Exploring pharmacists views, knowledge and perceptions regarding generic medicines in the Western Cape

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ACRONYMS AND ABBREVIATIONS

GDP : Gross Domestic Product

GP – General Practitioner

MBC : Minimum Bactericidal Concentrations

MCC : Medicines Control Council

MIC : Minimum Inhibitory Concentration

MMAP : Maximum Medical Aid Price

NHS : National Health System

NTI :Narrow Therapeutic Index

OTC : Over The Counter

SAPC : South African Pharmacy Council

WC : Western Cape

WHO :World Health Organisation

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DATABASES SEARCHED

Pubmed
South African Medical Journal
South African Pharmaceutical Journal
Medscape
ScienceDirect

TERMS USED

Generic medication
Bioequivelance studies
Pricing
Policies
Perception, attitudes and behavior of generic substitution
Cost saving with use of generics
Mandatory generic substitution
Voluntary generic substitution
Healthcare South Africa
Benefits of generic medicines
Generic prescribing
Factors impeding generic usage

ABSTRACT

BACKROUND

In 1996, South Africa adopted a National Drugs Policy. An important objective of this policy focused on promoting the use of generic medicines in the country to ensure that medicines are accessible to the majority of South Africans. Pharmacists play a vital role in influencing patients' choice of medication, thus highlighting the importance of gaining all health professionals' support for the quality and utilization of generic medicines.

OBJECTIVES

This study sought to assess and evaluate the perceptions, views, knowledge and willingness to recommend generic medicines by pharmacists that are located within the Western Cape, as well as to explore pharmacists' perceptions towards the safety, quality, and efficacy of generic medicines. In addition, the study assessed pharmacists' views on current policy with respect to substitution of generic medicines as well as to determine if these views vary in the different practice settings. Finally the study assessed pharmacists' views on the pricing system of generics as well as their opinion on promotion of these medications.

METHOD

A cross-sectional online survey, which targeted 1730 pharmacists living in the Western Cape, was conducted, using SurveyMonkey, from 7 September to 7 October 2014. Data collected included participant demographics, qualification, experience, education, knowledge and perceptions of generic medication. Survey Monkey was used to produce graphical representations of the data and data was exported onto Microsoft excel in order to make analytical comparisons.

RESULTS

A total of 321 pharmacists responded to the questionnaire (a response rate of 18,6%). 82% of pharmacists stated there is no difference in safety between original brand and generic medicines. Majority of respondents (74%) believed that generic medicines are therapeutically equivalent to the original medicines. However, 39% of pharmacists stated that original medicines are of a better quality than their generic counterparts. A large number (more than 60%) of pharmacists reported concerns of bioequivalence as their main problem when switching to a generic medicine.

CONCLUSION

Majority of Pharmacists in the Western Cape had a positive outlook on generic medication and supported and encouraged its use. Concerns were raised however, regarding quality, safety, and effectiveness of generic medicines as well as doubts in the reliability of certain generic manufacturing companies. Pharmacists' opinions could negatively impact generic usage in South Africa, therefore continuing education and awareness campaigns should be implemented in order to re-confirm pharmacists' knowledge of generic medicines being bioequivalent and of equal quality to branded medicines. Furthermore, pharmacists should be encouraged to report Adverse Drug Reactions in order to resolve any quality issues

DECLARATION

In fulfilment of the requirements of the degree of Masters of Pharmacy (Pharmacy Practice) in the Discipline of Pharmaceutical Sciences, School of Health Sciences, University of KwaZulu-Natal, Durban, South Africa, I Naseema Shaikh declare that

(i) The research reported in this dissertation, except where referenced, is my original work.

(ii) This dissertation has not been submitted for any degree or examination at any other university.

(iii) This dissertation does not contain other person's data, pictures, graphs or other information, unless specifically acknowledged as being sourced from other persons.

(iv) This dissertation does not contain other persons' writing, unless specifically acknowledged as being sourced from other researchers. Where other written sources have been quoted, then:

a) Their words have been re-written but the general information attributed to them has been referenced:

b) Where their exact words have been used, their writing has been placed inside quotation marks, and referenced.

(v) Where reference to a publication for which I am a principal author, I have referenced the "In Press" publication.

Student Signature_____

Date_____

CHAPTER 1

INTRODUCTION AND BACKGROUND

1.1 Importance of medicines in Healthcare

Medicines are a crucial component of healthcare. Making it easily accessible and cost effective for the population however, is an on-going challenge. Medicines play an important role in managing the health needs of a population, particularly with regard to the care of chronic diseases, the provision of preventive care services such as immunisation and family planning, as well as health education. [(1)] It is therefore important to ensure the availability and accessibility of affordable quality medicines to all segments of the society. A primary health care system without medicines is, however, like a river without water. [(1)]

Households in Africa have insufficient access to essential medicines. Barriers to access that have been identified are as follows:

- The ex-manufacturer price influences access. This can best be addressed through regulating the price of medicines along the supply chain. [(2)]
- Inefficiencies in the supply and distribution chain. A tracking system to assess the availability of medicines through the medicine supply chain should be implemented. [(2)]
- A simplified, universal, and transparent regulatory approval process particularly for generic medicines that is efficient. [(2)]
- An effectively implemented generic substitution policy. [(2)]

Measures should be taken in order to ensure that all citizens are provided with safe, quality and efficacious essential medicines.

1.2 South Africa's Healthcare system

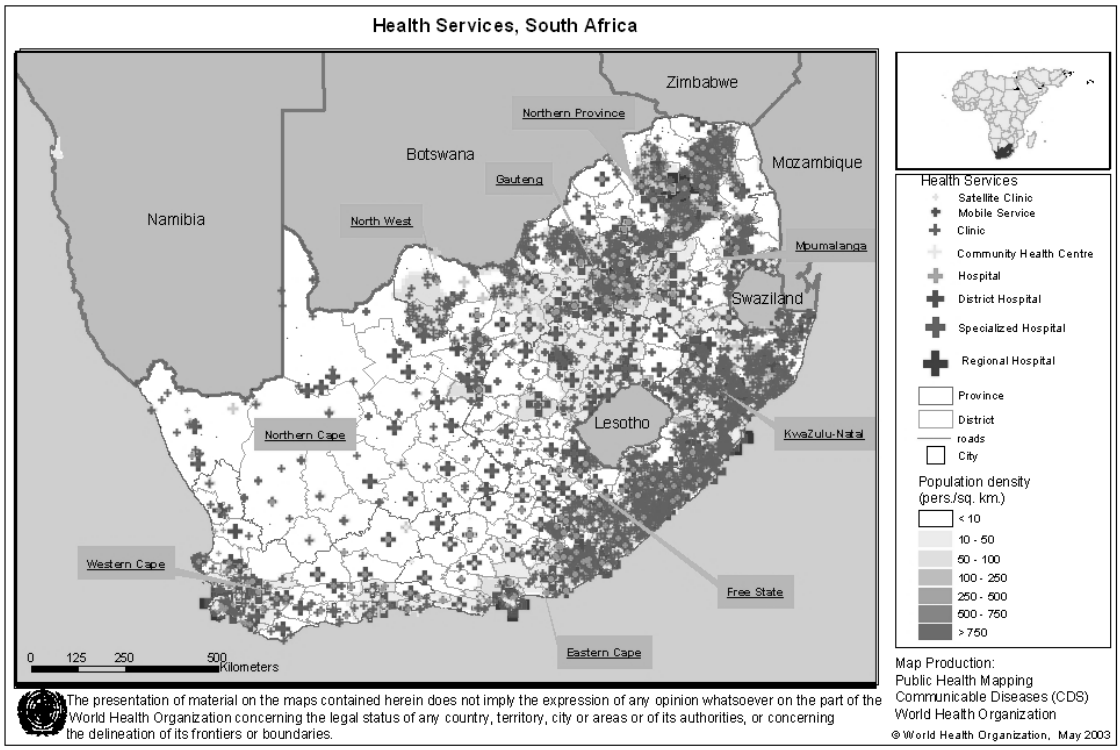
Health care in South Africa ranges from the most basic primary health care services, offered freely by the State, to highly specialised, hi-tech health tertiary healthcare services that are available in both the public and private sector. [(3)] The public sector is however, financially

overburdened and critically under-resourced in several areas. Despite approximately 40% of all government expenditure being directed toward healthcare, the public health sector still remains under pressure to deliver services to essentially 80% of the population. [3]

In 2011, total health expenditure was R248.6-billion, approximately 8,3% of GDP, which was, above the 5% recommended by the World Health Organisation (WHO) and relatively high by international standards. Despite this high expenditure, health outcomes remain poor in comparison to similar middle-income countries. [3] This forms a strong argument so that the challenge facing the South African health system is efficient and equitable use of available resources. [4]

Figure 1: Map of Health Services in South Africa

(World health organisation, May 2003)



1.3 South Africa and generic medicines

The cost of medical care is increasing rapidly, making healthcare unaffordable for an increasing proportion of South Africa's population. [5] As access to healthcare increases, there is greater demand for medicines in the country. [5] One way to reduce the cost of medication

without affecting the quality of medical care is to substitute the original (branded) products with generic medication. [6]

In 1996, South Africa adopted a National Drugs Policy, and an important objective of this policy focused on promoting the use of generic medicines in the country. The policy states: "*It will be incumbent on the pharmacist, prior to dispensing a prescription, to inform the patient on the benefits of generic substitution and to ensure that substitution takes place with the patient's full understanding and consent*". [7] The intention of this policy is to increase the accessibility of affordable healthcare to the majority of people living in South Africa. Generic medicine usage in South Africa however, still remains low with an evaluation released by the National Association of Pharmaceutical Manufacturers (NAPM) revealing that only 20% of South African prescriptions are made up of generic medicines. [3]According to comments by the chairman of the organisation, Muhammed Bodhania, *''there has only been a 1% increase in the use of generics from a value perspective over the last five years, while the increase in the total cost of medicines has increased substantially more than that''* [3], He suggests that legislative changes be made in order to allow manufacturing companies to launch generic medicines into the market as soon as the original medicine patent expires. By increasing the availability and utilisation of generic medicines, NAPM estimates al almost R24 billion saving for the country. [3]

The MCC should also focus more attention on ridding the market of medicines illegitimately marketed from foreign countries. This is important to prevent sub-standard medicines from being sold. Medicines imported from internationally recognised companies should be registered as soon as possible and post market surveillance implemented in order to ensure that medicines are efficacious and safe.

1.4 Pharmacists and generic substitution

The role of the pharmacist has been changing over the past two decades, as they are now an integral team member in the provision of health care. For pharmacists, their greater involvement in medication selection means greater responsibility towards their customers and an increased need for accountability. [8] Pharmacists are the key role-players in generic substitution as they are the most likely health care professional to interact with patients regarding use and safety of medicines. Generally, patients want reassurance from the

pharmacist that the generic medicine is as good as the brand name medicine when they get substituted. As trusted health care professionals and having the requisite education, pharmacists are in the perfect position to provide time, reassurance and advice about medication. [9]

Patient counselling by pharmacists is of vital importance in empowering consumers to make informed decisions about their medical treatments and take responsibility for their own health. [10] Adequate counselling by pharmacists will improve communication between patients and health care providers and aid and encourage effective use of medicines so that patients see the pharmacist as more than just dispensers of medication but as advisers and consultants that are experts in providing medicine related education and ensuring rational and effective medication usage. [11] The pharmacists need to be more active in counselling patients when there is a change in the patients' prescription (change from brand name to generic medication, change of manufacturer, etc.). Pharmacists are an important information source and thus should provide patients with the information necessary to reduce existing patient confusion about generic medicines. It has been determined in various studies that pharmacists are a profession that patients have confidence in. [12] It is likely that if pharmacists are confident about generic medicines, then they are likely to convince patients to swop to generic medicines with greater reassurance.

With the advent of the mandatory requirement of the offer of generic substitution in South Africa by pharmacists, it is imperative to investigate the knowledge, views and perceptions of pharmacists in the country with regards to generic medicines, in order to assess if they are enabling the implementation of the policy.

1.5 Study objectives

1) To assess the perceptions of generic medicines of pharmacists who are located within the Western Cape Region
2) To evaluate these pharmacists' perceptions (based on their observation), views (based on their biased opinions), knowledge of and willingness to recommend generic medicines.
3) To explore these pharmacists perceptions of the safety, quality, and efficacy of generic medicines.

4) To assess these pharmacists' views on current policy with respect to substitution of generic medicines.
5) To assess these pharmacists' views on the pricing system of generics as well as their opinion on promotion of these medications
6) To determine if views in the different practice settings vary.

CHAPTER 2: LITERATURE REVIEW

The focus of the literature review is on definition of terms as well as other studies undertaken with regards to the implementation of generic prescribing and generic substitution within the pharmaceutical environment in South Africa and internationally.

2.1 Definition of generic medicines

Generic medicines have been used extensively for decades and are comparable versions of brand-name medicines. [13] The active pharmaceutical ingredient in a generic medicine and its branded counterpart are chemically identical, generic medicines typically cost far less than brand-name medicines because of smaller start up costs. [14] Generic medicines have the same strength, dosage form, and route of administration as the brand name medicine, but do not need to contain the same inactive ingredients. [15]

2.2 Safety Standards

In order for a generic medicine to be approved, generic medicine manufacturers must prove that their medication is bioequivalent to the brand name or originator medicine. In South Africa, it must meet rigorous standards established by the Medicines Control Council (MCC), which is the regulatory body that reviews the bioequivalence data, thus ensuring that the generic medicine performs the same as its respective brand name medicine, whether as an immediate or controlled release dosage form. The MCC also has stringent regulations with regards to identity, strength, quality, purity, and potency of the medication. Some variation in purity, size, strength and other parameters can and does occur during manufacturing for all medicines, however, the MCC limits how much variability is acceptable. [15]

All generic manufacturing, packaging, and testing sites have to pass the same quality standards as those of brand name medicines, and the former must meet the same specifications as any brand name product. In fact, many generic medicines are made in the same manufacturing plants as brand name medicines. [15]

2.3 Bioequivalence studies in South Africa

In order for a generic medicine to be approved by the MCC it must prove to be bioequivalent to its original counterpart. Bioequivalence studies ensure that both medications have equivalent bioavailability. This means that the rate and extent of absorption of active ingredients or active metabolites from a product into the systemic circulation between the two medications must be similar.

In South Africa the following are needed for registration [16] :

- *"Bioavailability e.g. serum levels are needed*
- *Testing generic in vitro activity against known laboratory strains i.e. MIC, MBC, Time-kill curves and SMR after exposure*
- *Testing in vivo activity in animal models and even in humans*
- *Shelf–life: Random sampling and monitoring –post marketing surveillance"*

A study by Walker et al (2006) researched the South African approach toward the assessment of generic medicines. [17] Various bioequivalence issues have been recently addressed in order to ensure that all medications are of the highest safety, efficacy and quality. Important issues addressed included the criteria for acceptance and recommended bioequivalence intervals, as well as the use of a foreign reference product and the process of assessing highly variable medicines. In addition, the use of "old" bio-studies submitted in support of an application is subject to expiry date. [17]

- In Vitro Testing

In vitro testing in South Africa is an integral component to ensure medicine safety and quality. In 2005, Liebowitz L et al compared the in vitro activity of Aspens generic injectable cephalosporins to that of the original medicines. It was noted that the MIC values of the generic and original medicines were comparable. [16] However, testing has also revealed unfavourable results in some cases.

