

**CONTROLLING SOUTH AFRICA'S PRIVATE HEALTH  
CARE EXPENDITURES: THE PERCEPTIONS AND  
EXPERIENCES OF PRIVATE HEALTH CARE  
PROVIDERS ABOUT GENERIC MEDICINES – IN THE  
MAFIKENG DISTRICT, NORTH WEST PROVINCE,  
SOUTH AFRICA.**



060007638U

North-West University  
Mafikeng Campus Library

---

**DR P.E.K. SEODI**

**2004**

**CONTROLLING SOUTH AFRICA'S PRIVATE HEALTH CARE  
EXPENDITURE: THE PERCEPTIONS AND EXPERIENCES OF  
PRIVATE HEALTH CARE PROVIDERS ABOUT GENERIC  
MEDICINES IN THE MAFIKENG DISTRICT, NORTH WEST  
PROVINCE, SOUTH AFRICA.**

**BY**

**DR PATIENCE ELIZABETH KEROTSE SEODI**

**A Mini Dissertation submitted in partial  
fulfillment of the requirements for the  
Degree of**

**MASTERS OF BUSINESS**

**ADMINISTRATION (FINANCIAL MANAGEMENT)**

**UNIVERSITIES OF NORTH-WEST/ LIVERPOOL**

**2004**

**SUPERVISOR: DR M.P.MAAGA**

244437222

LIBRARY	
Call No	TH 338-433621
2004-04-30 SE0	
Acc No	04/50153
UNIVERSITY OF THE NORTH WEST	

61665500X  
118673995

## **ABSTRACT**

### **PERCEPTIONS AND EXPERIENCES OF PRIVATE HEALTH CARE PROVIDERS IN MAFIKENG ABOUT GENERIC MEDICINES**

**BY**

**Patience Elizabeth Kerotse Seodi**

This was a study which sought to investigate the perceptions and experiences of private health care providers in Mafikeng, North West Province about generic medicines. The escalating cost of medicine in South Africa and elsewhere in the world has necessitated government intervention to come up with strategies to make health care accessible and affordable to the majority of the people.

In South Africa, the Medicine and Related Substances Control Amendment Act (Act 101 of 1965), was implemented in May 2003. The Act makes it compulsory for pharmacist to offer patients generic medicines, apart from exceptions listed by the Medical Control Council and, if substitution takes place, to inform the doctor.

The study was a prospective, cross- sectional survey of private health care providers in the greater Mafikeng area using a self- administered structured questionnaire. Participants received a structured questionnaire by hand mail and were given the same time to complete it. The questionnaires were then collected from their respective rooms.

The main outcome measures were age, level of education, current occupation/profession and their perception and experiences about generic medicines. The total number of respondents was thirty two (32) out of forty (40) private health care providers who received the copies of the questionnaires. One questionnaire was incompletely answered and was therefore excluded from the final analysis. Seven questionnaires were returned unanswered. Age ranged from 26 to 51 and all had one or two university degrees.

On average, private health care providers in Mafikeng perceived generic medicines and patent medicines to be identical and bioequivalent. Majority of the respondents prescribed generic medicines as their first line of treatment and were aware of the mandatory generic substitution law. According to the respondents, the majority of patients were not well informed about generic medicines. Majority of respondents were satisfied with the safety, quality, performance characteristics, intended use and route of administration of generic medicines.

There is a need for a common essential drug list that will be used by all medical aids schemes in South Africa, wider generic prescribing in both the public and private health sector, speeding up the process of manufacturing generics, health care providers complying fully with the mandatory generic substitution law, parallel importation of generic medicines when a need arises and a widespread promotional campaigns targeting mainly consumers and health professionals.



### **DEDICATION**

This work is dedicated to my late parents **Simon Modisaotsile** and **Sophy Mafini Seodi**. They are still important in my life.

I thank them both very graciously.

### **ACKNOWLEDGEMENTS**

I would like to thank most sincerely the following:

1. All my colleagues in the private health care industry in the greater Mafikeng area Zeerust, Thusong, Itsoseng, and Mmabatho, who acted as study materials.
2. The Hospital Manager, Victoria Private Hospital, Mafikeng.
3. The Driver, Ampath Laboratories, Johanna Morule, and Galaletsang Moseki who helped in distributing and collecting all data captured questionnaires.
4. DR C.Teu, who assisted with compiling the questionnaire.
5. My son, Gaopalelewe Mhlongo, who helped with typing.

I would like to thank my husband, Mr Patrick Mhlongo, who assisted with proof reading and editing the whole manuscript. Thank you also for your support throughout the study period.

A special word of appreciation is definitely reserved for the supervisor DR M.P. Maaga (Ph.D), director of research at the university of North – West, whose help and guidance were most valuable.

## **TABLE OF CONTENTS**

<b>1. Chapter 1: Background and</b>	
<b>Orientation .....</b>	<b>1</b>
<b>2. Chapter 2: Literature Review. ....</b>	<b>8</b>
<b>3. Chapter 3: Methodology and</b>	
<b>Data Gathering Procedures .....</b>	<b>17</b>
<b>4. Chapter 4: Results and Analysis.....</b>	<b>21</b>
<b>5. Chapter 5: Discussions, Conclusion</b>	
<b>and Recommendations.....</b>	<b>30</b>
<b>6. Bibliography.....</b>	<b>38</b>

## **LIST OF APPENDICES**

1. <b>Appendix A:</b> Data Capture Questionnaire.....	<b>41</b>
2. <b>Appendix B:</b> Comparison of Prices between Brand and Generic Medicines .....	<b>46</b>
3. <b>Appendix C:</b> The Medical Council Control List of Non-substitutable medicines.....	<b>47</b>

## **LIST OF TABLES**

1. <b>Table 1:</b> Private Health Care Provider's perceptions about the identity of generic medicines to patent medicines.....	21
2. <b>Table 2:</b> Private Health Care Provider's perceptions about the bioequivalence of generic medicines to patent medicines .....	22
3. <b>Table 3:</b> The rate at which Private Health Care Provider's prescribe generic medicines as their first line of treatment.....	23
4. <b>Table 4:</b> Private Health Care Provider's Awareness with regards to the New Legislation on Generic substitution.....	24
5. <b>Table 5:</b> Patients Awareness and perception about generic medicines.....	25
6. <b>Table 6.1</b> Satisfaction with regards to the safety of generic medicines.....	26
7. <b>Table 6.2:</b> Satisfaction with regards to the quality of generic medicines.....	26
8. <b>Table 6.3</b> Satisfaction with regards to performance characteristics of generic medicines.....	27
9. <b>Table 6.4:</b> Satisfaction with regards to the intended use of generic medicines.....	28
10. <b>Table 6.5:</b> Satisfaction with regards to the route of administration of generic medicines.....	28

## **CHAPTER 1:**

### **BACKGROUND AND ORIENTATION**

#### **1.1 INTRODUCTION**

The right to health care is entrenched in the Constitution of the Republic of South Africa, (Act 108 of 1996), even though that right is limited by the available resources. According to Shisana (2001), South Africa (SA) spends 8.5% of its gross domestic product (GDP) on health care, higher than the 5% recommended by the World Health Organisation (WHO). Seven million people in South Africa are currently served by medical aid schemes. If these consumers were suddenly to use the public health sector, medical aid companies might collapse. Currently the rate of increase of medical aid premiums exceeds the rate of inflation. One of the reasons for the escalating of premiums relates to use, sometimes overuse of very expensive diagnostic equipment and drugs. It is in the best interest of the state to keep the private health sector functional, but costs need to be contained (SAMJ, Dec 2001).

Elliot (2003) stated that the vast majority of people living in developing countries have limited or no access to many medicines that have saved and extended the lives of those in developed countries. The World Health Organisation estimates that a third of the world's population, some 2 billion or more people lack regular access to essential medicines such as penicillin. Between 5 and 6 million people living with HIV/AIDS in developing countries need anti-retroviral medicines now, but only 300,000 get them. In Africa, 1% of the people with HIV get antiretroviral medicines ([www.aidslaw.ca](http://www.aidslaw.ca) access date 12/12/2003).

Taylor (2000) states that year-on-year healthcare inflation that is greater than the consumer price index (CPI) is a grave concern. The author argues that unless managed

carefully, private healthcare insurance will become unaffordable for many people in South Africa. Medscheme ( Medical aid funder ), one of the biggest medical aid schemes in South Africa introduced the Medicine Price List (MPL) comprising of generic medicines as an attempt to contain soaring medical costs and healthcare inflation in the private healthcare without compromising the quality of care members receive (SAMJ, Dec 2000).

