

UNIVERSITY OF KWAZULU-NATAL

**The Impact of South African Medical Aid Scheme Regulations of Designated Service
Providers on Independent Community Pharmacies in the Chatsworth area**

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ABSTRACT

Community pharmacies play a vital role in providing primary health care to the community, since they are easily accessible. The objective of the study was to evaluate the impact of medical aid scheme regulations of Designated Service Providers on the future of independent community pharmacies as well as how this regulation affected patient care. A qualitative study was employed at eight independently owned community pharmacies in the Chatsworth area. Data were collected using semi-structured interviews and permission was gained from each participant to record the interview. The data was then transcribed and analysed using NVivo software.

With regards to the impact of Designated Service Providers on the future of independent community pharmacies the following themes were identified: financial strain, pharmacist as an entrepreneur as decreased and customer relationship has been strained. Similarly, to identify how the regulation affected patient care these themes of patients' rights, generic substitution and penalty co-payments were among the few that was revealed. The study also identified the challenges faced by independent community pharmacies with patients due to the medical aid scheme regulations which were compromised quality of patient care, monitoring patient medicine profile and the changing role of a pharmacist. Revisiting legislation and framework for pharmacy is necessary to ensure that optimal pharmaceutical is rendered to the patient.

TABLE OF CONTENTS

ABSTRACT	6
List of Figures	10
List of Tables	11
ABBREVIATIONS	12
1. INTRODUCTION	1
1.1. Background	1
1.2. Motivation for the study.....	2
1.3. Problem statement.....	3
1.4. Aim and objectives of the study.....	4
1.5. Research questions	4
1.6. Significance of the study.....	5
1.7. Research method	5
1.8. Limitations of the study.....	5
1.9. Structure of the study	6
1.10. Summary.....	6
2. LITERATURE REVIEW	7
2.1. Introduction	7
2.2. Medical aid schemes	7
2.3. History of pharmaceutical industry.....	10
2.4. Key trends in the pharmaceutical industry.....	10
2.5. Modern society demands of pharmaceuticals	11
2.6. Evolution of health care around the world.....	13
2.7. Evolution of health care in South Africa.....	14
2.8. History of pharmacy.....	15
2.9. Pharmacy in South Africa	17
2.10. Role of a pharmacist.....	18

2.11.	Community pharmacists	20
2.13.	Pharmacists and patient relationships	22
2.14.	Pharmacist's relationship with other health care professionals	23
2.15.	Pharmacist ethical behaviour and code of conduct	23
2.16.	Service quality to build customer relationships	24
2.16.1.	Tangibles	24
2.16.2.	Reliability	24
2.16.3.	Responsiveness.....	25
2.16.4.	Assurance	25
2.16.5.	Empathy	25
2.17.	Corporate pharmacies	26
2.18.	Government legislation and regulations on health care system in South Africa...26	
2.19.	Patient rights	27
2.20.	Medical aid schemes.....	28
2.21.	Industry timeline.....	Error! Bookmark not defined.
2.22.	Evolution of designated service providers.....	29
2.23.	Concerns of designated service provider's.....	31
2.24.	Summary.....	31
3.	RESEARCH METHODOLOGY.....	33
3.1.	Introduction	33
3.2.	The research design.....	34
3.3.	Research approaches	35
3.4.	Location of the study.....	36
3.5.	Research population	36
3.6.	Sample and sampling method	37
3.7.	Selection criteria.....	39
3.8.	Data collection.....	39

3.9.	Validity and reliability	40
3.10.	Study limitations.....	40
3.11.	Ethics	41
3.12.	Summary.....	41
4.	RESULTS AND DISCUSSION	43
4.1.	Introduction	43
4.2.	Data analysis	43
4.3.	Thematic analysis.....	44
	Objective 1	46
	Objective 2.....	52
	Objective 3.....	58
5.	CONCLUSION AND RECOMMENDATIONS	62
5.1.	Introduction	62
5.2.	Answers to the research problem	62
5.3.	Implications to the study	62
5.4.	Conclusion.....	63
5.5.	Recommendations	64
6.	REFERENCES	65
	APPENDIX I – Ethical clearance	71
	APPENDIX II – Informed consent.....	72
	APPENDIX III – Interview schedule	74
	APPENDIX IV – Turnitin report.....	76

List of Figures

Figure 1. Challenges in Global Health Care	9
Figure 2. Smart Health Innovation.....	14
Figure 3. Evolution of Health Care in South Africa	15
Figure 4. Evolution of the Pharmacist	16
Figure 5. The Stakeholders in Community Pharmacy Sector	21

List of Tables

Table 1. Trending Drugs in Pharmaceutical Industry	12
Table 2. Statistics for Registered Pharmacists	17
Table 3. Advantages and Disadvantages of Corporate Pharmacies.....	26
Table 4. Types of Non-Probability Sampling Methods	38

ABBREVIATIONS

CEO	Chief Executive Officer
CPD	Continued Professional Development
CMS	Council for Medical Schemes
DOH	Department of Health
DSP	Designated Service Provider
DHMS	Discovery Health Medical Scheme
DF	Dispensing Fee
EDL	Essential Drug List
GEMS	Government Employees Medical Scheme
GPP	Good Pharmacy Practice
ICPA	Independent Community Pharmacy Association
ICD 10	International Statistical Classification of diseases and Related Health Problems 10 th ed
KZN	Kwa-Zulu Natal
MCC	Medicine Control Council
NHI	National Health Insurance
OTC	Over the Counter
PMB	Prescribed Minimum Benefits
SEP	Single Exit Price
SAPC	South African Pharmacy Council
SCA	Supreme Court of Appeal
WHO	World Health Organisation

CHAPTER 1.

“The awareness that health is dependent upon habits that we control makes us the first generation in history that to a large extent determines its own destiny.” – Jimmy Carter

1. INTRODUCTION

1.1. Background

The origins of the pharmaceutical industry date as far back as the middle ages with apothecaries which offered traditional remedies based on folk knowledge. The industry, as we know it today, is rooted more strongly with the industry that originated in the latter half of the 19th century. The industry was born by the marriage of the scientific revolution that promoted experimentation and the industrial revolution that had transformed the manufacturing of goods. One of the fundamental pillars to the development of the pharmaceutical industry was the rapid growth in demand for drugs. This was propelled by population growth, improved standards of living and the discovery of medical disorders that were not understood previously (Malerba and Orsenigo, 2015, pp 664-687).

Today, the manufacture, use and distribution of pharmaceuticals is critical in ensuring a healthy population and it is the most vulnerable members of the population that are negatively impacted by the poor distribution of pharmaceuticals (Antonie, Simkins, van Dalsen, Chetty, Collocott, Toxopeus and Doodnath, 2018, pp 43-45). In South Africa, the pharmaceutical industry is valued R48.6 billion in 2017 in terms of supply. The private sector accounts for 69% of the industry whilst 31% is accounted for by the public sector. The paradox of this lies in the fact that the majority of South Africans depend on the public sector. The expenditure differential between the two sectors is due mainly to the fact that medicines are supplied to the public sector at a much lower cost (Antonie, Simkins, van Dalsen, Chetty, Collocott, Toxopeus and Doodnath, 2018, pp 72-73).

Since it is most commonly the lowest income sector that relies on public health, governments are expected to provide health care, and the resulting medicines, at low costs. This means that these medicines have to be heavily subsidised to ensure that the poorest communities can have access to these life-saving drugs (Shafiq, Kösters and Muhammad, 2015, pp 1-15). To ensure

a steady flow of medicines governments have had to look at ways at lowering the costs of drugs and have turned to importing them from countries that are able to produce these drugs at lower costs.

1.2. Motivation for the study

There are few other healthcare professions that are more harshly affected by changes in legislation as the pharmacist. In South Africa, pharmacy is the only profession where unqualified/unprofessional ownership is allowed, and the professional fee is capped. The provision for Designated Service Providers (DSPs) in the Medical Schemes, 1998 (Act 131 of 1998, Regulation 7) was intended to encourage DSP arrangements between medical schemes and healthcare providers to ensure the proper delivery of Prescribed Minimum Benefits (PMBs) to all beneficiaries to all schemes. If patients want to consult with service providers that are not contracted to their medical aid scheme, the patient will have to pay a penalty co-payment. This penalty co-payment from a consumer's perspective restricts a patient's choice of healthcare provider and thereby has a negative impact on freedom of choice, the patients' well-being and other pharmacies the right to compete.

The South African Government's launch of open ownership of pharmacies in 2003 intended to improve access of pharmaceutical services to the less developed sectors of the population. The change in legislation had an unplanned consequence of corporatization of pharmacies. This led to corporate entities opening more pharmacies in urban areas which inevitably led unfair competition with community pharmacies resulting in the closure of many of these independent community pharmacies (Thakur-Rajbansi, 2009, pp 13-16).

Independent community pharmacies were places in which customers could speak to their pharmacists and pharmacist in turn, cared about their customers enough to ensure that they supplied these customers with the best medication possible. Nowadays, these pharmacists are battling to survive due to the entrance of corporate pharmacies, dispensing fee (DF) structure, use of generic substitution and the implementation of designated service providers by medical aid schemes in South Africa (Basak, van Mil and Sathyanarayana, 2009, pp 612-618). This is of real concern as the pharmacist used to be a major role player in the healthcare supply chain and was usually the last person in the chain that saw the patient (Leung, Saini and Ritchie,

2018, pp 1-15). The regulation of closed DSPs has forced patients to get their chronic prescriptions dispensed at corporate and courier pharmacies. These patients have seen a reduction in their rights to choose their healthcare provider. The emergence of courier pharmacies has further disadvantaged the patient from being counselled by a pharmacist upon refill of their chronic prescriptions. This legislation allows for unfair business practice which is negatively affecting independent community pharmacies as well as the patient (Fatti and du Toit, 2013, pp 5-14).

1.3. Problem statement

In South Africa, independent community pharmacies represent a pool of resources available to enhance primary healthcare delivery across the country. Usually a patient's first line of treatment is initiated by the pharmacist. Medical aid scheme introduction of closed DSPs has caused concern since many independent community pharmacies are now moving to corporate pharmacies (Independent Community Pharmacy Association, 2018). It is almost impossible for a pharmacist to become an entrepreneur within the independent community sector as the costs are too high and the profits are non-existent. DSPs restricts a patient to use of a service provider to ones that are allocated by their scheme without consultation. According to the National Patients' Rights Charter every patient has the right to choose their own healthcare provider or facility, the regulation of closed DSP removes the patient's freedom of choice.

(Independent Community Pharmacy Association, 2016) the use of courier pharmacies for dispensing of chronic medication as undermined the importance of patient counselling which is a primary function of a pharmacist. Courier pharmacies do not offer face to face counselling like a community pharmacy. Patients speak to call centre operators not necessarily a pharmacist. When items are out of stock or if there is a generic substitution of a medicine the courier pharmacy makes a note on the parcel and it is delivered to the patient. The patient is not advised accordingly or given the option to decide if they agree to the generic substitution or if they have any reactions to the new medicine dispensed. In the case of out of stock medicines the patient is forced to get a prescription to purchase the required medicines from the local pharmacy. Courier pharmacies do not dispense over the counter (OTC) and acute prescriptions. The pharmacist can only provide the best pharmaceutical care to the patient when

the pharmacist as the comprehensive pharmaceutical history. DSP arrangements by medical aid for chronic medicines often leave the independent community pharmacist in despair, since they do not have access to the patients' medicine history. Independent community pharmacies can dispense OTC and acute prescriptions. When counselling the patient on their acute prescription, the pharmacist is forced to offer fragmented care. The pharmacist cannot eliminate drug-drug interaction and drug-disease adverse effects.

1.4. Aim and objectives of the study

In South Africa the use of DSP contracts or networks has been a common place especially since medical schemes have a statutory obligation to pay for the closed list of Prescribed Minimum Benefits (PMBs). It is therefore important to understand how medical aid regulations of DSPs has affected independent community pharmacists' survival. Furthermore, how these regulations have impacted on the independent pharmacist's ability to assist in the healthcare requirements of the patient.

- To explore the impact of Designated Service Providers on the future of independent community pharmacies.
- To examine how this regulation has affected pharmacist-patient care.
- To understand the challenges faced by independent community pharmacies with patients due to the medical aid scheme regulations.

1.5. Research questions

- What is the assessment of the future of independently owned community pharmacies?
- Does this regulation of DSPs infringe on patients' rights?
- Did the relationship between independently owned pharmacies and their patients deteriorate?

1.6. Significance of the study

There is no other healthcare profession severely affected by changes in legislation as the pharmacist. In South Africa pharmacy is the only profession where lay ownership is allowed, and professional/dispensing fee is regulated at a capped maximum (Thakur-Rajbansi, 2009, pp 31-36). Closed DSP's as a tremendous impact on the community. Community pharmacies also employ and skill the community members. DSP's are either large corporate pharmacies or courier pharmacies. Community pharmacists differentiate themselves from the chain pharmacies through long standing relationships with patients and the community. Community pharmacies trade till late hours, open on weekends and public holidays. Community pharmacy plays a vital role in providing over the counter medicines (OTC), acute, emergency, chronic medicines to patients. If these community pharmacies close since the business is unprofitable, this will limit the patients' access to healthcare.

1.7. Research method

A qualitative study was employed in the research. The population was independently owned pharmacies that have been practicing for greater than 15 years in the Chatsworth area. The data was collected by a semi-structured interview and was audio recorded. Upon completion the data was transcribed and NVivo 11 programme was used to analyse the data.

1.8. Limitations of the study

The research was focused in the Chatsworth area a suburban of Durban, whilst this regulation affects the entire of South Africa. The research was conducted over a two-month period and therefore shows only a 'snap-shot'. Since the healthcare industry in South Africa is continuous evolving, this research should be conducted at fixed periods to gain a holistic valuation. The researcher had difficulty gaining gatekeepers permission from one body, therefore the researcher had to engage each pharmacy before getting the permission. The South African Pharmacy Council (SAPC) did not have updated data on the number of independent pharmacies that had closed.

1.9. Structure of the study

CHAPTER 1: Introduction of the study. This chapter includes the motivation for the study, the problem statement, the objectives of the study, the research questions, as well as the limitations.

CHAPTER 2: Literature Review. This chapter outlines the theoretical framework of the study. This includes the evolution of the pharmacy and healthcare in South Africa and the world, the role of pharmacist and patient rights. It also includes government legislation and how it as affected community pharmacies and patient care. The literature review also discusses small business enterprise and the profitability of independently owned pharmacies and corporate franchise pharmacies.

CHAPTER 3: Research Methodology. This chapter describes the different type of research methods. It describes the research design and procedures used to collect the data for this study.