Two combination generic Tuberculosis medicines, called Ebsar and Antib - 4 that were manufactured in India and registered in South Africa were removed from the market in 2008 after in-vitro testing revealed that the medicines contained subtherapeutic quantities of two of

the active ingredients. These tests were important as concerns were raised regarding possible TB medicine resistance. [16]

2.4 International bioequivelance studies

Numerous studies have been conducted internationally, assessing the bioequivelance between generic and original medicines. A study by Bobo et al (2010) reviewed the effectiveness and tolerability of 966 patients that were swopped from original to generic clozapine. [18] Most of the patients tolerated the switch without any worsening of symptoms or adverse effects.There was no increased intensive service utilization, or adjustments to medication. [18] Current evidence indicates that the effectiveness and safety of generic clozapine formulations in patients who were previously on brand-name clozapine is the same. There is a very low risk of poor outcome after switching to a generic clozapine formulation appears but this is difficult to predict. [18]

A study, conducted by Borgheini (2003), presented data that compared the bioequivalence and therapeutic efficacy of original psychoactive medicines with those of the corresponding generic products. [19] Results indicated that plasma levels of phenytoin were reduced to 31% after a switching from a brand-name to a generic product. In addition, some studies (controlled) of carbamazepine indicated that there was a recurrence of convulsions after switching to a generic formulation. [19] Finally, an investigation by the US Food and Drug Administration with regards to the recurrence of seizures when generic valproic acid was switched for a brand-name product determined that there was a difference in bioavailability between the two medicines. [19]

- In Vitro Testing

Lambert (2003) compared the pharmaceutical quality of 34 ceftriaxone generic products with Rocephin as the reference standard. [20] It was found that 18 quality standards from the European and US Pharmacopoeias were violated. These included violations on sterility and impurities, with 88% of products failing to meet clarity standards and 15% failing to achieve the claimed assay content. All 34 generics failed to meet Roche specifications for Rocephin. [20]

A study by Nightingale (2005) compared the quality of 65 generic clarithromycin products manufactured in 18 countries with that of the original medicine. [21] The results demonstrated

that the generic medicines were not comparable in vitro to that of the original medicine. Nine percent of the generic medicines failed to contain between 95 – 105% clarithromycin claimed on the label. About 34% released less active ingredient than the original and 19% of generics exceeded the 3% limit for impurities. [21] A similar study by the same author was conducted in 2000 in Latin America, Asia, Africa and Pacific regions assessing 40 different clarithromycin products. These results revealed that 20% of generics failed to contain the labelled amount of medicine, 70% released less medicine than the original and 60% exceeded the impurity limit. [22] The level of impurities may reflect the quality of manufacturing practises used in preparing new medicines, and are thus indicative of good manufacturing practises. [21]

Bioequivalence studies are an important aspect of medicine research in order to confirm results relating to efficacy and safety of medicines conducted in clinical trials. These tests however should continue to be reviewed after the medicine becomes available to the market as problems can arise later. An example of this occurred in November 2004 whereby Ranbaxy withdrew all its antiretrovirals post approval. This was due to discrepancies found in the documentation relating to proof of the products bioequivalence with the original medicine. [16]

2.5 Generic substitution policy in South Africa

Generic substitution involves professional intervention by the pharmacist through:

- Assessment of whether or not it is advisable for the patient to substitute the prescribed medicine with that of a generic product. [23]
- Making a selection of the most suitable generic medicinal product. [23]

The Medicines and Related Substances Act (as amended) only permits generic substitution within the criteria set by the section 22F [24]:

- *"Pharmacists must inform patients with a prescription for dispensing, of the benefits of the substitution;*
- *When substitution has taken place, the pharmacist must take reasonable steps to inform the prescriber of such substitution; and*
- *Pharmacists may dispense the generic instead of the medicine prescribed, unless:*

- *expressly forbidden by the patient to do so;*
- *the prescriber has written in his or her own hand on the prescription the words "no substitution" next to the item prescribed;*
- *the retail price of the generic is higher than that of the prescribed medicine;*
- *The product has been declared not substitutable by the MCC".*

The MCC guidelines for South Africa prohibits the substitution of medications in a few instances, these are:

- Agents with a narrow therapeutic range
- Agents known to have erratic intra and inter – patient responses
- If the medication is likely to give significant bioavailability problems
- If the patient is critically ill, geriatric or elderly

2.6 Pricing of generic medicines in South Africa

The cost of medicines is rapidly escalating in South Africa and various systems have been implemented in order to make medicines as affordable as possible. [25]

Medical aid schemes have contributed to high medicine cost in South Africa through the over-utilisation of health care facilities. Therefore, in 1985, the Pharmaceutical Society of South Africa (PSSA) implemented the Maximum Medical Aid Price (MMAP) in the private sector. [26] This system encourages the use of generic medicines by contracting medical aid schemes to pay only a specified maximum price for generically equivalent medicines. Another benefit of the MMAP is encouraging rational medicine use by making general practitioners more aware of their prescribing practices. [26]

A study conducted by Deroukakis (2006), found that although generic prescribing is practiced in the public sector, the beneficiaries of medical aid schemes have the option whether or not to choose a generic medicine, if a branded medicine is prescribed. [27] The difference in the cost of the final medicine selected (if higher than the medicine on the formulary of the medical scheme) is borne as a co-payment by the patient. According to this study, Discovery Health introduced a new policy in January 2004 in their support for generic

substitution. Through this policy a 10% levy would be waived on the medication bill of beneficiaries who opted for generic medicines. This aimed to increase the use of generic medicines in an effort to diminish health care costs. The study indicated that the greatest increase in medical aid claims for generic medicines occurred prematurely, in anticipation of the implementation of the law. [27]

2.7 Pricing of generic medicines internationally

Health care costs are rising significantly around the world. [28] There is an increase in chronic diseases due to ageing populations with stricter clinical targets for managing these patients. The continued launch of new and more expensive medicines as well as rising patient expectations have also contributed to high medical costs. [28] In an attempt to reduce the cost of generics and promote its use, many countries have implemented cost saving pricing policies. A study conducted by Hassali et al (2013), explored the generic medicine policies implemented in eight countries [29]:

- In the United States, patients are encouraged to use generic medicines by making them pay significantly lower co-payments when selecting generic medicines. [29] In 2009, the average co-payment for a generic medicine was $7 while branded medicines reached up to $75. [30]
- In the United Kingdom, the Drug Tariff Price of generic medicines is set well below the price of branded medicines. [31] In order to further encourage the use of generic medicines, manufacturers offer substantial discounts to pharmacies, exceeding 60 – 80% for some medicines. [32]
- In Australia, a mandatory 12.5% price reduction policy was implemented in 2005. The policy stipulates that the first new generic version of a medicine must be priced at least 12,5% below the current lowest priced brand. [29] Generic medicine manufacturers also provide significant discounts of up to 50% to pharmacies thereby promoting the use of these medicines. [33]
- In Japan, financial incentives are provided to physicians that prescribe generic medicines and to pharmacists if generic medicine usage in their pharmacy is over 30% in a 3 month period. [29] In addition, pharmacists are given financial incentives to educate consumers about generic medicines. [34]

2.8 Cost saving benefits of Generic substitution in South Africa

In South Africa, like other developing countries with limited health care budgets, generic medicines can be a cost-saving policy alternative as generic medicines are considerably less expensive than innovator medicines. [35] A study conducted in Durban by Abdool Karim et al (1996) explored the potential savings from generic prescribing and generic substitution in South Africa. [36] This was done by collecting computer printouts of prescriptions from pharmacists as well as the original doctor's prescription and pricing them for comparison. It was found that the cost of the prescription as dispensed was 1,4% below that of the original doctors prescription. [36] There is therefore a marginal benefit from the current low substitution rate of 13,9% by pharmacists with a maximum potential saving of 9,9% from generic prescribing and substitution. The study concluded that although cost savings were marginal, generic substitution has the potential to reduce medicine costs. [36]

Generic substitution in the private sector has the potential to cut medication costs significantly. [27] The Medicines and Related Substances Control Amendment Act No. 90 of 1997 was designed to enable the government to undertake a variety of actions in order to ensure a supply of affordable medicines. [27]

Research into cost savings from generic prescribing and substitution of three medicine classes of antihypertensives, hypolipidaemic agents and antidepressants in South Africa has shown that, depending on the medicine involved, savings range from 9,9–59,7% (mean 41,1%). [37] It has also been reported that further savings of 10% could be gained if generic prescribing and substitution are practised to maximum capacity in South Africa. [37]

According to research carried out by van der Westhuizen et al from 2004, savings of 9,3% over a 3-year study period could have been made with generic substitution of antidepressants. This translated to a 0,4% saving for the total database. It was however noted that total substitution would be unlikely, as in 40–60% of cases prescribers and patients would opt for the innovator or brand-name product. [35]

Reports have indicated that approximately 45% of brand medicines in the South African market are currently substituted for less expensive generics, as compared to 54% in the US. [35] There is therefore still some room for potential further savings to be made. [35] A study was conducted by McIntyre et al (1996) to investigate the extent to which generic prescribing by private sector medical doctors as well as generic substitution by private community

pharmacists was practiced in South Africa and to determine the potential savings from this. [4] It was found that both generic prescribing and generic substitution are able to reduce medicine costs. However these practices need to be actively encouraged in order to achieve maximum capacity. It was however, noted that the potential savings from generic prescribing and substitution are at most 9,9% in the absence of any changes in types of medicines prescribed. It was recommended that generic prescribing be encouraged through continuing medical education programs for private medical practitioners in South Africa. [4]

However, successful uptake of the generic substitution policy is dependent on society having confidence in the efficacy, safety and quality of generic medicines. The table below (2.1) was published by Boyce and Bartlett in a review in the South African Medical Journal (1990). [26] From this table it can be seen that significant savings were gained through the use of generic medicines from as far back as 1989 when fewer generics were on the market. As generic companies manufacture more medicines, it is hoped that competition between manufacturers and an increase in demand for generics will further reduce prices and increase savings.

Table: 2.1 Examples of price differences between original and generic brands in South Africa, March 1989 (Boyce and Bartlett, 1990)

	Wholesale Price (R)			
Generic Product	Pack size	Original Brand	Generic Brand	% Saving
Ampicillin 250mg capsules	20	5,94	4,58	22,9
Methyldopa 250mg tablets	100	36,12	19,72	45,4
Allopurinol 300mg tablets	30	30,63	15,36	49,9
Co-trimoxazole tablets	20	13,31	5,20	60,9
Propranolol 40mg tablets	50	23,67	7,33	69,0
Diazepam 5mg tablets	100	25,45	3,83	85,0
Furosemide 40mg tablets	250	177,43	14,70	91,7

These results can be compared to more recent studies. One such study was conducted by Gray A et al (2009), [38] focussing on the potential cost savings from substituting generics for original medicines in 25 chronic diseases. The results revealed that between 19.5% and 97% savings can be achieved through generic substitution. The study also found a correlation between the cost difference of generic and original medicines and the number of generics available for a specific disease state. It was observed that in most cases, as the number of generic versions were available, the cost difference between the original and the generic medicines increased. [38]This is due to competition within the market. South African manufacturing companies should therefore be encouraged to continue producing generic medicines in order to increase the number of generic options available, increase competition and therefore reduce costs of medication. [38]

By comparing recent data with older studies, we can observe the progression in the generic policy benefits over the past 3 decades and entrench the importance of on-going cost saving advantages from generic substitution.

2.9 Generic substitution in South Africa

Although generic medicine usage in South Africa is increasing, it is still relatively low compared to Western countries. This slow uptake of generic usage could be attributed to a lack of trust in the medication by physicians, pharmacists and consumers due to a belief that generics are of an inferior quality. It can be seen in Table (2.2), published by McDonald (2004) that generic medicine use in South Africa is significantly lower than other major developed countries. [39]

Table: 2.2 Comparing generic medicine usage in South Africa to other major countries (Mc Donald, 2004)

Country	Generic Medication as a % of Market
South Africa	19
United Kingdom	70
United States of America	75
Germany	74

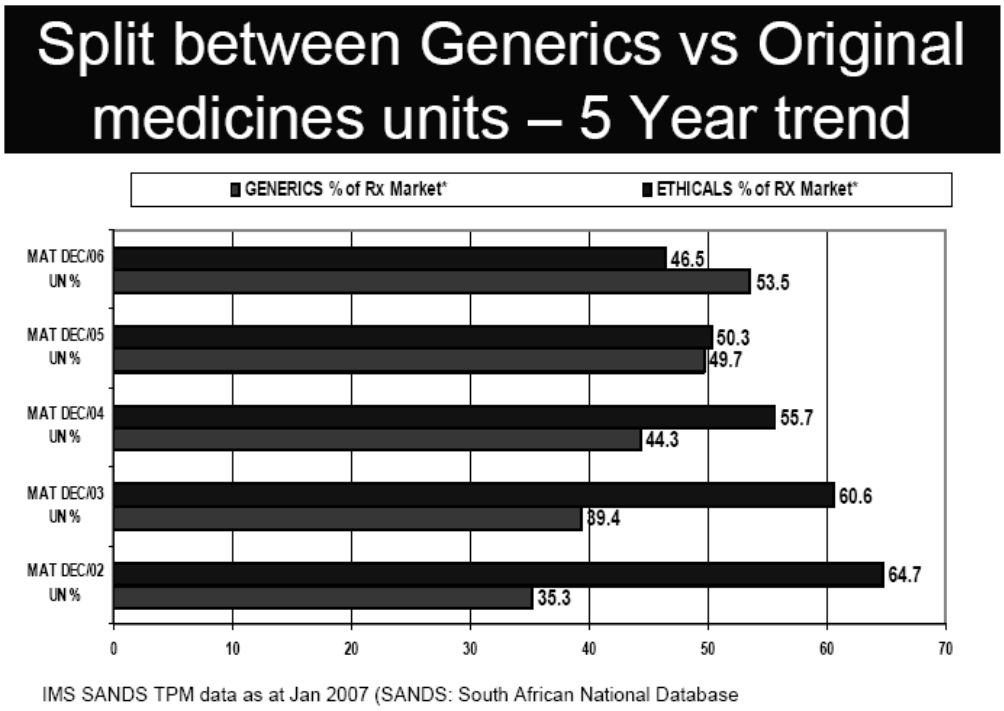
Doubts surrounding generic medicines is however still a concern. Possible reasons for this could be [40]:

- Patients wanted to stick to brands they recognise and trust
- Lack of trust in generic companies
- Non-transparency of decision making by regulatory authorities leading to distrust
- Provision of incentives by manufacturers to both prescribers and pharmacists influencing which medicines are prescribed and dispensed
- Anecdotal evidence of generic medicines being of a low quality
- The huge effort that is required to get prescribers to prescribe generic medicines

A study conducted by Kyenda et al (2004), reviewed a total of 2352 prescriptions by doctors in Umtata. [41] Of these prescriptions, it was noted that 57,7% were medical aid patients and 41,7% were cash patients. The prescribing trends revealed that 10,4% of prescriptions contained generics alone. 83,2% of prescriptions contained only original medicines and 6,4% of prescriptions had both generic and original medicines. [41] Generic prescribing is therefore low in this area and prescribing doctors should be educated on rational medicine use and encouraged to prescribe generic medicines.

Figure 2 below provides insight into the percentage of generic and original medicines available in the South African market over a 5-year period. Through this graph, it is evident that generics are progressively increasing in usage with 35% of the market being generics in 2002 to almost 54% in 2006. Generics now make up a larger proportion of the medicine industry than originals. These findings are a positive indication that the country is moving more toward cost saving medicine use as manufacturing companies are actively producing generic medicines.

