AN INVESTIGATION INTO THE USE OF GENERIC MEDICINES BY FAMILY PRACTITIONERS

by

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Dedication

I thank my parents, Dr and Mrs Purohit, for their inspiration and guidance; and my husband, Dr. Dushyant Desai, whose continuous support has made this possible. Finally, I dedicate this to my young children, Veeral and Bijal.

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ABSTRACT

Background

Good health care is becoming increasingly unaffordable. A wider use of generic medicines offers significant cost savings. As the family practitioner is the gatekeeper in prescribing medicines, his attitude towards generic medicines is crucial. The factors that influence family practitioners' prescription of pharmaceuticals require investigation.

Objectives

The primary objective of this study is to assess attitudes and perceptions that family practitioners have towards generic medicines and evaluate factors that influence its prescription. The secondary aim is to assess the individual characteristics and personality traits of family practitioners that may impact on generic prescription.

Methods

This study is a convenient sample of 198 family practitioners that are surveyed by means of a questionnaire. Responses were based largely on a Likert scale and evaluated by factor analysis.

Results

Using factor analysis, five factors identified in the order of importance are as follows:

1) *Patient factors*: It is primarily the patients' disease profile and their financial capacity that determines the use of generic versus ethical drugs.
2) *Clinical autonomy of the family practitioners*: Family practitioners resent their clinical decisions being challenged by managed care organisations.
3) *Strategies promoting generics*: Improved marketing by the generic pharmaceutical industry and the provisions of acceptable financial incentives are likely to promote wider use of generics.

4) *Cost of medicines*: Most family practitioners are price-sensitive. A further reduction in the price of generic medicines is therefore likely to increase the use.
5) *Specialists' opinion*: Specialists use fewer generics and their choice of medication is respected by family practitioners. A wider use of generic medicines by specialists will positively impact on generic prescription by family practitioners.

Personality traits and individual characteristics of the family practitioners do not affect their prescription of generic medicines. It is noted that most family practitioners have encountered specific instances of reduced efficacy, an increased side-effect profile, substandard packaging, erratic availability and poor patient confidence with the use of generic drugs.

Conclusion

In order to bring about a reduction in the healthcare costs by promoting wider use of generics, different stakeholders in the industry need to act synergistically. All stakeholders need to increase the awareness of generic medicines by continuing health education. Specific recommendations for the generic pharmaceutical industry include increased marketing, further reduction in the price of generics and implementation of research and surveillance studies to ensure satisfactory clinical efficacy of their drugs. Medicines Control Council need to closely monitor the number and quality of available generic medicines. Managed care organisations need to respect the clinical autonomy of family practitioners and work closely with them. Finally, acceptable and ethical incentives need to be considered for family practitioners, the gatekeepers, to achieve the objective of wider use of generic medicines.

Key words: Generic medicines, Family practitioners, Prescription, Managed care organisations, Pharmaceutical Industry

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GLOSSARY:

1) World Health Organisation.....WHO
2) Gross Domestic Product.....GDP
3) Consumer Price Index.....CPI
4) Return On Investment.....ROI
5) Human Immune Deficiency Virus.....HIV
6) Acquired Immune Deficiency Syndrome.....AIDS
7) United States of America.....USA
8) Federal Drug Administration .....FDA
9) Chief Executive Officer.....CEO
10) Over The Counter.....OTC
11) Medicines Control Council.....MCC
12) National Drug Policy..... NDP
13) Pharmaceutical Manufacturers Association .....PMA
14) World Trade Organisation.....WTO
15) Trade-Related Intellectual Property .....TRIP
16) Statistical Package for Social Sciences.....SPSS

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CHAPTER 1: INTRODUCTION

"Attitude is more important than the past, than education, than money, than circumstances, than failures, than successes, than what other people think or say or do. It is more important than appearance, giftedness or skill. It can make or break a company, a church, a home, or a network. We are in charge of our attitudes. Life is 10 % what happens to you and 90 % how you react to it."
(P. Ramlachan KZNMCC Infogram, 2000).

1.1 THE PROBLEM STATEMENT

The public health sector with its limited resources is unable to provide satisfactory health care. Thus, a significant proportion of people have no option but to turn to the private sector, where, a family practitioner meets their health requirements. However, exorbitant health care costs in the private sector is making good health care increasingly unaffordable (Chetty M, 2000). Generic medicines by offering significant savings provide cost-effective medicines in the private sector. Here, the family practitioner is the main provider of health care. He* is the gatekeeper in prescribing medicines (Ito S *et al*, 1995). His attitudes towards generic medicines, as well as the factors that affect generic prescription, are important in achieving the wider use of generic medicines together with the cost-effective health care.

* For grammar convenience, both the family practitioners and the patients are referred to in the male gender.

1.2 BACKGROUND AND RATIONALE FOR THE STUDY

Major international agencies such as the World Health Organisation (WHO) and the World Bank, have increasingly recognised that investing in health is crucial for the development. At the macroeconomic level, in general, it is recognised that the state of the economy of a country has a strong influence on the health of its population. Developmental policies have the potential to enhance, or impede, progress in achieving Health for All. The percentage of Gross Domestic Product (GDP) spent on healthcare in South Africa in 1997 was 4,1 % at R 28 billion, growing to 4,3 % at R 38 billion in 2000 (Treagus R, 1997). The South African health care system needs to control the continuing rise of health care costs. As indicated by Taylor B, *et al,* (2000), South African medical inflation has outstripped the Consumer Price Index (CPI) due to a variety of factors, including new treatment methods in hospital, new technology in the surgery; and newer, more potent drugs, coupled with a wider treatment of disorders due to medical breakthroughs. The trends in South African health care industry, and its cost drivers, are similar to the global trends —i.e. cost-escalation (Chetty M, 2000). This can be attributed to:

a) Fee-For-Service and the third party payment system.
b) The unregulated private sector.
c) The surge of fast spreading diseases like HIV/AIDS and its impact on the cost of the health care.
d) The medical aid crises (15% solvency).
e) The impact of hospitalisations.
f) Limited management expertise.
g) The demand for service for which people are unwilling to pay.

Furthermore, Bisseker C, (2001), verifies that generics in South Africa account for only 20 % of all the drugs sold (compared with 60 % in the USA). She believes that, switching to these lower-priced generics drugs should decrease the pharmaceutical expenditure, which in the private sector is as high as R16 billion each year—almost 45 % of total medical aid payments. In South Africa, as Chetty M, (2000), points out, the private sector is poorly regulated. It attends to about 23 % of the population but accounts for 60 % of the total health care expenditure--of this, 80 % of the total expenditure is on drugs. The family practitioner is part of this private sector.

All the above factors affect the family practitioner in the private sector, where he is the "gate-keeper" in providing cost-effective health care to the public. Due to the fact that a large sector of the population cannot afford the rising costs of healthcare, there is a need for cheaper, but top quality medicines. Generic medicines, by being top quality drugs, and cheaper than the ethical* drugs, fulfil this need. Generic drugs are introduced once the patent on the original brand drug expires. Generic drugs and their manufacturing companies are thus in direct competition, with the more expensive ethical drugs and their manufacturing companies. Linda Philip, Chief Executive Officer (CEO) of Aspen Pharmacare, a South African generics manufacturing company, claims that one can save up to 60 % on prescription changes and make the medical aid go further (Aspen Pharmacare, July 2001). Taylor B *et al*, (2000), also propose increased use of the older generic drugs, as opposed to the newer, patented, more expensive ethical drugs. This will increase the efficiency of public money, since the efficacy and quality of treatment, would be ensured at a lower cost. Camarena F *et al,* (1999), support this proposal as well, as this cost-saving exercise will help to reduce the pharmaceutical expenditure in the health care budget that is already strained to its limits.

However, Shelton D, (1998), discloses an important factor in the low use of generics. He claims that physician scepticism is an important reason why the doctors continue to prescribe ethical drugs. Goetzl D, (2000), too, has uncovered a widely held belief, among some family practitioners and patients, that generic medicines are not as good as the ethical drugs. Thus, there is mistrust and hesitation on part of the patients and family practitioners alike to use generic medicines. Another reason for the continuous use of the ethical products, beyond the period of patent expiration, is because of the strong brand loyalty that is built, with proven track record of fifteen or more years. The ethical drugs are thus tried and tested, and have stood the test of time. It is for this reason, that even when cheaper generics are launched, the price of the original ethical drug may continue to rise rather than fall (Goetzl D, 2000).

* The terms ethical and brand drugs are used interchangeably.

Managed care organisations also play a significant role in the prescription of generic medicines by family practitioners. Pharmaceutical outcomes management, in the form of managed care organisations, seek to identify the most effective therapy, delivered in the most efficient manner; for the purpose of enhancing patient care. As analytical tools, pharmacoeconomic and pharmaceutical outcomes studies provide valuable information relative to the costs and consequences of drugs as used by doctors. Family practitioners, together with such other members of the health care team, serve an important role as the therapeutic outcomes managers by ensuring that the economic, clinical, and humanistic dimensions of medicines are all well balanced when treatment is selected (Sepalaki L 1997).

The family practitioner is the main provider of acute primary care, preventive care, and the continuing management of chronic conditions (Sepalaki L, 1997). His role in this cost saving exercise cannot be overlooked. It is, therefore, important to determine his attitudes and perceptions as well as the factors that affect his prescription.

