

**Gordon Institute
of Business Science**
University of Pretoria

**Optimal governance of and stakeholder involvement in
a medicines regulatory authority to enable
pharmaceutical innovation**

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

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Abstract

The South African medicines regulatory authority will shortly be moving from under the control of the National Department of Health to become a Section 3A public entity with its own governance structure. This presents the ideal opportunity to address the urgent need for evaluation of stakeholder engagement and mechanisms to improve the efficiency of the regulatory authority. This research was designed in order to join and contribute to the on-going conversation regarding the optimum functioning of the medicines regulatory authority by evaluating stakeholder engagement and governance, through the perceptions of stakeholders involved in the regulation and approval of medicines in South Africa. Governance, stakeholder and industry dynamics theory provided the foundation on which the research was based, allowing the researcher to create a lens through which the results of the research were viewed.

Qualitative, deductive exploratory research was performed using perceptions of twelve respondents. These included key stakeholders involved in the provision of pharmaceuticals, as well as medicine regulatory decision-makers. Perceptions of previous experiences with, and proposed future optimal frameworks for, stakeholder interaction and governance of the medicines regulator to enable innovation in the pharmaceutical industry were derived from in-depth interviews.

The research found many areas of improvement urgently needed in the current model of governance of the medicines regulatory authority. New academic insight was developed into the efficiencies needed within a medicines regulatory authority, as well as the stakeholder interactions to improve efficiencies and operating conditions within the pharmaceutical industry. It was found that internal efficiencies within the medicines regulatory authority as well as more effective stakeholder interaction framework would better enable innovation of products and processes within the pharmaceutical industry.

Analysis of themes derived from in-depth stakeholder interviews, along with the literature review, was used to construct a framework of optimal governance and stakeholder interaction of the new medicines regulatory authority. This provides a contribution to theoretical management literature and provides guidance for regulators and stakeholders to create an efficient regulatory system to allow for innovation and result in better quality healthcare for the public.

Keywords

Governance, key stakeholders, innovation, medicines regulatory authority

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 before for any degree or examination in any other University. I further declare that I have obtained the necessary authorisation and consent to carry out this research.

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*“What counts in life is not the mere fact that we have lived.
It is what difference we have made to the lives of others
that will determine the significance of the life we lead.”*

- Nelson Mandela

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Abbreviations

CEO	Chief Executive Officer
GIBS	Gordon Institute of Business Science
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
ITG	Industry Task Group
MCC	Medicines Control Council
MOU	Memorandum of Understanding
NGOs	Non-Governmental Organisations
SADC	Southern African Development Community
SAHPRA	South African Health Products Regulatory Authority

Chapter 1: Introduction to the Research Problem

1.1 Introduction

The South African Medicines Control Council (MCC) is a subsidiary of the National Department of Health. It applies the regulations of the Medicines and Related Substances Act 101 of 1965, and is responsible for the registration of medicines and medical devices, allowing permission for sale to the South African market. The MCC is a medicines regulatory authority that governs the manufacture, distribution, sale and marketing of medicines. No medical products may be legally sold before meeting the requirements of the MCC in terms of quality and efficacy (Medicines Control Council, 2016).

Through the amendment Bill 6 of 2014, the medicines regulator of South Africa, the MCC will shortly be moving away from under the control of the National Department of Health (Republic of South Africa, 2014). The medicines regulatory authority will become a Section 3A public entity, the South African Health Products Regulatory Authority (SAHPRA), with its own corporate structure (Gray, Vawda & Jack, 2015). As a Section 3A public entity, SAHPRA will become independent of the Department of Health, but will still be responsible to the Minister of Health and it will receive funding partly from the government and partly from funds raised for services rendered (Gouws, 2015, 2016). Restructuring will include a formation of its own governance framework and subsequent review of its policies. Assessment of the governance and stakeholder engagement to enable innovation of products and processes, as performed in this research, is imperative to ensure efficiency of the structure of SAHPRA.

The pharmaceutical industry in South Africa is plagued with challenges such as long approval times for registration of medicines, competition from generic drug manufacturers and a reduction in the discovery of innovative medicines. In addition to this, pricing pressures have affected the pharmaceutical companies' margins and profitability of the industry (Fatti & du Toit, 2013). The main source of frustration for the pharmaceutical industry is long timelines for registration of medicines. This can be attributed to a lack of capacity of the regulatory authority and subsequent poor relations with the pharmaceutical industry.

Innovation is the transformation of technology, creative ideas and resources to provide a new differentiated product, service, technology or process (Baregheh, Rowley & Sambrook, 2009). The current regulations and governance of the pharmaceutical industry pose a barrier to innovation and the frequent production of new pharmaceutical products. This negatively affects public health outcomes, by reducing the number of medicines available to the public to treat disease (Aagaard, 2015). An analysis and restructuring of the governance framework and stakeholder relations is thus urgently needed. This problem creates an opportunity for the research and the development and establishment of an optimal framework for governance of the medicines regulatory authority.

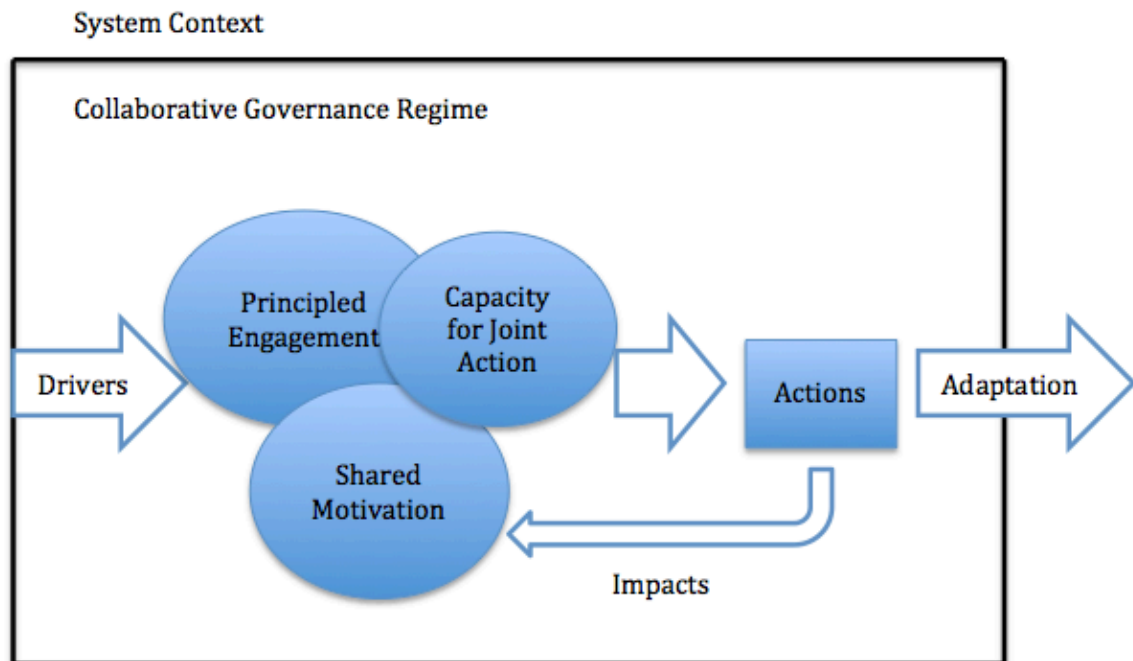
Stakeholder buy-in is essential for the implementation of effective governance strategies to ensure cooperation and goal achievement (Kim & Kim, 2016). For pharmaceutical companies, having insight into and contribution towards regulatory policy development enables the minimisation of risk and effectiveness of product development strategies. This enhances the provision of better quality pharmaceutical products to the public. On the other hand, governments and regulators may benefit by leveraging off the strengths of private pharmaceutical companies, such as with high capacity and skills availability. Stakeholder engagement and consultation ensures the support of policies and efficacy of results (Campos, Norman & Jadad, 2011). Cohesion between the medicines regulatory authority and government with pharmaceutical companies ultimately results in the availability of better quality healthcare to patients.

In a study performed by McCaffrey, Smith and Martinez-Moyano (2007), it was found that the level of cooperation between regulators and industry was dependent on “mutual familiarity and the levels of trust between them” (p. 321). It is imperative for strong relationships to be formed between regulators and the industry, to enable legitimacy of both parties (McCaffrey, Smith and Martinez-Moyano, 2007). This enables mutually beneficial relationships to increase efficiency of the medicines regulatory authority and industry for the benefit of society as a whole.

Collaborative governance is defined as “the processes and structures of public policy decision making and management that engage[s] people constructively across the boundaries of public agencies, levels of government, and/or the public, private and civic spheres in order to carry out a public purpose that could not otherwise be accomplished” (Emerson, Nabatchi & Balogh, 2012, p. 3). A framework was created for collaborative governance in a system context, as indicated below in Figure 1. This

included the incorporation of principled, capacity for joint action and shared motivation as collaboration dynamics, along with drivers that lead to action and the impact of policy (Emerson, Nabatchi & Balogh, 2012). This framework will be used as a base for the framework of governance that will be developed in this research.

Figure 1: Integrative Framework for Collaborative Governance (Adapted from Emerson, Nabatchi & Balogh, 2012)



Although useful as a base for understanding collaboration between stakeholders, the above-mentioned framework does not take into account innovation, which this research will incorporate. It also requires a more in-depth description and more breadth of indicators, as mentioned by the authors (Emerson, Nabatchi & Balogh, 2012).

Innovation of products and processes is essential to enable competitiveness of an industry. In the current dynamic operating environment, strategic innovation is central for sustainability of companies within the pharmaceutical industry. There is constant pressure for pharmaceutical companies to provide cheaper and more affective products (Aagaard, 2015). The pharmaceutical industry is operating in a complex environment and therefore requires alignment to the changing needs of stakeholders through consistent innovation (Suzuki, 2015). Innovative new medicines are constantly needed in South Africa to address the burden of diseases that affect the country, for example, HIV, tuberculosis and malaria treatment. The pharmaceutical industry needs

to evolve to embrace globalisation and an open-market system that will improve its global competitiveness (Fatti & du Toit, 2013).

Innovation policy analysis and creation involves learning processes through the accumulation of knowledge and experience (Borras, 2011). Research performed by Borras (2011) indicated that learning ability is influenced by organisational capacity. However, the study did not show the extent to which stakeholder involvement could influence learning processes for policy-makers. This research will aim to provide insight into the need for stakeholder involvement to provide capacity for learning in policy-making.

A study was performed by Caerteling, Halman, Song, Doree and Bij (2013) into the effects of government championship on the success of projects involving technological innovation. It was found that government support towards innovative projects lead to positive performance of the projects (Caerteling, Halma, Song, Dorée & Bij, 2013). Further research was suggested into government regulation of innovation, enhancing the research on regulatory policies and innovation, which was performed in this study.

1.2 Research Problem and Purpose

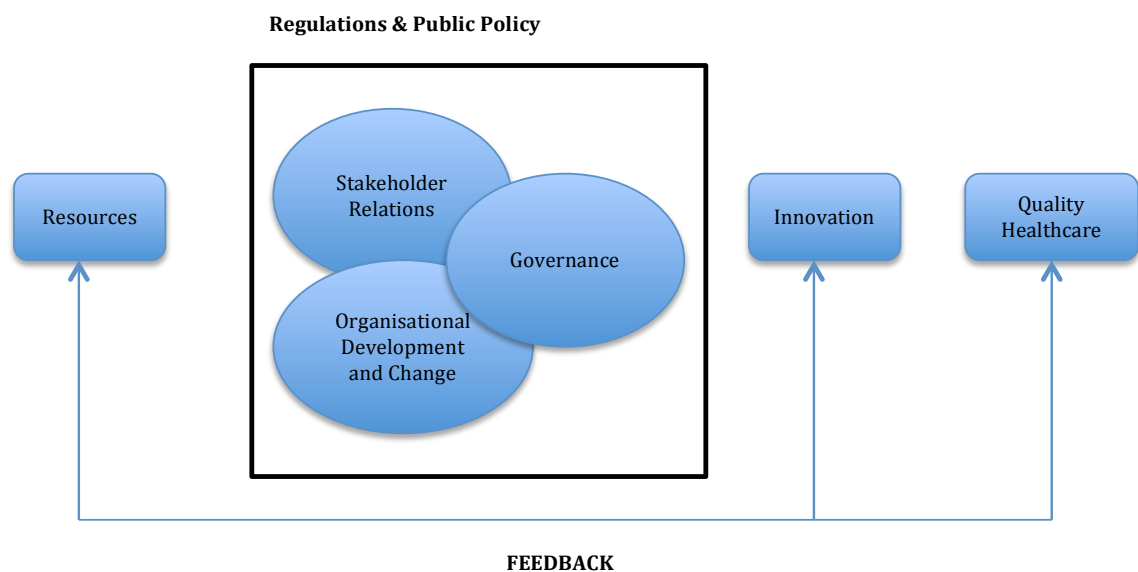
The restructuring and movement of the MCC to SAHPRA presents an ideal opportunity to assess and re-evaluate value provided to stakeholders in order to create an optimal governance framework to enable innovation within the industry. The purpose of the research was to provide a framework of optimal governance for SAHPRA to address stakeholder needs and encourage innovation. Stakeholder perceptions allowed the creation of this framework. This research problem was selected in order to understand better the optimal governance requirements for a Section 3A public entity regulatory body to enable an innovative environment for its stakeholders. With emerging innovations in the pharmaceutical space, stakeholder collaboration is vital to creating effective institutional policies (Poole & Van de Ven, 2004).

Although the research is contextualized in a pharmaceutical industry in South Africa, it provides value to other regulatory organisations by identifying governance and stakeholder interaction needed to enable innovation. It also provides theoretical value and contributes to research through an analysis into optimal stakeholder relations between regulators and private institutions. In addition, it provides a foundation on which further research may be performed into the correlation between stakeholder relations and business performance.

The objectives of the research were to identify perceptions of the current medicines regulator to its stakeholder relations and governance. In addition to this, the research aimed to identify perceptions of private pharmaceutical companies and industry experts of interaction with the current medicines regulator, as well as proposed optimal practices for the new medicines regulatory authority. This information, together with the literature review, was used to construct a framework of optimal governance and stakeholder interaction with the new medicines regulatory authority in order to enable innovation in the pharmaceutical industry.

The Open Systems Framework was used to analyse the pharmaceutical industry in South Africa and adapted to include the role of public policy and regulations in the feedback mechanism to enable innovative outputs of the system. This was used as a lens through which the research was conducted, in order to gain an overall perspective of the elements of the regulation of medicines and public policy that convert resources into innovation and quality healthcare, as depicted below in Figure 2.

Figure 2: Open Systems Framework for the Pharmaceutical Industry



Source: Author's Own

Various models and theories have been developed to describe governance, public policy-making and change management. However, this literature has focused on the context of private organisations, which have significantly different agendas and environments to that of the medicines regulatory authority. The stakeholder engagement and consultation needed for the change management of the medicines regulatory authority will be analysed in this research.

Chapter 2: Literature Review

2.1 Introduction

The research begins with a synopsis of relevant literature followed by an account of the research methodology. The literature review provides a critical analysis of the theories that pertain to the concept of governance and stakeholder management of the medicines regulatory authority, as well as innovation in the pharmaceutical industry. A conceptual definition of governance and stakeholders is provided to enable clarity in the research performed.

The themes of governance and stakeholder theory are examined to provide a foundation on which the research was based. The theories are then expanded through the use of the Open-Systems, competition and Porter's Diamond models. Change management theory is then analysed to follow the process of the restructuring of the medicines regulator. The research is contextualised through the background of medicines regulation in South Africa and highlights the importance of and challenges facing innovation of products and processes in the pharmaceutical industry.

The research uses the theories of stakeholder management and governance of the medicines regulatory authority, and ultimately creates a framework with which optimal governance through stakeholder interaction may be enabled, in order to enable innovation in the pharmaceutical industry.

2.2 Industry Dynamics

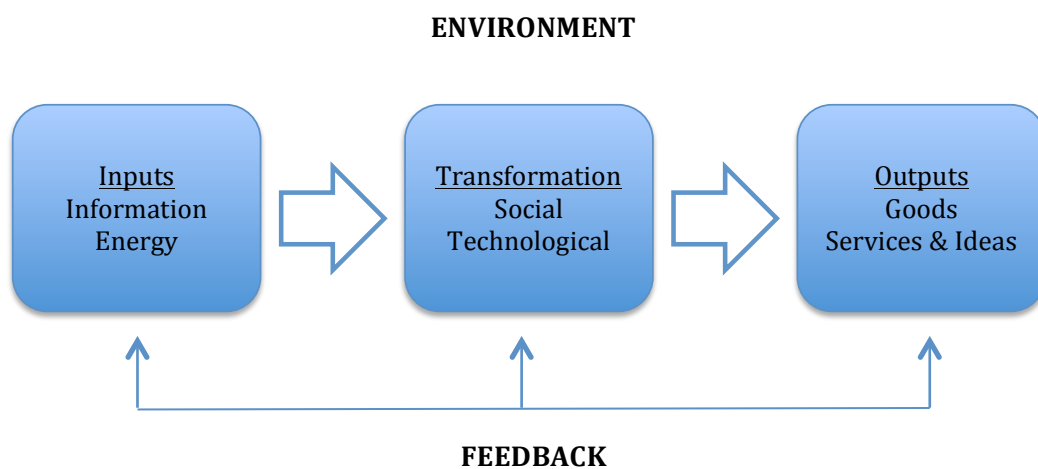
Analysis of the dynamics within an industry is critical to gaining a fundamental overview for ensuring alignment of competencies of organisations to industry trends. Diagnosis of the functioning of an industry allows identification of opportunities for improvement and interventions (Cummings & Worley, 2015). It also enables an assessment of the attractiveness or barriers of a market for entry, and level of competition (Fainshmidt, Smith & Judge, 2016).

In this section, industry dynamics theories are discussed. The Open Systems Model for flow of information within an environment in order to ensure alignment with trends in the environment is first assessed. Porter's Five Forces for analysis of industry, Porter's Diamond theory of clusters to enhance competitiveness and competition, involving the cooperation of rival firms to enhance the industry as a whole, are also discussed.

2.2.1 Open Systems Model

Systems Theory views organisations as functioning units comprised of smaller sub-units, such as departments. This describes the Open-Systems Model, which portrays the organisation’s interaction with its external environment (Figure 3). A process occurs through a feedback mechanism to convert inputs to outputs. Open systems involve an exchange of information across boundaries between the system and its environment, which may influence or be influenced by the organisation (Cummings & Worley, 2015). This describes the environment in which the pharmaceutical industry should operate.

Figure 3: Open Systems Model (Adapted from Cummings & Worley, 2015)



Scott (2014) defines institutions as comprising “regulative, normative, and cultural-cognitive elements that, together with associated activities and resources, provide stability and meaning to social life” (p. 56). They are collections of knowledge and people in a formalised structure that come together for a purpose or cause (Scott, 2014). Institutions are social structures that regulate behaviour and define the “rules of the game” (Poole & Van de Ven, 2004, p. 261).

Organisations need to adapt to the changing external environment and changing rules of the game in order to achieve legitimacy (Poole and Van de Ven, 2004). This is related to the Open-Systems theory in which organisations receive feedback from their external environment. Open and honest institutional policies that lead to trust between institutions and their stakeholders result in a positive reputation effects and collaboration (Doy & Guay, 2006).

Davey, Brennan, Meenan and McAdam (2010) found that the use of open business models might better enable healthcare companies to readily react to changing

healthcare needs and provide more efficient healthcare technology. The same applies to pharmaceutical companies, who may use foundational information available in open systems to provide a base for more complex development of new emerging technologies and pharmaceutical innovations. Open innovation enables the use of external ideas from other companies to share risks and enable better information at the early stages of innovation development, placing companies in a more strategic position to address and overcome regulatory barriers to innovation (Davey, Brennan, Meenan & McAdam, 2010).

2.2.2 Porter's Industry Analysis

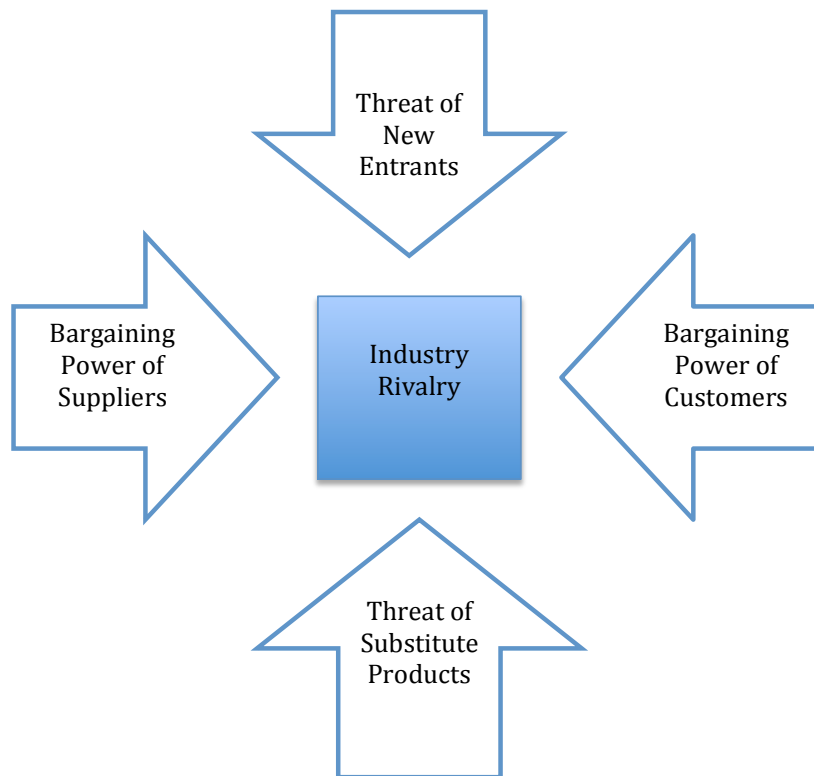
Porter (1998) defines clusters as “groups of interconnected firms, suppliers, related industries and specialised institutions in particular fields that are present in particular locations” (p. xii). Clusters, along with open systems, provide many advantages, by enhancing productivity and innovation. Organisations in a cluster may leverage relationships and encourage “knowledge spill-over and innovation” (Kuah, 2002, p. 208). Porter developed the Diamond Model to explain competitive advantage of clusters. Porter (1990) explains that competitiveness should involve enabling “factor conditions” (p. 77) or resources and infrastructure, “demand conditions” (p. 77) or home market conditions, “related and supporting industries” (p. 77) and “firm structure and rivalry” (p. 77) or capacity to innovate and align to goals.

Fainshmidt, Smith and Judge (2016) argued that an extension of Porter's Diamond Theory should include the quality of public governance, as this has been found to directly affect the strategic positioning and competitiveness of organisations. Governance affects the stability of policy and ability of companies to “establish organisational boundaries according to learning and innovation rather than by using time and resources to deal with transaction cost considerations” (Fainshmidt, Smith & Judge, 2016, p. 96).

2.2.3 Porter's 5 Forces

Michael Porter developed the Five Forces Model to describe the level of rivalry and competitive advantage in an industry, as in Figure 4 below (Narayanan & Fahey, 2005). This model is one of the most widely known strategic frameworks used to assess forces impacting an industry, as its generic elements may be applied broadly to a wide range of organisations (Vining, 2011). However, it does not take into account institutional impacts on an industry, which is a significant threat in emerging economies (Narayanan & Fahey, 2005).

