the NHI (Batras, Duff & Smith, 2014).

In their 2013 report on the contribution of the private sector to the South African economy, Econex goes into great detail about the importance of the private healthcare sector (Econex, 2013). The report makes the point that the private healthcare sector is multi-dimensional and consists of large numbers of participants, including:

- Private hospitals;
- Healthcare practitioners;
- Medical schemes and administrators;
- Upstream industries responsible for supplying goods and services to the sector;
- Downstream industries, which assist in the distribution of resources.

As a result, any impact on the private health sector will have significant repercussions as it employs many people and facilitates significant economic activity. The report further identifies pharmaceutical companies as the biggest upstream providers in the

private healthcare sector in South Africa, feeding through the entire country via multiplier effects and interlinkages.

It is argued that policy reform has a tremendous effect on organisations that are direct recipients of the change initiative (Oreg et al., 2013), thereby proposing the importance of the change recipients' perspectives on policy change. In a report by Frost and Sullivan (2011) it has been suggested that the planned cost containment of the NHI will benefit generic companies whilst branded (R&D) companies will lose out and might even consider pulling out of South Africa.

South Africa's NHI approach is largely focusing mainly on a reengineered primary healthcare (PHC) system (Naidoo, 2012) and community outreach services using a comprehensive PHC package of services. However, global market trends have seen a significant shift in the commercial operating model of pharmaceutical companies, from big research hubs focusing on primary healthcare, to the current model of a lean and focused company, with a research footprint within key innovative bio-clusters (Gautam & Pan, 2016).

It is against this backdrop that this study was designed, focusing on the response of leading Research and Development (R&D) pharmaceutical companies to the planned implementation of the National Health Insurance (NHI). As important role players in healthcare service delivery, the behaviour of healthcare service providers is considered a significant determinant on whether the goals of NHI can be achieved.

In the new NHI landscape of South Africa, R&D pharmaceutical companies will have to consider the strategic approach that they will pursue not only based on their individual goals, but inevitably, companies will need to decide how to satisfy contending stakeholder demands while pursuing sustainable long-term growth in this changing and competitive market.

A review of the literature to date does not provide evidence of what the requirements are for branded / R&D pharmaceutical companies to remain sustainable within the reformed healthcare system under NHI in South Africa, or how these organisations are responding to the imminent reform. Therefore, this study's primary objective was to investigate the behaviours of R&D pharmaceutical companies in response to change accompanying the NHI, viewed from their perspectives as the change recipients and the world around them.

1.2 Research Objective

It was the researcher's assumption that, in response to the planned reform, leading R&D pharmaceutical companies in South Africa will adapt their strategic approach and/or operational model in order to partner with the NHI, thereby ensuring long-term sustainability within this new business environment.

Therefore, considering the integral role of pharmaceutical companies in South Africa's healthcare system, this research aimed to shed light into the way that these organisations in the private sector are responding to- and preparing for the impending implementation of the NHI.

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1.3 Research scope

The scope of this study was confined to leading Research and Development (R&D) pharmaceutical companies in South Africa's private healthcare sector. Although much has been written about the inequalities of the current healthcare system and the planned reform through implementation of the NHI, there has been no clarity provided regarding how stakeholders in the private sector are preparing for this reform to ensure their long-term sustainability.

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2 LITERATURE REVIEW

2.1 Introduction

Ramjee and Mcleod (2010) define private healthcare stakeholders according to their role in the health system:

- Revenue Collection: individual members of the public, organised labour, employers, brokers and all taxpayers (including those paying income tax, value added tax, fuel levy and customs and excise taxes);
- Pooling: medical aids and medical aid members;
- Purchasing: medical aid, medical aid administrators, managed-care organisations; and
- Delivery: private hospitals, pharmaceutical industry, medical practitioners, nurses, traditional healers, pharmacists and pharmacy owners.

The private health sector is a large industry and has great economic importance. The degree to which the private healthcare sector interacts and affects other industries in the economy is significant. Each group of contributors in this sector, from hospitals, doctors and nurses, allied health professionals, service providers, medical schemes and administrators to other health insurers – are connected to other upstream (and downstream) industries in the economy. Therefore, any impact on the private healthcare sector, regardless of magnitude, will have significant consequences as it employs many people and facilitates significant economic activity (Econex, 2013).

The implementation of the NHI is expected to significantly impact private institutions that are involved in the supply chain of purchasing and delivery of healthcare services such as pharmaceutical companies, medical device companies, wholesalers, distributors and pharmacies. This is evidenced by the following statement from the NHI policy paper: “In order to implement an effective National Health Insurance, there will be a reconfiguration of the institutions and organisations involved in the funding, pooling, purchasing and provision of health care services in the South African health system” (Department of Health, 2011).

South Africa has previously been recognised as a global leader in medicine for a long time and some of the world's leading pharmaceutical companies are represented locally, feeding through the entire country via multiplier effects and interlinkages. Pharmaceutical and life sciences companies are among the most analysed and evaluated organisations in business today. As the largest upstream service provider in the healthcare system (Econex, 2013), the pharmaceutical industry is under constant scrutiny from decision-makers and influencers across the globe for the dichotomy that seems to exist between profitability and access to healthcare for all.

Frost and Sullivan (2011) have suggested that the planned cost containment of the proposed NHI will benefit generic pharmaceutical companies whilst branded companies will lose out and might even consider pulling out of South Africa. As important role players in healthcare service delivery, the behaviour of healthcare service providers are considered a significant determinant on whether the goals of NHI can be achieved. In the new NHI landscape in South Africa, pharmaceutical companies will have to consider the strategic approach that they will pursue not only based on their individual goals, but inevitably companies will need to decide how to satisfy contending stakeholder demands while pursuing sustainable growth in a competitive market.

Considering the shifting landscape of healthcare, the pharmaceutical industry is challenged to evolve and the roll-out of the NHI accelerates this call to action. It is evident that the environment in which pharmaceutical companies operate is complex, highly regulated and rapidly changing. In order to prepare for the new environment that will accompany the implementation of NHI, pharmaceutical leaders will have to align their current portfolio offerings to the needs of their stakeholders in this dynamic environment.

The primary objective of this study was to investigate the behaviours of leading Research and Development (R&D) pharmaceutical companies in response to change accompanying the NHI and seek to understand what the new requirements are for R&D pharmaceutical companies to operate within the NHI, thereby ensuring long-term sustainability of these organisations. To do this, an important point of departure was to contextualise the world around pharmaceutical companies and the goals that they are trying to achieve in it.

Therefore, this study explored the response of leading R&D pharmaceutical companies' to the NHI through the lenses of stakeholder theory, complexity theory and

organisational change theory. In addition, a brief overview of the current general operating model of major R&D pharmaceutical companies is described. Through these lenses it will be possible to explore how leading R&D pharmaceutical companies are responding to- and preparing for the future healthcare landscape of NHI. This literature review also assists in contextualising the enablers and barriers for the successful implementation of NHI, as perceived by the study participants and their organisations.

2.2 Current Pharmaceutical Operating Model

The past couple of decades have seen significant transitions in the commercial operating models of big pharmaceutical companies. In the 1990's to early 2000's, the big pharma model was a large, diversified company with multiple research and development global hubs, focused on primary care businesses driving a significant share of revenue with minimal contribution from emerging markets. However, market trends have seen the operating model transition to the current pharmaceutical model of a lean and focused company, with a research footprint within key innovative bio-clusters and an increasing revenue stream from biologics, speciality products and emerging markets (Gautam & Pan, 2016).

Studies have identified the declining R&D productivity (Paul, 2010), growth of emerging markets (Looney, 2010) and the transitioning of commercial models (Kessel, 2011) as the key revenue contributors, as cited by Gautam and Pan (2016). Data collected by Gautam and Pan (2016) revealed four trends in the shaping of big pharma's operating model:

- From massive to lean organisations: focusing on areas of strengths;
- From research hubs to hotspots: broadening access to external innovation and collaboration by localising research units;
- Focus shift from primary care to speciality products: targeted medicines for high unmet medical needs;
- Market focus shifts from West to East: growth from emerging markets due to strong demand and economic fundamentals.

South Africa's NHI approach is largely based on that of Brazil, focusing mainly on a reengineered primary healthcare (PHC) system (Naidoo, 2012) and community

outreach services using a comprehensive PHC package of services. However, the trend of pharmaceutical companies shifting their focus to speciality products is evident from IMS health data (2014), revealing increased revenues from speciality medicines and biologics for most big pharma companies. Although it is expected that the demand for new therapies will continue to grow (IMS Health, 2014), the pharmaceutical industry faces significant challenges ranging from patent expirations, to regulatory requirements, access, pricing and reimbursement. In an effort to remain competitive within these markets, two operational strategies have emerged:

- A diversified business that includes diagnostics, generic products, devices, innovative drugs, consumer- and animal health; and
- Pure biopharma companies which focuses primarily on innovative drugs.

The strategies for the aforementioned models are diverse, ranging from asset-swapping to focus on leadership businesses, geographic expansion and exit non-aligned portfolios, to restructuring of R&D and acquisitions and partnerships.

The four key trends (Massive to lean; hubs to hotspots; primary care to speciality; West to East) will continue to shape big pharma's operating model for the foreseeable future. The main challenge still to overcome is the affordability of drugs, especially in lower-income countries. Novel therapies are expensive and new pricing and reimbursement models such as coverage assistance, tiered pricing, as well as pay-for-performance methods are required to make them accessible for patients. All healthcare stakeholders (government, payers, and healthcare companies) are under pressure to provide sustainable healthcare, especially in emerging economies, like South Africa, where healthcare systems are largely out-of-pocket (Gautam & Pan, 2016).

The biggest challenge for pharmaceutical companies in South Africa remains market access. The high regulation of pharmaceuticals in South Africa, as well as the inflexibility on pricing by the government has become a barrier to effective price competition and is hampering patient access to innovative medicines (EyeForPharma, 2015). A number of variables add to the complexity of market access in the country:

- Differing practices of the nine provinces, each governed by its own health department ultimately reporting to the national Department of Health; as well as
- Pricing split between public- and private sectors;

- Access is further complicated by the absence of a central Health Technology Assessment (HTA) body in South Africa at present;
- Fixed single exit pricing (SEP);
- It is also illegal to offer rebates, discounts or alternative incentives in reimbursement packages.

Besides price considerations, there is a need for more detailed review of the clinical evidence for drugs available in South Africa in order to close current gaps. There is a clear need for a “reimbursement dossier which can be shared with private health providers and public payers, in much the same way pharma in the UK does with NICE” (EyeForPharma, 2015).

The third international Pharmaceutical Pricing and Reimbursement Information (PPRI) Conference in 2015 focused on challenges in pricing and reimbursement policies for medicines (Vogler, Zimmerman, Ferrario, Wirtz, de Joncheere, Pedersen, Dedet, Pars, Mantel-Teeuwisse & Babar, 2016). Research highlighted at the conference, showed that commonly used policies regarding pharmaceutical pricing and reimbursement are not sufficiently effective to address current challenges. There is a need for fundamental reforms to ensure broader access to medicines, particularly to innovative and potentially more effective and / or safe medicines, while safeguarding the financial sustainability of health systems and working towards universal health coverage (Vogler, et. al., 2016).

The imminent NHI and clear need for a central HTA means that various pharmaceutical products will undergo new assessments. It is important to review pricing policies in order to facilitate the transition to a NHI (Wouters & Kanavos, 2015).

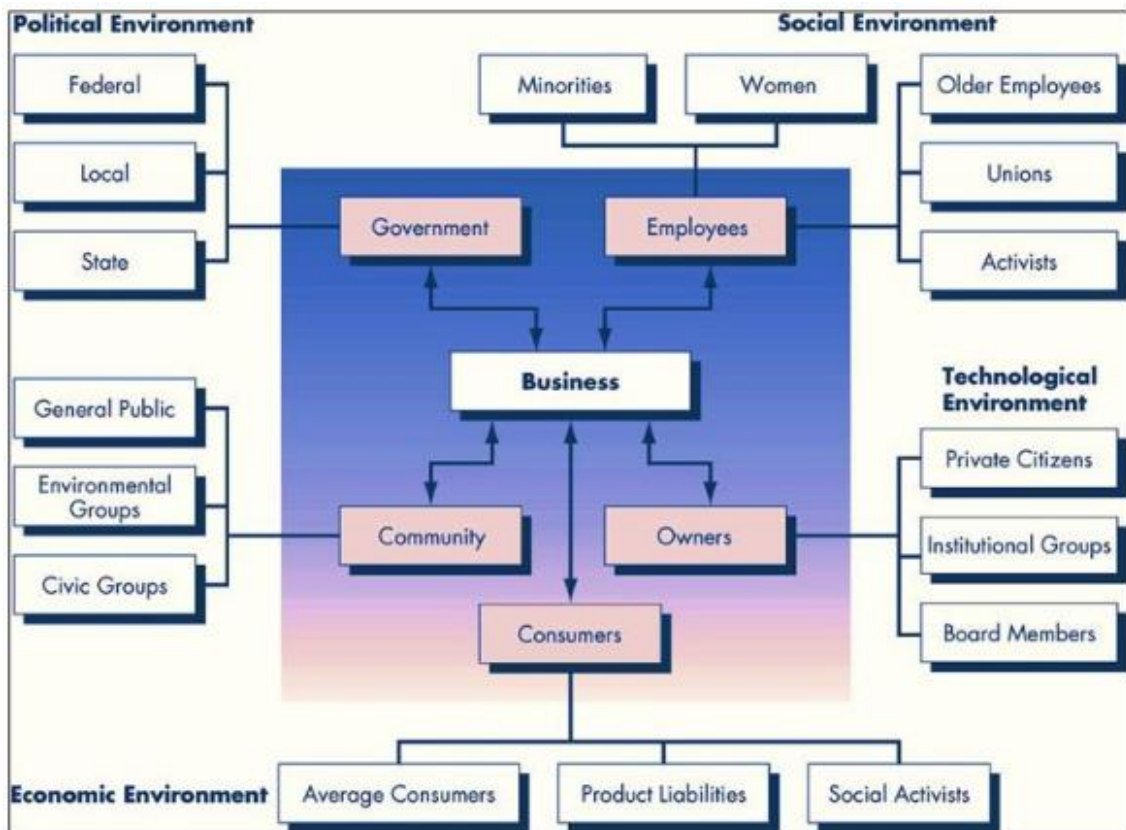
Considering the PHC focus of the NHI, as well as the challenges pertaining to access, pharmaceutical companies represented locally will have to review the relevance of their operational model and strategic approach in order to remain a profitable entity within the new healthcare system.

2.3 Stakeholder Theory

Bucholtz and Carroll (2012) define a stakeholder as an individual or a group that has one or more of stakes in the organisation. Stakeholders can affect, or is affected by, the organisation's actions, decisions, policies, practices and goals.

Due to considerable changes occurring both internally and externally in business and its environment, managers underwent a conceptual shift in how they perceived the firm and its multilateral relationships with stakeholders. This became known as the stakeholder view of the firm, as depicted in Figure 1 (Bucholtz & Carol, 2012).

Figure 1 - Stakeholder view of the firm (Bucholtz & Carroll, 2012)



By taking the stakeholder view of the firm, one can reflect on the various individuals and groups that comprise the firm's internal and external environments. It is clear that a two-way exchange of influence exists between stakeholders and the organisation. It is based on this premise that it is imperative for pharmaceutical companies to take a stakeholder view of the firm, identifying the many different individuals and groups

embedded in the internal and external environments. In addition to identifying its stakeholders, it is imperative that pharmaceutical companies prioritise their stakeholders as primary- or secondary stakeholders, as well as in terms of the salience of those stakeholders.