1.3 AIMS OF THE STUDY

- The primary aim of the study was to elucidate the attitudes and perceptions that the family practitioners have towards the use of generic medicines.
- The secondary aim of the study was to evaluate the factors that affect the prescription of pharmaceuticals by the family practitioners.
- The study will also assess the individual characteristics and the personality traits of family practitioners that impact on the prescription of generic medicines.

This study, thus, aims to fill the gap in the knowledge regarding the family practitioners' attitudes and perceptions towards generic medicines as well as the factors that affect its prescription.

1.4 STRUCTURE OF THESIS

Chapter 1 Introduction. This chapter includes the problem statement, background and rationale for the study; as well as the aims of the study.

Chapter 2 Review of Literature. This chapter includes a brief review of the generic medicines and the pharmaceutical industry. It also discusses the pivotal role family practitioners play in the society, together with the factors that affect his prescription. It also includes a brief review of the South African health care industry.

Chapter 3 Methods. This chapter describes the research sample, research design and methodology, the questionnaire, as well as the procedures used to collect and analyse the data.

Chapter 4 Results. This chapter comprises of the research findings. It includes the key issues of the attitudes and perceptions of family practitioners, and the factors that influence the use of generic medicines. The individual characteristics of the family practitioners, problems encountered by the use of generic medicines, as well as the strategies recommended by family practitioners are discussed in this chapter.

Chapter 5 Research Conclusions and Recommendations. This chapter discusses the research findings, draws conclusions and makes broad recommendations regarding the management implications for the South African government, generic pharmaceutical industry and managed care organisations. It concludes by suggesting the areas for further research.

CHAPTER 2: REVIEW OF LITERATURE

2.1 THE PHARMACEUTICAL INDUSTRY AND GENERIC MEDICINES

"New medicines, and new cures, always work miracles for a while". **(William Heberden, 1710-1801)**

Antiviral cocktails developed by the pharmaceutical industry have made AIDS (Acquired Immune Deficiency Syndrome) a chronic illness for some patients, rather than a death sentence (Kuchayr M, 1996). Apart from the vital role it provides in the continuing development of medicines, the pharmaceutical industry has a considerable impact on a country, in terms of job creation and economic upliftment. South Africa has relatively well-developed pharmaceutical manufacturing industry. Pharmaceutical industry companies have, nevertheless, enjoyed extraordinarily high levels of profitability for many years. The industry has been able to sustain high gross margins, and the drug prices of ethical drugs to the end user have largely remained unchallenged. The median return on investment (ROI) for US-based pharmaceutical companies for ethical drugs for the period 1989-1993 was 9.6 % (7.8 %-70.6 %), compared to ROI of 4.1% for other chemical companies (Collings P, 1997). US sales have increased to an estimated $50,5 billion in 2000. The 20 largest firms account for 75 % of industry sales (Collings P, 1997). The generic drug industry emerged in the 1970s as a solution to contain costs and curb the rapidly rising prescription drug prices. The Drug Price Competition and Patent Term Restoration Act of 1984 in the USA also accelerated the use of generic drugs (Ferryandis J, 1999).

2.1.1 PATENT LAWS AND GENERIC MEDICINES

When the patent protection for the original ethical drug is terminated, the brand drug can be produced as a generic drug. Pharmaceutical companies involved with the manufacture of generic drugs must then register and ensure bio-equivalence of generic medicines (Dighe S, 1999). Bio-equivalence means that when the generic

medicines are to be compared to the original brand drug, generic medicines have at least 80 % of biological availability of the active substance in the body as the ethical drug (Goonetilleke A *et al,* 1998). Generic medicines are thus essentially similar to, and, interchangeable with, the original ethical medicinal product. The stringent and comprehensive approval process by Federal Drug Administration (FDA), in the United States of America (USA), ensures quality of generic medicines marketed in the USA and worldwide. It does not lower any standards for generic drugs and thus assures health professionals and patients of the safety and efficacy of generic medicines (Chow S *et al,* 1997).

A generic medicine has to be marketed in accordance with the patent law (Collings P, 1997). Patent laws provide innovators with monopoly rights on a product, or a process, for a limited period of time. These are the incentives for innovation. Without market–driven drug prices, consumers are unable to reward those researchers who succeed in alleviating suffering, preventing disease, and preserving life. Also, the drug companies need to recoup these research costs, as well as their investments in the "blind alley" drugs, that falter after years of study (Dighe S, 1999). International patent law and world trade rules allow governments to issue a compulsory license, enabling a local company to produce a patented drug, if this is judged to be in the public interest (Kuchayr M, 1996).

2.1.2. THE INDEPENDENT GENERIC PHARMACEUTICAL INDUSTRY ALLIANCE (IGPA)

The Independent Generic Pharmaceutical Industry Alliance (IGPA), an international body, promotes harmonisation of the generic pharmaceutical industry. The IGPA is an official representative body of the generic industry that interacts with WHO, allied organisations, and governments around the world, regarding the regulatory and legal issues relating to the registration and marketing of generic medicines. It seeks strict and effective controls to prevent the production of, and trade in, the counterfeit versions of generic and ethical medicines (Nicolaou S, 1999)

2.1.3 FACTORS FAVOURING GENERIC DRUG COMPANIES

It is expected that generic sales should soar from $2,84 billion in 1993, to $5,89 billion, in the year 2001 (Monane M *et al,* 1998). Some of the factors favouring the generic pharmaceutical industry are:

- Generic products are generally cheaper than the original drugs, as they do not involve the same outlay in research and development costs.
- Increased demand for generics by the growth of mail-order prescription drug business, a rising demand by the elderly, and an increased demand from the not-for-profit institutions, all favour the use of lower priced generic drugs. The fact that the retail trade economics favours the use of cheaper generic drugs is yet another factor that has increased its demand (Monane M *et al,* 1998).
- Strong cost containment pressures from the governments around the world, the managed care organisations, and the patient groups encourage the use of generics (Dunn B, 1997). It is predicted that the market for generic drugs should enjoy strong growth over the next 5 to 10 years (Monane M *et al,* 1998).
- The availability of new products is declining. In 1993, the FDA in the USA approved 70 new drugs, 249 generics, and 51 biological products. This was 16 short of its 1992 record and the numbers have further declined each year (Monane M *et al,* 1998).
- The changing quality perceptions of generic drugs have boosted generic sales. In the US, Monane M *et al,* (1998), report high public acceptance of generics together with increasingly favourable response from the doctors and pharmacists.

These factors favour the generic drug industry and encourage the prescription of generics by the family practitioner.

2.1.4 CHALLENGES FACED BY THE GENERIC PHARMACEUTICAL INDUSTRY

All prescription drugs face the generics threat sooner or later. Despite their lower price, generic drugs have not gained much of the market share—only 8 % of all the prescription drugs in 1997 in the U.S (Kalbhen J, 1999). The road to higher generic sales and profits is still strewn with plenty of challenges:

- As a result of intensive research, the "pure" active drug molecule is isolated making the newer drugs better, safer and "purer" with considerably improved pharmacological profile and the side-effect profile. This often makes previous, older generic drugs redundant (Mehl B, 2000). This is a major threat for the generic pharmaceutical industry.
- Other challenges by the pioneer drug makers include filing with the FDA for the extension of patent life, campaigning against generic competition by intensive lobbying, citizens' petitions, court challenges, and other activities (Fredrick J, 2000).
- Another big challenge for the generic pharmaceuticals, as Stolberg S, (2000), reveals is the demand from consumers for the new generation pharmaceuticals over the older generic drugs. This demand is partly due to the intensive research and development efforts together with the direct-to-consumer advertising from the ethical drug makers (Fredrick J, 2000). This has a big impact on the physicians' prescribing habits as patients pressure their doctors for the newest medicines.
- In order to remain competitive for the future markets, generic pharmaceutical companies will also need to differentiate their products. There will be a very limited market for "me-too" generic drugs, as the only new drugs that will be allowed in a formulary for the purposes of prescription, will be those that are cost-effective as compared to existing products (Suh D *et al,* 2000).
- Another problem generics face is that the difference in pricing and profitability between the ethical and generic drugs is slowly decreasing. This affects profit margin of the dispensing doctors and pharmacists; and this in turn, affects their attitudes towards prescribing generics (Kalbhen J, 1999).

- The off-patent market is imperfectly segmented between the price-sensitive and insensitive sector as discovered by Suh D *et al* (2000). After patent expiration, multiple-source generic drugs compete largely with each other in the price-sensitive market, decreasing their profit margin. Kalbhen J, (1999), has observed that the generic makers have yet to recover from the period in the mid 1990s, when the rampant competition within the generic drug industry depleted its profitability and forced an overhaul of many companies' operating strategies and pricing structures. Since then, Rankin K, (1997), has noted that the U.S. generic drug industry has realigned to work together to advance their common interests.

In an era of unprecedented competition for customers and channels of distribution, profitability has become paramount. As a result, Ferriman A, (2000), has observed that the retail pharmacy executives and buyers now report that the generic pharmaceutical companies are far more service and information oriented than they were and are steadily improving in supply-chain management. Moreover, according to Fredrick J, (2000), many generic makers are now involved in research and development of their own line of pioneer drugs. This should eventually benefit the consumers—family practitioners as well as the patients.

2.1.5 CHALLENGES FACED BY ETHICAL PHARMACEUTICAL INDUSTRY

Competition in the ethical pharmaceutical market is very intense. Competitiveness has traditionally been based on a company's ability to innovate, i.e. introduce a steady stream of new patent-protected products. However Suh D *et al,* (2000), have questioned the long-term value of a strong technology and product focus as the market becomes more price-sensitive and gets crowded with too many similar products. Most of the therapeutic segments of the market are mature, and as Treagus R, (p. 22, 1997), states in his research report, "...technology is now being equalised much more rapidly in the pharmaceutical industry, thus closing the window of opportunity for new products. Pioneer products no longer have the staying power against chemically and clinically similar products that are virtually substitutable.