All medicines have a chemical name and a brand name. Pharmaceutical companies that develop new medicines have exclusive rights to produce those medicines for 17 to 20 years. After this period, any company can, with the U.S. Food and Drug Administration (FDA)'s approval, manufacture the chemical equivalent of the brand-name medicine (The Generic Dictionary Feb/March 2001).

Generic medicines in general cost less than patent medicines because their manufacturers do not have to set prices to recover expensive research and development cost. The research and development to bring a new compound onto the market in the US is about R6-billion. The bio-equivalent study and testing to develop its generic medicine in South Africa is less than R1-million. Other reasons why generic medicines cost less is that after patent expiry the raw materials are more widely available on world markets and because the original manufacturers no longer have the sole right for selling, there's more competition between producers. Once the FDA approves a generic medicine, it is considered as safe and effective as its brand-name counterpart (The Generic Dictionary Feb/March 2001).

A generic medicine is one that has the same chemical ingredients, strength and formulation, tablet, syrup, capsule and powder as the original product. The Medicine Control Council (MCC) in South Africa checks each medicine for safety and efficacy before it is registered. There may be a slight difference in the rate at which the drug is released into the body after consumption, but the MCC ensures that this variation is within accepted norms. Medicines also contain inactive ingredients, which are used to formulate the active ingredient into a tablet, cream or other preparation. These inactive

ingredients are called excipients and different manufactures do not always use the same ones when formulating their product. As a result medicines containing the same active ingredient, but made by different manufactures may vary in appearance. The excipients used may create small differences between them, such as the amount it takes for a tablet to dissolve in the gut and be absorbed into the bloodstream. These differences are however rarely significant, which is why generic medicines and branded medicines are (with a few exceptions) interchangeable ([www.egagenerics.org](http://www.egagenerics.org), access date 11/24/2003).

In South Africa, the cost of medicines is particularly important considering the dramatic depreciation of the rand versus major currencies. This decline in the country's currency negatively influenced the cost of imported medicines and also the costs of raw materials that are used for the local manufacturing of drugs.

The Medicine Price List (MPL) is a reference pricing system that is based on similar principles as the current Maximum Medical Aid Price (MMAP). The MPL is more inclusive and based on a more realistic pricing system. This preempts pending legislation regarding the Medical and Related Substances Control Amendment Act 90 of 1997, which makes provision for mandatory substitution of generics, albeit in different format. The ultimate objective, is to make healthcare services affordable to most South Africans (The Generic Dictionary May/June 2002).

More stringent rules are also followed in Europe. For generic medicines, like for all pharmaceutical products, pharmaceutical quality is of paramount importance. In order to prove quality, all pharmaceutical companies seeking marketing approval in the European Union (EU) have to comply with stringent rules, including the submission of detailed documents to the component authorities. These documents contain:

- A full composition of the medical product (i.e. active substance and excipients).
- A description of the manufacturing method.
- A description of the control methods employed by the manufacturer.
- Results of pharmaceutical tests on the active substance and the finished products.
- A recent manufacturing license and certificate of Good Manufacturing Practice.



In this way the EU law prevents unethical repetition of extensive experiments on humans and animals, whilst still guaranteeing the same quality, safety and efficacy profile of generic and originator medicines ([www.egagenerics.com](http://www.egagenerics.com), access date 12/12 2003).

According to Gray (2001) medicine prices are one of the key issues determining access to healthcare service, as a result government intervention in most countries is warranted on the basis that medicines are not ordinary articles of trade. Specifically, their demand and supply characteristics do not follow classic market principles. Market forces rarely reflect true social costs and benefits and cannot meet objectives such as equity. The options open to governments that choose to intervene can be characterized in a number of ways. They can either be direct, primary legal measures that have an immediate effect on suppliers or consumers or indirect, usually market-related measures, which entail financial implication for the various actors. They may either target prices themselves or consumption. Resort to price control are more common in developed than in developing countries, even though price sensitivity might be greater in countries with poorer social security systems (Affidavit 4183/98).

The promotion of generic medicines has long been supported by the World Health Organisation (WHO) and it is mentioned in every policy analysis or model policy document produced by that body. While this policy is contested by those with vested interests, it cannot be said to be peculiar to South Africa's approach. The generic promotion policies seek to improve the rationality of medicine prescribing by limiting the use of confusing trade names in both education and practice. The policies also limit the impact of marketing activities by manufacturers without totally denying them the use of the trademark concerned. Further, the policies increase the potential for competition between manufacturers of products considered equivalent ([www.generic-pharmacy.com](http://www.generic-pharmacy.com), access date 11/24/2003)

In 1994 South African government convened a Drug Policy Committee to advise the national department of health on the component parts of a new policy. The drug policy

sought to ensure the availability and accessibility of essential medicines to all citizens. It also aimed at promoting the rational use of drugs and to develop the local pharmaceutical industry and local production of essential drugs (Affidavit 4183/98).

The National Association of Pharmaceutical Manufacturers (NAPM) held South Africa's first generic medicine week in Cape Town on the 23rd June 2003. The main objective of this conference was to inform health care providers and consumers about the new law and the generic medicines industry. NAPM focused on the following:

- Generics ensures access to quality, safety and effective medicines while reducing cost;
- Generics are safe and effective as patent medicines;
- Generics are approved by the Medicines Control Council; and
- Because less money is spend on advertising, research and development, the medicines are affordable and are therefore available to more South Africans (Sapa 2003).

## **1.2 STATEMENT OF THE PROBLEM**

In this study the perceptions and experiences of private health care providers about generic medicines in Mafikeng, North West Province, South Africa was investigated. Section 22F of the Medicine and Related Substances Control Act (Act 101 of 1965) places an obligation on pharmacists or dispensing doctors to inform the patient of generic substitution and the advantages these may have, where possible and applicable.

## **1.3 OBJECTIVE OF THE STUDY**

The main objective of the study is to determine the perceptions and experiences of private health care providers in the Mafikeng area of the North West Province about generic medicines.

#### **1.4 RATIONALE OF THE PROBLEM.**

The introduction of the Medicine Price List comprising of generic medicines by Medscheme and the mandatory generic substitution law has received mixed feelings by most private health providers. Some believe it is the best cost-effective way of controlling high costs of medicines, whilst others disagree. The current rate of medical aid premiums exceeds the rate of inflation. One of the reasons for the escalation of premiums relates to use, sometimes overuse of very expensive diagnostic equipment and medicines. Generic medicines have not been widely used in South Africa unlike in countries like the United State of America. It is in the best interest of the government to keep the private health sector functional, but costs need to be contained. The main focus of this study was to investigate the perceptions and experiences of private doctors about generic medicines in Mafikeng.

#### **1.5 RESEARCH QUESTIONS.**

In order to establish the perceptions and experiences of private health care providers about generic medicines, this study intended to answer the following questions:

- Are generic medicines identical to patent medicines?
- Are generic medicines bioequivalent to patent medicines?
- At what rate are generic medicines prescribed as first line treatment?
- Are private health care providers aware of the mandatory generic substitution?
- Are consumers aware of generic medicines?
- Are private health care providers satisfied with the safety, quality, performance characteristics, intended use and route of administration of generic medicines?

It is hoped that this study will help policy makers in the South African private health care industry in finding better ways to cut the escalating medical costs and to make health care affordable to all citizens of the country.

## **1.6 RESEARCH DESIGN**

The design that was used in this research was a survey. A self administered questionnaire was used. Primary data collection was conducted by using a non-personal method that used a self-administered questionnaire. Fielding (1993) suggests that the use of self-administered structured questionnaires with a small sample of respondents is a more appropriate method in qualitative research.

## **1.7 SAMPLING PROCEDURE.**

Stratified random sampling was used. The sample for this research consisted of private health care providers in the greater Mafikeng area including Mmabatho, Mafikeng. Itso seng and Thusong who also rendered service at Victoria Private Hospital in Mafikeng. The primary reason for selecting these areas was to minimise traveling costs, time and distance.

## **1.8 DATA COLLECTION PROCEDURE.**

The questionnaire was distributed by hand mail to all the health care providers. It was explained to them that they would remain anonymous and that they were not obliged to respond to the questionnaire. Respondents were also informed that the questionnaires will be collected from their respective consulting rooms. The respondents were requested to answer questions to the best of their perceptions and experiences with the use of generic medicines. The questions required one answer, either yes or no, aware or not aware, satisfied, dissatisfied or indifferent. Respondents were also requested to give a brief explanation to some of their answers. Respondents received questionnaires at the same time and all were given one week to complete them. The same people who initially distributed the questionnaires collected them from the respondents' rooms.

## **CHAPTER 2:**

### **LITERATURE REVIEW**

The purpose of this chapter is to reflect the literature reviewed for this study.