CHAPTER 4: Results and Discussion. This chapter analyses the data collected and analysed using the NVivo 11 software.

CHAPTER 5: Conclusions and Recommendations for future study. This chapter provides recommendations for future studies and suggestions for a synergistic relationship between policy holders and independently owned pharmacies taking into consideration and opinion of the patients.

1.10. Summary

The pharmaceutical industry is highly regulated and as an effect on service delivery, freedom of choice of the patient and the viability of small business. The rapid emergence of chain pharmacies and courier pharmacies has eradicated the hope of a pharmacist being an entrepreneur. Changes in legislation as harshly affected the community pharmacist in effectively fulfilling their role as a pharmacist.

2. LITERATURE REVIEW

2.1. Introduction

The objective of the pharmaceutical industry is to create innovative new drug therapies for patients to assist in living longer and healthier lives. In the United States of America and European countries over 650,000 million people work in the pharmaceutical industry, 1.6 million in China, over 400,000 in India and many more world-wide (Read, 2014). Pharmaceutical innovation has contributed to 73% of the total increase in life expectancy between the years 2000 and 2009 in 30 countries (Read, 2014). Innovative pharmaceutical development is now focused on effectively treating “the right patient, at the right time, with the right medicine, at the right dose,” (Read, 2014). Throughout the world pharmacists are an essential link in the healthcare value chain (Venkata and Reddy, 2017, pp 19). Pharmacists are the only health profession that is accessible without an appointment therefore it is often the first contact made by patients (Mossialos, Naci and Courtin, 2013, pp 135-148).

In South Africa the overall health care market is defined by the rising cost of healthcare and medical scheme cover, extremely concentrated funders, uninformed and disempowered patients and regulations with no accountability (Competition Commission South Africa, 2018). The private health care market shows a steady increase in medical aid scheme premiums together with out of pocket payments for the members. The state of the private healthcare market is due to the regulations in the 1980s and re-regulation which has resulted in the status quo.

2.2. Medical aid schemes

There are 270 plans that various medical aid schemes offer but members cannot compare these plans with those that are best suited for them. Medical aid schemes seem to make the plans more affordable but reduce the range of benefits over a period. These are some of the factors that cause the members to be disempowered. There is no means for the member to assess the

value of service that the schemes offer. Schemes and administrators are not effective in using buying power to negotiate contracts that will benefit the member by reducing premiums and out of pocket payments. Current examples are:

- the inadequate management of Prescribed Minimum Benefit (PMB) payments to decrease scheme disclosure of compulsory PMB costs,
- payments from saving accounts in place of risk pool,
- recognising that the database for the members are not always correct and therefore this introduces the value of Designated Service Provider (DSP) networks,
- no valid data to prove that supply induced demand is evaluated, monitored and managed.

There are 20 open medical aid schemes available (Council for Medical Schemes, 2018c).

BESTMED	MAKOTI
BONITAS	MEDIHELP
CAPE	MEDIMED
COMPCARE WELLNESS	MEDSHIELD
DISCOVERY HEALTH	MOMENTUM
FEDHEALTH	SELFMED
GENESIS	SIZWE
HEALTH SQUARE	SUREMED
HOSMED	THEBEMED
KEYHEALTH	TOPMED

Discovery Health Medical Scheme (DHMS) dominated the open scheme market with 55% of members. The largest restricted medical aid scheme is Government Employees Medical Scheme (GEMS). Discovery Health and Medscheme represent 76% of the gross contribution income (GCI), which results in a concentrated market. Other medical aid schemes have not challenged these dominant schemes in the market, since there is lack of innovation (Antonie, Simkins, Augustine, Barlow, Doodnath, Fonkam, Meyers, Morris, Phaahla, Pieters and von der Heyde, 2016, pp 7-8).



Figure 1. Challenges in Global Health Care Source: (Taylor, 2018)

The report by (Deloitte, 2018) acknowledges the mammoth challenges being encountered by the global healthcare industry. To improve healthcare services and to lessen the pressures on the healthcare system, all stakeholders should pool their resources, experiment with new strategies that works and use innovative technological advancements to reduce administrative costs in order to sustain and empower the industry.

2.3. History of pharmaceutical industry

The pharmaceutical industry plays a vital function in formulating drugs and vaccines to decrease and treat different diseases conditions, while improving the patient's quality of life (Nead, 2017). The pharmaceutical industry finds, creates, manufactures and promotes the drugs for use as medicine Pharmaceutical drugs were discovered in the 19th and 20th century through research into bacteria and chemistry. During this time governments all over the world started to realise that they had a duty to deliver services to safeguard and improve health care of each citizen (Test, 2007).

2.4. Key trends in the pharmaceutical industry

Global trends are redefining the pharmaceutical industry and pharmaceutical companies will have to adapt in to meet the requirements that these trends produce. These include:

- The rising incidence of chronic diseases that have put a strain on the healthcare budget,
- The increasing demand for medicines from emerging economies compared to that of developed economies,
- Regulators that are more cautious when approving new medicines due to the demand of innovative medicines by modern society.
- Pricing of pharmaceuticals are uncertain since it is regulated by the government.

Japan and Germany are influenced by international pharmaceutical industries to launch stringent price regulations on new medicines due to the concern of over-priced generic medicines (Nead, 2017). It is therefore necessary for pharmaceutical companies to be

transparent in the pricing structure. According to (Mentesana, Rotz, DStrang and Swanick, 2017) the patient-first business model establishes the pharmaceutical company as a valued partner in society. This model will demonstrate that the pharmaceutical company is focused on the patients' well-being, and in turn will create a higher chance of regulatory success and increases sales growth. Patients will reveal personal information to pharmaceutical companies and regulators if the information provided will assist in improved health care. Due to the technological innovation health care providers and pharmaceutical companies have developed smartphone applications to monitor, access and communicate with patients. In doing so, pharmaceutical companies can understand the patients' needs.

2.5. Modern society demands of pharmaceuticals

The pharmaceutical companies are constantly improving and formulating new drugs to assist patients with precise, accurate dosing as well as making compliance easier this is a key factor driving the demand of pharmaceuticals drugs. Another driving force of demand is the increase number of chronic conditions and the constant advancements in technology. The pharmaceutical industry is using innovative research methods by combining technological advancements to meet the demands of the evolving health care (Nead, 2017). According to (Nead, 2017) current industry trends point towards one drug treating multiple chronic conditions as seen in Table 1.

Table 1. Trending Drugs in Pharmaceutical Industry Source: (Nead, 2017)

DRUG COMPANY	DRUG	INDICATION	CHRONIC CONDITION	FORECAST SALES BY 2022 (USA \$)	MARKET ENTRY (Year)
Eli Lilly	Abemaciclib	Monotherapy & Combination Therapy	Breast Cancer	1.792	2018
Johnson & Johnson	Apalutamide	Monotherapy & Combination Therapy	Prostate Cancer	1.135	2018
AstraZeneca	Acalabrutinib	Combat Beta cell Cancer	Mantle cell lymphoma	900	2018
Roche	Emicizumab		Heamophilia A	1.788	2018
Aimmune Therapeutics	AR101	Manage peanut allergies	Peanut Allergy	N/A	2018

Technological advancements drive pharmaceutical companies to engage in risks to gain a competitive advantage. At times the risk exposure can negatively affect the growth of the company. Government legislation and medical aid scheme regulations on pricing structures, dispensing fees, designated service providers, use of generic drugs and patency affects the entire pharmaceutical value chain. Pharmaceutical companies are challenged with the demands of modern society to formulate and develop new drugs to manage and treat both chronic and acute conditions with ease. The growing concern of pharmaceutical companies are the administrative and sales costs associated with research and development which is critical in order for pharmaceutical companies to remain competitive. The following factors are forcing pharmaceutical companies to enhance their strategies and use different methods to increase growth (Nead, 2017):

- Expiring patents,
- Generic companies have entered the industry and have increased competition,
- Decreasing sales growth rate,
- Decline in the quantity of innovative drugs being developed, and

- Stringent regulatory standards.

According to (Nead, 2017) pharmaceutical CEOs need to capitalise in innovations to create opportunities for the future. The pharmaceutical industry is the most innovative industry since health care is constantly evolving.

2.6. Evolution of health care around the world

Healthcare is the fundamental key to the happiness and welfare of all people (World Health Organisation, 2017b). The barriers to decent health are limited access to skilled healthcare professionals, poor access to quality medicines and the unaffordable cost of healthcare. Medicines are an essential part of disease prevention programmes and treatment plans. The cost of medicines is compromising the affordability of healthcare. Therefore, it is critical to manage the cost of medicines and utilise the limited resources in ensuring maximum healthcare for people. There is a need for a system of assuring the integrity of the medicine supply chain to ensure the quality of medicines used in the treatment of patients (International Pharmaceutical Federation, 2012, pp 6-7).

The Good Pharmacy Practice (GPP) provides a framework of quality standards and guidance for pharmacists. The ultimate standard for the GPP is the patients' welfare. The core activity for the pharmacist, under GPP, is to assist patients in the optimal use of medicines by supplying quality medicines, providing appropriate information, counselling the patient and monitoring the effects of the medicines. The GPP ensures pharmacists contribute to the promotion of the rational prescribing and dispensing of medicines.

The pharmaceutical industry is an essential part of the healthcare system, by supplying medicines and vaccines for the majority of healthcare treatments. A functional healthcare system must guarantee that pharmaceutical products are of the highest quality, suitably procured and distributed to meet the healthcare requirements of the patient (South African Pharmacy Council, 2018b).

In the 21st century stakeholders in the health care sector are continuously striving for ways to be innovative, delivering patient-centred health care in a cost-effective manner and, with the use of technology, facilitate “smart” health care (Deloitte, 2018).

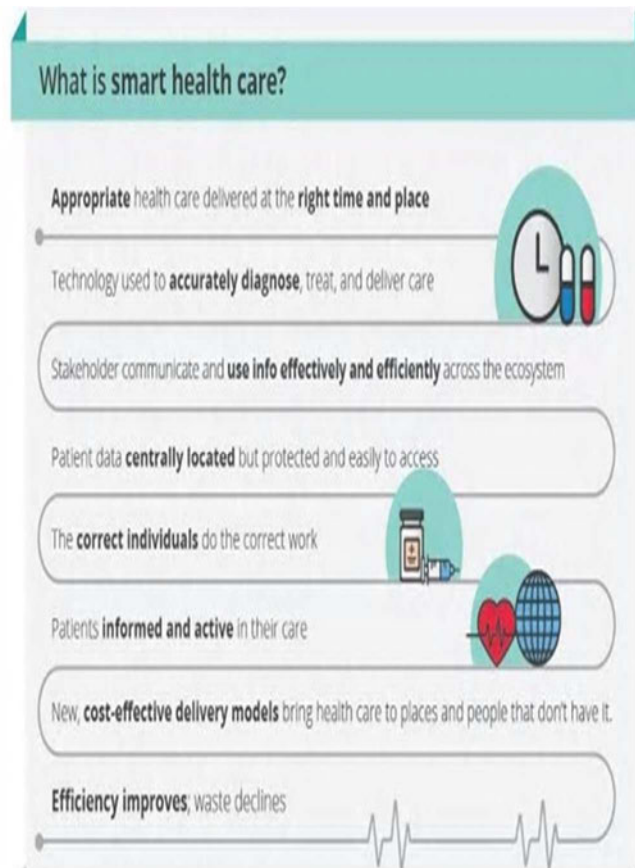


Figure 2. Smart Health Innovation Source: (Deloitte, 2018)

2.7. Evolution of health care in South Africa

The history of South Africa is intricately connected to the history of health care in South Africa. (Katu, 2018, pp 134-148) provides six phases to the health care system in South Africa as shown in figure 1 below.

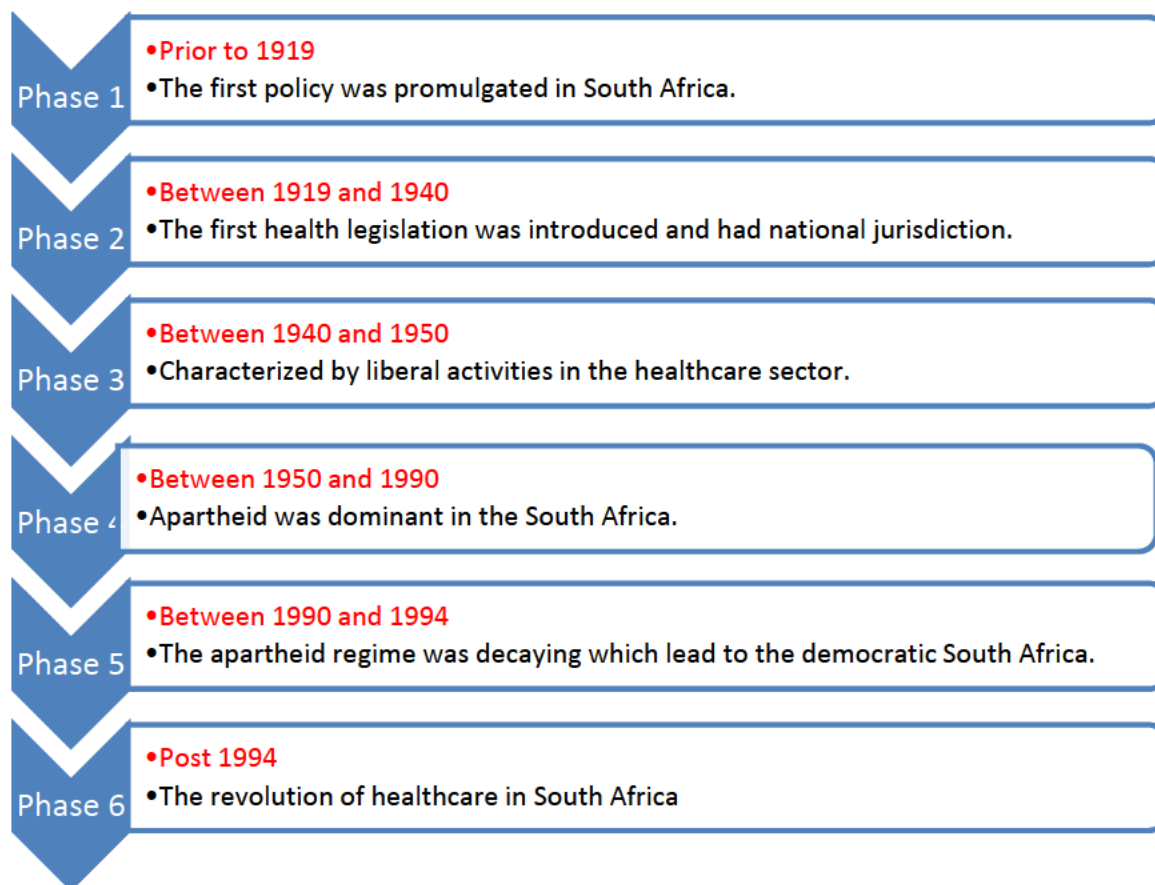


Figure 3. Evolution of Health Care in South Africa Source: (Katuu, 2018, pp 134-148)

South Africa's health care system has undergone a revolution post-apartheid. The South African health care system is two tier comprising of the private and public sector (Competition Commission South Africa, 2018). The government implementation of the health policy, ensuring each citizen of South Africa has access to quality health care. The policy is aimed towards the delivery of safe, effective, and cost-effective health care services. As universal health care undergoes a process of transformation, pharmacists will have a critical role in managing systems and policy development, to make certain the provision of equitable patient care and access to medicines in both private and public sector (Gray, Riddin and Jugathpal, 2016, pp 36-41).