Figure 4: Porter's Five Forces Model (Adapted from Vining, 2011)



Institutional theory explains “how organisations seek legitimacy within a given environment” (Doh & Guay, 2006, p. 49) to adjust to trends in the environment. Narayanan & Fahey (2005) proposed that Porter's Five Forces Model should be adjusted in emerging economies, as these differ to developed economies, in which formal institutions are available that support industry.

Porter's Five Forces Model may be used to analyse public organisations, as analysis of the external political and economic environment by every organisation is essential to enable alignment with industry trends (Vining, 2011). However, Vining (2011) argued that a sixth force of political influence should be included in the model when applied to public organisations, as political influence may either enable or restrict operations.

Thus, the research conducted is pertinent in assessing the impact that the medicines regulator, as an institution in a developing economy, impacts the level of rivalry and competition in the pharmaceutical industry. In addition, with the medicines regulator moving from a public organisation, falling under the Department of Health, to a Section 3A public entity semi-private organisation, the level of political influence should, in theory, be reduced.

2.2.4 Coopetition

Coopetition involves competition and collaboration between organisations in an industry or between units in an organisation, where competitive organisations cooperate with each other (Kozyra, 2012). Advantages of cooperation include the sharing of resources, learning, risks and costs, as well as economies of scale for smaller companies, while competition encourages innovation in the search for market share (Bouncken & Kraus, 2013). The formation of strategic alliances is one form of coopetition, where mutually beneficial cooperation between organisations occurs to combine resources in order to achieve organisational goals (Kozyra, 2012).

Companies in the pharmaceutical sector are under pressure to ensure constant innovation, including new product development. In order to keep up with the rapid pace of technological development in the operating environment, companies have begun to cooperate and share resources, such as with licensing and learning (Li, Zheng & Wang, 2016). Collaboration at national and international level with competing organisations positively affects organisational performance. Cohesion between companies enables innovation by reducing opportunistic behaviour, creating trust and a culture of information sharing (Guler & Nerkar, 2012).

Through coopetition, companies can leverage competitor resources and knowledge to increase their learning and innovation. Bouncken and Fredrich (2016) found that cooperation aims for the creation of a larger market or a “bigger pie” (p. 1753), after which companies engage in competition for market share or a “share of the pie” (p. 1753). In the resource-based view of coopetition, value is created through “complementary and supplementary resources” (Li, Zheng & Wang, 2016, p. 168) of organisations collaborating.

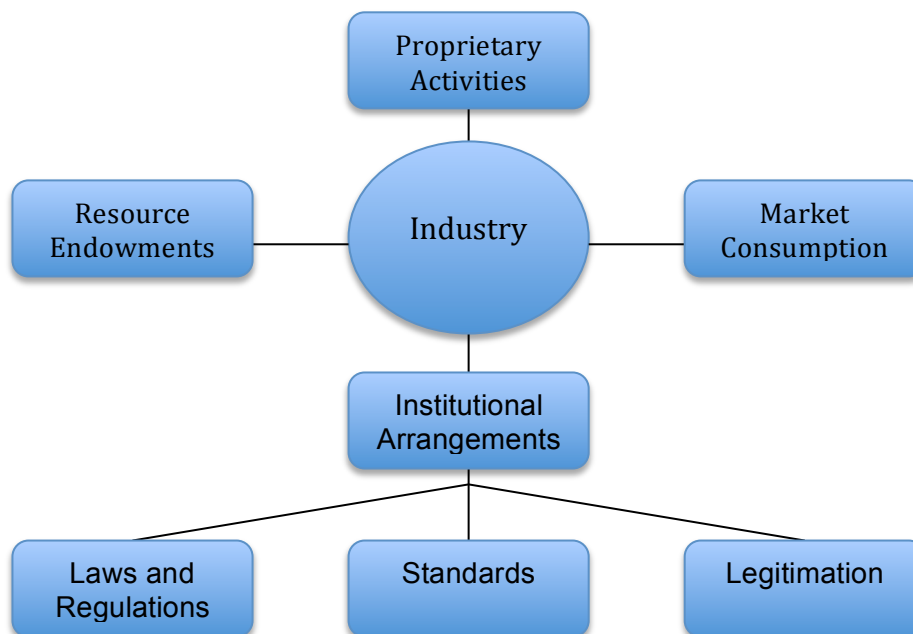
However, the literature does not highlight the limitations to the theory of coopetition, as valuable intellectual property may be compromised if systems are not in place to protect it. This is particularly important in the pharmaceutical industry, where patent protection is vital for competitive advantage.

2.3 Innovation and the Operating Environment

To remain competitive in any industry, continuous alignment to changing market conditions and trends is necessary through innovation. Dynamic capabilities are needed to enable product changes and focus on core competencies to provide a competitive advantage and unique market offering (Grünbaum & Stenger, 2013).

Innovation is the transformation of technology, creative ideas and resources to provide a new differentiated product, service, technology or process (Baregheh, Rowley & Sambrook, 2009). Poole and Van de Ven (2004) created a framework for creation and acceptance of technological innovations, including the entities necessary for the approval and commercialisation of innovation, as presented below in Figure 5. Poole and Van de Ven (2004) identified four subsystems as key components, including “institutional arrangements” (p. 284) to regulate the technology, “resource endowments” (p. 284) to provide knowledge and funding, “consumer demand” (p. 284) to create a market for the innovation and “proprietary activities” (p. 284) including competent employees and scientific knowledge. This is applicable to the pharmaceutical industry under research and the subsystems involved in introducing innovations.

Figure 5: Augmented View of Industry (Adapted from Poole & Van de Ven, 2004)



Ambidexterity of a company is defined as “ability to exploit existing assets and positions in a profit-producing way and simultaneously to explore new technologies and markets” (O’Reilly & Tushman, 2011, p. 5). It involves utilisation of the organisation’s resources and core competencies to sense and take advantage of emerging opportunities and trends while maintaining existing market spaces. Trends may involve new technologies, new markets and changing regulations (O’Reilly & Tushman, 2011). Wang and Rafiq (2014) found that exploration enables “radical innovation” (p. 58) and results in sustainability of an organisation, while exploitation leads to “incremental

innovation” (p. 58) and better short-term results. In order to enable operation of a company in a dynamic environment, contextual ambidexterity is of utmost importance. An ambidextrous culture within the organisation enables an empowering environment that encourages innovation and leads to increased competitiveness of companies (Wang & Rafiq, 2014).

Explorative innovation may be used to meet existing market demands and even shape demands or create new markets, as well as increasing organisational learning. This strategy carries a high risk, while incorporating exploitative innovation strategies in conjunction with exploration may mitigate these risks, as existing markets provide stability. Combining the two strategies enables companies to be more flexible and adapt to the external environment, increasing competitive advantage and performance of a company (Comez, 2016). Ambidexterity is central to an organisation’s survival, especially when operating in a dynamic and complex environment (O’Reilly & Tushman, 2011).

2.4 Innovation in the Pharmaceutical Industry

In the current dynamic operating environment, need for innovation in the pharmaceutical industry is high, with increasing market pressure and competition requiring new, cost-effective medicines to be produced (Aagaard, 2015). To cope with this pressure, pharmaceutical companies are increasingly using the method of “open innovation” (Wu, Little & Low, 2016, p. 206), which involves using external sources of technology and expertise, such as customers, suppliers and academia, to enhance internal innovation and commercialisation of new products.

The healthcare industry globally operates within a highly innovative environment, with new emerging technologies such as nanotechnology, biotechnology and DNA technology revolutionising the diagnosis and treatment of diseases and promotion of health. As a well-informed stakeholder group, the public demand for innovations is high, increasing pressure on companies to adapt to changing needs (Davey, Brennan, Meenan & McAdam, 2010).

Intra-firm collaboration and coopetition is essential to adapting to fast technological changes and disruption in the industry, as well as the need for consistent new product development (Li, Zheng & Wang, 2016). This incorporates a resource-based view of the organisation to assess capacity for innovation and subsequent leverage of strategic

partnerships to fill the necessary gaps in internal resources to meet innovation goals (Wu, Little & Low, 2016).

The research and development of a new medicine may take up to 12 years, while regulatory barriers requiring complex testing and proof of efficacy of medicines delay the registration process further. Due to strict regulatory requirements, ensuring structure in pharmaceutical innovation efforts is vital in managing the registration process of products. However, this may reduce ambidexterity and innovative activity through stifling of creativity (Aagaard, 2015).

Suzuki (2015) conducted a study with 50 pharmaceutical companies and found that innovation was critical to competitiveness of the companies. It found that adapting to changes in the environment through innovation enabled higher performance of companies. The study found that the companies' ambidexterity enabled positive organisational performance (Suzuki, 2015).

Operating in a highly regulated environment, the pharmaceutical industry in South Africa currently consists of mostly cheaper generic alternatives to medicines that have reached their patent expiry. Entering the market requires innovative strategies that enable competitiveness of companies (Fatti & du Toit, 2013). In achieving this, it is important for pharmaceutical companies to ensure responsible innovation to provide effective, quality products and better healthcare to the public.

Guler and Nerkar (2012) showed that informal networks formed enhance innovative capacity of pharmaceutical companies. Collaboration with local competitors showed an increase in innovation and positive organisational performance, enabling information-sharing and more productive research and development (Guler & Merkar, 2012). However, this research failed to take into account how governance of the regulatory authority and resulting policies may enable innovative capacity of the industry.

2.5 Public Policy

Bozeman (2013) found that those creating public policy rarely take into account organisational theories. He found that policy theory is highly contextualised and opposite to organisation theory, that may be applied to various organisations in different environments. Both individual and organisational behavioural change theories may explain the development of public policies. However, these theories do not take into account a comprehensive collaborative approach, which enables implementation

of policy (Hendriks, Jansen, Gubbels, De Vries, Paulussen & Kremers, 2013).

Most research in the public policy field has been performed on private organisations and not Section 3A public entities or government, where the context is different. For example, the public is more critical of mistakes made by government and regulatory authorities, as highlighted by the media (Hendriks, Jansen, Gubbels, De Vries, Paulussen & Kremers, 2013). It was found that highly specialised institutions are at high risk of inferior policy creation and management without the incorporation of organisational theories (Bozemann, 2013).

Publicness Theory states that all organisations, regardless of sector, are affected by the political and economic environment surrounding them (Bozeman, 2013). Thus, it is important not to create policies in isolation but take into account the broader environment of business and wider stakeholders. Organisations may differ in whether funding, control and ownership are public or private. Although there have been many debates as to whether public or private organisations perform better, there has been limited research performed on the matter (Andrews, Boyne & Walker, 2011).

2.6 Regulation of Medicines in South Africa

According to institutional theory, in order for a company to be able to market a product, institutions must be established in order to regulate standards and prices (Poole & Van de Ven, 2004). The pharmaceutical industry in South Africa suffers from high regulation and long approval times (Fatti & du Toit, 2013). The Medicines Control Council (MCC) assesses each product for quality and efficacy before it can legally be sold on the market. The MCC currently falls under the National Department of Health and receives a limited budget that results in a lack of sufficient staff members and reduced capacity to meet demands. As a result, registration time for a new product currently takes on average three years (Ruff, 2015).

Globally, other more resourced regulators such as the Food and Drug Administration in the USA have a much higher capacity and therefore quicker registration times, of an average of just over one year (Sacks, Shamsuddin, Yasinskaya, Bouri, Lanthier & Sherman, 2014). South Africa is a difficult market to predict since registration times may be long and therefore market dynamics may change by the time a product is allowed into the market.

The pharmaceutical industry in South Africa is dynamic, and companies need to keep abreast of the competitive landscape and medicines regulatory environment to sustain an advantage. There appears to be a great deal of collaboration in the industry, while generic medication competition is high (Fatti & du Toit, 2013).

2.6.1 SAHPRA

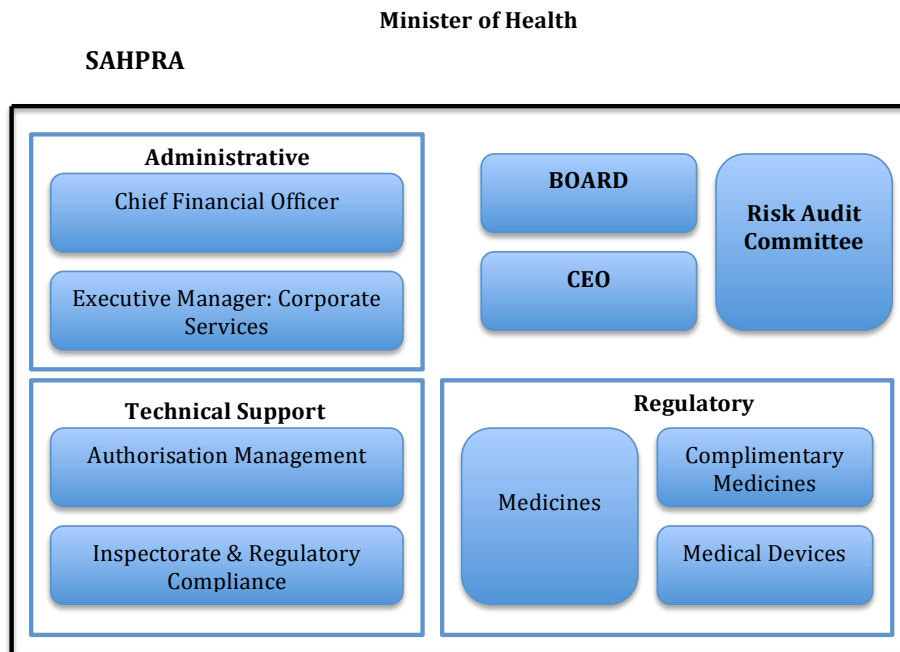
SAHPRA will become a Section 3A public entity and must become compliant with the Public Finance Management Act, along with other institutions such as the Council for Medical Schemes, the Human Sciences Research Council and the National Research Foundation, among others (Department of National Treasury, 2015). SAHPRA will become its own juristic entity with its own rights and duties, as an organ of the state outside of the public service. As a Section 3A public entity, it will be independent of the Department of Health, but still responsible to the Minister of Health (Gouws, 2015). It is estimated that the new SAHPRA structure will cost R100 million more annually than the existing MCC structure of the medicines regulatory authority (Gray, 2009). This funding will be received partly from the government and partly from funds raised for services rendered as the regulatory authority (Gouws, 2016).

As depicted below in Figure 6, the Board of SAHPRA will be appointed by the Minister and have governance and fiduciary duties. The Board will then appoint the Chief Executive Officer, who will then appoint evaluation committees to assess medicines, medical devices, complimentary medicines and active pharmaceutical ingredients (Gouws, 2015). Challenges for SAHPRA have been identified as being the recruitment of skilled staff and capacity building for regulatory matters and to advise the Chief Executive Officer (CEO), as well as change management including regulatory decision-making moving from a part-time council to full-time employees of the regulatory authority (Gray, 2009).

The previous Act 101 relied heavily on external experts who have primary jobs elsewhere and limited time availability for review of medicines registration applications, hence extending timelines for registration of products. Act 101 is outdated due to scientific advances and increasing complexity of registration of innovative products. Amendment Act 72 of 2008 aimed to increase in-house capacity through the retention of fees for services rendered and strengthening SAHPRA as a juristic entity. SAHPRA will, as a result, have more efficient use of resources, including law enforcement and international regulatory cooperation agreements for knowledge sharing and harmonisation (Gouws, 2016). The amendment Act 72 of 2008 was approved by

Cabinet and Parliament and signed into law by the President. However, it has not yet been implemented due to short-comings in the legislation that needed to be addressed.

Figure 6: Structure of SAHPRA (Adapted from Gouws, 2015)



The amendment Act 14 of 2015 was created to address the short-comings in Act 72 and to enable the strengthening of SAHPRA. It was approved by Cabinet & Parliament and signed by the President. Implementation is pending. Act 14 provides for the establishment of the Board and its functions and responsibilities. It also provides for the recognition of work done by selected regulators to create efficiencies in the regulatory process (Gouws, 2016). It is hoped that the new structure will increase the capacity needed to register products and timely approve amendments to registered products to allow better access to medicines.

Even the most innovative technology or product is useless without a successful business model to ensure effectiveness of market access and creation of value. Likewise, the business model of SAHPRA needs to ensure that the service offering is provided to create value for stakeholders. The business model should articulate the value created through the service offering of the organisation, define the specific market to which the value is aimed, identify efficient revenue generation and result in a competitively value-adding service (Chesbrough, 2010).

2.6.2 Medicines Regulatory Harmonisation

The United States Food and Drug Administration (2015) defines medicines regulatory harmonisation as the “process by which technical guidelines are developed to be uniform across participating authorities” (para 1), while regulatory convergence is the process by which “regulatory requirements across countries or regions become more similar or aligned” (para 1). These processes involve the adoption of global standards on medicines regulation and governance, including regulatory mechanisms, standards and regulations (United States Food and Drug Administration, 2015).

Medicines regulatory authorities in developing countries often lack the human, financial and infrastructural resources to enable adequate regulation of medicines. Medicines regulatory harmonisation and convergence enables better utilisation of resources available and a more efficient output for medicines regulatory authorities. It involves sharing of information and technology, enabling a more efficient registration and regulation process and resulting in improved access to quality medicines for the public (World Health Organization, 1999).

Many regional medicines regulatory harmonisation groups exist worldwide, including the Association of South-East Asian Nations, Asia-Pacific Economic Cooperation, Gulf Cooperation Council, Pan American Health Organisation and Southern African Development Community (SADC), of which South Africa is a member (Lakkis, 2012). The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was formed in 1990, involving Europe, Japan and the United States. It was formed to reduce duplication of medicines registration requirements and align registration processes to enable more efficient access to medicines for the public. ICH guidelines are an internationally recognised standard (International Convention on Harmonization, 2010).

Research conducted by Narsai, Williams and Mantel-Teeuwisse in 2012 involving 33 representatives from pharmaceutical companies in South Africa found that some companies resisted exportation of products to other countries due to the costs and time involved in the registration of medicines in these countries. Results also showed that 82% of research participants were in favour of harmonisation of medicines legislation (Narsai, Williams & Mantel-Teeuwisse, 2012). However, medicines regulatory harmonisation has not been successfully achieved in the SADC region yet, due to factors including different organisational capacities and resources of the regulatory authorities (Lakkis, 2010).

Globalisation and increasing need for innovation has created a necessity for medicines regulatory harmonisation. Harmonisation of regulatory activities with other recognised authorities benefits all stakeholders as resource utilisation is maximised, expertise may be drawn upon from other more resourced countries and the efficiency of medicines regulatory authorities increases to expand access to markets for pharmaceutical companies. This results in cost reduction to the healthcare system and better access to safe, effective medicines to the public (Narsai, Williams & Mantel-Teeuwisse, 2012).

2.7 Governance

The United Nations defines governance as the exercise of political, economic and administrative authority in the management of a country's affairs at all levels (United Nations, 2012). It comprises of "the complex mechanisms, processes and institutions through which citizens and groups articulate their interests, mediate their differences and exercise their legal rights and obligations" (Siddiqi, Masuda, Nishtar, Peters, Sabri, Bile & Jama, 2009, p. 14). Health systems governance involves the rules, leadership and stewardship that allow the "promotion and protection of health" (Siddiqi et al., 2009, p. 14) of a society, resulting in better treatment outcomes.

Although there are many challenges in finding an exact definition of governance, it is clear from the literature that at the heart of good governance is transparency, lawfulness, stakeholder relations and accountability (United Nations, 2012). Siddiqi et al. (2009) proposed ten elements for assessing good healthcare governance, including "strategic vision, participation and consensus orientation, rule of law, transparency, responsiveness, equity and inclusiveness, effectiveness and efficiency, accountability, intelligence and information and ethics" (p. 13). Good governance promotes growth of the economy and development of a country (Siddiqi et al., 2009). It involves steering a system in a direction that enables efficient regulation and monitoring for a particular purpose, such as effective healthcare of the population. Fundamental values of governance include public good, the rule of law and protection of human rights (Barbazza & Tello, 2014).

Governance involves a "network of actors" (Robichau, 2011, p. 118) and management of relationships with key stakeholders to achieve strategic goals. Not only shareholders, but all stakeholders need to be engaged in order for the organisation to achieve its goals. It is therefore important for effective public relations to provide a

framework for governance to align to shareholder and stakeholder needs (Kim & Kim, 2016).

Tools used for governance involve relationships of “control, coordination, collaboration and communication” (Barbazza & Tello, 2014, p. 8). Hierarchy is often used as an effective governance tool, while “governance by markets” (Robichau, 2011, p. 124) describes another tool of governance, in which public-private partnerships and collaboration between government or regulators and the private sector leverages strengths and enables better management. Kim and Kim (2016) proposed a theoretical framework of a corporate governance strategy using public relations. Kim and Kim (2016) found that an effective communication strategy is vital for “buffering” (p. 123) against risks that external stakeholders will negatively affect operations, while “bridging” (p. 123) aligns value offering of an organisation to trends and stakeholder needs.

Collaborative governance involves governance through the formation of inter-organizational collaborations. Vangen, Hayes and Cornforth (2015) argued that through horizontal integration, rather than a vertical focus of top-down management and hierarchical power, collaborative governance is a more effective method of regulation. This analysis is in line with Emerson and Nabatchi’s view on collaborative governance, as an effective way to integrate stakeholder views and reduce risks in the formation of policies (Emerson & Nabatchi, 2015).

Collaborative governance has been known to increase social capital and regulatory compliance. However, there is limited literature on the measurement of effectiveness of “cross-boundary collaboration” (Emerson & Nabatchi, 2015, p. 719). The collaborative governance framework created by Emerson, Nabatchi and Balogh (2012), as presented in Figure 1, included elements of principled engagement, capacity for joint action and shared motivation as collaboration dynamics, along with drivers that lead to action and impact. This may be applied to the pharmaceutical industry system’s context. However, the model neglects various elements including adaptation of policies, as well as the importance of leadership in collaborative governance.

This shortcoming was addressed later to some extent by Emerson and Nabatchi (2015), who developed a matrix to conceptualise and analyse the creation and implementation of policies through collaborative governance, as presented in Table 1 below. The matrix uses the performance levels of actions, outcomes as well as adaptation of collaborative governance regimes.

**Table 1: Performance Dimensions of Collaborative Governance Regimes
(Adapted from Emerson & Nabatchi, 2015)**

Unit of Analysis/ Performance Level	Participant Organisation	Collaborative Governance Regime	Target Goals
1. Actions/ Outputs	Efficiency	Efficacy	Equity
2. Outcomes	Effectiveness	External Legitimacy	Effectiveness
3. Adaptation	Equilibrium	Viability	Sustainability

This matrix is useful in the analysis of collaborative governance regimes and may be used to enhance the research through understanding of the performance indicators influencing collaborative governance in the pharmaceutical industry. The “Performance Dimensions of Collaborative Governance Regimes” in Table 1 highlights that governance and policies must be efficient, effective and equitable. It also shows that in order to ensure adequate adaptation, policies must be viable and sustainable (Emerson & Nabatchi, 2015). Sustainability through stakeholder engagement is essential. A focus on structures, processes and actors is imperative when allocating resources and directing collaborative operations (Vangen, Hayes & Cornforth, 2015). Although the literature effectively examines the need for stakeholder collaboration in governance processes, it fails to incorporate the elements of governance that will lead to innovation, which is vital to the sustainability of any organisation and industry.