The retail growth for major generic markets is forecasted to grow to US\$28.2 billion in 2005, a growth of 51.7%. From the current state of the leading 35 molecules worldwide in US dollars terms, 13 will lose their patent protection over the next five years. Major patent expiries during the period in all major therapy classes are Central Nervous System ( Antidepressants ), Cardiovascular System (Ace Inhibitors ), Alimentary Tract ( Proton Pump Inhibitors ) and the Respiratory System ( Antihistamines ), ([www.egagenics.com](http://www.egagenics.com) access date 29/11/03)

In Europe, governments promote rational prescribing generic interchangeability and emphasis on cost-effectiveness and integrated care. The United Kingdom, with the highest prices in Europe, manages to keep medicine expenditure to about 10% of health care costs. Australia is recognised as the exception, which has managed to both curtail prices and improved the rationality of medicine use ([www.egagenics.com](http://www.egagenics.com) access date 29/11/03).

According to Nightingale (2001) of the generic dictionary, for both the ethical and generic medicines, the Food and Drug Administration (FDA) works with the pharmaceutical companies to assure that all drugs marketed in the United States of America meet specifications for identity, strength, quality, purity and potency. In approving a generic drug, the FDA requires many rigorous tests and procedures to assure that the generic drug is interchangeable with the ethical drug under all approved indications and conditions of use. In addition to tests performed prior to market entry, the FDA regularly assesses the quality of products in the market place and thoroughly



researches and evaluates reports of alleged drug product in equivalence (The Generic Dictionary 2001).

In the European Union (EU) an application for a generic medicine can be made during a patent period but all the development, testing and related work required to make such an application is not allowed according to the current interpretation of the national patent law. As a result, generic medicines can be delayed by around two years, i.e. the time it takes to get market authorization. This results in a loss of around €1 billion per annum, creating dependency on imports, job losses and it puts the EU generic industry at a competitive disadvantage in the world of generic market, which is estimated to reach €38 billion in 2003; more commonly, the development work and the first wave of manufacturing are carried out outside the EU, where Bolar-type provisions exist, and the generic medicines are imported shortly after patent expiry. A “Bolar” provision allows all development, testing and experimental work required for the registration of a generic medicine to take place during the patent period of the original product ([www.egageneric.com](http://www.egageneric.com) access date 29/11/03).

Another obstacle in the EU regarding generic medicines is data exclusivity. This exclusivity guarantees protection for branded pharmaceuticals by preventing health authorities, during a given period, 6 or 10 years, from accepting applications for generic medicines. The effective period of market protection is the given period of data exclusivity plus the period to register and market the generic medicine, i.e. a further two to three years ([www.egagenerics.com](http://www.egagenerics.com) access date 29/11/03).

In South Africa, the situation is slightly different, for example. Aspen Pharmaceutical, the country's largest generic company, was allowed to manufacture Stavudine, an antiretroviral medicine without being sued by the original producer. Aspen also has received voluntary licenses from GlaxoSmithKline to develop generics of AZT and 3TC and Combiver, a combination of the two, as well as voluntary license from Boehringer Ingelheim to produce, distribute and sell Nevirapine. Nevirapine is marketed world wide by Boehringer Ingelheim as Viramune. This will have a positive impact on healthcare in

the country especially when one considers the pandemic of HIV and AIDS and the recent decision by the national government to start a nationwide rollout of antiretroviral medicines in all public health centers. Aspen is also in a position to export Nevarapine to thirteen other countries in the Southern African Development Community (SADC) region, that is Angola, Botswana, Democratic Republic of Congo, Lesotho, Malawi, Mauritius, Mozambique, Namibia, Seychelles, Swaziland, Tanzania, Zambia and Zimbabwe (SA Pharmacist's Assistant 2002).

There are, however still other generic antiretroviral drugs that have been registered in South Africa but cannot be sold legally as this would override the patent protection, a cornerstone of the world trade law. Activist groups such as the Treatment Action Campaign are trying to push the government to issue compulsory licenses which will enable businesses in the country to produce drugs on the basis of a national emergency. In fact, the government has the legal power to seize the patents of vital drugs in situations where companies cannot, or will not, meet demand. Under South Africa's patent act, passed in 1978, the government can ask the patent commissioner to force patent holders to grant licenses to local medicine manufacturers, a process known as compulsory licensing. Despite the high HIV/AIDS toll in South Africa, the government has not yet enacted this enforcement ([file://A:\South Africa,2003](#)).

The South African Treatment Action Campaign has pointed out that the South African law is in fact "TRIPS-plus". This means that it gives stronger protection to intellectual property than the World Trade Organisation (WTO)'s agreement of Trade Related Aspects of Intellectual Property Rights (TRIPS) demands. Both South Africa's Patent Act and the Medicines Act are TRIPS compliant, that is they respect the western drug companies' 20-year patents on essential medicines. WTO TRIPS agreement allows exceptions in cases of "national emergency" or in "circumstances of extreme urgency". In such cases, compulsory licensing is allowed if royalties are paid to the patent-holder. ([file://A:\South Africa,2003](#)).

In August 2003, the World Trade Organisation (WTO) and developed countries agreed to allow flexibility in patent rules in order to make it easy for (some) developing countries to import generic drugs if they lack the ability to produce their own. The Canadian government announced in September 2003 that it would amend patent laws to allow generic pharmaceutical companies to produce and export patent-protected medicines to countries unable to manufacture their own. This initiative received a warm response in Canadian NGO's and international organisations such as the UNICEF. In contrast, the International Federation of Pharmaceutical Manufacturing Association criticised the initiative, saying it was premature and unhelpful ([www.aidslaw.ca](http://www.aidslaw.ca) access date 12/12/2003).

Since the announcement, Canadian civil society organisations have called on the government to ensure that its legislation will fully implement the flexibility reflected in the August 30 WTO decision and therefore will not be limited to exporting generic medicines for only certain diseases and only to countries facing health emergencies. They noted that statements by government officials have only referred to "pandemics" such as HIV/AIDS, tuberculosis and malaria and to helping countries facing "emergencies" ([.../BRIDGES CANADA TO AMEND PATENT ACT, ALLOW GENERIC MEDICINE EXPORTS.ht](http://BRIDGES CANADA TO AMEND PATENT ACT, ALLOW GENERIC MEDICINE EXPORTS.ht)).

The Moroccan association against AIDS (ALCS) denounced the agreement reached on the 30<sup>th</sup> August 2003 at WTO on the importation by poor countries of generic medicines. The association said that the agreement is no solution to the problem of access to medicine. It also argued that the agreement actually imposed a series of complex administrative and legal constraints to developing countries, both importing and exporting ones, in order to protect the interests of the western pharmaceutical industries at the expense of the health of millions of persons in the world ([file://A:Morroccan Anti-Aids association criticizes WTO agreement on generic medicine.htm](http://file://A:Morroccan Anti-Aids association criticizes WTO agreement on generic medicine.htm)).

On the 1<sup>st</sup> April 2002 Medscheme (medical aid funder) in South Africa introduced the Maximum Price List (MPL) with the attempt to establish a cost-effective benchmark



price for prescribed medicines and to offer the best value for money in that particular medicine class. According to Roux (2002), the strategy to contain healthcare costs is based on sound business management principles and the clinical well being of the patients and the financial well being of medical schemes are the primary focus of this strategy. Generic medicines comprised over 50% of all the prescriptions in the United States of America, Canada and Europe, but less than 25% in South Africa by the year 2002 (Medical Chronicles, March 2002).

When doctors prescribe the listed medicines for their patients on Medscheme administered schemes, the scheme pays the full amount. If, however, a doctor chooses to prescribe a more expensive medicine (ethical medicine), the patient will be expected to pay the doctor the difference between the price listed and the higher cost medicine. Medscheme further asserts that no medical practitioner is forced to prescribe in a different way. Should doctors wish to prescribe a medicine that is not on the approved MPL, they are entirely free to do so, but should inform patients on the cost implication (Medical Chronicle, March 2002).

Medscheme implemented even a stricter policy for chronic medication authorisation. The company realised that switching a patient's generic or therapeutic medication requires a telephone discussion between a clinical staff member and a doctor, a time-consuming process which delays medicine authorisation and interrupts doctors who may be busy with other patients. Due to the increase in membership on medical aid schemes administered by Medscheme and to ease the rollout of the MPL, this process was automated. A letter was sent to both doctors and patients informing them which medicine has been recommended. Products with generic alternatives are changed to the most appropriate, cost-effective alternatives available. For example prozac® to deprozan®, generic substitution and imovane® to zopimed®, a therapeutic substitution. In exceptional cases a doctor may motivate the use of an alternative product to that which is recommended by calling the Medi-Serve Motivation Line ([www.medscheme.co.za](http://www.medscheme.co.za) access date 6/24/2002).