2.8. History of pharmacy

Apothecary existed from 2600 BCE to prehistoric Babylon. Apothecary was a medical profession who formulates and dispenses *materia media* to health care professions and patients

(Wikipedia Contributors, 2018a). The modern pharmacy has replaced apothecary. Apothecaries researched herbal and chemical components preceded modern sciences and the pharmaceutical industry. Between the 15th and 17th century apothecaries acquired the title of a skilled profession. Nevertheless, this created tensions between medical professions and the apothecaries. By the 19th century medical professionals had taken on an institutionalised form and narrowed the role of apothecaries to that of pharmacists.

Pharmacy historically used scientific and medicinal theories, pharmaceutical devices, classes of medicines, indications and legislations that are vital for a regulated profession (Agnes, 2016). The investigation in pharmacy history was dependent on the formularies, pharmacopoeias, apothecaries, regulatory affairs and legislation. The history of medicine and chemistry is related to pharmacy. Prehistorically men used nature to treat ailments and soon, as technical developments were introduced, the evolution of health began. In 1867, Shuttleworth created the Canadian Pharmaceutical Society searching for national reform, standards and advancement in the pharmaceutical industry. In 1871, the Pharmacy Act of Ontario was established. This act defined pharmacy's scope of practice as well as responsibility (Shea, 2013).

The Evolution of the Pharmacist

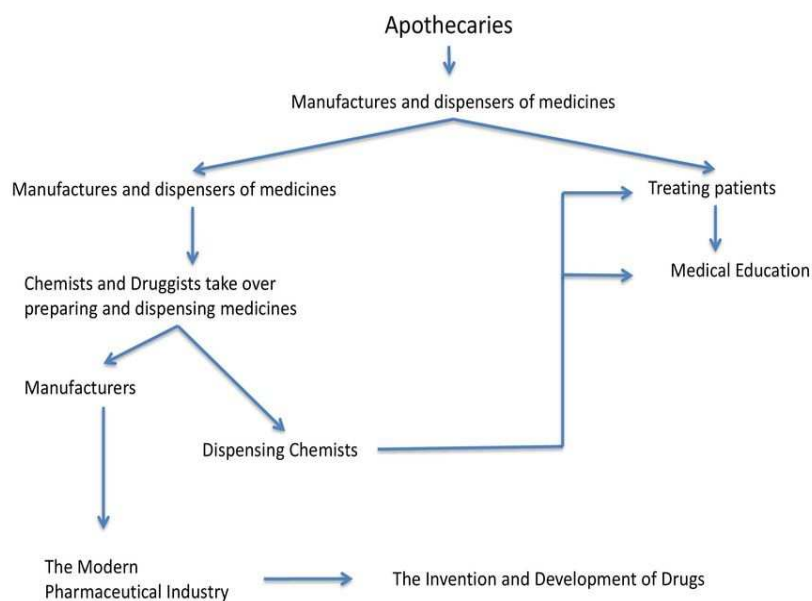


Figure 4. Evolution of the Pharmacist Source: (Hawkins, 2017)

2.9. Pharmacy in South Africa

The pharmacy is the final step in healthcare value supply chain. (South African Pharmacy Council, 2018c) defines the pharmacy as any place wherein or from which any service specially pertaining to the scope of practice of a pharmacist is provided (Pharmacy Act, 1974). The role of a pharmacist in South Africa is defined by the South African Pharmacy Council (SAPC).

The 7 categories of pharmaceutical institutions:

Table 2. Statistics for Registered Pharmacists Source: (South African Pharmacy Council, 2018d)

Sector	No. of Registered Persons and Organisation
Academic Institution	10
Community Pharmacy	3402
Consultant Pharmacy	11
Institutional Private	310
Institutional Public	653
Manufacturing Pharmacy	272
Wholesale Pharmacy Private	216
Wholesale Pharmacy Public	5

Majority of pharmacists practice in the community pharmacy sector. The institutional pharmacies are situated in hospitals and health centres. Wholesale pharmacies are primarily found in the private sector and a few are based in provisional facilities. Manufacturing pharmacies are located solely in the private sector. Consultation pharmacies are in not direct contact with patients or medicines, and only offer consultancy services in the private sector. Academic institutions are located at public universities. Apart from the registered pharmacists, pharmacy personnel consist of pharmacy students, pharmacy interns, community pharmacists, learner basic pharmacy assistants, post basic pharmacy assistants, and the recent pharmacy technicians. All these personnel must be registered with the South African Pharmacy Council.

2.10. Role of a pharmacist

By the 20th century the pharmacists role dramatically changed due to the development of the pharmaceutical industry (Agnes, 2016). Pharmacy was moving away from a drug orientated profession to one which is patient driven. Pharmacy today involves the knowledge and supply of pharmaceutical medicines which maintain health, increase the physical and mental wellness of patients, formulated to diagnose and control diseases to extend life. Pharmacists also has the role of educator, researcher, leader, manager, entrepreneur, mentor etc. (John, 2018).

According to the World Health Organisation, pharmacists are health care professionals whose professional responsibility is to ensure that people receive maximum therapeutic benefit from the medicines. This necessitates them to be in touch of pharmaceutical developments, laws pertaining to pharmacy, up to date skills, knowledge of medicines and technology. The pharmacist plays a vital role in improving access to health care and providing health promotion to people.

In 1997, WHO endorsed the International Pharmaceutical Federation FIP Council. This council was introduced to provide guidance to all pharmacy organisations throughout the world with regards to the development of the Good Pharmacy Practice (GPP) guidelines (Modern Pharmacy, September 1999). In terms of the Pharmacy Act, 1974, has amended the purpose of the South African Pharmacy Council to include:

“uphold and safeguard the rights of the general public to universally acceptable standards of pharmacy practice in both the private and public sector” and to “establish, develop, maintain and control universally acceptable standards of practice.”(Kandhai, 2011, pp 15-33).

Pharmacy practice involves the supply of health care improvement products and to assist with health problems and to optimise the use of medicines. There are six aims of pharmacy practice as stated by (International Pharmaceutical Federation, 2012, pp 6-7):

- to be accessible to patients with or without an appointment,
- to identify and manage health problems,
- to promote health care,
- ensuring effective use of medicines,
- to protect the patient from the side effects of medicines, and
- maximising the use of limited resources to the best of the pharmacist ability.

A pharmacist is a dynamic, patient-orientated and information driven professional, who uses their competence and skills to meet the healthcare requirements of the community. All registered pharmacists in South Africa are governed by the South African Pharmaceutical Council. The role of a pharmacist is (South African Pharmacy Council, 2018a):

- a custodian of medicines;
- formulator, manufacturer, distributor and controller of safe, effective and quality medicine;
- advisor on the safe, rational and appropriate use of medicine;
- provider of essential clinical services including screening and referral services;
- provider of health care education and information
- provider of pharmaceutical care by taking responsibility for the outcome of therapy and by being actively involved in the design, implementation and monitoring of pharmaceutical plans; and
- provider of cost effective and efficient pharmaceutical services.

The pharmacist is a care giver by providing caring and interactive services to the patient. Most problems can be managed by the pharmacist since health care products and services are available from the pharmacy (Mossialos ,et al., 2013, pp 135-148). The pharmacist is also a decision maker since the goal is to evaluate the symptoms and decide on the most appropriate form of treatment using his knowledge and skills. Therefore, the pharmacist must have confidence and have a vast knowledge of disease conditions and treatments available to interact with healthcare professionals or patients (Hall, Donovan and Wilkes, 2018, pp 1043-1057). The pharmacist takes on the role of leadership, which involves having the confidence to make decisions, communicate and manage efficiently. The pharmacist must ensure that medication is correctly stored, so the product stability is maintained. In addition, the pharmacist must accurately prescribe medication for the treatment of the regimen required and that drug-drug and drug-food interactions, allergies and contra-indications are eliminated. The pharmacist must be capable of managing resources and be effective in assisting patients to understand the importance of adherence to the guidelines when taking their medicines (Anderson, 2002, pp 391-404). Be knowledgeable to explain the possible side effects of the medicines to patients and emphasis the importance to patients to report side effects to the pharmacist (Mossialos ,et al., 2013, pp 135-148). The pharmacist must undergo continuous professional development

since the pharmaceutical industry is rapidly evolving (Hall ,et al., 2018, pp 1043-1057) The pharmacist has a responsibility to tutor pharmacy assistants and pharmacy interns and pharmacist provide guidance and knowledge to others.

2.11. Community pharmacists

Community pharmacies are easily accessible and this places pharmacist at the forefront of patient care in most low and middle income countries (Miller, Hutchinson and Goodman, 2018, pp 9-16). Community pharmacies embody a vital part of primary care (Santuari, 2017, pp 495-513). In Italy, the health care legislation allows for pharmacies to be privately or publicly owned. In India, there has been steady growth of pharmacy chains where there are approximately 800 000 medicine retailers of which 4% are corporate chain pharmacies(Miller ,et al., 2018, pp 9-16). Community pharmacies play a vital role in the ongoing treatment, support and monitoring of chronic conditions. Pharmacists have now extended their role in the management and prevention of chronic conditions (Schindel, Yuksel, Breault, Daniels, Varnhagen and Hughes, 2017, pp 148-161). In the United Kingdom, regulations allow for the provision of support for chronic conditions which goes beyond the traditional dispensing role of pharmacists. The community pharmacist can reduce the strain of the limited resources available in the health care system by providing primary health care services (Hall ,et al., 2018, pp 1043-1057). In response to the changing pharmaceutical industry, community pharmacists must offer higher levels of excellent service and professionalism (Kandhai, 2011, pp 15-33).

2.12. Stakeholders in community pharmacy industry

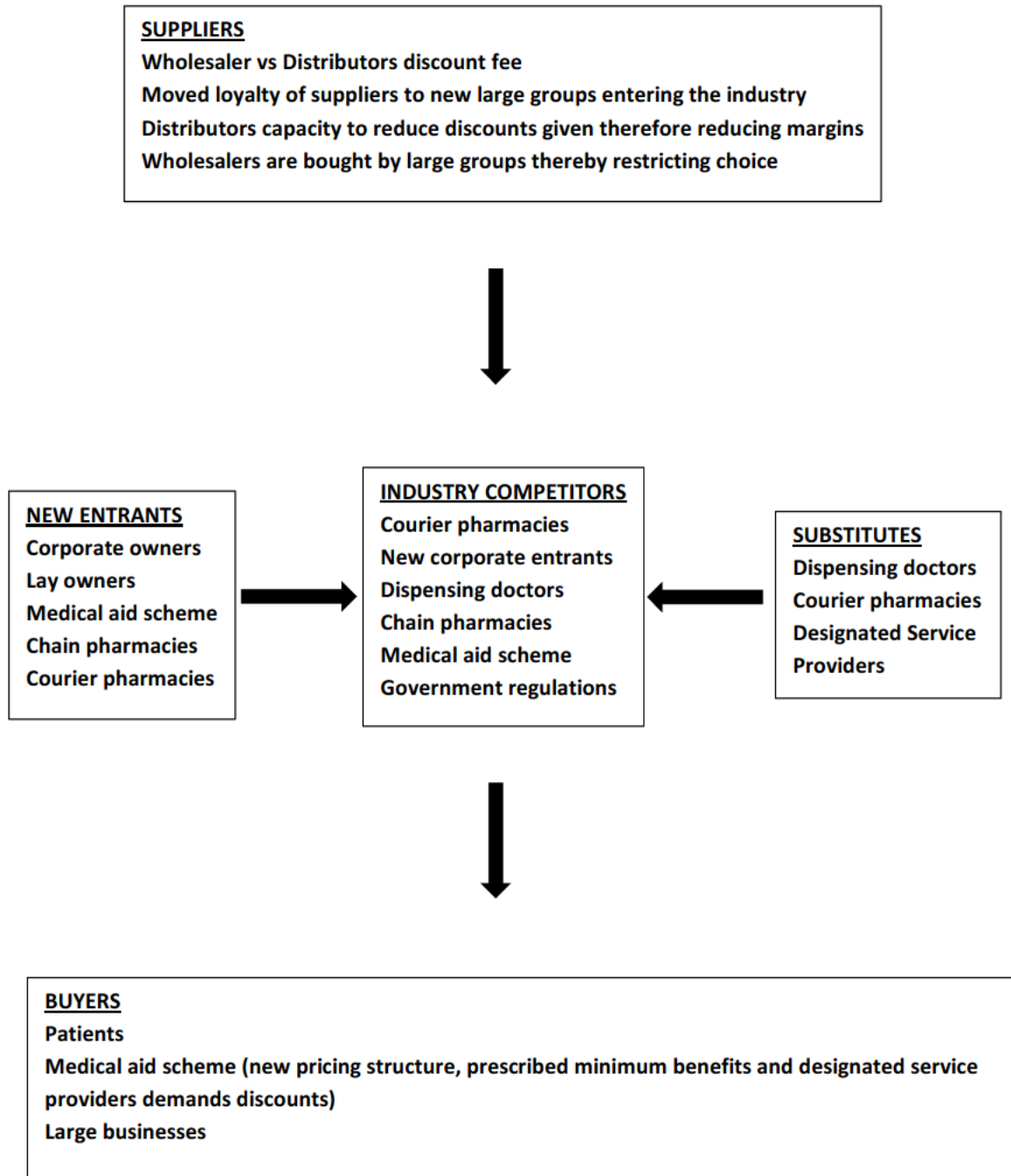


Figure 5. The Stakeholders in Community Pharmacy Sector Source: (Antonie ,et al., 2016, pp 7-11)

As shown in Figure 5 when the market is deregulated there are new entrants and new strategies. New entrants usually cater to a specific customer segment, such as the price-driven customer. The pharmacy market is highly regulated and is limited in their ability to offer high discounts due to the Single Exit Price and the Dispensing Fee. Technology is also an entry driving tool e.g. the use of courier pharmacies as DSPs. Deregulation means that prices drop faster than costs, so margins are minimal. More pharmacies are under pressure due to the increased financial strain of losing chronic patients to preferred provider pharmacies governed by the patient's medical aid scheme. The increase in bankruptcies is common and will lead to market consolidation. These consolidations will result in an increase in mergers and affiliations. If independent pharmacies change to a corporate chain pharmacies, it increases their chance of survival in the market (Strong, 2013).