Figure 2: Generic and Original medicine usage in South Africa (2002 – 2006) (South African National Database, Jan 2007)



2.10 Generic substitution internationally

Encouraging greater use of generic medicines is an internationally recognised practice for reducing costs of medicines to patients. A study published by Shrank et al (2010), in the United States, evaluated the relationship between three state-level policies and generic substitution rates after the patent expiration of Zocor®, one of the world's top-selling medications. [(42)] To address the increasing cost of medicines, states had implemented varying generic substitution policies. These policies differed in the extent to which pharmacists or patients can influence the choice of medicine. Some states had adopted mandatory generic substitution laws that required pharmacists to substitute a generic for a branded medication if the prescriber did not otherwise specify. [(42)] Some states did not require pharmacists to substitute generics, providing them with more discretion with regard to medication utilization. In addition, other states required the patient to provide consent prior to substitution of a generic. It was found that states implementing policies that required a patient to consent before generic substitution had a 25% lower rate of generic substitution. [(42)] The study concluded that while it was generally appealing to provide patients with more choice in their medical care, a more restrictive approach to generic substitution may lead to cost

savings without compromising quality, providing greater opportunities to invest healthcare dollars more cost-effectively. [42]

The pharmaceutical expenditure in Sweden has increased during the last few decades. [43] A mandatory generic substitution policy was introduced on 1 October 2002 with the aim of reducing the growth in pharmaceutical expenditure. [43] A study conducted by Andersson et al (2007), investigated the implementation of the policy and whether it was associated with changes in patients' expenses and reimbursed cost for prescribed pharmaceuticals that were included in the Swedish Pharmaceutical Benefits Scheme. [43] The study found that the introduction of generic substitution was associated with a shift in trend from an increase into a decrease in expenditure for both for patients and society. This suggested that generic substitution has contributed to a reduction in the growth of pharmaceutical expenditure. [43] In the UK, generic medicine use was raised as a means of reducing the NHS (National Health Scheme) medicines bill in the Greenfield Report of 1983. [44] This recommendation was not implemented, but activity to encourage generic prescribing did result in a change in doctors' prescribing habits towards the greater use of generics. Within a decade, the overall shape of the NHS market had changed such that by 1993 generic products accounted for 11% of the NHS expenditure on medicines and 41% of the volume. [44]

As evidence mounts, governments are more convinced that generic substitution of branded products plays an important role in limiting the cost of medicines in many countries. However, strict regulations are required to ensure that marketed generics are bioequivalent to branded products

2.11 Factors impeding generic medicine use

Physician prescribing behaviour is an important influence in generic medicine use. An obstacle to this may be physicians concerns about the safety and efficacy of generic medicines as well as a tendency to prescribe by habit. [45] A study conducted in United States outpatient practices in 2007 found that the most physicians link medicines to their brand name rather than generic name. [46] This results in physicians prescribing by brand name. This reflects the tendency of physicians to prescribe by habit rather than an intentional use of brand name medicine. In this scenario, allowing pharmacists to substitute generic medicines can be a key factor in maintaining high generic usage. [46]

Differences between branded and generic medicines exist that may influence the physician to prescribe the branded medicine. [45] Generic medicines may differ from the branded medicine in terms of inactive ingredients without interfering with therapeutic equivalence comparisons. [44] Patients may present with sensitivities or allergies to inactive ingredients that may require the use of a branded medicine. Physicians may erroneously believe that there are safety or efficacy differences between the branded and the generic medicine. [45]

A study conducted with 1253 pharmacists by Kobayashi et al (2011) in Japan found that most pharmacists were in favour of dispensing generic medicines, but that they would need to determine if generic medicines were appropriate for the patient. [47] They provided three reasons for preventing them from undertaking generic substitution:

- *"The generic medicine may not be in stock or no generic equivalent is available yet in the market,* [47]
- *Only a very small cost savings resulting in patients' objections, physicians' objections and* [47]
- *Presence of scepticism in the quality of generic medicines and inadequate medicine information from generic manufacturers".* [47]

2.12 Studies relating to perceptions and knowledge of Generic medicines in South Africa

Although physicians and pharmacists select appropriate medicines on the patients' behalf, it is still the final choice of the patient whether or not to use the generic medicine. [45] Patients can communicate to their physicians or pharmacists their preference for branded medicines. Patients can discuss with their physician or pharmacist what their preferences are. Patients' preference for branded medicines may depend on a number of factors, including medicines the patient is currently using or has used in the past, knowledge about the specific generic or branded medicines, general knowledge about generics and branded medicines, and financial incentives to use generic medicines. [45]

A South African study relating to patients/consumers perceptions of generic medication was conducted by Patel et al, in the cities of Durban, Cape Town and Johannesburg between December 2005 and January 2006. [48] This study explored South African consumer perceptions of medicine quality and whether these perceptions influenced how people procured and used their medicines. [48] The outcome of the study revealed that generic

medicines were considered to be poor quality by consumers and treated with suspicion. Consumers indicated that their influence was limited in terms of selection of prescription medicines and that they would accept generic substitution if it was supported by the doctor rather than the pharmacist. The findings emphasized the importance of strategic initiatives targeted at consumers and prescribers regarding the quality of generic and essential medicines. [48]

There are, however, only a few studies concerning health providers' attitudes and perceptions. Pharmacists often being the first point of contact for consumers can be a very important source of information to introduce generic medicines, [49] hence, quality use of generic medicines can be promoted with a better understanding of pharmacists' views, knowledge and perceptions. [50] With the increasing emphasis on pharmaceutical care in the practice of pharmacy, the role of pharmacists has been undergoing vigorous expansion. A key factor in the success of pharmaceutical care is the quality of patient-pharmacist relationships. Patients trust pharmacists to manage their health and well-being and thus pharmacists are required to accept responsibility to care for the well-being of the patients. [51] This trust is based on the expectation that pharmacists will do what is best for patients. [51]

2.13 International studies relating to perceptions and knowledge of Generic medicines

A cross-sectional descriptive study by Chong et al (2011) involving the entire population of practicing community pharmacists was undertaken in the State of Penang, Malaysia. [52] A self-completed anonymous mail questionnaire was used to explore the pharmacists' views on generic medication and concluded that *"the pharmacists' have lack of information and/or trust in the generic manufacturing and/or approval system in Malaysia and that the issue should be addressed by pharmacy educators and relevant government agencies"*. [52]

A similar cross-sectional descriptive study involving community pharmacists in Amman-Jordan in 2013 was undertaken, using a self-completed anonymous questionnaire. [53] This study, however, found that most of Jordanian pharmacists are positive about generic medicines in general with more than 80% of the pharmacists supporting generic substitution and being in favour of implementing a compulsory generic substitution policy. [53]

In both studies, implementing generic medicines prescribing and substitution policies in order to improve the medicines affordability was a recommendation as the majority of the community pharmacists in Penang and Amman. Generic substitution policy is being implemented by these pharmacists by actively promoting generics in their current practice. (52)

Another interesting study was conducted in New Zealand by Babar et al (2010) that also explored the views and opinions of pharmacists relating to generic medicines. (50) The results of this study revealed that only about one-third of pharmacists had the correct knowledge of the definition of generic medicines, which reflects the variability in pharmacists' knowledge and perceptions of generic medicines. While most of the pharmacists acknowledged the economic benefits of generics to the health care system, they were concerned about quality, safety, and effectiveness issues. (50)

A study by Gossell-Williams (2005) was conducted in Jamaica, exploring the acceptance and perceptions of generic substitutions by physicians yielded interesting results. (54) Less than 50% of responding physicians were prescribing generic medicines willingly as they had doubts about whether a generic was therapeutically equivalent or bioequivalent to the original medicine. The study concluded that greater emphasis should be targeted towards improving physician confidence in the therapeutic equivalence of generics. (54)

In both these studies, health care professionals showed very low understanding of generic medicines, and their lack of awareness denied patients of the benefits of cost-effective appropriate treatment. The studies indicated that there is a need for education on generic medicine supported by adequate support facilities for appropriate, affordable, safe, and effective use of generic medicines.

A study by Fischer et al (2003), undertaken in the United States, assessed the potential savings from increased use of generic medicines in the elderly as it was found that little was known about the extent to which such savings are achieved in medicine benefit programs serving them. (55) The study compared the expenditures for brand name prescriptions and determined what would have been paid for generic versions of the same medicines in a Medical aid program and in a non- Medicaid medicine insurance program for the elderly. The findings suggested a large amount of unrealized savings nationally on prescription medicines in health insurance programs serving the elderly. (55) This is an important finding as the population of older patients in the United States is increasing and thus generic substitution

can avoid excess expence without compromising clinical outcomes. The study also concluded that US physicians have a poor understanding of the FDA regulations covering generic products and vary widely in their beliefs and actions regarding generic substitution. [55] The study suggested that marketing information might convince physicians or patients that brand-name medicines offer superior efficacy or demands higher manufacturing standards, even if no data supports this assertion. [55]

2.14 Factors influencing consumer purchasing of generic vs. originator medicines

The cost of medicines in developing countries, may add up to 30-40% of health expenditure. In most cases, these payments are made by patients purchasing medication for self-medication and rarely on prescription. [56] By determining how and why consumers make these choices and understanding what factors influence their behaviour, steps can be taken in order to ensure that these precious resources are spent as safely and productively as possible. [56]

A study conducted by Igbinovia (2007) attempted to assess the impact that demographic factors such as race, income, educational level and age, have on the use of generic vs. branded medicine. [57] The study yielded interesting results as it was found that the white population are less likely to use generic medicines when compared to blacks possibly due to the differences in income distribution between the 2 races. [57] Age was also a determining factor as results revealed that older people were more likely to buy generic medicines instead of branded medicines. As far as educational level was concerned, findings suggested that the higher the educational level, the more likely the consumer was to choose generics. This was most evident with female participants. The impact of factors such as the availability of medical aid, cost, and safety of medicines were also assessed and it was found that people with medical aid had a greater tendency to choose branded medicines over generic medicines when compared to cash patients, as they did not have the burden of paying for their medication directly.[57]

In America, more than $20 billion/year was spent by consumers on over the counter (OTC) medication. [58] A survey based study conducted in The United States in 2012 sought to determine the factors influencing US consumers' choice to purchase generic medicines as opposed to brand name OTC medicines. [58] The study found that the majority of participants

indicated that OTC generic medicines are equally as effective and safe as brand name medication. Although economic factors play a vital role in influencing consumer's decision to choose generic medications, various factors, such as advertising, duration of OTC effectiveness, severity of illness, preferable dosage form of medication, safety, relief of multiple symptoms, and loyalty to a preferred company, will influence consumers decisions to pay more for a brand name medicine. [58]

In both these studies it was important to explore the factors influencing consumers' choice of generic medicines versus brand name medicines, in order to increase awareness and use of generic medication. Through this understanding, cost saving strategies can be implemented for consumers in order to help curb rising medicine costs. In both cases, better education lead to better use of generics. This suggests that pharmacists are able to influence patient choices by better educating patients on generic medicines.

2.15 Rationale for study

Pharmacists play an integral role in the decision-making process for medicine use. Pharmacists make decisions as to which generic medicines to stock and/or dispense as well as promote generic medicine use in their practice by educating patients on the use of these agents. However, there are various factors that influence their decision-making process, such as differences in pharmacists 'attitudes towards the use of generic medications in their practice, the therapeutic index of the medication as there would be a tendency to avoid medicines with a narrow therapeutic index (NTI), as well as the quality of generic products across suppliers.

This study in South Africa was aimed at investigating the knowledge, perception, and attitude of community pharmacists towards generic medicines in order to encourage the use of generic medication. Through this, wider support can be gained from health professionals' for the quality and rational use of generic medicines. There is little known about the perception of pharmacists to generic substitution in this country, as a factor that may hinder or assist this policy initiative by this category of health care workers.

CHAPTER 3: METHODOLOGY

3.1 Study location

The Western Cape Province

Of the nine provinces in South Africa, the Western Cape (WC) is the fourth largest in terms of both area and population. It encompasses an area of 129,449 square kilometres and 5,8 million inhabitants. [59] The vast majority of the population (89,6%) live in urban areas, which comprises of metropolitain areas and secondary cities or small towns. [60] This figure is relatively high compared to the national average 63 – 37 urban – rural split according to a paper published by Punt et al (2005) that evaluated the profile of the Western Cape Province. [60] About two-thirds of the Western Cape inhabitants live in the Metropolitan area of Cape Town, which is also the provincial capital. [58] Table 3.1 below provides an insight into the vast number of public health facilities available that caters for the health needs of each of the 5 districts in the province. [61]

Considering that the majority of South Africa's population had little or no access to quality medical attention until the 1990s, the healthcare system in Cape Town has made great strides to improve its standards and serve the communities that need it most. [61] According to statistics released by the South African Pharmacy Council (SAPC), [62] the Western Cape has the second largest number of registered pharmacists (15,18%) (See Table 3.2). The Western Cape Province was chosen as the area of study, as the researcher resides in this area. In addition it has a large number of pharmacists that would provide a population and a sample large enough to extract as accurate results as possible. This province was also selected as it boasts world reknowned hospitals such as Groote Schuur and leading medical schools in Cape Town and Stellenbosch. The city of Cape Town has become a hub for research and innovation, with the Third Global Symposium on Health Systems research being hosted recently in 2014. Through this, one would anticipate that pharmacists would be implementing the generic substitution policy better.

Table 3.1: List of facilities located within the Western Cape (Expat arrivals, 2014)														
List of facilities 2013	Community health centres	Community Day Centres	Clinics	Mobile Clinics	Satellite Clinics	Total Primary Healthcare Facilities			District Hospitals			Regional Hospitals		
						2013	2012	2011	2013	2012	2011	2013	2012	2011
City of Cape Town	9	37	82	4	17	149	149	159	9	9	9	2	5	5
West Coast District	0	1	26	20	20	67	67	69	7	7	7	0	0	0
Cape Winelands District	0	6	42	28	6	82	82	84	4	4	4	2	2	2
Overberg District	0	1	22	14	7	44	44	47	4	4	4	0	0	0
Eden District	0	5	33	21	12	71	71	76	6	6	6	1	1	1
Central Karoo District	0	1	8	10	3	22	22	20	4	4	4	0	0	0
Western Cape	**9**	**51**	**213**	**97**	**65**	**435**	**435**	**455**	**34**	**34**	**34**	**5**	**8**	**8**

	Table: 3.2 Number of Pharmacists registered with SAPC in 2014 in each South African Province (SAPC, 2014)	
Province	Total Registered	Total Registered (%)
Eastern Cape	939	7,03
Free State	429	3,21
Gauteng	4463	33,40
Kwa Zulu Natal	1717	12,85
Limpopo	436	3,26
Mpumalanga	530	3,97
Northern Cape	171	1,28
North West	601	4,50
Western Cape	2028	15,18
Unknown	2050	-
South Africa	**13364**	**-**

3.2 Study design

A cross sectional study was conducted by means of an electronic questionnaire, using Survey Monkey from 7 September 2014 to 7 October 2014. Surveys have been widely used as a research technique to assess pharmacists' views, knowledge and perceptions. The study followed a quantitative method design and involved the analysis of numerical data.

3.3 Questionnaire development

A literature review on similar studies held around the world was conducted using electronic databases. This insight allowed for the development of a questionnaire that thoroughly explored the relationship between pharmacists and the use of generic medication. Once the questionnaire was constructed, using the online program SurveyMonkey, supervisors from the Discipline of Pharmaceutical Sciences gave feedback on the appropriateness of questions, layout, sequence and themes. (Thus face validity was conducted) The first part of the questionnaire included demographic data such as age, gender, years of experience and pharmaceutical sector of work. The second part assessed knowledge of generic medication,

safety, quality and effectiveness using Likert Scale measures. Participants chose a number from 1 – 5 each corresponding to options from strongly disagree to strongly agree. The third part assessed perceptions relating to generic medicines manufacturing as well as pricing. The last part evaluated the pharmacists' behaviour when dealing with generic medicines. The majority of questions were close ended, however, pharmacists were provided the opportunity to give comments (refer to Appendix A for the Questionnaire).

3.4 Sampling

RAOSOFT information

A sample size was calculated from the population in order to gain a variety of data and establish accuracy of results. A list of the contact information of 2003 registered pharmacists residing in the Western Cape was obtained from the South African Pharmacy Council (SAPC). Of this, 230 had no email addresses and 43 emails bounced, resulting in a sample population of 1730. Sample size was calculated with a 5% margin of error, a 95% confidence interval and a 50% response distribution using 'Raosoft' [63], a sample size calculator. A random sample of 315 was therefore required. The total population of 1730 pharmacists was therefore selected after taking into consideration the possibility of non-respondents in order to arrive at the required sample size.

3.5 Data collection

Surveys were emailed for a month starting from the 7th of September; thereafter reminder emails were sent to pharmacists every few days until the 7th of October until a total of 321 pharmacists had responded.

3.6 Statistical Analysis

An exploratory data analysis plan was used. The objectives were to suggest possible hypotheses relating to the causes of observed phenomena, to assess the assumptions on which statistical inference were based, to support the selection of appropriate statistical tools and techniques as well as to provide a basis for further data collection. P and Chi-Squared values were calculated for graphs using 'Social Science Statistics, 2014' .In order to reject the null hypothesis and prove a significant finding, the chosen significance level for the P-value was set at 5% ($P < 0,05$). Descriptive statistics were also used in order to provide a quantitative description on the demographics of all respondents. Further analysis was also conducted to

identify if differences existed between variables such as age, gender and pharmaceutical practice sector.

3.7 Ethical Considerations

The ethical approval was obtained from the Biomedical Research Ethics Committee on the 19th of August 2014 (Brec REF: BE317/14) (see Appendix B). Participants were required to sign (or tick) an informed consent agreement before answering the questionnaire. The consent form indicated that participation was voluntary and that respondents could withdraw at any time. Respondents' anonymity was assured and results were analysed in aggregate form only.

CHAPTER 4: RESULTS

Out of the 1730 pharmacists that were emailed the questionnaire, 321 of them had responded, which equated to a response rate of 18.6%. Descriptive data will be presented first and analytical results thereafter.