2.8 Stakeholder Theory

Stakeholders are “any group or individual that can affect or is affected by the achievement of a corporation’s purpose” (Freeman, 2004, p. 229). It is important, therefore, to include all parties that will be affected by the implementation of a new policy or disruptive technology in the decision-making process. This will improve buy-in and uptake as well as enable stakeholder needs to be met. Stakeholder opposition may result in the failure of an initiative if sufficient collaboration and discussions have not been held (El-Gohary, Osman & El-Diraby, 2006).

The Semantic Model describes stakeholder interaction in a project. Five main elements were listed, including processes, products, constraints, actors and resources (El-Gohary, Osman & El-Diraby, 2006). Stakeholders involved in medicines regulation are

pharmaceutical companies who produced the medicines and own the intellectual property rights of the medicines, regulatory authorities that register the medicines and patients that use the medicines. In addition, other healthcare organisations that hold a significant stake in the registration of medicines include the Department of Health, private hospitals and other healthcare providers, as well as civil society.

A study conducted by Toyo (2012) involved an analysis of 13 respondents from 7 healthcare firms to assess their response to the disruptive change of the introduction of National Health Insurance to South Africa. It was found that the firms would aim to strengthen government relations, build capacity and improve their product offering (Toyo, 2012). This study showed that stakeholder relations, and particularly interaction between industry and regulators is imperative for change management and the adaptation to environmental trends.

To enable competitive advantage for an organisation in an industry, it is imperative to identify the relevant stakeholders involved in the lifecycle of a product. Stakeholder importance varies over time and it is important to ensure “transformational adaptation” to changing environmental needs with regards to stakeholder management (Verbeke & Tung, 2013). In the pharmaceutical industry, even once a regulatory authority has registered a medicine, post-marketing surveillance is needed to ensure lifecycle monitoring of the product (Meijer, Boon & Moors, 2013). For this, engagement with civil society is needed for a more bottom-up approach in post-marketing surveillance, which was proved effective by Meijer, Boon and Moors (2013) for the early introduction of HIV medicines in the Netherlands.

It was argued by Meijer, Boon and Moors (2013) that stakeholders involved in the regulation of medicines should not be limited to experts in the field. “Lay stakeholders” also have the ability to contribute to the field and that regulations should be created democratically. There has been increasing worldwide concern over the quality of regulation of medicines, due to fatal incidences and subsequent withdrawal from the market of medicines such as Vioxx (Meijer, Boon & Moors, 2013). The public has shown contempt towards the secrecy involved in medicines regulations and called for greater transparency. Although lay stakeholder involvement does not necessarily lead to improved regulatory processes, it improves satisfaction and trust in regulations of medicines (Meijer, Boon & Moors, 2013). It is therefore imperative to include all stakeholders involved in pharmaceutical regulations when creating regulations and processes to govern medicines.

The focus on patients as stakeholders in medicines regulation is important but their preferences are often overlooked in policy-making. This includes decisions relating to pharmaceutical coverage and clinical guidelines. There has been a raised awareness of the importance of patient preferences in policy-making worldwide. Increased focus on patients as a key stakeholder groups has been found to increase legitimacy of decisions made by regulatory authorities and the pharmaceutical industry (Utens, Dirksen, van der Weijden & Joore, 2016).

2.9 Organisational Development and Change

With globalisation and rapid technological development, change is inevitable and an integral part of the competitiveness and relevance of an organisation. Organisational Development is defined as “a system-wide application and transfer of behavioural science knowledge to the planned development, improvement, and reinforcement of the strategies, structures, and processes that lead to organization effectiveness” (Cummings & Worley, 2015, p. 2). Diagnosis of organisations involves an analysis of the environment in which an organisation exists, its strategy including its organisational structure, human resources, technology resources and management processes as well as the resulting organisational culture. The diagnosis involves an analysis of organisational effectiveness, including financial performance, productivity and stakeholder satisfaction (Cummings & Worley, 2015). This diagnostic model is shown below in Figure 4.

Figure 7: Organisation-Level Diagnostic Model (Cummings & Worley, 2015)



An organisational-level diagnosis of the MCC is important to establish the environment in which it operates, its resources and design components, culture and strategy and the resultant organisational effectiveness in terms of productivity and pharmaceutical industry stakeholder satisfaction. This provides a foundation for the change management process to be conducted on transformation to SAHPRA.

Kurt Lewin developed a model of planned change involving the three-step model of “unfreezing”, “moving”, then “refreezing” (Burnes, 2004, p. 986) behaviour of individuals to allow adaptation of a new culture and method of thinking. However, it is argued that this is a simplistic ideology that assumes organisations are relatively static. Organisations need to adopt continual change and developing a culture of flexibility to align to the environment (Burnes, 2004). This holds through for the medicines regulatory authority in its transition from the MCC to SAHPRA.

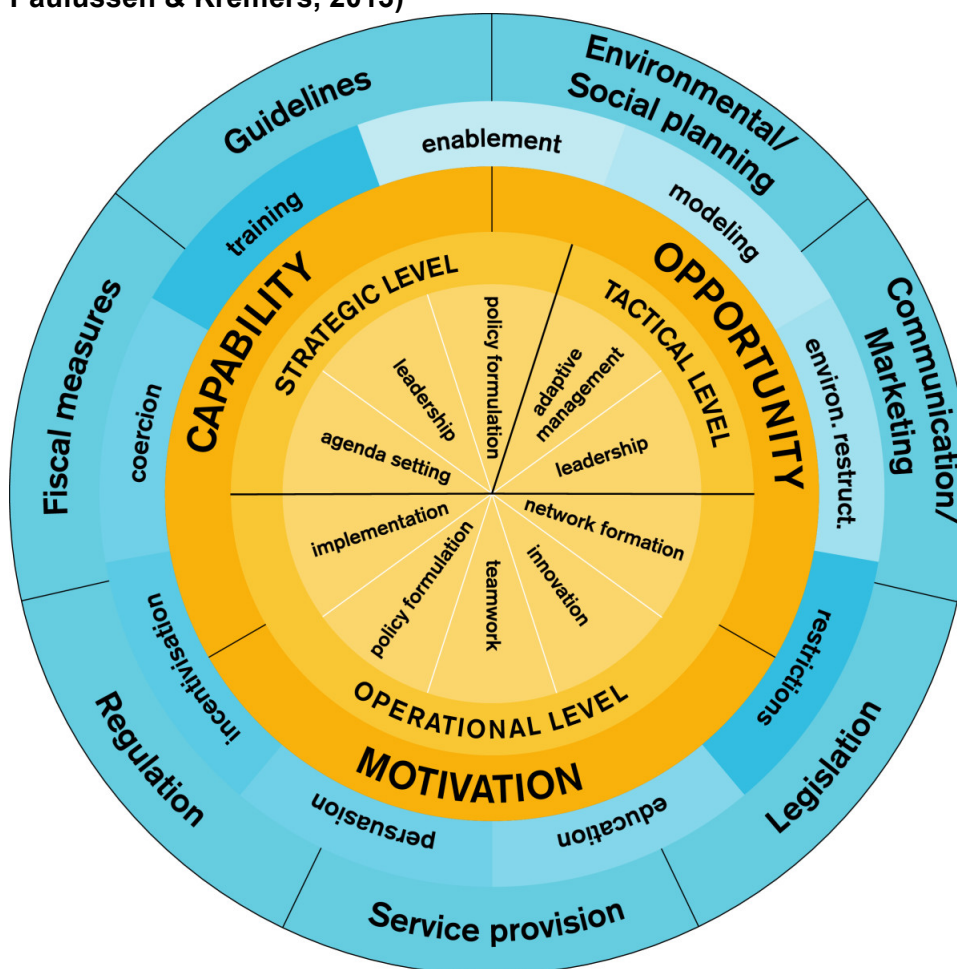
The “Positive Model” of change involves identification and retention of the organisation’s strengths. It assumes that employees respond more favourably to change if it is believed to be positive. The model involves a redirection of energy into identifying problems, assessing best practice and envisioning and aspiring to achieve these best practices (Cummings & Worley, 2015). This may be in the form of benchmarking against other companies with which the organisation will aim to align itself with. Cultural stagnation must be avoided to enable a flexible and adaptive organisation that can change with the changing environment surrounding it (Burke, 2013).

With the MCC moving away from a government entity to a larger Section 3A public entity with its own governance structure, change management is essential to adapting to its new corporate environment. Organisational change involves taking the organisation in a new direction and significantly altering the organisational structure and processes (Burke, 2013). The literature has limited reference to the role of motivational factors in behavioural change for public health policy-making. As the literature on behavioural change for government and regulatory organisations is limited, it is important to understand the factors that influence change in the formation of public policies.

Business model innovation is vital for the success of any organisation. Strong leadership within organisations is needed to ensure organisational change and constant business model reinvention to align with changing environmental needs (Chesbrough, 2010). Chesbrough (2010) found that, in order to achieve successful business model innovation, organisations need to appoint leaders internally to manage and be accountable for the delivery of ambidexterity of the organisation and effectuation of the business model.

Hendriks, Jansen, Gubbels, De Vries, Paulussen and Kremers (2013) created a behaviour change ball, as shown below in Figure 8, that includes multiple elements of organisational behaviour of policy-makers, includes factors that influence policy-making and methods of influence. Both individual and organisational change theories were applied to develop an integrated model with which to analyse policy-making (Hendriks, Jansen, Gubbels, De Vries, Paulussen & Kremers, 2013). This may be applied in this research to the creation of medicines regulatory policies. However, this model does not highlight the need for stakeholder engagement in organisational change and policy-making. This is an important variable and will be examined in this research.

Figure 8: The Behaviour Change Ball (Hendriks, Jansen, Gubbels, De Vries, Paulussen & Kremers, 2013)



2.10 Conclusion

The literature review provides a theoretical framework for analysis of stakeholder perceptions of the medicines regulatory authority. Of importance, stakeholder engagement was found to be a key element of governance (Robichau, 2011). The importance of open innovation and barriers to creativity in the pharmaceutical industry due to regulations are highlighted (Wu, Little & Low, 2016).

Through an Open-Systems Model, as created by Cummings and Worley (2015), the pharmaceutical industry would be able to receive feedback from stakeholders and the environment to produce innovative outputs, as in Figure 2. Operating in an open system enables legitimacy of institutions and trust between them and stakeholders (Doy & Guay, 2006). Porter's Diamond Model shows that competitive advantage of clusters within an industry involves factor conditions and resources (Porter, 1990). However, Porter does not include the factor of public governance that affects industry competitiveness (Fainshmidt, Smith & Judge, 2016). Aligned with cluster theory is the theory of co-opetition, where competing companies in an industry form strategic alliance to combine resources, enabling better research and development, innovation as well as risk mitigation (Kozyra, 2012).

Ambidexterity of the pharmaceutical industry is vital for sustainability and competitiveness, with the need to align to environmental trends and needs (O'Reilly & Tushman, 2011). Open innovation and co-opetition would enable the pharmaceutical industry to adapt to disruptive technology and increase capacity for innovation (Li, Zheng & Wang, 2016). This was researched by Guler and Merkar (2012), who showed that local collaboration improved organizational performance. However, this research failed to take into account how governance of the regulatory authority could enable innovation and affect organizational performance.

Most research on public policy is focused on private organisations and not governmental or regulatory institutions (Hendriks, Jansen, Gubbels, De Vries, Paulussen & Kremers, 2013). Although organizational theory may be applied universally to all organisations, the context in which the medicines regulatory authority operates is markedly different to that of private organisations. The medicines regulatory authority operates in a highly dynamic and complex environment, and must therefore maintain high levels of governance to ensure transparency, lawfulness and accountability (United Nations, 2012). The regulatory authority needs to work with

stakeholders to create a collaborative governance system to increase acceptance of policies and regulatory compliance (Emerson & Nabatchi, 2015).

The literature has shown that in order to effectuate policy, collaborative governance and change management is essential. Although broadly researched, the areas of governance and stakeholder management have not incorporated the element of enabling innovation. The literature also fails to integrate the roles of the regulator and other stakeholders to allow collaborative governance in order to creating policies to enhance innovation in an industry. It also does not account for structural changes to the extent of moving from a government department to a semi-private organisation.

The research conducted is used to fill gaps in the literature through the analysis of perceptions of stakeholders in medicines regulations, and subsequent formation of the optimal governance structure for the medicines regulatory authority to enable innovation. Drawing on the literature and theories around the research topic, the research report conceptualises the methodology to answer research questions. Chapter 3 outlines the questions that were answered in the research conducted, in order to create an optimal governance framework of the medicines regulator to allow approval and adoption of innovation in the pharmaceutical industry. The research addresses the gaps in literature and theory surrounding regulatory governance and stakeholder theory to enable innovation.

Chapter 3: Research Questions

3.1 Introduction

The literature review outlined the need for collaborative stakeholder engagement in the governance of the medicines regulatory authority to enable innovation within the pharmaceutical industry. The need for efficient stakeholder interaction in the decision-making process was established and it is clear that with the move of the MCC to SAHPRA, adequate change management processes to enhance policies through consultation with the external stakeholders within the industry is key to success.

From the literature review as presented in Chapter 2, research questions were developed intended for qualitative open-ended interviews of industry experts, current and previous members of the MCC and senior managers of pharmaceutical companies involved in regulatory activities. Analysis of the results of the research questions allowed creation of the optimal governance framework and stakeholder engagement needed to allow efficient approval and adoption of innovation in the pharmaceutical industry.

3.2 Research Questions

Research Question 1: What is the perception of stakeholders on the interaction between the current medicines regulatory authority (MCC) and other stakeholders in the industry?

Research Question 2: What would be the optimal stakeholder interaction process for the new medicines regulatory authority (SAHPRA)?

Research Question 3: How have decisions made by the medicines regulatory authority affected responsible innovation in the industry?

Research Question 4: What would be the optimal framework for governance of SAHPRA to enhance innovation in the pharmaceutical industry?

Chapter 4: Research Methodology

4.1 Research Design

The research was qualitative, due to the lack of research around the subject, and exploratory, due to the future focus of the subject, in design. Although research exists regarding governance and stakeholder engagement, the combination of the two and inclusion of innovation components was not found by the researcher. Exploratory studies enable the development of new insights from theory and were appropriate for this study as the topic was relatively unknown by the researcher (Saunders & Lewis, 2012). The data was extracted over a short period of two months, which was a cross-sectional study.

According to Singh (2015), qualitative research use in the management sciences is increasing, with growing need for evidence-based knowledge to enable decision-making and create organisational improvement. Qualitative research allows the inclusion of philosophy in theory building and analysis of multiple opinions on a subject. It also enables use of case study analysis and perceptions to guide formation of frameworks and theories (Singh, 2015).

A qualitative research design enables the use of expression and perceptions of interviewees to deduct concepts and to draw theory from the data extracted in the form of opinions and experiences. Perceptions of participants in qualitative research may be used to provide insights into theory not readily available or that has not been studied extensively. Written and verbal accounts of experiences may be analysed qualitatively to enable isolation themes and form theories and frameworks (Klag & Langley, 2013).

A qualitative deductive approach to the research was used. A deductive research approach is defined as “testing of a theoretical proposition by using a research strategy designed to perform this test” (Saunders & Lewis, 2012, p. 108). It was a useful technique for the purposes of this research, as prior theory derived from the literature was tested according to results obtained from the data collection process. Deductive research may be used when the “premises and the conclusion of the inferences are assumed to be uncertain” (Politzer & Baratgin, 2016, p. 78) and where prior theory is tested and use to create further theory, such as in the development of frameworks. This was a useful qualitative method for analysis of the perceptions identified from the

research participants, as a framework for optimal governance of the regulatory authority, could be inferred.

4.2 Universe

The universe of relevance included the stakeholders involved in the provision and regulation of pharmaceutical products.

Key informants from the following stakeholder groups were used:

1. Current and previous decision makers of the Medicines Control Council (MCC)
2. Industry experts involved in policy formulation from academia, consultant institutions and Non-Governmental Organisations (NGOs)
3. Senior managers of pharmaceutical companies involved in regulatory activities

4.3 Sampling

Purposive and snowball sampling was used, which was non-probability in nature. Purposive sampling is used where the researcher actively selects samples based on predetermined criteria, which was useful in this study to enable generalisations to be made (Saunders & Lewis, 2012). The number of interviewees was 12. This number was tailored according to the point that data saturation was reached, and when no new codes were formed.

As the research conducted was qualitative in nature, the sample size was relatively small, including senior decision makers and experts in the regulation of medicines in South Africa. The sample was taken over three stakeholder groups, including from the current medicines regulatory authority, pharmaceutical industry and experts in the industry, in order to gain unbiased and broad perspectives. Table 2 below depicts the numbers from the three stakeholder groups that were interviewed:

Table 2: Number of Interviewees of Each Stakeholder Group

Stakeholder Group	Number of Interviewees
1. Current and previous members of the MCC	3
2. Industry experts involved in policy formation	4
3. Senior managers of pharmaceutical companies	5

4.4 Unit of Analysis

The unit of analysis for the research was the perceptions of individuals involved in the pharmaceutical industry who are affected by or affect policies or decisions of the medicines regulator, as listed in Section 4.2.

4.5 Measurement

4.5.1 Research Instrument

Semi-structured, one-on-one interviews with standardised, open-ended questions were used, based on the Research Questions presented in Chapter 3. In-depth interviews are an ideal method of conducting exploratory research, allowing formation of themes from perceptions of interviewees (Saunders & Lewis, 2012). As limited research has previously been performed on the topic, this presented an ideal method of research. In-depth interviews with the three different sample groups, including members of pharmaceutical companies, industry experts and the MCC, were used. The unstructured interview method was useful, as the nature of the research was explorative in design (Welman, Kruger & Mitchell, 2007).

Interviews were conducted at a location convenient for the interviewee, mostly at their work place or at a café. Individuals were identified by the researcher and contacted via email to be invited to participate in the research. The topic and purpose of the research was explained and a convenient time and place for the interview was arranged. Prior to the interview being conducted, participants were provided with an information sheet detailing the ethical and confidential nature of the research, then asked to sign a consent form before beginning the interview.

Different interview guidelines, which were aligned to research questions in Chapter 3, were used for each group, which are provided in Appendices 1 to 3. These guidelines were piloted to determine acceptability, validity and reliability of the method. The pilot testing used was chosen out of convenience and questions in the interview guidelines were adjusted upon feedback from the pilot sample.

4.5.1.1 Data Collection Tool

The semi-structured interviews involved the use of Interview Guidelines, presented in the Appendices, which were adjusted slightly for each of the three stakeholder groups. Interview Questions were developed from the four Research Questions presented in Chapter 3. These are presented below in Table 3.

Table 3: Research Question and Interview Guideline Mapping

Research Questions	Interview Questions
Research Question 1 What has been the perception of stakeholders on the interaction between the current medicines regulatory authority (MCC) and other stakeholders in the industry?	1. Who are the stakeholders involved in the approval and adoption of medical technologies and new pharmaceutical products?
	2. What are your experiences in dealing with the other stakeholders, in particular the pharmaceutical industry and MCC?
Research Question 2 What would be the optimal stakeholder interaction process for the new medicines regulatory authority (SAHPRA)?	5. What do you think should be the optimal format for stakeholder engagement with other stakeholders for SAHPRA?
	6. Are there other stakeholders who should be involved in the regulation of medicines who are not being involved?
Research Question 3 How have decisions made by the medicines regulatory authority affected responsible innovation in the industry?	3. How do you think regulations have affected pharmaceutical companies to innovate, including products and processes)?
	7. How could the medicines regulatory authority better enable innovation in the pharmaceutical industry?
Research Question 4 What would be the optimal framework for governance of SAHPRA?	4. How do you think the current MCC governance structure and processes could be improved?
	8. What will the optimal governance framework be for SAHPRA to enable better stakeholder interaction and innovation?

4.5.1.2 Pre-testing

Interview guidelines were piloted using two interviews with senior regulators from pharmaceutical companies. Piloting of interviews enables objective assessment of the reliability and validity of the research method, enabling adjustments to be made to improve quality of the method (Saunders & Lewis, 2012). The pilot interviewees identified ambiguous or confusing questions. The interview guidelines and language were then adjusted according to suggestions given by the pilot interviewees.

4.5.2 Data Gathering Process

Conducting semi-structured interviews is an ideal method of performing exploratory research, as they provide structure, while still allowing flexibility (Cooper & Schindler, 2012). The process involved in-depth, face-to-face and Skype interviews. Interview guidelines with prior themes extracted from literature and that were aligned to the research questions in Chapter 3 were used to provide structure and ease of

comparison but still allowing freedom of expression and new emergent ideas to be generated (Cooper & Schindler, 2012).

Due to the qualitative nature of the research method, the researcher's biases and experiences may have had an impact on the questions asked and results derived from the interviews. Recognising this, biased questioning was avoided and participants were encouraged to define the content of the interviews. The interview guidelines provided a framework for the interview, while allowing freedom for the interviewees to determine the content of the interview. The researcher led the interview and ensured that the content remained relevant to the research topic.

The researcher performed an introduction to the research and explained the main themes being analysed, including definitions used. The main content around governance, stakeholder interaction and innovation in the pharmaceutical industry was highlighted. Informed consent was obtained prior to commencement of the interviews. Eight open-ended, unbiased questions were asked of the research participants and allowed emergence of themes and constructs. The researcher ensured that interest and respect was shown throughout the interview, and that experiences and perceptions were documented using hand-written notes, while still maintaining eye contact to ensure engagement with the participants. Interviews were digitally recorded to enable analysis, along with the hand-written notes, following the research.

The data collection and analysis processes was performed as follows:

1. The interview guideline was piloted with a small group of people knowledgeable of the research process;
2. Key stakeholders were approached to be invited to participate in the study;
3. Participants were put at ease and the process of confidentiality was explained;
4. Interviews were conducted;
5. Interviews were recorded electronically;
6. Recorded interviews were analysed.

Most participants that were approached for the research were enthusiastic and willing to give of their time to be interviewed. Some participants seemed reserved and guarded when answering questions in order to represent their organisation correctly. Only a small number of members of the regulatory authority were willing or able to be interviewed, possibly due to the sensitive political nature of the change management from MCC to SAHPRA. The response rate was 1 in 2 people who were approached.

4.5.3 Analysis Approach

Theoretical and analytical codes were identified from repeated themes in the interviews, and were grouped into concepts and categories. The most important process in the qualitative research is identification of themes, which are identified throughout the process of the research (Welman, Kruger & Mitchell, 2007). Common emerging themes and patterns were noted, as well as those that appear to be outliers to results. Content analysis and interpretation of results compared to theoretical propositions were performed, which allowed formation of emergent themes (Saunders & Lewis, 2012). A proposed governance framework was then created using emergent themes.

During the interview stage, constant analysis of emergent themes was performed by the researcher, allowing linking of concepts through the lens of the literature presented in Chapter 2. A more detailed analysis of themes from the interviews was performed in the post-interview period. Here, recorded interviews and notes taken were analysed by the researcher in detail and structured according to the order in which the questions were asked, in order to fully explore emergent insights. Interesting quotations provided by the interviewees pertaining to the resultant themes were noted.

Time taken to analyse interviews varied from 4 to 6 hours each, depending on the actual length of the interview and complexity of responses by the interviewee. Recorded interviews were repeatedly listened to and linked to the notes taken by the researcher during the interviews.