GPNet, which represents 2500 doctors in the private practice, was quick to come out against Medscheme's plan. Whilst the association agreed to high prescribing rate of ethical medication, it was concerned that there was insufficient South African pharmaeconomic data and clinical studies to support the quality of South African manufactured generic medicines. The association was also concerned that Medscheme would merely move healthcare costs downstream. If generic medicines failed to work, patients would be referred to specialists and hospitals which are other major cost drivers in the industry. GPNet was also concerned about doctors' integrity. GPNet recommended that there should be an inclusion of an investigation into administration costs, since a significant percentage of healthcare costs is attributed to administration. Prescribing only generics was not the answer to costs savings, particularly for those patients with sensitivity to certain ingredients and for those who were seriously ill and who had no margin for error ([www.insurance-times.net](http://www.insurance-times.net) access 6/24/2002 ).

Generic medicines are also perceived by health professionals as medicines that will not lead the way but will always follow in the 21<sup>st</sup> Century. Diseases largely poorly treated hitherto such as cancers, Parkinson's, Alzheimer's, heart diseases, obesity, auto-immune diseases, psychiatric disorders and viral infections will be effectively targeted by a new generation of drugs based on DNA technology, combination chemistry, molecular design, new-age vaccines and other advanced technologies (SAMJ, Oct 2001) .

Levin ( 2001 ) argues that patients should provide for their own medical needs by contracting with the medical financiers without doctors being involved in these negotiations. Medical schemes must become medical financiers and not managed health care administrators. This is also supported by the fact that managed health care in the United State of America has succumbed to an inevitable death and it is in disarray in South Africa (Medical Chronicles, June 2001).

The South African Medical Association (SAMA), an association representing medical doctors in the private health sector believed that Medscheme action could seriously compromise patient care and doctor's clinical independence. SAMA maintains that the

Department of Health, Medical Control Council, medical aid schemes and administrators and all health care providers should formulate national guidelines on cost-saving strategies (Medical Chronicles, November 2002).

The Pharmaceutical Manufacturer's Association of South Africa (PMA) which represents generic manufacturers also argues that reimbursement prices will simply be set at the cost of the cheapest therapeutic treatment. It is not taken into consideration is that a newer or ethical drug might well keep the patient out of the emergency room or operating theatre where costs could surge ten-fold (SAMJ, Oct 2001).

Jardine (2001) states that evidence is accumulating that generic substitution of arrhythmic drugs can result in deterioration through recurrence of arrhythmia, pro-arrhythmia and death. The Cardiac Arrhythmia Society of Southern Africa, a special group of the South Africa Heart Association, therefore contends that anti-arrhythmic drugs should not be substituted by generic preparations, because of the life-threatening nature of ventricular tachyarrhythmia's, the narrow therapeutic index of the drugs concerned, and the lack of any clinical efficacy data on the generic (SAMJ, Oct 2001).

Haylene (2001) based his agreement to the use of generics on the study of two formulations ( innovator vs. generic ) of beclamethasone dipropionate 400ug twice daily administered per metered dose inhaler, in adults with moderate to severe asthma, which showed that the drugs were therapeutically equivalent (SAMJ, Jan 2001).

On the 2 May 2003, an amendment to Section 22F of the Medicines and Related Substances Control Act (Act 101 of 1965) came into effect in South Africa. This Act does not necessarily enforce generic substitution, but the dispensing pharmacist or dispensing doctor is obliged to inform the patient of the generic substitutes and the advantages these may have, where possible and applicable. The Act also determines that the ethical product should be provided if the following conditions are met;

- The prescribing doctor indicates in his or her own handwriting on the prescription that the original agent should not be substituted by a generic equivalent.

- The patient prefers to use the ethical product and indicates in his or her handwriting on the prescription that he or she has been thoroughly informed on the advantages of generic substitution, but still refuses it.
- The product appears on the list not be substituted. This list is provided by the South African Medicines Control Council.

If the retail price of the generic medicine is higher than that of the ethical medicine (SA Pharmacist's Assistant, Nov/Dec 2002)

Since this Act came into effect, the price of some brand medicines has dropped sharply. According to Bodhanian (2003), one company had put an annual increase of about 20% on the price of its original product, unaware that a generic had just been registered. When the generic was launched, it came in at about 50% of the price of the brand product. In response, the original supplier dropped its price to 10% below the generic price. Bodhanian expects the use of generics to double over the next few years (Keeton C.2003).

In the United Kingdom, pharmacists are obliged by law to dispense whatever the doctor has written on the prescription. If the doctor has prescribed a medicine by its brand name, the pharmacist must dispense that brand. However, if a medicine has been prescribed by its generic name, the pharmacist can dispense whatever version of the medicine is available, because each version will have the same therapeutic effect. For this reason regular medicine may vary in appearance each time a prescription is renewed. There are a few exceptions to this. There are a handful of medicines that the doctor must prescribe by the brand name. These include:

- Modified-release theophylline for asthma.
  - Modified-release aminophylline for asthma.
  - Modified-release diltiazem for angina and high blood pressure.
  - Modified-release nifedipine for angina and high blood pressure.
  - Cyclosporine, which is an immunosuppressant.
  - Lithium, which is a mood stabilizer for manic depression.
  - Carbamazepine, phenytoin and sodium valproate for epilepsy
- ([www.netdoctor.co.uk](http://www.netdoctor.co.uk) access date 29/11/03).



If a patient takes any of the above medicines it is important that he or she takes the same brand because different brands of these medicines may differ significantly in the way they are absorbed. If a different brand than usual is taken, the blood levels of the active ingredient could stray outside the required therapeutic range. If the amount in the blood becomes low, the effect of the medicine may be lost; if the amount in the blood level becomes too high, there may increase the chances of side effects ([www.netdoctor.co.uk](http://www.netdoctor.co.uk) access date 29/11/03).

In South Africa medical aid fees are expected to increase by 12% to 13% in the year 2004, according to the annual survey of the Board of Healthcare Funders (BHF). Open schemes will go up by 12.5% and restricted schemes by 12.9%. The increases are lower than in the previous years, but are still more than double the rate of inflation. The increases are driven by medical inflation, reserve- building, benefit enhancement and an ageing population. These four factors account for 80% of the increase. Meanwhile, the Council for Medical Schemes has recommended a 4.9% increase in what medical aids will cover for visits to doctors (Shevel A. 2003).

According to the SAMA the average annual increases in the payments to health providers have been less than 10% while medical aids have been lifting their rates by 15% or more. The increases are going towards brokers and administration fees. Reserve building is a problem for many medical aid schemes. Although the industry's reserve level has improved, it still falls short of the minimum requirement of 22.5% of the total premiums in 2003 and this figure was expected to jump to 25% in 2004 (Shevel A, 2003).

The BHF argues that several changes are needed before any significant reduction in the rate of annual increases is seen. These include regulation of the private hospital sector, creating alternative reimbursement models, altering consumer and provider behaviour and regulatory support for the medical scheme funding environment (Shevel A, 2003).

This chapter dealt with the different views regarding generic medicines and patent medicines. The next chapter deals with the methodology used in the study.

## **CHAPTER 3**

### **METHODOLOGY AND DATA GATHERING PROCEDURES**

#### **3.1 STATEMENT OF THE PROBLEM**

In this study the perceptions and experiences of private health care providers about generic medicines in Mafikeng, North West Province, South Africa was investigated. Section 22F of the Medicine and Related Substances Control Act (Act 101 of 1965) places an obligation on pharmacists or dispensing doctors to inform the patient of generic substitution and the advantages these may have, where possible and applicable.

#### **3.2 OBJECTIVE OF THE STUDY**

The main objective of the study is to determine the perceptions and experiences of private health care providers in the Mafikeng area of the North West Province about generic medicines.

#### **3.3 RATIONALE OF THE PROBLEM.**

The introduction of the Medicine Price List comprising of generic medicines by Medscheme and the mandatory generic substitution law has received mixed feelings by most private health providers. Some believe it is the best cost-effective way of controlling high costs of medicines, whilst others disagree. The current rate of medical aid premiums exceeds the rate of inflation. One of the reasons for the escalation of premiums relates to use, sometimes overuse of very expensive diagnostic equipment and medicines. Generic medicines have not been widely used in South Africa unlike in countries like the United State of America. It is in the best interest of the government to keep the private health sector functional, but costs need to be contained. The main focus of this study was to

investigate the perceptions and experiences of private doctors about generic medicines in Mafikeng.