Primary stakeholders are most influential to an organisation, as they have a direct stake in its success (Buccholtz & Carroll, 2012). In the case of pharmaceutical companies, primary stakeholders include shareholders, employees, customers (doctors and nurses), patients and business partners.

Although the stake of secondary stakeholders is indirect, they may be influential in affecting the organisation's reputation or public standing (Buccholtz & Carroll, 2012). Secondary stakeholders in the pharmaceutical industry include government and regulatory bodies, patient groups, media and academics, as well as industry associations.

Stakeholder theory is relevant in the complex and changing landscape of healthcare, as it promotes an ethical approach to managing organisations. Harrison, Freeman and Sá de Abreu (2015) argue that managing for stakeholders provide improved strategic agility, as organisations are able to make base decisions on higher quality information.

Buccholtz and Carroll (2012) further posit that the responsibility of an organisation to these stakeholders is not avoidable, as they may wield significant power and are representative of the public society. Furthermore, it is imperative to engage all stakeholders in a reform process in order to avoid and resolve disputes (Wouters & Kanavos, 2015), as well as to overcome any potential barriers identified.

In 2010, Ramjee and McLeod reviewed the responses by the private sector stakeholders to NHI. The review revealed that there was a concern regarding the potential impact of the NHI, however, there was also willingness from these stakeholders to participate and engage (Ramjee and McLeod, 2010). A primary concern that emerged from the review conducted by Ramjee and McLeod in 2010, before the release of the policy document on NHI, was around the lack of stakeholder consultation and transparency. Stakeholder theory promotes the ethical and fair management of stakeholders through stakeholder engagement, in pursuit of more balanced objectives that meet the demands of all stakeholders (Harrison, Freeman & Sá de Abreu, 2015).

The prominence of stakeholders in terms of their legitimacy, power and urgency can greatly assist organisations in understanding potential stakeholder impact. Buccholtz and Carroll (2012) describe these three attributes as follows:

- Legitimacy refers to the perceived validity or appropriateness of a stakeholder's claim to a stake in the organisation;
- Power refers to the stakeholder's ability to produce an effect on the business;
- Urgency refers to the degree to which the stakeholder's claim on the business calls for the business's immediate attention.

The organisation's responsibility to these stakeholders, as well as the stakeholders' potential threat to, or cooperation with the organisation, will significantly affect the organisation's strategic actions.

Wouters and Kanavos (2015) highlight the importance of allocating responsibilities through clearly defined rules, as well as providing clarity on the roles of governmental stakeholders in the new system.

Considering the stakeholder analysis provided above, it is clear that the government, patients, medical practitioners and academia, shareholders and employees are most likely to be impacted by any changes in the strategic approach and / or operating model of pharmaceutical companies. It is also evident that stakeholder engagement is an integral part of an organisation's strategy, in order to ensure its sustainability in the long run. By adopting an inclusive stakeholder approach, an organisation is in a better position to determine the most suitable acquisitions in order to successfully implement change (Harrison, Freeman & Sá de Abreu, 2015).

The principle of stakeholder engagement is to create sustainable value and ensure as many win-win situations as possible. Almost every business transaction involves a stakeholder at some point in the value chain. By recognising how stakeholders are impacted by - or impacting on the business, it is possible to establish the needs of all stakeholders and aspire to meet these needs as often as possible. In doing so, it is possible to minimise challenges or barriers and reduce the problem of a dominant group. In recognising the complexity of stakeholders, one is able to differentiate consequences based on who is being affected (Freeman, Harrison, Wicks, Parmar, De Colle, 2010).

The stakeholder approach is relevant in this study as it assists to build a case for the role of external pressures that impinge on an organisation beyond its own internal structures. Wouters and Kanavos (2015) posit that pharmaceutical policy should align with national health priorities and reiterate the fact that the main objective of pharmaceutical policy is to ensure equal access to effective medicines.

The Department of Health acknowledges that the planned timeline for the implementation of the NHI is ambitious by international standards, but deems this timeline to be achievable (Matsoso and Fryatt, 2013). However, successful implementation of the NHI within the timelines suggested will only be possible if government has multi-stakeholder support. By engaging with stakeholders through public-private collaborations, South Africa can enable a “state-of-the-art” system, resulting in significant cost savings for many stakeholders.

Public-private partnerships (PPP’s) refer to the balanced collaboration between the public and private sectors in order to achieve common objectives, by sharing risks, costs and benefits, whilst leveraging the different resources and skills of the various partners involved. Although there is no clear understanding of the main drivers that lead to successful PPP’s, a situational analysis is required for each unique partnership, in order to determine the likelihood of success (Torchia, Calabrò & Morner, 2015).

Collaborative partnerships with industry in the private sector will not only optimise access to healthcare, but also assist in creating patient-centered formularies (Chou, Lakdawalla & Vanderpuye-Orgle, 2015). Torchia, Calabrò and Morner (2015) posit that, where public interest is at stake and due to the stronger position of the private sector, government is required to play a more active role in PPP’s and careful policy reflection is needed. The role of government is crucial in the successful implementation of a PPP (Biginas & Sindakis, 2015).

In order for the implementation of PPP’s to be successful, the interests of all stakeholders should carefully be considered through extensive stakeholder engagement (Torchia, Calabrò & Morner, 2015). As an emerging market at the verge of implementing a significant healthcare reform, South Africa has the opportunity to learn from countries that have successfully implemented PPP’s and NHI. In so doing, it is imperative to note the importance of regularly assessing PPP’s in order to ensure reliability and transparency, thereby mitigating the risk of converting public healthcare into a commodity (Biginas & Sindakis, 2015).

2.4 Complexity Theory

The inherent complexity of the healthcare system is increasingly more visible due to constant changes in healthcare. In order to find innovative solutions for advancement, leaders need to understand the complexities of the healthcare system (Weberg, 2012).

Complexity theory principles are increasingly being utilised to understand system-level behavior, as well as organisational change in complex settings such as healthcare organisations. The theoretical framework of complexity theory supports intervention design and policy implementation (Caffrey, Wolfe & McKevitt, 2016) that works with the complexity of the setting in question. Complex adaptive systems (CASs) are defined as systems in which the components comprising it “interact and mutually affect each other to generate new behaviours”. Therefore, by changing one element in this system, the behaviour of the entire system can be significantly impacted (Lowell, 2016).

Healthcare settings are considered “complex adaptive systems” as they consist of a number of stakeholders whose actions are unpredictable, yet interconnected (Brand, Fleming & Wyatt, 2014) and bound by a common objective (Thompson, Fazio, Kustra, Patrick & Stanley, 2016). Tuffin (2016) describes multi-faceted organisations like National Health Services (NHS) as behaving like complex adaptive systems and suggests that such large organisations would benefit from complexity theory-informed management strategies. Caffrey, Wolfe and McKevitt (2016) posit that structure, a product of time and history, will directly influence the course of the system.

The changing conditions, within which individuals operate, are characterised by unpredictability and uncertainty, requiring constant evolution. Complexity theory highlights the dynamic and relational properties of a setting and identifies those aspects that enable stakeholders to employ new ways of thinking, working and relating. The ongoing uncertainty and instability result in the unfolding of “varying patterns and structures as the system evolves and organizes itself into something new” (Lowell, 2016). For pharmaceutical companies, this translates into understanding and working within the NHI’s environmental and its relational characteristics.

Thompson, et.al. (2016) posit that complexity theory is often described by authors in literature through aspects that describe how communication and stakeholder relationships can influence and contribute to changes within the system. Meaningful

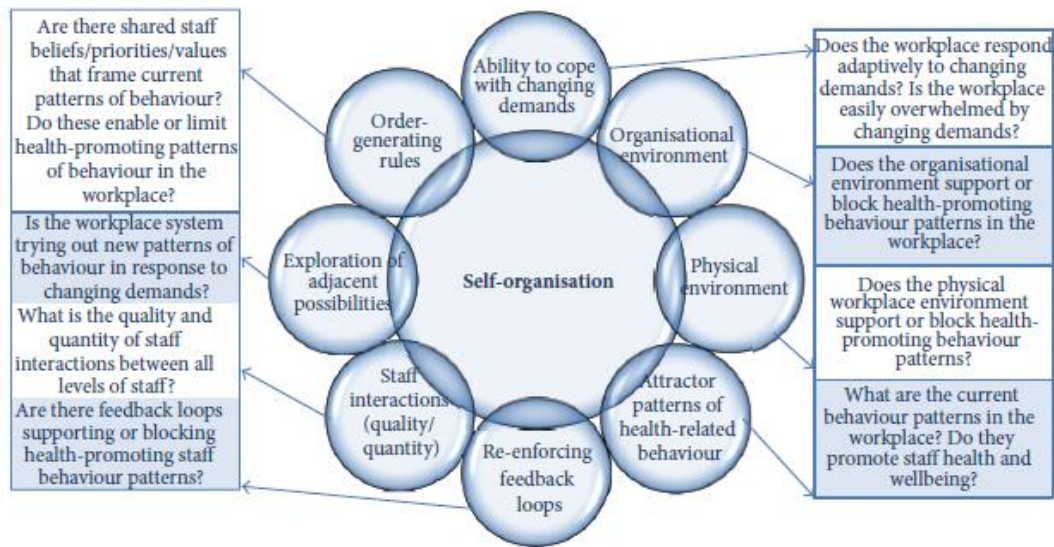
change often occurs spontaneously through the interactions of individuals involved, instead of being enforced from the top down (Tuffin, 2016).

The value of a CAS lies in both the agents within the system, as well as their relationships among each other, governed by simple rules such as the vision, mission and value statements of the organisation (Weberg, 2012). Trust and respect are promoted through positive interactions and collaboration between agents in the system, creating a sense of mutuality that inevitably increases interconnectedness (Lowell, 2016). Descriptions thus often include the importance of relationships, diversity and communication within complex systems, the collective impact of disparate parts on the system, as well as self-organisation.

Brand, Fleming and Wyatt (2014) utilised the principles of complex adaptive systems theory to develop “The Workplace of Well-being (WoW)” framework. This framework guides the exploration of interrelated workplace characteristics contributing to the ability of a workplace system to self-organise into new patterns of behaviour. The complexity-informed WoW framework is useful in the context of the healthcare environment as it assists in (Figure 2):

- Supporting setting-appropriate intervention activities: identifying enablers and barrier to system-level behaviour change;
- Creating a change-conducive setting: by addressing setting-related enablers and barriers;
- Describing the importance of local context: interventions work with the dynamic system;
- Redefining “Best Practice”: transfer of interventions to new complex systems;
- Ensuring sustainability of interventions in new complex systems: the intervention changes the way in which the system behaves.

Figure 2 – The Workplace of Well-being (WoW) framework (Brand, Fleming & Wyatt, 2014)



Complexity theory is relevant in this study to identify dynamic and relational properties of the NHI setting, as well as those aspects that will enable R&D pharmaceutical companies to employ new ways of thinking, working and relating within the NHI environment. Companies striving to ensure their survival and sustainability in a rapidly changing business environment need to be able to produce innovations on an ongoing basis, whilst adapting to various circumstances both internally and externally, as well as anticipate the need for change (Lowell, 2016).

The role of complexity leaders, such as government and senior executives within R&D pharmaceutical companies, is to remove any barriers so that innovations can emerge and develop a connectedness to agents in the system (Weberg, 2012).

As healthcare systems are considered complicated, it is possible to utilise complexity theory in order to reduce the system, study the individual – in this case R&D pharmaceutical companies – and seek to improve one’s understanding of the overall system’s nature and processes (Thompson et.al., 2016). Due to the high level of interactions within a CAS system like the NHI, even one change in an element can have a significant impact on the behaviour of the system as a whole (Burnes & Cooke, 2013; Lowell, 2016). This connectedness is evident in the healthcare system of South Africa if one considers the upstream- and downstream interlinkages of the sector’s stakeholder groups. Kotter (2012) posits that a shared purpose and connectedness

enable people to achieve more than initially imagined, increasing the system's adaptability and resilience.

Complexity theory proposes the flexibility of organisations by maximising their adaptation to the environment within which they operate (Lowell, 2016). For R&D pharmaceutical companies in South Africa, this may translate to the diversification of their product offering locally in order to align with the country's disease burden. In addition, leaders of complex systems should continuously encourage creativity in solving problems (Lowell, 2016). In this instance, alternative reimbursement models and public-private partnerships (discussed earlier) are examples of creative solutions to the unique challenges in South Africa.

Effective leadership in complex systems demonstrate their commitment to a new direction (Kotter, 2012) and realise that the solutions to problems are often offered by agents closest to these problems. This notion underlines the significant role of stakeholder engagement within complex systems, like healthcare. All stakeholders within complex systems should be included in the process of solutions development (Lowell, 2016).

2.5 Organisational Change Theory

In order to effectively implement health and development strategies, there is a need for the building of capacity or organisations, communities and systems in relation to structures, processes and resources required for policy advocacy, development, implementation and evaluation. Where organisational development is a strategic priority, the development of partnerships to address health determinants is considered an area of practice. Health promotion participants like pharmaceutical companies, are thus placed in the role of policy entrepreneurs and champions of change in diverse settings like the NHI (Batras, Duff & Smith, 2014).

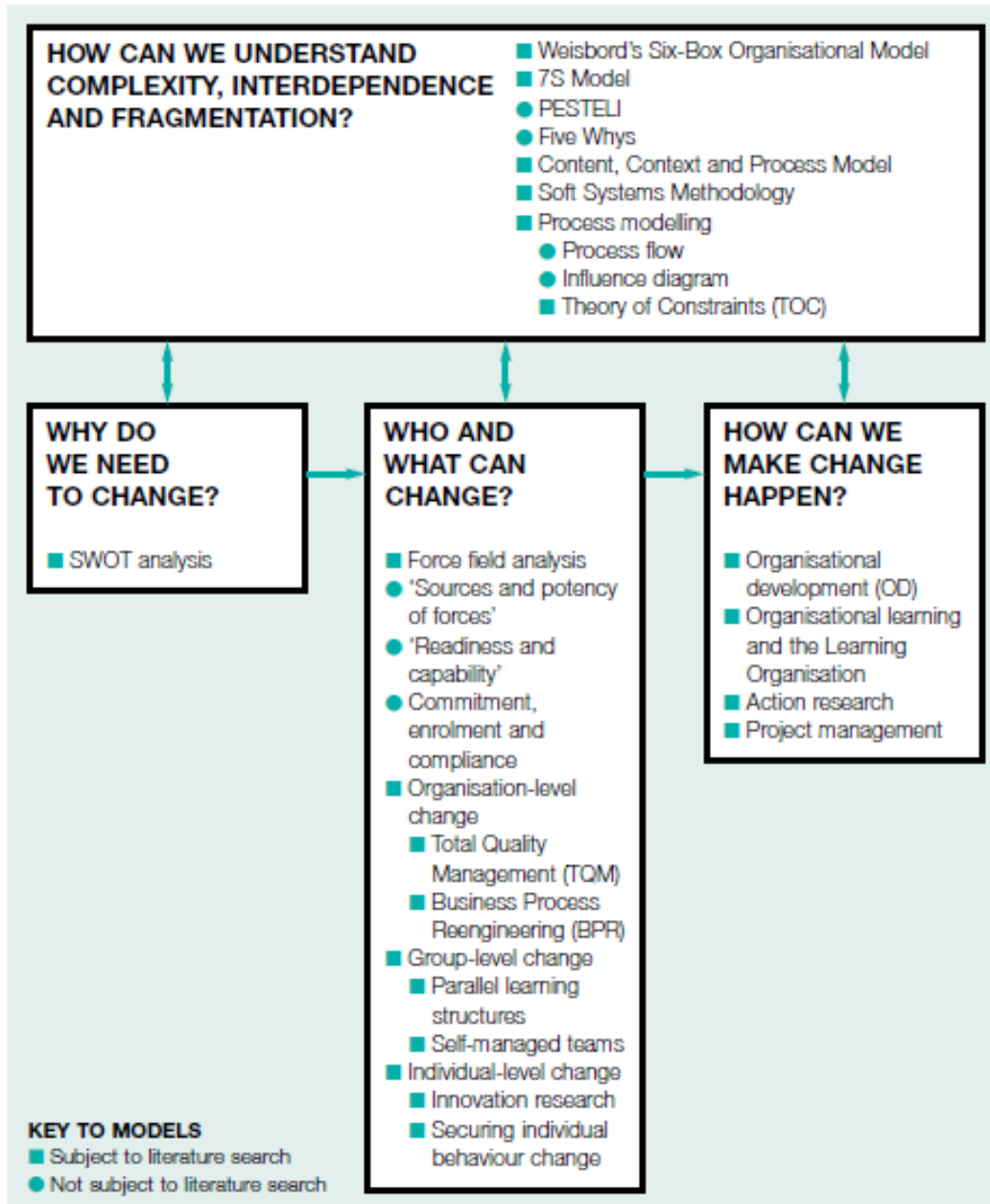
Organisational change theory suggests that time, persistence and interdisciplinary engagement are required to embed change and ensure long-term institutional change. In areas where human behavior plays a significant role, like healthcare, a systematic approach is a prerequisite to successful change implementation (Douglas & Sutherland, 2009). A common theme in organisational theory is that sustainability is linked to the extent of elasticity of shape and pace of the change implementation by change recipients. In the context of NHI in South Africa, this means that time and continued effort are required embed change. The sustainability of R&D pharmaceutical

companies will depend on their ability to align their strategic approach to fit within the NHI environment.