Codes are used to make sense out of raw data and assign sense to it (Welman, Kruger & Mitchell, 2007). Once analysis on a question-by-question basis of each interview was completed, codes were collated. These were used to organise information derived from the interviews into a coherent set of themes. Statistical analysis of qualitative data is useful to display information in a quantifiable manner, such as identifying the frequency of occurrence of themes (Welman, Kruger & Mitchell, 2007). A frequency table in Microsoft Excel was constructed for each of the 8 interview questions according to emergent themes in each interview. Ranking was performed according to the frequency of emergence of each theme from the interviews. The ranked themes were then analysed according to the research questions to which the interview questions were linked.

4.6 Limitations

Validity indicates that a method measures what it is intended to and the research findings are directly linked to the research objective. Reliability indicates that the method used is repeatable to allow results that are consistent (Saunders & Lewis, 2012). Interpretation of results may have been skewed due to bias of the researcher's expectations. Unstructured interviews involve the researcher's direct involvement and therefore may lead to bias (Welman, Kruger & Mitchell, 2007).

Non-probability sampling by its very nature may also have led to respondents' views not necessarily representing those of the population of interest. In order to limit bias, interview guidelines were standardised and piloted prior to implementation. Participants were given freedom to determine the content of the interview, while the interview guidelines were used to provide a framework and direction for the broad subject of each question.

Limitations included the fact that the research assessed opinions of stakeholders and situations may evolve differently to expectations of participants in the research. In addition to this, qualitative research is in itself subjective and at risk of being affected by the researcher's bias and experiences (Saunders & Lewis, 2012). Other limitations identified included the following:

- As the movement of the medicines regulatory authority to become a Section 3A public entity is in the future, opinions may change as the situations change.
- The researcher was not an expert in interviewing, which may have led to an impact on results.
- Samples were chosen out of convenience and do not necessarily represent the views of all stakeholders involved in the pharmaceutical industry.
- The three stakeholder groups chosen were not necessarily all of the stakeholders involved in medicines regulation and therefore scope was narrow.
- Members of the stakeholder groups chosen may have been biased in their experiences and not necessarily representing opinions and experiences of all members of the stakeholder groups.
- A limited number of the regulatory decision-makers were available to be interviewed. Some members of pharmaceutical associations and regulatory authority refused to participate due to the sensitive nature of the research topic or time constraints.

4.7 Ethics

Ethics approval was obtained from the Gordon Institute of Business Science and the University of Pretoria's Health Sciences Ethics Committee. The research carried a low risk and approval to use data was sought on interview of the research participants.

Chapter 5: Results

5.1 Introduction

This chapter provides results from the in-depth interviews that were conducted. The data was analysed according to research questions and opinions were captured and interpreted qualitatively, as outlined in Chapter 4. Results were grouped according to the three different study sample groups that participated in the interviews.

5.2 Sample Demographics

Three stakeholder groups were identified by the researcher and participants invited from each group. These included current and previous decision-makers from the MCC, senior managers of pharmaceutical companies involved in regulatory activities and industry experts involved in policy formulation. The demographics of the sample are included below in Table 4.

Table 4: Information on Interviewees

Stakeholder Group	Number of Interviewees
1. Current and previous members of the MCC	3
2. Industry experts involved in policy formation	4
3. Senior managers of pharmaceutical companies	5

5.3 Presentation of Results

Results are presented in Chapter 5.4 according to the Research Questions posed in Chapter 3 and questions from the Interview Guideline in Appendices.

5.4 Results for Research Question 1

Research Question 1: What is the perception of stakeholders on the interaction between the current medicines regulatory authority (MCC) and other stakeholders in the industry?

The aim of Research Question 1 was to identify the experiences of key stakeholders in the pharmaceutical industry on interaction with the MCC and other stakeholders identified. The interview questions pertaining to this Research Question were constructed to understand the frustrations and satisfactory elements that the key stakeholders found to be present when contacting and working with the current

medicines regulator. The qualitative open-ended question used during the interviews provided data to enable the development of perceived themes of stakeholders involved in the regulation of medicines, as presented in Table 5 below.

5.4.1 Important Stakeholders in the Pharmaceutical Industry

Table 5: Perceptions of Stakeholders Involved in Regulation of Medicines

Rank	Construct	Frequency
1	Pharmaceutical companies	9
2	Regulators/ academics	8
3	Other government departments	5
4	Professional associations and practitioners	3
5	Other medicines regulatory authorities	2
5	Civil action groups	2
6	Public/ patients	1
6	Distributors	1

The major themes that emerged were that pharmaceutical companies and academics or external regulators were the main stakeholders involved in the regulation of medicines. Another theme that emerged from the interviews was the involvement of other government departments as major stakeholders in the process. For example, one MCC member stated: “from an essential medicines point of view, the Department of Health is a main stakeholder because essential medicines are rushed through the process”. Another MCC member stated: “the mandate of the public health system is to allow all stakeholders to understand what is happening in the regulatory environment or stakeholders to at least understand the basis for the regulator’s decision”. The member also stated, “The regulator has an important role in supporting enabling access to priority public health medicines and that includes drugs that are intended for priority diseases”.

Some interviewees highlighted the need to include patients as stakeholders in regulation of medicines, while others discussed that it was not the role of the regulatory authority to include patients into decisions. Although interviewees had different perceptions of the stakeholders that were taken into account when regulating medicines, most noted that more stakeholders should be included in the process, as discussed in Section 5.5.2.

5.4.2 Understanding Experiences of Interaction with Stakeholders

Table 6 below identifies the themes that emerged from the interviews with regards to experiences of interaction with stakeholders.

Table 6: Experiences of Interaction with Stakeholders

Rank	Construct	Frequency
1	Administrative inefficiencies eg Long time-lines for registration	11
2	Frustration/ lack of trust/ loss of respect from industry towards the MCC	8
2	Poor communication from MCC	8
3	Lack of transparency and commitment from MCC	6
4	Good, structured dialogue between MCC and industry through trade associations	5
4	Good guidelines and high trust in robust standards	5
4	Unwillingness to cooperate and give feedback from MCC	5
5	Industry produces poor applications sometimes and does not support MCC with comment on guidelines	3
5	Issues raised with MCC not addressed	3
6	Standards inconsistent with capacity eg different evaluators give different responses	2
7	Lack of clarity of policies and alignment of Act, regulations and guidelines - poor interpretation by MCC and industry	1
7	Lack of support of regulatory departments by management in industry	1
7	Industry and MCC working together to avoid a credit rating downgrade	1
7	Feelings of persecution from MCC's side	1

Most themes that emerged indicated the experiences of stakeholders with the MCC, while the two highlighted themes in Table 6 above signified experiences within the pharmaceutical industry. These two themes included that pharmaceutical companies sometimes produces poor applications and does not provide comment to the MCC guidelines, as well as that there was a lack of support of regulatory departments. Significant emphasis was placed by many interviewees on the lack of trust between the pharmaceutical industry and medicines regulatory authority, emerging as a main barrier to communication between the two stakeholders. One regulatory pharmacist stated: “There is a trust issue because of the past experiences that [industry] has had and you cannot really blame industry”. Another expert in the pharmaceutical industry stated: “Because the reputation in the past has not been great, we go there with some sort of reservation [as industry]”.

All participants saw administrative inefficiencies, such as long timelines for registration of products, as weakening the relationship between the industry and MCC. One industry expert stated: “The basic problem is inefficiencies - that is the heart of the problem. And I don't think it's any one person's fault. You are sitting with an authority that hasn't got the resources to do what it did 40 years ago”. A member of the MCC stated “Sometimes medicines take long to be registered because of various issues. It could be that the list of questions that is asked by the regulator requires the applicant to do more work and that could justify a reason for a longer registration timeline. But if it is simply sitting in a backlog and no one has looked at it, then clearly that's a problem”.

The MCC was seen by many interviewees as lacking the resources to enable sufficient communication with the industry. As one regulatory pharmacist stated: “The MCC does not have the capacity to evaluate”. Interviewees from the MCC also noted this theme. One regulator from the MCC stated: “Industry has been disappointed with the performance... of the MCC... We've got a bit of a bad reputation - we have a backlog... From the regulator there is a big need and a promise to improve... That is what has been communicated to industry and it has been well-received”. To add to this, a member of the MCC stated, “You need a proactive approach to ensure that stakeholder relationships are always maintained at a level that is seen as productive for public health”.

It was agreed by many interviewees that the MCC adhered to high standards that are “world class”. Some interviewees cited that the level of engagement from the MCC was sufficient. One participant stated: “My view is that [the MCC] does engage pharmaceutical industry - it is a structured engagement”. Another pharmaceutical industry expert stated: “[The MCC has] actually invited industry in to come and discuss and come up with suggestions and to soundboard what they are planning to do going into the future”.

The Industry Task Group (ITG) is an industry association that is comprised of various pharmaceutical associations that meet with the MCC frequently. Although some interviewees believed there was good consultation and structured dialogue through structures such as the ITG, there were perceptions that the MCC was at times unwilling to consider industry's agenda with regards to market access. One industry expert stated: “[the MCC] doesn't take account of industry's requirements. It doesn't understand industry's need to get products to market quickly... It doesn't feel obliged to

respond to that”. The MCC was seen by many interviewees as lacking consistency between evaluators’ regulatory decisions and clarity on guidelines and policies. It was also seen as not to always take into account suggestions made by stakeholders. One expert in the pharmaceutical industry stated: “we give our input but we're not sure it is going to be taken seriously”.

Although some participants cited that the industry was inherently collaborative, with the industry and regulatory authority working together to avoid a credit rating downgrade, many interviewees stated that the medicines regulatory authority did not have the capacity for sufficient consultation with the industry on decisions made with regards to regulatory policies. It was also noted that the pharmaceutical industry was not always sufficiently responsive with regards to guidelines and policies sent out for comment by the MCC. As one industry expert stated: “A lot of people [in industry] complain instead of taking ownership of something and doing something about it”. Another regulatory pharmacist stated that “Industry tends to go and consult on things that are important to them [at the time] and not when MCC asks for something. If they ask for something and we feel it is irrelevant at that time, then we don't comment. Meanwhile, it impacts us later on”. A regulatory from the MCC stated: “It takes two to tango... it's a two-way street” and that trust and collaboration is needed from both the pharmaceutical industry and MCC. Another expert in the pharmaceutical industry stated, “Industry needs to start realising that if you want to be a partner, you've got to put in effort and come up with viable proposals in line with what is happening internationally”.

5.5 Results for Research Question 2

Research Question 2: What would be the optimal stakeholder interaction process for the new medicines regulatory authority (SAHPRA)?

The aim of Research Question 2 was to determine the perceptions of stakeholders involved in the regulation of pharmaceuticals to the ideal method of interaction between the medicines regulator and stakeholders. The questions posed in the interviews intended to enable the creation of an optimal framework for stakeholder management for the new medicines regulatory body, SAHPRA.

5.5.1 Optimal Methods of Stakeholder Engagement for SAHPRA

Table 7: Optimal Stakeholder Interaction Methods

Rank	Construct	Frequency
1	Engagement through platforms such as ITG for most policy and guideline formation	9
2	Increased transparency of MCC operations	7
2	Allow a mechanism for company-specific engagement (sometimes ITG biased)	7
3	Increase engagement with industry eg workshops	5
4	Increase staff capacity for stakeholder engagement	3
5	Need policies to be implementable and clear	2
6	Engage with patients eg through media to advertise breakthroughs	1
6	Maintain stakeholder engagement structures as is	1

Most interviewees saw the ITG as an ideal platform for engagement with the medicines regulatory authority. Currently used for communication between the pharmaceutical industry and MCC, collaboration on regulations through the ITG was seen to continue to be a useful method of stakeholder engagement for the future SAHPRA. One regulatory pharmacist stated: “I think ITG is a good idea because if you have every company going with their thoughts, then you'll have... 60 companies probably giving the same idea. Whereas if you have ITG, companies meet together to decide what they want to propose and MCC can focus on the key issues. If everybody went with their own ideas then MCC would just be bombarded then they wouldn't know what is critical”. A medicines regulator from the MCC reiterated this theme, stating: “ITG is a fantastic forum for discussion because at ITG it's a regulator meeting and it's very thorough in the sense that you go through every single unit... And industry has the opportunity to ask questions”. Concern was raised around the lack of input of complimentary medicines and medical device companies in forums such as ITG, who “are not aware of the changes in regulations first of all, changes in the law, because they are not involved in these sorts of forums. So they are going to get a surprise... when they are being legislated and their products will be taken off the market”.

However, it was found by some interviewees that engagement through the ITG might sometimes be biased according to agendas of the individuals participating in the top leadership positions in the organisation. One expert from the pharmaceutical industry stated that with the ITG, “there is limited opportunity to speak to the authority and as a result everything gets condensed... to a few issues that then get fed through and there's no engagement on those issues... There's no fine tuning”. The expert also noted “the MCC should be represented by more senior people than who are doing it at

the moment. It should be administrative officers. It should be senior policy makers, maybe a committee member”. Another expert in the pharmaceutical industry stated: “It is just interaction with a selected group of people [at ITG]”. A member of the MCC stated: “It is clearly not ideal to use an ITG framework to address individual concerns because then you would find that framework would be overwhelmed by individual issues”.

A theme that emerged was the need to better enable company-specific interactions with the regulatory authority in the future, to address company or product-specific issues. One regulatory pharmacist stated: “If you're talking about a specific clinical trial or specific indication [for a product] you want to register... it would be confidential so would have to be between the company and MCC. I think if you are talking about variations or amendments in general then you can say it could go through ITG”.

One executive from a multinational pharmaceutical company stated: “From a pharmaceutical industry point of view I think we engage often with MCC and the same will apply with SAHPRA”. However, many interviewees noted the need for increased clarity on guidelines and policies, as well as more regular consultation between the pharmaceutical industry and SAHPRA than what is occurring between the pharmaceutical industry and MCC. One expert from the pharmaceutical industry stated that what “would be hugely valuable is that when SAHPRA brings out a guideline, they would just set half an hour aside to explain why they are doing something so that industry can go away with some insight”. In order to achieve this, it was noted by interviewees that increased staff capacity would be need for SAHPRA.

5.5.2 Other Stakeholders That Should be Involved in the Regulatory Process

Table 8: Other Stakeholders that Should be Involved

Rank	Construct	Frequency
1	Other regulatory authorities/ experts	6
2	Advocacy groups	5
3	Patients should not be communicated with	4
4	Patients should receive communication from SAHPRA	2

Most interviewees stated the need for the regulatory authority to align with the standards and decisions of other regulatory authorities. As one regulatory pharmacist from a multinational pharmaceutical company stated: “the other stakeholders that I think are important, especially for us, are the African [regulatory authorities]”. It was

suggested that harmonisation of guidelines and regulatory processes with other recognised regulatory authorities would enable faster registration of products and access to the market. Innovator products require specific expertise for evaluation for registration and therefore it was noted that involving other stakeholders involved in the regulation of these medicines and devices would be useful to increase capacity of the medicines regulatory authority.

Although some interviewees indicated that patients should not be involved in the decision-making process of the approval and adoption of medicines, one regulatory pharmacist stated that “maybe as industry we could make a better effort in reaching out to patients in assisting them to know that our drugs get registered and they have to follow a process and that’s how they know they are safe”. The pharmacist went on to state: “I don’t even think patients in this country know that our [medicines regulatory] body is called the Medicines Control Council and that we have a process of registration. Whereas, if you talk WHO, [patients] hear it on the TV. They know that there is the World Health Organisation that does certain things... You never hear anything about MCC”. However, other interviewees indicated that this was not the role of the MCC. As a member of the MCC stated: “the public will not participate [in the regulatory process] but the need of the public is one of our mandates... You’ll have to establish what the public need is... approval will take that into consideration”.

5.6 Results for Research Question 3

Research Question 3: How have decisions made by the medicines regulatory authority affected responsible innovation in the industry?

The aim of Research Question 3 was to determine the perceptions of interviewees on the role of the medicines regulator in enabling or inhibiting innovation in the pharmaceutical industry. The interview questions intended to identify experiences and opinions of stakeholders of whether medicines regulations currently provide barriers or provisions for pharmaceutical innovation.

5.6.1 Ways that Medicines Regulations Affect Innovation

Table 9: Effect of Medicines Regulation on Innovation

Rank	Construct	Frequency
1	Long regulatory timelines hamper time to market and innovation	8
2	MCC does not have enough resources to cope with innovation in the industry	5
3	Innovative products are overregulated	4
3	Old, outdated MCC legislation does not align with new innovations	4
3	Little innovation done in South Africa	4
4	Regulations do not affect innovation - internal systems are stricter than MCC	2
5	MCC security on dossiers is poor - overseas companies do not want to send sensitive IP information	1
5	Reduces innovation of poor quality products in favour of the consumer	1

Some interviewees cited that regulations do not impact innovation in the pharmaceutical industry, as much of the innovation is performed by overseas affiliates of the company and not in South Africa. One regulatory pharmacist noted that the internal systems of the multinational companies are often much stricter than the requirements of the MCC, stating, “I work at a company that has their own internal systems which I find a lot stricter than local [ones]”. One expert in the pharmaceutical industry stated: “there is nothing stopping anyone doing what they want if they understand the guidelines and do what they are supposed to do”. Another member of the MCC stated: “I don't think the MCC has an influence on what mother companies decide and what strategic processes they follow to get medicines to the market and what medicines they get”. Another expert in the pharmaceutical industry stated that restrictions on innovation of poor quality products that have no scientific base is in favour of the consumer, stating that there will be significant changes in the complimentary medicine market, but that “you are probably realistically at the end of it going to end up with really good products that should be on the market”.

However, one expert in the pharmaceutical industry argued: “There is huge concern [from overseas pharmaceutical companies] over the way industry data is respected”. It was noted that administrative inefficiencies in the MCC have resulted in the poor handling of sensitive confidential information about company products, which has created a barrier of mistrust and “the reluctance of overseas companies to channel [innovative data] through to their counterparts on the ground [in South Africa] to get it through the authorities”. The expert continued to say that this is “because there are

trade secrets and know-how that they don't want to go through to the MCC when the security on our [medicines registration] dossiers is known to be the worst in the world”.

It was noted that process innovation was affected by administrative inefficiencies in the regulatory authority. For example, one regulatory pharmacist stated: “if you choose to change an [Active Pharmaceutical Ingredient] supplier or if you choose to add an additional Finished Product manufacturer sometimes you are going to sit in an MCC queue for a good 24 months and that impacts your supply”. This theme was linked to impact on economic performance of pharmaceutical companies, with one expert in the industry stating: “If you need to change your [Active Pharmaceutical Ingredient] source... Eventually you won't be able to supply your market... It's not that we're greedy or we want to make a big profit, but it is also business... You have to be profitable to continue”.

Inefficiencies in administration that lead to barriers to innovation were linked to capacity restrictions on the part of the medicines regulatory authority. One executive from a multinational pharmaceutical company stated that “[the MCC's] workload over the last few years has more than quadrupled, but... capacity and resources have [only] grown 10 or 15%”. These barriers to innovation were cited as leading to economic difficulties for companies who need to get products to market quickly in order to be sustainable. For example, one expert from the pharmaceutical industry stated: “To date, no biosimilars (generic versions of expensive biological medicines) in South Africa have been approved”. The expert went on to say that “if [the MCC's] aim is to get affordable medicines to the patient then especially on a high-cost drugs like biologics, biosimilars could make access easier”.

Another theme that emerged was that updating of legislation to be aligned with international standards would improve innovation. As one regulatory pharmacist stated that when evaluating innovative products, “the [European Union] and other developed regulatory authorities take a risk benefit ratio and ultimately it's the prescriber's decision [to prescribe or not] and the MCC doesn't allow us that and there is no room for negotiation”. Another expert in the pharmaceutical industry stated: “We've got some very specific South African requirements and sometimes our overseas counterparts don't understand the reason for it”.

In terms of innovator products, a theme that emerged was that the MCC currently lacks the expertise to evaluate complex new products. As one expert in the pharmaceutical

industry stated: “There are not a lot of people that understand [biosimilars]... [Applications] are sometimes given to the wrong evaluators who don't understand the technology or class of medicine”.

5.6.2 Methods of Better Enabling Innovation

Table 10 below presents the themes that emerged from the interviews regarding proposed methods to better enable innovation through the medicines regulatory authority

Table 10: Methods to Enable Innovation

Rank	Construct	Frequency
1	Improve capacity, resources and timelines of the MCC	11
2	Improve consistency and transparency in regulatory application process, such as electronic tracking system	6
3	Harmonisation of regulatory requirements and recognising decisions made by other regulatory authorities	5
4	Decrease administrative burden by stratifying process for amendments and assessing duplicate dossiers together, reducing fast-tracking to acceptable level, risk-sharing framework	4
5	Improve staff attitudes at the MCC	3

The main theme that emerged from the interviews conducted was the overwhelming need to improve medicines evaluator capacity and resources, as well as reduce registration timelines in order to better enable innovation in the pharmaceutical industry. As one expert from the pharmaceutical industry stated: “the problem is the administration of the MCC and the infrastructure that they've got and problem they've created for themselves by favouring generics. And these new breakthroughs... aren't able to come through”. The expert went on to say: “There are only probably about 20 or 30 new medicines that come through a year - the rest of the 2000 to 3000 medicines are all generics... And a lot of them are not being put on the market so they aren't reducing prices”. In order to increase regulatory capacity, one member of the MCC stated: “You do this through partnerships. You do that through engagement with other regulatory authorities. You do that with engagements with expertise and experts both locally and internationally, including entities like the World Health Organisation to support developing that capacity”.

Another theme that emerged from the interviews was the need to harmonise regulatory requirements with other medicines regulatory authorities and to recognise decisions made by other authorities to expedite the registration process of innovative products.

As one regulatory pharmacist stated: “MCC is sometimes stricter [than other regulatory authorities]. [Overseas affiliates] Cannot understand that because they feel like if something has been approved, why are we making it an issue?” Another regulatory pharmacist reiterated this theme, stating that “strategically, the MCC needs to realise that it does not have the resources they need to do what other countries are doing”, and that it needs to recognise other regulatory authorities’ decisions. A member of the MCC echoed this sentiment, stating, “As we start to regulate [innovative] products, it’s not about reinventing the wheel. It’s not about redoing regulatory reviews where that has already been done competently by another regulatory authority that we align ourselves with. But it is about having a mechanism in place that will allow us to adopt and accept those decisions with a level of comfort that we require as a country”.

One medicines regulator from the MCC stated that with the amendment of the outdated Act 101 of 1965, the MCC is “now permitted to do a knowledge-share with other regulatory authorities where in the past we weren’t and that benefits everybody”. In order to better enable the assessment of new innovative products, the regulator indicated that the MCC now has Memorandums of Understanding (MOUs), stating: “we’ve got MOUs at this stage with [the two regulatory authorities] Swissmedic and MHRA (the United Kingdom’s Medicines and Health products Regulatory Authority). We can always lean on them”.

Another theme that emerged was the need to decrease administrative burden by stratifying processes and reducing the fast tracking of unnecessary applications. For example, one expert in the pharmaceutical industry cited the frustration of innovator companies that generic products are fast-tracked, resulting in many generic versions of the same product being on the market, while new and innovative products are side-lined. The expert stated that the “focus is on generics, and specific classes of medicines get priority. [These are] not the only medicines that the country needs so [the MCC] needs to relook at their priorities”.