4.1. Descriptive Results of the Study

4.1.1Demographics of the respondents

It can be noted in Table 4.1 that more than 60% of respondents were female.

Table: 4.1

Demographic Data – Gender of participant

Gender	Response (n= 312)	Response (%)
Male	124	39,7
Female	188	60,3

Table: 4.2

Demographic Data – Age of Participant

Age	Response (n = 312)	Response (%)
20 – 30	48	15,4
31 – 40	88	28,2
41 – 50	63	20,2
>50	113	36,2

The majority (36%) of the total responses came from individuals in the > 50 years age category.

4.1.2 Educational Qualifications, Years of Experience and Sector of Employment of respondents

Table: 4.3 Basic Pharmaceutical Qualification of Participant		
Qualification	Response (n= 312)	Response (%)
Dip. Pharmacy	34	10,9
Bachelor of Pharmacy	230	73,7
Postgraduate qualification	48	15,4

The majority of respondents (73%) possessed a qualification in bachelor of pharmacy, with more than 15% of pharmacists also holding a postgraduate qualification (Table 4.3). Interestingly, the majority of respondents came from pharmacists that were working in the pharmaceutical field for the longest time, with almost half (46%) of respondents coming from those with over 20 years of pharmaceutical experience (Table 4.4).

Table: 4.4 Years of Experience of Participant		
Years	Response (n= 310)	Response (%)
1 – 5	43	13,9
6 – 10	49	15,8
11 – 15	49	15,8
16 – 20	26	8,4
>20	143	46,1

Most pharmacists (40,4%) worked within community pharmacies, with the second most common sector being public institutions (22,0%). 55 pharmacists responded that they worked in other fields, the most common being managed health care and research (Table 4.5).

Table: 4.5 Pharmaceutical sector Currently working in		
Sector	Response (n= 332)	Response (%)
Community Pharmacy	112	40,4
Institutional (private)	41	14,8
Institutional (public)	61	22,0
Academic institution	20	7,2
Wholesale Pharmacy	9	3,2
Manufacturing pharmacy	29	10,5
Consultant Pharmacy	5	1,8
Other	55	-

Some of the most common responses are tabulated below

Table: 4.6 Other common Pharmaceutical employment sectors	
Sector	Response (n= 37)
Managed health care	13
Retired	10
Research	6
Medical aid	4
Locum	4

4.1.3 Pharmacists' knowledge of generic medicines

More than 70% of pharmacists agreed that generic medicines are therapeutically equivalent and interchangeable with their original counterparts (see Table 4.7). Majority (82%) of pharmacists disagreed with the statement that generics are less safe than original medicines. Most respondents (80%) reported no difference in side effects between generic and original brands. Although 54% of respondents felt there was no difference in quality between original and generic medication, more than 20% of pharmacists believed that original medicines underwent stricter safety regulations than generic medicines.

Table: 4.7

Pharmacists' knowledge of generic medicines

Answer Options	Strongly Disagree	Disagree	Neither Disagree or Agree	Agree	Strongly Agree	Rating Average	Response Count
Generic medicines are a copy of original medicines	3,8%	10,3%	12,8%	52,8%	20,3%	3,8	290
Generic medicines are interchangeable with original medicines	0,3%	8,6%	13,1%	56,6%	21,4%	3,9	290
Generic medicines are therapeutically equivalent to original medicines	1,0%	7,9%	16,3%	50,5%	24,2%	3,9	289
Generic medicines must be in the same dosage form (such as tablet, capsule) as original medicines	3,1%	16,7%	8,3%	42,0%	29,9%	3,8	288
Generic medicines are less safe than original medicines	32,9%	49,5%	13,1%	3,5%	1,0%	1,9	289
Only those generic medicines which are made by some local reputable manufacturers are safe	20,8%	35,1%	17,0%	21,1%	5,9%	2,6	288
Generic medicines are manufactured after the patent expiry of originator/innovator	2,0%	2,8%	4,1%	55,9%	35,1%	4,2	290
Original medicines are of a better quality than generic medicines	18,8%	35,3%	28,8%	13,4%	3,8%	2,5	292
Original medicines are required to meet higher safety standards than generic medicine	25,0%	44,4%	10,8%	15,3%	4,5%	2,3	288
Original medicines produce fewer side effects than generic medicines	29,5%	50,0%	14,6%	5,6%	0,35%	2,0	288
Low-priced medicines are as effective as high-priced medicines	1,0%	6,2%	20,7%	46,2%	25,9%	3,9	290
answered question							293
skipped question							26

4.1.4 Pharmacists' perceptions of generic medicines

About 70% of pharmacists believe that locally manufactured medicines are more affordable and have the same level of effectiveness as original medicines (see Table 4.8). However, a significant disparity was observed with the statement that few local companies are reputable generic medicine manufacturers, with 46% disagreeing with this statement and 38% agreeing with it. More than half of the respondents believed that pharmacists should be educated more about prices of medicines and that confidence should be built in the patient about the low cost brand.

Table: 4.8

Pharmacists' perceptions of generic medicines

Answer Options	Strongly Disagree	Disagree	Neither Disagree or Agree	Agree	Strongly Agree	Rating Average	Response Count
I believe that locally manufactured medicines are more affordable than original medicines	1,4%	9,6%	19,5%	53,9%	15,6%	3,7	282
I believe that locally manufactured medicines are of the same effectiveness as original medicines	0,4%	2,1%	24,8%	56,4%	16,3%	3,9	282
I view generic medicines as being of a poorer quality than original medicines	23,5%	49,5%	30,0%	5,0%	1,1%	2,1	281
I think generic medicines produce more side effects than original medicines	24,6%	54,6%	15,1%	4,9%	0,7%	2,0	284
I believe low-cost medicines are as safe as high-cost medicines	0,4%	3,9%	16,3%	59,9%	19,5%	3,9	282
I believe that multinational products are of a better quality than locally produced products	19,7%	45,8%	22,2%	12,3%	0%	2,3	284
I believe that the local companies in South Africa are not following Good Manufacturing Practice (GMP) guidelines as well as multinationals	27,9%	48,4%	19,4%	3,9%	0,4%	2,0	283
I view few local companies as reputable generic medicine manufacturers	11,7%	33,9%	15,9%	30,0%	8,5%	2,9	283
I believe that pharmacists should be educated more about prices of medicines	4,3%	17,4%	20,6%	40,8%	17,0%	3,5	282
I believe that generic medicines are only meant for the poor	51,8%	43,3%	2,1%	2,5%	0,4%	1,6	282
I think that confidence should be built in the patient about the low-cost brand	1,1%	3,5%	11,0%	53,9%	30,5%	4,1	282
Wider use of generic medicines will mean that less money will be used for research and development of new pharmaceuticals.	14,9%	37,9%	22,7%	18,1%	6,4%	2,6	282
						answered question	284
						skipped question	35

4.1.5 Factors associated with support for generic substitution

The most popular reason for pharmacists recommending a generic alternative to patients was 'cost to customer', with 91% of respondents choosing these options. Other significant reasons were 'medical scheme requirement' and 'proven bioequivalence' with 80% and 66% of responses respectively.

Table: 4.9
Reasons for recommending a generic alternative

Answer Options	Response Percent	Response Count
Cost to customer	91,6%	261
Having no other choice	22,5%	64
Customer preference	56,1%	160
Availability of stock	58,9%	168
Customer appearance	2,8%	8
Cost effectiveness	73,0%	208
Proven bioequivalence	67,0%	191
Medical scheme requirement	80,0%	228
Do not recommend generics	0,7%	2
Other (please specify)		10
	answered question	**285**
	skipped question	**34**

4.1.6 Factors affecting generic substitution

Most pharmacists (83%) responded that they would dispense the original medicine if the customer refused to accept a generic. Only 14% of pharmacists would take the time to persuade the patient to use a generic instead. A significant 60% of respondents stated that doubts regarding bioequivalence of generics were one of the problems when switching to a generic alternative. Patients' lack of confidence in generic medications relating to efficacy and safety was also a problem encountered. Another major factor influencing generic substitution is stock availability of the generic medicines.

Table 4.10: Factors Affecting Generic Substitution		
Answer Options	**Response Percent**	**Response Count**
Approach when a patient refuses a generic		
I dispense the Original	82,4%	225
I persuade the patient	14,3%	39
I direct him/her to the prescriber	2,6%	7
I direct him/her to another pharmacy	0,7%	2
Possible problems that you have noticed when switching to a generic medicine		
No idea	17,5%	40
Concern about losing the patient	8,3%	19
Too much effort to persuade the patient	23,6%	54
Doubts about the bioequivalence	60,3%	138
Other		64
Other possible problems noticed when switching to a generic medicine		
Patient distrust in generic medicines	28,1%	18
Side effects and ineffectiveness experienced with generic medicines	23,4%	15
No problems experienced	18,8%	12
Patient non-compliance	3,1%	2
Public sector only uses generics	3,1%	2

In terms of other problems that were encountered, there were 2 common responses. About 28% of pharmacists cited a lack of patient confidence in generic medicines as being a problem. The reasons that they gave were that patients want exactly what the doctor prescribes or they may have doubts about the efficacy and safety of generics.

The 2nd common response was that side effects and ineffectiveness was observed when patients were switched to a generic medicine. Twenty three percent of pharmacists believed that the quality of generic medicines was not equal to that of originals and they do not believe that generic medicines are bioequivalent to their original counterparts.

4.1.7 Information sources for generics

As can be seen from Table 4.11, almost 80% of pharmacists find out about the availability of generic alternatives to original medicines through medicine manufacturers and more than 50% used medical journals and international literature as a source of information. The list of generic medicines that can be obtained on computer dispensing software was also a common source of information for pharmacists. The open ended question asking for any further comments relating to generic medicines received 91 comments. Pharmacists' opinions regarding generic medicines were generally positive and most supported their use as long as it was manufactured from a reputable company. A few respondents expressed concerns about differences in quality of efficacy of generic medicines amongst different manufacturing companies but do believe that generic medicine has an important role to play in South Africa.

Table: 4.11 Information source to find out about the availability of a generic alternative to an original medicine		
Answer Options	**Response Percent**	**Response Count**
Medication manufacturer representatives	79,3%	219
Medication wholesaler	20,7%	57
Medical journals	51,8%	143
Medicine company written information	40,9%	113
From pharmacist/ colleagues/peers	49,3%	136
From patients	10,9%	30
From doctors	20,3%	56
Informational literature (newsletters, articles)	56,2%	155
From internet/websites/e-mails	34,4%	95
From meetings/conferences	30,8%	85
Other (please specify)		44
	answered question	**276**
	skipped question	**43**

4.1.8 Other comments regarding generic medicines

The open ended question at the end of the survey allowing pharmacists to submit any views or recommendations they have regarding generic medication yielded 91 responses. Almost 10% of responses had positive feedback relating to the cost saving advantages of generic medication. About 8,7% of responses discussed generic manufacturers. They felt that not all generic manufacturers were reliable and they would only dispense medication from companies they trusted. More than 11% of respondants thought that generic medication was not bioequivalent to original medicines and were doubtful about substituting certain original chronic medication with generic alternatives. Some of the most common responses are presented below:

"Generic medicines are of fundamental importance to our health system and they should be supported in every way. They are critical for increasing access to cost-effective care (amongst all populations, not just the poor) and more needs to be done to change the wrongful perception of consumers and providers (doctors and pharmacists) that generics are inferior."

"As a pharmacist I would like to have insight in the practical side of the use of generics. Sometimes a doctor will say that some generics are less efective that others. How can I take part in this discussion if I have no proof that there is in fact not a difference."

"Quality not always good. Availability sometimes a problem".

"I have no problem recommending generic equivalents".

"Medical professionals require more training/guidance about generic medicines."

"The MCC ensures bioequivalence of all available generics"

"I will recommend a generic product if I am satisfied the manufacturer is reputable"

"Would not use generic medicines for drugs with narrow therapeutic window"

"I believe that generics are cost-effective alternatives to originator drugs and pharmacists should promote them more actively".

"In my experience I have found patients claiming to have undesirable responses (side-effects, adverse effects, allergic reactions) to generics and not the original drug. I suspect it is the different excipients that could have been used to make it more affordable or just the patients' mental state because they are aware that it is not the original."

4.2. Analytical Results of the study

4.2.1Gender comparisons of pharmacist's knowledge of generic medicines

Tabulated below (Table 4.12), are the responses given by pharmacists regarding their knowledge of generic medicines and a comparison between male and female responses. A significant difference between responses is noted when the calculated P value is < 0,05. In this table, however, there are no significant findings. This implies that male and female pharmacists had similar responses regarding their knowledge of generic medicines

4.2.2Pharmaceutical sector comparisons of pharmacist's knowledge of generic medicines

Table 4.13 has one significant recording with a P value of 0,005 relating to safety of generic medicines. The statement was that '*Original medicines are required to meet higher safety standards than generic medicine'.* The biggest difference is this category was by consultant pharmacists. Pharmacists working in the other sectors all had the fewest number of 'strongly agree with the statement' responses. However, almost half of consultant pharmacists (40%) strongly agreed that original medicines are required to meet higher safety standards than generic medicine. This misconception can lead to a lack of trust and promotion of generic medicines.

Table: 4.12: Gender Comparison of Pharmacists knowledge of generic medicines							
STATEMENT	LIKERT SCALE						
	STRONGLY DISAGREE	DISAGREE	NEUTRAL	AGREE	STRONGLY AGREE	CHI-SQUARE	P VALUE
Generic medicines are a copy of original medicines						3,05	0,55
Male	3,39	6,78	12,71	54,24	22,88		
Female	4,00	12,57	13,14	51,43	18,86		
Generic medicines are interchangeable with original medicines						1,21	0,88
Male	0,00	7,69	11,97	57,26	23,08		
Female	0,57	9,09	13,64	56,25	20,45		
Generic medicines are therapeutically equivalent to original medicines						4,89	0,3
Male	0,00	5,98	18,80	53,85	22,22		
Female	1,7	9,66	14,20	47,73	25,57		
Generic medicines must be in the same dosage form (such as tablet, capsule) as original medicines						3,31	0,51
Male	3,42	15,38	5,13	43,59	32,48		
Female	2,84	17,61	10,23	40,34	27,27		
Generic medicines are less safe than original medicines						2,65	0,62
Male	35,04	47,01	11,11	5,13	0,85		
Female	31,82	50,57	14,20	2,27	1,14		

Only those generic medicines which are made by some local reputable manufacturers are safe						3,70	0,45
Male	22,22	34,19	11,97	23,08	6,84		
Female	19,89	35,80	19,89	19,32	5,11		
Generic medicines are manufactured after the patent expiry of originator/innovator						2,60	0,63
Male	1,71	4,27	3,42	58,97	33,33		
Female	2,27	1,70	4,55	53,41	36,93		
Original medicines are of a better quality than generic medicines						3,90	0,42
Male	17,95	41,88	23,93	13,68	4,27		
Female	19,89	31,25	31,82	13,07	3,98		
Original medicines are required to meet higher safety standards than generic medicine						6,77	0,15
Male	29,06	47,01	8,55	10,26	5,98		
Female	22,16	42,05	11,93	18,75	3,41		
Original medicines produce fewer side effects than generic medicines						4,96	0,29
Male	33,33	48,72	10,26	5,98	0,85		
Female	26,70	50,57	17,05	5,11	0,00		
Low-priced medicines are as effective as high-priced medicines						2,01	0,73
Male	0,85	8,55	19,66	45,30	25,64		
Female	1,14	4,55	21,02	47,16	26,14		

Table: 4.13

Pharmaceutical sector comparison of Pharmacists knowledge of generic medicines

STATEMENT	LIKERT SCALE						
	STRONGLY DISAGREE	DISAGREE	NEUTRAL	AGREE	STRONGLY AGREE	CHI-SQUARE	P VALUE
Generic medicines are a copy of original medicines						19,05	0,27
Community Pharmacy	2,73	8,18	11,82	60,00	17,27		
Institutional (private and public)	4,42	8,83	12,41	50,42	23,92		
Academic Institution	0,00	27,78	11,11	44,44	16,67		
Manufacturing and Wholesale Pharmacy	1,79	10,72	21,43	47,32	18,75		
Consultant Pharmacy	20,00	0,00	0,00	60,00	20,00		
Generic medicines are interchangeable with original medicines						16,24	0,44
Community Pharmacy	0,91	8,18	16,36	60,91	13,64		
Institutional (private and public)	0,00	11,85	6,58	57,46	24,12		
Academic Institution	0,00	5,56	16,67	55,56	22,22		
Manufacturing and Wholesale Pharmacy	0,00	3,71	9,26	59,72	27,32		
Consultant Pharmacy	0,00	0,00	0,00	40,00	60,00		
Generic medicines are therapeutically equivalent to original medicines						18,30	0,31
Community Pharmacy	0.91	9,09	23,64	49,09	17,27		
Institutional (private and public)	0,88	8,92	11,14	51,05	28,03		