2.13. Pharmacists and patient relationships

A pharmacist needs to create a safe and trusting relationship with their patients which encourages the patient to return to the pharmacy for further assistance. The pharmacist needs to make a positive impact on the patient. Good service is patient-orientated, meeting all the patients requirements while practising within the law (Murad, Chatterley and Guirguis, 2014, pp 1-20). Every patient that enters the pharmacy and requests for a medicine is an opportunity for the pharmacist to start a discussion with the patient. At times a patient might not purchase medicines, but it is important for the pharmacist to take time to listen to the patients. The layout and appearance of the pharmacy gives an indication of the type of service is to be expected by the pharmacist and the assistance that could be provided. It is also important for the pharmacist to portray a professional image to their patients (Gault, 2016).

Community pharmacies improve access to health care and improve people's choices (van Eikenhorst, Salema and Anderson, 2017, pp 17-38). Community pharmacies save patients time as well as provide convenient service since they are usually situated close to the patients' residence and many community pharmacies offer a delivery service. Patients use community pharmacies out of habit (Kaae, Traulsen and Norgaard, 2014, pp 852-862). Pharmacists needs to enable customers with knowledge to empower them about self-care rather than the customer just purchasing a direct request (van Eikenhorst ,et al., 2017, pp 17-38). Community also

pharmacies need to offer a comprehensive healthcare service to the community (Kandhai, 2011, pp 15-33). Patients must be able to receive affordable healthcare advice and services at one pharmacy. Additional special services must be offered by community pharmacies like diagnostic and screening tests. These tests should be monitored for each patient and may be used as a vital tool for doctor referrals. The community pharmacist should take interest in the activities in the community such as drug campaigns, health awareness projects, etc. and use the opportunities to gain the community's trust and develop professionalism. A community pharmacist can gain competitiveness by becoming a Drug-Wise pharmacist, this allows the pharmacist to be the first point of contact for assistance in treating drug and medicine addiction (Kandhai, 2011, pp 15-33).

2.14. Pharmacist's relationship with other health care professionals

The Good Pharmacy Practice states that:

“A pharmacist must at all times endeavour to co-operate with professional colleagues and members of other health professions so that patients and the public may benefit” (South African Pharmacy Council, 2017).

All health care professionals' goal is for the patient to get optimal treatment. It is important for the pharmacist to form a relationship with the patient's doctor. Therefore, it is vital for all health care professionals to work collectively to attain an optimal strategy best suited for the patient. A study in the United Kingdom to improve health care delivery showed that pharmacists working at the same location as the general doctor, had better communication channels as well as direct access to patient medical records which is necessary for optimal service (Anderson, Zhan, Boyd and Mann, 2018, pp 1-6).

2.15. Pharmacist ethical behaviour and code of conduct

Pharmacists are required to comply with the Code of Ethics while practicing within the laws of South Africa. Ethical and legal issues may arise, leaving the pharmacist in an ethical predicament. Pharmacists have an ethical and legal responsibility to improve patients'

understanding of how their actions and behaviors can result in negative outcomes (Naicker, 2003, pp 11-23). According to (Kandhai, 2011, pp 15-33), in business, there is a ambiguity between ethics and profits. “Being ethical does not necessarily guarantee success but it does strengthen the professional qualities of the pharmacy’s business performance and a business’s competitive position over the long-term.” (Truter, 2000, pp 28-32). Practicing in an ethical manner upholds the dignity and honor of the pharmacy and the profession.

2.16. Service quality to build customer relationships

According to (Kandhai, 2011, pp 15-33), “Service quality is a measure of how well the service level delivered matches customer expectations – on a consistent basis”. Ultimately, the patient is always the judge of the quality of service received from the pharmacy. Patients tend to use service providers of their choice based on their preference (Mpanza, 2016, pp 13-14). Therefore, all healthcare providers must offer the best quality of service to build the patient’s trust. Based on their experience, patients provide the best analyses of service quality:

2.16.1. Tangibles

The physical facilities are assessed by the appearance and impact on service quality. The location of the pharmacy e.g., how far must the patient travel to reach the pharmacy. The environment of the pharmacy, the surroundings must be friendly and warm. The patient must be comfortable to communicate with the pharmacy staff. The pharmacy layout must be spacious, and the medicines must be found with ease. There must be a private counselling area for privacy. All staff must carry themselves with pride and professionalism. This will increase the quality of service they can provide to the patient.

2.16.2. Reliability

It is said that “The customer is King”, therefore satisfying the patients requests and dealing with dissatisfied patients in an amicable manner is vital in building a relationship with patients. Build a sense of trust and loyalty amongst staff and patients to prevent patients losing their confidence in the pharmacy. Reliability is the hub of exceptional service.

2.16.3. Responsiveness

Staff must provide a prompt efficient service to patients. Staff must display a zeal to assist patients, giving the patient their complete attention. For an ill patient waiting in line to be assisted can lead to undesired assessment of service quality.

2.16.4. Assurance

All pharmacy staff including the pharmacist must have knowledge and skills of recent and relevant health developments. Since health care is evolving rapidly, all pharmacy staff must undergo continuous professional training and development. Knowledge is power; therefore, pharmacy must use their knowledge to build confidence and trust with patients.

2.16.5. Empathy

All health professionals must understand and care for the patients. Patient compliance with drug therapy is increased when the patient is satisfied with the health care professional (Berger, 2000, pp 21).

Community pharmacists should proactively strive to increase the quality of service offered to the community. They must provide a service differentiation and encompasses the patients changing health care requirements. Pharmacists have a competitive advantage of building close relationships with patients as compared to corporate pharmacists due to their constant interaction with the patient (Naicker, 2003, pp 11-23). Pharmacists must use this to the best of their ability not only to satisfy the patient's present need but also to predict the emerging needs of their patients. The aim of every business is a satisfied customer, likewise every pharmacist should ensure that the patient is counselled, optimal pharmaceutical care is given to the patient and the patient's expectations are met or exceeded.

2.17. Corporate pharmacies

The Pharmacy Act of 1974 was amended in 2003. This made provision for open-ownership pharmacies in South Africa. This change in legislation created the pathway for chain stores to open pharmacies. Since 2004 the Department of Health in South Africa regulates the prices of medicine sold by every pharmacist. Corporate pharmacies capitalize on profit rather than professional and customer relationships development (Naicker, 2003, pp 11-23). Some corporate pharmacies belong to subsidiaries of wholesale and manufacturing pharmacies. When buying stock corporate pharmacies purchase it directly from these wholesalers at a reduced price. This is how corporate pharmacies sell front shop products at such competitive prices. Corporate pharmacies certainly represent a threat to the survival of independent community pharmacies.

ADVANTAGES	DISADVANTAGES
Standardised quality	Profit driven business focused
Improved efficiencies	Loss of pharmaceutical environment
Encourages effective competition	Less personalized service – decrease quality of care
Lower costs to customers	Opposition from Pharmacy Councils
Increase in the number of pharmacies and pharmacists	Possible decrease in pharmacist accountability
Expansion of new services	Additional infrastructure development
Increased accessibility	Potential loss of service in rural areas

Table 3. Advantages and Disadvantages of Corporate Pharmacies (Antonie ,et al., 2016, pp 7-11)

2.18. Government legislation and regulations on health care system in South Africa

Over the past decades, the global structure of the pharmaceutical industry's regulations has transformed profoundly. Pharmaceutical and regulatory structures throughout the world are unstable and extremely dependent on technical support and donors (Pezzola and Sweet, 2016, pp 2-18). Pharmaceutical policy ranges from licensing, pricing, prescribing, formulary management, rational drug use, pharmaceutical economics, and affordability of medicines

(Babar, Gammie, Seyfoddin, Hasan and Curley, 2018, pp 1-13). Recently the South African pharmaceutical industry has moved its focus to become more patient-centered (World Health Organisation, 2017a). Due to the current challenges in the economy, pharmaceutical companies and healthcare professions need to adopt new strategies to deliver superior results for patients. The South African pharmaceutical industry is extremely regulated. It is governed by the Medicine Act and Pharmacy Act. The Medicines Control Council (MCC) regulates medicines in South Africa (Spotlight, 2016). This council ensures that safe, effective medicines are registered for use in South Africa. In South Africa the private health sector is governed by the Medicine and Related Substances Act 101 of 1965 (Medicine Act, 1965), Pharmacy Act 53 of 1974 (Pharmacy Act, 1974) and the Council for Medical Scheme Act of 1998 (Schemes Act, 1998). These policies ensure that there is maximum access to medicine, the quality of medicines received by the patients is of the highest and safest, regulates the cost of medicines and promotes rational medicine use (Babar ,et al., 2018, pp 1-13).

2.19. Patient rights

According to (World Health Organisation, 2018) “*health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*”. It further goes on to state that “*governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures*”.

To heal the injustices of apartheid, South Africa adopted the Constitution of the Republic of South Africa known as the Constitution (Act 108 of 1996) including a Bill of Rights. It is a legal document and stipulates the expectations from government. The Bill of Rights is the foundation of democracy in South Africa. It states that it:

“enshrines the rights of all people in our country and affirms the democratic values of human dignity, equality and freedom” (Department of Health, 2007).

(Cohen and Ezer, 2013, pp 7-19) (cited in Nevhuthalu, 2016, pp 12-20), state that “*Human rights principles require services to patients should meet the standards set out in international and regional human rights norms and agreements.*” The citizens of South Africa cannot be denied access to health care due to their race, gender, economic state and religion. Professional ethics is a moral obligation and displays care for the community (Rowe and Moodley, 2013, pp 15-16). Vertical and horizontal application of the Bill of Rights pertains to individuals and business

entities known as non-state agencies (Nevhotalu, 2016, pp 12-20). The vertical application is related to the individual in relation to the government, which means that the Bill of Rights protects the citizens of South Africa from things done to them by the government. Horizontal application are issues between citizens and businesses (Department of Health, 2007). Private business and organizations have their own set of policies which may be contrary to the Bill of Rights. If these business's internal policies have as a negative effect on the private and public interest, then it is unconstitutional. Patients are the final decision maker regarding their health care and not the doctor. Members of medical aid schemes have a right to information about the scheme and to challenge the decisions made by the scheme (Nevhotalu, 2016, pp 12-20).

According to the Patient's Rights Charter "*A member of a health insurance or medical aid scheme is entitled to information about that insurance or medical aid scheme and to challenge, where necessary, the decisions of such health insurance or medical aid scheme relating to the member. Everyone has a right to choose a particular healthcare provider for services, or a particular health facility for treatment provided that such choice shall not be contrary to the ethical standards applicable to such healthcare providers or facilities, and the choice of facility is in line with prescribed service delivery guidelines.*"

Members have a right to select a specific healthcare provider of their choice provided it does not be contrary to the ethical standards. All citizens of South Africa have the right to know the healthcare provider.

2.20. Medical aid schemes

In South Africa, medical schemes are the leading channels for providing health care insurance in the private health sector (McLeod and Ramjee, 2007, pp 47-70). Medical schemes are governed by the Medical Scheme Act (Act 131 of 1998) and health insurance governed by the Long and Short – term Insurance Act of 1998. Medical aid schemes are another key role player in the supply of medicine in South Africa, in the dispensing of medicines from pharmacists and dispensing doctors. Hence, medical aid schemes control the cash flow of pharmacists and dispensing doctors. All medical schemes in South Africa is governed by the Council for Medical Schemes (CMS).

The Council for Medical Schemes (Morton, Pattison, Langley and Powell, 2015, pp 17-29) regulates the pharmaceutical industry by:

- Safeguarding the public and notifying them about their rights and obligations pertaining to medical schemes,
- Addresses complaints raised by members of the public,
- Supervising of all persons that are affiliated with medical schemes and regulatory bodies and ensure that they adhere to the Medicine Scheme Act,
- Assists in the management and governance of medical schemes,
- Advisor to the Minister of Health on suitable regulatory and policy amendments, and
- Executes the regulatory mandate by collaborating with other bodies.

According to the Council for Medical Schemes (Council for Medical Schemes, 2018a):

- the number of medical schemes in South Africa have decreased from 82 in March 2017 to 80 as of March 2018 consisting of 21 open schemes and 59 restricted schemes
- scheme membership is at 8.9 million
- membership contribution has increased to R163.0 billion

There are 270 plans that various medical aid schemes offer but members cannot compare these plans with those that are best suited for them. Medical aid schemes seem to make the plans more affordable but reduce the range of benefits over a period. These are some of the factors that cause the members to be disempowered. There is no means for the member to assess the value of service that the schemes offer. Schemes and administrators are not effective in using buying power to negotiate contracts that will benefit the member by reducing premiums and out of pocket payments. Current examples are:

- the inadequate management of Prescribed Minimum Benefit (PMB) payments to decrease scheme disclosure of compulsory PMB costs,
- payments from saving accounts in place of risk pool,
- recognising that the database for the members are not always correct and therefore this introduces the value of Designated Service Provider (DSP) networks,
- no valid data to prove that supply induced demand is evaluated, monitored and managed.

2.21. Evolution of designated service providers

The Medical Schemes Act No. 131 of 1998 was promulgated with the intention to provide members with continuous, affordable and accessible healthcare. With the increasing cost of healthcare globally, medical schemes are contracting with service providers in an attempt to make healthcare more affordable and accessible. In the United States the Kaiser Permanent system is implemented and in South Africa the use of designated service providers is common. Medical schemes negotiate with service providers to provide its services at a lower rate (Erasmus, Ranchod, Abraham, Bloch, Carvounes and Dreyer, 2016).

The DSP is paid a set tariff that is predetermined contractually (Erasmus, Ranchod, Abraham, Carvounes and Dreyer, 2016). The South African government had expressed concern over service providers abusing Regulation 8 of the Medical Scheme Act in which PMB costs will be paid in full. This allows for service providers to manipulate the diagnosis to get paid more when it is a PMB condition (Shafiq ,et al., 2015, pp 1-15). CMS introduced Prescribed Minimum Benefits (PMBs) which is the minimum healthcare benefits each medical scheme must cover in South Africa. These benefits are mandated by the Minister of Health in the Medicines Schemes Act. This means a medical scheme must pay for the diagnosis, treatment and care of a patient's PMB condition in full without imposing any co-payments. The savings option on a medical scheme account cannot be used to fund any PMBs.