5.7 Results for Research Question 4

Research Question 4: What would be the optimal framework for governance of SAHPRA to enhance innovation in the pharmaceutical industry?

Research Question 4 was aimed at determining, through information gathered from the interviewees, the ideal framework for the creation of rules and regulations for this new

medicines regulatory authority, SAHPRA. It was aimed at proposing a structure of governance to not only reduce barriers, but also promote innovation through adequate stakeholder engagement.

5.7.1 Factors Used to Improve the MCC Governance Structure

Table 11 below presents the themes that emerged from the interviews regarding factors of MCC governance that should be improved.

Table 11: Improvements Needed of MCC Governance

Rank	Construct	Frequency
1	Improved transparency, such as of Standard Operating Procedures and legislative processes	10
2	Increase capacity and infrastructure at MCC and registration timelines	8
3	Improve communication such as on the website	7
4	Improve consistency and attitudes between evaluators	4
4	Increase interaction with evaluators	4
5	Reduce administrative inefficiencies eg fast-tracking for essential medicines	2
5	Involve industry more in the creation of guidelines in the early stages	2
6	Adhere to Department of Health and King 3 guidelines	1
6	Use a fair process of policy creation through parliament	1

An overwhelming theme that emerged from the interviews was the need for increased transparency of the medicines regulatory authority. One expert in the pharmaceutical industry stated: “If [the MCC] is open and transparent and we know what they want to achieve and we understand the thought process, it is much easier to implement and get the buy-in”. Another expert in the pharmaceutical industry stated: “the MCC needs to be very clear on policy, because you can’t help them on regulations if you don’t understand their policy”. A member of the MCC stated that a Regulatory Assessment Report “needs be made available to all stakeholders and should be published for everyone to see so that we understand the basis of [the MCC’s] regulatory decision... It is imperative for South Africa to move towards that kind of framework or at least being able to publish the justification for its decision”.

As an example to increase transparency, the need to include a tracking system to ensure applications for registration were accounted for was suggested, as well as increased accountability for medicines evaluators. One expert from the pharmaceutical industry stated: “the communication around what happens to a [medicines registration] dossier is a huge problem... There is no document tracking system”. Another

regulatory pharmacist stated: “They need to have an electronic data management system which is visible to everyone so you can see exactly where everything is”. In line with this, a member of the MCC stated that “requiring the regulator to account for its regulatory timelines is important and what South Africa needs to do is take the step that other regulators have taken a long time ago and that is to implement a "Stop Clock" system that says that following receipt of a completed application, the regulator will take a defined time to submit questions to the applicant on that issue”.

A theme that emerged was the need to increase communication with specific evaluators, especially around complex products. One expert in the pharmaceutical industry stated: “It is very challenging because you can't just pick up your phone and talk to someone”. Another MCC member stated that “more meetings should occur - there should be much more collaboration”.

There was a call from interviewees to increase consistency between and interaction with medicines registration evaluators, as well as to increase involvement with other stakeholders in the creation of policies, regulations and guidelines, especially at the early stages of creation. One regulatory pharmacist stated: “Most of the time we just get a draft guideline, then you look at the draft and comment on it. But when they were drafting the guideline, the initial thoughts of industry were not in there”. One medicines regulator from the MCC stated: “Guidance documents as they stand today are out-dated”.

Another theme that emerged from the interviews included the need to adhere to internationally recognised governance frameworks, such as the King 3 Code, as well as maintenance of independence from politics and a fair process of legislation creation through parliament. One executive of a multinational pharmaceutical company stated, “[medicines] policy development and creation, legislation and regulation... is fair and reasonable... The bigger issue is our implementation of policy and its application predictively and with certainty is a problem”.

5.7.2 Optimal Governance Framework for SAHPRA

Table 12 below presents the themes derived from the research conducted regarding the factors that will enable the optimal governance framework for SAHPRA.

Table 12: Optimal Governance Framework for SAHPRA

Rank	Construct	Frequency
1	Better communication, transparency, consultation and engagement with stakeholders	9
2	Regular engagement with industry throughout process for guideline and policy development eg through ITG and workshops	8
2	Increased capacity and accountability eg Key Performance Indicators for all staff	8
3	Harmonisation and convergence with other regulatory authorities, or abbreviated review of applications	6
4	Adapt regulations to South Africa's needs	5
5	Performance agreements with evaluators and clear timelines for registration	4
6	Focus on King 3 and Department of Health governance policies	3
7	Align with other successful Section 3A companies	1
7	Competent Board members and independence from political interference	1

The need to harmonise legislation with other medicines regulatory authorities, as well as to recognise decisions made by other regulatory authorities in order to streamline administrative burden was noted by interviewees. One member of the MCC stated “The way we [should] approach the establishment of SAHPRA is a best practice framework informed by international experience of other regulatory authorities in terms of what were the best things that promoted efficiencies that allowed for better systems for monitoring and evaluation framework of regulatory performance”. The MCC member stated that “South Africa is looking at other regulators to try to benchmark systems and processes”.

Another theme that emerged was the need to adapt regulations and policies to the South African context. As one regulatory pharmacist stated: “When the MCC looks at the global way, they often think it will work here, but that’s not necessarily the case because we face different challenges here”. Another expert in the pharmaceutical industry stated: “SAHPRA is rapidly increasing the costs of registrations and inspections, which they are equating to what we see in the rest of the world... but we might be overpricing ourselves [due to small market size]”.

The theme around transparency and consistency of medicines evaluators was consistent throughout the interviews, with one expert in the pharmaceutical industry stating that “there needs to be consistent interpretation of policy documents within the authority and whoever they use to do their assessments. And that has to be a whole process of standardisation and interpretation of documents”.

Another theme that emerged from the interviews was the need for stakeholder involvement from the start of any regulatory process. As one regulatory pharmacist stated: “the [governance] process should start with the industry. It should start with people who are going to be doing the submission or providing the data... When you work with [a policy or guideline] you can quickly see the advantages and disadvantages or the pros and cons or what might be a challenge. When we come in at the end, it is too late”. One medicines regulator from the MCC stated that with SAHPRA, “there is definitely scope for public forum”. A member of the MCC stated: “I think what this change will do is make everyone more accountable to the process so that I think will already improve stakeholder collaborations and negotiations because a lot of the communication problems and a lot of the issues are timelines issues. If they can be resolved, there can be much more amicable discussions that occur”. Another MCC member stated, “People need to be telling SAHPRA how they want things done”.

A theme that emerged was the need for the independence of the medicines regulatory authority to ensure good governance. One executive from a multinational pharmaceutical company suggested that the governance of SAHPRA would depend upon “the make-up and constituency of the Board and particularly the lesser level of meddling by the responsible Minister”. Another MCC member stated that SAHPRA “will probably be run more like a business, so those kinds of business processes which deal with stakeholders could be adopted by SAHPRA”.

A member of the MCC involved in the transition to SAHPRA stated: “The Board of SAHPRA is in fact the governance Board that will oversee both governance and fiduciary obligations of the entity. But it will have another fundamental role and that is it will oversee the development of the organisational objectives, the attainment of those objectives and its performance in doing that”. The member went on to say: “The Board needs technical insight into what is needed - what are the priorities in the country, what are the priorities on a global level and how does the regulator need to do that. The approval of products won’t happen the way that it is currently happening... that will happen through an advisory structure that is aligned with the work under the

Chief Executive Officer”. The interviewees all indicated that there is a need for change in structure of the governance of the medicines regulator, which was predicted by the MCC member involved in the transition to SAHPRA.

One member of the MCC stated, “SAHPRA is about doing things differently. It is about regulatory transparency. SAHPRA is about accountability of the regulator. SAHPRA is about the opportunity to do things differently”.

5.8 Conclusion

This chapter contained the results to the 8 interview questions that were used in the semi-structured interviews conducted. Although there appeared to be sensitivity to the subject of the research, resulting in a research sample that was difficult to reach, a good sample of the three stakeholder groups could be interviewed. Themes emerged that were supported by the literature in Chapter 2, identifying experiences of stakeholders in the pharmaceutical industry to regulatory issues, as well as perceptions of optimal stakeholder involvement and governance to enable innovation in the industry. These results were used to answer the 4 research questions proposed in Chapter 3. The results presented in this chapter will be discussed in Chapter 6, linking the constructs identified to the literature presented in Chapter 2 around the research topic.

Chapter 6: Discussion of Results

6.1 Introduction

Results presented in Chapter 5 were discussed in this chapter, allowing comparison of emergent themes and constructs to the literature presented in Chapter 2. The results presented in Chapter 5 were explored and discussed in this Chapter, from the Research Questions presented in Chapter 3 using the qualitative open-ended research interviews as discussed in Chapter 4. Through the lens of the literature presented in Chapter 2, identification of the optimal governance framework and stakeholder engagement needed to allow efficient approval and adoption of innovation in the pharmaceutical industry was possible.

6.2 Discussion of Results for Research Question 1

Research Question 1: What is the perception of stakeholders on the interaction between the current medicines regulatory authority (MCC) and other stakeholders in the industry?

Research Question 1 sought to identify the perceptions of stakeholders on the identity of current stakeholders taken into account during the registration of medicines in South Africa, as well as other stakeholders who should be involved. It was aimed at identifying the perceived relationships between the stakeholders and strengths or weaknesses in stakeholder relations in the pharmaceutical industry. According to Verbeke and Tung (2013), stakeholder importance varies over time and it was important to note if perceived stakeholders were aligned with those suggested in the literature to be “any group or individual that can affect or is affected by the achievement of a corporation’s purpose” (Freeman, 2004, p. 229). These included experts as well as lay stakeholders and patients. Research Question 1 also sought to establish the industry dynamics and whether Porter’s Diamond Theory is relevant in the pharmaceutical industry in South Africa (Porter, 1990). The results from the research provided new insight into the importance of stakeholders in the pharmaceutical industry, as perceived by stakeholders themselves.

6.2.1 Important Stakeholders in the Pharmaceutical Industry

The data from the interviews supported the notion that stakeholders include “any group or individual that can affect or is affected by the achievement of a corporation’s purpose” (Freeman, 2004, p. 229). The results also contributed to new understanding of stakeholder importance as perceived by stakeholders in the pharmaceutical industry in South Africa. Table 5 represents the stakeholders involved in the regulation of medicines, as perceived by the interviewees. The data was analysed based on frequency of themes and ranked accordingly. The most common stakeholders perceived were pharmaceutical companies, with the second highest being academic regulators. Interviewees also perceived other governmental departments as being the third most important stakeholder, while professional associations, other medicines regulatory authorities, civil action groups, distributors and the public were also mentioned. This was consistent with the literature provided by Meijer, Boon and Moors (2013), indicating that lay stakeholders have the ability to contribute to the quality of medicines, as well as satisfaction and trust in the medicines regulatory authority.

Although only 2 out of the interviewees viewed civil action groups as being key stakeholders involved in the regulation of medicines in South Africa, one MCC member stated that this group was extremely important. The member stated: “If you look back at a decade of history, you understand the pivotal role that the Treatment Action Campaign played in our public health space. Whether it was in the area of allowing access to generic products that were and remain a public health priority like antiretrovirals, that advocacy played a very big role. Not just in convincing the regulators to develop the frameworks to develop access to those medicines but also to target other stakeholders like manufacturers in addressing the patent issues”.

The data was aligned with the literature including the findings of El-Gohary, Osman and El-Diraby (2006), who stated that stakeholder support is vital to successful initiatives within the pharmaceutical industry in South Africa. The interviewees were united in the view that pharmaceutical companies were the most important stakeholders in the regulation of medicines, but differed according to importance of other stakeholders, such as the public and other government departments.

6.2.2 Understanding Experiences of Interaction with Stakeholders

The results from Research Question 1 supported the literature pertaining to Narayanan and Fahey's proposal that Porter's Five Forces Model should incorporate formal institutions that support industry, such as the MCC and industry bodies (Narayanan & Fahey, 2005). The results from the research conducted support the view that the pharmaceutical industry rivalry in South Africa is affected by all of Porter's Five Forces, as well as by the formal institutions such as the MCC. Furthermore, Publicness Theory as proposed by Bozemann (2013), in which all organisations are affected by the political and economic environment surrounding them, was supported by the results derived from the research conducted.

Porter's Diamond Model, as introduced in the literature review, is aligned with the pharmaceutical industry, as evident in the results in Chapter 5 (Porter, 1990). Here, pharmaceutical companies leverage relationships and encourage "knowledge spill-over and innovation" (Kuah, 2002, p. 208). Results from this research conducted indicated that poor relationships lead to lack of communication and knowledge sharing. Administrative inefficiencies were seen by all but one interviewee as the major experience in interaction between the medicines regulatory authority and stakeholders. For example, one regulatory expert from a pharmaceutical company stated: "Timelines are a big issue and I know that currently at the moment there are always backlogs... even for fast-track applications we waited for a year. A new product [registration] takes between 4 to 6 years".

The results from the interviews conducted highlighted the lack of trust and frustration as a main theme in terms of relationship between the medicines regulatory authority and other stakeholders. As one MCC member stated: "It is important that the relationship between the regulator and its key stakeholders is seen as one that always requires attention. That it's not one that will normally be a cool fluffly relationship". In agreement with this, one expert in the pharmaceutical industry stated: "The MCC at the moment is way under-resourced and they actually do not have the capacity to deal with people complaining, so if you complain to them that you aren't happy but you don't put a proposal that they can adopt... They will just stick with what they have got".

Most stakeholders saw the intention of the MCC to improve relationships with stakeholders, for example, one regulatory pharmacist from a pharmaceutical company stated: "[The MCC] comes across as a barrier, instead of someone who is allowing access to medicine. So it is trying to build that confidence back into our health

authority”. Another expert in the industry stated: “We can see the intention is to improve... we are seeing progress. It is slow, but we are seeing progress”.

The results contributed additional themes to the literature provided. For example, surprisingly, there were differing opinions from stakeholder as to the level of trust and consultation within the industry. Some stakeholders viewed the MCC as having robust standards and therefore a high level of trust and respect was due to them, while others saw a lack of communication with the pharmaceutical industry as a major factor contributing to a lack of trust in the MCC. However, it was clear from the results of the research conducted that stakeholder satisfaction was seen as a key output of the MCC. This supported Cummings and Worley’s diagnostic model of an organisation, as presented in Figure 7 (Cummings & Worley, 2015).

Another major theme that was highlighted by most interviewees was that the MCC currently communicates poorly with the pharmaceutical industry. This would further contribute to the lack of trust and respect from industry. For example, one pharmaceutical expert stated: “I don’t think [the MCC is] highly communicative with industry in terms of making policy decision - I think that is probably a weakness”.

However, the results also supported the findings of Hendriks, Jansen, Gubbels, De Vries, Paulussen and Kremers (2013), who found that the public is highly critical of mistakes made by government and regulatory authorities. Three interviewees viewed the pharmaceutical industry as cooperating poorly with the MCC. For example, one pharmaceutical expert stated that: “industry has a tendency to complain all the time [regarding timelines and regulations]... But not many people take the time to write a concrete proposal of how the MCC can fix those problems”. This lack of collaboration in the pharmaceutical industry may damage the performance of the industry as a whole, resulting in a lack of mutual information sharing, as found by the literature (Li, Zheng & Wang, 2016; Guler & Nerkar, 2012).

The results obtained were aligned with the argument of Fainshmidt, Smith and Judge (2016), that Porter’s Diamond Theory should include the quality of public governance, as the quality of regulations in the pharmaceutical industry has clearly affected industry dynamics. As Fainshmidt, Smith and Judge (2016) argued, the research conducted indicated administrative inefficiencies leading to long timelines for registration of medicines strongly affected the pharmaceutical industry and industry dynamics.

The results from Research Question 1 supported the findings of Fatti and du Toit (2013), who indicated that the pharmaceutical industry in South Africa suffers from high regulation and long approval times. Results also supported Ruff's (2015) findings that limited capacity to meet demands has led to long medicines registration approval times. Collaboration and competition within the industry is key for efficiencies and improved outputs. As discussed in Chapter 2, cooperation enables the sharing of resources and leveraging of strengths of organisations to enable a more efficient healthcare system (Bouncken & Kraus, 2013). Analysis of Research Question 1 identifies the gaps in stakeholder relations, specifically cooperation and competition, in the pharmaceutical industry in South Africa. This may be remedied through formation of strategic alliances to achieve organisational goals.

6.2.3 Conclusive Findings for Research Question 1

The research findings for Research Question 1 provided new theory pertaining to stakeholder importance in the regulation of medicines in South Africa, with stakeholders interviewed having different opinions of their level of importance. The research provided a valuable contribution to the literature, indicating the gaps in stakeholder relations and need for integration of groups of stakeholders to enable better functioning of the pharmaceutical industry. It was found necessary to include all parties that will be affected by the implementation of a regulatory decision in the decision-making process. "Lay stakeholders" also have the ability to contribute to the field and that regulations should be created democratically, which will improve satisfaction and trust in regulations of medicines, as found by Meijer, Boon and Moors (2013) and confirmed through this research.

It was found that there was generally perceived to be lack of trust and collaboration between stakeholder and the medicines regulatory authority, due to long timelines of registration from administrative inefficiencies as well as lack of feedback and communication from the pharmaceutical industry's side to the regulatory authority. There were differing opinions amongst stakeholders as to the level of communication and trust within the industry. However, it was agreed by most interviewees that administrative issues within the medicines regulatory authority resulted in a large barrier to good stakeholder relations, which required improvement to enable more innovation in the industry.

6.3 Discussion of Results for Research Question 2

Research Question 2: What would be the optimal stakeholder interaction process for the new medicines regulatory authority (SAHPRA)?

Research Question 2 sought to identify the optimal processes for stakeholder interaction as perceived by the interviewees for the future medicines regulatory authority, SAHPRA. It also sought to identify stakeholders not engaged by the current medicines regulatory authority, the MCC, which should be involved by the future medicines regulatory authority, SAHPRA.

6.3.1 Optimal Methods of Stakeholder Engagement for SAHPRA

The research found that a stakeholder relations between key groups within the pharmaceutical industry required improvement to enable better collaboration within the industry. The results of the research conducted are aligned with the literature that management of relationships with key stakeholders is key to achieve strategic goals (Robichau, 2011). However, valuable new insights regarding specific methods of stakeholder engagement pertaining to the pharmaceutical industry in South Africa were obtained through analysis of the results of the research.

Almost all interviewees saw the benefit of continuation of pharmaceutical industry platforms such as the ITG as the most beneficial format for stakeholder engagement. As one MCC member stated, “I think that is the way to go - through umbrella bodies and setting up formal meetings through those structures, rather than individuals”. This shows a certain level of cooperation in the pharmaceutical, where mutually beneficial cooperation between organisations occurs to combine resources in order to achieve organisational goals (Kozyra, 2012).

However, many interviewees stated their concern of pharmaceutical industry forums as being the only method of stakeholder interaction. For example, many stated their concern that certain companies in the forums in leadership positions have the agenda biased in favour of their companies’ issues, while other companies’ issues are not necessarily addressed. This indicates that more collaboration and cooperation is needed in the industry to improve trust, a culture of information sharing and organisational performance (Guler & Nerkar, 2012).

One expert from the pharmaceutical industry stated that it would be constructive “if a more collaborative forum [than the ITG] could be created where your voice could be

heard”. Many interviewees agreed about the need for ability to approach the regulatory authority individually for company-specific issues. For example, one regulatory expert stated: “Companies always need to have individual consultation when required with the MCC - it is accepted worldwide that you can consult with the regulatory bodies about a specific product or problem because no products are the same”.

In terms of stakeholder strategies, most interviewees agreed with the need to increased transparency of the medicines regulatory authority, as well as increased staff capacity for stakeholder interactions to better improve communication. Some interviewees stated the need to increase frequency of stakeholder interaction, such as through workshops or seminars. The results of the research conducted are aligned with the findings of El-Gohary, Osman and El-Diraby (2006) that stakeholder opposition may result in the failure of the medicines regulatory authority’s initiatives if sufficient collaboration and discussions have not been held.

6.3.2 Other Stakeholders That Should be Involved in the Regulatory Process

An important theme emerged that most interviewees saw the need to harmonise legislation and converge regulatory requirements to those of other recognised medicines regulatory authorities. Lack of harmonisation with other medicines regulatory authorities was seen as a barrier to effectiveness of the MCC. It emerged that medicines regulatory harmonisation and convergence would enable better utilisation of resources available and a more efficient output for the medicines regulatory authority in South Africa.

Medicines regulatory harmonisation and convergence is something that is currently being legislated in the creation of SAHPRA, which will greatly enhance the effectiveness of the medicines regulatory authority. Most interviewees from all three of the stakeholder groups interviewed indicated that harmonisation and convergence of regulatory requirements, recognition of regulatory decisions and involvement of other regulatory authorities as stakeholders of SAHPRA would speed up registration of medicines in South Africa and enable better utilisation of capacity of the medicines regulatory authority. This was in alignment with the research conducted Narsai, Williams and Mantel-Teeuwisse (2012), in which 82% of respondents from pharmaceutical companies in South Africa were supportive of the harmonisation of medicines regulatory requirements.

Interestingly, there was a disagreement between interviewees as to whether patients or the public should be involved as stakeholders in the regulation of medicines. Some indicated that it was the prerogative of the medicines regulator to communicate with patients to educate them about the medicines regulatory process, while others indicated that they did not view this as being a role of the medicines regulatory authority. This was consistent with the literature provided by Utens, Dirksen, van der Weijden and Joore (2016), who showed that patients are often overlooked in the policy-making process, but their involvement is important to substantiate the legitimacy of the medicines regulatory authority and pharmaceutical industry as a whole.

Some interviewees indicated the need for the medicines regulatory authority to involve advocacy groups in the regulatory process. This would possibly be brought about by better communication strategies and transparency, as mentioned in the previous Research Question, as consistent with the findings of Meijer, Boon and Moors (2013), who found that lay stakeholders may increase accountability and transparency of the medicines regulatory authority.

However, other stakeholders saw pharmaceutical companies as the main stakeholder who is, and should continue to be, the main focus of the medicines regulatory authority. This is because, as one expert in the pharmaceutical industry stated: “The problem is, if you involve too many people you could slow down the process”. This was a significant finding, as the perceptions of most of the stakeholders were on the need for the medicines regulatory authority to focus attention and improve the relationship with its main stakeholder group, being the pharmaceutical companies.

6.3.3 Conclusive Findings for Research Question 2

The results from the research conducted provided valuable new insight into the perceptions of stakeholders involved in the pharmaceutical industry with regards to stakeholder interaction of the medicines regulatory authority. It showed that there is an urgent need for more collaboration and cooperation within the industry is necessary to allow optimal output of quality healthcare to the public. Analysis of the research conducted enabled the creation of an optimal stakeholder interaction process and the analysis of important stakeholders who should be considered by the medicines regulatory authority. The perceptions of the interviewees are consistent with Cummings and Worley (2015) who proposed an organisational-level diagnostic model that included performance, productivity and stakeholder satisfaction as measures of organisational effectiveness.

6.4 Discussion of Results for Research Question 3

Research Question 3: How have decisions made by the medicines regulatory authority affected responsible innovation in the industry?

Research Question 3 sought to establish the perceptions of the interviewees as to the ways that medicines regulations in South Africa affect innovation. Innovation in this regard was stated as encompassing product and process innovation within the industry. Research Question 3 also sought to establish methods of better enabling innovation in the pharmaceutical industry in the future.