Academic Institution	0,00	0,00	5,88	70,59	23,53		
Manufacturing and Wholesale Pharmacy	1,79	11,61	21,43	40,18	25,00		
Consultant Pharmacy	0,00	0,00	0,00	40,00	60,00		
Generic medicines must be in the same dosage form (such as tablet, capsule) as original medicines						15,79	0,47
Community Pharmacy	0,91	15,45	10,00	40,91	32,73		
Institutional (private and public)	5,26	16,23	9,65	41,67	27,20		
Academic Institution	0,00	27,78	5,56	44,44	22,22		
Manufacturing and Wholesale Pharmacy	12,18	24,36	1,93	43,59	17,95		
Consultant Pharmacy	0,00	20,00	0,00	20,00	60,00		
Generic medicines are less safe than original medicines						16,29	0,43
Community Pharmacy	29,09	46,36	19,09	3,64	1,82		
Institutional (private and public)	36,75	50,42	7,10	4,84	0,90		
Academic Institution	38,89	50,00	11,11	0,00	0,00		
Manufacturing and Wholesale Pharmacy	35,42	55,33	9,26	0,00	0,00		
Consultant Pharmacy	60,00	20,00	0,00	20,00	0,00		
Only those generic medicines which are made by some local reputable manufacturers are safe						13,51	0,64
Community Pharmacy	15,60	37,61	18,35	20,18	8,26		
Institutional (private and public)	24,39	32,71	21,29	16,36	5,31		
Academic Institution	22,22	27,78	11,11	27,78	11,11		
Manufacturing and Wholesale Pharmacy	26,79	41,07	5,36	25,00	1,79		

Consultant Pharmacy	25,00	25,00	0,00	50,00	0,00		
Generic medicines are manufactured after the patent expiry of originator/innovator						15,32	0,50
Community Pharmacy	0,92	4,59	3,67	56,88	33,94		
Institutional (private and public)	2,63	2,19	4,83	54,39	35,97		
Academic Institution	11,11	0,00	11,11	50,00	27,78		
Manufacturing and Wholesale Pharmacy	0,00	0,00	6,25	64,01	29,74		
Consultant Pharmacy	0,00	0,00	0,00	50,00	50,00		
Original medicines are of a better quality than generic medicines						21,86	0,15
Community Pharmacy	15,45	28,18	32,73	16,36	7,27		
Institutional (private and public)	21,05	40,36	24,56	11,85	2,19		
Academic Institution	16,67	50,00	27,78	0,00	5,56		
Manufacturing and Wholesale Pharmacy	12,07	48,49	29,74	9,70	0,00		
Consultant Pharmacy	60,00	0,00	20,00	20,00	0,00		
Original medicines are required to meet higher safety standards than generic medicine						34,44	**0,005**
Community Pharmacy	21,30	41,67	13,89	17,59	5,56		
Institutional (private and public)	30,13	37,13	9,35	20,31	3,10		
Academic Institution	27,78	55,56	11,11	5,56	0		
Manufacturing and Wholesale Pharmacy	26,79	63,40	0,00	8,04	1,79		
Consultant Pharmacy	0,00	40,00	20,00	0,00	40,00		

Original medicines produce fewer side effects than generic medicines						20,20	0,21
Community Pharmacy	22,22	51,85	17,59	7,41	0,93		
Institutional (private and public)	30,70	45,62	16,23	7,46	0,00		
Academic Institution	50,00	44,44	5,56	0,00	0,00		
Manufacturing and Wholesale Pharmacy	26,79	66,07	7,15	0,00	0,00		
Consultant Pharmacy	60,00	40,00	0,00	0,00	0,00		
Low-priced medicines are as effective as high-priced medicines						9,20	0,90
Community Pharmacy	0,91	6,36	21,82	48,18	22,73		
Institutional (private and public)	0,88	7,90	16,67	46,06	28,51		
Academic Institution	5,56	5,56	11,11	55,56	22,22		
Manufacturing and Wholesale Pharmacy	0,00	3,57	23,22	50,90	22,32		
Consultant Pharmacy	0,00	0,00	50,00	25,00	25,00		

4.2.3 Age category comparison of Pharmacists knowledge of generic medicines

Three significant results were found in this comparison (Table 4.14). The first statement was 'Generic medicines are a copy of original medicines'. The biggest disparity was found in the 20 – 30 age group. Although the majority of pharmacists in this age category agreed with the statement, almost a quarter (24,45%) disagreed, believing that generics are not identical to their original counterparts. Respondents in the other age categories had a much smaller percentage disagreeing with the statement.

The second significant finding was related to generic medicine manufacturers. More than a third (37,50%) of respondents in the >50 age category agreed with the statement that '*Only those generic medicines which are made by some local reputable manufacturers are safe'.* Agreement in the other age categories was much lower, ranging from 13,33% in the 20 – 30 age group to 29,27% in the 31 – 40 age group.

The third significant finding was related to efficacy of generic medicines. Only 62,85% of respondents in the >50 age category agreed with the statement that '*Low-priced medicines are as effective as high-priced medicines'* compared to a range of 73 – 82% in the younger age groups.

Table 4.14: Age category comparison of Pharmacists knowledge of generic medicines							
STATEMENT	LIKERT SCALE						
	STRONGLY DISAGREE	DISAGREE	NEUTRAL	AGREE	STRONGLY AGREE	CHI-SQUARE	P VALUE
Generic medicines are a copy of original medicines						24,02	**0,02**
20-30	6,67	17,78	13,33	44,44	17,78		
31-40	2,44	12,20	18,29	42,68	24,39		
41-50	8,33	11,67	6,67	61,67	11,67		
>50	0,94	4,72	12,26	58,49	23,58		
Generic medicines are interchangeable with original medicines						14,19	0,29
20-30	0,00	11,11	4,44	57,78	26,67		
31-40	1,20	9,64	14,46	46,99	27,71		
41-50	0,00	10,17	10,17	62,71	16,95		
>50	0,00	5,66	16,98	60,38	16,98		
Generic medicines are therapeutically equivalent to original medicines						17,32	0,14
20-30	0,00	11,11	13,33	40,00	35,56		
31-40	1,19	3,57	13,10	53,57	28,57		
41-50	3,45	6,90	15,52	56,90	17,24		
>50	0,00	11,43	20,00	48,57	20,00		

Generic medicines must be in the same dosage form (such as tablet, capsule) as original medicines						18,67	0,10
20-30	0,00	9,09	6,82	43,18	40,91		
31-40	3,70	14,81	4,94	39,51	37,04		
41-50	1,69	28,81	8,47	42,37	18,64		
>50	4,72	15,09	11,32	43,4	25,47		
Generic medicines are less safe than original medicines						13,13	0,36
20-30	37,78	51,11	6,67	2,22	2,22		
31-40	36,59	42,68	13,41	6,10	1,22		
41-50	26,67	61,67	8,33	1,67	1,67		
>50	32,38	46,67	18,10	2,86	0,00		
Only those generic medicines which are made by some local reputable manufacturers are safe						27,66	**0,01**
20-30	33,33	31,11	22,22	11,11	2,22		
31-40	26,83	29,27	14,63	20,73	8,54		
41-50	15,00	48,33	21,67	10,00	5,00		
>50	14,42	34,62	13,46	31,73	5,77		
Generic medicines are manufactured after the patent expiry of originator/innovator						13,69	0,32
20-30	2,27	0,00	6,82	47,73	43,18		
31-40	3,61	1,20	3,61	50,60	40,96		
41-50	0,00	1,67	3,33	58,33	36,67		
>50	1,89	5,66	3,77	61,32	27,36		

Original medicines are of a better quality than generic medicines						14,48	0,27
20-30	24,44	40,00	26,67	4,44	4,44		
31-40	25,30	32,53	22,89	12,05	7,23		
41-50	16,67	38,33	28,33	15,00	1,67		
>50	13,08	33,64	33,64	16,82	2,80		
Original medicines are required to meet higher safety standards than generic medicine						12,74	0,39
20-30	22,22	55,56	8,89	11,11	2,22		
31-40	34,15	32,93	8,54	18,29	6,10		
41-50	20,34	47,46	15,25	15,25	1,69		
>50	21,90	46,67	10,48	15,24	5,71		
Original medicines produce fewer side effects than generic medicines						13,14	0,36
20-30	34,09	50,00	11,36	4,55	0,00		
31-40	34,94	40,96	15,66	7,23	1,20		
41-50	27,12	62,71	6,78	3,39	0,00		
>50	24,76	50,48	19,05	5,71	0,00		
Low-priced medicines are as effective as high-priced medicines						22,52	**0,03**
20-30	2,22	8,89	15,56	37,78	35,56		
31-40	0,00	4,82	13,25	44,58	37,35		
41-50	0,00	3,33	21,67	56,67	18,33		
>50	1,90	7,62	27,62	45,71	17,14		

Table 4.15: Years of experience comparison of Pharmacists knowledge of generic medicines							
STATEMENT	LIKERT SCALE						
	STRONGLY DISAGREE	DISAGREE	NEUTRAL	AGREE	STRONGLY AGREE	CHI-SQUARE	P VALUE
Generic medicines are a copy of original medicines							
1-5	7,69	12,82	20,51	38,46	20,51	25,78	0,06
6-10	4,44	17,78	13,33	46,67	17,78		
11-15	2,13	14,89	8,51	40,43	34,04		
16-20	4,00	4,00	24,00	60,00	8,00		
>20	2,94	6,62	10,29	61,03	19,12		
Generic medicines are interchangeable with original medicines						24,08	0,09
1-5	0,00	10,26	7,69	58,97	23,08		
6-10	2,22	6,67	13,33	51,11	26,67		
11-15	0,00	10,64	10,64	44,68	36,17		
16-20	0,00	20,00	20,00	52,00	8,00		
>20	0,00	5,88	13,97	62,50	16,91		

Generic medicines are therapeutically equivalent to original medicines						31,63	**0,01**
1-5	0,00	7,69	15,38	41,03	38,46		
6-10	0,00	4,44	15,56	55,56	24,44		
11-15	0,00	8,51	10,64	44,68	38,30		
16-20	8,00	0,00	16,00	64,00	12,00		
>20	0,74	11,03	18,38	50,00	17,65		
Generic medicines must be in the same dosage form (such as tablet, capsule) as original medicines						24,97	0,07
1-5	0	7,69	7,69	41,03	43,59		
6-10	2,22	20,00	2,22	46,67	24,44		
11-15	4,26	8,51	6,38	36,17	44,68		
16-20	0	24	20	36	20		
>20	4,41	19,85	8,82	42,65	23,53		
Generic medicines are less safe than original medicines						14,73	0,54
1-5	35,90	51,28	7,69	2,56	2,56		
6-10	40,00	51,11	4,44	4,44	0,00		
11-15	38,30	36,17	17,02	6,38	2,13		
16-20	20,00	60,00	20,00	0,00	0,00		
>20	30,88	50,00	14,71	2,94	0,74		

Only those generic medicines which are made by some local reputable manufacturers are safe						20,51	0,20
1-5	38,46	33,33	17,95	5,13	5,13		
6-10	26,67	24,44	17,78	22,22	6,67		
11-15	21,28	36,17	17,02	21,28	6,38		
16-20	8,00	36,00	28,00	20,00	8,00		
>20	16,18	38,24	13,97	25,00	5,15		
Generic medicines are manufactured after the patent expiry of originator/innovator						37,00	**0,002**
1-5	0,00	0,00	10,26	41,03	48,72		
6-10	8,89	2,22	2,22	55,56	28,89		
11-15	4,26	2,13	6,38	40,43	48,94		
16-20	0,00	0,00	0,00	72,00	28,00		
>20	0,00	4,41	2,94	62,50	30,15		
Original medicines are of a better quality than generic medicines						18,74	0,28
1-5	23,08	41,03	28,21	5,13	2,56		
6-10	22,22	42,22	20,00	8,89	6,67		
11-15	31,91	25,53	25,53	12,77	6,38		
16-20	20,00	36,00	24,00	16,00	4,00		
>20	12,50	34,56	33,82	16,91	2,94		

Original medicines are required to meet higher safety standards than generic medicine						19,62	0,24
1-5	20,51	53,85	7,69	15,38	2,56		
6-10	40,00	40,00	6,67	11,11	2,22		
11-15	38,30	27,66	10,64	17,02	6,38		
16-20	20,00	40,00	8,00	20,00	4,00		
>20	17,65	48,53	13,24	15,44	5,15		
Original medicines produce fewer side effects than generic medicines						19,07	0,26
1-5	30,77	51,28	15,38	2,56	0,00		
6-10	37,78	37,78	11,11	11,11	0,00		
11-15	40,43	38,30	12,77	8,51	2,13		
16-20	28,00	52,00	16,00	0,00	0,00		
>20	22,79	56,62	15,44	4,41	0,00		
Low-priced medicines are as effective as high-priced medicines						29,38	**0,02**
1-5	0,00	7,69	17,95	38,46	35,90		
6-10	2,22	2,22	8,89	46,67	40,00		
11-15	0,00	6,38	14,89	42,55	38,30		
16-20	0,00	16,00	16,00	48,00	20,00		
>20	1,47	5,15	27,21	50,00	15,44		

4.2.4 Years of experience comparison of Pharmacists' knowledge of generic medicines

Three significant results were found in this comparison (Table 4.15). The first was related to therapeutic equivalence of generic medicines. In this question it was interesting to note that while the response rate of strong disagreement with the statement that *'Generic medicines are therapeutically equivalent to original medicines'* was below 0,74% in 4 of the years of experience groups, the 16 – 20 years of experience group had a response of 8%. Within the >20 years of experience group, there was the lowest agreement rate of 67,65% compared to the 76 – 83% agreement range in the groups with less experience.

The second significant finding was related to the manufacturing policy of generic medicines. The statement was '*Generic medicines are manufactured after the patent expiry of originator/innovator'.* In this comparison, all groups had agreements of >80%. Interestingly, the highest agreement was by pharmacists with the greatest experience, with 100% in the 16 – 20 year group and 92,65% in the >20 year group. The greatest disagreement was found with 6 – 10 years of experience, (11,11%). In the 1 – 5 and 16 – 20 year category no respondents disagreed with this statement.

The third significant finding was related to efficacy of medicines. In this question, the statement posed was that '*Low-priced medicines are as effective as high-priced medicines'* The lowest agreement rate in this question was found in the 16 – 20 years group (68%) and the >20 years group (65,44%), compared with high agreement rates of 80,85% in the 11 – 15 year group and 86,67% in the 6 – 10 year group. A significantly high 16% of respondents in the 16 – 20 believed that low-priced medicines are not as effective as high- priced medicines. This was much higher than the other groups which whose disagreement response ranged from 4,44 – 7,69%.