The competitive arena has become tougher in the pharmaceutical industry with maturing markets, generics, shorter life-cycles, and stronger inter-nationalisation of drug markets...." For the pharmaceutical industry, pressure to limit and regulate drug prices is also mounting from governments, managed care organisations, insurance companies and the patient groups. In addition to these pressures, the industry is facing more demanding regulatory and drug licensing requirements, labour force rigidity, escalating research and development costs, and shorter product life cycles, as most markets shift away from lucrative ethical drugs towards cheaper generic substitutes.

Marketing strategy and implementation have become ways of developing differential advantage in the industry. Marketing and positioning are all about making price less important to the family practitioner, and some of the other benefits of the product more important. This feature of the market has led to fierce and costly market share battles, as companies have attempted to maintain their sales levels (Corstjens M, 1991). Marketing costs are thus being driven upwards, as the companies find it increasingly difficult to differentiate their products. This has also led to the continuing rise in the price of ethical drugs, as patients and family practitioners struggle to fit the required newer, better, but costlier medications into their increasingly restricted health budgets.

2.1.6 STRATEGIES USED BY THE ETHICAL PHARMACEUTICAL INDUSTRY

When the patent life runs out, and generics are introduced, ethical drug company has five possible options: to reduce its price, to introduce a 'fighter' generic, to maintain the *status quo,* to increase its price, or to extend its patent life.

- **Reducing the price**

  By reducing the price of the ethical drugs, the attractiveness of the dispensing generics is reduced. This policy aims at maintaining the sales volume of the ethical drug by reducing its profit margin (Bae J, 1997). The actual price reduction strongly depends on the quality and credibility of the generic and its manufacturing company together with the brand loyalty to the original drug. The ethical drug is still protected by marketing communication (e.g., sales force effort), but some sales loss does occur when generics are introduced

(Suh D *et al,* 2000). This allows family practitioners to prescribe ethical products at reduced prices, even when generics are available.

- **Introduction of "fighter" generic**

  The introduction of a "fighter" generic by the original drug manufacturer is becoming increasingly popular with some companies. This approach aims at marginalising 'foreign' generics, while keeping the ethical drug untouched. The key problem with this approach is that it might lead to increased cannibalisation of the ethical drugs, not only by the competing generics, but also by its own generic. Some pharmaceutical industry companies try to avoid this problem, by creating a new company (and a new company name) for launching generic products (Ferryandis J, 1999). This provides the opportunity for the family practitioner to prescribe proven, well researched but cheaper medication to his patients.

- **Keeping the same price**

  Some pharmaceutical industry companies maintain the *status quo* and do not change the price of the original drug or introduce a fighter generic. (Ferryandis J, 1999).

- **Raising the price**

  Company and trademark loyalty are crucial factors in the success of any pharmaceutical industry product. Often, even after a patent has expired, brand loyalty towards the trademark of the original drug remains an important barrier to entry for the competitors. This brand loyalty towards the ethical drugs explains both the continued market dominance of some drugs beyond the patent expiration, as well as their increase in price. This approach capitalises on the brand and the company loyalty of the family practitioners as well as the patients (Goetzl D, 2000).

- **Extension of patent life**

  Ethical drug companies use legal loopholes to extend patents of their most lucrative brands and delay the entry of cheaper generics into the market. Intellectual property protections enacted over the past two decades have increased the average patent life of the new drugs by at least 50 % according to a report by the National Institute for Health Care Management (Gottlieb S, 2000). Ethical name drugs now have a patent life of 14-15 years, compared to an average of 8 years in the early 1990s.

  Ethical drug companies have also perfected the art of filing multiple subsequent patents on a drug, delaying the date when it loses patent protection (Gottlieb S, 2000). This delays the time when a generic is available for the family practitioner to prescribe for his patients. Although the patent protections were intended to provide incentives for innovation, they have also brought higher prices for consumers and larger profits for ethical drug companies, while preventing the entry of cheaper generic drugs in the markets.

2.1.7 RECENT TRENDS IN THE PHARMACEUTICAL INDUSTRY

Reinforced by economies of scale, price pressures, and the regulation of drug industry by more harmonised governments, pharmaceutical companies have been forced to think on a global scale.

Up until recently, there was a cottage industry consisting of community and hospital pharmacies, pharmacist consultants, "over-the-counter" (OTC) drug companies, wholesalers, drug utilisation review companies, claims processors, third-party programme switchers (companies that switch claims to the appropriate processors), mail-order pharmacies, prescription benefit managers, generic companies, and ethical pharmaceutical companies, each competing for a share of the business (Lexchin J, 2000). The coalescence of buyers, payers, hospitals and medical providers in the drug distribution system, has had a dramatic effect on the stakeholders, including the pharmacists and family practitioners.

Each stakeholder is affected, in some way, when integration occurs within health care and drug distribution. Self–medication, or OTC medicines are pharmaceutical products that can be freely purchased by consumers without a doctor's prescription. Companies that sell OTC products have also attracted the interest of prescription drug manufacturers (Lexchin J, 2000). Furthermore, it is anticipated that many of the prescription drugs will be de-scheduled and made available to consumers. These drugs are franchised for life and their market expands very rapidly. Demand for these self-medication drugs is expected to strengthen as patients and their medical schemes opt to avoid expensive doctor consultations (Lexchin J, 2000).

Many ethical companies have recently been interested in having a generic company, as they have realised that by the year 2002, 75 % of all oral prescriptions dispensed in the USA will be generic. During the period between 1992 and 1995, 60 drugs with sales over $13,5 billion lost exclusivity in the US and 40 more drugs with sales over $12 billion will lose exclusivity between 1996 and 2002 (Lexchin J, 2000). This has given further impetus to the manufacture, and use of generic medicines. Many brand drug manufacturing pharmaceutical companies have recently purchased a number of generic manufacturers and distributors, or they are forming strategic alliances (e.g. Stein Pharmaceutical and Miles Inc, a subsidiary of Bayer AG) (Lexchin J, 2000). This should make the higher quality drugs available at lower prices for the family practitioner and his patients.

The advent of vertical and horizontal integration or mergers and acquisitions indicates that the drug distribution system is forming into a managed oligopoly. Oligopolies operate in the biggest and wealthiest segments of the economy, where fees account for most of the industry output (Matthews J, 1996). This trend, however, may not be in the best interests for the consumer (the patient) and the family practitioner.

The various stakeholders in the pharmaceutical industry—ethical and generic manufacturers—have been analysed briefly. Another significant stakeholder is the doctor, who prescribes the medication. It is therefore important to examine his attitudes and perceptions, together with the factors that affect his prescription.

2.2 THE FAMILY PRACTITIONER

2.2.1 FAMILY PRACTITIONER AS A GATEKEEPER

The typical family practitioner provides an amalgam of acute, preventive care and chronic disease management, for a population sufficiently small and wealthy to support a personal service. They facilitate efficient and effective clinical management pathways to benefit all. The innate ability of family practitioners allows them to act as the trusted coordinators and "gate-keepers" of their patients' health care needs (Spurgeon P, 1998). The family practitioner facilitates work with the secondary care providers (hospital doctors/ specialists). In instances where patients directly present themselves to the specialists of their choice, bypassing family practitioners, there is not a single point of co-ordination for care. In these cases, investigations may be repeated, channels of communication between clinicians do not get used effectively, and inappropriate consultants may be used to deliver care (Boyce D *et al,* 1990). Family practitioners, with their broad base of general medical knowledge and a good grasp of communication skills, help their patients understand what is happening to them, keep them informed, and enable them to make more informed choices. Whether this is in choice of a specialist clinician, an interpretation of a hospital letter, or an operative procedure, family practitioners perform a useful and powerful role as their patient's guides (Spurgeon P, 1998).

However, family practitioners are neither employees nor agents of the health authority. Indeed, most family practitioners feel that their primary duty is to their own patients (Spurgeon P, 1998). Family practitioners view the promotion of good medical practice as their first duty, but as Green A, (1999), advises, they also need to be aware of the limited health care budget and promote the cost-effective generic medicines. It is therefore important to learn about the types of family practitioners, their attitudes and perceptions of generic medicines, as well as their prescribing habits.

2.2.2 ATTITUDES, BEHAVIOUR AND PRESCRIBING HABITS OF THE FAMILY PRACTITIONER

Attitudes and prescribing habits of the family practitioner play an important role in the pharmaceutical consumption. In order to learn about the drugs as prescribed by the family practitioner, one needs to understand the process that precedes the prescription of the drugs by the family practitioner.

In this context, the "hierarchy of effects" (HE) proves to be a very valuable tool depicting how a family practitioner reacts. In this model, the family practitioner first has to be aware that the specific generic version of the drug is available, and then he must show a positive interest in it before his intention to prescribe it. The actual prescription and the purchase of the drug are still dependent on the availability of the drug in the retail outlets, and the pharmacist dispensing it. Once the first prescription and purchase (trial) is made, the doctor may on the next occasion repeat the same prescription, if he was happy with its initial outcome. The result is the increased use of generic medicines, ultimately leading to the increased market share of the generic medicines. Such repeated use of generics by the family practitioner should lead to the cost saving. The HE model shown below depicts the chain of events (Corstjens M, 1991).