Although several change models have been outlined throughout literature, including extensive reports on the work of Kurt Lewin, it is evident that the change model utilised within a given environment will also dictate the leadership style required for managing the change (O'Malley, 2014). Of interest is the fact that O'Malley (2014) reviewed the role of leadership during each stage of Kotter's 2007 change model, and identified leadership styles that promote organisational engagement and shared vision as imperative to the successful implementation of change. Although leadership was highlighted during the research interviews as an important element in the healthcare landscape, the leadership style most suited in the context of NHI is beyond the scope of this study. The importance of stakeholder engagement and shared vision or the alignment of goals remains an important point of discussion.

In an effort to provide guidance on the vast literature surrounding organisational change, Iles and Sutherland (2001) grouped key models into four main clusters, focusing on four questions (Figure 3).

Figure 3 – Change management tools, models and approaches (Iles & Sutherland, 2001)



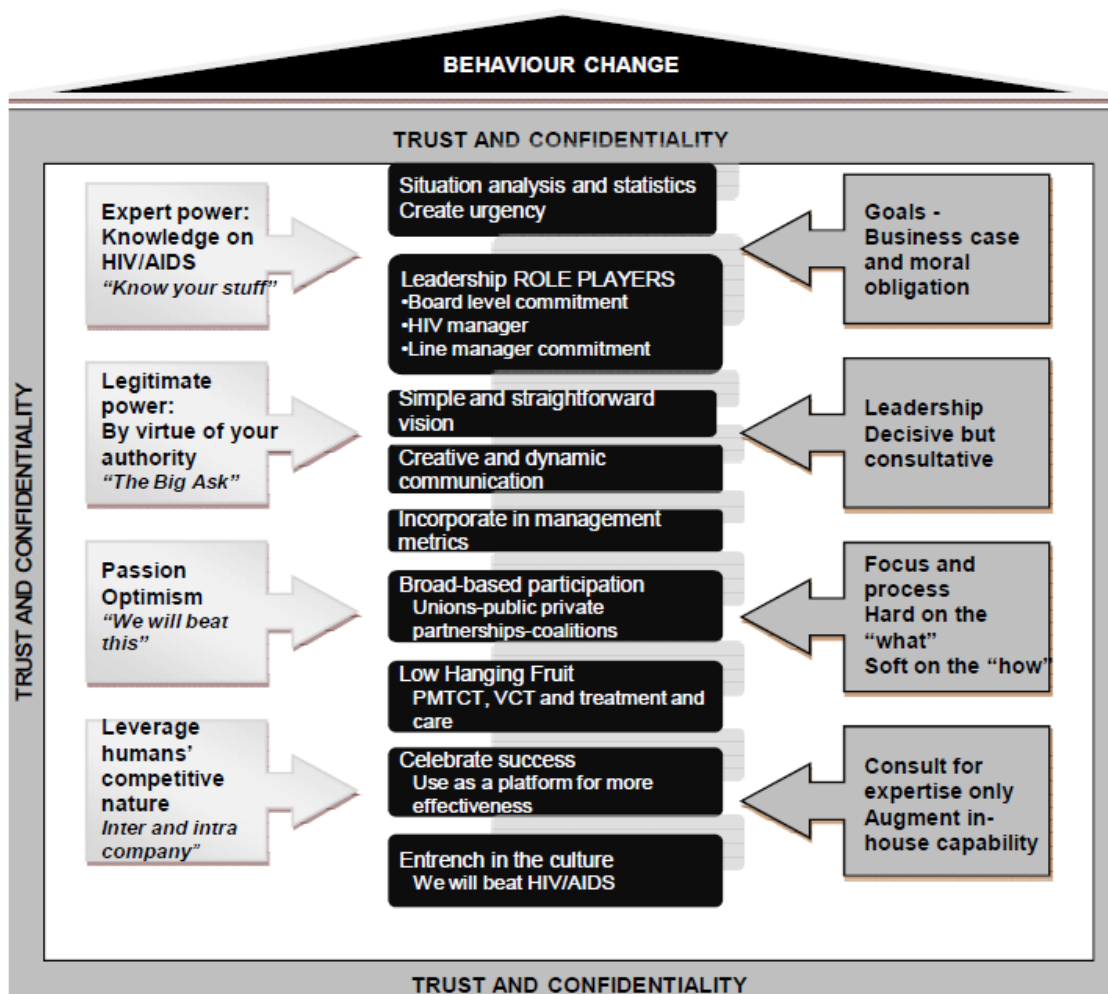
Four main questions bring key models together that demonstrate the importance of extensive analyses of the local situation, multi-stakeholder input / engagement and planning the intervention accordingly:

1. How can we understand complexity, interdependence and fragmentation?
2. Why do we need to change?

3. Who and what can change?
4. How can we make change happen?

Douglas and Sutherland (2009) recommended a nine stage change model for the successful implementation of a HIV / AIDS intervention (Figure 4).

Figure 4 – Essential organisational change elements for successful HIV / AIDS intervention (from Douglas & Sutherland, 2009)



The proposed model is a best practice, results-based model that highlights the significant value of trust and stakeholder engagement, with behavioural change as the ultimate outcome. Based on the interview findings, the researcher reflected on the stages and dimensions of this change model, in order to assess the status of the

proposed change that will accompany the NHI from the perspective of the research participants.

The model utilises the nine stages of change in order to create a sense of urgency around the need for change. The involvement of leadership across different levels in the system and the need for communication of the vision, are both highlighted as imperative to the successful intervention. Furthermore, the strategy for change (depicted to the right of the model) and leadership traits / behavioural constructs (depicted to the left of the model) will significantly influence the success and effectiveness of the change (Douglas & Sutherland, 2009).

The model outlined above is applicable to the complex healthcare system of South Africa and can be utilised to illustrate the salient points raised by the research participants, pertaining to both their response to the implementation of NHI, as well as the barriers and enablers pertaining to the successful implementation of NHI.

2.6 Literature Comments

The literature review identifies important frameworks that have assisted in contextualizing the organisational environment in which the policy change of NHI will occur. These models have provided the framework for identifying and analysing factors that influence R&D pharmaceutical companies' response to the healthcare policy reform and implementation under NHI.

Firstly, the evolution of the pharmaceutical operational model provides insight into the global strategies of these organisations. The imminent implementation of the NHI will bring a major healthcare reform to South Africa. Although much has been written about the unequal healthcare system of South Africa, as well as the anticipated impact of the NHI, there is little more than a passing notice of the recipients' response to this change process.

The literature illustrates the significance of stakeholder engagement and collaboration for the successful implementation of a reform initiative. In preparation for the planned change that accompanies a NHI, this research sought to identify how R&D pharmaceutical companies are aligning their local strategies with stakeholder demands.

Social science literature, especially the research by Kurt Lewin, identifies important theoretical models to help analyse normative behaviour of a collective during a change

process. Cummings and Worley (2009) posit that, the majority of Lewin's work has formed the basis on which many models for planned change and organisational design have been built. Lewin developed the field theory and group dynamics theory in order to comprehend the behaviour of social groups and what maintained them. The 3-step model and action research were proposed to change the behaviour of these groups. Lewin argued that one could not analyse forces impinging on a change recipient in isolation, but rather, it is essential to account for all these forces as a whole and their interrelatedness to one another. As all these parts are interdependent, changes in one part of the field has the propensity to change the entire landscape, depending on the valence of the forces affected (Burnes & Cooke, 2013).

Considering the complex and changing environment of healthcare in South Africa, a single theory is not sufficient to explore the intricacies of the system. Rather, the researcher explored the role of stakeholder engagement during organisational change within a complex environment.

Therefore, the theories of stakeholder analysis, organisational change and complexity theory, were collectively explored in this study. The purpose of exploration of these theories was to determine how leading R&D pharmaceutical companies perceive the changing healthcare environment and sought to understand the rationale behind the behavioural tactics of these organisations, in preparation for NHI.

3 RESEARCH QUESTIONS

3.1 Logic of the Inquiry

At the core of this research is an investigation into R&D pharmaceutical companies' perspectives of- and responses to the reform process under the NHI in South Africa. Rather than considering the relevance of the proposed change, this study turned its focus to the preparation of these R&D pharmaceutical companies for the imminent change, in order to remain sustainable in the long-term.

3.2 Research Questions

Insights gained from the literature review in Chapter 2 were utilised to frame a set of research questions that were formulated to guide this investigation

3.2.1 *Research Question 1*

Are the current operational models of leading Research and Development (R&D) pharmaceutical companies in South Africa's private sector relevant in the new landscape of NHI? If not, how are these companies adapting their operational model in order to function sustainably in an NHI environment?

This first question not only sought to identify the participants' perspective of the current healthcare system of South Africa, but also the historical context of how this system came to be, as well as the participants' perception on the need for a healthcare reform in the form of a National Health.

3.2.2 *Research Question 2*

How are these R&D pharmaceutical companies adapting their strategic approach in order to partner with the government in an NHI environment?

- a. *Are these R&D pharmaceutical companies undergoing organisational change or employing any change tactics ("scenario planning") in preparation for the NHI?*
- b. *How are these R&D pharmaceutical companies aligning stakeholder expectations with their strategic direction, if applicable?*

This question sought to explore the relevance of stakeholder relationships in the current environment and how these relationships have evolved. Furthermore, this question investigated the alignment of goals between stakeholders from the perspective of the change recipient, and sought to understand the rationale behind the behaviour of the organisations in response to the proposed healthcare reform

3.2.3 *Research Question 3*

From the perspective of these leading R&D pharmaceutical companies, what are the perceived enablers and / or barriers to ensuring sustainability within the NHI environment?

This question sought to understand the perceived challenges and opportunities in the healthcare system from the perspective of the interviewee. In addition, the question explored the interviewees' perceptions of the way forward in order to ensure the successful implementation of the proposed NHI.

4 RESEARCH METHODOLOGY

4.1 Research Design

This study followed an in-depth exploratory design, investigating structural forces that impact pharmaceutical companies in South Africa in the face of imminent healthcare services reform accompanying implementation of the NHI.

Although policy reform, scenario planning and stakeholder response to change are not new phenomena, this study sought to explore these from the point of view of leading R&D pharmaceutical companies in South Africa's private sector, in response to the new NHI landscape. Accordingly, as Saunders and Lewis (2012) suggest, in a study seeking to investigate an old subject in new light or ask new questions in a field where what is going on is not clearly defined, an exploratory design would be the most appropriate approach.

A qualitative approach was employed as the researcher was concerned not only with how these pharmaceutical companies are preparing for the NHI, but also with the rationale underpinning those selected change tactics employed by R&D pharmaceutical companies. Qualitative research is valuable when the researcher is concerned with providing new insights on phenomena or unexplored issues, providing rich nuance about the empirical phenomena in question by either extending prior research or exploring new contexts (Bettis, Gambardella, Helfat & Mitchell, 2014).

Zikmund, Babin, Carr and Griffin (2013) state that a qualitative approach to research allows the researcher to work inductively in the research setting and to explore elaborate interpretations of the phenomena under investigation. In addition, a primary advantage of qualitative research is that it is more open to adjusting and refining of research ideas as an inquiry proceeds (Wisker, 2001).

4.2 Research Philosophy

This study employed the principles of pragmatism. A pragmatic philosophy argues that the research question(s) and objectives form the most important precursors of the adopted research philosophy (Saunders & Lewis, 2012) and enables the researcher to focus on what works in the context of the research. The central idea in pragmatism, applicable to this study, is that the researcher is guided by that which is possible

(Saunders & Lewis, 2012); thus working in positivism, critical realism and / or interpretivism. The pragmatic view enables the researcher to integrate multiple perspectives to best answer the research question(s).

4.3 Research Population

Saunders and Lewis (2012) define a research population as the complete set of group members that form the focus of the research query. Although the proposed healthcare reforms are aimed at an overhaul of the entire healthcare system of South Africa, the proposed NHI recommends a radical reform process that will significantly change the way business will be conducted in the future. As a result of the cost-containment strategy in the public sector, the implementation of NHI is expected to impact pharmaceutical companies significantly.

Therefore, the target population was drawn from leading research and development (R&D) pharmaceutical companies in South Africa's private healthcare sector.

4.4 Unit of Analysis

Zikmund, Babin and Carr (2013) define a study's unit of analysis as the "who and what" that is being studied and at what level of aggregation. The unit of analysis dictates who provides the raw data for the research.

This study's unit of analysis was restricted to senior executives within the identified pharmaceutical companies in the private healthcare industry of South Africa.

4.5 Sampling and Sampling Methods

A combination of non-probability sampling techniques was employed (Saunders & Lewis, 2012) in order to establish relevance. The sampling method was purposive in nature (Zikmund, 2003). The purposive sampling was based purely on the judgement of the researcher.

Respondents were chosen according to their experience and expertise, thus no attempt was made either to ensure randomness or set up a representative probability sample (Zikmund, 2003).

A combination of three non-probability sampling techniques were employed to define the most appropriate data sources representative of the target population under investigation:

- Quota sampling - this method will enable the researcher to ensure that certain characteristics in the population under investigation are represented in the selected sample (Saunders & Lewis, 2012, p.137).
- Purposive sampling - in order to ensure maximum variation and heterogeneity. This is a sampling method where “the researcher’s judgement is used to select sample members based on a range of possible reasons and premises” (Saunders & Lewis, 2012, p.138).
- Snowballing - In order to ensure that all relevant stakeholders are reached. This method ensures that appropriate subsequent sample members are identified by the initial sample members (Saunders & Lewis, 2012, p.139).