### **3.4 RESEARCH QUESTIONS.**

In order to establish the perceptions and experiences of private health care providers about generic medicines, this study intended to answer the following questions:

- Are generic medicines identical to patent medicines?
- Are generic medicines bioequivalent to patent medicines?
- At what rate are generic medicines prescribed as first line treatment?
- Are private health care providers aware of the mandatory generic substitution?
- Are consumers aware of generic medicines?
- Are private health care providers satisfied with the safety, quality, performance characteristics, intended use and route of administration of generic medicines?

It is hoped that this study will help policy makers in the South African private health care industry in finding better ways to cut the escalating medical costs and to make health care affordable to all citizens of the country.

### **3.5 RESEARCH DESIGN**

The design that was used in this research was a survey. A self administered questionnaire was used. Primary data collection was conducted by using a non-personal method that used a self-administered questionnaire. Fielding (1993) suggests that the use of self-administered structured questionnaires with small sample of respondents is a more appropriate method in qualitative research method.

### **3.6 SAMPLING PROCEDURE.**

A simple random sampling was used. The sample for this research consisted of private health care providers in the greater Mafikeng area including Mmabatho, Mafikeng, Itsoseng and Thusong who also rendered service at Victoria Private Hospital in Mafikeng. The primary reason for selecting these areas was to minimise traveling costs, time and distance.

### **3.7 DATA COLLECTION PROCEDURE.**

The questionnaire was distributed by hand mail to all the health care providers. It was explained to them that they would remain anonymous and that they were not obliged to respond to the questionnaire. Respondents were also informed that the questionnaires will be collected from their respective consulting rooms. The respondents were requested to answer questions to the best of their perceptions and experiences with the use of generic medicines. The questions required one answer, either yes or no, aware or not aware, satisfied, dissatisfied or indifferent. Respondents were also requested to give a brief explanation to some of their answers. Respondents received questionnaires at the same time and all were given one week to complete them. The same people who initially distributed the questionnaires collected them from the respondents' rooms.

### **3.9 ORGANIZATION OF THE STUDY**

This study is organised into five chapters. Chapter One presents a brief socio-historical background of private health care cost in South Africa and elsewhere in the world. This chapter also focuses on the requirements of manufacturing generic medicines, their safety and efficacy before they are registered.

Chapter Two is the review of literature that focused on patent medicines and patent law both in South Africa and in other countries. The chapter also focuses on the views of different healthcare organisation regarding the mandatory generic substitution in South Africa.



Chapter Three describes the research design, methodology and procedures used in the study.

Chapter Four provides results and analysis of the data obtained through a non-personal self-administered questionnaire.

Chapter Five is the conclusion of the study. It provides discussions, conclusions and recommendations flowing from the research findings, and the implications for future research.

## **CHAPTER 4**

### **RESULTS AND ANALYSIS**

The respondents comprised of private health care providers who rendered service at Victoria Hospital in Mafikeng. They were medical general practitioners, medical specialists and dentists. Their age ranged between 26 and 51. Twenty five of the respondents were male and eight were female. The majority of the respondents had their private practices in Mafikeng.

Copies of the questionnaires were sent to forty (40) private health providers and thirty three (33) questionnaires were completed; thirty two (32) questionnaires were correctly completed and one (1) questionnaire was incorrectly completed and was not included in the final analysis. Seven (7) questionnaires were returned without being completed.

**Table 1: Private Health Care Provider's perception about the identity of generic medicines and patent medicines.**

**Are generic medicines identical to patent medicines?**

	<b>YES</b>	<b>NO</b>	<b>TOTAL</b>
<b>Medical Pr</b>	12	6	18
<b>Specialist Pr</b>	6	6	12
<b>Dentist</b>	1	1	2
<b>TOTAL</b>	19 59%	13 41%	32 100%

Table 1 shows that 59% of the respondents perceived generic medicines as identical to patent medicines with regard to their biochemical formulae and their quality as well as their clinical outcome. Forty one (41%) of the respondents perceived generic medicines

not to be identical to patent medicines because of poor quality and their differences in the pharmacokinetics.

**Table 2. Private Health Care Provider's perception about the bioequivalence of generic medicines and patent medicines.**

**Are generic medicines bioequivalence of patent medicines?**

	YES	NO	TOTAL
<b>Medical Pr</b>	11	7	18
<b>Specialist Pr</b>	7	5	12
<b>Dentist</b>	2	0	2
<b>TOTAL</b>	20 63%	12 38%	32 100%

Table 2 shows that twenty (63%) of the respondents perceived generic medicines to be bioequivalent to patent medicines for two reasons. These were:

- They have the same molecular structure and the same mechanism of action.
- They have the same efficacy and quality.

The participants who regarded generic medicines not bioequivalent to patent medicines made up 38%. Their reasons were:

- Generic medicines were less potent.
- The manufacturing processes were different.
- Their half life ( $t_{1/2}$ ) was also different.

**Table 3. The rate at which private health care providers prescribe generic medicines as first line treatment.**

**Do you prescribe generic medicines as your first line of treatment?**

	<b>YES</b>	<b>NO</b>	<b>TOTAL</b>
<b>Medical Pr</b>	15	3	18
<b>Specialist Pr</b>	3	9	12
<b>Dentist</b>	1	1	2
<b>TOTAL</b>	19 <b>59.38%</b>	13 <b>40.63%</b>	32 <b>100%</b>

Table 3 shows that nineteen (59%) of the respondents prescribed generic medicines as their first line of treatment because they were cheaper than patent medicines and were readily available. Twelve of this 59% indicated that they were also restricted by the medical aid schemes and the legislation to prescribe generic medicines as their first line of treatment. This is also confirmed by the fact that the majority believed that prescribing generics more often than patent medicines would help in lowering the cost of health care in South Africa.

Thirteen (41%) of respondents indicated that they do not prescribe generic medicines as their first line of treatment. Their reasons included:

- Generic medicines were less potent and inefficient than patent medicines.
- They have experienced poor clinical outcome in most cases in the past.
- This poor response lead to repeated visits to the doctor and in some cases even hospitalisation.

It is interesting to note that the nine out of twelve specialists in this study stated that they did not prescribe generic medicines as their first line of treatment for the same reasons given above.

**Table 4. Private Health Care Providers Awareness with regards to the New Legislation on Generic Medicines.**

	<b>AWARE</b>	<b>NOT AWARE</b>	<b>TOTAL</b>
<b>Medical Pr</b>	16	2	18
<b>Specialist Pr</b>	8	4	12
<b>Dentist</b>	2	0	2
<b>TOTAL</b>	26 <b>81.25%</b>	6 <b>18.75%</b>	32 <b>100%</b>

Table 4 shows that 81% of the respondents were aware of the new legislation on generic medicines, i.e. the amendment of section 22F of the Medicine and Related Substances Act (Act 101 of 1965). Only six (18.75%) of the respondents were not aware of this amendment.

The majority of respondents (94%) indicated that they did not write “no substitution” on the scripts to the pharmacist when a patent medicine was prescribed even though mandated by the act to do so. This means that the responsibility of finally deciding what medicine to dispense was left entirely to the pharmacist and the patient. Another reason could be that the majority of the respondents prescribed generic medicines as their first line of treatment.

The respondents who prescribed generic medicines as their first line of treatment perceived this new amendment of section 22F of the act to interfere with doctors’ autonomy to prescribe. Respondents also felt that the government wants to dictate terms for them even though they are qualified to dispense.

**Table 5. Patient awareness and perception about generic medicines.**

	<b>AWARE</b>	<b>NOT AWARE</b>	<b>TOTAL</b>
<b>Medical Pr</b>	3	15	18
<b>Specialist Pr</b>	2	10	12
<b>Dentist</b>	0	2	2
<b>TOTAL</b>	5 15.63%	27 84.38%	32 100%

Table 5 reflects that twenty seven (84%) respondents believed that patients were not well informed about generic medicines. They were not aware of the benefits of using generic medicines. The majority of patients did not even ask for generic medicines. They were happy with whatever the doctor prescribes for them as long as they get well. This was supported by the fact that patients were willing to use generic medicines without questioning their doctors. Even though the majority of patients are willing to use generic medicines, they regarded them to be of inferior quality when told about their price.

Five (15.63%) respondents believed that patients were well informed about generic medicines. These were patients who are educated and cost conscious.

**Table 6.1 Satisfaction with regards to the safety of generic medicines.**

	<b>SATISFIED</b>	<b>DISSATISFIED</b>	<b>INDIFFERENT</b>	<b>TOTAL</b>
<b>Medical Pr</b>	15	1	2	18
<b>Specialist Pr</b>	7	2	3	12
<b>Dentist</b>	2	0	0	2
<b>TOTAL</b>	24 75%	3 9.38%	5 15.63%	32 100%

In table 6.1 twenty four (75%) of the respondents were satisfied with the safety of generic medicines. About fifteen percent were indifferent and only nine percent were dissatisfied. The reason given by those who were dissatisfied was that they had poor previous clinical response with generic medicines.