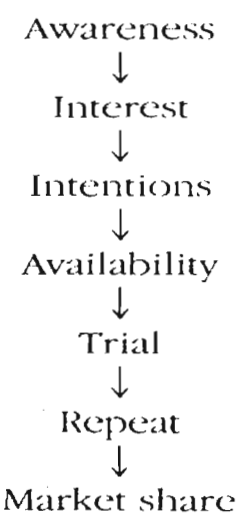

Figure 1 The hierarchy of effects (Source: Corstjens M, 1991) p. 121

Another facet of family practitioners' prescribing habits affecting generic prescription, as described by Corstjens M, (1991), considers family practitioners' response towards an innovation or a new drug. The graph below illustrates this point.

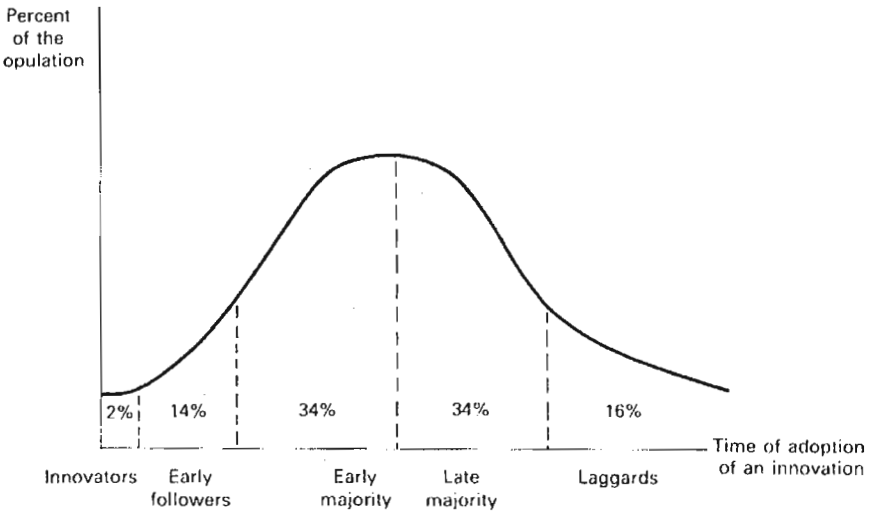

Figure 3.5 Adopter categorization

Figure: 2 Adopter Categorisation (Source: Corstjens M, 1991) p. 56

This "Bell shaped" curve, originally devised by Rogers, E, (1962), above shows the percentage of family practitioners adopting a new ethical drug with time (Corstjens M, 1991). The newer ethical drugs are often better because of their superior pharmacological profile, and less side-effect profile. The development of newer drugs, thus, represents a significant threat to the continuous use of the older generic drugs. About 50 % (34 % + 14 % + 2 %) of the doctors will readily accept the newer innovative drugs. Approximately 34 % of the doctors form "late majority" while the remaining 16 % of the doctors are "laggards" who will embrace a newer drug much later. From this one can envisage the doctors' response to a new ethical drug before the older drugs are discarded.

Spurgeon P, (1997), identified several behavioural/attitudinal criteria to categorise the type of family practitioner, and linked this up with his prescribing habits. This approach classifies the family practitioners and their prescribing patterns into:

- "Key doctors approach" – identifies family practitioners that are heavy prescribers of a particular product. Such family practitioners tend to become loyal users of the product and, once happy, are unwilling to change to alternate ethical or generic products.
- "Price sensitive" – Such family practitioners are quick at replacing ethical products by generic drugs, as the latter are cheaper.
- "Side effects sensitive" – Such family practitioners are often highly focused on side effects of the drugs and are, therefore, keen to try newer drugs with a reduced side effect profile. These doctors tend to use generic drugs less often.
- "Advertisement sensitive"-- These family practitioners are sensitive to marketing strategies of the ethical pharmaceutical industry. They are keen to try newer drugs provided there is sufficient data to back their decision. These types of doctors are more responsive to strategies like free samples, sponsored medical updates, mailings and literature citing clinical research trials.

Spurgeon P, (1997), also categorises the family practitioners according to their price-sensitivity and age. He found that younger doctors tend to be more price sensitive and, therefore, more likely to prescribe generics; and that the older, more established, family practitioners were less price sensitive, less receptive to generics, and more sensitive to the sales reps of the ethical drugs.

Corstjens M, (1991), classifies the family practitioner and his prescribing habits according to the doctor's lifestyle criteria. He linked their attitudes and perceptions to their prescribing habits in a following manner:

1. "Disillusioned": (Estimated 12% of the family practitioner population)	Such doctors describe themselves as being disillusioned by the profession. They look for new drugs as a means of contributing to their patients' health and tend to be disappointed by existing drugs.

2."Overstretched": (Estimated 12% of the family practitioners population)	Such doctors are demotivated, as they feel overworked. These tend to be above average prescribers of the proven established drugs. They usually have little time to read scientific information about newer drugs.
3."Postgraduates" (Estimated 19% of the family practitioner population)	These are keen on formal methods of education (symposia, medical journals, postgraduate courses). They want to develop themselves. They have a pronounced orientation towards generics and are not spontaneously driven to new drugs.
4. "Experimentalists" (Estimated 19% of the family practitioner population)	Such doctors are confident to try new drugs, they look at the pharmaceutical industry as a source of information.
5. "Progressive" (Estimated 19% of the family practitioner population)	Such doctors are broad -minded doctors, and are keen to further develop themselves as doctors. They tend to be positively disposed to clinical trials and newer drugs.
6. "Self-satisfied" (Estimated 19% of the family practitioner population)	These doctors are usually successful, and more complacent. They don't see a need to be involved in further formal education and are usually not keen to see medical reps.

The pharmaceutical industry uses these behavioural, attitudinal and psychographic approaches to develop a competitive edge in marketing their products to the family practitioners. Such segmentation is used as a strategic marketing tool to a varying extent by the pharmaceutical industry (Corstjens M,1991). Thus, by knowing the type of family practitioners, their perceptions and attitudes, their individual prescribing habits can be better understood and predicted. With these factors in mind, one needs to examine, some of the factors affecting the prescription of the family practitioner.

2.3 FACTORS AFFECTING THE PRESCRIPTION OF PHARMACEUTICALS BY THE FAMILY PRACTITIONER

2.3.1 INTRODUCTION

There are many factors that affect the family practitioner's prescription of the pharmaceuticals. Continuous pressure on finances, increasing litigation, accreditation schemes, pressure for greater accountability for the time and money, outcomes measurement/management, evidence based medicine, and rising patient expectations are some of these factors (Monane M *et al*, 1998). The family practitioner is affected by all around him, starting with patient factors (e.g., wanting the best, but the choice limited by costs), specialist advice and co-prescription, managed care organisations with their formularies and more subtle factors of advertising, and the incentives to prescribe ethical medicines.

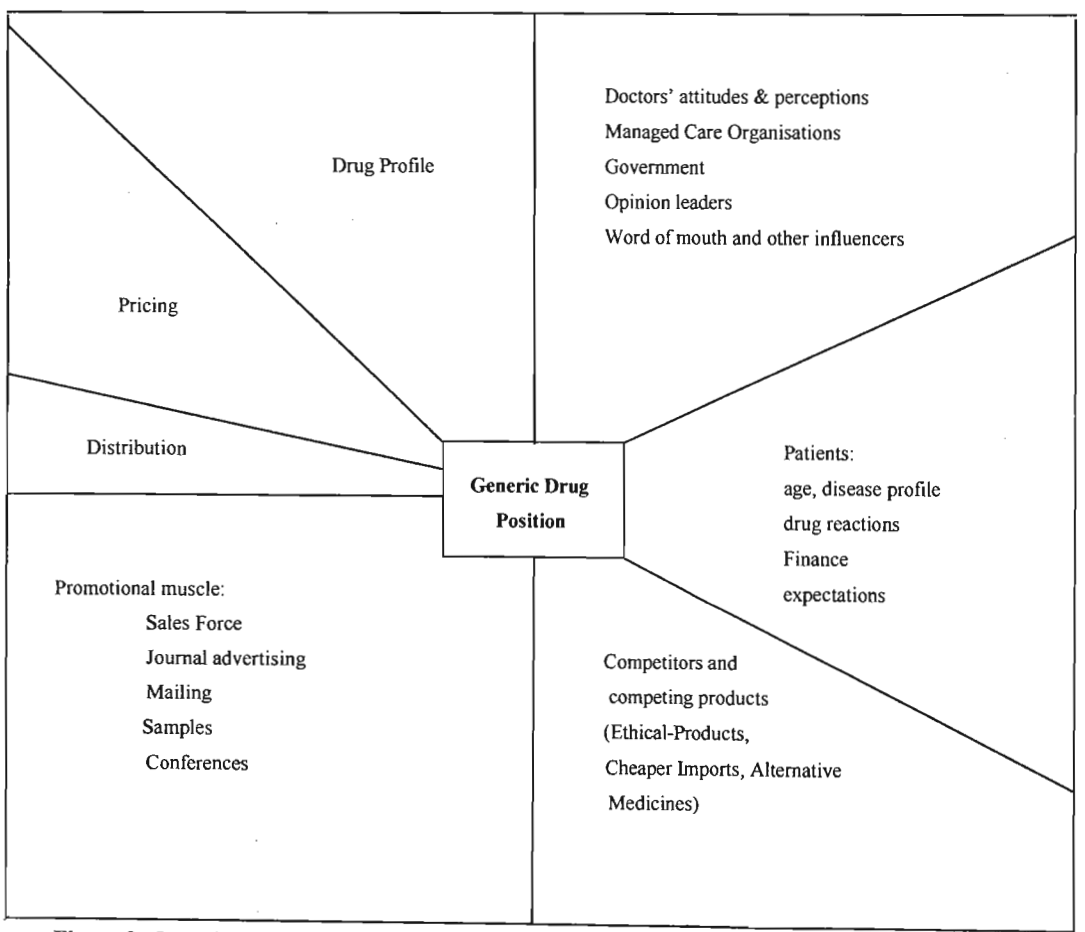

Figure 3: Generic Drug positioning factors (Adapted from Corstjens M, 1991) p. 88

2.3.2 MANAGED CARE ORGANISATIONS

2.3.2.1 GENERAL

As prescription drug costs increased during the 1970s, traditional third party programs tried to control costs by reducing dispensing fees and encouraging substitution of lower-cost generics. These third-party programs evolved into "managed care" programs by attempting to improve quality care and patient outcomes (Van E, 1998). Managed care organisations have a difficult task of addressing three competing goals simultaneously: (1) increasing access (2) improving quality and patient outcomes, and (3) controlling costs. While managed care organisations attempt to balance all three goals, short-term rewards and competitive forces usually necessitate that cost control be the first priority (Monane M *et al,* 1998).