4.6 Sample size

The goal of qualitative research is saturation and typically requires small sample sizes, with the goal of the research being relevance instead of representivity (Chipp, 2015).

Sample sizes are a function of many variables such as time constraints, budget availability, and measurement versus insights, respondent availability, as well as the research design: whether it is exploratory, causal or descriptive in nature.

The sample size was drawn from the industry association: The Innovative Pharmaceutical Association of South Africa (IPASA) comprising of 25 pharmaceutical companies in South Africa that are research based. Assuming a standard response rate of 20% - 30%, the required sample size was five to seven respondents.

A sample size of five to seven was considered adequate, given the nature of this study, influenced by time constraints and availability of respondents.

4.7 Data Collection Methods

A combination of data collection methods were employed in this study, to ensure that the researcher adhered to the statistical requirements of the research design and in order to have obtained diversity. The following three data collection methods were utilised:

- A systematic review of available literature to help frame the context of South Africa's healthcare system;
- In-depth face-to-face or telephonic interviews employing a semi-structured and open-ended format, in order for the interviewer to explore the objectives in more depth (Saunders & Lewis, 2012). Wisker (2001) also postulates that in-depth interviews are used when respondents such as experts in a field are not easy to find or easily available to be interviewed, and when the researcher is trying to dig deeper and go beyond political correctness. The interview guideline is an extension of the research questions stated in Chapter Three (See Appendix 1).
- Written documents that take the form of relevant policy documents such as the White Paper Policy on National Health Insurance, as well as any official documents submitted in response to these policy documents.

A total of eight pharmaceutical companies, as well as the Innovative Pharmaceutical Association of South Africa (IPASA), gave written approval for participating in this research project. In the end, a total of five pharmaceutical companies were interviewed due to the following reasons:

- One pharmaceutical company withdrew consent shortly prior to the interview, due to concerns regarding the sensitivity of the nature of information in this study;
- One pharmaceutical company did not respond to attempts to confirm an interview date;
- One pharmaceutical company's interview was cancelled an hour prior to the interview due to travelling delays on the executive's part;

- And finally, the interview with IPASA could not be confirmed after numerous attempts to align schedules for an appropriate interview date and time.

Although this was a small sample size, it is important to note that the level of seniority and experience, as well as the quality of respondents provided the researcher with the confidence to limit the sample size to key experts.

Table 1 – Study participants

PARTICIPANT	DESIGNATION
Participant 1	General Manager
Participant 2	General Manager
Participant 3	Regional Director
Participant 4	General Manager
Participant 5	Head of Division

The interviewer requested permission from the participants to audio record the interviews. Permission was granted from all participants, allowing the researcher to observe non-verbal communication during the interview.

4.7.1 *The interview guide*

The interview guide (Appendix 1) was an extension of the research questions stated in Chapter Three. The researcher pre-tested the interview guide with people who displayed similar traits to those in the research population.

The interview guide was formulated based on the theories discussed in Chapter Two: Stakeholder Theory, Complexity Theory and Organisational Change Theory. In addition, a literature review of the historical context of South Africa's healthcare system, as well as the current pharmaceutical operational model was employed to formulate questions that would provide insight into the rationale behind these companies' behavioural tactics.

4.8 Data Analysis Approach

This study employed an exploratory design that enabled the researcher to utilise the data collection instrument of semi-structured interviews, to yield qualitative data (Chipp, 2015).

The audio files from the recorded interviews were sent to a third party for transcription. This qualitative data collected, was divided into non-text and text data to facilitate the manual data analysis. Interview material was summarised and meanings were condensed, categorised and structured into a sensible narrative, allowing the researcher to look for patterns in the data and test alternative explanations for these patterns (Saunders & Lewis, 2012).

Each recorded interview was listened to several times and transcribed. The transcriptions were evaluated and verified for accuracy by the researcher against the original interview recording. Each recording was analysed in the context of the research questions and the researcher's review of the literature, in order to identify content themes in the data. The researcher deduced that the frequency of certain themes or issues raised by respondents, or the depth of the discussion on a specific theme or issue, indicated the level of importance or the role of these issues within the context of the research topic.

The issues or themes identified per interviewee were ranked according to a ranking system (Table 4, Chapter 5) that evaluated the depth of interviewee response or the frequency of recurrence of the theme by the interviewee. The "average" was taken to be the average score per theme or issue across all interviewees' responses per question. Therefore, the higher the average calculated, the higher the inferred importance of the identified theme or issue. The "%" reflects the percentage of participants that raised the issue per question

4.9 Data Reliability and Validity

Saunders and Lewis (2012, p. 127) define data validity as “the extent to which data collection methods accurately measure what they were intended to measure and that the research findings are really what they profess to be about.” This study sought to understand how leading R&D pharmaceutical companies in South Africa’s private sector are preparing for the planned implementation of the NHI. All interviewees were decision-making senior executives within their respective organisations.

Saunders and Lewis (2012, p. 128) define data reliability as “the extent to which data collection methods and analysis procedures provide consistent findings”. To ensure consistency in data collection, an interview guideline (See Appendix 1) was utilised to orient interviewees to the issues to be covered in each interview. Semi-structured, open-ended questions enabled the interviewee to freely express their views and convey the subject in their own way in order to limit subject- and / or observer bias.

4.10 Triangulation

Triangulation is aimed at an increased understanding of a complex phenomenon in which agreement among different sources confirm validity (Rittiichainuwat & Rattanaphinanchai, 2015). This finding suggests a better understanding of the links between theory and empirical findings, as well as to enable researchers to challenge theoretical assumptions and develop new theory.

This research triangulated findings from the interviews with content analysis and literature reviews. The approach of exploring this topic through various data sources, data collection methods and different perspectives in analysing findings, assisted the researcher in ensuring robust findings that are well-developed and provide rich insights.

4.11 Limitations of Study

No study is without limitations. Some of these limitations are inherent to a qualitative study of this nature, while some are particular to this study.

- Exploring different perspectives on existing subject matter may help to identify new insights. Conclusions from a study of this nature are often built from

extrapolating findings into meaningful narratives. Therefore, follow up research is necessary to confirm any conclusions.

- Sampling bias: although the study population in this research is clearly defined, selection of the sample requires the researcher to make a judgment call on who the most appropriate sources of data will be. Although every effort is made to ensure a fair representation of the research population, there is still a risk that other important sources were overlooked.
- Due to the nature of the field of this study (healthcare), as well as the sensitivity of the topic, access and time constraints presented the highest challenge as the interviewees were high profile industry opinion leaders. It is possible that this potentially increased the risk of an under-represented sample group.
- Interviewee bias: semi-structured interviews give rise to the interviewer introducing cognitive bias into the study, through the interviewer's body language, facial expressions or follow up questions that could unconsciously influence the response given by the interviewee.
- Interviewer bias: As an employee in the pharmaceutical industry, an unintended bias based on the interviewer's previously held hypotheses or expectations on the results of the research is possible.
- Sensitive data – This study was conducted on a topic of great uncertainty and mixed stakeholder perceptions on the potential impact and the sustainability of private stakeholders in the NHI environment. In addition, the Competition Commission of South Africa has extended its inquiry on pricing and anticompetitive behaviour in South Africa's private healthcare system, as commissioned by the minister of health (South Africa, The Competition Commission, 2015). Therefore, it is possible that access to potential participants was further restricted due to the nature of the research subject.

5 RESULTS

5.1 Introduction

This chapter presents the results of the research questions as stipulated in Chapter 3. Data was collected through a combination of three methods in order to ensure a comprehensive understanding of the subject matter. The three data collection methods utilised were systematic review of available literature, in-depth face-to-face semi-structured and open-ended interviews, as well as written documents in the form of relevant policy documents.

The interviews performed as part of this research project have provided valuable insight into how Research and Development Pharmaceutical companies in South Africa are responding to the proposed National Health Insurance.

This chapter starts with a summary of the interviews conducted and a discussion of the processes followed by the researcher in order to ensure the accuracy and validity of the data collected. This is followed by a discussion of the interviews in the context of the research questions as stipulated in Chapter 3.

5.2 Summary of interviews conducted

The researcher planned to conduct five to seven interviews, until a point where data saturation was reached (Saunders & Lewis, 2012). A total of eight pharmaceutical companies, as well as the Innovative Pharmaceutical Association of South Africa (IPASA), gave written approval for participating in this research project. In the end, a total of five pharmaceutical companies were interviewed due to the following reasons:

- One pharmaceutical company withdrew consent shortly prior to the interview, due to concerns of the sensitivity of the nature of information in this study;
- One pharmaceutical company did not respond to attempts to confirm an interview date;
- One pharmaceutical company's interview was cancelled an hour prior to the interview due to travelling delays on the executive's part;

- And finally, the interview with IPASA could not be confirmed after several attempts to align schedules for an appropriate interview date and time.

Three of the five interviewees were General Managers of the organisations, one interviewee was a Regional Director and one interviewee was the Head of their respective division.

Interviews were conducted with interviewees representative of the change recipients: five highly influential executives representing leading R&D pharmaceutical organisations in the private healthcare sector. Based on product portfolio offering, R&D pharmaceutical companies can be segmented into diversified-, semi-diversified-, specialised- and niche organisations. The five interviewees represented these four segments.

By the end of the fifth interview, nothing new of any significance was heard and given the quality of data collected at that point, as well as the respondents interviewed, the researcher did not seek any additional interviews (data saturation achieved). In-depth interviews were then used to contextualise the change process from the perspective of the change recipients.

Given the nature of this study, influenced by time constraints and availability of respondents, the sample size of five was considered adequate. Although this was a smaller sample size than initially planned, it must be noted that the level of seniority and experience, as well as the quality of respondents provided the researcher with further confidence to limit the sample size.

5.3 Data analysis

The respondents demonstrated a profound knowledge of the subject. All respondents spoke freely about the proposed NHI, as well as public-private partnerships and their perspectives about the current challenges faced. Before asking the research questions, the objective of the research was discussed, as well as the rationale for the topic under investigation. Prior to each interview, a copy of the interview guide was emailed to the participants, in order to ensure transparency.

The interviewees were asked nine research questions in order to understand their organisations' behaviours in response to the NHI. The average duration of the

interviews was 41.51 minutes. The average length of the transcriptions was 6 880 words.

Table 2 – Interview statistics

PARTICIPANT	DESIGNATION	LENGTH (MIN.)	WORD COUNT
Participant 1	General Manager	58.32	10 225
Participant 2	General Manager	35.25	5 376
Participant 3	Regional Director	36.14	6 102
Participant 4	General Manager	41.56	6 343
Participant 5	Head of Division	36.26	6 354
	AVERAGE	41.51	6 880
	TOTAL	207.53	34 400

As the researcher utilised a semi-structured interview guideline and an exploratory approach to the research, not every interview followed the same order of questioning. However, contextual information about the topic remained consistent across all interviews.

Each transcript was studied in detail in order to identify key themes emerging from each research question. Data from the interviews were coded based on the issues raised as a means of analysing the information.

The researcher prepared a summary table for each interview question based on the issues raised or themes emerging as shown in Table 3 (adapted from Shongwe, 2010).

Table 3 – Key data themes identified

THEMES IDENTIFIED			
PARTICIPANT	A	B	C
Participant 1			
Participant 2			
Participant 3			
Participant 4			
Participant 5			

The issues or themes identified per interviewee were ranked according to a ranking system (Table 4 below) that evaluated the depth of interviewee response or the frequency of recurrence of the theme by the interviewee. The "average" was taken to be the average score per theme or issue across all interviewees' responses per question. Therefore, the higher the average calculated, the higher the inferred importance of the identified theme or issue. The "%" reflects the percentage of participants that raised the issue per question.

Table 4 – Theme ranking

RANKING	DESCRIPTION
0	Not mentioned
1	Brief discussion / response
2	Adequate discussion / response
3	Detailed discussion / response
4	Detailed discussion / response with examples

5.4 Results for Research Question 1:

Establish the relevance of the pharmaceutical operational model in the environment of NHI

The primary objective of the interviews was to get an overall view of events occurring in the pharmaceutical industry from the perspective of industry experts. In order to answer the first question, the researcher commenced with an initial background discussion on the state of healthcare in South Africa, to build rapport and in order to understand the rationale behind the behaviours of the participants and their organisations in preparation for NHI.

Are the current operational models of leading Research and Development (R&D) pharmaceutical companies in South Africa's private sector relevant in the new landscape of NHI? If not, how are these companies adapting their operational model in order to function sustainably in an NHI environment?

From the interview guide (Appendix 1), question 1 was intended to establish the context of the interview and questions to follow, while questions, 2, 3 and 4 were designed to explore the participants' views in light of the current healthcare landscape

and proposed implementation of NHI. Major themes were identified as having an average score of 1.0 or more. Although several themes / issues were raised, the researcher will only be discussing recurring themes across the questions asked.

The results for each of the aforementioned question from the interview guide are tabulated in Tables 5, 6 and 7 in order of importance as per the scoring criteria.

Table 5 – Interview guide question 1 results: What is your opinion of South Africa’s current healthcare industry and the proposed implementation of NHI?

PARTICIPANTS							
THEMES	1	2	3	4	5	AVG	%
Inequality	2.0	4.0	2.0	3.0	3.0	2.8	100
Reimbursement / Pricing / Access	3.0	4.0	0.0	0.0	0.0	1.4	40
Leadership	3.0	0.0	0.0	3.0	0.0	1.2	40
Capability / skill of the private sector	3.0	0.0	3.0	0.0	0.0	1.2	40
Capability / skill of the state sector	3.0	0.0	3.0	0.0	0.0	1.2	40
Economy	3.0	0.0	0.0	3.0	0.0	1.2	40
Stakeholder engagement	3.0	0.0	0.0	2.0	0.0	1.0	40
Constitutional / Social right	3.0	0.0	2.0	0.0	0.0	1.0	40

Table 6 – Interview guide questions 2 and 3 results: What is your current operational model focused on? What informed this operational model?

PARTICIPANTS							
THEMES	1	2	3	4	5	AVG	%
Operational model: Diversification	4.0	4.0	4.0	3.0	4.0	3.8	100
Reimbursement / Pricing / Access	0.0	4.0	3.0	3.0	4.0	2.8	80
Investment by pharma	0.0	0.0	4.0	4.0	4.0	2.4	60
Alignment / Misalignment of goals	3.0	0.0	4.0	0.0	4.0	2.2	60

Table 7 – Interview guide question 4 results: How will the implementation of NHI affect your operational model / strategic approach?

PARTICIPANTS							
THEMES	1	2	3	4	5	AVG	%
Operational model: Diversification	4.0	4.0	4.0	4.0	4.0	4.0	100
Reimbursement / Pricing / Access	3.0	4.0	3.0	4.0	4.0	3.6	100
Alignment / Misalignment of goals	0.0	4.0	4.0	0.0	4.0	2.4	60
Investment by pharma	0.0	0.0	4.0	3.0	3.0	2.0	60

The results from table 5 are discussed separately in order to provide context.

From tables 6 and 7, four major themes recurred and as such, were identified as important: Diversification of the Operational Model, Reimbursement / Pricing / Access, Alignment / Misalignment of goals and Investment by pharmaceutical companies.

5.4.1 *The need for change - Interview guide question 1 (Table 5)*

The results from this question confirmed the participants' support of a healthcare reform in South Africa, in order to afford greater access to healthcare and reduce inequality.

"If you ask the question to any South African citizen and especially healthcare player, 'Is there justification for a national health insurance or some type of access to universal health care?', I think the answer is unquestionably yes, because this country, because of its unique history, has had to carry the cross of inequity and there's no more that you can look at it so eloquently demonstrated, as in health."