**Table6.2 Satisfaction with regards to the Quality of Generic Medicines**

	<b>SATISFIED</b>	<b>DISSATISFIED</b>	<b>INDIFFERENT</b>	<b>TOTAL</b>
<b>Medical Pr</b>	9	3	6	18
<b>Specialist Pr</b>	5	4	3	12
<b>Dentist</b>	2	0	0	2
<b>TOTAL</b>	16 50%	7 21.88%	9 28.13%	32 100%

Table 6.2 shows that sixteen (50%) of the respondents were satisfied with the quality of generic medicines. This figure is low when one considers that the majority of respondents in this study indicated that they prescribe generic medicines as their first line of treatment. It could be that they do so because of the new generic legislation.



Nine (28%) of the respondents were indifferent with the quality of generic medicines. Seven (21%) of the respondents were dissatisfied with the quality of generic medicines. The reason for this dissatisfaction was that they perceived generic medicines to be poor in their quality and showed an increase in side effects.

**Table 6.3 Satisfaction with regards to performance characteristics of generic medicines.**

	<b>SATISFIED</b>	<b>DISSATISFIED</b>	<b>INDIFFERENT</b>	<b>TOTAL</b>
<b>Medical Pr</b>	10	1	7	18
<b>Specialist Pr</b>	7	2	3	12
<b>Dentist</b>	2	0	0	2
<b>TOTAL</b>	19 <b>59.38%</b>	3 <b>9.38%</b>	10 <b>31.25%</b>	32 <b>100%</b>

The data reflected in Table 6.3 shows that nineteen (59.38%) of the respondents were satisfied with the performance characteristics of generic medicines and ten (31.25%) were indifferent. Three (9.38%) of the respondents were dissatisfied with the performance characteristics of generic medicines. However, no reason was given for this.



**Table 6.4 Satisfaction with regards to the Intended Use of Generic Medicines.**

	<b>SATISFIED</b>	<b>DISSATISFIED</b>	<b>INDIFFERENT</b>	<b>TOTAL</b>
<b>Medical Pr</b>	12	0	6	18
<b>Specialist Pr</b>	8	2	2	12
<b>Dentist</b>	2	0	0	2
<b>TOTAL</b>	22 <b>68.75%</b>	2 <b>6.25%</b>	8 <b>25%</b>	32 <b>100%</b>

Table 6.4 reflects that twenty two (68.75%) of the respondents were satisfied with the intended use of generic medicines and eight respondents (25%) were indifferent. One (6%) respondent was dissatisfied with the intended use of generic medicines. No reason was given for this perception.

**Table 6.5 Satisfaction with regards to the route of administration of generic medicines.**

	<b>SATISFIED</b>	<b>DISSATISFIED</b>	<b>INDIFFERENT</b>	<b>TOTAL</b>
<b>Medical Pr</b>	16	0	2	18
<b>Specialist Pr</b>	9	1	2	12
<b>Dentist</b>	2	0	0	2
<b>TOTAL</b>	27 <b>84.38%</b>	1 <b>3.13%</b>	4 <b>12.50%</b>	32 <b>100%</b>

Table 6.5 shows that twenty seven (84.38%) of respondents were satisfied with the route of administration of generic medicines. This could be that a patent tablet form normally will have a generic tablet form, making the route of administration of both types of medicine the same. Four (12.5%) of the respondents were indifferent with the route of administration of generic medicines. One (3%) respondent was dissatisfied with the route

of administration of generic medicines. The recurrent occurrence of side effects was the reason for the dissatisfaction.

This chapter dealt with the results and analysis obtained from the respondents. The next chapter emphasizes on discussions, conclusion and recommendation for the study.

## **CHAPTER 5:**

### **DISCUSSIONS, CONCLUSION AND RECOMMENDATIONS**

The survey results of this study suggest that on average the private health care providers perceive generic medicines and patent medicines to be identical and bioequivalent. Fifty nine percent (59%) of private health care providers in the study perceived generics to be identical to patent medicines. Sixty three percent (63%) perceived generics to be bioequivalent to patent medicines. These figures suggest that there is still insufficient South African pharmaeconomic data and clinical studies to support the quality of South African manufactured generic medicines. The same sentiments were raised by GPNet when Medscheme announced the implementation of the Maximum Price List in 2002 ([www.insurance-times.net](http://www.insurance-times.net) access date 6/24/2002).

According to the study, on average (59.38%) private health care providers prescribe generic medicines as their first line of treatment. This figure is higher than the one suggested by the National Association of Pharmaceutical Manufacturers, which is 20%. It is interesting to note that the nine specialist practitioners in this study indicated that they did not prescribe generic medicines as their first line of treatment. Their main reason is that of previous poor clinical outcome that lead to repeated visits and in some cases even hospitalisation. The respondents felt that prescribing generic medicines was not the only answer to cost saving particularly for those patients with sensitivity to certain ingredients and for those who are seriously ill and who have no margin of error. This could mean that in cases where specialist intervention is necessary the cost of medicine could increase even more. There is a need for a wider use of generic medicines in the private sector in order to lower the cost of healthcare.

According to the National Association of Pharmaceutical Manufacturers (NAPM), South Africa still lags behind in its use of generic medicines. Generic medicines account for almost 52% of the volume of all prescriptions, whereas this figure is as low as 20% in South Africa. The organisation believes that the wider use of generic medicines could

save the country around R24-billion per year. It also believes that there is still a role for patented medicines that can provide patients with the latest technology to cure disease and eliminate the need for costly surgery and hospitalization. "The patented medicines of today and tomorrow are our generics of the future" (<http://www.southafrica.info/public-services/citizens/health/genericdrugs.htm>).

The chairman of NAPM, Muhammad Bodhanyia also emphasized the importance of the increased use of generic medicines. He said that although the use of generic medicines has recently increased in volume terms, 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 medicine has increased substantially more than that. Cost containment is still and will remain number one priority of the managed healthcare industry. There are many approaches to this challenge and one of them is to regulate the medical scheme industry. The premium increase in the medical aid schemes goes mainly to administrators, brokers and reserves. The medical aid schemes often claim they are required to provide prescribed minimum benefits and build reserves, but less than 2% of contributions goes into reserves ([www.napm.co.za](http://www.napm.co.za), access date 29/11/03).

There is also a need for some legislative change to speed up the process of manufacturing generics in order to make them accessible and available to consumers. According to NAPM, the "uninhibited" extension of patents delays the production of generics and manufacturers of generic medicines need to provide samples of their generics for registration to the MCC. However, manufacturers are unable to do so because of patent protection over the original medicines. This results from when the patent expires and when the generics become available.

Banoo (2003) states that measures to ensure availability of generic medicines should include the following;

- Generic drug policy, based on safety, quality and efficacy.
- Expedited registration of essential drug list.
- Expedited registration of generic drugs and others approved by the Minister.

- Five year re-licensing system for all products before expiration of patent.

Banoo (2003) cited measures to ensure effective utilization of generic medicines to include the following:

- Essential Drug List programme.
- Generic prescribing in the public sector.
- Limited prescription privileges to other healthcare professionals.
- Licensing of dispensers.
- Generic substitution by pharmacists.

According to Banoo (2003) measures to ensure efficient financing of generic medicines to include the following:

- International tendering under prescribed conditions.
- Compulsory licensing
- Parallel importation
- Pricing committee which should include transparent pricing system distribution and dispensing fees (Banoo S, 2003)

The European Generic Medicines Association perceived the following as important measures to stimulate generic medicines:

**Supportive legislation and regulation to include the following:**

- Abbreviated registration procedures (focusing on drug quality).
- Product development and authorisation during patent period (Bolar).
- Provisions which permit, encourage or require generic prescription or substitution.
- Requirement that labels and drug information be made available on generic medicines.

**Quality assurance capacity:**

- Development of substitution, non-substitution lists.
- Procedures to demonstrate bioequivalence.
- National quality assurance capability.
- National drug manufacturing and drug outlet inspection capability.

**Public and Professional acceptance:**

- Required use of generic names in all education and training of health professionals.
- Brand-generic and generic-brand name indexes to be made available to health professionals.
- Required use of generic names in clinical manuals, drug bullets and other publications.
- Widespread promotional campaigns targeting consumers and professionals.