Table 4.16: Gender comparison of pharmacists perceptions of generic medicines							
STATEMENT	LIKERT SCALE					CHI-SQUARE	P VALUE
	STRONGLY DISAGREE	DISAGREE	NEUTRAL	AGREE	STRONGLY AGREE		
I believe that locally manufactured medicines are more affordable than original medicines						8,85	0,07
Male	0,87	10,43	11,30	59,13	18,26		
Female	1,78	10,06	24,85	50,30	13,61		
I believe that locally manufactured medicines are of the same effectiveness as original medicines						3,64	0,46
Male	0,87	2,61	20,87	57,39	18,26		
Female	0,00	1,78	28,40	55,03	15,38		
I view generic medicines as being of a poorer quality than original medicines						3,07	0,55
Male	24,35	46,09	20,87	6,96	1,74		
Female	22,49	52,07	21,30	3,55	0,59		
I think generic medicines produce more side effects than original medicines						1,73	0,78
Male	28,70	51,30	14,78	5,22	0,87		
Female	22,49	57,99	15,38	4,73	0,59		

I believe low-cost medicines are as safe as high-cost medicines						1,68	0,79
Male	0,87	3,48	15,65	61,74	19,13		
Female	0,00	4,14	16,57	59,17	20,12		
I believe that multinational products are of a better quality than locally produced products						8,23	**0,04**
Male	23,48	48,70	13,91	14,78	0,00		
Female	17,75	44,97	27,81	10,65	0,00		
I believe that the local companies in South Africa are not following Good Manufacturing Practice (GMP) guidelines as well as multinationals						8,21	0,08
Male	36,52	45,22	14,78	4,35	0,00		
Female	22,49	51,48	22,49	3,55	0,59		
I view few local companies as reputable generic medicine manufacturers						5,92	0,21
Male	15,65	31,30	11,30	33,04	8,70		
Female	9,47	36,69	18,93	27,81	8,28		
I believe that pharmacists should be educated more about prices of medicines						5,07	0,28
Male	6,96	20,00	18,26	40,00	14,78		
Female	2,37	15,98	21,89	42,01	18,34		
I believe that generic medicines are only meant for the poor						3,58	0,47
Male	53,91	39,13	2,61	3,48	0,87		
Female	50,30	46,75	1,78	1,78	0,00		

I think that confidence should be built in the patient about the low-cost brand						4,48	0,35
Male	2,61	3,48	11,30	53,04	30,43		
Female	0,00	3,55	10,65	55,03	30,77		
Wider use of generic drugs will mean that less money will be used for research and development of new pharmaceuticals.						13,69	**0,008**
Male	20,00	33,91	14,78	24,35	6,96		
Female	11,24	41,42	27,81	14,20	5,92		

4.2.5 Gender comparison of pharmacists' perceptions of generic medicines

Two significant results were found in this comparison (Table 4.16). The first was related to the quality of multinational vs locally manufactured medicines. Both gender groups had the majority of respondents disagreeing with the statement that '*I believe that multinational products are of a better quality than locally produced products',* with a disagreement rate of 72,18% amongst males and a 62,72% disagreement rate amongst females. The only significant finding was the high rate of neutral responses in females (27,81%) compared to males (13,91%), implying that almost a third of females are unsure of the quality of multinational vs locally manufactured medicines.

The second significant finding was related to the research and development of pharmaceuticals. Both gender groups had just over half of respondents disagreeing with the statement that '*Wider use of generic drugs will mean that less money will be used for research and development of new pharmaceuticals'*, with a disagreement rate of 53,91% amongst males and a 52,66% disagreement rate amongst females. Again there was a high rate of neutral responses amongst females (27,81%) compared to males (14,78%). The greatest difference was found in the agreement responses with 11% more males than females agreeing with the statement

Table 4.17: Pharmaceutical sector comparisons of pharmacists perceptions of generic medicines							
STATEMENT	LIKERT SCALE						
	STRONGLY DISAGREE	DISAGREE	NEUTRAL	AGREE	STRONGLY AGREE	CHI SQUARE	P VALUE
I believe that locally manufactured medicines are more affordable than original medicines						19,87	0,23
Community Pharmacy	0,93	9,26	16,67	53,7	19,44		
Institutional (Private and Public)	2,78	7,25	22,72	52,78	14,49		
Academic Institution	0,00	17,65	29,41	41,18	11,76		
Wholesale and Manufacturing Pharmacy	0,00	17,36	5,56	71,53	5,56		
Consultant Pharmacy	0,00	20,00	60,00	20,00	0,00		
I believe that locally manufactured medicines are of the same effectiveness as original medicines						8,94	0,92
Community Pharmacy	0,93	0,93	30,56	52,78	14,81		
Institutional (Private and Public)	0,00	3,62	19,48	58,33	18,58		
Academic Institution	0,00	0,00	23,53	70,59	5,88		
Wholesale and Manufacturing Pharmacy	0,00	1,85	34,86	46,53	21,76		

Consultant Pharmacy	0,00	0,00	40,00	40,00	20,00		
I view generic medicines as being of a poorer quality than original medicines						32,91	**0,008**
Community Pharmacy	18,52	49,07	26,85	5,56	0,00		
Institutional (Private and Public)	27,41	47,90	18,79	3,63	2,28		
Academic Institution	17,65	70,59	11,76	0,00	0,00		
Wholesale and Manufacturing Pharmacy	13,61	54,63	11,81	9,96	0,00		
Consultant Pharmacy	40,00	20,00	0,00	20,00	20,00		
I think generic medicines produce more side effects than original medicines						15,54	0,49
Community Pharmacy	21,10	53,21	17,43	8,26	0,00		
Institutional (Private and Public)	23,34	55,60	14,47	4,06	2,25		
Academic Institution	23,53	64,71	5,88	5,88	0,00		
Wholesale and Manufacturing Pharmacy	29,17	63,43	7,41	0,00	0,00		
Consultant Pharmacy	60,00	40,00	0,00	0,00	0,00		
I believe low-cost medicines are as safe as high-cost medicines						12,82	0,69
Community Pharmacy	0,92	2,75	20,18	58,72	17,43		
Institutional (Private and Public)	0,00	5,88	14,03	59,26	20,84		

Academic Institution	0,00	6,25	12,50	75,00	6,25		
Wholesale and Manufacturing Pharmacy	0,00	0,00	7,41	65,28	27,32		
Consultant Pharmacy	0,00	0,00	40,00	60,00	0,00		
I believe that multinational products are of a better quality than locally produced products						17,96	0,12
Community Pharmacy	16,51	38,53	25,69	19,27	0,00		
Institutional (Private and Public)	17,72	53,05	16,90	12,34	0,00		
Academic Institution	5,88	70,59	23,53	0,00	0,00		
Wholesale and Manufacturing Pharmacy	50,47	40,97	21,76	11,81	0,00		
Consultant Pharmacy	40,00	40,00	0,00	20,00	0,00		
I believe that the local companies in South Africa are not following Good Manufacturing Practice (GMP) guidelines as well as multinationals						20,84	0,18
Community Pharmacy	22,94	48,62	24,77	3,67	0,00		
Institutional (Private and Public)	26,34	52,69	17,79	3,19	0,00		
Academic Institution	11,76	58,82	17,65	11,76	0,00		
Wholesale and Manufacturing Pharmacy	34,72	59,72	3,71	0,00	3,70		
Consultant Pharmacy	40,00	40,00	20,00	0,00	0,00		

I view few local companies as reputable generic medicine manufacturers						19,51	0,24
Community Pharmacy	8,26	37,61	22,02	25,69	6,42		
Institutional (Private and Public)	10,89	36,38	13,72	31,77	7,27		
Academic Institution	11,76	11,76	17,65	47,06	11,76		
Wholesale and Manufacturing Pharmacy	13,66	33,57	16,21	27,32	9,26		
Consultant Pharmacy	50,00	25,00	0,00	25,00	0,00		
I believe that pharmacists should be educated more about prices of medicines						26,23	**0,05**
Community Pharmacy	9,17	22,02	22,94	34,86	11,01		
Institutional (Private and Public)	7,29	24,53	18,23	37,70	12,26		
Academic Institution	0,00	18,75	31,25	43,75	6,25		
Wholesale and Manufacturing Pharmacy	0,00	8,10	25,47	52,78	13,66		
Consultant Pharmacy	0,00	20,00	0,00	80,00	0,00		
I believe that generic medicines are only meant for the poor						10,13	0,86
Community Pharmacy	45,37	47,22	4,63	1,85	0,93		
Institutional (Private and Public)	49,71	42,53	3,67	3,63	0,47		
Academic Institution	64,71	35,29	0,00	0,00	0,00		

Wholesale and Manufacturing Pharmacy	42,13	56,02	0,00	1,85	0,00		
Consultant Pharmacy	80,00	20,00	0,00	0,00	0,00		
I think that confidence should be built in the patient about the low-cost brand						12,67	0,70
Community Pharmacy	1,85	3,70	13,89	56,48	24,07		
Institutional (Private and Public)	0,93	1,85	9,65	62,03	25,55		
Academic Institution	0,00	0,00	12,50	75,00	12,50		
Wholesale and Manufacturing Pharmacy	6,25	1,85	11,81	45,37	34,72		
Consultant Pharmacy	0,00	0,00	0,00	60,00	40,00		
Wider use of generic drugs will mean that less money will be used for research and development of new pharmaceuticals.						30,58	**0,02**
Community Pharmacy	7,41	35,19	22,22	26,85	8,33		
Institutional (Private and Public)	14,52	37,87	17,87	21,54	8,22		
Academic Institution	11,76	70,59	11,76	5,88	0,00		
Wholesale and Manufacturing Pharmacy	15,51	35,42	29,17	18,06	1,85		
Consultant Pharmacy	40,00	20,00	20,00	0,00	20,00		

4.2.6 Pharmaceutical sector comparisons of pharmacists' perceptions of generic medicines

Three significant results were found in this comparison (Table 4.17). The first was related to the quality of generic medicines. The statement presented to pharmacists was that '*I view generic medicines as being of a poorer quality than original medicines'*. Significant findings were found amongst academic and consultant pharmacists. 88,24% of academic pharmacists disagreed with the statement compared to a mere 45,93% of community pharmacists. A significantly high number of consultant pharmacists (40%) believed that generic medicines are of a poorer quality than original medicines. This was much higher than the other groups which ranged from 0% of academic pharmacists to 9,96% of wholesale & manufacturing pharmacists.

The second was related to education of pricing. Significant findings were found amongst wholesale and manufacturing pharmacists as well as consultant pharmacists. 80% of consultant pharmacists agreed with the statement that '*I believe that pharmacists should be educated more about prices of medicines',* while less than half (45,87%) of community pharmacists agreed that pharmacists require more education on pricing of medication. Almost a third of community and institutional pharmacists disagreed with this statement compared to only 8,10% of manufacturing pharmacists.

The third was related to the research and development of pharmaceuticals. The most significant finding in this question was in the academic institution category. 82,35% of academic pharmacists disagreed with the statement that '*Wider use of generic drugs will mean that less money will be used for research and development of new pharmaceuticals.'* Compared to a range of disagreement from 42,6% amongst community pharmacists to 60% amongst consultant pharmacists. More than a third of Community pharmacists (35,18%) believed that wider use of generics will negatively impact development of new pharmaceuticals.

Table 4.18: Age category comparison of pharmacists perceptions of generic medicines							
STATEMENT	LIKERT SCALE						
	STRONGLY DISAGREE	DISAGREE	NEUTRAL	AGREE	STRONGLY AGREE	CHI SQUARE	P VALUE
I believe that locally manufactured medicines are more affordable than original medicines						10,43	0,58
20-30	2,33	11,63	25,58	39,53	20,93		
31-40	2,47	11,11	22,22	46,91	17,28		
41-50	1,70	8,48	15,25	62,71	11,86		
>50	0,00	9,80	16,67	59,8	13,73		
I believe that locally manufactured medicines are of the same effectiveness as original medicines						17,30	0,14
20-30	0,00	2,33	20,93	62,79	13,95		
31-40	0,00	2,50	20,00	51,25	26,25		
41-50	1,69	0,00	22,03	62,71	13,56		
>50	0,00	2,91	33,01	52,43	11,65		
I view generic medicines as being of a poorer quality than original medicines						22,99	**0,03**
20-30	26,19	66,67	4,76	2,38	0,00		
31-40	31,25	43,75	17,50	7,50	0,00		
41-50	18,64	55,93	20,34	3,39	1,70		
>50	18,45	43,69	31,07	4,85	1,94		

I think generic medicines produce more side effects than original medicines						14,99	0,24
20-30	25,58	62,79	6,98	4,65	0,00		
31-40	32,93	47,56	12,20	7,32	0,00		
41-50	22,03	61,02	11,86	3,39	1,70		
>50	19,42	53,40	22,33	3,88	0,97		
I believe low-cost medicines are as safe as high-cost medicines						14,45	0,27
20-30	0,00	6,98	13,95	55,81	23,26		
31-40	1,23	3,70	13,58	54,32	27,16		
41-50	0,00	0,00	13,56	67,80	18,64		
>50	0,00	4,90	20,59	61,76	12,75		
I believe that multinational products are of a better quality than locally produced products						16,18	0,07
20-30	18,60	48,84	30,23	2,33	0,00		
31-40	24,39	51,22	13,41	10,98	0,00		
41-50	18,64	50,85	15,25	15,25	0,00		
>50	17,48	37,86	29,13	15,53	0,00		
I believe that the local companies in South Africa are not following Good Manufacturing Practice (GMP) guidelines as well as multinationals						20,1	0,07
20-30	28,57	50,00	16,67	4,76	0,00		
31-40	41,46	35,37	17,07	6,10	0,00		
41-50	23,73	55,93	16,95	1,69	1,69		

>50	19,42	54,37	23,30	2,91	0,00		
I view few local companies as reputable generic medicine manufacturers						16,44	0,17
20-30	11,63	27,91	11,63	39,53	9,30		
31-40	14,63	25,61	19,51	26,83	13,41		
41-50	16,95	40,68	11,86	23,73	6,78		
>50	6,86	40,20	16,67	31,37	4,90		
I believe that pharmacists should be educated more about prices of medicines						30,4	**0,002**
20-30	0,00	6,98	13,95	55,81	23,26		
31-40	4,94	12,35	13,58	40,74	28,40		
41-50	3,39	23,73	23,73	37,29	11,86		
>50	5,88	22,55	26,47	37,25	7,84		
I believe that generic medicines are only meant for the poor						10,98	0,53
20-30	55,81	41,86	2,33	0,00	0,00		
31-40	57,32	39,02	0,00	3,66	0,00		
41-50	49,15	45,76	1,69	1,69	1,69		
>50	46,53	46,53	3,96	2,97	0,00		
I think that confidence should be built in the patient about the low-cost brand						17,70	0,13
20-30	2,33	2,33	6,98	41,86	46,51		
31-40	1,22	2,44	8,54	50,00	30,51		
41-50	0,00	3,39	10,17	55,93	30,51		

>50	0,99	4,95	14,85	61,39	17,82		
Wider use of generic drugs will mean that less money will be used for research and development of new pharmaceuticals.						23,48	**0,02**
20-30	18,60	37,21	34.88	6,98	2,33		
31-40	18,52	39,51	18,52	17,28	6,17		
41-50	20,34	45,76	13,56	16,95	3,39		
>50	6,86	33,33	25,49	24,51	9,80		

4.2.7 Age category comparison of pharmacists' perceptions of generic medicines

Three significant results were found in this comparison (Table 4.18). The first was related to the quality of generic medicines. The statement presented to pharmacists was that '*I view generic medicines as being of a poorer quality than original medicines'*. The most significant finding within this question was amongst pharmacists between the ages of 20 – 30 years. Almost all of the youngest pharmacists (92,86%) disagreed with this statement. This was significantly higher than the other groups which ranged from 62,14% amongst pharmacists >50 years of age to 74,57% amongst pharmacists in the 41 – 50 age category.

The second was related to education of pricing. The statement presented to pharmacists was that '*I believe that pharmacists should be educated more about prices of medicines.'* The most significant finding within this question was again amongst pharmacists in the 20 -30 age group. Almost 80% of pharmacists within this category agreed that pharmacists require more education on pricing. This was significantly higher than the other groups which ranged from 45,09% amongst pharmacists >50 years of age to 69,14% amongst pharmacists in the 31 – 40 age category.

The third was related to research and development of pharmaceuticals. The most significant finding in this question was amongst pharmacists >50 years of age. More than a third (34,31%) of pharmacists in this category agreed with the statement that '*Wider use of generic drugs will mean that less money will be used for research and development of new pharmaceuticals.'* Compared to a range of agreement from 9,31% amongst pharmacists in the 20 – 30 year age group to 23,45% amongst pharmacists in the 31 – 40 year age group. Almost two thirds (66,1%) of pharmacists in the 41 – 50 year age category believed that usage of generics does not hamper research and development of pharmaceuticals compared to just 40% of pharmacists in the >50 years age group.