Managed care organisations promote the use of generic medicines by family practitioners. From their perspective, an increased expenditure on drugs means less resources for other areas of health care such as consultation, investigations, and hospitalisation. Better managed drug therapy and wiser use of more appropriate drugs in managing disease will contribute substantially to better management of the diseases, fewer physician visits, hospitalisations, less complicated hospital care; and shorter hospital stays (Monane M *et al,* 1998). Superficial assessment of drug acquisition cost, per member per month (PMPM) charge, and drug utilisation rates have thus become irrelevant in the total context of disease management (Boyce D *et al,* 1990).

According to Ito S, (1995), managed care organisations claim that their interventions improve benefits and reduce risks of the prescribed medications, while placing only a minor burden on the physician and patient. Failure to heed such cost considerations, explains Lexchin J, (2000), will result in increasingly unaffordable contributions by consumers or result in the insolvency of the managed care organisations. There is also a risk that these changes may occur on an *ad hoc* basis if performance management is not built in. Managed care organisations, by offering medical aids and medical insurance to the patients, now directly influence the family practitioner and his prescribing habits.

2.3.2.2 STRATEGIES USED BY MANAGED CARE ORGANISATION

Managed care organisations are thrusting heavily in the direction of pharmacoeconomics, to ensure effectiveness in using the least expensive of the appropriate drugs for therapy. Managed care operates at both macro and micro level. It aims to develop greater consistency and accountability on the delivery of individual patient care by doctors (Seplaki L, 1998). The two common strategies used are as follows:

- *Case management and utilisation management*

Case management employs selected primary care physicians or "preferred providers" (usually general practitioners, internists and paediatricians) as "gatekeepers" who are held accountable for the approval and coordination of all health care services. These organisations typically employ doctors to "monitor and control" the use of pharmaceuticals by other doctors in an attempt to put efficiency-quality dichotomy in place (Sepalaki L, 1997). Such preferred providers are positively disposed to cost containment of the managed care organisations but this system is perceived by many as going to a doctor who is not accountable to the patient. This system has not been successful everywhere (Sepalaki L, 1997).

Utilisation Management or *Utilisation Review* is concerned with reducing unnecessary care by means of a scrutiny of past, current, and planned services. Typically, a senior nurse is employed to review and possibly question the doctor regarding the care given or planned for the hospitalised patient. It is a technique which focuses on individual patients and is often viewed as a relatively aggressive, challenging clinical practice, and, in turn "clinical freedom and autonomy" of doctors (Spurgeon P, 1998).

- *Financial Incentives*

This involves either penalising the doctors for over-utilisation of the schemes, or rewarding them for prescribing the "correct" medication that is "legally" allowed by the medical schemes. In one study, in 1993, in the USA, 41 % of managed care organisations penalised physicians for hospital over-utilisation, and violating prescription policies. As a result, this system has not been successful everywhere.

According to Spurgeon P (1998), managed care organisations that offer financial incentives to the family practitioners have also been criticised. This is because of the demoralising and divisive effects of providing financial incentives to the family practitioners, for them to act in ways that are alien to their professional principles. Moreover, the doctors also tend to view the accountancy-driven health care with suspicion (Fijn R, 1999). Meanwhile, in South Africa, there are also moves to grade doctors according to their cost effectiveness in respect of medical schemes. Doctors can earn more than 50% of the money paid for the drugs they prescribe. This has sparked fears that patients could be "under-serviced" by doctors who get paid higher consultation fees, depending on how they rate, in terms of the drugs they prescribe. Health industry sources have warned that the move could backfire on patients, with doctors prescribing drugs with financial targets in mind, rather than a patient's best health interests at heart (Taylor B *et al*, 2000).

❖ *Formularies*

Managed care organisations however, experience great pressure to control costs, and a formulary system is one effective mechanism to maintain some type of cost-quality dichotomy (Sepalaki L, 1997). The primary goal of a formulary system is to foster safe, appropriate, and effective drug therapy. Formularies promote older products, explain new clinical guidelines or prescribing protocols, and present the results of drug use review or audits (Monane M *et al,* 1998). Other goals include drug-monitoring requirements, monitoring patient compliance, and the ease of use of medications as well as promoting patient and physician educational needs (Fijn R, 1999). Monane M *et al* (1998) report that formularies can save managed care organisations as much as 10% on pharmaceutical costs. The savings are to be found in the following areas:

- Employing a less costly medication within a therapeutic category.
- Increasing the use of generic pharmaceutical products.
- Employing drug monitoring, drug review, and drug utilisation programmes.
- Implementing therapeutic substitution protocols.

Economic dividends are available through contracting strategies, increased generic utilisation, rebate initiatives, and controlled utilisation. The larger savings, however, in utilising the formulary process, is to support optimal health outcomes and disease management initiatives.

Managed care organisations have tough "legislation" in place to greatly reduce pharmaceutical costs. Besides having formularies, managed care organisations influence family practitioners by introducing prior authorisation for expensive drugs, second opinions, educational requirements and peer review (ISAP, Issue 7,1995). Managed care organisations thus exert a significant influence the family practitioners.

2.3.2.3. MANAGED CARE ORGANISATIONS AND THE FAMILY PRACTITIONERS

Van E (1998), states that, traditionally, doctors have focused mainly on the clinical dimension, selecting the most efficacious medication for their patients with little knowledge or consideration of its cost. He claims that until recently most doctors paid little attention to costs, and had little idea of the price of twenty drugs they most commonly recommend. Boyce D *et al*, (1990) recommend that family practitioners be aware of the limited resources of health care, to ensure and promote the cost-effective medicines by using generics as often as possible. Santell J, (1996), also calls for the need for the family practitioner to take a broader perspective, a *pharmacoeconomic* perspective, when prescribing medications. In addition, Matthews J, (1996), advocates both the physician and the consumer involvement in the medical care delivery, with the attention focused on humanistic as well as the economic side of health care.

In general, it feels as if the family practitioner is being increasingly scrutinised, and needs to justify his clinical decisions more explicitly to managed care organisations. Whilst there is nothing wrong with this in principle, Alger A, (1999), warns that it is important to note that decisions in such complex areas of medicine depend on an enormous number of variables, each difficult to pin down precisely, and doctors, on whom the system depends, are still fiercely independent. Sepalaki L, (1997), has also noted that doctors resent being evaluated in areas in which they feel competent. There are always risks, as Spurgeon P, (1998), points out, in trying to

turn an inexact art with some logic, into an exact science with answers to everything. The risks grow if one tries forcibly to corral the self-driven professionals in a direction, which feels wrong to them. He has also observed, that family practitioners tend to respond in a reactionary manner to the proposals made from outside of their profession. He has concluded, that where the authorities have tried to impose a performance management framework onto doctors, the task was painful and unproductive. Noting this, it is not surprising when Monane M *et al*, (1998) revealed that the managed care organisations have had a limited success in achieving their aims. They have also uncovered substantial criticism by both doctors and patients, regarding a drop in satisfactory health care delivery.

In view of these shortcomings, it has been observed that the management of managed care organisations have recently embarked on a positive approach of working in conjunction with doctors, and link their measurement to new activity, new accreditation, and new incentives (ISAP, Issue 6, 1995). The incentives are now varied -- both financial and non-financial and given directly, or indirectly. These managed care organisations positively develop the role of the family practitioner as a "gatekeeper," while allowing for his clinical autonomy and freedom, in making decisions best for his patients (ISAP, Issue 7, 1995). In such situations, Chetty M, (2000), has found that doctors do tend to co-operate much more in achieving the cost control mechanisms; including the use of generic medicines.

2.3.2.4 MANAGED CARE ORGANISATIONS AND THE PATIENT

Patient factors like the patient's age, his disease profile, availability of the medications, drugs' idiosyncratic reactions, and patient's finances, all play a part in the doctor's decisions when prescribing medications. For instance, in patients aged 65 and older, more medications are consumed than any other patient group, and, therefore, it is reasonable to expect their overall spending on pharmacotherapy to rise (Monane M *et al,* 1998). This trend is both necessary and appropriate, as medication use, remains one of the most cost-effective methods that the family practitioner uses to manage the medical conditions of older patients.