"In terms of public sector - that's still where the majority of the population depends on their healthcare...When we look at what people actually have access to in the public health sector, there's still a very big gap. So in my opinion, I do think that there is a need for it."

"My opinion is very much aligned with government. And that is that the current state of play is, number one not sustainable, completely inequitable and really we should be doing better for citizens in this country if we actually committed to patients like we all say we are, we should be doing better. So, I'm in full support of reforming the health care system."

"That's what you would like to have, what we aspire to, that everyone deserves a basic, this basic can be defined, but it should be a good healthcare coverage, independent of the socio economic status."

Participants echoed the fact that access to healthcare is a social right. They also highlighted concerns regarding stakeholder involvement, aligning ideologies and the implementation, as well as funding of a NHI. It is evident that clarity is still needed.

“I don’t think morally or socially anyone can argue with the premise or the prospect of national health insurance... the question is how do you pass the ideology and how do actually start getting into service delivery? How do you include all stakeholders and can all stakeholders play a real role in national health and national health insurance as we see it now.”

“When we talk about the funding mechanisms for the NHI we are also asking these questions as a polarity to say NHI on its own versus private health care. I think that’s the wrong stand point to take it on. It’s not a polarity, there should be co-existence and there should be pro-subsidization across any model in the world. Being it an insurance model, for private insurance, on your household and your car facilities, all of it being cross-subsidized one way or the other... Our society cannot exist globally and locally without pro-subsidization.”

“Private, public they’re just at the moment, in a dire straits and I also doubt whether they really have the willingness to really do it.”

Although there is a lot of support for public-private partnerships, participants expressed their concerns regarding the capabilities or skills in the public sector and the need to improve on this, as well as the reliance on the skills / capabilities of the private sector.

“When I look at the way things are being up-skilled in the public sector, if you look at the government hospitals, the big academic hospitals - what they call the tertiary hospitals - there’s still a lot of work that has to be done to able to take those masses.”

“It will definitely create a lot of pressure in the private institutions and my concern is that it is actually collapse our private healthcare system. So there’s a very fine line between developing the public healthcare system and making it a true National Health access and putting so much pressure on the private sector that it would collapse and then there is no balance.”

There is also a call for strong, transparent leadership and guidance from both the government as well as global leaders within the pharmaceutical organisations, in order to address the current uncertainty and provide clarity.

“...you’ve got leaders who are not looking a long term perspective on health care.”

“What is really at the end of the day driving this government? ... We just do not seem to have a government that is really genuinely trying their utmost to improve the economic environment, to attract investment, to lower barriers of entry into the economy.”

“But when you look at what government really wants from pharma, we actually don't know.”

With the challenges that the healthcare industry currently faces, the participants highlighted the need for stakeholder engagement on access solutions.

“So when we talk about accessibility of molecules at a price point that will be relevant for NHI conditions, and for the global population, most of that is being satisfied under basic chronic conditions from a medicine price point of view.”

“...guys you need to talk to us, you engage us - we need to look at alternative models because we've got something you don't have.”

“How do you cost a free system? That's the most difficult thing to do. Imagine you tell someone it's free - what type of impact does that have on utilisation if it's free? ...On the pharmaceutical side, it is just as bad, just as naïve - our naivety is the pricing.”

“...here is a formula and approach that we would be comfortable with and we believe would be sustainable for our businesses...”

From the responses it is clear that these leading R&D pharmaceutical companies support the need for a healthcare reform. However, it is also evident from participants' responses, that there are still many unanswered questions and a clear need for stakeholder engagement in order to address pricing and access in the public sector, through inclusive decision-making.

“Let me first say the problems that we are facing are bigger than the government alone and it's bigger than the private sector alone. So the problem that we have to solve has to be co-created by all stakeholders.”

5.4.2 Interview guide question 1 (Table 5)

The Four major themes were identified during the discussions of questions 2, 3 and 4: Operational model – diversification; Alignment / Misalignment of goals; Pricing / Reimbursement; and the Investment of Pharmaceutical companies in South Africa.

Although the companies interviewed represented the specialised, niche, semi-diversified and diversified portfolios, the consensus amongst the majority of participants was the need for diversification in terms of product offering, in order to align with the disease burden of the country. Companies are also moving away from the traditional model of a sales force, instead focusing on consultative, expert positions.

“...most of the pharmaceutical business models are all moving in one direction and that is the direction of specialised products. But if you think of it the business model globally is moving towards specialised and a lot locally we’re moving to less specialised.”

“If we talk specialised operating model... those molecules will be supported - not in a traditional pharmaceutical model by putting field force behind it. It might be a MSL model that will specifically be linked to that.”

“We have primary healthcare and specialised. Bulk of our business in South Africa is still under the primary healthcare...”

“We look where the innovation know how takes us and only down the line we actually find out whether this kind of treatment is conducive to primary care, GP or it is specialist.”

“So two things we’ve flagged as very important one is we have to really diversify our offering within the public sector.”

“...the operational model we have is very much of a hybrid model...”

“So currently the business model, and it might be the same in other companies, has been focused around your established medicines is your public sector medicines and anything that's new and innovative you launch in the private sector...everything needs to be launched in both the public and the private sector at the same time. And we've employed a strategy in terms of field force

which is a lot more key account, access and policy focused within the public sector and not just a straight forward sales rep model.”

“...we do see a lot of relevance with a primary care kind of strategy within the national health insurance. However, the large emerging part of our business now which is around our pipeline and around where we see future growth is in the specialty business and so from that perspective we're going to be investing there as well. So I think it's about balancing where your investment goes to make sure that you're relevant.”

“I would say pricing and access models are so sophisticated, because of reference pricing in the world. It is for companies to decide what is feasible based on the demands that are in the world and the patent protection they have for those molecules, that's a very interesting discussion.”

Participants expressed the misalignment between the pharmaceutical business model and the objectives of the state sector, with a need for stakeholder involvement to co-create solutions. Participants again stressed the importance of leadership.

“Here is government saying in South Africa our focus is on primary healthcare and the multi-national businesses are saying, well our focus is going to be on specialised products...”

“So you can understand that all stakeholders are very important, but it's for the government to lead the way in discussion forms how we are going to co-create the solutions, because capacity is the biggest problem.”

“... what we need to do is to perhaps be engaging with decision makers and stakeholders around national health that allows us to introduce our specialty business to them. Because there certainly is value to be had. I think building a national health plan around primary care is the right thing to do. But, the way I see it is any efficiencies that are generated from there should be used to give patients access to the most specialised diseases. So it's not about saving money - it's about efficient spending of the money that gives more access and I think that's something that we're supportive of.”

“There's a huge mismatch between our current portfolios; definitely our future portfolios and the disease burden, not just of Africa, but the whole of the

emerging markets. So it's going to be very difficult if you're a pharmaceutical company in South Africa and you're not part of a global player who's got an emerging market strategy and I don't think specialised focus is an emerging market strategy."

"I think our global CEOs has let us down, they're pretty short term in their thinking and not being creative at all; not being innovative and yet we are being constantly told to reinvent the models and show creativity and innovation and yet if you look up for a role model in our industry, nobody really stands out."

"And it's also the question we have here now: how far shall we kind of go back to the beautiful, mature brands that we have and how much effort shall we put behind them because we do see that we are struggling with the innovate fronts. There you're just left far more vulnerable and in some point in time the generics are coming and if they're good generics, so be it fine, you know that's our contract with society. Our period is up and we leave the legacy behind."

From the discussions with participants, it became evident that the product pricing and access for a specific R&D pharmaceutical company will depend on their operational model and segmentation, as well as their willingness / ability to create innovative / alternative reimbursement models.

"I would say pricing and access models are so sophisticated, because of reference pricing in the world. It is for companies to decide what is feasible based on the demands that are in the world and the patent protection they have for those molecules, that's a very interesting discussion."

"Diversified companies... Their opportunity to partake in any kind of adjustable access model is quite easy, because the ease of production and manufacturing locally to empower the economy and also to sell at different at prices points are absolutely differing in price flexibility point of view. Semi-diversified... They also have a reasonable kind of ability to do that."

"Specialised companies... They are mostly pure play companies and their biologics molecules and are much larger than the average company, and the reason for that being; other companies are also into biologics in a form of vaccines and can also qualify like that. But you do know the obstacles in producing very large molecules in terms of consistency. Local production and

price points on those molecules based on the life cycle is quite challenging in itself.”

Niche companies seem to have to least amount of flexibility in pricing and access. Participants clarified the current price points for basic conditions in the state sector and private sector, as well as the access to medicines in the private sector.

“So for your basic chronic conditions; the top ten chronic conditions, all of those top ten currently on the IMS databank that we have access to, 80 percent of patients can get in the private sector access to those molecules from under a R100.00, but nobody states their data, and 50 percent of patients get it under R50.00. So when we talk about accessibility of molecules at a price point that will be relevant for NHI conditions, and for the global population, most of that is being satisfied under basic chronic conditions from a medicine price point of view. In the government sector we know that those prices I have now mentioned drops then by 70-80 percent in terms of access for the government to get access to those prices.”

“If we look at how many people are accessing private healthcare by purchasing currently it is 14 million people of the population. That is much more than the 9 million people that are on medical aids, that are already putting into the system because they need access to medication. The average price point however, of medication on generic clone medication you will see that people are defaulting to the more expensive generics or clones currently in the private sector, which is not currently a true reflection of what people can get access to drugs at. It can be as lower price points.”

“We should be congruent on the commercial side as well as the science side of what we can do and try to find a good way where we could offer this in South Africa, knowing that the potential will be minimal. But at the same time in South Africa at the end of the day, it’s really about access, what can we do for access. So South Africa will not help us, we have our own deep profitability, it’s really only access.”

“...our biggest lack of capabilities in the area is market access or reimbursements or slashed pricing.”

“What we see as innovation payers definitely see as an incremental cost - it’s a liability to them.”

“We try to connect the dots and go back and say how do we make sure that we engaged them on another option other than pricing...we cannot survive if our price buying drops from private to public they’re definitely not going to enjoy the margin that they’re currently enjoying at the moment and sustainability will come into question.”

“...you can’t have two prices; how can you have universal healthcare, equal care for equal need - how can you discriminate on price? How can you now say it’s universal healthcare? It’s equal care for equal need so why isn’t there equal pricing at pharmaceuticals? Why discriminate? The whole thing about NHI is to eradicate discrimination in the health care system but they discriminate on pricing.”

Participants again raised lack of clarity on what the government requires from R&D pharmaceutical companies, in the context of pricing and access. Participants raised as their significant level of investment in the country as a concern, as there is a feeling of mistrust and no appreciation from government for these efforts.

“...we give the drug X for free, all over the world... we’ve also got other portfolios here; we’ve got the life sciences division... And then we’ve got the consumer health division, which is all of your over the counter medication, then we’ve obviously got our specialised drugs... So we wanted to know from government what it is that they want from us.”

“When we actually look at the cost of the API’s to manufacture these drugs... and our product is very well priced, it’s actually like R56 for a month’s treatment. Problem is, it’s still not competitive enough for government. So what do they really want?”

The interlinkages created throughout South Africa by R&D pharmaceutical companies were evident from the discussions. The majority of participants raised the significant investment by R&D pharmaceutical companies back into South Africa, as examples of their ongoing commitment to healthcare in the country, in both the private- and public sectors.

“Companies like ours are investing here, we own factories, we employ people, we making medicine accessible and affordable, but it’s still not good enough to actually have a public tender. So we’d like to under a bit more what the expectation really is.”

“Even for a company like this that has a variety of portfolios. It also can't be a situation where the government wants the pharma companies to give everything but then they don't give back because then how do you sustain a business?”

“Also in the private sector...we will just have to adjust a little bit the way we doing clinical trials, with whom are we doing it and then we are just a purely private healthcare company. And depending on how we now succeed with decision, this may have consequence... “

The theme of investment by R&D pharmaceutical companies is raised again later.

5.5 Results for Research Question 2:

Aligning stakeholder expectations with strategic direction

The role of stakeholders in strategy formation was explored in question 2. The aim was to investigate the alignment or misalignment of goals between stakeholders from the perspective of the change recipient (R&D pharmaceutical companies), and sought to understand the rationale behind the behaviour of the organisations in response to the proposed healthcare reform.

How are these R&D pharmaceutical companies adapting their strategic approach in order to partner with the government in an NHI environment?

- a. *Are these R&D pharmaceutical companies undergoing organisational change or employing any change tactics (“scenario planning”) in preparation for the NHI?*
- b. *How are these R&D pharmaceutical companies aligning stakeholder expectations with their strategic direction, if applicable?*

From the interview guide (Appendix 1), questions 5 and 6 were designed to explore these views. Major themes were identified as having an average score of 1.0 or more.

Although several themes / issues were raised, the researcher will only be discussing recurring themes across the questions asked.

The results for each of the aforementioned question from the interview guide are tabulated in Tables 8 and 9 in order of importance as per the scoring criteria. From these results four major themes recurred and as such, were identified as important: Diversification of the Operational Model, Reimbursement / Pricing / Access, Alignment / Misalignment of goals and Investment by pharmaceutical companies. Stakeholder engagement was identified as the most important theme.

Table 8 – Interview guide question 5 results: Identifying stakeholders

PARTICIPANTS							
THEMES	1	2	3	4	5	AVG	%
Stakeholder engagement	4.0	4.0	3.0	3.0	4.0	3.6	100
Public-Private Partnerships	0.0	4.0	4.0	0.0	4.0	2.4	60
Constitutional / Social right	1.0	4.0	0.0	0.0	3.0	1.6	60
Alignment / Misalignment of goals	0.0	0.0	4.0	0.0	4.0	1.6	40
Investment by pharma	0.0	4.0	4.0	0.0	0.0	1.6	40
Leadership	3.0	1.0	1.0	1.0	0.0	1.2	100
Capability / skill of the state sector	3.0	3.0	0.0	0.0	0.0	1.2	40
Reimbursement / Pricing / Access	3.0	0.0	0.0	0.0	2.0	1.0	40
Inequality	2.0	3.0	0.0	0.0	0.0	1.0	40

As this was discussed earlier in this chapter, the researcher will discuss Stakeholder engagement in context of Research question 2, in Chapter 6.

During the interview discussions, questions 5 and 6 (Tabulated in tables 8 ad 9) were linked in order to understand how the change recipients identify their stakeholders and then align their strategic approach to stakeholder expectations.

Table 9 – Interview guide question 6 results: How is your organisation preparing for NHI / adapting your strategic approach?

PARTICIPANTS							
THEMES	1	2	3	4	5	AVG	%
Scenario Planning	1.0	3.0	4.0	4.0	4.0	3.2	100
Operational model: Diversification	4.0	4.0	4.0	0.0	4.0	3.2	80
Capability / skill of the private sector	4.0	4.0	0.0	0.0	4.0	2.4	60
Capability / skill of the state sector	3.0	4.0	0.0	0.0	4.0	2.2	60
Stakeholder engagement	0.0	4.0	0.0	0.0	4.0	1.6	40

From question 5, nine themes were identified, of which two were not raised before. From question 6, five themes were identified, of which two themes were not raised in the previous questions. Many of the themes have already been reported in tables 5 to 7; therefore, only new information will be discussed where applicable. The new themes identified are: Public-Private Partnerships (PPP's), Scenario Planning, Capability of state sector, Capability of private sector and Stakeholder engagement.