Table 4.19: Years of experience comparison of pharmacists perceptions of generic medicines							
STATEMENT	LIKERT SCALE						
	STRONGLY DISAGREE	DISAGREE	NEUTRAL	AGREE	STRONGLY AGREE	CHI SQUARE	P VALUE
I believe that locally manufactured medicines are more affordable than original medicines						13,20	0,66
1-5	2,70	8,11	27,03	43,24	18,92		
6-10	4,44	8,89	24,44	46,67	15,56		
11-15	0,00	10,87	15,22	52,17	21,74		
16-20	0,00	16,00	20,00	48,00	16,00		
>20	0,76	9,85	16,67	59,85	12,12		
I believe that locally manufactured medicines are of the same effectiveness as original medicines						25,67	0,06
1-5	0,00	0,00	27,03	56,76	16,22		
6-10	0,00	2,22	6,67	68,89	22,22		
11-15	0,00	6,67	2,22	42,22	28,89		
16-20	0,00	0,00	32,00	56,00	12,00		
>20	0,76	1,52	3,30	56,06	11,36		
I view generic medicines as being of a poorer quality than original medicines						30,61	**0,02**
1-5	27,03	59,46	10,81	0,00	0,00		
6-10	26,67	60,00	4,44	4,44	2,22		

11-15	36,96	30,43	21,74	10,87	0,00		
16-20	20,00	48,00	28,00	4,00	0,00		
>20	16,67	49,24	28,03	4,55	1,52		
I think generic medicines produce more side effects than original medicines						20,78	0,19
1-5	27,03	62,16	8,11	2,70	0,00		
6-10	26,67	57,78	6,67	8,89	0,00		
11-15	38,30	38,30	17,02	6,38	0,00		
16-20	16,00	60,00	16,00	4,00	4,00		
>20	19,70	56,82	18,94	3,79	0,76		
I believe low-cost medicines are as safe as high-cost medicines						18,72	0,28
1-5	0,00	2,70	16,22	56,76	24,32		
6-10	2,22	4,44	8,89	57,78	26,67		
11-15	0,00	6,52	15,22	47,83	30,43		
16-20	0,00	4,00	24,00	56,00	16,00		
>20	0,00	3,03	17,42	65,91	12,88		
I believe that multinational products are of a better quality than locally produced products						12,21	0,43
1-5	16,22	51,35	27,03	5,41	0,00		
6-10	20,00	51,11	22,22	6,67	0,00		
11-15	29,79	44,68	12,77	12,77	0,00		
16-20	20,00	40,00	32,00	8,00	0,00		

>20	17,42	43,94	21,97	16,67	0,00		
I believe that the local companies in South Africa are not following Good Manufacturing Practice (GMP) guidelines as well as multinationals						21,65	0,15
1-5	29,73	51,35	16,22	2,70	0,00		
6-10	35,56	33,33	20,00	8,89	0,00		
11-15	12,77	21,28	17,02	2,13	0,00		
16-20	24,00	40,00	32,00	4,00	0,00		
>20	21,21	57,58	18,94	1,52	0,76		
I view few local companies as reputable generic medicine manufacturers						15,86	0,46
1-5	16,22	29,73	18,92	29,73	5,41		
6-10	8,89	22,22	17,78	40,00	11,11		
11-15	19,15	34,04	10,64	23,40	12,77		
16-20	4,00	36,00	24,00	24,00	12,00		
>20	10,61	39,39	13,64	29,55	6,06		
I believe that pharmacists should be educated more about prices of medicines						28,23	**0,03**
1-5	0,00	10,81	18,92	45,95	24,32		
6-10	2,22	8,89	8,89	53,33	26,67		
11-15	8,70	17,39	17,39	36,96	19,57		
16-20	0,00	20,00	20,00	36,00	24,00		
>20	5,30	21,97	25,76	37,88	8,33		

I believe that generic medicines are only meant for the poor						10,28	0,85
1-5	56,76	43,24	0,00	0,00	0,00		
6-10	60,00	35,56	2,22	2,22	0,00		
11-15	55,32	42,55	0,00	2,13	0,00		
16-20	40,00	56,00	0,00	4,00	0,00		
>20	46,97	43,94	3,79	3,03	0,76		
I think that confidence should be built in the patient about the low-cost brand						26,75	**0,04**
1-5	0,00	2,70	8,11	40,54	48,65		
6-10	4,44	2,22	4,44	46,67	42,22		
11-15	0,00	6,38	8,51	48,94	36,17		
16-20	0,00	0,00	12,00	60,00	28,00		
>20	0,76	3,79	14,39	59,85	19,70		
Wider use of generic drugs will mean that less money will be used for research and development of new pharmaceuticals.						28,50	**0,03**
1-5	16,22	37,84	37,84	5,41	2,70		
6-10	20,00	28,89	28,89	20,00	2,22		
11-15	19,57	47,83	6,52	15,22	10,87		
16-20	20,00	44,00	12,00	24,00	0,00		
>20	9,85	36,36	23,48	21,21	8,33		

4.2.8 Years of experience comparison of pharmacists' perceptions of generic medicines

Four significant results were found in Table 4.19. The first was related to the quality of generic medicines. The statement presented to pharmacists was that '*I view generic medicines as being of a poorer quality than original medicines'.* 86% of pharmacists with 1 – 5 and 6 – 10 years of experience disagreed with this statement. This was significantly higher than the larger age groups with just 66% disagreeing in the >20 years' experience category, 67% in the 11 – 16 year category and 68% in the 16 – 20 year category. More than 10% of pharmacists in the 11 – 15 years of experience category believed that generics are of a poorer quality than originals, whilst there was a zero agreement response amongst the youngest pharmacists.

The second was related to education of pricing. Significant findings were found amongst pharmacists in the 6 – 10 years of experience category as well as the >20 years of experience category. 80% of pharmacists with 6 – 10 years of experience agreed with the statement that '*I believe that pharmacists should be educated more about prices of medicines',* while less than half (46,21%) of pharmacists with >20 years of experience agreed that pharmacists require more education on pricing of medication.

The third was related to confidence in generics. The statement presented to pharmacists was that '*I think that confidence should be built in the patient about the low-cost brand.'* Significant findings were found amongst pharmacists in the 1 – 5 years of experience category and the 16 – 20 years of experience category. Almost 90% of pharmacists with the least number of years of experience agreed with this statement compared to less than 80% of pharmacists with the greatest number of years of experience. There was a zero disagreement response rate amongst pharmacists in the 16 – 20 years of experience category.

The fourth was related to research and development of pharmaceuticals. The most significant finding in this question was amongst pharmacists with 1 - 5 years of experience. 8,11% of pharmacists in this category agreed with the statement that '*Wider use of generic drugs will mean that less money will be used for research and development of new pharmaceuticals.'* This was significantly lower compared to the other groups which ranged from 22,22% amongst pharmacists with 6 – 10 years of experience to 29,54% amongst pharmacists with > 20 years of experience. More than a third (37,84%) of the youngest pharmacists had a neutral response to this statement compared to just 6,52% of pharmacists in the 11 – 16 years of experience category

CHAPTER 5: DISCUSSION

Generic medicine usage has increased significantly in recent years, due to their lower cost. Through their use, healthcare expenditure can be reduced and this is greatly beneficial to developing countries like South Africa where cost saving strategies are vital for the economy. There are only a few studies that have explored the perceptions and views of pharmacists towards generic medicine use. Therefore, in this study, we aimed to evaluate the views, knowledge and perception of pharmacists about generics. Most pharmacists seemed well informed and confident in the use of generic medication. More than 70% of respondents believed that generic medicines are therapeutically equivalent, equally safe and interchangeable with their original counterparts, yet only half believed that generic medicines were of the same quality as original medications. Many believed that this was due to original medications having stricter safety standards. Although South African regulating bodies ensure optimal safety and efficacy of all medicines are maintained through stringent quality inspections, some substandard medicines have entered the market as in the case of the Tuberculosis generic medications that were removed from the market in 2008. These findings can lead to doubts in the confidence of pharmacists towards generic medicines. Efforts should be made to improve the functioning of the MCC and ensure that all medicines are assessed according to international standards prior to registration as well as ongoing post market evaluations carried out to prevent defects in medicine batches.

Generally, it was found that respondents were supportive of generic medicines; however, many believe that generic substitution is not suitable all the time. Several pharmacists reported that consumers experienced therapeutic nonequivalence following generic substitution. Patients' lack of confidence in generic medications relating to efficacy and safety was also a problem encountered, yet only 14% of pharmacists would take the time to educate and persuade the patient to use a generic instead. If consumers are educated sufficiently on generic substitution and its benefits, they may be more accepting of these agents.

The majority of respondents believed that generic medicines are cost-effective with more than 90% of pharmacists citing cost to customers as a reason for them recommending a generic alternative. "Medical Scheme requirement" was also a major influence for pharmacists to practice generic substitution. The Mediscor Medicines Review reported that in 2010, 50% of patients in South Africa that are insured with medical aid schemes, prefer to

use generic medicines when they are available, [12] which is an increase from 48,8% in 2009. The South African Government has implemented a strict legislation on pricing in order to reduce the high cost of healthcare in the country. Policies obliging pharmacists to offer and dispense more affordable generic alternatives to their customers have also been implemented.

5.1 Comparison of study with International studies

5.1.1 Bioequivelance

A study, conducted in Ireland by Dunne et al (2013), revealed that pharmacists in Ireland were more trusting toward generic medicines compared to those in the Western Cape. [64] In Ireland, 98% of pharmacists believed that generics are similar to originals, compared to 74% of Western Cape respondents that agreed that generic and original medicines are therapeutically and biologically equivalent. Results from a study conducted by Babar et al, in New Zealand (2010), were similar with approximately 70% of respondents believing that a generic medicine is bioequivalent to the original brand medicine. [50] In Malaysia, a similar study was conducted by Chong et al. [52] A comparison of this study revealed that Malaysian pharmacists were less trusting of generic medicines than Western Cape pharmacists with only 50% of Malaysian pharmacists believing that generic medicines are therapeutically equivalent to originals. [52] This is similar to a study in Jamaica by Gossell-Williams (2005) where physicians were questioned on whether generics and original medicines were bio-equivalent. [54] There was equal distribution between agreement and disagreement with this statement suggesting lack of confidence in the performance of the generics available in Jamaica and Malaysia.

- Comparisons within current study:

Almost a quarter of respondents in the 20 -30 age group disagreed with the statement that '*generics medicines are a copy of original medicines*' ($p = 0,02$). Generic medicines are in fact bio-identical to their original counterparts with regard to use, dosage, strength, route of administration, safety, quality and side effects. This misconception amongst the group of pharmacists that should be most well informed about generics due to their recent graduation needs to be addressed. These are the pharmacists of the future that are responsible for providing cost effective healthcare and rational medicine use to patients. They are integral in promoting generic medicine use and educating patients and other healthcare workers about it.

5.1.2 Cost Effectiveness

The results of this study do bear similarities to other international studies. Pharmacists in the New Zealand study and the Western Cape had similar views on the cost efficacy of generic medicines, with 70% of New Zealand respondants [50] and 73% of Western Cape respondants citing cost effectiveness as being a reason for recommending generic medicines. The cost of generics versus the original medicine was also shown to be a major factor in the acceptance of generics by physicians in Jamaica [54] No significant differences in opinions between categories of Western Cape pharmacists were found in this study as there was a general consensus that generic medicines are more cost effective.

5.1.3 Therapeutic Efficacy

Half of the New Zealand respondents believed that the original brands are more effective than generic medicines. [50] This study, however, revealed more positive findings with 72% of Western Cape pharmacists proclaiming no difference in efficacy between generic and original medicines. In Ireland, however, 96% of pharmacists believed that generics are as effective as their original counterparts implying that health professionals have very positive outlooks on generic medicines in this country. [64]

- Comparisons within current study:

More than a third of pharmacists over the age of 50 (62,85%) were doubtful about the efficacy of low priced medicines compared to high priced medicines. This was sigificantly higher than in the younger age categories ($p = 0,03$). These findings mirrored that of the years of experience category where there was more than a 25% difference in the agreement rate between the most experienced pharmacists and those in the 11 – 15 year group ($p = 0,02$). This misconception could be due to older pharmacists having previous experiences of low quality medicine. However, currently the MCC ensures that all medication, regardless of its price abides by the same safety and efficacy standards.

Within the >20 years of experience group, only 67,65% of pharmacists agreed that *'Generic medicines are therapeutically equivalent to original medicines'* compared to the 76 – 83% agreement range in the groups with less experience. It is evident that a pharmacist's length of time in practice significantly influences their knowledge of generic medicines ($p = 0,01$) The study carried out in New Zealand also found that pharmacists with a shorter length of time in

practice had a better understanding of generic medicines as compared to more experienced pharmacists. (p = 0,03) According to an article by Woolston C (2015), which discussed the History of Generic Medcines, he noted that as recently as 40 years ago, medication manufacturing companies could release new products onto the market with far less testing than is required today. [65] The medicine's safety and effectiveness was only determines came after it became available to the market. An example of this dangerous approach was when the sedative thalidomide caused thousands of devastating birth defects around the world and was then only removed off the shelves. [65]

5.1.4 Quality

Pharmacists in the Western Cape appear to have greater trust in the quality of generic medicines, with only 17% believing that original medicines were of a higher quality than generics. In New Zealand, however, 65% of respondents suggested the original medicines are of a higher quality than generic medicines. [50] 21% of Malaysian pharmacists believed that generics were inferior in quality to original medicines. [52]

- Comparisons within current study

In this study, findings relating to the quality of multinational versus locally manufactured medicines between the genders revealed that males appeared slightly more informed on the equal quality of both products, with a 10% higher disagreement rate to the statement that '*I believe that multinational products are of a better quality than locally produced products',* (p = 0,04)

The statement relating to the quality of generic medicines compared to originals revealed very significant findings. 40% of consultant pharmacists believed that generic medicines are of a poorer quality compared to 0% of academic pharmacists (p = 0,008). It can be assumed that academic pharmacists have better knowledge and expertise regarding the MCC's stringent quality testing of all medicines whether generic or original.

Almost all pharmacists (92,86%) in the 20 – 30 year age group compared to only 62% in the >50 year group did not view generic medicines as being of a poorer quality than original medicines (p = 0,03). It can be assumed that the youngest pharmacists, having been exposed to most recent research on the stringent quality and efficacy of generic medicines are therefore more confident in them. Years of experience results mirrored these findings with a correlation between less experienced pharmacists and confidence in generics (p = 0,02).

5.1.5 Safety

This study provided positive feedback on pharmacists' knowledge of safety of generic and original medicines, with only 4% of respondents believing that original medicines were safer than their generic counterparts and 20% believing that original medicines are required to meet higher safety standards than their original counterparts. In New Zealand, however, almost a third (28%) of pharmacists mentioned that original brands were safer than generics. [50] A high 80% of pharmacists in the Western Cape disagreed that generic medicines produce more side effects than original medicines, compared to a 62% disagreement rate by Malaysian pharmacists implying that hesitancy still remains in Malaysia regarding generic medicine usage do to a negative outlook on the side effect profile of these medicines. [52]

- Comparisons within current study:

The misconceptions relating to safety of generics was particularly evident in the results from Table 17, where it was noted that the majority of consultant pharmacists strongly believed that original medicines are required to meet higher safety standards than generics (p = 0,005). More than a third of respondents in the >50 age group agreed with the statement that '*Only those generic medicines which are made by some local reputable manufacturers are safe'*. (p =0,01) These statements are incorrect as the MCC has the same stringent regulations and qualities testing of generics as original medicines and all manufacturers have to abide by these regulations. These findings are a cause for concern as the main role of consultant pharmacists is to promote Health Care Improvement through managed health care, with the emphasis on health education and medicine intervention. Their aim is give the patient the best, but also the safest and most cost effective medication therapy. Consultant therapists are therefore integral in promoting generic medicines. However, if they have misconceptions regarding the safety of generics, this may hinder their promotion of generic medicines.

5.1.6 Education

Pharmacists in both Ireland and the Western Cape were not keen on educating patients on generic usage with 21% of pharmacists in Ireland encouraging generic use and only 14% in the Western Cape. [64]

- Comparisons within current study

80% of consultant pharmacists compared to just 45,87% of community pharmacists agreed with the statement that '*I believe that pharmacists should be educated more about prices of*

medicines.' (p = 0,05) It is important for pharmacists to have adequate knowledge on the prices of medicines so that they choose the most cost effective treatment for patients. Community pharmacists in particular have a vital role in ensuring rational medicine usage and the importance of this role should be brought to their attention.
Almost 80% of pharmacists in the 20 – 30 age group believed that pharmacists should be educated more about prices of medicines. This was significantly higher than the oldest pharmacists where only 45% felt the same way (p = 0,002). Similar results were found in the years of experience category (p = 0,03). A theory for these results is that the younger pharmacists are more keen on learning and improving there knowledge on medicine pricing. Whereas older pharmacists who have more experience with the medicines available are already familiar with medicine prices and do not feel the need for further education.
Almost 90% of pharmacists with the least number of years of experience compared to less than 80% of pharmacists with the greatest number of years of experience agreed that confidence should be built in the patient about the low-cost brand (p = 0,04). Although these findings were not vastly different, it was interesting to note that the newer pharmacists were more concerned about rational medicine use and promoting the use of safe and effective medicines at the lowest possible cost. This is important in reducing the financial burden of the high cost of healthcare in the country.
The link between experience and knowledge was not true for all statements however, as it was seen when the statement that '*Generic medicines are manufactured after the patent expiry of originator/innovator'* was discussed. In this comparison, the highest agreement (100%) was by pharmacists with the greatest experience (p = 0,002). This implies that the more experienced pharmacists had a better understanding of the manufacturing protocol of generic medicines.