However, as Monane M *et al* (1998) explain, that despite the above factors, if the family practitioner stays with any regimen within the formulary, then costs tend to decrease over the years, as more and more of the medication becomes available as cheaper generics. But, if the doctor keeps replacing the drugs with the newer patented drugs, then the cost of drugs do increase. As the financial resources available for looking after the health of an aging population are limited, generic drugs are increasingly used in the western countries as a means for meeting its growing demand (Monane M *et al,* 1998).

Another important factor that often arises is that of patient expectations. Patients expect the very best of medicines even though financial constraints make them unaffordable (Alger A, 1999). This is often the result of smart direct-to-consumer marketing and advertising by the ethical pharmaceutical industry (Ault A, 1997). Many patients in the "price insensitive" category specifically demand ethical medicines.

As a result, many medical schemes now have "legislative" measures that affect patients and the doctors (in the form of a levy), whereby a patient, who chooses the ethical drug instead of generic medicine, must pay a higher co-payment, or pay the difference in price between the ethical and generic drugs (Alger A, 1999). Most medical aids, as part of the managed care organisations, now refund the member up to the generic level, for all the ethical drugs that have generic equivalents (Boyce D *et al,* 1990).

As noted by Monane M *et al,* (1998), medical schemes and managed care organisations are beginning to shift some of the responsibility for healthcare onto their members. The aim is for the consumer to take a greater responsibility for payment at the point of consumption and consumers of healthcare are becoming more knowledgeable and more discriminating. Beckman M, (1995) has remarked on the recent trend of the medical aids to encourage, and even reward, patients to be frugal in their use of health services and medicines. Educated consumers are therefore less

likely to visit their family practitioner with a simple self-limiting ailment and are less likely to request an antibiotic for a common cold. They will rather visit their local pharmacy and purchase an "over-the-counter" form of self-medication. Thus, managed care organisations directly influences patient prescription and limits his choice of drugs.

2.3.3 SPECIALIST PRESCRIBING AND THE FAMILY PRACTITIONER

Family practitioners generally respect a specialist's opinion and specialists tend to favour the ethical products over the generics (Ito S, 1995). Data on referrals shows that specialist prescribing tended to shift to more chronic use and that the cost of specialist prescribing is on average 23 % higher than for the family practitioner prescriptions. This is partly due to the increased use of the ethical drugs. Although specialists seem to have fewer opportunities for generic substitution, the potential for savings is greater than for family practitioners (Ito S, 1995). The number of prescriptions and the related costs increase greatly when patients are referred from primary care of family practitioners to secondary care of specialists (Mehl B, 1998).

2.3.4 MARKETING OF ETHICAL DRUGS

Ethical drug companies with their bigger marketing muscle tend to have more advertising power. They advertise directly to consumers (patients) via TV, radio, newspapers, journals and e-mail advertisements instead of promoting their products exclusively to doctors. Doctors, too, are constantly inundated with information regarding the competing products, advertising, visits by sales reps, sponsored conferences by sales reps to exotic locations, etc (Corstjens M, 1991). Limited exposure, memory and information-processing capacity, together with selective and distorted perceptions, often allow important gaps to develop between the objective facts and the subjective perceptions of the brand drug offerings, in the mind of the family practitioner. Moreover, the 'halo' effects severely bias product perceptions. In view of this, Hoffman L, (2000), has called for the need to have guidelines/advertising standards and watchdog committees to monitor marketing of pharmaceuticals to doctors and consumers.

2.3.5 GOVERNMENT AND LEGISLATION IN SOUTH AFRICA

A key element for restructuring of the South African national health system is to restrict the health sector expenditure, by focusing on more efficient and effective use of existing resources and promoting the cost-containment by the wider use of generic medicines. Encouraged by the worldwide recognition of the effectiveness of generic medicines, the South African government also advocates greater use of generics (NDP, 1996). The Medicines and Related Substances Act, which became a law in South Africa, actively encourages generic substitution by the pharmacist, unless specifically prohibited to do so by the doctor (NDP, 1996). In the public sector, generics are widely used.

The provision of safe, effective drugs that meet approved standards and specifications is achieved through the Medicines Control Council (MCC), which rationalises drug registration, among its many other functions. By having stringent criteria for drug registration, MCC assures South African family practitioners the safety of the drugs available in the country (Moodley I, 1996).

2.3.5.1 NATIONAL DRUG POLICY (NDP)

The provision of essential medicines in South Africa depends on an extensive, but vulnerable, infrastructure that is highly dependent on overseas expertise and technology. The pharmaceutical sector, as part of the health sector, reflected its deficiencies, most notably, the lack of equity access to essential drugs. Noting this, the Department of Health, implemented the National Drug Policy in November 1994, with the primary aim of equity in health care for all. Other goals of the National Drug

Policy include ensuring an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all the citizens of South Africa, and the rational use of drugs by prescribers, dispensers and consumers (NDP, 1996). The Drug Policy Committee plans to achieve its goals by the following plan of action:

- To develop a pricing plans for drugs in the public and private sectors.
- To develop specific strategies to increase the use of generic drugs.
- To rationalise the structure for Pharmaceutical Industry Services.

- To develop an Essential Drugs List to be used in the public sector and prepare treatment guidelines for the health personnel.
- To prepare a plan for effective procurement and distribution of drugs in South Africa, particularly in the rural areas.

By having an Essential Drugs List, enforced legislation, and better procurement and distribution channel for generics, the South African government is actively promoting the use of generics by family practitioners. With this in mind, it is important to review the South African health care industry in more detail.

2.4 SOUTH AFRICAN HEALTH CARE INDUSTRY

2.4.1. SOUTH AFRICAN PHARMACEUTICAL MARKET

In South Africa, health care is big business. South Africans are spending more of their disposable income on health care now than in previous years. Spiralling health costs, the new Medical Schemes Act, and demographic factors, such as an ageing population and the HIV epidemic, are pressurising medical schemes and government to manage health care benefits and expenditure more assiduously than before (Henderson C, 2000). With medicines accounting for almost 60% of private health care expenditure, (excluding anti-retrovirals, chemotherapeutics, immuno-suppressives and hospital medicines) and the rate of medicine inflation outstripping consumer price index, it is vital that pharmaceutical costs be contained (Henderson C, 2000).

The South African pharmaceutical market can be divided into a private and public sector. The public sector is funded from the fiscus, and caters primarily for the unemployed and the impoverished sections of the population. The demand in this segment of the market is for basic, quality, affordable medicines. Pharmaceutical industry sales to the public sector account for nearly 75% in volume, but amounts to a slender 22% in Rand value. This market dynamic has led to a pattern of cross-subsidisation, as pharmaceutical companies have been forced to increase their prices in the private sector in order to preserve their overall margins. The family practitioner operates in the private sector.

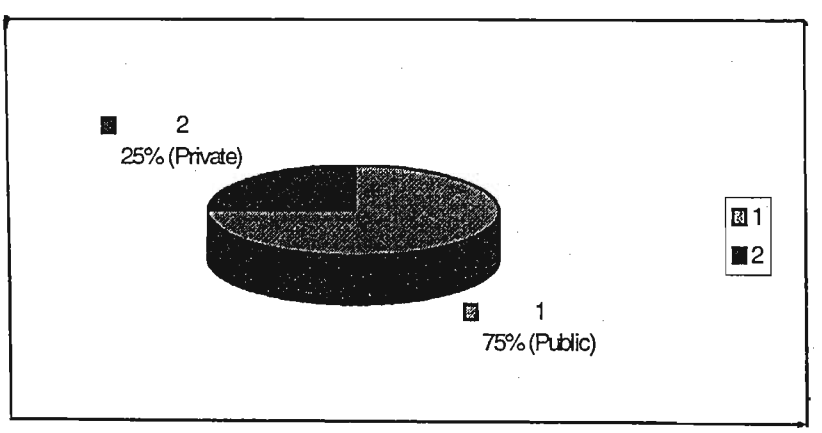

Figure: 4 Pharmaceutical Market: Unit Volume Split (Source: Treagus R, 1997)

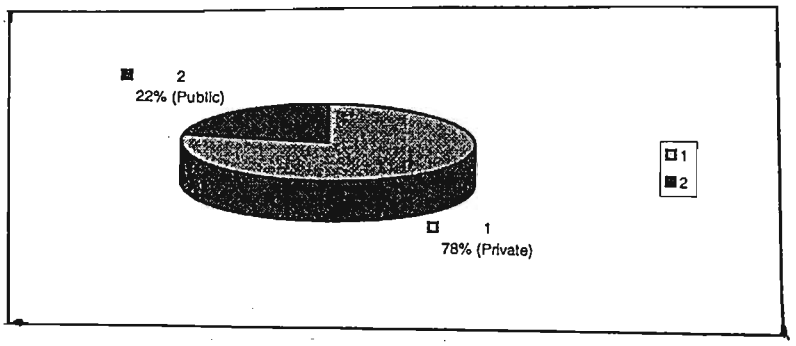

Figure: 5 Pharmaceutical Market: Rand Value Split (Source: Treagus R, 1997)

Pharmaceutical sales in the private sector are highly profitable, accounting for 25% of unit volumes and 78% in value. The private sector is funded by medical insurance schemes, and caters primarily for the economically active, urbanised sections of the population. Consumers in the private sector, which concerns the family practitioner, continue to demand high quality, technically advanced drugs. The composition of this private sector market therefore reflects a typical first-world structure.