PMB's (Council for Medical Schemes, 2018b) cover the diagnosis, treatment and care of the following:

- Any emergency medical condition,
- 270 diseases called the Diagnosis and Treatment Pairs (DTPs), including cancer and hypertension, and
- 25 chronic conditions on the Chronic Disease List (CDL) including diabetes, epilepsy and asthma.

Provision for Designated Service Providers in the Medical Schemes Act 131 of 1998 was intended to encourage DSP arrangements between medical schemes and healthcare providers to ensure the proper delivery of PMBs to all beneficiaries of all schemes. The important reason why DSPs were introduced is mainly for schemes to ensure that their members get proper care at an appropriate place at an affordable price. Medical schemes are in a better position to determine the financial implications since they can negotiate pricing and manage care

conditions for the delivery of care to its members. If a healthcare provider is a DSP, you are guaranteed that the claims for any PMB condition is paid in full. DSPs claimed to create healthcare affordable and accessible to all.

To be a DSP, service providers will have to accept contracted payments agreements with tariffs that fall below input costs. Service providers cannot negotiate a fee. Therefore, healthcare professionals may have to lower their fees to abide by the contractual agreement between medical schemes. These contractual arrangements create a vertical constraint in the industry which can be anticompetitive. The contractual agreement increases the barriers to entry. Restricted contracting can relax competition by reducing inter-brand competition and facilitate collusion. Members are obligated to obtain their healthcare services from DSPs listed by their medical scheme. The amendment of the Regulation 8 of the Medical Scheme Act 131 of 1998 ensures that the member will not have to co-pay for expenses incurred for a PMB condition (Thomas, 2017, pp). If a member voluntarily uses a non-DSP, the member will then be liable to pay the co-payment. If a service was not readily available from a DSP or there is no DSP near the member's place of business or residence, then the member can choose a non-DSP without any co-payment being charged by the medical scheme.

2.22. Concerns of designated service provider's

The anti-competitiveness of designated service providers can lead to closure of non-DSPs on the foundation of market power. DSPs remove the option of patient choice. A decrease in patient choice results in a loss of patient utility. There are two main barriers for access of health care namely, unaffordable transport and disrespectful healthcare providers (Harris, Goudge, Ataguba, McIntyre, Nxumalo, Jikwana and Chersich, 2011, pp 102-123). Policy makers must address these challenges experienced by the patients and assess the quality of health care rendered by health care providers.

2.23. Summary

In South Africa's healthcare environment, which is faced with a tremendous shortage of healthcare professionals, independently owned community pharmacies enhance primary healthcare services in all communities. The introduction of medical aid scheme regulations of designated service providers as restricted patients access to community pharmacies. If patients decide to continue using their community pharmacies who are not designated service providers selected by their medical aid schemes these patients will be penalised. Ultimately the patient's right to choose is removed by their medical aid scheme.

In this chapter the literature reviewed has shown that the importance of a community pharmacist, and how regulations have impacted on healthcare. This study will attempt to better understand the relationship of community pharmacies and the patients and the pharmacist as an entrepreneur.

3. RESEARCH METHODOLOGY

3.1. Introduction

This chapter describes the research methodology applied in the study. The research is focused on the impact of medical aid scheme regulations on independent community pharmacies. This chapter provides a framework of the methodology employed to conduct the research.

The researcher depicts the structure of a basic research project as shown in Figure 6. The research design, research approach will be discussed. The researcher will go on to discuss the location of the study, the population, sample size and sampling method. Thereafter, the data collection instruments that are used in a qualitative study will be discussed. An overview of the reliability and validity will be discussed to assess the data quality control. The researcher will then discuss the data analysis process which involves data reduction and data display. The researcher briefly highlights the ethical considerations and limitations of the study.

3.2. The research design

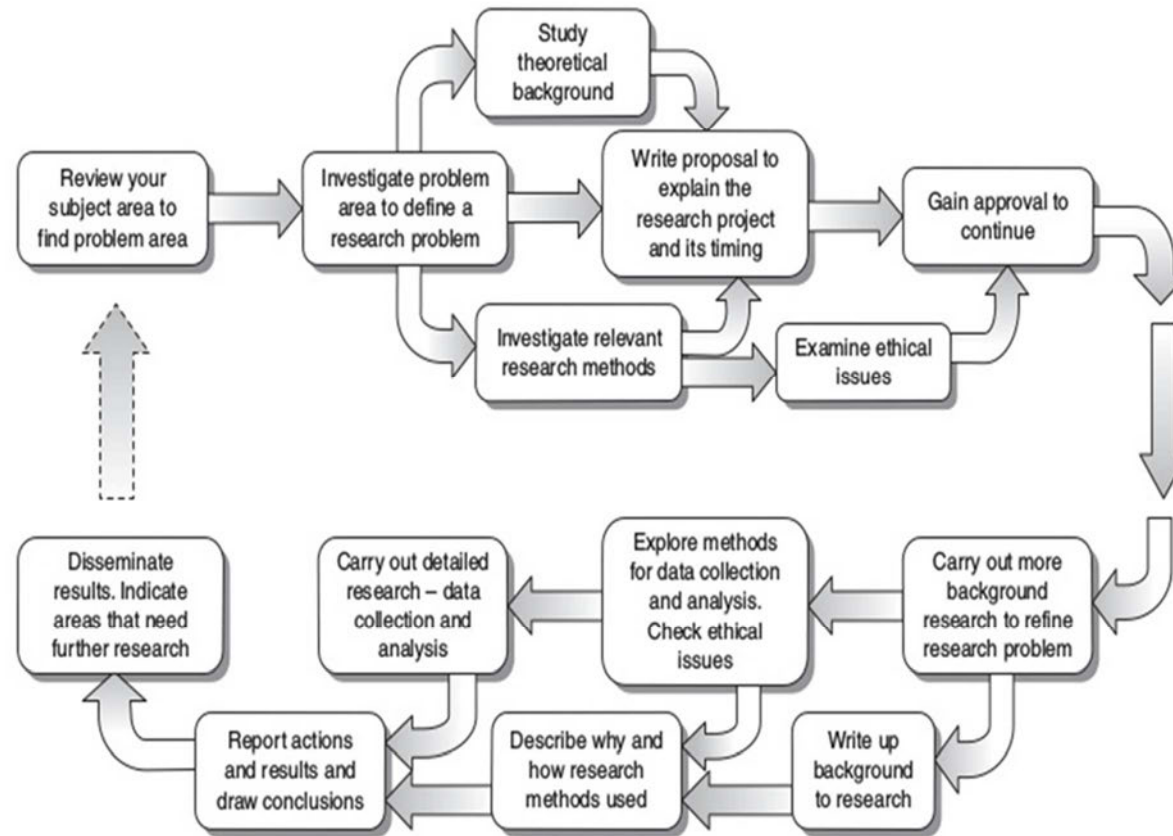


Figure 6. Structure of a typical Research Project Source: (Walliman, 2017, pp 129-130)

According to (Sekaran and Bougie, 2016, pp 95-96) research design uses the research objectives as a foundation to generate a framework in which data is collected, measured and analysed. The research design is actually the plan of how the researcher anticipates to conduct the study. Research designs are types of study within quantitative, qualitative as well as mixed methods methodologies (Creswell and Creswell, 2018, pp 3-5). An exploratory qualitative research design was conducted to evaluate the impact of medical aid scheme regulations of Designated Service Providers (DSPs) on independent community pharmacies.

3.3. Research approaches

There are three approaches to use when conducting research, qualitative, quantitative and mixed method approach (Creswell and Creswell, 2018, pp 3-5). Quantitative research is used to distinguish numeric data and qualitative research is used to distinguish non-numeric data (Saunders, Lewis and Thornhill, 2016, pp 165-172). Mixed method approach incorporates both quantitative and qualitative approaches. Qualitative research is usually expressed in words instead of numbers. Generally, people's beliefs, norms and standards are being investigated using qualitative research approach. Therefore, (Lewis, 2015, pp 473-475) states "qualitative research depends on the careful definition of the meaning of words, the development of concepts and variables, and the plotting of interrelationships between these".

Qualitative research approach is used when exploring and understanding the problem. The research process involves developing questions and procedures, collecting data usually at the participant's environment, data is analysed by highlighting the themes and the researcher interprets the data. Qualitative research usually involves a smaller number of participants interviews are used which are labour intensive. A large number of participants are not required for the purpose of statistical analysis.

Quantitative research approach is used to assess objective theories by examining variables. These variables are measured by instruments, so the number data can be analysed using statistical software.

Mixed Method research approach involves collected data using both qualitative and quantitative approaches and might include philosophical assumptions and theoretical frameworks. Triangulation is common in mixed method approach.

In this study the researcher used a qualitative research method due to the number of participants the qualitative approach was opted for to assess the impact of medical aid scheme regulations on independent community pharmacies.

3.4. Location of the study

The research was conducted in the Chatsworth area situated in a suburb of Durban in Kwa-Zulu Natal. The participants were independent community responsible pharmacists and owners. Generally independent community pharmacists were also the owners of the pharmacies. These pharmacists were targeted due to their experience as a pharmacist in the retail sector. These participants have been exposed to the past regulations and new regulations of medical aid schemes.

3.5. Research population

(Sekaran and Bougie, 2016, pp 240) describes “the population as the entire group of people, events, or things of interest that the researcher wishes to investigate.” The population of the study are the independent community pharmacists which are the owners as well as the responsible pharmacist.

3.6. Sample and sampling method

(Sekaran and Bougie, 2016, pp 241) refers to “a sample is a subset of the population. It comprises some members selected from it.”

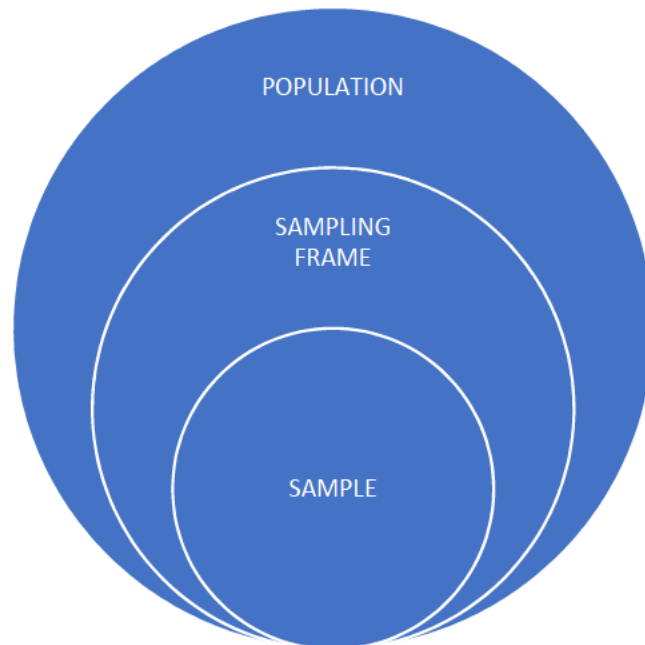


Figure 7. Sampling Frame in Relation to Population Source: (Lewis, 2015, pp 473-475)

The researcher used non-probability sampling since a qualitative research method was employed. There are three types of non-probability sampling:

Table 4. Types of Non-Probability Sampling Methods Source: (Creswell and Creswell, 2018, pp 188-189)

Sampling Design	Description	Advantages	Disadvantages
Convenience Sampling	Most easily accessible participants are selected	Convenient, not expensive	Not generalised
Judgement Sampling	Participants are selected based on their expert knowledge of the research topic	Significant way to investigate	Not generalised to entire population
Quota Sampling	Participants are conveniently selected from a predetermined quota	Where minority participation is important	Not easily generalised

The judgement sampling method was selected since the researcher did not want to generalise the findings but selected participants that met the goals of the study. The participants were selected due to their exposure and experience to both the patients as well as the financial management of the pharmacy.

Although non-probability sampling is less desirable and not often used (Creswell and Creswell, 2018, pp 185-189), the researcher used this type of sampling for the convenience and availability of the participants. (Yin, 2011, pp 88-89) the common types of non-probability sampling are:

Purposive sampling: researchers select participants for their experience and perceptions.

Snowball sampling: researchers are referred to others who have similar to or different experience and perceptions from the participants.

Convenience sampling: researchers chose any available and willing people as participants in the study. (Crossman. A, 2018) states that this type of sampling as its shortcomings since the researcher as no control over the representativeness of the sample.

The researcher had contacted all independent community pharmacies in the Chatsworth area and then determined the number of pharmacists willing to participate in the study. After assessing the response of the pharmacists willing to participate in the study, the researcher had decided to use a non-probability sample type.

3.7. Selection criteria

The participants were selected on the years of practising in retail pharmacies. Ethical clearance had to be obtained prior to arranging interviews with the participants. This process involved obtaining gatekeepers' letters from the owners of the independent community pharmacies agreeing to participate in the study. Ethical clearance was thereafter granted.

3.8. Data collection

According to (Saunders ,et al., 2016, pp 437-439) data collection instruments are the devices used to collect data. Data are two types of data sources that is primary and secondary (Sekaran and Bougie, 2016, pp 113-114). Primary data refers to the data obtained by the researcher first hand on the aims of the study while secondary data refers to sources that already exist.

In this study a structured interview is the primary instrument for data collection Appendix 111. According to (Saunders ,et al., 2016, pp 456-458) “qualitative research is often associated with an interpretive philosophy. It is interpretive because researchers need to make sense of the subjective and socially constructed meanings expressed about the phenomenon being studied”. By using this type of data collection instrument, it allowed each participant to discuss their specific views regarding the impact on medical aid schemes regulations of designated service providers on independent community pharmacies. The participant spoke freely and expressed their views in their own words. By using a qualitative research method, the researcher produced a rich descriptive data which highlighted the themes of the research topic. The interviews of each participant took approximately 20 minutes each and was conducted at the pharmacy. The

interviews were audio recorded and then the researcher transcribed into a word document. The transcribed interviews were used for the data analysis.

3.9. Validity and reliability

(Leung, 2015, pp 324-325) states “validity in qualitative research means “appropriateness” of the tools, processes and data. Whether the research question is valid for the desired outcome, the choice of methodology is appropriate for answering the research question, the design is valid for the methodology, the sampling and data analysis is appropriate, and finally the results and conclusions are valid for the sample and context”. According to (Creswell and Creswell, 2018, pp 199-202) “qualitative validity is one of the strengths of qualitative research and is based on determining whether the findings are accurate from the standpoint of the researcher, the participant”.

Reliability in qualitative research relies on consistence (Leung, 2015, pp 324-325). It refers to the precise replication of the processes and results. It refers to which a research instrument will produce the same result on different instances. Reliability relates to which a measurement is free of random errors. The data was collected from responsible pharmacists in independently owned community pharmacies. The participants were also the owners of the pharmacy. The opinions were given from the experienced participants’, so the researcher assumed that the information collected was a reliable and valid source. The researcher recorded the interviews with a recording device, which guaranteed that the quotes used was valid and reliable.