5.1.7 Research

When the statement that '*Wider use of generic drugs will mean that less money will be used for research and development of new pharmaceuticals'*, significant findings were obtained through various comparisons. Almost a third of males in this study agreed with this statement, an 11% higher response rate than females (p = 0,008). In another comparison, more than 80% of academic pharmacists compared to only 42,6% of community pharmacists agreed with the statement (p = 0,02). Being directly involved in research and development of new pharmaceuticals, it is not surprising that academic pharmacists had the greatest positive

response. More than a third (34,31%) of pharmacists in the >50 year age category agreed.' This was significantly higher than the 9,31% agreement amongst pharmacists in the 20 – 30 year age group (p = 0,02). Although medicine discovery is a complex, high risk and high cost endeavour, older pharmacists should be informed about the benefits of research into new medicines especially those in the treatment of chronic diseases.

According to a statement by Stiglitz J (2006), a former World Bank chief economist, medicine companies in developing countries spend more on advertising and marketing than on research. More research is carried out on lifestyle drugs than on life saving medicines, and almost nothing on diseases that affect developing countries only. [66] This is because the poor population cannot afford medicines, and medicine companies make investments that yield the highest returns. [66]

5.2 Role of health professionals

Health professionals, especially general practitioners (GP), can greatly influence consumers' acceptance of generic medicines as great trust is placed in their expertise and knowledge. In this survey a few pharmacists indicated that consumers preferred to check with their GP before using a generic medicine despite them being aware that the generic medicine contained the same ingredients as the branded medicine. In order to promote the use of generic medicines by consumers, it would be beneficial for prescribers to mention that a generic brand might be offered by the pharmacist when they collect their medication. If the brand substitution is acceptable to the prescriber, this brief advice and reassurance may be enough to secure the patients trust in generic medicines.

Pharmacists play an integral role in the provision of education to consumers regarding the efficacy and safety of generic medicines. If consumers are satisfied with the quality of information received from Health professionals, they will be more accepting of generic medicines. However, in order for consumers to have greater trust in generics, pharmacists need to have confidence in their safety and efficacy. Strategies aimed at educating pharmacists and dispelling doubts regarding the quality control testing of these medications is important in order to increase generic substitution in South Africa. In this study, a number of pharmacists commented that more training and guidance on generic medicines should be aimed at pharmacists.

5.3 Areas for future research

Generic medicines are a vital component of South Africa's health care system; however, much research is still required on the full impact of the use of generic medicines. By exploring pharmacists' perceptions and knowledge of generic medicines, we can move toward understanding the use of generics and their likely impact and influence it may have on patient compliance.

Due to the relevance of this topic throughout South Africa, the survey can be expanded to other parts of the country in order to draw more accurate generalisation of the results. These findings should be of great interest to pharmacists and other health professionals and especially to the government. It will enable them to develop and implement strategies to improve patient's knowledge and views of generic medicines, with pharmacists being the key health professionals likely to positively influence patients' decisions. The data obtained from this study provides a base on which to develop, implement, and evaluate primary care interventions. This can be used in order to provide accurate information and create awareness amongst the public regarding generic medicines [(50)] Further studies focusing on patient perceptions, generic substitution policies, as well as the impact of biologicals on medicine usage in South Africa are required in order to improve rational medicine usage in the country and provide patients with the best treatment options available.

5.4 Limitations of the Study

- Although the required sample size was reached, the low response rate may have yielded unreliable data. A bigger sample size is required to make accurate and valid associations between variables such as gender, age and years of experience.
- The survey was limited to Western Cape pharmacists, and therefore is not a true reflection of the opinions of all South African pharmacists. The survey would need to be expanded nationally in oreder to make generalised comments.
- The reliability of the survey data may be unclear as answer options such as 'strongly agree' or 'neutral' may be interpreted differently by respondents.

- Subjective surveys can influence respondents to provide answers that present themselves in a favourable manner thereby leading to responses that are inaccurate or biased.

CHAPTER 6: CONCLUSION

The purpose of promoting the use of generic medicines extends beyond the curbing of medical expenses. The ultimate aim is to try to provide all South African citizens with medical services that are inexpensive, effective, safe and of a high quality by effectively utilising the limited healthcare resources available. In order to increase the use of the generic medicines, it is important to continue efforts aimed at securing patients and health professionals' trust in the quality and efficacy of generic medication through the provision of information. Furthermore, it is important to raise awareness about these medications amongst healthcare professionals and patients in order for them to gain confidence in generic medicines and increase their willingness to actively use generic medicines.

From the results, it can be seen that like consumers, some pharmacists maintain erroneous beliefs about generic prescription medication. For instance, even though the MCC states that generic medication must be therapeutically equivalent to brand name medication, many pharmacists still remain doubtful about the quality, stable supply, and information available on generic medicines. To correct these misperceptions and encourage generic substitution, health organisations should implement education strategies targeting prescribers and pharmacists.

Pharmacists' play an integral role in encouraging generic medication use by consumers and efforts to increase generic medication use directed at pharmacists should be maintained. [67] Medicine expenditure can therefore be reduced and access to precious resources can be increased, in order to meet the urgent health care needs within South Africa. [68] In light of this, the present study was aimed at shedding some insight into the confidence that pharmacists have in generic medication. They have a strong influence on consumers' perception of generic medication and choice of medication so these results can be used to implement educational campaigns aimed at health professionals as well as create awareness amongst consumers, and perhaps input into undergraduate curriculum for more knowledge about generic medicines quality.

CHAPTER 7: RECOMMENDATIONS

The provision of explanation by pharmacists and other healthcare workers, as well as advertisements on generic medication will strongly influence patients' motivations to change to generic medications.

- As a means to improve the provision of information on generic medication, medicine information sheets should be handed to patients when pharmacists are dispensing. This should include information on availability of generic medication as well as prices and an inventory. [69]
- Governments should improve awareness by implementing campaigns (pharmacy awareness week) and direct-marketing, targeting the public on the use of generic medication as well as improve the training of pharmacists (undergraduate level) on the importance of generic substitution as well as provide guidance to them. [69]
- Mass educational efforts (radio and television campaigns) aimed at increasing consumers' knowledge and attitudes toward generics should be implemented in order to encourage them to play an active role in managing their medical conditions. Through the provision of accurate and informative advice those with low levels of literacy will be able to overcome their misconceptions about generic medicines. [9]
- Policymakers and researchers should address the questions surrounding the therapeutic equivalences of generic medication, to both pharmacists and patients
- In addition, given the complexity of the health care system, it is likely that a number of generic policies will have to be combined in a more comprehensive approach before generic medication utilisation can be maximised. [69]
- Researchers should make greater efforts towards studying consumer's decision-making processes and the factors influencing it.
- The communication and quality of information provided between patients and health care professionals about the equivalency of brand name and generic medicines should improve

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APPENDIX A : QUESTIONNAIRE

EXPLORING PHARMACISTS VIEWS, KNOWLEDGE AND PERCEPTION REGARDING GENERIC MEDICINES IN THE WESTERN CAPE

Dear Pharmacist

My name is Naseema Shaikh, a Masters Student from the University of KwaZulu-Natal.

You are invited to participate in a research study conducted by the University of KwaZulu-Natal. Your participation is strictly voluntary. Before agreeing to participate, you should know enough about it to make an informed decision. If you have any questions, please ask and be sure you are satisfied with the answers before participating.

The purpose of this study is to explore pharmacists' views, knowledge and perception regarding generic medicines in Western Cape. This will involve evaluating pharmacists' perceptions, views, and knowledge of and willingness to recommend generic medicines as well as exploring their perceptions of the safety, quality, and efficacy of generic medicines and views on current policy with respect to substitution of generic medicines.

The aim is to encourage the use of generic medication and gain wider health professionals' support for the quality utilization of generic medicines. Participation in this study will be the completion of the electronic questionnaire and forwarding of the completed survey to the researcher. This data will then be used to draw conclusions relating to the subject matter.

There are no known risks associated with this research project other than possible discomfort with the following:

• You will be asked to be completely honest about yourself when completing the form.
• You will be asked questions about personal experiences relating to generic medications whilst working as a pharmacist as well as your opinions and views relating to the topic

Possible benefits from participation in this project are:

• You will have an opportunity to reflect on your experiences.
• You will contribute to our knowledge about the views, and perceptions regarding generic medicines which may be extrapolated to other parts of the country.
• This data can assist researchers to identify any misconceptions relating to generic medications and implement initiatives aimed at encouraging the use of generic medication by health professionals

This study has been ethically reviewed and approved by the UKZN Biomedical research Ethics Committee (approval number BE317/14).

Remember, participation is voluntary. You may choose not to participate, and you may withdraw at anytime during the research project. In addition, you may choose not to answer any questions with which you are not comfortable. You will NOT be penalized in any way should you choose not to participate or to withdraw.

We will do everything we can to protect your privacy. As part of this effort, your identity will not be revealed in any publications that result from this study. The information in the study records will be kept strictly confidential. Individual data will be stored securely and will be made available only to persons conducting the study. No reference will be made in oral or written reports that could link you to the study.

In the event of any problems or concerns/questions you may contact the researcher at:
Cellphone – 0723734475
Email – naseema_1@yahoo.com

Or the supervisor (Prof Fatima Suleman) at sulemanf@ukzn.ac.za

or the UKZN Biomedical Research Ethics Committee, contact details as follows:

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1. I have been informed of the following (tick all that are relevant)

2. Agreement to Participate in Study

◯ Agreement to Participate in Study
I agree to participate
◯ I do not agree to participate

☐ I have been informed about the study entitled "Exploring pharmacists' views, knowledge and perception regarding generic medicines in Western Cape" by Naseema Shaikh

☐ I understand the purpose and procedures of the study

☐ I have been given an opportunity to answer questions about the study and have had answers to my satisfaction.

☐ I declare that my participation in this study is entirely voluntary and that I may withdraw at any time without affecting any treatment or care that I would usually be entitled to.

☐ If I have any further questions/concerns or queries related to the study I understand that I may contact the researcher via email or telephone

☐ If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact BREC or Prof Fatima Suleman

DEMOGRAPHIC CHARACTERISTICS

WHAT IS YOUR AGE?

20 - 30	31 – 40	41 - 50	> 50

WHAT IS YOUR GENDER?

MALE	FEMALE

WHAT BASIC PHARMACEUTICAL QUALIFICATION DO YOU POSSESS?

DIP. PHARMACY	BACHELOR OF PHARMACY	POSTGRADUATE QUALIFICATION

HOW MANY YEARS OF EXPERIENCE DO YOU HAVE?

1 - 5	6 – 10	11 - 15	16 - 20	> 20

WHICH PHARMACEUTICAL SECTOR DO YOU WORK IN?

COMMUNITY PHARMACY	INSTITUTIONAL (PRIVATE)	INSTITUTIONAL (PUBLIC)	ACADEMIC INSTITUTION	WHOLESALE PHARMACY	MANUFACTURING PHARMACY	CONSULTANT PHARMACY

KNOWLEDGE OF GENERIC MEDICINES

Select an option from 1 – 5 based on how strongly you agree or disagree with the statement: 5=strongly agree, 4=Agree, 3=neither disagree nor agree, 2=Disagree, 1=Strongly disagree.

	5	4	3	2	1
Generic medicines are a copy of original medicines					
Generic medicines are interchangeable with original medicines					
Generic medicines are therapeutically equivalent to original medicines					
Generic medicines must be in the same dosage form (such as tablet, capsule) as original medicines					
Generic medicines are less safe than original medicines					
Only those generic medicines which are made by some local reputable manufacturers are safe					
Generic medicines are manufactured after the patent expiry of originator/innovator					
Original medicines are of a better quality than generic medicines					
Original medicines are required to meet higher safety standards than generic medicine					
Original medicines produce fewer side effects than generic medicines					
Low-priced medicines are as effective as high-priced medicines					

PERCEPTIONS OF GENERIC MEDICINES

Select an option from 1 -5 based on how strongly you agree or disagree with the statement: 5=strongly agree, 4=Agree, 3=neither disagree nor agree, 2=Disagree, 1=Agree.

	5	4	3	2	1
I believe that locally manufactured medicines are more affordable than original medicines					
I believe that locally manufactured medicines are of the same effectiveness as original medicines					
I view generic medicines as being of a poorer quality than original medicines					
I think generic medicines produce more side effects than original medicines					
I believe low-cost medicines are as safe as high-cost medicines					
I believe that multinational products are of a better quality than locally produced products					
I believe that the local companies in South Africa are not following Good Manufacturing Practice (GMP) guidelines as well as multinationals					
I view few local companies as reputable generic medicine manufacturers					
I believe that pharmacists should be educated more about prices of medicines					
I believe that generic medicines are only meant for the poor					
I think that confidence should be built in the patient about the low-cost brand					
Wider use of generic drugs will mean that less money will be used for research and development of new pharmaceuticals.					

WHAT REASONS WOULD YOU HAVE FOR RECOMMENDING A GENERIC ALTERNATIVE

Tick the appropriate block. More than 1 option may be chosen

COST TO CUSTOMER	
HAVING NO OTHER CHOICE	
CUSTOMER PREFERENCE	
AVAILABILITY OF STOCK	
CUSTOMER APPEARANCE	
COST EFFECTIVENESS	
PROVEN BIOEQUIVELANCE	
MEDICAL SCHEME REQUIREMENT	
DO NOT RECOMMEND GENERICS	

WHAT WOULD BE YOUR APPROACH WHEN A PATIENT REFUSES A GENERIC

I DISPENSE THE ORIGINAL	I PERSUADE THE PATIENT	I DIRECT HIM/HER TO THE PRESRIBER	I DIRECT HIM/HER TO ANOTHER PHARMACY	OTHER

If other, please specify:

_____
_____

WHAT ARE THE POSSIBLE PROBLEMS THAT YOU HAVE NOTICED WHEN SWITCHING TO A GENERIC MEDICINE

NO IDEA	CONCERN ABOUT LOSING THE PATIENT	TOO MUCH EFFORT TO PERSUADE THE PATIENT	DOUBTS ABOUT THE BIOEQUIVELANCE	OTHER

HOW DO YOU NORMALLY FIND OUT ABOUT THE AVAILABILITY OF A GENERIC ALTERNATIVE TO AN ORIGINAL DRUG? PLEASE SELECT ALL THAT APPLY

DRUG MANUFACTURER REPRESENTATIVES	
DRUG WHOLESALER	
MEDICAL JOURNALS	
DRUG COMPANY WRITTEN INFORMATION	
FROM PHARMACIST/ COLLEAGUES/PEERS	
FROM PATIENTS	
FROM DOCTORS	
INFORMATIONAL LITERATURE (NEWSLETTERS, ARTICLES)	
FROM INTERNET/WEBSITES/E-MAILS	
FROM MEETINGS/CONFERENCES	
OTHER	

If Other, Please specify

_____

_____

APPENDIX B: ETHICAL APPROVAL LETTER

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

19 August 2014

Mrs Naseema Shaikh
P.O. Box 1158
Wandsbeck
3631
naseema_1@yahoo.com

Dear Mrs Shaikh

PROTOCOL: Exploring Pharmacists' views, knowledge and perception regarding generic medicines in Cape Town: Degree Purposes (Masters). BREC REF: BE317/14.

EXPEDITED APPLICATION

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 17 June 2014.

The study was provisionally approved pending appropriate responses to queries raised. Your responses received on 31 July 2014 to queries raised on 28 July 2014 have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval and may begin as from 19 August 2014.

This approval is valid for one year from **19 August 2014.** To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2004), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be **RATIFIED** by a full Committee at its meeting taking place on **09 September 2014.**

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

Professor D.R Wassenaar
Chair: Biomedical Research Ethics Committee