According to Treagus R, (1997), the public sector has effectively driven the price of pharmaceuticals down to almost one-tenth of the prices paid for the same drug in the private sector. This cross-subsidisation has created a significant pricing distortion in the private market. It partly explains the high medical inflation and the high cost of medicines in the private sector, which is where the family practitioner operates. Also, the increased inefficiencies and weaknesses in the public sector distribution system, gives rise to theft, fraud and counterfeiting of drugs. It has been estimated that this pharmaceutical crime, costs the industry between R500 million and R1.2 billion annually, is yet another factor contributing to price distortions (Moodley I, 1996).

Ethical drugs currently account for 80% of the total South African pharmaceutical market (Treagus R, 1997). Generic substitution has been legislated in USA for a number of years and 60:40 dollar value split exists between ethical and generic products. As this legislation is not yet promulgated in South Africa, the current rand value split in the use of pharmaceuticals is 80:20 with the majority of medicines being administered consisting of ethical drugs (Aspen Pharmacare, July 2001).

Table 1 below shows the high percentage of ethical prescription drugs being dispensed. Hence, the importance of this project.

TABLE 1: S.African pharmaceutical industry market – Value of sales

		RAND (MILLIONS)	% SHARE
	Ethical	2257	34
	Generic	564	8
Prescription		*2821*	*42*
	Pharmacy	1880	28
	Supermarket	500	8
Self-medication		*2380*	*36*
Total Private		**5201**	**78**
	Ethical	900	13
	Generic	600	9
Total Public		**1500**	**22**
GRAND TOTAL		***6701***	***100***

(Source: Treagus R, 1997)

Increasingly, managed care is believed to be the solution to cost containment and to national health care (Chetty, M 2000). One of the objectives of managed care is to curb the rise in health care expenditure in the hospital and pharmaceutical sectors (Moodley I, 1996). Managed care partly does this by promoting the use of generic medicines by the family practitioner.

However, one problem that remains is the erratic supply of generic medicines. In the instances where generics have been enforced, Ferriman A, (2000), has observed that hospitals have come to a standstill because of serious drug shortages. In view of this, Moodley I, (1996), has called for the government to implement the incentives that favour the production, the use and the distribution of generics in the country. This will ensure the availability of essential generic drugs at all times, thereby promoting its use by family practitioners.

2.4.2 GENERIC MEDICINES FOR HIV/AIDS DRUGS IN SOUTH AFRICA

Brewing since the advent of South African democracy in 1994, and the promises of the health sector transformation, an extraordinary drug war between the South African government and the US pharmaceutical industry manufacturers, took on global proportions in 1998-1999 (Schoofs M, 2000). The government had long battled with the ethical pharmaceutical companies, over plans to import generic versions of drugs for which the companies have patents, and planned legislation to do so (Ryan C, 1997). Because of the disregard of the rights of the local pharmaceutical companies, the Pharmaceutical Manufacturers Association (PMA) challenged this legislation at the Constitution Court. Mirryena Deeb, chief executive officer of the PMA stressed the need for their intellectual property rights to be respected (Bond P, 1999).

The multinational pharmaceutical companies interpreted this as an infringement of their patent law, as well as the direct contravention of the World Trade Organisation's (WTO) trade-related intellectual property (TRIP) agreement, of which South Africa is a signatory (Love J, 1999).

The US government promptly applied powerful pressure points to repeal a clause allowing potential importation of generic substitutes, parallel importing, and imposition of compulsory licensing (Love J, 1999). At stake were also the international power relations between developing countries and the pharmaceutical industry. The US government exerted mounting pressure, and kept South Africa on its "watch list" of the countries that may violate trade interests. With the possibility of economic sanctions, it was possible that the US government may lay a complaint with the WTO (Bisseker C, 1997).

Nevertheless, on the World Aids Day (1 December, 2000), the former US President Bill Clinton announced that the USA would develop a co-operative approach. He issued an executive order stating the USA will not challenge any intellectual property law, or policy, imposed by a Sub-Saharan African government, that promotes accesses to HIV/AIDS pharmaceuticals and medical technologies (Dowell W, 2000). USA subsequently abandoned the threat of trade sanctions, against countries like

South Africa which were planning to produce cheap generics for the patented drugs (Baleta A, 2000). On 28 May 2000, South Africa cautiously welcomed an offer by five major drug companies, to cut the price of HIV/AIDS treatments; but not at the expense of giving up the right to seek cheaper, generic alternatives (Henderson C, 2000). Thus cheaper generics may theoretically be produced for the patented drugs, and be available for the family practitioners, in South Africa, to treat their HIV patients. This may happen soon (Aspen Pharamacare, July 2001).

CONCLUSION

There is now consensus by most stakeholders in the health care scenario that it is necessary to implement the cost saving measure of the wider use of generic medicines to limit the health care expenditure. Since the family practitioners are the main prescribers of these medications it is important to identify the following:

- Identify the attitudes and perceptions that the family practitioners have regarding generic medicines.
- Identify the factors that affect the family practitioners' prescribing habits.
- It will also assess the individual characteristics and the personality traits of the family practitioners as related to their prescription of generic medicines.

This study aims to fill the gap in the knowledge about the family practitioner's receptiveness, his attitudes and perceptions as well as the factors that affect his prescriptions of generic medicines.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 INTRODUCTION

The primary aim of this study is to identify the attitudes and perceptions family practitioners have towards generic medicines. The secondary aim of this study is to evaluate some of the factors that affect the prescription by family practitioners. It will also observe the differing individual characteristics of family practitioners, if any, that affect the prescription of generic medicines. The research methods are discussed together with the study design, sample and collection methods. Details of the questionnaire and the statistical methods used are also discussed.

3.2 RESEARCH DESIGN

This is a descriptive cross-sectional study, where the aim is to examine the relationships between variables. This type of study design offers an in-depth analysis of the variables such as attitudes and perceptions of family practitioners, by asking questions related to their beliefs of generic medicines as well as the factors that affect their prescription. It has an *ex post facto* design.

3.3 DESCRIPTION OF THE RESEARCH SAMPLE

Sample defines the selected group of people or elements, and is a subset of the population selected to participate in a research study. The unit of analysis was the registered and practicing family practitioner.

A total of 300 family practitioners were invited to participate in this study. About 200 family practitioners were approached at the regular family practitioners' meetings (Guild meetings), and about 100 family practitioners were approached directly at their practicing surgery. Prior permission was sought from the executive committee of each Guild in the area. The sample is a convenience sample. The objectives of the research were explained to the family practitioners, and its anonymous and confidential nature was emphasised. The family practitioners were reassured of the independence of the study, in terms of the study not being sponsored by any of the pharmaceutical companies or its agencies and hence free from its bias.

The subjects volunteered their participation and, in turn, an executive summary of the research findings was promised as a feedback to those interested. The questionnaire, in a stamped self-addressed envelope, was given personally to each of the participating family practitioners. In view of the time constraints of this research, the respondents' attention was drawn to the deadline date and they were requested to return the completed questionnaire immediately, or by post, or by facsimile. The doctors who preferred to fill in the questionnaire immediately were given 10-15 minutes in quiet surroundings. The family practitioners that preferred to fill in the questionnaire at their leisure, posted the completed questionnaire to the author. A follow up phone call was made to the doctors, and the executive committee of the guilds, to thank the doctors for their participation in the study.

The family practitioners were approached in the metropolitan cities of Durban, Johannesburg, Cape Town, Harare and Lusaka over a period of two months (January 2001-February 2001).

3.4 VALIDITY AND RELIABILITY

Validity refers to the degree to which an instrument measures what it is intended to measure, and this was ensured by rigorous effort exerted in the designing of the questions. Experts from the University of Natal also critiqued the instrument. The pre-testing of the instrument served to detect the overlooked core themes and further improved the validity. The carefully structured questionnaire, chosen after a pilot test, with ten family practitioners was considered to be plausible; i.e. meeting the criteria of face validity, with no obvious sensitivities, and that they were clear and unambiguous. Thus the face and content validity was established.

Reliability analysis was conducted by means of the Cronbach Alpha tests of internal consistency.

3.5 RESEARCH STUDY INSTRUMENT —THE QUESTIONNAIRE

The measuring instrument for the data collection was a questionnaire. The data was largely quantitative in nature, with mainly close-ended Likert type questions with a few open-ended questions. The questions were designed to probe the respondents' attitudes and perceptions towards generic drugs, as well as the factors that affect their prescription. The questionnaire was 3 pages in length and contained a total of 32 questions. It was divided into 4 sections as follows:

Q1-Q5: Categorises family practitioners and gives the demographics of each respondent.

Q6-24: Details the questions that explore the attitudes and perceptions of family practitioners together with the factors that affect their prescription.

Q25-Q30: Details the questions that categorises some of the personality traits of the family practitioners that impact on their generic prescription.

Q31-Q32: Details the optional open-ended questions, regarding the problems encountered by the use of generic medicines as well as the strategies to further increase its use.

The answers provided the basis for an in-depth statistical analysis of the responses to the questionnaire. Correlational and factor analysis was used to analyse the data using Statistical Package for Social Sciences (SPSS), a statistical software programme.

3.6 DATA ANALYSIS

Planning data analysis involved coding and selecting the appropriate statistical techniques to analyse the data using SPSS. Descriptive statistics using descriptive analysis, frequencies, and the cross-tabulations were used to analyse the demographics and the characteristics of the family practitioners. Descriptive statistics and factor analysis were used to analyse the questions involving the attitudes and perceptions of family practitioners as well as the factors that affect their prescription. Factor analysis was conducted to reduce, organise and give meaning to the data.