6.4.1 Ways that Medicines Regulations Affect Innovation

Analysis of the research conducted showed that improvement of internal efficiencies within the medicines regulatory authority, as well as the collaboration of important stakeholders within the industry, is needed. This would better enable innovation of products and processes within the pharmaceutical industry.

Analysis of the results obtained provided contribution to theory in that administrative burden and resulting long timelines of registration of products was seen to be a major barrier to innovation in the South African pharmaceutical industry. The results obtained from the research conducted also supported Poole and Van de Ven's framework for the creation and acceptance of technological innovations, as presented in Figure 5, including institutional arrangement, resource endowments, consumer demand and proprietary activities (Poole & Van de Ven, 2004). The research showed that interviewees viewed poor institutional arrangements, as part of Poole and Van de Ven's framework (2004), such as out-dated laws and regulations and long timelines as severely affecting innovation. It was noted by most interviewees that the long timelines resulting from administrative issues at the MCC reduce innovation in the pharmaceutical industry by increasing the time to market of innovative products. For example, one senior executive at a pharmaceutical company stated: "Our regulation leads to red tape and administrative burden and that increases the cost of doing business... We suffer from quite a big administrative burden hangover".

One outlier in the interview sample stated that regulation of medicines by the MCC is at a good standard, as it increases quality of products on the market in favour of the consumer. However, more interviewees viewed innovative products as being overregulated by the MCC, as well as the fact that MCC legislation is outdated, with the Medicines and Related Substances Act 101 being written in 1965, and the legislation

does not align with new innovative thinking in the industry. The results from Research Question 3 indicated a frustration on the part of the pharmaceutical industry that the lack of ability to innovate due to regulatory issues decreases competitive advantage. This was supported by Comez (2016), who stated that ambidexterity enables organisations to adapt to the rapidly changing environment. The results also support O'Reilly and Tushman (2011), who noted that most organisations operate in a complex, dynamic environment and require ambidexterity in order to survive.

The results of the research conducted show a misalignment of the medicines regulatory authority with the changing needs of the external environment, lacking the Open Systems Model proposed by Cummings and Worley (2015). The movement from the MCC to SAHPRA provides a unique opportunity to completely overhaul the Medicines and Related Substances Act 101 of 1965 and create a more updated Medicines Act that is better aligned with international best practice in the regulation of medicines and related substances. This opportunity has been recognised by the MCC, who, as one Medicines Control Officer stated is “doing benchmarking exercises now [with other regulatory authorities]... to see what are those gaps [in regulations] and how can we bridge those gaps”. As one MCC member stated, “The MCC is not the first regulator to have a backlog - the FDA as we speak currently has a generics backlog. The Australian TGA is currently working on a mechanism to work on its own backlog... but if you expect that the MCC in its current format hasn't changed since Act 101 of 1965, that model is in dire need of change”.

Some interviewees noted that little innovation of products is performed in South Africa and is rather done overseas in bigger markets. It was also noted that internal company structures regulating the innovation of products and processes are actually more thorough and stricter than the MCC's requirements. This was an interesting point, which concurs with the risk-sharing approach of regulation of medicines that will be discussed in Section 6.4.2. An outlier in the interview sample stated that currently overseas affiliates are unwilling to provide sensitive intellectual property data to the MCC, as the MCC's security on medicines dossiers is poor and they view this as a security risk. This may be mitigated in future by SAHPRA with the movement to electronic records and better capacity for control of dossiers, with reduced administrative backlog as discussed in Section 6.2.

These findings indicated a lack of open innovation of the pharmaceutical companies in South Africa, as described by Davey, Brennan, Meenan and McAdam (2010). The

medicines regulatory authority, as an institution, has the ability to define the “rules of the game” of innovation in the South African pharmaceutical industry (Poole and Van de Ven, 2004). Transparent institutional policies and alignment with the changing environmental needs in the pharmaceutical industry would in turn encourage open innovation of pharmaceutical companies in the country and increased effectiveness. These changes could also improve intra-firm collaboration and competition, which is apparently lacking, according to the research conducted, in the pharmaceutical industry in South Africa. This would help more innovative product development (Li, Zheng & Wang, 2016).

6.4.2 Methods of Better Enabling Innovation

All except one interviewee stated the need to improve capacity, resources and timelines of the medicines regulatory authority to encourage better innovation in the pharmaceutical industry in South Africa. This was a major theme that was consistently stated in almost every interview and appears to be a major concern for all stakeholders in the pharmaceutical industry and was aligned with the findings of Aagaard (2015), who stated that strict regulatory requirements may stifle creativity and innovation.

Aligned with this and another theme that was analysed consistently was the need to harmonise and converge regulatory requirements and recognise decisions of other medicines regulatory authorities, in order to reduce the burden on the medicines regulatory authority. This theme concurs with the literature, which proposes sharing of information and technology between medicines regulatory authorities through harmonisation and convergence, enabling a more efficient registration and regulation process and resulting in improved access to quality medicines for the public (World Health Organization, 1999). However, the themes that emerged from the research conducted added a construct of linking this increased capacity utilisation and efficiency to resulting innovation within the pharmaceutical industry.

Another method of enabling innovation in the pharmaceutical industry that was noted was the need to improve consistency and transparency in the application process. This method was seen to be vital to improving relations and enabling stakeholders to know clear requirements for applications. This was aligned with the findings of Doy and Guay (2006), who stated that open and honest institutional policies increase trust between institutions, such as the MCC, and their stakeholders. For example, one expert in the pharmaceutical industry stated: “Business needs certainty. It doesn’t actually matter how good or bad the rules are but business needs to know what the rules are. Once

you know the rules and what you've got to do you can plan and budget and you can work towards achieving them. At the moment there is so much uncertainty about which way exactly the MCC is going that it hurts the industry, employment and growth because no one wants to invest until they have certainty. So it is important for the MCC to speed up [regulatory] timelines”.

A theme that emerged was that the perceived overregulation of innovative products by the MCC may be mitigated by the harmonisation of legislation and other regulatory requirements with other medicines regulatory bodies. This was aligned with the research conducted by Narsai, Williams and Mantel-Teeuwisse (2012), in which harmonisation of regulatory activities with other recognised authorities benefits all stakeholders, through more efficient resource allocation and utilisation to produce a more efficient regulatory system. Harmonisation, as well as recognising decisions made by other medicines regulatory authorities with which the MCC aligns itself to, would reduce time to market and mitigate the risk of reduced innovation in the pharmaceutical industry.

A risk-sharing approach to medicines regulation was another theme that emerged from the results of the interviews. It was noted that internal company structures were often seen as stricter than medicines regulatory requirements by the regulatory authority and therefore the regulatory authority may adopt a risk-sharing model. This is where products may be brought to market quicker with the view that the quality risk is shared between the pharmaceutical company and medicines regulatory authority. This may reduce the time taken for registration and amendment of product applications, bringing innovative products to market quicker and implementing innovative processes faster than before, while reducing the burden on the medicines regulatory authority.

6.4.3 Conclusive Findings for Research Question 3

Research Question 3 analysis showed that improvement of internal efficiencies within the medicines regulatory authority and better collaboration between key stakeholders in the pharmaceutical industry are necessary to enable innovation of products and processes. The findings of Research Question 3 indicated the lack of innovation in the pharmaceutical industry in South Africa, due to a number of factors as mentioned in this Chapter including regulatory barriers and long timelines for registration of products. The results of the research conducted were useful in analysing the factors that contribute to the lack of innovation, as well as the creation of methods to better enable innovation in the pharmaceutical industry, such as through improved capacity of and

trust in the medicines regulatory authority, risk-sharing approaches, harmonisation and convergence of requirements and recognition of other medicines regulatory authority decisions.

6.5 Discussion of Results for Research Question 4

Research Question 4: What would be the optimal framework for governance of SAHPRA to enhance innovation in the pharmaceutical industry?

Research Question 4 sought to establish the optimal governance framework of SAHPRA to enhance innovation in the pharmaceutical industry in South Africa. This optimal governance framework was proposed using results from the interviews that were derived from perceived improvements needed to the current MCC governance structure, as well as perceptions on the future structure of SAHPRA by interviewees.

6.5.1 Factors Needed to Improve MCC Governance Structure

The research found many areas of improvement needed in the current model of governance of the medicines regulatory authority. It was found that internal efficiencies within the medicines regulatory authority were needed through specific themes that emerged from the research conducted. Health systems governance involves the rules, leadership and stewardship that allow the “promotion and protection of health” (Siddiqi et al., 2009, p. 14) of a society, resulting in better treatment outcomes. It was shown in the research that a urgent change in governance structure of the medicines regulatory authority is needed to produce better treatment outcomes of the healthcare industry.

An overwhelming theme that emerged from the results of the research conducted was the need to improve transparency of the processes conducted in the regulation of medicines. Aligned with this is the need to involve industry in the early stages of policy creation. As one expert in the industry stated, “Industry needs to sit with government and understand their policy... What is their fear/ concern and from there you can start creating guidelines”. This was consistent with the findings of Doy and Guay (2006) who found that transparency leads to trust between an institution and stakeholders, but had an additional element of theory in the case of the pharmaceutical industry in that increased transparency would better enable innovation.

Another theme that emerged in the results of the research conducted was the dire need to improve communication with the industry and to increase capacity and infrastructure of the medicines regulatory authority. Increased staff capacity would free

up regulators to communicate on a more frequent basis with the pharmaceutical industry and create a stronger framework for stakeholder interaction. Participants saw this as being the main opportunity to create better efficiencies and improvement of relationships with the pharmaceutical industry.

As one expert in the pharmaceutical industry stated, “There isn't the infrastructure that's needed, which has resulted in... bad attitudes from the side of the authority”. Increased human resource and infrastructure capacity would free up the regulatory authority and result in better job satisfaction and attitudes. This would improve administrative efficiencies and, as one expert in the pharmaceutical industry stated: “The biggest expectation [of the pharmaceutical industry] is the improvement of timelines”. This is consistent with the findings of Fatti and du Toit (2013), who stated that frustrations occur due to high regulation and approval times.

Other less frequent themes that emerged were the need to overhaul the processes of regulation in terms of reviewing and streamlining out-dated processes, such as giving priority to some medicines of which there are already many generic versions on the market.

6.5.2 Optimal Governance Framework for SAHPRA

The results of the research conducted were consistent with the literature surrounding the definitions of governance, including transparency, lawfulness, stakeholder relations, responsiveness, effectiveness and efficiency, accountability, intelligence and information (Siddiqi et al., 2009; United Nations, 2012). However, unique theory around the optimal governance framework to address stakeholder needs and encourage innovation emerged. It was shown through the research conducted that improvement of the medicines regulatory authority's governance framework is necessary if innovation within the industry will be enabled, resulting in the production of better quality healthcare.

A main theme that emerged from the research conducted was that most stakeholders interviewed expected better communication, transparency, consultation and engagement between SAHPRA and stakeholders. A Medicines Control Officer from the MCC stated: “There is really going to be very active dialogue between companies and SAHPRA. That is in our model. There are going to be portfolio managers who are constantly communicating [with industry]”. This theme was in accordance with the findings of Emerson and Nabatchi (2015), who proposed that collaborative governance

is an effective way to integrate stakeholder views and reduce risks in the formation of policies.

Results showed that stakeholders also believed that regular engagement with industry for policy and governance issues of the medicines regulatory authority would be essential for the success of the regulator. This is aligned with the findings of Kim and Kim (2016), that effective communication strategy is vital for “buffering” (p. 123) against risks that external stakeholders will negatively affect operations, while “bridging” (p. 123) aligns value offering of an organisation to trends and stakeholder needs. Increased engagement would result in better stakeholder relations, a major theme that emerged as lacking in the former MCC due to insufficient capacity of the regulator and an ideal opportunity for the new SAHPRA to address. Unsurprisingly, increased capacity and accountability of the medicines regulatory authority was seen as a vital element of an optimal governance framework.

From the results of the interviews conducted, the theme emerged that good governance of SAHPRA will be dependent upon the leadership displayed by the heads of the new medicines regulatory authority. As one executive of a multinational pharmaceutical company stated: “At the end of the day [governance] depends on the Board and the CEO (Chief Executive Officer) that you put in”.

Another major theme that emerged from the interviews conducted was the need to align governance of the medicines regulatory authority with other regulatory authorities, create best international practice and streamline administration and policy creation. This was consistent with the literature surrounding the intentions for harmonisation and knowledge sharing with other medicines regulatory authorities (Gouws, 2016). It is also clear from interviews with MCC members that the medicines regulatory authority intends to do this. For example, one MCC member stated: “Given the likelihood that we will begin to implement and benchmark systems with regulatory authorities that we align ourselves with, we will probably have a framework that will align with a harmonised strategy for review and evaluation of generic medicines including harmonised guidelines in that regard”.

Minor themes emerged that regulations would need to be adapted to South Africa’s needs, with a focus on King 3 and Department of Health governance policies. This was an interesting result, as although SAHPRA will be a Section 3A entity, it has been recognised by stakeholders as still being accountable to the Department of Health with

governance and fiduciary duties and, as such, not completely independent. This theme was consistent with statements by the current Registrar of Medicines of the MCC (Gouws, 2015). Therefore, governance will not be completely independent of government but will require a combination of both government and private governance standards.

The results of the research conducted are aligned with the notion that good governance would promote growth of the economy and development of the country (Siddiqi et al., 2009). The change from the MCC to SAHPRA provides a unique opportunity to change the structure of the medicines regulatory authority to promote better governance. It was indicated by interviewees that this would include technical experts on the Board of SAHPRA. As one MCC member stated: “the Board of SAHPRA will have a mix of technical people as well as people that are experienced in the governance issues on the legal side on the finance side and on the policy side. So SAHPRA will be one of the Boards that South Africa has that will have a technical understanding of the work that it is meant to be doing”.

6.5.3 Conclusive Findings for Research Question 4

Analysis of Research Question 4 showed the urgent need to review the business model used for the medicines regulatory authority, including the framework around governance and stakeholder interaction. Efficiencies of the internal structures and processes within the medicines regulatory authority, as well as better stakeholder interaction, was seen to be vital for improvement of the pharmaceutical ecosystem as a whole. Through increased capacity, communication with industry, transparency, benchmarking and harmonisation with international standards, as well as adherence to King 3 and Department of Health requirements, it emerged that SAHPRA would be able to create an effective governance structure. New insight into the role of harmonisation of legislative requirements to enable innovation in the pharmaceutical industry emerged, as well as the need for collaborative governance to enable more efficient processes within the medicines regulatory authority. Analysis of the results allowed the creation of a framework of optimal governance for SAHPRA to address stakeholder needs and encourage innovation. This is further discussed in Chapter 7.

Chapter 7: Conclusion

7.1 Introduction

The chapter summarises the results and discussion around the results obtained from the semi-structured interviews, as presented in Chapter 5 and 6. It provides recommendations to the stakeholders involved in the regulation of medicines based on the findings, and also acknowledges the limitations of the research. It provides suggestions for further research to be conducted, using the findings presented in this research. Although the topic being researched proved to be a sensitive one, resulting in a research sample that was difficult to reach, a contribution to management literature was possible.

Through the conduct and analysis of the semi-structured interviews, the research objectives were met and contribution to literature around the research topic was achieved. The research conducted agreed with existing research around the topic while also contributing significantly to the literature through the creation of a new framework that combines the governance, stakeholder engagement and innovative components of the topic. This framework is useful in the theoretical and management application, as discussed in this chapter.

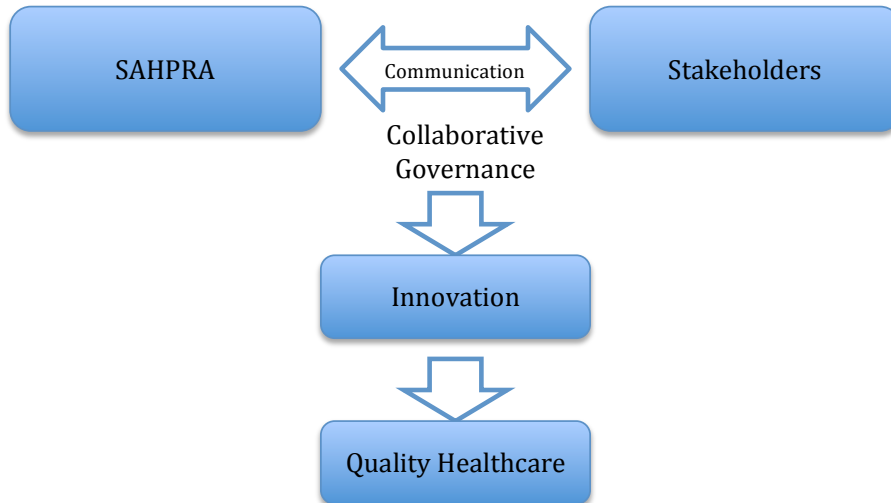
The research found many areas of improvement urgently needed in the current model of governance of the medicines regulatory authority. New academic insight was developed into the efficiencies needed within a medicines regulatory authority, as well as the stakeholder interactions to improve efficiencies and operating conditions within the pharmaceutical industry. It was found that internal efficiencies within the medicines regulatory authority as well as a more effective stakeholder interaction framework would better enable innovation of products and processes within the pharmaceutical industry.

7.2 Interaction of SAHPRA and Its Key Stakeholders

Figure 9 below portrays the interaction between SAHPRA and its key stakeholder groups necessary to enable collaborative governance, leading to innovation and quality healthcare provision to the public. Collaborative governance involves using other public and private stakeholder in the processes and structures of public policy decision-making for a public purpose. This includes principled engagement, capacity for joint action and shared motivation as necessary elements for collaborative governance to

take place (Emerson, Nabatchi & Balogh, 2012). This is possible through regular two-way communication and feedback between SAHPRA and its stakeholders.

Figure 9: Interaction of SAHPRA and Its Key Stakeholders



Source: Author's Own

Through the formation of strong relationships between SAHPRA and its key stakeholders, enabled through constant two-way communication and feedback, a strengthening of trust and cooperation is possible. Collaboration governance on the formation of policies, regulations and guidelines, as well as shared accountability, provides the mechanism through which innovation of products and processes within the pharmaceutical industry is enabled. This results in quality healthcare provision to the public. The stakeholder dynamics of the industry and governance structure of SAHPRA are detailed in Chapter 7.3 and 7.4 respectively.

7.2.1 Innovation

Innovation in the pharmaceutical industry is enabled and driven through organisational effectiveness of SAHPRA. Through the elements encompassed in the stakeholder relations and governance of the medicines regulatory authority, such as administrative efficiencies, communication and transparency, the effectiveness of SAHPRA drives innovation in the industry. A reduction in regulatory barriers leads to more innovation in the industry and alignment with the changing external environment, which results in a more efficient healthcare system (Aagaard, 2015; Suzuki, 2015). For example, a reduction in time to market of new products and implementation of new processes is possible, enabling an environment of change and alignment to changing external environment needs.

The availability of innovative products and efficiency that result from innovative processes within the pharmaceutical industry enables efficiencies within the system and alignment with public healthcare needs. This drives the ability to deliver quality healthcare to the public.

7.2.2 Quality Healthcare

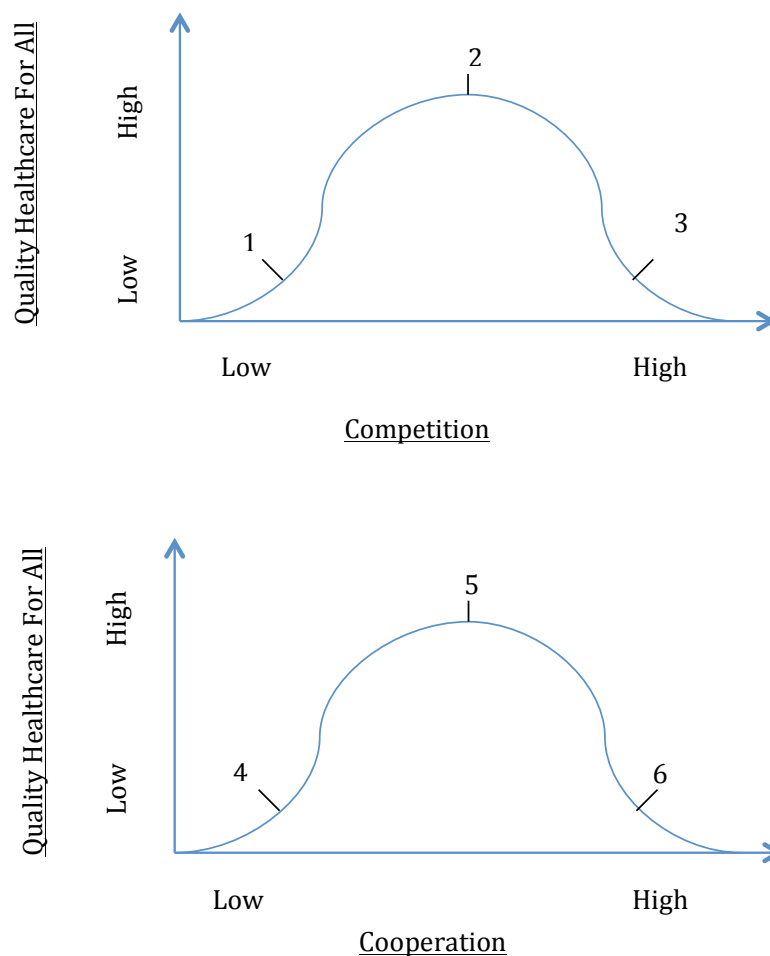
The final output of the SAHPRA Optimal Governance Framework is quality healthcare. This output is the primary function of the healthcare industry and a common goal that all stakeholders within the pharmaceutical industry strive towards, regardless of other factors that result from success such as profits. Through organisational effectiveness of SAHPRA, and resulting innovation within the industry, quality healthcare may be achieved for the public. Stakeholders within the healthcare system, through collaboration and sharing of resources, should work together to produce the primary output of a good quality healthcare provision, measurable through reduction in disease burden and availability of medication on the market. Coopetition to better enable this resource sharing is discussed in Chapter 7.3.

7.3 Stakeholder Dynamics

Important stakeholders in the regulation and approval of pharmaceutical products are pharmaceutical companies, regulators, government departments, professional associations, practitioners, other medicines regulatory authorities and NGOs. Interaction and collaboration between these groups to enable leveraging of strengths and sharing of resources is important for efficiencies within the regulatory and healthcare system.

As discussed in Chapter 2, coopetition involves competition and collaboration between organisations in an industry, where competitive organisations cooperate with each other (Kozyra, 2012). This leads to advantages such as shared resources, risks and costs, as well as economies of scale for smaller companies (Bouncken & Kraus, 2013). An optimal level of competition and collaboration within the pharmaceutical industry is necessary to ensure constant innovation to remain relevant, while encouraging knowledge sharing and open-source information to enable more efficient use of research and design. Coopetition within the industry is vital for effectiveness and efficiency of the pharmaceutical industry. An optimal level of cooperation and competition should be reached, as indicated in Figure 10 below.