5.5.1 *Interview guide question questions 5 and 6 (Tables 8 and 9)*

Themes identified: Public-Private Partnerships (PPP's); and Stakeholder engagement

The discussions with participants highlighted the fact that stakeholder engagement and partnerships between the private- and public sectors are both key factors for the successful reform of the healthcare landscape in South Africa.

“There are a few initiatives that I can tell you about that we are doing, we have to leap frog the process forward. How do you leap frog a process forward? It's very practical processes that are going to happen. So the first one for capacity creation is infrastructure, and that's where PPP's are taking place.”

The discussions highlighted the investment from R&D pharmaceutical companies, into the education of healthcare professionals and patients, often partnering with other stakeholders in the value chain (for example diagnostic companies and pharmacies) to achieve these goals.

“...the single biggest gap that I see in stakeholder engagement is patients.”

“Then there is in terms of medical nurses and students where people are being sent to foreign countries to train as doctors. Companies locally are sponsoring medical students to study medicine because it is very costly, from rural communities. Pretoria University has now doubled their capacity intake in the last few months they have launched that project. But even if we do all of that it still doesn't address the servicing component.”

“...there are many forums that are currently taking place, not pertaining specifically to NHI, but solving problems within the health care sector.”

“...But a lot of the tenders are not centrally managed from a logistical point of view it is managed by provinces. And that's where IT infrastructure, supply chain issues are a key concern for that, but there's a model there are partnerships happening on how to prove that system. There is a project going, multiple projects going but not specifically to NHI and do we co-create to solve it.”

“So between practical solutions in the supply chain, between technology components we will have to leap focus components and it will not be very clear cut or linear thinking that will bring us to solutions how to change the healthcare situations in South Africa.”

“...this start of changing of focus of how do we educate the patient better? How do we manage their diseases or support them to manage their disease? How do we develop doctors that are still in the public sector for them to actually be able to contribute more in the current jobs they have and going forward? So I think, and I don't think it is just unique to these companies, I think it's been sort of a shift of pharma where we are very educed on trying to help patients to be healthier to prevent diseases from deteriorating further.”

“And we've actually partnered with pharmacies and now we want to roll out the same program with government...”

“But the core thing for me there is still trust and until we overcome that piece it's going to be difficult to collaborate because at the moment the perception is we can afford it we should fund it. I mean and that's leading to public-private partnerships as well and the framework for public-private partnerships is I can't afford you can and therefore you should pay. It's the wrong principle.”

“We are planning over the coming two years to sign Memorandum of Understanding with multiple government departments. So that really elevates all the work that we do not just in selling medicines, just in manufacturing. But also in capability development, in training of healthcare professionals, in clinical trial development all of those types of things I think all of those things are absolutely relevant to a strong health care system and will do one of two things. One will establish us with a good reputation with government in general. And then eventually potentially show that we're not here just to sell medicine because currently that's what it looks like”

The responses from the participants reinforced the uncertainty that seems to exist around the implementation of NHI. “Without knowing the expectations that government has from us, we cannot plan for the end goal.”

“...scenario planning works well if you know what the end will be... We can try and plan different scenarios but we don't know what the end result is, what is going to be the expectation from us.”

In the absence of direction from government as to the expectations for R&D pharmaceutical companies, participants again stressed the importance of stakeholder engagement and consultation.

“...surely if they approached us, pharma, and they can do it through our societies, I mean all of our CEOs belong to IPASA. If they actually went and said, from your company for example you're stronger in oncology this is what we would like to partner with us; your company is strong in diabetes, this is what we would like from you. If they could be that specific then we would know what to negotiate with, then we would then have an idea, this is their expectation, how can we go back to our parent company and get the buy-in or the negotiation going to actually actively partner.”

“I think in a way we can have the plans in place, so what we're currently doing is we don't have active scenarios drawn up in the sense of this is what we're going to do and this is how we're going to do it, however what we have started doing is opening our internal doors because the one thing I will still learn throughout the years.”

“...we sit a lot in the different divisions together and say is there an offering that we can give that would include life sciences that would include consumer health, speciality and primary care? The thing is shooting in the dark in a way, because I think if the time comes that we get told you have to come to the table with something, we will be able to pretty quickly go to the table with something but is it what they want? I don't know and I don't think so.”

“So obviously government and academia represent two of the major stakeholders in terms of a national health insurance and we try to engage as often as possible for two reasons. I think number one the still one of the big priorities that we are trying to fulfill is for them to trust us, for them to trust that we have similar intentions, that we're here to assist them in health care system strengthening and that we're here to partner with them in terms of access to medicines, patient outcomes.”

“...we've been very conservative around serious scenario planning, what we rather than doing is saying we need to be as relevant as possible. Therefore I don't necessarily want to take a bet on one thing happening vs another .what we rather doing is saying how do we best diversify our portfolio within the public sector so that irrespective of what scenario plays out we're ready to participate and that comes from I would say three key pillars. one is what are we currently be selling in the public sector and how can we make sure that we sustain that business going forward , then two is what is in our current existing portfolio and in our short term pipeline and how do we know make sure that when we launch.”

“...we'll have as many doors as possible open and we will be showing a willingness to want to collaborate and be part of the system change and for now I think that's a bigger priority for us than actually going out and saying OK if this happens, how do we react?”

Emerging Themes: Capabilities / skills of the state- and private sectors

Respondents expressed their concerns about the current lack of resources and skills within the state sector, which will in turn, put significant pressure on the private sector. It is evident that the private sector possesses a great deal of skill, which can be leveraged through stakeholder engagement and PPP's.

“...how do I get enough health care professionals into the new NHI system how do I get the private sector to play a role in the NHI system because those health professionals and private hospitals in my view they've got leverage for the new system.”

“We actually don't even look at as private sector because the truth is a lot of what we do in terms of capability building and upgrades are really public sector and we've even sponsored research and development projects which is academia. So I think there's a lot that we're doing that's potentially not recognized.”

“I think in the public sector is a big gap in the sills set the skills set as related to care givers you haven't got enough of them and then the other one is the

administration side is who is running the laundry who is running the lifts who is supplying the food.”

“They don’t even have capacity; you see that’s the second piece we’ve got to talk about --so it’s infrastructure and then it’s the health care, the human resources component that we have to address and then it’s the funding mechanism.”

“. So they end up leaning on the private sector, which has the expertise and the ability to do the distribution for them. I don’t think they’ll do it for free, so it’s actually going to cost them more to distribute their drugs, but if they had maybe taken the time to sit with experts from UTI and learn from them, and fix their supply chain they wouldn’t be in the situation they’re in.”

“The only disadvantage they have there is a lot of skill and expertise missing and they can’t really do it in the sense that we should.”

5.6 Results for Research Question 3:

Barriers and enablers to the successful implementation of the NHI

This question sought to understand the perceived challenges and opportunities in the healthcare system from the perspective of the interviewee. In addition, the question explored the interviewees’ perceptions of the way forward in order to ensure the successful implementation of the proposed NHI.

From the perspective of these leading R&D pharmaceutical companies, what are the perceived enablers and / or barriers to ensuring sustainability within the NHI environment?

From the interview guide (Appendix 1), questions 7 and 8 were designed to explore these views, with question 9 giving the interviewee the opportunity to raise any additional issues that the researcher may not have covered. Major themes were identified as having an average score of 1.0 or more. Although several themes / issues were raised, the researcher will only be discussing recurring themes across the questions asked. The results for each of the aforementioned questions from the interview guide are tabulated in Tables 10 and 11 in order of importance as per the scoring criteria.

Table 10 – Interview guide question 7 results: What do you perceive to be the barriers and enablers of collaboration with government in NHI?

PARTICIPANTS							
THEMES	1	2	3	4	5	AVG	%
Stakeholder engagement	0.0	3.0	4.0	4.0	4.0	3.0	80
Pricing / Reimbursement / Access	4.0	3.0	0.0	0.0	0.0	1.4	40
Public-Private Partnerships (PPP's)	0.0	4.0	1.0	0.0	0.0	1.0	60
Capability / skill of the state sector	4.0	0.0	1.0	0.0	0.0	1.0	40

Table 11 – Interview guide question 8 results: What do you think is the way forward?

PARTICIPANTS							
THEMES	1	2	3	4	5	AVG	%
Stakeholder engagement	4.0	4.0	4.0	4.0	4.0	4.0	100
Leadership	4.0	4.0	0.0	3.0	3.0	2.8	80

From these results no new themes were identified, but rather, participants reiterated their sentiment on issues raised earlier in the discussions. The most pertinent is illustrated below.

5.6.1 Interview guide question questions 7 and 8 (Tables 10 and 11)

Stakeholder engagement and Leadership

“I think the way forward would be for them to actively ensure that their plan is a solid one. I think in a way it’s been very internally driven by them, as opposed to seeking proper council from outside.”

“And there are countries that are example of that have actually done that. They have gone to learn from experts before implementing.”

“So ironically enough the barriers I believe to them not being successful in their pilots has mostly to do with the fact that they haven’t been able to commit private sector G.P.’s to signing up.”

“I think in the industry very well informed about what’s. We review the policies, we interpret them. We look at best practices and we’re trying to collaborate...we’re as committed to achieving this as everybody else and I don’t believe that the healthcare professional on the ground is even anywhere near as committed to healthcare system reform as we are.”

“...maybe this is the reason why public-private partnerships are controversial, because you’ve got into the community and you potentially said come and do this with us because that’s what we’re trying to achieve, but no one’s asked the G.P. what their unmet need is.”

“So I think engagement. Transparency about how the system works. And to be honest a proposition, a business case for why it’s important for them to do this and perhaps you know it needs to be a pilot project which is obviously, a project that includes more stakeholders.”

“So you have best practice, transparency, engagement and then finding those ones that are really willing to work with you and building a business case that’s... You know we talk about our philosophy of all we do business and it’s about win-win; win for patients, win for customers. I don’t see how this is a win-win for the healthcare professional working in a community area.”

“It’s a very big challenge and I really feel for the implementers and the policy makers but I think that... the faster they realize that they need to have more friends than enemies, the easier it’s going to be for them to implement anything.”

“...something so fundamental needs to have a very good public or multi-stakeholder involvement looking at all those different barriers and how could we address them and how can we move things forward...then it’s a kind of a give and take thing and that should end in a win-win ideally because it’s a massive, massive challenge.”

“We need to talk about how we can create millions of jobs, how we can make an environment that attracts foreign investment, this kind of stuff. I mean that’s the fundamental and actually, one should have the courage to say also to the government who wants to have that look, that’s absolutely great and fully supportive but with the current leadership and the current government you have, you will never achieve it because you will not create the environment to make this successful.”

“... get really some folks in that have ideally been trained, who really have the genuine interest of the country at their heart. And if you do that you will see that relatively quickly you will see far more positive outlook, this outlook will give a far more positive sentiment, people will start to consume more, you will have an environment where also the foreign investments they have a far more predictable future, they start to pile investments into our country and then you will start getting going.”

“So in terms of the way forward will be absolutely deciding amongst multiple stakeholders what the common objectives will be for all stakeholders. We’ve got to define common purpose, common objectives and it doesn’t have to be broad-based. It can be very narrow, but if we are not finding that common ground to start the discussion from, we will not take this NHIPs and access to quality healthcare forward.”

“And government is in a key position to start shaping the dialog for all stakeholders.”

“I think we need work streams for co-creating solutions and a lot of experts from the world...”

“I will definitely say the government is over-burdened by the issues at hand.”

5.7 Conclusion

This chapter presented results from both the systems review as well as interviews with 13 executives, two industry experts and two journalists. The systems review helped frame the historical context of South Africa’s healthcare system and place in context the relevant stakeholders within the private healthcare industry. The interviews with the executives, experts and journalists served to help comprehend the change process from the recipients’ perspectives. These results are analysed comprehensively in Chapter 6.

6 INTERPRETATION OF RESULTS

Although several models pertaining to the change process have been developed over the years in an attempt to give insight into managing this process, this research did not attempt to develop another model or theory. Rather, it sought to understand how change recipients, in this case leading R&D pharmaceutical companies, contextualise and adapt to the change process. In so doing, this research aimed to confirm how leading R&D pharmaceutical organisations in South Africa's private healthcare sector are responding to- and preparing for the impending implementation of the NHI, and to understand the rationale behind these behaviours.

This chapter utilises the theoretical lenses as described in Chapter 2's literature view, to discuss and interpret the findings from the in-depth interviews with participants, presented in Chapter 5. Discussion of results focused on four research questions:

Research Question 1:

Are the current operational models of leading Research and Development (R&D) pharmaceutical companies in South Africa's private sector relevant in the new landscape of NHI? If not, how are these companies adapting their operational model in order to function sustainably in an NHI environment?

Research Question 2:

How are these R&D pharmaceutical companies adapting their strategic approach in order to partner with the government in an NHI environment?

- a. *Are these R&D pharmaceutical companies undergoing organisational change or employing any change tactics ("scenario planning") in preparation for the NHI?*
- b. *How are these R&D pharmaceutical companies aligning stakeholder expectations with their strategic direction, if applicable?*

Research Question 3:

From the perspective of these leading R&D pharmaceutical companies, what are the perceived enablers and / or barriers to ensuring sustainability within the NHI environment?

The results presented in Chapter 5 were obtained through a systematic review of the existing literature, in order to provide historical context of the study, as well as through in-depth semi-structured interviews with five opinion leaders from leading R&D pharmaceutical companies.

6.1 Discussion of Results for Research Question 1

Establish the relevance of the pharmaceutical operational model in the environment of NHI

The rationale for the analysis of the historical context of the healthcare landscape in South Africa was to understand whether the participants' see a need for a NHI and how this perception subsequently influences their and their organisation's preparation- and strategy for the implantation of NHI.

The findings from the interviews confirmed the inequality that exists in South Africa's healthcare system and the fact that all of the study participants supported the reform of the healthcare system.

"If you ask the question to any South African citizen and especially healthcare player, 'Is there justification for a national health insurance or some type of access to universal health care?', I think the answer is unquestionably yes, because this country, because of its unique history, has had to carry the cross of inequity and there's no more that you can look at it so eloquently demonstrated, as in health."

The participants echoed the sentiments of Coovadia et al (2009) about the dysfunctional healthcare system of South Africa that can be traced back to policies such as apartheid. Furthermore, participants supported the notion that failure of the post-apartheid government to overcome the massive health system challenges that it faced in 1994, has contributed to the persistence of this dysfunctional system (Coovadia et al, 2009).

From the responses it is clear that these leading R&D pharmaceutical companies support the need for a healthcare reform. However, it is also evident from participants' responses, that there are still many unanswered questions and a clear need for stakeholder engagement in order to address the challenges faced in the healthcare system.

The implementation of the NHI is expected to significantly impact private institutions that are involved in the supply chain of purchasing and delivery of healthcare services such as pharmaceutical companies, medical device companies, wholesalers, distributors and pharmacies. Pharmaceutical and life sciences companies are considered the largest upstream service provider in the healthcare system (Econex, 2013). As important role players in healthcare service delivery, the behaviour of healthcare service providers are considered a significant determinant on whether the goals of NHI can be achieved.

The literature review revealed the fact that global market trends have seen the pharmaceutical operating model transition from massive corporations to the model of a lean and focused company, with a research footprint within key innovative bio-clusters and an increasing revenue stream from biologics, speciality products and emerging markets (Gautam & Pan, 2016). This shift in focus is also evident from IMS health data (2014) revealing increased revenues from these portfolios. The interview results confirmed this global move to more specialised, personalised healthcare portfolios.

“...most of the pharmaceutical business models are all moving in one direction and that is the direction of specialised products. But if you think of it the business model globally is moving towards specialised and a lot locally we’re moving to less specialised.”