3.10. Study limitations

Due to the limited time period the researcher had to conduct the research, only eight independent community pharmacies in the Chatsworth area participated in the research. Therefore, the study is not a true representation of all independent community pharmacies in Chatsworth area.

3.11. Ethics

“Ethics refer to the standards of behaviour that guide your conduct in relation to the rights of those who become the subject of your work, or are affected by it” (Saunders ,et al., 2016, pp 239-245). Ethics in research aims to safeguard the participants from harm and adverse effects from the research activity. The researcher followed these guidelines to protect the participants:

- Explained the study benefits
- Explained to the participants their rights and protection
- Obtained a signed consent form

Ethical clearance was obtained from University of Kwa-Zulu Natal Humanities and Social Sciences Research Ethics Committee prior to conducting the research (Appendix 1) The gate keepers’ letters were obtained prior the interviews were conducted.

3.12. Summary

In this chapter the researcher presented the background for the methodology of the study.

In South Africa the use of DSP contracts or networks has being a common place especially since medical schemes have a statutory obligation to pay for the closed list of PMBs. It is therefore important to understand how medical aid regulations of DSPs has affected independent community pharmacists’ survival. Furthermore, how these regulations have impacted on the independent pharmacist’s ability to assist in the healthcare requirements of the patient.

The participants that were targeted had more than 10 years of experience in a retail community pharmacy and the participants were also owners of the pharmacy. This was an important criterion since the participant had exposure to the pre and post effects of the medical aid scheme regulations of designated service providers. Also, being the responsible pharmacist as well as the owner, the researcher got insight of the financial aspect as well as the changing role of a pharmacist and patient care. The researcher employed a qualitative approach using an interview as the primary instrument to gain insight for the study. Non- probability sampling was used since this is more suitable for qualitative research. The researcher used NVivo 11 software to

analyse the data collected and to find themes of the study. The following chapter four, the researcher will present the findings from the data compiled from the interviews conducted with the responsible pharmacists of each pharmacy.

4. RESULTS AND DISCUSSION

4.1. Introduction

In this chapter the researcher presented the results and discussion from the data collected from the interviews conducted with the responsible pharmacist of the eight pharmacies. The purpose of the study was to assess the impact of medical aid scheme regulations of closed DSP's on independent community pharmacies. The responsible pharmacist in each of the eight pharmacies were also the owners of the pharmacies. The researcher used NVivo 11 software to explore and analyse the data. The relevant themes were identified and presented. The researcher referred to the literature from chapter two of this dissertation to discuss the findings.

4.2. Data analysis

The main objective of qualitative data approach is to reach generalised statements by comparing several resources. There are three steps in data analysis: (Sekaran and Bougie, 2016, pp 337-339)

- Data reduction: involves the process of selecting, coding and categorising the data.
- Data display: refers to the depiction of data using graphs, charts etc. assists in making conclusions based on these patterns.
- Drawing of conclusions: final process of qualitative data analysis. The researcher defines themes and answers the research questions.

Data Reduction is the first phase of in qualitative data analysis. The researcher transcribed all the interviews, read and re-read the transcripts for accuracy. The researcher then underlined the similarities and differences noted from each line of the transcripts. The software NVivo 11 was used by the research to assist in the qualitative data analysis. The transcripts were imported to the programme and analysed for further themes.

Data Display by using the themes the researcher displayed the data. By using NVivo 11, the researcher was able to display the themes by exploring the data collected. The selection of

method of data analysis of qualitative research remains on a range from inductive to deductive analysis (Walliman, 2017, pp 16-19). Inductive analysis also referred to as “coding up” classifies themes from the data while deductive analysis is referred to as “coding down” which derives anticipated themes found in the research literature. Together both approaches generate new ideas, theories and hypothesis.

4.3. Thematic analysis

The researcher selected thematic analysis for this data since it permits both inductive and deductive reasoning. Thematic analysis requires the qualitative research data to be categorised into themes. NVivo 11 software analysed the data and the word frequently used words from the participants were produced in Figure 9. The researcher used these words to code all the data. Coding involves the process of identifying and organising the data by finding texts from the participants response (Creswell and Creswell, 2018, pp 192-198). The researcher then read the text and allocated the text to themes.



Figure 8. Word Cloud of Participants Source: The researcher, Generation of Themes NVivo 11 (2018)

The researcher used the words depicted in Figure 8 to review the codes to exclude redundancy. The researcher used the revised codes to generate themes for each of the objectives of the qualitative study.

The first objective of the study was to investigate the impact of medical aid scheme regulations on the future of independent community pharmacies. The researcher presented the views of the responsible pharmacists and contrasted it with the findings of the literature review from chapter two.

Objective 1

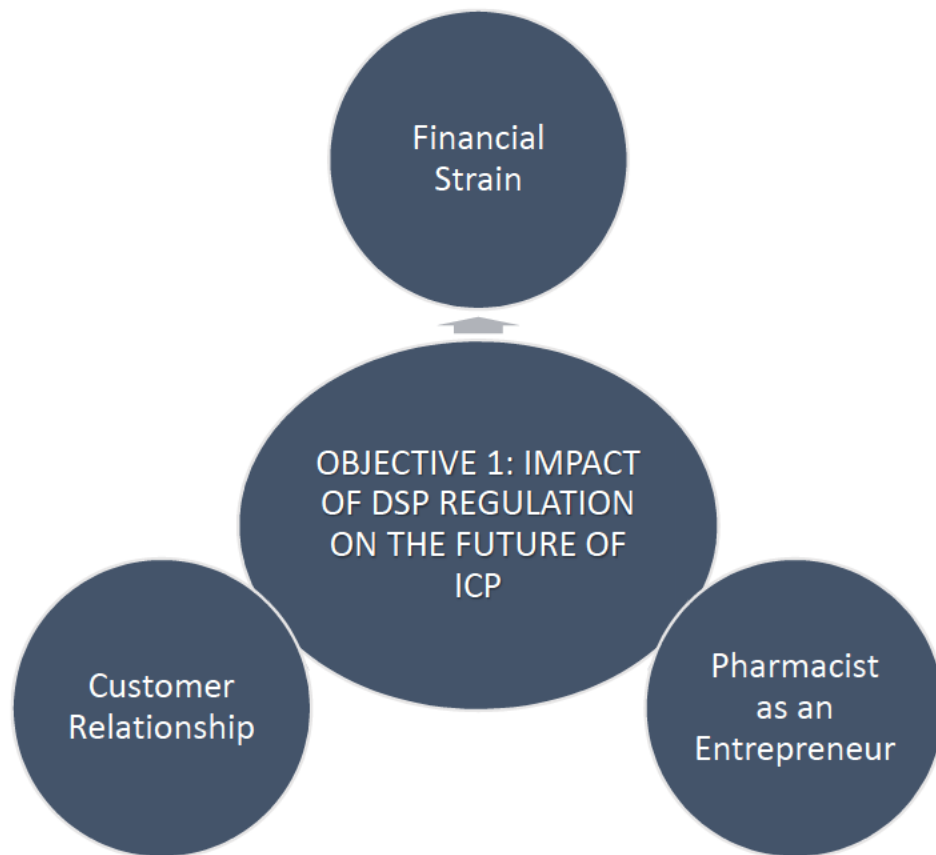


Figure 9. Themes for Objective 1 of the Study Source: The Researcher, NVivo 11 (2018)

Theme 1: Financial Strain

The researcher inquired about the impact of medical aid scheme regulation of Designated Service Providers on the future of independent community pharmacies. The theme provided insight as to the financial plight of independent community pharmacies. Corporate pharmacies are usually DSPs which presented a major threat to the survival of independent community pharmacies (Naicker, 2003, pp 11-23). It exposed the strains that pharmacists of independently owned community pharmacies encounter with regards to the Designated Service Providers regulation.

Participant 1 stated:

“This regulation of designated service provider networks has made it difficult to survive in the private sector. I have the monthly payments of running a business to think about, like rental of

the building, water, and electricity, creditors, staff salaries are just a few monthly expenses. Our future seems bleak.”

Participant 4 stated:

“It as a negative impact on my business, I lost so many chronic patients because they were forced to use a pharmacy allocated by their medical aid. This is utterly unfair.”

Participant 7 stated:

“This is so unfair to us independents. I can barely survive. I have not only lost chronic patients but also my front shop sales have dropped. I can’t compete with the corporate prices.”

Loss of competition

Many medical aid schemes appoint their Designated Service Provider’s (DSP) without taking into consideration any applications from other service providers to join their DSP network. Medical aid schemes like Bonitas/ Boncap network uses a single provider as the schemes DSP, a courier company Pharmacy Direct. After interviewing the participants in the eight independently owned community pharmacies, the researcher discovered that these pharmacists are willing to provide a given service at an agreed price. The limitation of providers within a closed DSP is illogical.

If these independently owned community pharmacies are given the opportunity to be a DSP, this will result in an increase patient access to healthcare and improve patient care. Limiting competition by using closed DSP will affect patient service. If the DSP network had numerous service providers, providing services at a fixed price, then the service provider will focus on the patient’s needs and clinical outcomes to increase their competitive advantage. (Competition Commission South Africa, 2018) investigated the ownership relationships between medical scheme administrators and Bonitas. Afro-Centric is an investment holding company that operates as subsidiaries that provide services to the healthcare industry. When a medical aid scheme, administrator and service provider are all linked in the same structure, competition is aligned.

Theme 2: Pharmacist as an Entrepreneur

The researcher inquired if community pharmacist will associate with the franchise pharmacies as a survival technique as lose their entrepreneurial role in their business. According to (Davies, 2013, pp 29-30) pharmacists became increasingly concerned about threats to their professional role due to the opening of corporate pharmacies.

Participant 2 stated:

“Before owning a pharmacy was such an achievement, you could easily make a good profit. There was no need for managerial skills because being a pharmacist in those times meant you are equipped to be an entrepreneur. But now, it is now so stressful to own a pharmacy the competition of franchise pharmacies is overwhelming.”

Participant 5 stated:

“Many independently owned pharmacies are struggling to survive ever since the emergence of these franchise pharmacies. These franchise pharmacies have buying power and are affiliated with wholesalers, so they get good deals and reimbursements that’s how they can price their front shop items at such a low mark up.”

Participant 7 stated:

“Being a pharmacist and a successful entrepreneur is non-existent nowadays. I am forced to consider to change to a franchise store to survive, even though I know I will be restricted by the franchise rules and won’t be my own boss. Maybe I might just close shop.”

To make healthcare accessible to all especially in the rural areas, in 2004 the South African government amended the law governing ownership of pharmacies. This change in legislation created the pathway for the corporate franchise pharmacies to emerge and disrupt the private healthcare sector. Instead of being located in rural areas to promote healthcare and make it accessible, these corporate franchise stores opened in urban malls. Community pharmacies are sensitive to a change in market dynamics.

The researcher discovered that many independently owned pharmacies are tempted to change to a franchise or corporate group of pharmacies to gain a competitive advantage. Corporate franchise pharmacies exist in the world and have both advantages and disadvantages (Mohammadzadeh, Yousefi and Sharifinia, 2014, pp 739-741). Corporate franchise

pharmacies offer lower costs due to economies of scale and have advanced technological systems available. Independently owned community pharmacies can't compete with these prices. Corporate pharmacies tend to have an advantage in DSP selection. Most of the participants have been affected the similarly with the DSP regulations with loss of chronic prescription. Chronic or repeat prescriptions is a constant monthly income for the pharmacy. The loss of these chronic patients has left independent pharmacies in drowning waters. These pharmacies are struggling to survive. The dream of many aspiring pharmacy students and pharmacists to own their pharmacy independently is rather bleak. ICPA emphasized that young pharmacy professionals are turning into slaves to corporate pharmacies (Moodley, 2018). Due to the long hours of corporate pharmacies, inability to open their own pharmacies, young pharmacists tend to be driven out of their profession (Miller ,et al., 2018, pp 9-16).

Theme 3: Customer Relationship

The researcher inquired about the customer relationship with the pharmacy and how it as changed due to the implementation of closed Designated Service Providers by medical aid schemes.

Participant 3 states:

“One of the benefits of filling your chronic prescription from our pharmacy was free delivery service to your home or place of work. I now have to charge the customer that delivery fee since they don't take their monthly chronic prescription from us. The delivery service generates some income for the pharmacy. Many customers don't understand this and it has strained our relationship.”

Participant 6 states:

“I have to try and compete with corporate pharmacies and do everything I can to make a profit, I stopped offering a deliver service and many of the patients in the community are upset about. I did this strategically so I can increase the feet entering the pharmacy, hoping the customer will buy something they see impulse buying, but I also lost some loyal customers even though they had a close relationship with our pharmacy.”

Participant 8 states:

“Out of convenience the patients also so get their acute or repeat prescriptions filled at corporate pharmacies. Since corporate pharmacies close early these patients come to us if they forgot to get their repeat prescriptions filled. I would usually sell a Schedule 3 emergency supply of medicines but since the patient chose to use the corporate pharmacies for medicines, we could have dispensed without a co-payment I won’t go that extra to assist the patient, I would insist on the prescription”

The most common source of health service available in the world is the community pharmacy (Malangu, 2014, pp 226-33). In South Africa community pharmacists offer primary healthcare services to the community, no appointment required and no consultation charge. Therefore, community pharmacists are described as the most accessible healthcare profession (Mossialos ,et al., 2013, pp 135-148). This results in patients building a trusting relationship with their community pharmacy. (Morton ,et al., 2015, pp 17-29) states that:

“the main difference [between the Independent workplaces and other pharmacies] is having a little talk with them about their medication...offer extra advice to them so they feel like somebody actually cares.”

The above statement shows the difference between community pharmacies and corporate or courier pharmacies. It is difficult for patients to build a relationship with corporate pharmacists since they are not easily accessible. The only contact made is when the patient goes to the store to fill their prescription unlike community pharmacies who are conveniently located in the residential areas, offer delivery services and are available to consult over the phone (van Eikenhorst ,et al., 2017, pp 17-38). Pharmacists must build relationships while providing services to the patient (Sabater-Galindo, Fernandez-Llimos, Sabater-Hernández, Martínez-Martínez and Benrimoj, 2016, pp 339-347).

The researcher used NVivo 11 software to search for commonly used words during the interview. The word “relationship” was used by all eight participants shown in figure 3 below.