**Economic factors:**

- Public and professional price information
- Reference pricing for reimbursement programmes.
- Retail price controls that favour generic dispensing.
- Support by social and private health insurance organizations([www.egageneric.com](http://www.egageneric.com))

The survey results suggest that the majority of private health care providers (81.25%) are aware of the new legislation on generic medicines that makes it compulsory for pharmacist to offer patients generic medicines (apart from exceptions listed by the Medicines Control Council) and if substitution takes place, to inform the doctor. The study also revealed that the majority of health care providers, however do not write “no substitution” on the scripts when a patent medicine is prescribed. They leave this responsibility to the dispensing pharmacist and the patient. The prescribing doctors need to be encouraged to comply fully with the requirements of the dispensing law in order to make life easy for both the dispensing pharmacist and the patient. It will help eliminate unnecessary phone calls to the doctor who at that time may be busy with other patients.

According to the survey, nineteen (59.38%) of respondents perceived the new legislation on generic medicines to interfere with the doctors’ autonomy to prescribe. Many felt that the government wanted to dictate terms for them even though they were qualified to dispense medicines. They believe that the continuing medical education (CME) that have



been recommended by the Health Professional Council of South Africa are adequate to keep doctors abreast with the latest technology and new medicines in the market. The National Convention on Dispensing and the South African Medical Association are currently continuing the constitutional challenge against the requirement that dispensing doctors should obtain a licence on the basis set out in the Medicines and Related Substances Control Act, No 101 of 1965 and the relevant regulations as promulgated. The main challenge relates to the fact that certain provisions in Act 101 of 1965 and the regulations relating to the licensing of dispensing doctors are considered to be unconstitutional. The act and regulations allow the director-general of the department of health to determine at his discretion whether a licence is to be granted, based upon facts which are not objectively ascertainable and also upon the proximity of other licensed health facilities in the vicinity of the premises from where the dispensing is to be carried out. Various legal developments have followed, characterized by postponements and lack of clarity on a number of issues, notably the supplementary course in pharmacy that medical practitioners are required to undertake and whether applications for licenses could be lodged prior to the completion of the said course (Medical Chronicle, Nov 2003).

The results of the study also suggest that the respondents felt that the majority of patients who use private health care services were not well informed about generic medicines. As a result, they did not ask for generics when given prescriptions. One can assume that the majority of patients still have faith in their doctors that is why they do not question them when it comes to prescribing. Another factor that was evident in the study was that patients perceived generic medicines to be of inferior quality when told about their low price.

An extensive consumer education is very important in order to improve and increase the use of generic medicines in South Africa both in the public and private sector. Patients need to be educated about the value of what they are buying. Kearney (2003) states that healthcare is an investment in the future, and need more public debate around the value of modern medicine and the costs involved in researching, developing and bringing new

drugs to the market- to ensure more informed consumers. Medical aid schemes need to work with employers in this regard and have meetings scheduled to discuss ways of doing this. The involvement of all stakeholders in the promotion of generic medicines is very important and the patient who is the most important stakeholder on this matter needs to be more involved and well informed (Medical Chronicle, Nov 2003).

Gray (1998) regards one of the defining characteristics of modern medical practice as that which has had gradual movement away from paternalistic practices to the notion of “your doctor knows best”; and to practices that more fully acknowledged and protected the right of patient autonomy. The measure, as included in the Act, involves all stakeholders including the patient in the decision making. Crucially, for the first time the act acknowledges the right of the patient to have a say in the matter. The right to participate in decision about one’s own health and health care is a human right. This right has been increasingly recognised in South African law, not least in the Choice on Termination of Pregnancy Act of 1996 (Affidavit, 4183/98).

In essence, the mandatory offer of generic substitution ensures the maximal involvement of all parties in making a drug choice and implicitly recognises patients’ right to choice. However, as has already been indicated a lot of consumer education needs to be urgently addressed in order to have positive results in this matter. Empowering pharmacists and doctors with accurate information about generics will certainly be a major step in the right direction.

Medical aid schemes also have an important part to play in this matter. Discovery Medical Aid Scheme has a programme called Vitality whose main objective is to make the patient a much more active and informed participant. It aims to get patients involved with their own health in every way they can. The programme also allows doctors and patients to work closely together, which can only lead to better results. The same sentiments were raised by the NAPM, when they held South Africa’s first generic week in Cape Town in June 2003 to inform consumers and health practitioners about the benefits of using generics more often than patent medicines. Patients need to know the



generic and patent names of the medicine they are taking. They also need to know the active ingredients and the dosages of the ingredients in the specific medication. Patients should also be encouraged to enquire about the proper use, that is, indications and contra indications, the instructions for optimal use, and must be informed of the warnings and precautions that are associated with the specific product. These steps could be achieved by making information available to patients in a manner that will make it easier for them to understand, for example, the use of indigenous languages and non scientific words.

In the study the majority of the private health providers were satisfied with the safety, quality, performance characteristics, intended use and route of administration of generic medicines. These are the requirements in line with the Medicines Control Council and the Food and Drug Administration that checks the safety and efficacy of the generic medicine before it is registered. The MCC beliefs that the South Africa's safety standards are in line with the world's best and the council has applied to become a member of the Pharmaceutical Inspection Convention. If accepted, South Africa will be one of a few developing countries with membership.

## **CONCLUSION**

The results of the study suggest that on average private health care providers are prescribing generic medicines as recommended in the mandatory generic substitution law. The wider use of generic medicines in both the private and public health sector will assist to contain the high cost of medicines and more people will eventually have access to health care.

## **RECOMMENDATIONS**

The following suggestions could help in containment of healthcare cost and making healthcare services affordable to all South Africans:

- An essential drug list that will be used by all medical aid schemes in South Africa.
- Generic prescribing in both the public and private health sector should be encouraged.
- Speeding up the process of manufacturing generics in South Africa is essential.

- Health care providers should comply fully with the mandatory generic substitution law.
- Parallel importation of generic medicines when a need arise should be the norm.
- Widespread promotional campaigns targeting consumers and professionals is essential.

There are certain inherent limitations about this study. These results should therefore be interpreted with such limitations in mind.

- The study has a geographic limitation and private health care providers in other regions may have different perceptions and experiences
- The number of private health care providers who participated in this study was small and their perceptions and experiences are not likely to reflect a national picture.
- Perceptions and experiences are variables that are not constant and are likely to change with time and as a result of other micro and macro-economic factors.

It is evident that although most private health providers perceive the use of generic medicines to be cost-effective, a lot of widespread promotional campaigns still have to be done targeting both the consumers and the professionals. There is therefore a need for more research to assess ways in which all stakeholders can work together to contain the increasing cost of health care in South Africa.

## **BIBLIOGRAPHY.**

Banoo S, 2003, Promoting Access To Generic Medicines: The South African Experience, Generic Drugs Consultative Group meeting, Washington.

Branded and Generic medicines, "Medicines",  
<http://www.netdoctor.co.uk/medicines/facts/brand-generic.htm>, 29/11/03.

Bridges Weekly Trade News Digest, "Canada to amend Patent Act, allow generic medicine export", Vol.7. No. 34, 15 October 2003, ... \BRIDGES CANADA TO AMEND PATENT ACT, ALLOW GENERIC MEDICINE EXPORT.ht

Dis-chem Discount Pharmacies, <http://www.dischem.co.za> 29/11/03.

Dixon N, 2003, "South Africa: Mbeki puts 'investor confidence' above lives",  
<file://A:\SOUTH AFRICA MBEKI puts 'investors confidence' above lives.htm> 12/2/2003.

Elliot R, "Protecting global health & human rights" Canadian HIV/AIDS Legal Network, October 2003, [www.aidslaw.ca](http://www.aidslaw.ca) 12/2/2003.

European Generic medicine Association, "Bolar- Making thr EU Generic Medicines Industry Competitive", [www.egagenecircs.com](http://www.egagenecircs.com) , 24/11/03.

Gray A. 1998, In The High Court of South Africa, Case no:4183/98, An Affidavit, 12/12/2003.

Generics make medicines more accessible to the average consumer,  
<http://www.napm.co.za/newsrelease.htm> 29/11/03.

Goodman M, 2003, "Changing the script", Discovery Health Partner, issue 3. 2003, pp 8-9.

Haylene N, 2001, "Therapeutic Equivalence Study of two formulations (Innovators vs. Generics) of Beclomethasone Dipropiates in Adult Asthma", SAMJ, Jan 2001, Vol. 91. No 1, pp 51-56.

Jardine R.M, 2001, "Generic Substitution of Anti-Arrhythmic Drugs, SAMJ, Oct 2001, Vol. 91, No. 10, pp 785.

Keeton C, 2003, " Branded vs. Generics, The changing face of medicine", Sunday Times Business times, 6 July 2003, pp 5.

List of Non-Substitutable Medicines, MCC Circular No: 16/94, Pharmaciae, May 2003. Vol 11, No 2, pp 22.

Levin A.M, "Crippling the Medical Body", Medical Chronicle, June 2003, pp 39.