In contrast to the global pharmaceutical operating model that has emerged, South Africa’s NHI is focusing on a reengineered primary healthcare (PHC) system that will focus mainly on community outreach services using a comprehensive PHC package of services (Naidoo, 2012). Based on the global healthcare demand for innovative medicines, analysts expect that the existing model of innovation / specialised healthcare will be viable for the foreseeable future (IMS Health, 2014), but over time a new approach will be needed to successfully address the difficult challenges ahead.

The majority of study participants interviewed, recognises the need for diversification in terms of product offering, in order to align with the disease burden of the country.

“The quadrupled burden of the disease in South Africa is still HIV, TB, Infectious diseases, child mortality. But when we go to the non-communicable diseases the NCD component, it’s the hypertension, hyperlipidemia, all of that we have to address. If you basket all of those together we must first address those needs and create capacity for them.”

Findings from the data collected suggest that the pharmaceutical organisations interviewed believe that their operational models are well positioned for the implementation of the NHI. Many of the R&D pharmaceutical companies are moving away from the traditional structure of a sales force, to a Medical Science Liaison (MSL) model that links to specialised medicines that target high unmet medical needs, as well as focusing on key accounts and policy creation.

This move is in line with research by Gautam and Pan (2016), which revealed several trends in the shaping of big pharma's operating model, including the following two which were echoed in the interview process:

- From massive to lean organisations: focusing on areas of strengths;
- Focus shift from primary care to speciality products: targeted medicines for high unmet medical needs.

“And we've employed a strategy in terms of field force which is a lot more key account, access and policy focused within the public sector and not just a straight forward sales rep model.”

“...the large emerging part of our business now which is around our pipeline and around where we see future growth is in the specialty business and so from that perspective we're going to be investing there as well.”

Participants expressed the misalignment between the pharmaceutical business model and the objectives of the state sector, which are primarily focused on a reengineered primary healthcare (PHC) system (Naidoo, 2012).

“Here is government saying in South Africa our focus is on primary healthcare and the multi-national businesses are saying, well our focus is going to be on specialised products...”

“I think building a national health plan around primary care is the right thing to do. But, the way I see it is any efficiencies that are generated from there should be used to give patients access to the most specialised diseases.”

Considering the PHC focus of the NHI, pharmaceutical companies represented locally will have to reconsider their operational models and strategic approach in order to remain a profitable entity within the new healthcare system.

“There’s a huge mismatch between our current portfolios; definitely our future portfolios and the disease burden, not just of Africa, but the whole of the emerging markets. So it’s going to be very difficult if you’re a pharmaceutical company in South Africa and you’re not part of a global player who’s got an emerging market strategy and I don’t think specialised focus is an emerging market strategy.”

“I think our global CEOs has let us down, they’re pretty short term in their thinking and not being creative at all; not being innovative and yet we are being constantly told to reinvent the models and show creativity and innovation and yet if you look up for a role model in our industry, nobody really stands out.”

In order to operate sustainably within emerging markets, the literature identifies two operational models / - strategies that have emerged (Gautam & Pan, 2016):

- A diversified business that includes diagnostics, generic products, devices, innovative drugs, consumer- and animal health; and
- Pure biopharma companies which focuses primarily on innovative drugs.

Findings from the interviews conducted confirm the implementation of these two aforementioned strategies, with companies locally adopting hybrid models (specialised medicines and primary healthcare), acquiring generics-focused companies and supporting their personalised healthcare portfolios with significant investment in diagnostic solutions, as well as the education of healthcare professionals and patients.

Still, the main challenge still to overcome remains the affordability of drugs, especially in lower-income countries such as South Africa. All healthcare stakeholders within the value chain (government, payers, and healthcare companies) are under pressure to provide sustainable healthcare, especially in emerging economies, like South Africa, where healthcare systems are largely out-of-pocket (Gautam & Pan, 2016).

The participants interviewed agreed with the research by Vogler et.al. (2016) that there is a need for fundamental reforms to ensure broader access to medicines, particularly to innovative and potentially more effective and / or safe medicines, while safeguarding the financial sustainability of health systems and working towards universal health

coverage. Interviewees echoed the need and willingness to collaborate with government in order to implement improved pricing- and alternative reimbursement models such as coverage assistance, tiered pricing, as well as pay-for-performance methods. Research highlighted at the conference, showed that commonly used policies regarding pharmaceutical pricing and reimbursement are not sufficiently effective to address current challenges. There is a need for (Vogler, et. al., 2016).

“So we really need to move towards outcomes based payments and outcomes based procurement even as opposed to where we now pay for a product because that's the only way it's going to be relevant and potentially that's something we can contribute as a multi-national industry because we're going to be in the solutions.”

6.1.1 Conclusion

All the interviewees not only supported the plan to reform the healthcare system of South Africa, but expressed their willingness to be actively involved in this transformation.

The global move towards specialised medicines and personalised healthcare (Gautam & Pan, 2016) is also prominent in South Africa. The findings from question one illustrates this strategy, but also reflects the fact that these R&D pharmaceutical companies are engaging with stakeholders in an attempt to align their objectives locally with that of government.

It is evident that the operational model for R&D pharmaceutical companies has shifted away from the traditional sales force structure. The current healthcare landscape calls for an operational model that mobilises specialists in policy creation and – implementation, market access and medical science liaisons. Findings from question one suggest that this new operational model will allow better stakeholder engagement along the value chain, in order to ensure improved access to medicines.

The biggest challenge for R&D pharmaceutical companies in South Africa remains market access. In their 2015 report titled “We need to talk”, EyeForPharma identifies the high regulation of pharmaceuticals in South Africa, as well as the inflexibility on pricing by the government as barriers to effective price competition that is hampering patient access to innovative medicines (EyeForPharma, 2015). All the interviewees agreed that pricing and access to medicines remain a challenge. However, all participants’ organisations have a strong focus on improving market access through

innovative reimbursement strategies and indicated their willingness to continuously engage with government and other stakeholders to ensure improved access solutions.

In terms of Question 1, it is evident that R&D pharmaceutical companies are of the opinion that they are well positioned to ensure sustainability within a NHI environment. Operational models vary from diversified, semi-diversified, specialised and niche; each with a product offering meeting patient demands in South Africa. From the perspectives of the research participants, preparation for the implementation of the NHI is centred around market access and extensive stakeholder engagement.

6.2 Discussion of Results for Research Question 2

Aligning stakeholder expectations with strategic direction

Research question one provided a great deal of context for the rationale behind leading R&D pharmaceutical companies' strategic approach. The challenges in the current healthcare landscape of South Africa, the proposed implementation of a NHI, as well as the global pharmaceutical operational model have shaped the strategic positioning and investment of these companies.

The findings from the interviews revealed a consistent theme regarding the significance of stakeholder engagement and public-private partnerships, especially considering the complex environment that is healthcare. In addition, results from Question 2 highlighted the pharmaceutical operational model, market access, alignment of stakeholder goals and the current investment from pharmaceutical companies in South Africa. Participants raised their concerns regarding the lack of direction from government pertaining to the role of R&D pharmaceutical companies within the NHI. Without this direction, R&D pharmaceutical organisations are focusing on remaining relevant, improving access to their medicines and investing in South Africa through education and public-private partnerships to name only two.

Participants identified the government, patients and academia or healthcare professionals as the most important stakeholders. In the context of R&D pharmaceutical companies, healthcare professionals and patients can be classified as primary stakeholders as they have a direct stake in the success of the business (Buccholtz & Carroll, 2012). Government is influential in affecting the reputation, public standing and success of pharmaceutical companies, especially considering the cost-containment strategies of the NHI, and can therefore be classified as secondary stakeholders (Buccholtz & Carroll, 2012).

However, in light of the extensive stakeholder engagement required to ensure successful implementation of the NHI, government was identified by participants as being in the key position to initiate dialogue among stakeholders. As such, in the context of NHI, government moves from a secondary- to a primary stakeholder for R&D pharmaceutical companies.

Considering the position of power that government holds, as well as the potential impact of the NHI on all the stakeholders in the healthcare system, it is imperative that government also consider their stakeholders. The South African government has an unavoidable responsibility to its stakeholders (Buccholtz & Carroll, 2012) to not only allocate responsibilities, but also to provide its stakeholders with the clarity on the roles of governmental stakeholders in the new system (Wouters & Kanavos, 2015).

The importance of engaging all stakeholders in a reform process has clearly been identified as a critical key to success, not only throughout the literature, but also through the discussions with the research participants. Communication and stakeholder relationships can significantly impact and contribute to changes within the system (Thompson et.al. 2016). By employing multi-stakeholder input, government will be able to avoid and resolve disputes (Wouters & Kanavos, 2015), as well as overcome any potential barriers identified. This inclusive approach to stakeholder engagement is crucial for the successful implementation of collaborative relationships in the form of public-private partnerships (Torchia, Calabrò & Morner, 2015).

Without the aforementioned engagement and guidance from government, a great deal of uncertainty exists for R&D pharmaceutical companies as to the requirements for participation within the NHI. The interlinkages created in the South African economy by R&D pharmaceutical companies (Econex, 2013), make them an integral part of the healthcare system. The principle of stakeholder engagement is to create sustainable value and ensure as many win-win situations as possible, and should thus form an integral part of any organisation's strategy, including that of the government for the implementation of NHI.

Wouters and Kanavos (2015) posit that pharmaceutical policy should align with national health priorities and reiterate the fact that the main objective of pharmaceutical policy is to ensure equal access to effective medicines.

Findings from the interviews identified the need for the building of capacity of skills within the public sector and the leveraging of private-sector skills to overcome this challenge. This finding is echoed by Torchia, Calabrò and Morner (2015), who posit

that capacity building can be achieved through public-private partnerships (PPP's) by leveraging the different resources and skills of the private and public sectors. Capacity building is imperative for policy advocacy, development, implementation and evaluation. Where organisational development, such as public sector capability, is a strategic priority, the development of partnerships to address health determinants is considered an area of practice. Pharmaceutical companies are thus placed in the role of policy entrepreneurs and champions of change in diverse settings like the NHI (Batras, Duff & Smith, 2014).

Findings from Question 2 reveal that R&D pharmaceutical companies are focusing their investments on improving access to their products, through public-private collaborations, alternative reimbursement models, and the education of patients and healthcare professionals in South Africa. Collaborative partnerships with industry in the private sector will not only optimise access to healthcare, but also assist in creating patient-centered formularies (Chou, Lakdawalla & Vanderpuye-Orgle, 2015). Through these innovative strategies, R&D pharmaceutical companies are striving to ensure their survival and sustainability in the great uncertainty that is the changing healthcare environment (Lowell, 2016).

A shared purpose and connectedness enable people to achieve more than initially imagined (Kotter, 2012) and promotes trust through collaboration by increasing interconnectedness (Weberg, 2012). Complexity theory proposes the flexibility of organisations by maximising their adaptation to the environment within which they operate (Lowell, 2016). Findings from Question 2 reiterate the willingness of R&D pharmaceutical companies in South Africa to collaborate with government and adapt strategically to the requirements of the NHI. However, without a clear understanding of the requirements to participate sustainably within the NHI, the extent of this flexibility remains uncertain.

Whilst awaiting further clarity from government, leaders of R&D pharmaceutical companies are demonstrating their commitment (Kotter, 2012) to healthcare in South Africa, by encouraging creativity in solving problems (Lowell, 2016). In this instance, alternative reimbursement models and public-private partnerships are examples of creative solutions to the unique challenges in South Africa.

The literature review and findings from Question 2, stress the involvement of leadership across different levels in the system and the need for communication of the vision, in order to ensure healthcare intervention. The situational analysis of the need for change, the strategy employed for change and leadership traits / behavioural

constructs will significantly influence the success and effectiveness of the change (Douglas & Sutherland, 2009; O'Malley, 2014; Iles & Sutherland, 2001; Torchia, Calabrò & Morner, 2015).

6.2.1 *Conclusion*

Research question one confirmed the fact that the R&D pharmaceutical companies interviewed believe that they are well positioned to function sustainably within a NHI environment. However, the need for clarity from government and improved stakeholder engagement were highlighted as challenges causing uncertainty regarding government expectations from pharmaceutical companies. This discussion led into Question 2 – how are R&D pharmaceutical companies aligning stakeholder expectations with their strategies.

Findings from Question 2 once again stressed the participants' grave concern regarding the lack of stakeholder engagement and expert consultation on the implementation of the NHI. Although the interviewees felt that their organisations were well positioned to meet the needs of the NHI, these beliefs were informed by internal analyses and ongoing stakeholder partnerships.

Furthermore, the need for fundamental reforms to ensure broader access to medicines, particularly to innovative and potentially more effective and / or safe medicines (Vogler, et.al., 2016), have been identified by the research participants as a key area of focus for each of them. Through innovative access solutions, R&D pharmaceutical companies will be able to ensure increased access to their medicines, while safeguarding the financial sustainability of health systems and working towards universal health coverage in collaboration with government (Vogler, et. al., 2016).

The lack of clarity regarding the role of R&D pharmaceutical companies does not bode well for trust in the successful implementation of the NHI. Trust and respect are promoted through positive interactions and collaboration between agents in the system, creating a sense of mutuality that inevitably increases interconnectedness (Lowell, 2016). The level of investment by R&D pharmaceutical companies in South Africa is evident from the research conducted, but “never seems to be enough. We must keep giving and the state just keeps taking.” There are several pockets of excellence initiated by these R&D pharmaceutical companies in the form of public-private partnerships that are increasing access to medicines, but are not acknowledged by several stakeholders in the value chain, including government.

The capabilities of the public- and private sectors were raised during the interviews as an area for collaboration and also development. Although public-private partnerships see the public sector leveraging skills from the private sector, whilst investment from the private sector aims to improve the capabilities of the public sector, the extent of the analysis required for this specific topic is beyond this research.

6.3 Discussion of Results for Research Question 3

Barriers and enablers to the successful implementation of the NHI

Findings from Question 3 not only identified the perceived challenges and opportunities in the healthcare system from the perspective of the interviewees, but also explored the interviewees' perceptions of the way forward in order to ensure the successful implementation of the proposed NHI.

From this question, no new themes emerged. Rather, participants echoed the literature sentiments regarding the importance of stakeholder involvement during the implementation of the change in the system. The principle of stakeholder engagement is to create sustainable value and ensure as many win-win situations as possible. Participants reiterated the fact that government should provide clarity regarding their roles and by engaging with all stakeholders, it is possible to minimise challenges or barriers. In recognising the complexity of stakeholders, one is able to differentiate consequences based on who is being affected (Freeman, Harrison, Wicks, Parmar, De Colle, 2010).

The need for stakeholder collaboration in order to ensure the successful implementation of the NHI can be reviewed through the complexity-informed WoW framework of Brand, Fleming and Wyatt (2014). The "Workplace of Well-being (WoW)" framework is useful in the context of the healthcare environment as it assists in:

- Supporting setting-appropriate intervention activities: identifying enablers and barrier to system-level behaviour change;
- Creating a change-conducive setting: by addressing setting-related enablers and barriers;
- Describing the importance of local context: interventions work with the dynamic system;
- Redefining "Best Practice": transfer of interventions to new complex systems;

- Ensuring sustainability of interventions in new complex systems: the intervention changes the way in which the system behaves.

Considering the need for clarity from government regarding the role of R&D pharmaceutical companies in the implementation of the NHI, it is imperative to involve more stakeholders in the consultation process and drive a new system-level behavioural change.