In Folder	References	Coverage
Internals	1	0,16%
Internals	2	0,29%
Internals	1	0,18%
Internals	3	0,51%
Internals	1	0,14%
Internals	4	0,55%
Internals	2	0,26%
Internals	2	0,34%

Figure 10. Summary of Word Tree Source: The Researcher, NVivo (2018)

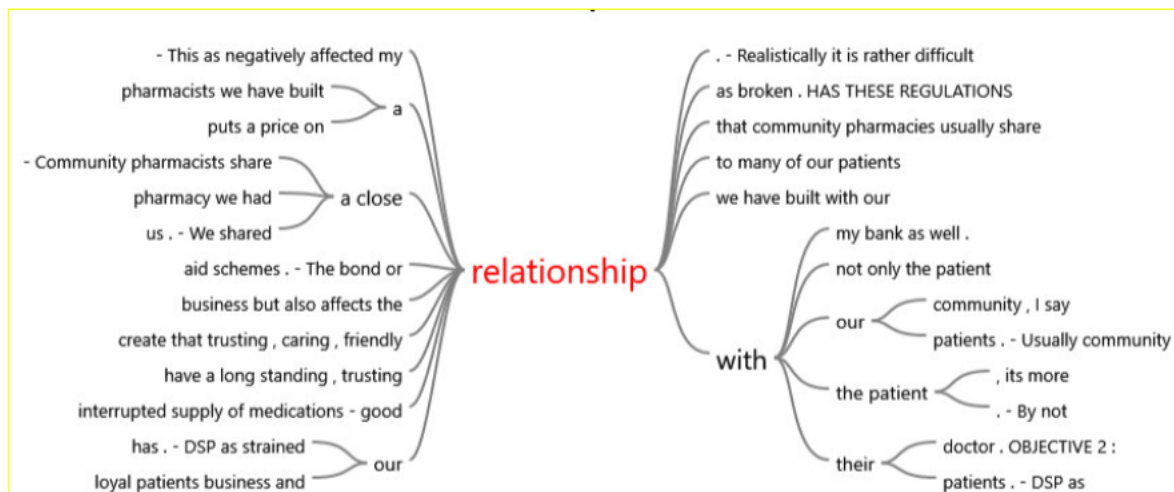


Figure 11. Importance of Customer Relationship Source: The Researcher, NVivo (2018)

The word tree analysis visually explains the important of relationship between patient and pharmacist.

“Community pharmacists share a close RELATIONSHIP to many of our patients”

“DSP as strained our RELATIONSHIP with our community”

“This negatively affected my RELATIONSHIP we have built”

Both Figure 10 and Figure 11 shows the importance of a pharmacist and patient relationship and how the regulations of closed DSP as broken this relationship.

Objective 2

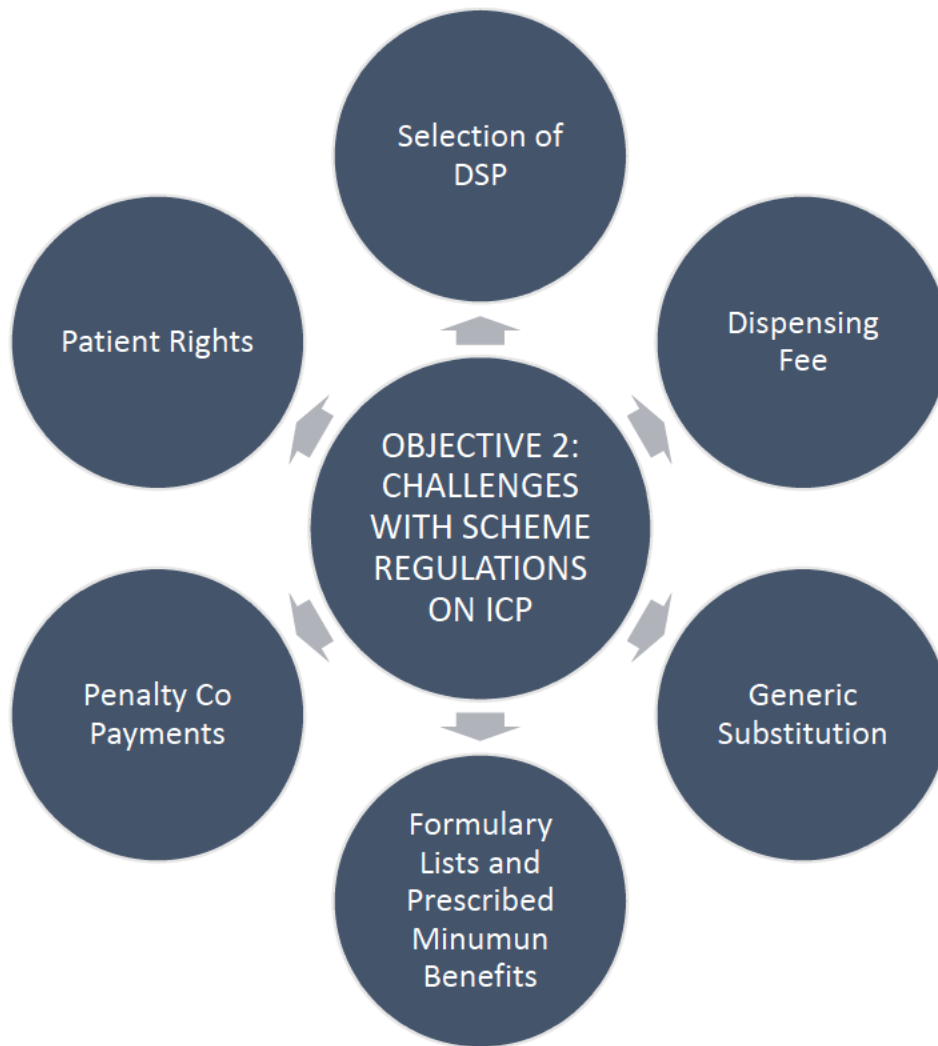


Figure 12. Themes for Objective 2 of the Study Source: The Researcher, Generation of Themes NVivo 11 (2018)

These themes emerged from objective two of the interview conducted with the eight participants. The researcher inquired about the challenges between medical aid schemes and independent community pharmacies. These themes provided insight as to the obstacles pharmacists face with medical aid scheme regulations and governmental policies and how this as affected their ability to provide patient care.

Theme 1: Selection of Designated Service Providers

Participant 1 stated:

“It is unfair towards community pharmacies. Why must only the corporate pharmacies be given preference? We should all be given the opportunity we apply to be preferred providers of medical aid schemes.”

Participant 2 stated:

“The selection criteria are not transparent and leaves community pharmacies at a disadvantage. Why can't it be opened to all pharmacies? I am sure all pharmacies would want the opportunity to a DSP”

Participant 6 stated:

“Community pharmacies are disadvantaged with DSP contracts. We should be given a chance to apply to belong to a network for medical aid schemes. It seems like only corporate pharmacies have the privilege of being appointed as DSP's.”

Medical aid schemes must be transparent when selecting a DSP. Medical aid schemes that use closed DSP networks, forces the members to use healthcare providers decided by the scheme. If the members do not comply with this and choose to use a non- DSP, then the member is punitively punished with a penalty co-payment. Corporate franchise and courier pharmacies can afford to accept the low dispensing fee rates offered my medical aid schemes and therefore, are appointment as DSP's for the scheme. As mentioned by the participants, they also want the opportunity to apply for the DSP contracts and are willing to charge medicines at the same price as the corporate franchise to retain their patient profiles.

(Mpanza, 2016, pp 13-14) suggests the contract between medical aid schemes and DSPs focuses on saving money for the scheme and not the member. The members of each scheme have a legal right to be involved in the decision making of their healthcare requirements. Patients who have a good relationship with their healthcare provider have a more active role in decision making (Vahdat, Hamzehgardeshi, Hessam and Hamzehgardeshi, 2014, pp 1-7). Medical aid schemes must consider the members opinion when deciding on the selection of DSP's.

Theme 2: Dispensing Fee and Single Exit Price

Participant 1 stated:

“This is the maximum fee a pharmacist can make as a profit. The fee is ridiculous. How can you sustain a business on 26% or R26? We are the only profession governed by a fee.”

Participant 5 states:

“It is actually the mark up price, the profit that we can make which is absurd. It adds a lot of pressure on me as the pharmacist and owner to sustain my business.”

Participant 8 states:

“This dispensing fee is minimal. Independent pharmacies cannot continuously rely on other aspects of the pharmacy in order to make a profit e.g. clinic services, front shop promotions. This in turn puts a lot of pressure on the staff as well the working environment.”

The introduction of the Single Exit Price and regulated dispensing fees have reduced the pharmacy's profit substantially. Not dispensing the chronic medicines decreases the average cost of the SEP and thereby reduces the average income from that sale. In the UK, national policy changes are creating more competition in the retail pharmacy sector hence changing the role of a pharmacist. Changing the remuneration of pharmacist result in motivation and increase provision of patient care (Hall ,et al., 2018, pp 1043-1057).

Theme 3: Generic Substitution

Participant 2 stated:

“The formulary and generic items change and we are forced to keep a wide variety of generics. This results in stock getting expired on the shelf, wasting money.”

Participant 3 stated:

“Sometimes doctors write ‘no substitution’ on the prescription but medical aids only pay for generics. This results in the patient paying for it out of their pocket. Sometimes the patient can't afford it buy the full quantity of original meds and buys a few at a time and disrupts treatment.”

Participant 8 stated:

“There are many generics available and it is impossible to stock all of it. Patients are forced to pay for this difference in price if we don’t keep the cheapest generic that their medical aid pays for. Many patients reduce the quantity they buy per month due to financial constraints and this affects the management of their condition.”

The participants expressed the patients concerns over generic substitution. Doctors together with pharmacists need to work as a team to provide the best pharmaceutical care for the patient. (Kohli and Buller, 2013, pp 155-60) mentioned that previous studies indicated that lower income earners and less knowledgeable patients tend to have a negative attitude towards generics. Therefore, patient education and counselling are vital in making healthcare affordable. The Patient Rights Charter states that the patient must have knowledge on their medical aid scheme. It is therefore the responsibility of the medical aid scheme to communicate and provide information regarding the scheme rules with an explanation for the patient.

Theme 4: Formulary Lists and Prescribed Minimum Benefits

Participant 4 stated:

“Formulary lists and PMB are the most troublesome especially for patients that are on lower plan medical aid. Even though the doctor orders an item that is much more effective in treating the patient’s condition, medical aid forces us to dispense what they think will help the patient.”

Participant 5 states:

“Formularies change for each medical aid. So, if you are a DSP you have to abide by using formularies and ICD 10 codes, if we don’t then medical aid informs the patient that we are non-compliant and sends the member a list of compliant pharmacies to use as their DSP for chronic meds. It is impossible to keep all formularies and generics this results in expired or dormant stock.”

Each medical aid scheme as a Prescribed Minimum Benefits (PMBs) providing minimum healthcare requirements for the members at an affordable price. Medical aid schemes negotiate a price with healthcare providers and contract with these providers as DSPs. The formulary list

is the list of prescribed medicines that medical aid schemes that pay for provided it is a PMB condition. Service providers are forced into these contracts in order to keep their chronic patients.

Health Market Inquiry (Competition Commission South Africa, 2018) investigation revealed the following:

- Medical aid schemes struggled to contract with specialists as DSPs to treat PMB conditions
- Medical aid schemes focused on price and not outcome-based contracts
- Members of schemes are not educated on the process of PMB payments
- There is no system allocated to review medical aid compliance on payment of PMBs to monitor if the member pays out of their pocket or from their savings
- The PMB structure as not been reviewed

Theme 5: Penalty Co-Payments

Participant 6 states:

“Patients who still choose to use us to obtain their chronic meds out of convenience are forced to pay the penalty co-payment. This is totally unfair as the price is the same as the DSP pharmacies.”

Participant 7 stated:

“These penalty co-payments are unfair as the scheme is pushing the patient into a corner to take the medicines at the pharmacy of the schemes choice. It inconveniences the patient.”

Participant 8 stated:

“This is a huge disadvantage to the patient. Schemes force patients into using DSP of their choice even though the member has access to a community pharmacy near to their home. This is just an inconvenience to the patient. Members are punished for not being obedient to the scheme rules.”

Regulation 8(2)(b) of Medical Schemes Act allows for a co-payment to be imposed on a member that uses a non-DSP. Medical aid schemes abuse Regulation 8(2)(b) by charging punishing the patient with this penalty co-payment if choosing to use a non-DSP. The penalty co-payment is calculated as the percentage of the total value of the prescription which includes the SEP plus the DF. Penalty co-payments is unfair business practice (Independent Community Pharmacy Association, 2018, pp).

Theme 6: Patient Rights

This theme explored the National Patients' Rights Charter, the right to choose a healthcare provider. It shows how these regulations of Designated Service Providers are violating the patient's constitutional rights.

Participant 2 states:

“This regulation of DSP restricts the patient from choosing their preferred pharmacy. This is against the patient's Constitutional Right. The patient must be given the freedom to choose.”

Participant 7 states:

“Patients should have the right to choose their healthcare provider whom they are comfortable with. This contradicts our Constitution. It is an infringement of our rights.”

Closed DSP networks impact negatively on the patient's right to choose a service provider of their choice. The National Patients' Charter states that every patient as the right to choose their own health care provider or health facility (Test, 2007). The charter includes patients' rights to:

- Included in decision making
- Access to healthcare
- Knowledge on medical aid scheme
- Treated by a named healthcare provider
- Continuity of care

The Consumer Protection Act 68 of 2008 states that the consumer the right to choose a supplier and that the consumer can't be bullied into using a service.