Figure 10: Competition Between Stakeholders



Source: Author's Own

Figure 10 above displays the importance of the balance between competition and cooperation between stakeholders in the pharmaceutical industry. Each stakeholder in the pharmaceutical industry should establish the level of cooperation needed with the medicines regulatory authority. Competition encourages innovation in an industry, in the search for market share (Bouncken & Kraus, 2013). Too little competition in the industry leads to a lack of innovation in products and processes, while an excess of competition leads to mistrust and lack of collaboration (3). The graph displays the optimal level of healthy competition in the industry that results in innovation (2), leading to optimal level of quality healthcare in the industry. Too little cooperation between stakeholders (4) results in lack of open innovation, as shown from the research conducted into the pharmaceutical industry in South Africa. Too much cooperation and lack of privacy (6) may result in lack of data security and patent protection, leading to loss of intellectual property. This in turn could reduce innovation in the industry and

result ultimately in the reduced quality of healthcare. Optimal cooperation (5) between stakeholders in the industry would result in optimal communication and collaboration to enable innovation and quality healthcare provision to the public.

The formation of strategic alliances is one form of cooperation, where mutually beneficial cooperation between organisations occurs to combine resources in order to achieve organisational goals (Kozyra, 2012). Strategic alliances between stakeholders in the pharmaceutical industry are vital to leverage strengths of each stakeholder and maximise efficiencies. Collaboration at national and international level with competing organisations positively affects organisational performance. Cohesion between companies enables innovation by reducing opportunistic behaviour, creating trust and a culture of information sharing (Guler & Nerkar, 2012).

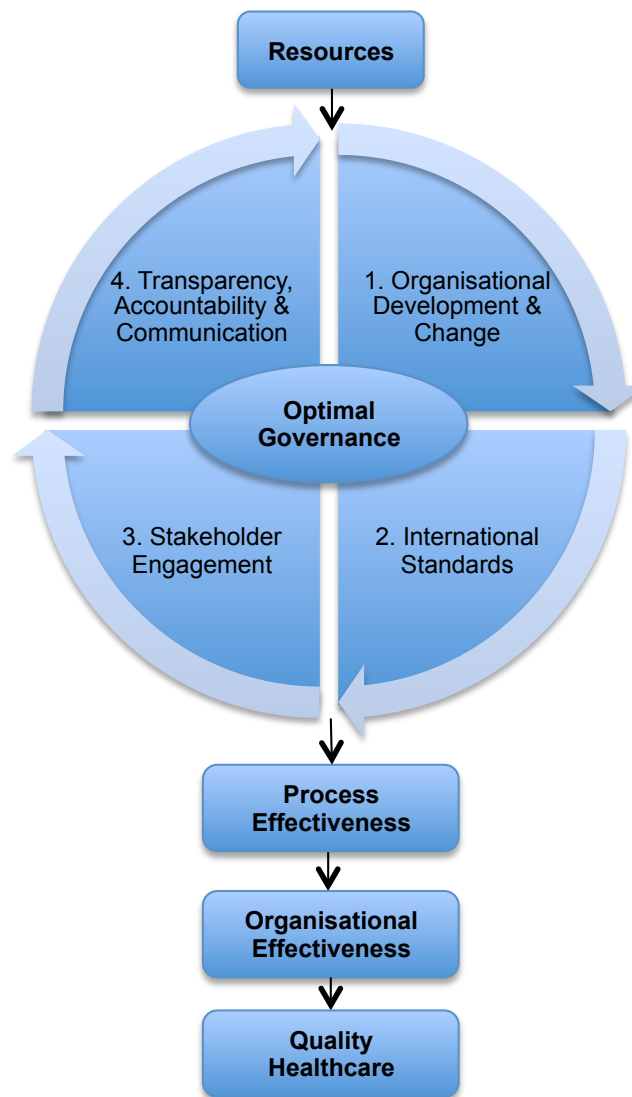
7.4 Creating a Framework for Optimal Governance of SAHPRA

7.4.1 Developing the “SAHPRA Optimal Governance Framework”

The purpose of the research was to analyse the perceptions of stakeholders involved in the regulation of medicines in South Africa in order to create a framework of optimal governance for SAHPRA to address stakeholder needs and encourage innovation. The “SAHPRA Optimal Governance Framework” was developed by using the themes derived from the qualitative research conducted, integrated with the literature around the topic. It incorporates the elements necessary for organisational effectiveness of SAHPRA. Various models as included in the literature were used to form the foundation of the model, including the Integrative Framework for Collaborative Governance, Open Systems Model and Organisation-Level Diagnostic Model (Emerson, Nabatchi & Balogh, 2012; Cummings & Worley, 2015). This SAHPRA Optimal Governance Framework is presented in Figure 11 below.

The framework created included new academic insight such as the role of stakeholder relationships and governance, as well as the need for international standards such as with the harmonisation of legislation with other regulatory authorities to improve innovation in the industry. The framework designed is aimed at reflecting the conversion of resources through optimal governance into organisational effectiveness of SAHPRA.

Figure 11: The SAHPRA Optimal Governance Framework



Source: Author's Own

7.4.2 Explanation of the “SAHPRA Optimal Governance Framework” Framework

7.4.2.1 Resources

Resources are a key input in the framework to enable effectiveness of the medicines regulatory authority, as discussed in Section 6.4.2. The Open Systems Framework for the Pharmaceutical Industry, as shown in Figure 2, also showed resources as a key input to enabling quality healthcare. These resources include technological, financial and infrastructural resources, as well as the human resources.

A key resource is the mandate of the organisation. This includes a shared vision and

motivation of the organisation to ensure effectiveness and enable collaborative governance, as discussed in Emerson, Nabatchi and Balogh's Integrative Framework for Collaborative Governance and confirmed through the results of this research (Emerson, Nabatchi & Balogh, 2012).

These resources provide the capacity of the regulator to function effectively and without them, effectiveness and efficiency is compromised. This was shown from the results of the interviews conducted, where a lack of administrative and technical human resource capacity in the MCC cause administrative inefficiencies and long timelines of registration. Resources available through mechanisms such as fees charged for applications may be pooled and used by the medicines regulatory authority to ensure sufficient capacity. Resources are the key input that drives the rest of the SAHPRA Optimal Governance Framework.

7.4.2.2 Organisational Development and Change

As discussed in the literature review, to remain competitive in any industry, continuous alignment to changing market conditions and trends is necessary through innovation of any organisation, including that of the medicine regulatory authority. Dynamic capabilities are needed to focus on core competencies to provide a competitive advantage and unique market offering for SAHPRA (Grünbaum & Stenger, 2013). Internal innovation of SAHPRA is necessary to allow external innovation in the pharmaceutical industry. This internal innovation is possible through organisational development and change.

The research shows that the medicines regulatory authority is in urgent need of business model innovation. As discussed in Chapter 2.9, Chesbrough (2010) found that, in order to achieve successful business model innovation, organisations need to appoint leaders internally to be accountable for results. Likewise, in the transition of the MCC to SAHPRA, strong leaders need to be appointed internally to ensure that the change management process and business model innovation is successful. Barriers to effective innovation and change management may be overcome in the medicines regulatory authority through leadership within the organisation to enable a change culture. The "Positive Model" of change is needed, as discussed in Section 2.9, involving identification and retention of the organisation's strengths through ensuring perceptions that change is seen as positive and necessary to achieve best practice (Cummings & Worley, 2015). This would be an effective model of change management from the MCC to SAHPRA.

7.4.2.3 International Standards

The governance of SAHPRA encompasses the use of the King 3 code, as well as Department of Health requirements. Other elements of the effective governance of SAHPRA includes administrative efficiencies such as risk-sharing approaches with pharmaceutical companies as discussed in Section 6.4.2, as well as good regulatory timelines for registration of products.

Harmonisation and convergence of regulatory requirements, as well as knowledge sharing with other international medicines regulatory authorities is another important element of the governance of SAHPRA. This will ensure organisational effectiveness through improved efficiencies of regulatory processes. It involves the adoption of global standards on medicines regulation and governance, including regulatory mechanisms, standards and regulations (United States Food and Drug Administration, 2015). Harmonisation and convergence of regulatory requirements, as well as knowledge sharing enables efficient resource maximisation and improved capacity of expertise to ensure that regulatory efficiencies are maximised.

7.4.2.4 Good Stakeholder Relations

Good stakeholder relations between the key stakeholders of the medicines regulatory authority, including pharmaceutical companies, government, NGOs, other medicines regulatory authorities and patients are essential for the effectiveness of SAHPRA. Platforms such as the ITG and other societies are ideal for the regular engagement necessary with the pharmaceutical industry, while one-on-one engagement with companies is necessary for company-specific issues. Good stakeholder relations are an essential element in the SAHPRA Optimal Governance Framework, as regular engagement with stakeholders enables collaborative governance. This was discussed by Emerson, Nabatchi and Balogh (2012) and confirmed through the research conducted. Stakeholder interaction also ensures alignment with needs of both the medicines regulatory authority and stakeholders.

It is important to include all stakeholders to an extent in the decision-making process, such as through communication and dialogue to address concerns. This is needed to mitigate any opposition, which may result in the failure of an initiative if sufficient collaboration and discussions have not been held (El-Gohary, Osman & El-Diraby, 2006). Stakeholder involvement enables the leveraging of resources for a more efficient regulatory process. It also leads to stakeholder satisfaction, as found by Meijer, Boon and Moors (2013) and confirmed through this research.

7.4.2.5 Transparency, Accountability and Communication

Transparency, accountability and communication of the medicines regulatory authority are also key elements that result in organisational effectiveness of SAHPRA. These elements externally enable a relationship of trust between stakeholders and SAHPRA, and internally allow better efficiencies within the organisation. Two-way communication with stakeholders through regular interaction is vital for the success of SAHPRA. For example, industry societies may be used for formal general communication, while one-on-one interaction may be used to address specific company needs. An important tool for ensuring transparency, accountability and communication of SAHPRA is the need for an electronic tracking system to show the situation of applications in the regulatory approval pipeline. Internal accountability through service-level agreements of technical evaluators of medicines registration applications is needed for efficiencies and effective governance.

Good governance encompasses transparency, lawfulness, stakeholder relations and accountability (United Nations, 2012). It is therefore imperative that SAHPRA improves on these elements to ensure that governance excellence is achieved.

7.4.2.6 Optimal Governance

As discussed in Chapter 2, governance involves a “network of actors” (Robichau, 2011, p. 118) and management of relationships with key stakeholders to achieve strategic goals. Not only shareholders, but all stakeholders need to be engaged in order for the organisation to achieve its goals. It is therefore important for effective public relations to provide a framework for governance to align to shareholder and stakeholder needs (Kim & Kim, 2016). The research conducted provided the framework of optimal governance of the SAHPRA to align to these stated stakeholder needs.

Health systems governance involves the rules, leadership and stewardship that allow the “promotion and protection of health” (Siddiqi et al., 2009, p. 14) of a society, resulting in better treatment outcomes. It was shown through the research conducted that an overhaul of the medicines regulatory authority’s governance framework is necessary if innovation within the industry will be enabled, allowing provision of better treatment outcomes of the healthcare system. Policies, regulations and guidelines need to be created that are robust, of international quality aligned with South African needs and are implementable. The systems and processes used within SAHPRA need to be managed by a strong leadership team that enable constant strategic and operational alignment with the external environment and stakeholder needs, through

good communication. Administrative efficiencies will be maximised to ensure timelines for approval of registration of products, leading to improved effectiveness of the organisation.

7.4.2.7 Process Effectiveness

Organisational change involves taking the organisation in a new direction and significantly altering the organisational structure and processes (Burke, 2013). Through the effective change management process of the MCC to SAHPRA, the resulting change in governance and organisational structure will lead to process effectiveness of the organisation. Through the optimal governance of SAHPRA, strategic goals will be achieved and there will be a focus on structures and processes within the organisation.

Cummings and Worley (2015) define organisational development as the “reinforcement of the strategies, structures, and processes that lead to organization effectiveness” (p. 2). Through the operational efficiencies possible with the change from MCC to SAHPRA, administrative improvements will be made such as shorter timelines for registration of products, better lines of communication with stakeholders and a stronger system for addressing stakeholder concerns.

7.4.2.8 Organisational Effectiveness

Organisational effectiveness and good performance of the medicines regulatory authority is the primary output of the SAHPRA Optimal Governance Framework. This encompasses stakeholder satisfaction of the key stakeholders identified in the framework, as well as trust and cooperation. Organisational effectiveness is the primary output of an organisation, according to Cummings and Worley (2015) and is vital to enabling innovation in the pharmaceutical industry. Effectiveness and efficiencies created through optimal governance of SAHPRA and good stakeholder relations will enable an environment of external innovation in the pharmaceutical industry to thrive. This will in turn lead to quality healthcare. Organisational effectiveness of SAHPRA will be measurable through monitoring and evaluation of stakeholder satisfaction and feedback from the industry. This will be possible through industry societies and one-on-one interaction with stakeholders. Organisational success will also be measurable through financial performance indicators of SAHPRA.

7.4.2.9 Quality Healthcare

As discussed in Section 7.2.2, quality healthcare for all is the ultimate result of the optimal governance and stakeholder relations of SAHPRA. This is a shared goal of all stakeholders within the healthcare industry. Through organisational effectiveness of

SAHPRA, and resulting innovation within the pharmaceutical industry, quality healthcare provision may be achieved for all. This output is measurable through reduction in disease burden and availability of medication on the market.

7.4.3 Summary of the “SAHPRA Optimal Governance Framework”

Technological, human and financial resources are a key input that drives stakeholder relations and governance of SAHPRA. Good relations with key stakeholders through regular engagement, transparency and communication enables good governance. Governance of SAHPRA includes the King 3 and Department of Health requirements, administrative efficiencies, harmonisation and convergence well as accountability. Good governance drives the key output of organisational effectiveness of SAHPRA, which includes stakeholder satisfaction, trust and cooperation. This drives innovation in the pharmaceutical industry, which results in quality healthcare for the public. Good feedback mechanisms are essential for the effectiveness of SAHPRA, with regulator engagement with stakeholders, as well as alignment of resources requirements with the needs of the medicines regulatory authority.

7.5 Implications for Management

The results of the research conducted indicated that existing literature around the theory available in the distinctive subjects of innovation, stakeholder relations and governance is relevant. However, key stakeholders within the pharmaceutical industry in South Africa, including the medicines regulatory authority, require a new model of stakeholder relations and governance to enable innovation. With the change in structure and movement of the medicines regulatory authority from the MCC to SAHPRA, an ideal opportunity is presented to review stakeholder relations with the pharmaceutical industry, government departments, NGOs and patients to enable collaborative governance and encourage innovation. This in turn will result in better organisational effectiveness of the medicines regulatory authority and accordingly better quality healthcare to the public.

7.5.1 Implications for SAHPRA

Business model innovation is vital for the effectiveness of SAHPRA. The management of the medicine regulatory authority may adopt the framework developed by the researcher, ensuring that stakeholder engagement is optimised when creating policies, regulations and guidelines. Communication and transparency of SAHPRA is vital to enabling trust of stakeholders to enable good governance. This will ensure buy-in and collaboration and provide benefit to all sectors influenced by the policies, regulations

and guidelines. It also highlights the importance of harmonisation and convergence of regulatory requirements with other regulatory bodies in order to improve efficiencies and governance. Recognition of decisions of and knowledge sharing with other medicines regulatory authorities will also increase capacity utilisation for better governance of SAHPRA. These elements will lead to organisational effectiveness and stakeholder satisfaction, enabling innovation in the pharmaceutical industry and promoting quality healthcare.

The framework also highlights the importance of resources to drive the processes within SAHPRA to enable stakeholder engagement and governance. From the research conducted, it emerged as imperative for the medicines regulatory authority to ensure adequate human, financial and technological resources to enable capacity. Retention of fees charged for applications for registration or amendments to dossiers was suggested as an ideal mechanism for SAHPRA to ensure adequate resource availability.

SAHPRA requires a strong leadership team within the organisation to drive the change management process from the MCC to SAHPRA, through effective business model innovation and the creation of a “Positive Model” for change. This model involves identification and retention of the organisation’s strengths to frame change as positive and aligned to best practice (Cummings & Worley, 2015). A culture for change and innovation within SAHPRA itself is vital to create organisational effectiveness and result in stakeholder satisfaction and financial performance, leading to quality healthcare provision to the public.

7.5.2 Implications for Pharmaceutical Companies and Societies

Through cooptation within the industry, companies can leverage competitor resources and knowledge to increase their learning and innovation. The sharing of resources such as research and development, as well as licenses, results in more efficient process of innovation within the industry. This in turn increases the market for pharmaceutical products, after which companies may engage in competition for market share or a “share of the pie” (Bouncken & Fredrich, 2016, p. 1753).

The framework may also be adopted by the pharmaceutical industry to better enable innovation of products and processes through regular engagement with the medicines regulatory authority. The framework portrays the ability of the pharmaceutical companies to influence governance of the medicines regulatory authority through

communication and collaborative governance. Industry bodies may also see their role as key stakeholders in the communication between pharmaceutical companies and the medicines regulatory authority. The framework shows the need for participation of the pharmaceutical companies and industry societies in workshops and constant two-way communication with SAHPRA to enable alignment of priorities and enable regulatory issues to be addressed.

7.5.3 Implications for NGOs and Patients

NGOs may also see their role in the SAHPRA Optimal Governance Framework as key stakeholders in the regulation of medicines. Acting as both patient advocates as well as allies providing technical support to the government and medicines regulatory authority, NGOs may play a pivotal role in the regulation of medicines. Feedback to the medicines regulatory authority is important to align patient and societal priorities and ensure that SAHPRA addresses patient concerns and needs. Good relations between the NGOs and other key stakeholders in the regulation of medicines is vital for the healthcare ecosystem to maximise efficiencies of activities and share resources, resulting in better quality healthcare provision to the public.

7.5.4 Implications for Government

Government may see its role in the governance of the medicines regulatory authority, as although SAHPRA will be moving out from the Department of Health, as a Section 3A public entity, it is still accountable to the Minister of Health and therefore governed in part by the Department of Health. Good governance will therefore be dependent on good communication between the Department of Health and SAHPRA to ensure accountability and adherence to policies. Communication between the government and medicines regulatory authority is important for alignment of programmes with public health priorities and needs of the public health system. For example, prioritising the registration of essential medicines and those of priority diseases for the public health system in South Africa is essential and adequate relations between SAHPRA and government are important to ensure efficient prioritisation of medicines registrations for particular products. The relations between the government and other key stakeholders, such as pharmaceutical companies and NGOs, is also important to leverage the strengths of each stakeholder to ensure better resource utilisation.

7.6 Limitations of the research

Validity indicates that a method measures what it is intended to and the research findings are directly linked to the research objective. Reliability indicates that the method used is repeatable to allow results that are consistent (Saunders & Lewis, 2012). Interpretation of results may have been skewed due to bias of the researcher's expectations. Unstructured interviews involve the researcher's direct involvement and therefore may lead to bias (Welman, Kruger & Mitchell, 2007).

Non-probability sampling by its very nature may also have led to respondents' views not necessarily representing those of the population of interest. In order to limit bias, interview guidelines were standardised and piloted prior to implementation. Participants were given freedom to determine the content of the interview, while the interview guidelines were used to provide a framework and direction for the broad subject of each question.

Limitations included the fact that the research assessed opinions of stakeholders and situations may evolve differently to expectations of participants in the research. In addition to this, qualitative research is in itself subjective and at risk of being affected by the researcher's bias and experiences (Saunders & Lewis, 2012). Other limitations identified included the following:

- As the movement of the medicines regulatory authority to become a Section 3A public entity is in the future, opinions may change as the situations change.
- The researcher was not an expert in interviewing, which may have led to an impact on results.
- Samples were chosen out of convenience and do not necessarily represent the views of all stakeholders involved in the pharmaceutical industry.
- The three stakeholder groups were not necessarily all of the stakeholders involved in medicines regulation and therefore the scope was narrow.
- Members of the stakeholder groups chosen may have been biased in their experiences and not necessarily representing opinions and experiences of all members of the stakeholder groups.
- A limited number of the regulatory decision-makers were available to be interviewed. Some members of pharmaceutical associations and regulatory authority refused to participate due to the sensitive nature of the research topic or time constraints.

7.7 Suggestions for future research

Building on from the qualitative research that provides a foundation for future research, it is suggested that quantitative research be conducted into the financial performance and customer satisfaction as outputs of the medicines regulator to determine the effectiveness of the strategy with regards to stakeholder interaction and governance. Impact of new governance and stakeholder engagement frameworks on innovation in the industry may be measured by assessing the difference between number of innovative products on the market before and after the framework change.

The model developed may also be tested in other industries, assessing applicability to regulators of other industries. This research may be qualitative in nature, and provide other aspects of stakeholder relations, governance and innovation that are not necessarily perceived specifically in the pharmaceutical industry. It may be useful for the medicines regulatory authority to conduct its own research and expand the research around the topic, enabling better access to key regulators and providing an understanding of the perceptions of other stakeholders in the industry. Understanding relationships between pharmaceutical companies in the South African industry and perceptions of competitiveness could enable better insight into the innovative drivers in the industry.

7.8 Conclusion

The research conducted was aimed at joining the on-going discussion around the governance and efficiency of the new medicines regulatory authority, SAHPRA. It sought to fill the gap in academic literature regarding the linking of stakeholder interaction, governance and innovation in the pharmaceutical industry. It was successful in identifying the optimal governance framework for SAHPRA to enable stakeholder interaction and enable innovation in the pharmaceutical industry, as well as the roles of key stakeholders within the pharmaceutical industry. It allowed identification of the key stakeholders within the pharmaceutical industry in South Africa, as well as the key elements of governance of the medicines regulatory authority, and how these link to innovation through increased capacity, efficiency and resulting organisational effectiveness of SAHPRA. The framework developed indicates how technological, financial and human resources input into SAHPRA result, through good stakeholder relations and governance, in the final output of quality healthcare to the public.

References

- Aagaard, A. (2015). Key differences and similarities in ways of managing and supporting radical pharmaceutical front end innovation— a case study of the pharmaceutical industry. *International Journal of Innovation Management*, 19(1), 1-25.
- Andrews, R., Boyne, G. A., & Walker, R. M. (2011). Dimensions of publicness and organisational performance: A review of the evidence. *Journal of Public Administration Research and Theory*, 21(3), i301-i319.
- Barbazza, E., & Tello, J. E. (2014). A review of health governance: definitions, dimensions and tools to govern. *Health Policy*, 116(1), 1-11.
- Baregheh, A., Rowley, J., & Sambrook, S. (2009). Towards a multidisciplinary definition of innovation. *Management Decision*, 47(8), 1323-1339.
- Borrás, S. (2011). Policy learning and organisational capacities in innovation policies. *Science and Public Policy*, 38(9), 725-734.
- Bouncken, R. B., & Kraus, S. (2013). Innovation in knowledge-intensive industries: The double-edged sword of coepetition. *Journal of Business Research*, 66(10), 2060-2070.
- Bouncken, R. B., & Fredrich, V. (2016). Learning in coepetition: Alliance orientation, network size, and firm types. *Journal of Business Research*, 69(5), 1753-1758.
- Bozeman, B. (2013). What organisation theorists and public policy researchers can learn from one another: Publicness theory as a case-in-point. *Organisation Studies*, 34(2), 169-188.
- Burke, W. W. (2013). *Organisation change: theory and practice*. Thousand Oaks: Sage Publications.
- Burnes, B. (2004). Kurt Lewin and the planned approach to change: a re-appraisal. *Journal of Management Studies*, 41(6), 977-1002.