Medical Chronicle, Editorial, "Doctors react to Medscheme pricing list", March 2002, pp1

Medical Chronicle, Editorial, "Dispensing Doctors Pursue constitutional Challenge Against Licensing Requirements" November 2003, pp3.

Medical Costs –Doctors gripe about Medscheme's strategy, [http:// www.insurance-times.net/Editorials/2002/April2002/medical\\_costs\\_.htm](http://www.insurance-times.net/Editorials/2002/April2002/medical_costs_.htm) 6/24/2002

Medical Schemes Drug strategy to reduce costs, <http://www.insurance-times.net/Editorials/2002/April2002/medical-schemes-.htm> 6/24/2002.

Morrocan Anti-AIDS association, Morocco- Regional, Politics, 9/10/2003.

Push for more generic medicines-South Africa, [www.southafrica.info/public-services/citizens/health/genericdrugs.htm](http://www.southafrica.info/public-services/citizens/health/genericdrugs.htm), 29/11/03.

Reaction to Medicine Pricing Strategy,  
[www.medscheme.co.za/GoodPractice/GoodPracticeApril2002/Improved.htm](http://www.medscheme.co.za/GoodPractice/GoodPracticeApril2002/Improved.htm), 6/24/2002.

SA's first generic week informs consumers, practitioners, Sapa,  
<http://www.doh.gov.za/docs/news/2003/nz0623.html> 2/29/2004.

SA Pharmacist's Assistant, Editorials, "Boehringer Ingelheim grants a voluntary license for nevirapine to South Africa company Aspen Pharmacare", Vol 2, No 6, November/December 2002, pp16.

Shevel A. "Medical aid rates to gallop ahead of inflation", Sunday Times Business Times, 14 December 2003, pp1

Shisana O, "Health Insurance and Tax based Funding of Health", SAMJ, Dec 2001, Vol 19 No 12, pp 1048,1051.

Taylor B, Ramsey G, "Drug costs and costly drugs- a way forward" SAMJ, Dec 2000, Vol 90, pp 1202- 1203.

**Appendix A.**

**Data Research Questionnaire**

**Researcher:** DR P.E.K. SEODI, Bsc Ed (Unibo), MB.ChB (Medunsa)

**The perception and experiences of private health care providers about generic medicines- a Mafikeng case study (North- West Province).**

Dear respondent

Thank you for taking time to answer the following questions. The purpose of this study is to determine the perceptions and experiences of private health care providers about generic medicines. It is hoped that the results of this study will assist policy makers in the health industry to develop policies that are all inclusive and make health care accessible and affordable to all in South Africa.

Please note that you are not obliged to answer this questionnaire. If you answer the questionnaire you will remain anonymous. You are also requested to answer the questions to the best of your ability. The questions will require yes or no, satisfied, dissatisfied or indifferent. In some questions you will be requested to give a brief explanation. The questionnaire will be collected from your rooms.

Yours truly,

DR P.E.K. SEODI



## **DATA CAPTURE QUESTIONNAIRE**

### **The perception of private health care providers about generic medicines in Mafikeng (North-West Province)**

#### **SECTION 1. Profile of Respondents**

Please select the applicable

1. Age

- 1.1 26 – 30 \_\_\_\_\_
- 1.2 31 – 35 \_\_\_\_\_
- 1.3 36 – 40 \_\_\_\_\_
- 1.4 41 – 45 \_\_\_\_\_
- 1.5 46 – 50 \_\_\_\_\_
- 1.6 51 and above \_\_\_\_\_

2. Gender

- Male \_\_\_\_\_
- Female \_\_\_\_\_

3. Practice Location

- Mafikeng \_\_\_\_\_
- Itsoseng \_\_\_\_\_
- Zeerust \_\_\_\_\_
- Lichtenburg \_\_\_\_\_
- Other (specify) \_\_\_\_\_

4. Education Level ( mark the applicable)

- 4.1 First degree \_\_\_\_\_  
4.2 Second degree \_\_\_\_\_  
4.3 Specialist degree \_\_\_\_\_

5. Occupation /Profession (mark the applicable)

- 5.1 Medical General Practitioner (private) \_\_\_\_\_  
5.2 Medical Specialist (private) \_\_\_\_\_  
5.3 Dentist (private) \_\_\_\_\_

SECTION 2.

PERCEPTIONS, EXPERIENCES AND / OR BELIEFS about Generic Medicines.

Mark with X where applicable

1. Generic medicines are identical to patent medicines.

Yes \_\_\_\_\_ No \_\_\_\_\_

2. Briefly explain \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

3. Generic medicines are bioequivalent to patent medicines.

Yes \_\_\_\_\_ No \_\_\_\_\_

4. Briefly explain \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

5. Do you prescribe generics as first line treatment.

Yes \_\_\_\_\_ No \_\_\_\_\_

6. Briefly explain \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

7. Are you aware of the mandatory generic substitution law.

Aware \_\_\_\_\_ Not aware \_\_\_\_\_

8. The wider use of Generic medicines in the private sector will lower the cost of health care.

Yes \_\_\_\_\_ No \_\_\_\_\_

9. Briefly explain \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

10. Do you always write "no substitution" on your script to the pharmacist when a Patent medicine is prescribed?

Yes \_\_\_\_\_ No \_\_\_\_\_

11. Are patients aware of generic medicines?

Aware \_\_\_\_\_ Not aware \_\_\_\_\_

12. Briefly Explain \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

13. Do patients regard generics as of inferior quality when told about their low cost?

Yes \_\_\_\_\_ No \_\_\_\_\_

14. Briefly explain \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

15. Do patients ask for generic prescriptions?

Yes \_\_\_\_\_ No \_\_\_\_\_

16. Are patients generally willing to use generic medicines?

Yes \_\_\_\_\_ No \_\_\_\_\_

INDICATE WITH X YOUR LEVEL OF SATISFACTION.

17. Generic medicines are safe to use.

Satisfied \_\_\_\_\_ Dissatisfied \_\_\_\_\_ Indifferent \_\_\_\_\_

18. If dissatisfied, briefly explain \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
19. Generic medicines are of good quality.

Satisfied \_\_\_\_ Dissatisfied \_\_\_\_ Indifferent \_\_\_\_

20. If dissatisfied, briefly explain \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

21. Satisfied with their performance characteristics.

Satisfied \_\_\_\_ Dissatisfied \_\_\_\_ Indifferent \_\_\_\_

22. If dissatisfied, briefly explain \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

23. Satisfied with their intended use.

Satisfied \_\_\_\_ Dissatisfied \_\_\_\_ Indifferent \_\_\_\_

24. If dissatisfied, briefly explain \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

25. Satisfied with their route of administration.

Satisfied \_\_\_\_ Dissatisfied \_\_\_\_ Indifferent \_\_\_\_

26. If dissatisfied, briefly explain \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Appendix B.**

**Comparison of Prices between Brand and Generic Medicines.**

	BRAND (R)	GENERIC (R)	SAVING(R) per month
Hypertension	283.47	133.57	150
Gout	197.71	65.21	132
Insomnia	242.00	115.49	126
Depression	585.08	118.00	460
Upper Respiratory	148.39	102.99	45
Pain & Fever	27.50	12.11	15.39

Source: <http://www.dischem.co.za>

## **Appendix C.**

### **The Medical Control Council List of Non-Substitutable Medicines.**

Carbamazepine tablets  
Chlorpromazine tablets  
Dexamethasone tablets  
Diethylstilboestrol tablets  
Digoxin tablets  
Disulfiram tablets  
Ethinyl Oestradiol tablets  
Fluoxymesterone tablets  
Furosemide tablets  
Glibenclamide tablets  
Hydralazine and Hydrochlorothiazide combination tablets  
Hydrocortisone tablets  
Hydrocortisone Acetate injection  
Isoproterenol Metered Dose inhaler  
Isoethrane Metered Dose inhaler  
Isosorbide Dinitrate sustained release tablets and capsules.  
Levodopa tablets and capsules  
Nifedipine: all extended/delayed release formulations  
Oestrogens, Conjugated tablets  
Oestrgens, Esterfied tablets  
Penicillin G Benzathine injection  
Phenyton tablets and capsules



Phytomenadione injection  
Prazosin Hydrochloride tablets 5mg\*  
Prednisolone tablets  
Prednisolone Acetate injection  
Prednisolone Tebutate injection  
Prednisone tablets  
Promethazine tablets  
Propylthiouracil tablets  
Reserpine tablets  
Reserpine and Trichloromethiazide combination tablets  
Theophylline controlled release tablets/capsules  
Triacinelone tablets  
Trichloromethiazide tablets  
Warfarin Sodium Tablets

Reference: MCC Circular No: 16/94