Objective 3

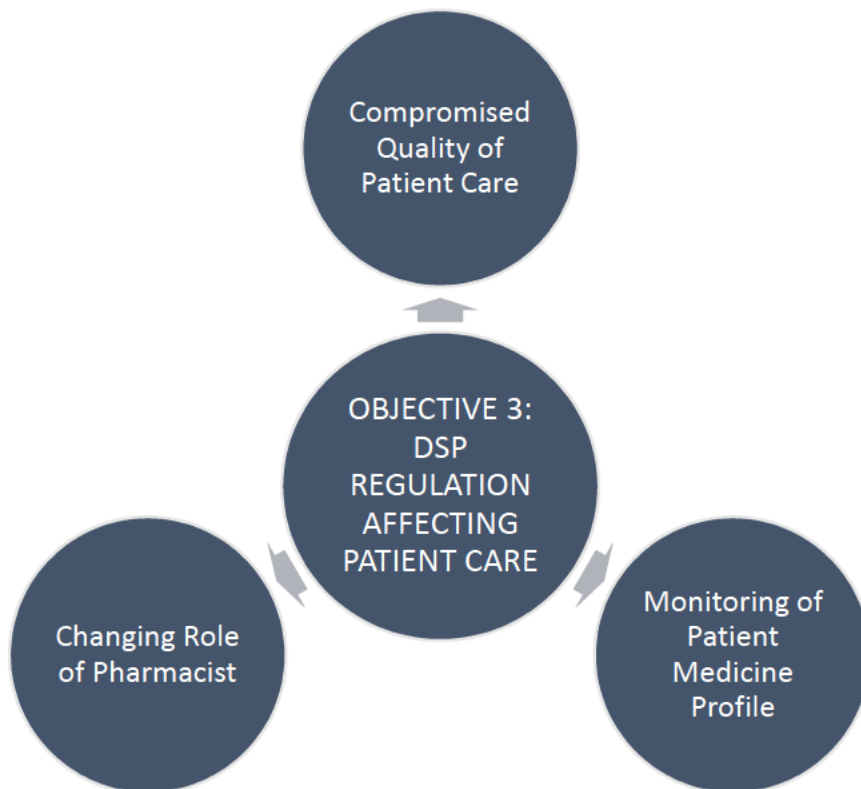


Figure 13. Themes for Objective 3 of the Study Source: The Researcher, Generation of Themes NVivo 11 (2018)

The researcher inquired on how patient care is affected with the regulation of Designated Service Provider. All participants in the study has similar responses to this research objective.

Theme 1: Compromised Quality of Pharmaceutical Care

Participant 3 stated:

“Numerous occasions patients come to the pharmacy with surplus of meds they received from the courier pharmacy designated by the member’s scheme. They want to sell the medicines to us because they have too many unused boxes because doctor stopped their medication or they don’t know what the medication is used for. They usually want to swop the medicines for medicines that the courier pharmacy didn’t send.”

Participant 5 stated:

“By not having the patient’s complete medicine history I don’t have the confidence to offer the patient the best care they require. I can only assist the patient with the information they give to me a lot of times the patients don’t even know the name of their medicines.”

Participant 6 stated:

“I am forced to dispense medicines that the patient’s medical aid pays for, even though I know that there is another product available which will work more efficiently for the patient. But my hands are tied since most patients don’t have extra cash to pay for medication over and above their monthly contributions to medical aid.”

Participant 8 stated:

“Courier pharmacies lack individual care since there is no direct contact with the patient. Sometimes courier pharmacies don’t deliver on time due to post office strikes etc. These patients come to buy the meds from us but unfortunately, we don’t have a valid prescription so we can’t sell the scheduled meds. This comprises their health.”

The Code of Conduct (South African Pharmacy Council, 2008) requires the pharmacist to provide assistance and to counsel on the safe and appropriate use of medicines. Courier pharmacies don’t dispense acute or OTC prescriptions, results in the patient using multiple pharmacies to obtain medicines. Among the elderly there is a growing concern of inappropriate medicine use which harms the patient’s well-being (Scott, Hilmer, Reeve, Potter, Le Couteur, Rigby, Gnjidic, Del Mar, Roughead and Page, 2015, pp 827-834). Pharmacist must be extra vigilant when prescribing OTC medicines to patients without access to their chronic medicine therapy.

Theme 2: Monitoring of Patient Medicine Profile

All the participants’ responses included monitoring of polypharmacy and drug interactions.

Participant 1 stated:

“It is so difficult to counsel a patient since we don’t have the full medicine history of the patient. I can’t advise the patient on any drug interactions with their chronic meds.”

Participant 2 stated:

“It’s difficult to counsel and give the patient the best information on their medicines and condition. Many patients don’t know the names of their chronic medications, so I won’t be able to assess for polypharmacy.”

Participant 4 stated:

“We don’t know what has changed in the patient’s life and medication history since they don’t take their chronic medicines from us, it’s difficult to check for polypharmacy and interactions.”

As mentioned the Code of Conduct (South African Pharmacy Council, 2008) makes emphasis that all healthcare practitioners should be accountable for the outcomes of drug therapy for the patient. Provision of pharmaceutical care implies that the pharmacist is directly accountable to the patients drug therapies (Anderson, 2002, pp 391-404). DSP regulation prevents the pharmacist from accessing the patients medicine therapy hence the pharmacist can’t fulfil the role of monitoring and adherence. By using multiple pharmacies for dispensing of medicines it is difficult to monitor interactions and polypharmacy (Look and Mott, 2013, pp 601-610). Pharmacists must apply their skills in providing efficient pharmaceutical care in preventing drug related problems by monitoring the patient’s medicine therapy (Nusair, Guirguis and Pharmacy, 2017, pp 349-357). Courier pharmacies don’t provide a one on one interaction with the patient. Patients that use courier pharmacies as a DSP are disadvantaged due to a lack on counselling and monitoring of medicine use.

Theme 3: Changing Role of Pharmacist

All participants shared the same opinions on this theme. The researcher only stated the responses of three participants who had the most amount of years in the retail industry i.e. Participant 4 had 28 years of experience, Participant 7 had 29 years of experience and Participant 8 had 34 years of experience.

Participant 4 stated:

“Community pharmacist role was patient-cantered. We build relationships with not just the patient but the entire family. The wellness of the patient was always first priority not the sale

of the product. Now with the opening of so many corporate pharmacies we have to compete with them, every sale makes a difference for our survival.”

Participant 7 stated:

“Our role as changed from providing patient care to a shopkeeper. We strive for profits now just to stay afloat in these strenuous times.”

Participant 8 stated:

“Those days I was proud of my profession, when only a pharmacist could own a pharmacy. We strived to provide optimal pharmaceutical care for every patient. We were the first contact if a patient required any advice on their health. We prided ourselves with customer relationships. Now our profession is driven by profit. It’s sad but in my opinion it’s the truth.”

The role of the pharmacist is constantly evolving together with the patient’s needs and expectation of services (John, 2018, pp). In South Africa, the introduction of the NHI has shifted the economy wider, therefore the services that pharmacists used to offer must be restructured to fit a new models of patient care. Dis-Chem pharmacies is the second largest retail pharmacy chain, boasting 137 pharmacies across South Africa. The gross profit for 2017 was R4.2 billion and increased to R4.8 billion for the current year. The primary focus of corporate pharmacies is shareholder profit and not patient care. Corporate pharmacies objective is to reach monthly targets and less attention is focused on the patient’s needs (Mohammadzadeh ,et al., 2014, pp 739-741). Pharmacists need to adapt professionally as well as an entrepreneur to meet the changing demands of healthcare.

5. CONCLUSION AND RECOMMENDATIONS

5.1. Introduction

The research of the impact of medical aid scheme regulations of DSPs on independent community pharmacies explains the dynamics of a highly regulated healthcare sector in South Africa. There is a broader vision by the pharmaceutical council to protect the profession of a community pharmacist which was once a scarce skill while ensuring their survival as entrepreneurs. The research emphasizes the patient's rights to affordable and accessible healthcare.

5.2. Answers to the research problem

The researcher as investigated the impact of medical aid scheme regulations of DSPs on community pharmacies in the Chatsworth area. The study shows how the independent pharmacies as well as the patients are affected by these regulatory changes. Chapter 5 of this study explains how the objectives have been met.

5.3. Implications to the study

The research highlights the problems encountered by independent community pharmacist in the Chatsworth area. By using a qualitative approach in the research, it illustrates the critical role of understanding the problems these pharmacists face. The results from this study can be used as a basis for further investigation the predicaments of independent community pharmacists in the Kwa-Zulu Natal province and throughout South Africa.

5.4. Conclusion

This research has explored a complex industry, the pharmaceutical sector. It is almost impossible for a pharmacist to become an entrepreneur. The financial costs to sustain a business is too high and the profits to survive are minimal. Therefore, recent graduates will be practicing in the corporate pharmacy chains. Entrepreneurship within pharmacy is dying and newly graduated pharmacist will not be able to open a pharmacy. Therefore, recent graduates will be employees of a profit driven monopolistic corporate enterprise.

This undesirable business practice will affect the pharmaceutical delivery value chain and it is imperative that the National Health Insurance is implemented. Access to healthcare in the rural areas is the biggest obstacle. Independent community pharmacies are located extensively throughout South Africa, prior the emergence of corporate pharmacy chains. This made healthcare accessible to all patients in the rural and urban areas due to their extensive trading hours, being available on call 24 hours, consulting with patients without appointments and offering clinical care.

In South Africa's healthcare system, which is encountering a shortage of healthcare professionals, independent community pharmacies represent resources available to enhance primary healthcare delivery across the country. The increasing closure of independently owned community pharmacies further deters potential students from entering the pharmacy profession. Independent community pharmacists are willing to abide by medical aid regulations and government's legislation on providing affordable healthcare. Government is required to create a flexible relationship with independently owned community pharmacies and this relationship must be maintained to provide a platform for a stable business environment. Pharmacist interventions are essential for drug monitoring, removing unnecessary drugs from repeat prescriptions and preventing possible adverse effects (Thomas, Huntley, Mann, Huws, Elwyn, Paranjothy and Purdy, 2014, pp 174-187). Policy makers have been driving pharmacists towards improving health care and disparities. The pharmacist requires the patient's holistic medical history to assess and monitor the patients' adherence.

5.5. Recommendations

The researcher feels based on the data, the medical aid scheme regulation on Designated Service Providers are negative towards the private sector pharmaceutical industry and for patient care, therefore it should be revised.

Government should invest in resources to monitor legislation once passed and how it affects the healthcare industry as a whole, from medical scheme, wholesalers, pharmacists and patients.

Before legislation is passed, the public must be able to voice their opinion on the subject and this information should be taken into consideration.

To measure the quality of healthcare that patients receive from corporate pharmacy chains, and the service these patients receive from independently owned community pharmacies.

FURTHER RESEARCH

A study to examine the patient's view on the impact of closed DSPs regulations as affected their health care.

A study to access the growth of an independent community pharmacy which changed to a franchise pharmacy.

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APPENDIX I – ETHICAL CLEARANCE



31 October 2018

Mrs Keshni Govender 200105638
Graduate School of Business and Leadership
Westville Campus

Dear Mrs Govender

Protocol Reference Number : HSS/1574/018M

Project title: The impact of South African Medical Aid Scheme regulations of designated service providers (DSPs) on independent community pharmacies in the Chatsworth area

Full Approval – Expedited Application

In response to your application received 4 September 2018, the Humanities & Social Sciences Research Ethics Committee has considered the abovementioned application and the protocol has been granted **FULL APPROVAL**.

Any alteration/s to the approved research protocol i.e. Questionnaire/Interview Schedule, Informed Consent Form, Title of the Project, Location of the Study, Research Approach and Methods must be reviewed and approved through the amendment /modification prior to its implementation. In case you have further queries, please quote the above reference number.

PLEASE NOTE: Research data should be securely stored in the discipline/department for a period of 5 years.

The ethical clearance certificate is only valid for a period of 3 years from the date of issue. Thereafter Recertification must be applied for on an annual basis.

I take this opportunity of wishing you everything of the best with your study.

Yours faithfully

.....
Professor Shenuka Singh (Chair)
Humanities & Social Sciences Research Ethics Committee

/pm

Cc Supervisor: Professor M Hoque
cc Academic Leader Research Dr E Mutumbara
cc. School Administrator: Ms Zarina Bullyraj

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APPENDIX II – INFORMED CONSENT

Informed Consent Letter 3C

UNIVERSITY OF KWAZULU-NATAL
GRADUATE SCHOOL OF BUSINESS AND LEADERSHIP

Dear Respondent,

Master of Management of Business Administration
Researcher: Keshni Govender (083 537 4880)
Supervisor: Prof Muhammad Hoque (031 260 8696)
Research Office: Mr P Mohun 031-260 8350

I, KESHNI GOVENDER a MBA student, at the Graduate School of Business and Leadership, of the University of KwaZulu Natal. You are invited to participate in a research project entitled **Impact of Medical Aid Regulations of Designated Service Providers on Independent Community Pharmacies in the Chatsworth area.**

The aim of this study is to: Evaluate the impact of the Designated Service Provider regulations on the future of Independent Community pharmacies. Through your participation I hope to understand the challenges between medical aid schemes and independent community pharmacies and how this as affected patient care.

Your participation in this project is voluntary. You may refuse to participate or withdraw from the project at any time with no negative consequence. There will be no monetary gain from participating in this survey/focus group. Confidentiality and anonymity of records identifying you as a participant will be maintained by the Graduate School of Business and Leadership, UKZN.

If you have any questions or concerns about completing the questionnaire or about participating in this study, you may contact me or my supervisor at the numbers listed above.

The survey should take you about 20 minutes to complete. I hope you will take the time to complete this survey.

Sincerely


Investigator: Keshni Govender

Date 12/10/2018

This page is to be retained by participant

UNIVERSITY OF KWAZULU-NATAL
GRADUATE SCHOOL OF BUSINESS AND LEADERSHIP

Master of Commerce Research Project
Researcher: Keshni Govender (083 537 4880)
Supervisor: Prof Muhammad Hoque (031 260 8696)
Research Office: Mr P Mohun (031 260 3093)

CONSENT

I.....(full names of participant) hereby confirm that I understand the contents of this document and the nature of the research project, and I consent to participating in the research project.

I understand that I am at liberty to withdraw from the project at any time, should I so desire.

SIGNATURE OF PARTICIPANT

DATE

.....

This page is to be retained by researcher

APPENDIX III – INTERVIEW SCHEDULE

INTERVIEW SCHEDULE

Demographics:

1. Are you the owner, pharmacist or Responsible pharmacist?
2. For how long have you been practicing in retail pharmacies as a pharmacist?
3. For how many years are you employed at this pharmacy?

Objective 1: To evaluate the impact of the DSP regulations on the future of independent community pharmacies.

Prompt: How do you feel about the DSP regulations?

Prompt: Please elaborate

Prompt: Has these regulations had an impact on the business?

Prompt: How?

Prompt: Why?

Prompt: Have you considered changing to a franchise group?

Prompt: Please explain why?

Prompt: Has DSP had an impact on you as a professional? How?

Objective 2: To evaluate the challenges between medical aid schemes and these independent community pharmacies.

Prompt: What are the challenges that you have encountered with medical aid schemes?

Prompt? Can you please explain?

Prompt: How do you feel about the Dispensing Fee being paid by schemes

Prompt: What about scheme payment for other services regulated by the pharmacy council board notice?

Objective 3: To understand how this regulation has affected patient care.

Prompt: How as it affected your patient care?

Prompt: What are your opinion on the rights of the patients?

Prompt: Has DSP affected your ability to offer the patient a maximum pharmaceutical service?

Prompt: What about penalty co-payments? Has this impact on affordability of medicines and services

APPENDIX IV – TURNITIN REPORT

Keshni Dissertation

ORIGINALITY REPORT

8%

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4%

INTERNET SOURCES

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