- Caerteling, J. S., Halman, J. I., Song, M., Dorée, A. G., & Bij, H. (2013). How relevant is government championing behavior in technology development?. *Journal of Product Innovation Management*, 30(2), 349-363.
- Campos, K. D. P., Norman, C. D., & Jadad, A. R. (2011). Product development public–private partnerships for public health: a systematic review using qualitative data. *Social Science & Medicine*, 73(7), 986-994.
- Chesbrough, H. (2010). Business model innovation: opportunities and barriers. *Long range planning*, 43(2), 354-363.
- Cooper, D. R., & Schindler, P. S. (2012). *Business research methods 12th ed.* New York: McGraw-Hill Education.
- Comez, P. (2016). The effects of ambidexterity and generative learning on new product performance: an empirical study. *Business Management Dynamics*, 5(8), 75-84
- Department of National Treasury. (2015). *Public institutions listed in PFMA schedule 1, 2, 3A, 3B, 3C and 3D.* Retrieved on 02.07.2016 from <http://www.treasury.gov.za/legislation/pfma/public%20entities/2015-04-30%20Public%20institutions%20Sch%201-3D.pdf>
- Cummings, T., & Worley, C. (2015). *Organisation development & change.* Stamford: Cengage learning.
- Davey, S. M., Brennan, M., Meenan, B. J., & McAdam, R. (2010). The health of innovation: Why open business models can benefit the healthcare sector. *Irish Journal of Management*, 30(1), 21.
- Doh, J. P., & Guay, T. R. (2006). Corporate social responsibility, public policy, and NGO activism in Europe and the United States: an institutional stakeholder perspective. *Journal of Management Studies*, 43(1), 47-73.
- El-Gohary, N. M., Osman, H., & El-Diraby, T. E. (2006). Stakeholder management for public private partnerships. *International Journal of Project Management*, 24(7), 595-604.

- Emerson, K., & Nabatchi, T. (2015). Evaluating the productivity of collaborative governance regimes: a performance matrix. *Public Performance & Management Review*, 38(4), 717-747.
- Emerson, K., Nabatchi, T., & Balogh, S. (2012). An integrative framework for collaborative governance. *Journal of Public Administration Research and Theory*, 22(1), 1-29.
- Fainshmidt, S., Smith, A., & Judge, W. Q. (2016). National competitiveness and Porter's diamond model: the role of MNE penetration and governance quality. *Global Strategy Journal*, 6(2), 81-104.
- Fatti, A., & du Toit, A.S.A. (2013). Competitive intelligence in the South African pharmaceutical industry. *Journal of Intelligence Studies in Business*, 1, 5-14
- Freeman, R. E. (2004). The stakeholder approach revisited. *Zeitschrift für Wirtschafts- und Unternehmensethik*, 5(3), 228.
- Gouws, J. (2015). *Legislation update and status of MCC/ SAHPRA and guidance to meet regulator's expectations*. Retrieved on 02.07.2016 from <http://sapraa.org.za/presentations/March2015/Legislation%20update%20and%20status%20of%20MCC%20SAHPRA%20-%20Dr%20Joey%20Gouws.pdf>
- Gouws, J. (2016). *Legislation, transition and implementation Medicines Control Council and SA Health Products Regulatory Authority*. Retrieved on 02.07.2016 from <http://www.saapi.org.za/wp-content/uploads/2014/05/Dr-Joey-Gouws-Status-of-MCC-SAHPRA-SAAPI-April-2016-Legislation-and-Transition-14-April-2016.pdf>
- Gray, A. (2009). Managing the interregnum – moving from the MCC to SAHPRA. *Healthcare Review 2009*
- Gray, A., Vawda, Y., & Jack, C. (2015). Health policy and legislation. *South African Health Review 2014/15*, 3.
- Grünbaum, N. N., & Stenger, M. (2013). Dynamic capabilities: do they lead to innovation performance and profitability?. *IUP Journal of Business Strategy*, 10(4), 68.

- Guler, I., & Nerkar, A. (2012). The impact of global and local cohesion on innovation in the pharmaceutical industry. *Strategic Management Journal*, 33(5), 535-549.
- Hendriks, A. M., Jansen, M. W., Gubbels, J. S., De Vries, N. K., Paulussen, T., & Kremers, S. P. (2013). Proposing a conceptual framework for integrated local public health policy, applied to childhood obesity-the behavior change ball. *Implementation Science*, 8(1), 1.
- International Convention on Harmonization. (2010). The value and benefits of ICH to drug regulatory authorities - advancing harmonization for better health. Retrieved on 29.09.2016 from http://www.ich.org/fileadmin/Public_Web_Site/News_room/C_Publications/ICH_20_anniversary_Value_Benefits_of_ICH_for_Regulators.pdf
- Kim, S., & Kim, J. N. (2016). Bridge or buffer: two ideas of effective corporate governance and public engagement. *Journal of Public Affairs*, 16(2), 118-127.
- Klag, M., & Langley, A. (2013). Approaching the conceptual leap in qualitative research. *International Journal of Management Reviews*, 15(2), 149-166.
- Kotter, J.P. (1995). Leading change: why transformation efforts fail. *Harvard Business Review*, 73(2), 59-67.
- Kozyra, B. (2012). Strategic alliance as a particular form of coopetition. *Global Management Journal*, 4(1/2), 27-38.
- Kuah, A. T. H. (2002). Cluster theory and practice: advantages for the small business locating in a vibrant cluster. *Journal of Research in Marketing & Entrepreneurship*, 4(3), 206-228.
- Lakkis, M. (2010). Global and regional drug regulatory harmonization initiatives. *Drug Information Journal*. 44(3), 289-297.
- Li, X., Zheng, Y., & Wang, C. L. (2016). Inter-firm collaboration in new product development in Chinese pharmaceutical companies. *Asia Pacific Journal of Management*, 33(1), 165-193.

- Mayosi, B. M., Lawn, J. E., van Niekerk, A., Bradshaw, D., Karim, S. S. A., Coovadia, H. M., & Lancet South Africa team. (2012). Health in South Africa: changes and challenges since 2009. *The Lancet*, 380(9858), 2029-2043.
- McCaffrey, D. P., Smith, A. E., & Martinez-Moyano, I. J. (2007). "Then let's have a dialogue": Interdependence and negotiation in a cohesive regulatory system. *Journal of Public Administration Research and Theory*, 17(2), 307-334.
- Medicines Control Council. (2016). *About the MCC*. Retrieved on 28.10.2016 from <http://www.mccza.com/About>
- Meijer, A., Boon, W., & Moors, E. (2013). Stakeholder engagement in pharmaceutical regulation: connecting technical expertise and lay knowledge in risk monitoring. *Public Administration*, 91(3), 696-711.
- Narayanan, V. K., & Fahey, L. (2005). The relevance of the institutional underpinnings of Porter's five forces framework to emerging economies: An epistemological analysis. *Journal of Management Studies*, 42(1), 207-223.
- Narsai, K., Williams, A., Mantel-Teeuwisse, A.K. (2012). Impact of regulatory requirements on medicines registration in African countries - perceptions and experiences of pharmaceutical companies in South Africa. *Southern Med Review*. 5(1), 31-37.
- O'Reilly, C. A., & Tushman, M. L. (2011). Organizational ambidexterity in action: How managers explore and exploit. *California Management Review*, 53(4), 5-22.
- Politzer, G., & Baratgin, J. (2016). Deductive schemas with uncertain premises using qualitative probability expressions. *Thinking & Reasoning*, 22(1), 78-98.
- Poole, M. S., & Van de Ven, A. H. (Eds.). (2004). *Handbook of organizational change and innovation*. New York: Oxford University Press.
- Porter, M.E. (1990). *The competitive advantage of nations*. New York: Free Press.
- Porter, M.E. (1998). *The competitive advantage of nations*. New York: Free Press.

- Republic of South Africa. (2014). Bill 6 of 2014. *Government Gazette*, 584(37361).
- Robichau, R. W. (2011). The mosaic of governance: Creating a picture with definitions, theories, and debates. *Policy Studies Journal*, 39(1), 113-131.
- Ruff, P. (2015). *Regulation and funding of medicines in South Africa*. Retrieved on 09.02.2016 from <http://am.asco.org/regulation-and-funding-medicines-south-africa>
- Sacks, L. V., Shamsuddin, H. H., Yasinskaya, Y. I., Bouri, K., Lanthier, M. L., & Sherman, R. E. (2014). Scientific and regulatory reasons for delay and denial of FDA approval of initial applications for new drugs, 2000-2012. *JAMA*, 311(4), 378-384.
- Saunders, M., & Lewis, P. (2012). *Doing research in business and management: An essential guide to planning your project*. London: Pearson Education.
- Scott, W.R. (2014). *Institutions and organizations: Ideas, interests and identities*. Thousand Oaks: Sage Publications.
- Siddiqi, S., Masud, T. I., Nishtar, S., Peters, D. H., Sabri, B., Bile, K. M., & Jama, M. A. (2009). Framework for assessing governance of the health system in developing countries: gateway to good governance. *Health policy*, 90(1), 13-25.
- Singh, K. D. (2015). Creating your own qualitative research approach: Selecting, integrating and operationalizing philosophy, methodology and methods. *Vision: The Journal of Business Perspective*, 19(2), 132-146.
- Suzuki, O. (2015). Unpacking performance benefits of innovation ambidexterity: Evidence from the pharmaceutical industry. *Management Revue*, 26(4).
- Toyo, Z.P. (2012). *Response of firms to impending disruptive change* (MBA mini-dissertation). Gordon Institute of Business Science, University of Pretoria. Retrieved from <http://repository.up.ac.za/dspace/handle/2263/23056>
- United Nations. (2012). UN system task team on the post-2015 UN development agenda. Retrieved from http://www.un.org/millenniumgoals/pdf/Think%20Pieces/7_governance.pdf

- United States Food and Drug Administration. (2015). Regulatory harmonization and convergence. Retrieved on 29.09.2016 from <http://www.fda.gov/BiologicsBloodVaccines/InternationalActivities/ucm271079.htm>
- Utens, C. M., Dirksen, C. D., van der Weijden, T., & Joore, M. A. (2016). How to integrate research evidence on patient preferences in pharmaceutical coverage decisions and clinical practice guidelines: A qualitative study among Dutch stakeholders. *Health Policy*, 120(1), 120-128.
- Vangen, S., Hayes, J. P., & Cornforth, C. (2015). Governing cross-sector, inter-organizational collaborations. *Public Management Review*, 17(9), 1237-1260.
- Vining, A. R. (2011). Public agency external analysis using a modified “five forces” framework. *International Public Management Journal*, 14(1), 63-105.
- Verbeke, A., & Tung, V. (2013). The future of stakeholder management theory: A temporal perspective. *Journal of Business Ethics*, 112(3), 529-543.
- Wang, C. L., & Rafiq, M. (2014). Ambidextrous organizational culture, contextual ambidexterity and new product innovation: A comparative study of UK and Chinese high-tech firms. *British Journal of Management*, 25(1), 58-76.
- Welman, C., Kruger, F., & Mitchell, B. (2007). *Research methodology 3rd edition*. Cape Town: Oxford University Press.
- World Health Organization. (1999). Effective drug regulation: what can countries do? Retrieved on 29.09.2016 from [http://apps.who.int/iris/bitstream/10665/65025/1/WHO_HTP_EDM_MAC\(11\)_99.6.pdf](http://apps.who.int/iris/bitstream/10665/65025/1/WHO_HTP_EDM_MAC(11)_99.6.pdf)
- Wu, A. Y. H., Little, V. J., & Low, B. (2016). Inbound open innovation for pharmaceutical markets: a case study of an anti-diabetic drug in-licensing decision. *Journal of Business & Industrial Marketing*, 31(2), 205-218.

Appendices

Appendix 1: Pharmaceutical Companies Discussion Guide

Introduction

Good Day,

Thank you for agreeing to take part in this research. My name is Amanda Calder and I am an MBA student at the Gordon Institute of Business Science (GIBS).

As you may be aware, the South African medicines regulatory authority, the Medicines Control Council (MCC) is moving away from being under to the control of the National Department of Health to becoming a Section 3A public entity, the South Africa Health Products Regulatory Authority (SAHPRA). This provides an ideal opportunity to review the regulator's strategy with regards to governance and stakeholder interaction. In this case, governance involves using rules, regulations, accountability and leadership to provide direction to achieve the regulator's goals and stakeholders are parties that may affect or be affected by decisions of the regulator, including you.

I would like to get your opinion on what your experiences have been so far with the MCC and what you will expect of SAHPRA, especially with regards to enabling innovation in the pharmaceutical industry. Please feel free to ask questions if you have any concerns or additional suggestions for the research. If you do not have any questions so far, we will proceed to the interview.

Participant's Information & Informed Consent Document

STUDY TITLE:

Perceptions of optimal governance of and stakeholder involvement in a medicines regulatory authority to enable pharmaceutical innovation

SPONSOR: N/A

Principal Investigators: Amanda Calder

Institution: Gordon Institute of Business Science (GIBS), University of Pretoria

DAYTIME AND AFTER HOURS TELEPHONE NUMBER:

Daytime numbers: 079 181 5444 **Afterhours:** 079 181 5444

DATE AND TIME OF FIRST INFORMED CONSENT DISCUSSION:

dd	mmm	ivy

:
Time

Dear Participant

Dear Mr. / Mrs. date of consent procedure/...../.....

1) INTRODUCTION

You are invited to volunteer for a research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the investigator. You should not agree to take part unless you are completely happy about all the procedures involved.

2) THE NATURE AND PURPOSE OF THIS STUDY

You are invited to take part in a research study. This research will be performed on the optimal governance structure for the South African Health Products Regulatory Association (SAHPRA) to address stakeholder needs and enable healthcare innovation. The aim of this study is to identify perceptions of the regulatory authority to relations with pharmaceutical companies, as well as perceptions and experiences of pharmaceutical companies with regards to interaction with SAHPRA's predecessor, the Medicines Control Council (MCC). By doing so we wish to learn more about the optimal future governance framework for SAHPRA needed to enable innovation in the pharmaceutical industry. Some problems could be serious and if identified early could save you from having problems later on.

3) EXPLANATION OF PROCEDURES TO BE FOLLOWED

This study involves answering questions with regards to your experiences with the MCC and perceptions around the optimal governance framework for SAHPRA. With your permission, the interview will be audio-recorded and files will be stored electronically on the researcher's computer, with access restricted to the researcher only, for a period of at least 10 years.

4) RISK AND DISCOMFORT INVOLVED.

There will be no compensation given for participation. Our interview is expected to last about an hour and will consist of a mixture of closed and open-ended questions.

5) POSSIBLE BENEFITS OF THIS STUDY.

As a stakeholder in the pharmaceutical industry, you are invited to participate in this research and it is envisioned that results from this research will be valuable in identifying an optimal framework for governance for SAHPRA.

6) I understand that I may at any time withdraw from this study without penalty.

7) HAS THE STUDY RECEIVED ETHICAL APPROVAL?

This Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, telephone numbers 012 3541677 / 012 3541330 and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2013), which deals with the recommendations guiding doctors in biomedical research involving human/subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it.

8) INFORMATION If I have any questions concerning this study, I should contact:

Amanda Calder Cell: 0791815444

Email: 16390483@mygibs.ac.za

Discussion Guide

Past

1. Who are the stakeholders involved in the approval and adoption of medical technologies and new pharmaceutical products?
2. What are your experiences in dealing with the other stakeholders, in particular the pharmaceutical industry/ MCC (trust, level of consultation, cooperation)? What are the challenges?
3. How do you think regulations have affected pharmaceutical companies ability to innovate (products and processes)?
4. How do you think the current MCC governance structure and processes could be improved?

Future

5. What do you think should be the optimal format for stakeholder engagement of SAHPRA (through the PSSA or societies, or directly from the company to the authority? Consultative?)
6. Are there other stakeholders who should be involved in the regulation of medicines who are not being involved?
7. How could the medicines regulatory authority better enable innovation in the pharmaceutical industry?
8. What will the optimal governance framework be for SAHPRA to enable better stakeholder interaction and innovation?

Appendix 2: Medicines Control Council Discussion Guide

Introduction

Good Day,

Thank you for agreeing to take part in this research. My name is Amanda Calder and I am an MBA student at the Gordon Institute of Business Science (GIBS).

With the Medicines Control Council (MCC) moving away from being under the control of the National Department of Health to becoming a Section 3A public entity, the South Africa Health Products Regulatory Authority (SAHPRA), this provides an ideal opportunity to review its strategy with regards to governance and stakeholder interaction. In this case, governance involves using rules, regulations, accountability and leadership to provide direction to achieve the regulatory authority's goals and stakeholders are parties that may affect or be affected by decisions of the regulator.

I would like to get your opinion on what your experiences have been so far as the MCC and what you think will be the ideal structure of governance at SAHPRA, especially with regards to enabling innovation in the pharmaceutical industry. Please feel free to ask questions if you have any concerns or additional suggestions for the research. If you do not have any questions so far, we will proceed to the interview.

Participant's Information & Informed Consent Document

STUDY TITLE:

Perceptions of optimal governance of and stakeholder involvement in a medicines regulatory authority to enable pharmaceutical innovation

SPONSOR: N/A

Principal Investigators: Amanda Calder

Institution: Gordon Institute of Business Science (GIBS), University of Pretoria

DAYTIME AND AFTER HOURS TELEPHONE NUMBER:

Daytime numbers: 079 181 5444 **Afterhours:** 079 181 5444

DATE AND TIME OF FIRST INFORMED CONSENT DISCUSSION:

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Time

Dear Participant

Dear Mr. / Mrs. date of consent procedure/...../.....

1) INTRODUCTION

You are invited to volunteer for a research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the investigator. You should not agree to take part unless you are completely happy about all the procedures involved.

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You are invited to take part in a research study. This research will be performed on the optimal governance structure for the South African Health Products Regulatory Association (SAHPRA) to address stakeholder needs and enable healthcare innovation. The aim of this study is to identify perceptions of the regulatory authority to relations with pharmaceutical companies, as well as perceptions and experiences of pharmaceutical companies with regards to interaction with SAHPRA's predecessor, the Medicines Control Council (MCC). By doing so we wish to learn more about the optimal future governance framework for SAHPRA needed to enable innovation in the pharmaceutical industry. Some problems could be serious and if identified early could save you from having problems later on.

3) EXPLANATION OF PROCEDURES TO BE FOLLOWED

This study involves answering questions with regards to your experiences with the MCC and perceptions around the optimal governance framework for SAHPRA. With your permission, the interview will be audio-recorded and files will be stored electronically on the researcher's computer, with access restricted to the researcher only, for a period of at least 10 years.

4) RISK AND DISCOMFORT INVOLVED.

There will be no compensation given for participation. Our interview is expected to last about an hour and will consist of a mixture of closed and open-ended questions.

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As a stakeholder in the pharmaceutical industry, you are invited to participate in this research and it is envisioned that results from this research will be valuable in identifying an optimal framework for governance for SAHPRA.

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8. What will the optimal governance framework be for SAHPRA to enable better stakeholder interaction and innovation?

Appendix 3: Industry Experts Discussion Guide

Introduction

Good Day,

Thank you for agreeing to take part in this research. My name is Amanda Calder and I am an MBA student at the Gordon Institute of Business Science (GIBS).

As you may be aware, the South African medicines regulatory authority, the Medicines Control Council (MCC) is moving away from being under to the control of the National Department of Health to becoming a Section 3A public entity, the South Africa Health Products Regulatory Authority (SAHPRA). This provides an ideal opportunity to review the regulator's strategy with regards to governance and stakeholder interaction. In this case, governance involves using rules, regulations, accountability and leadership to provide direction to achieve the regulator's goals and stakeholders are parties that may affect or be affected by decisions of the regulator, including you.

I would like to get your opinion on what your experiences have been so far with the MCC and what you will expect of SAHPRA, especially with regards to enabling innovation in the pharmaceutical industry. Please feel free to ask questions if you have any concerns or additional suggestions for the research. If you do not have any questions so far, we will proceed to the interview.

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Perceptions of optimal governance of and stakeholder involvement in a medicines regulatory authority to enable pharmaceutical innovation

SPONSOR: N/A

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Time

Dear Participant

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1) INTRODUCTION

You are invited to volunteer for a research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the investigator. You should not agree to take part unless you are completely happy about all the procedures involved.

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There will be no compensation given for participation. Our interview is expected to last about an hour and will consist of a mixture of closed and open-ended questions.

5) POSSIBLE BENEFITS OF THIS STUDY.

As a stakeholder in the pharmaceutical industry, you are invited to participate in this research and it is envisioned that results from this research will be valuable in identifying an optimal framework for governance for SAHPRA.

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Amanda Calder Cell: 0791815444

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Discussion Guide

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6. Are there other stakeholders who should be involved in the regulation of medicines who are not being involved?
7. How could the medicines regulatory authority better enable innovation in the pharmaceutical industry?
8. What will the optimal governance framework be for SAHPRA to enable better stakeholder interaction and innovation?

Appendix 4: GIBS Ethics Approval

Dear Amanda Calder

Protocol Number: **Temp2016-01006**

Title: **Perceptions of optimal governance of and stakeholder involvement in a medicines regulatory authority to enable pharmaceutical innovation**

Please be advised that your application for Ethical Clearance has been approved subject to the following conditions.

The consent statement should state confidentiality not anonymity.

Once you have made this minor amendment and submitted the changes to the Research Coordinator, you will be allowed to continue collecting your data.

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

Kind Regards,

Adele Bekker



Appendix 5: University of Pretoria Faculty of Health Sciences Research Ethics Approval

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567, Approved dd 22 May 2002 and Expires 20 Oct 2016.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 22/04/2017.



UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

28/07/2016

Endorsement Notice

Ethics Reference No.: Temp2016-01040

Title: GIBS: Perceptions of optimal governance of and stakeholder involvement in a medicines regulatory authority to enable pharmaceutical innovation

Dear Amanda Calder

The **New Application** as supported by documents specified in your cover letter for your research received on the 19/07/2016, was approved, by the Faculty of Health Sciences Research Ethics Committee on the 27/07/2016.

Please note the following about your ethics approval:

- Please remember to use your protocol number (**Temp2016-01040**) 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 Sommers; MBChB; MMed (Int); MPharMed; 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).

☎ 012 356 3085 ✉ fhsethics@up.ac.za 🌐 <http://www.up.ac.za/healthethics>
✉ Private Bag X323, Arcadia, 0007 - Tswelopele Building, Level 4-59, Gezina, Pretoria

Appendix 6: Turnitin Report



Turnitin Originality Report
 Research Report by Amanda Calder
 From Test your originality (GIBS Information Centre_99_1)

- Processed on 02-Nov-2016 10:41 SAST
- ID: 685304271
- Word Count: 34168

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[Submitted to University of Pretoria on 2016-06-13](#)

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<http://shsph.up.ac.za/pdf/EthicsResearchpackage.PDF>

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[Submitted to University of Pretoria on 2012-11-06](#)
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<http://repository.up.ac.za/bitstream/handle/2263/24799/dissertation.pdf?sequence>
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http://repository.up.ac.za/bitstream/handle/2263/44919/Zulu_Obsolescing_2014.pdf?sequence=1
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[Emerson, Kirk, and Tina Nabatchi. "Evaluating the Productivity of Collaborative Governance Regimes: A Performance Matrix". Public Performance & Management Review, 2015.](#)
- 12** < 1% match (student papers from 11-Aug-2015)
[Submitted to Northcentral on 2015-08-11](#)
- 13** < 1% match (Internet from 06-May-2010)
<http://www.equinetfrica.org/newsletter/index.php?issue=108>
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