“So you have best practice, transparency, engagement and then finding those ones that are really willing to work with you and building a business case that's... You know we talk about our philosophy of all we do business and it's about win-win; win for patients, win for customers. I don't see how this is a win-win for the healthcare professional working in a community area.”

6.3.1 Conclusion

As illustrated through the findings from Questions 1 and 2, ongoing stakeholder engagement and transparency are considered both the major barriers, as well as the key enablers, to the successful implementation of the NHI.

The private sector possesses a huge amount of capabilities and expertise which government can leverage to address current system challenges. As the development of partnerships to leapfrog South Africa's healthcare challenges is a strategic priority, pharmaceutical companies that already have these public-private partnerships in place, are thus placed in the role of policy entrepreneurs and champions of change in diverse settings like the NHI (Batras, Duff & Smith, 2014). In addition, the research participants suggested the implementation of work-streams in order to assess the progress of NHI and reduce any potential risks. Biginis and Sindakis (2015) echoed this need for regular assessment of PPP's in order to ensure reliability and transparency.

As illustrated throughout this research, it is imperative to engage all stakeholders in the reform process in order to avoid and resolve disputes (Wouters & Kanavos, 2015), as well as to overcome any potential barriers identified.

7 CONCLUSION AND RECOMMENDATIONS

7.1 Principal findings

This research aimed to shed light into the way that leading R&D pharmaceutical companies in South Africa's private healthcare sector are responding to – and preparing for the implementation of the NHI. Instead of exploring the relevance of the proposed change, this study turned its focus to the preparation of these R&D pharmaceutical companies for the imminent change, in order to remain sustainable in the long-term.

Three research questions were formulated to understand the rationale behind the behavioural tactics of R&D pharmaceutical companies and to identify the way forward as perceived by these organisations.

As a starting point, the researcher explored the current pharmaceutical operational model and how this model aligns with the needs of an emerging market like South Africa. The researcher found the participants' feedback to be aligned with current literature, confirming that global market trends have seen the operating model transition to the current pharmaceutical model of a lean and focused company, with a research footprint within key innovative bio-clusters and an increasing revenue stream from biologics, speciality products and emerging markets (Gautam & Pan, 2016). Although pharmaceutical companies can be segmented into four groups (diversified, semi-diversified, specialised and niche), two major operational models have emerged (IMS, 2014; Gautam & Pan, 2016):

- A diversified business that includes diagnostics, generic products, devices, innovative drugs, consumer- and animal health; and
- Pure biopharma companies which focuses primarily on innovative drugs.

The research findings confirmed the need for diversified pharmaceutical portfolios, as well as the shift away from traditional sales force models, in order to engage in policy decision-making discussions and to mitigate their risk in emerging markets. Participants in this research opined that they are well positioned to meet the needs of the current healthcare system, and as such, is instead focusing on increased stakeholder engagement, improved market access and public-private partnerships as some of their strategic tactics in order to meet stakeholder expectations.

Research participants supported the need for fundamental reforms such as pricing policies to ensure broader access to medicines, while safeguarding the financial sustainability of health systems and working towards universal health coverage (Vogler, et. al., 2016; Wouters & Kanavos, 2015). To this end, each of the R&D pharmaceutical companies interviewed confirmed their commitment to this notion, and have already been engaging with government regarding access solutions. Evidently, pharmaceutical companies have been placed in the role of policy entrepreneurs and champions of change in diverse settings like the NHI (Batras, Duff & Smith, 2014).

The findings from the interviews highlighted the fact that R&D pharmaceutical companies strongly support the initiative to reform the healthcare system of South Africa. Although several themes emerged from the data collected, the main theme that consistently recurred throughout this research was the importance of stakeholder engagement.

Freeman, et. al. (2010) posits that the principle of stakeholder engagement is to create sustainable value and ensure as many win-win situations as possible. By recognising how stakeholders are impacted by - or impacting on the business, it is possible to establish the needs of all stakeholders and aspire to meet these needs as often as possible, thereby minimising challenges or barriers. The research found several pockets of excellence that exist within the current healthcare system, where public-private collaborations and the investment of R&D pharmaceutical companies seek to leapfrog current challenges, in order to improve access to medicines and increase the capabilities of the public sector.

Furthermore, the literature suggests that healthcare settings are considered “complex adaptive systems”, consisting of a number of stakeholders whose actions are unpredictable, yet interconnected (Brand, Fleming & Wyatt, 2014; Tuffin, 2016) and bound by a common objective (Thompson, Fazio, Kustra, Patrick & Stanley, 2016). This complexity theory-informed approach to healthcare was echoed throughout the interviews, as all of the participants identified the interconnectedness of stakeholders and alignment of goals, as both the key barriers and enablers to the successful implementation of the NHI.

Participants reiterated the need for transparency and a shared vision that is governed by simple rules in order to further promote trust, interconnectedness and collaboration amongst all the stakeholders in the healthcare system (Weberg, 2012; Lowell, 2016). A systematic approach that would require time, persistence and interdisciplinary engagement, is a prerequisite to successfully embed change implementation in the

long-term (Douglas & Sutherland, 2009). Several research participants suggested expert consultation and the initiation of multi-stakeholder work streams in order to ensure the successful rollout of the proposed NHI.

7.2 Implications for management

The aim of this research was to establish how leading R&D pharmaceutical companies are responding to- and preparing for the imminent change accompanying the implementation of the NHI.

The researcher interviewed key executives from leading R&D pharmaceutical companies. The level of seniority and combined experience, as well as the quality of respondents provided the researcher with valuable insights into the current healthcare system. In addition, the researcher was able to identify key barriers and enablers to the successful implementation of NHI, from the perspective of the biggest upstream providers within the healthcare system – pharmaceutical companies.

Although several change models have been outlined throughout literature, research by O'Malley (2014) confirmed that the change model utilised within a given environment will also dictate the leadership style required for managing the change. His research further found that leadership styles promoting organisational engagement and shared vision are imperative to the successful implementation of change. Iles and Sutherland (2001) were able to bring key models together that demonstrate the importance of extensive situational analyses, multi-stakeholder input and planning the intervention accordingly. These findings were consistently supported by the interview findings of this research project.

The nine stage change model for the successful implementation of a HIV / AIDS intervention (Douglas & Sutherland, 2009), highlights the significance of trust and stakeholder engagement in change implementation. The model utilises the nine stages of change in order to create a sense of urgency around the need for change. The involvement of leadership across different levels in the system and the need for communication of the vision, are both highlighted as imperative to the successful intervention. The strategy for change implementation, as well as the leadership traits / behavioural constructs will significantly influence the success and effectiveness of the change (Douglas & Sutherland, 2009).

The model suggested by Douglas and Southerland (2009) can be applied to the complex healthcare system of South Africa and can be utilised to illustrate the salient

points raised by the research participants, pertaining to both their response to the implementation of NHI, as well as the barriers and enablers pertaining to the successful implementation of NHI. The points raised and depicted in the model include stakeholder engagement, leadership, simple and straightforward vision, communication and broad-based participation like public-private partnerships.

7.3 Limitations of the research

No study is without limitations. Some of these limitations are inherent to a qualitative study of this nature, while some are particular to this study.

- Exploring different perspectives on existing subject matter may help to identify new insights. Conclusions from a study of this nature are often built from extrapolating findings into meaningful narratives. Therefore, follow up research is necessary to confirm any conclusions.
- Sampling bias: although the study population in this research is clearly defined, selection of the sample requires the researcher to make a judgment call on who the most appropriate sources of data will be. Although every effort is made to ensure a fair representation of the research population, there is still a risk that other important sources were overlooked.
- Due to the nature of the field of this study (healthcare), as well as the sensitivity of the topic, access and time constraints presented the highest challenge as the interviewees were high profile industry opinion leaders. It is possible that this potentially increased the risk of an under-represented sample group.
- Interviewee bias: semi-structured interviews give rise to the interviewer introducing cognitive bias into the study, through the interviewer's body language, facial expressions or follow up questions that could unconsciously influence the response given by the interviewee.
- Interviewer bias: As an employee in the pharmaceutical industry, an unintended bias based on the interviewer's previously held hypotheses or expectations on the results of the research is possible.

- Sensitive data – This study was conducted on a topic of great uncertainty and mixed stakeholder perceptions on the potential impact and the sustainability of private stakeholders in the NHI environment. In addition, the Competition Commission of South Africa has extended its inquiry on pricing and anticompetitive behaviour in South Africa’s private healthcare system, as commissioned by the minister of health (South Africa, The Competition Commission, 2015). Therefore, it is possible that access to potential participants was further restricted due to the nature of the research subject.

7.4 Suggestions for future research

This study was able to establish how leading R&D pharmaceutical companies are preparing for the implementation of a major health reform, in order to ensure long-term sustainability, whilst aligning with stakeholder expectations. The researcher was able to discuss this important topic with key executives within these companies, who shared their extensive knowledge freely. As a result, several themes emerged which were beyond the scope of this research and are important topics to be explored in future research.

Participants expressed the importance of pricing solutions in order to improve access to medicines in South Africa. An important starting point could be to look at what the cost drivers are in research and development of medicines, and how to subsidize these costs globally. In addition, further research is required to establish clear policies to guide and define central HTA’s, benchmark pricing of medicines and the feasibility of implementing tiered pricing in a global setting.

An extension of the aforementioned pricing / cost research recommendations would be to explore the true impact of life-saving personalised healthcare on the country’s GDP in terms of the patient contributions. Several interviewees highlighted the importance of intellectual property and patency laws in access to medicines. This controversial topic deserves extensive analyses as the consequences of patent protections are potentially far reaching for all stakeholders in the healthcare system.

Through the numerous public-private partnerships that currently exist, gaps in central procurement and distribution of medicines have been identified. Therefore, the topic of improving supply chain delivery / logistics through PPP’s and decentralized procurement would be worthwhile exploring.

In keeping with the theme of stakeholder engagement, an important avenue to pursue is the view of healthcare professionals on their role in the implementation of the NHI. As mentioned in this research, the public sector relies heavily on the capabilities of the private sector and there is an expectation of increased “work sharing” that would impact private healthcare professionals significantly. The effect of brain-drain pre-NHI implementation versus post-NHI would be an interesting topic to explore.

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APPENDIX 1: Interview Guideline

a. Introduction and Background Information

- Welcome
- Discuss confidentiality of information
- Explain the purpose of interview and purpose of research
- Request to audio-record the interview

b. Theoretical Discussion

- Explain in simple terms the theoretical concepts under investigation, particularly:
 - Historical perspectives and critical inferences
 - Proposed policy reform and Policy implementation
 - Recipients' responses
 - Contribution of Private sector to South African economy

c. Objectives

The primary objective of this interview is to get an overall view of events occurring in the pharmaceutical industry from the perspective of industry experts.

Commence with an initial background discussion on the state of healthcare in South Africa, to build rapport.

Interview question 1: What is your opinion of South Africa's current healthcare industry and the proposed implementation of NHI?

Themes to be explored:

- Perceived state of the nations' health
- Personal / Professional role in the industry / country
- Perception of South African Government's role in the industry / country

- Personal views about the role of the private healthcare sector
- Challenges in the industry and underlying causes
- Feasibility of policy goals and timelines
- Impact of the proposed policy

Interview question 2: What is your current operational model focused on? Primary Health Care or speciality drugs / personalized healthcare? Combination of the two?

Themes to be explored:

- Allow interviewee to take me through the journey
- Explore specific nodal events

Interview question 3: What informed this operational model?

Themes to be explored:

- Allow interviewee to take me through the journey
- Explore specific nodal events
- Market trends
- Global strategy / pipeline / cost / corporate positioning

Interview question 4: How will the implementation of NHI affect your operational model?

Themes to be explored:

- Allow interviewee to take me through their view
- Pricing / Operational structure and Corporate strategy / Organisational design and transformation
- Stakeholder impact / Complexity theory / Organisational change theory

Interview question 5: Who are your main stakeholders within the NHI environment? What will be the role of these stakeholders within NHI as you see it? Have you started working with them in order to partner with them under NHI environment?

Themes to be explored:

- Allow interviewee to take me through their view
- Stakeholder theory / Social justice

Interview question 6: How is your organisation preparing for NHI / adapting your strategic approach?

Themes to be explored:

- Allow interviewee to take me through their view
- Scenario planning / Organisational design and transformation / Corporate strategy
- Stakeholder analysis / Complexity theory
- Collaborative relationships

Interview question 7: The DoH has so far not made much progress in implementing the reforms, in your opinion what has caused this delay? What do you perceive to be the barriers and enablers of collaboration with government in NHI?

Themes to be explored:

- Allow interviewee to take me through their view
- Political / Social climate
- Leadership competencies
- Business skills and attributes
- Legislation and Regulation (Market access and pricing)

Interview question 8: What do you think is the way forward?

Themes to be explored:

- Allow interviewee to take me through their view

Interview question 9: Is there anything else you wish to add that you think would be useful for this study?

Themes to be explored:

- Allow interviewee to take me through their view

Thank interviewee and request permission to call them should there be anything else I need further clarity on.

APPENDIX 2: Informed Consent Letter

Dear Participant,

I am conducting research to investigate responses to the NHI policy change from the perspective of recipients of a major change initiative (those whom the change initiative is meant to influence).

I will be interested in exploring organisational views on the proposed reform as well how pharmaceutical organisations are responding and in part contributing to the changing healthcare landscape in South Africa. Ultimately, the research is intended to contribute towards a broader empirical understanding of what the new requirements are for the pharmaceutical industry in South Africa, in order to partner with government in preparation for the NHI.

The interview is expected to last about an hour. Participation is voluntary and you may withdraw at any time without penalty. All data will be kept confidential by way of removing all company-specific details. All records obtained whilst in this study will be regarded as confidential. Results will be published or presented in such a fashion that participants remain unidentifiable. I, however, would like to ask your permission to audio record this interview for the purposes of backing up the data collected for future reference. Should you have any concerns regarding audio recording the interview, I can turn to note-taking by hand.

If you have any concerns, please contact either me or my supervisor. Our details are provided below.

Researcher

Charmain Bezuidenhout

charmain.bezuidenhout4@gmail.com

Supervisor

Zaheeda Cajee

zaheeda1@gmail.com



Signature of participant

Date

Signature of Researcher

Date

APPENDIX 3: GIBS Ethical Clearance

Dear Ms Charmain Bezuidenhout

Protocol Number: **Temp2016-01251**

Title: **The reform of pharmaceutical companies in South Africa's private sector in response to the National Healthcare Initiative**

Please be advised that your application for Ethical Clearance has been APPROVED.

You are therefore allowed to continue collecting your data.

We wish you everything of the best for the rest of the project.

Kind Regards,

Adele Bekker



APPENDIX 4: Medical Ethical Clearance

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
 • PWA 00002567, Approved dtd 22 May 2002 and Expires 20 Oct 2016.
 • IRB 0000 2235 IORG0001762 Approved dtd 22/04/2014 and Expires 22/04/2017.



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YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

18/08/2016

Endorsement Notice

Ethics Reference No.: Temp2016-01251

Title: The reform of pharmaceutical companies in South Africa's private sector in response to the National Healthcare Initiative

Dear Ms Charmain Bezuidenhout

The **New Application** as supported by documents specified in your cover letter for your research received on the 12/08/2016, was approved, by the Faculty of Health Sciences Research Ethics Committee on the 17/08/2016.

Please note the following about your ethics approval:

- Please remember to use your protocol number (**Temp2016-01251**) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

Ethics approval is subject to the following:

- The ethics approval is conditional on the receipt of 6 monthly written Progress Reports, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

Dr R Scribners; MChB; MMed (Int); MPharmD, PhD

Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

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