3.6.1 DEMOGRAPHICS OF THE RESEARCH SAMPLE

The demographics of the respondents were distinguished from each other, according to their city, age, duration and the type of their general practice (percentage of cash practice, dispensing versus non-dispensing practice), and percentage of generic drugs prescribed. These characteristics of the family practitioners were analysed using frequency studies and chi-square cross-tabulations using SPSS.

3.6.2 ATTITUDES OF THE FAMILY PRACTITIONERS AND THE FACTORS AFFECTING THE USE OF GENERIC MEDICINES

Attitudes and perceptions of family practitioners towards generic medicines and the factors affecting the wider use of generic medicines were tested by questions 6 to 24. These were analysed using descriptive frequency statistics as well as the factor analysis with SPSS.

3.6.3 PERSONALITY TRAITS OF FAMILY PRACTITIONERS AS RELATED TO GENERIC PRESCRIPTION

The family practitioner's view of his profession and his perception towards the available drugs reflects his keenness to try newer drugs versus the older generics. The results of these personality traits as they related to generic prescription were analysed by chi-square cross-tabulations using SPSS.

3.6.4 QUALITATIVE RESPONSES

Further insights were gained by supplementing the data with qualitative responses regarding the problems encountered by generic use, and the strategies recommended by the family practitioner that may increase generic use. The answers were coded using broad categories and frequency analysis was conducted.

CHAPTER 4: RESULTS

4.1 RESEARCH SAMPLE—DEMOGRAPHICS

The research questionnaire was given to 300 doctors. A total of 200 questionnaires were distributed during the guild meetings and other 100 given personally to the family practitioners at their surgery. A total of 198 responses (total response rate of 66 %) were received. Of the 198 responses, 118 responses were filled during the Guild meeting (59 % response rate) and 80 responses (80 % response rate) were received by direct visit to the doctor's surgery. Of the 198 family practitioners who completed the questionnaire, 76 % of the family practitioners were from South Africa (See Table 2 below). There were 71 % of the responses from the greater Durban area, with 2.5 % of the respondents from Cape-Town and Johannesburg each; 16 % of the responses were from Harare, Zimbabwe; whereas 8 % of the respondents were from Lusaka, Zambia.

TABLE 2: Analysis- Location demographics

CITY	FREQUENCY	PERCENTAGE
CAPE TOWN	5	2.5 %
DURBAN	141	71 %
HARARE	31	16 %
JOHANNESBURG	5	2.5 %
LUSAKA	16	8 %
TOTAL	**198**	**100 %**

The age group of the doctors was spread as follows: 6 % of the doctors were below the age of 30 years, with 31 % of the doctors in the age group of 31-40, 34 % of the doctors in the age group of 41–50 and the remaining 29 % of the doctors over the age group of >51.

TABLE 3: Analysis- Age demographics

AGE OF THE DOCTOR	FREQUECNCY	PERCENTAGE
< 30 YEARS	12	6 %
31-40 YEARS	61	31 %
41-50 YEARS	67	34 %
> 51 YEARS	58	29 %
TOTAL	**198**	**100 %**

Approximately half (44 %) were in practice for >15 years, with 58 % (14 % + 44 %) of the doctors being in practice for >10 years; 25 % of the doctors being in practice for 6-10 years, and 17 % of the doctors being in practice for 0-5 years. Thus, a significant population of the family practitioners consisted of mature doctors with established practices.

TABLE 4: Analysis- Duration of family practice

DURATION OF PRACTICE	FREQUECNCY	PERCENTAGE
0- 5 YEARS	34	17 %
6-10 YEARS	50	25 %
11-15 YEARS	27	14 %
> 15 YEARS	87	44 %
TOTAL	**198**	**100 %**

Moreover, the majority of these doctors (79 %) were dispensing doctors in the sample, (as seen in Table 5), with only 21 % of the doctors being non-dispensing doctors.

TABLE 5: Analysis- Dispensing versus non-dispensing doctors

TYPE OF DOCTOR	FREQUENCY	PERCENTAGE
DISPENSING DOCTOR.	156	79 %
NON-DISPENSING DOCTOR	42	21 %
TOTAL	**198**	**100 %**

Only 11% of the family practitioners had a predominant (i.e. >75%) cash-paying practice. This means that the majority of the doctors had a mixture of both cash paying and non-cash paying (medical-aids) patients. About 39 % of the doctors reported that < 25% of their patients were cash paying patients i.e. most were medical-aids patients. Cash paying patients tend largely to come from the poorer community.

TABLE 6: Analysis- Percentage of cash-paying patients in the practice

PERCENTAGE OF CASH PAYING PATIENTS IN THE PRACTICE	FREQUENCY	PERCENTAGE
<25 %	77	39 %
26-50 %	70	35 %
51-75 %	29	15 %
>75 %	22	11 %
TOTAL	**198**	**100 %**

For substantial cost savings in the health sector to be realised, at least 90 % of the doctors should be prescribing generics, 90 % of the times. However, in this study, only 39 % of the doctors report that >75 % of the total prescriptions are generic drugs. Around 61 % (3 % + 19 % + 39 %) of the family practitioners report that the total percentage of generic prescriptions is less than 75 %, with ethical drugs forming a significant proportion of the prescription drugs. The results are shown below in the Table 7.

TABLE 7: Analysis- Percentage of prescriptions being generic prescribed

PERCENTAGE OF PRESCRIPTIONS BEING GENERIC	FREQUENCY	PERCENTAGE
<25%	6	3 %
26-50%	39	19 %
51-75%	77	39 %
>75%	76	39 %
TOTAL	**198**	**100 %**

4.2 ATTITUDES OF FAMILY PRACTITIONERS AND THE FACTORS AFFECTING PRESCRIPTION OF GENERIC MEDICINES --DESCRIPTIVE ANALYSIS

4.2.1 Generics as a group of drugs - Are they satisfactory?

This is tested by three questions: Q10, Q11 and Q15. As shown in Table 8, about 46 % (37 % + 9 %) of the doctors agree that generic medicines are of comparable efficacy to the ethical drug, while a significant 27 % of the doctors (21% + 6%) disagree. Of note, is the response to Q10, where 30 % (20 % +8 % +2 %) of the doctors do not view, generics as evidence-based medicine. Nevertheless, a majority, 79 % (59 % +20 %) of doctors do accept generics as an acceptable compromise.

TABLE 8: Analysis- Generics as a group of drugs

Q15 I believe generic medicine efficacy is very comparable to the original ethical product.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	11	6 %
DISAGREE	42	21 %
NEITHER AGREE NOR DISAGREE	53	27 %
AGREE	73	37%
STRONGLY AGREE	19	9 %
TOTAL	**198**	**100 %**
Q10 I view prescription of generics as being without evidence-based.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	43	22 %
DISAGREE	95	48 %
NEITHER AGREE NOR DISAGREE	39	20 %
AGREE	17	8 %
STRONGLY AGREE	4	2 %
TOTAL	**198**	**100 %**
Q11 I believe that the use of generic medicines is an acceptable compromise.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	3	1 %
DISAGREE	15	8 %
NEITHER AGREE NOR DISAGREE	24	12 %
AGREE	117	59 %
STRONGLY AGREE	39	20 %
TOTAL	**198**	**100 %**

4.2.2 Cost of medicines influencing generic prescription

In the questionnaire, attitudes and perceptions of the family practitioner, as related to the exorbitant cost of medicines were tested by Q6, Q7 and Q8. Table 9 below shows that a majority 93 % (44 % + 49 %) of the doctors agree that the cost of medicines is an important factor when prescribing medicines. Moreover, 79 % (34 % + 45 %) of the respondents also admit, that the cost of medicines actually limits their ability to provide satisfactory care to their patients. Of note, 78 % (37 % + 41 %) of the doctors concede that the wider use of generic medicines is a cost-effective measure.

TABLE 9: Analysis- Cost of medicines influencing prescription

Q6 The cost of medicines limits my ability to provide satisfactory care.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	3	2 %
DISAGREE	22	11 %
NEITHER AGREE NOR DISAGREE	16	8 %
AGREE	90	45 %
STRONGLY AGREE	67	34 %
TOTAL	**198**	**100 %**
Q7 The cost of medicines is an important factor when choosing/prescribing treatment.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	1	1 %
DISAGREE	6	3 %
NEITHER AGREE NOR DISAGREE	6	3 %
AGREE	87	44 %
STRONGLY AGREE	98	49 %
TOTAL	**198**	**100 %**
Q8 I believe a wider use of generic medicines is an important cost effective measure.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	5	3 %
DISAGREE	14	7 %
NEITHER AGREE NOR DISAGREE	24	12 %
AGREE	74	37 %
STRONGLY AGREE	81	41 %
TOTAL	**198**	**100 %**

4.2.3 Patient factors influencing generic prescription

This can be further divided into:

I. Financial capacity of the patient

II. Patient and his disease

III. Patient's opinion

I. Financial capacity of the patient:

This is reflected by the results of Q9 and Q12 as shown in Table 10. A significant 25 % (20 % + 5 %) of the doctors do not prescribe generics for patients with satisfactory financial means, and another 8 % were neutral on this issue. By implication, patients with satisfactory financial means are prescribed ethical products. Cash paying patients are addressed in Q12. Here, 13 % (10 % + 3 %) of the doctors agree that the use of generic medicines is reserved for cash paying patients only, which generally, tend to come from the poorer community. But, 79 % (32 % + 47 %) of the respondents disagree that generics are prescribed for cash paying patients only.

TABLE 10: Analysis- Generic prescription & patient's financial capacity

Q9 I do not prescribe generic medicines for patients with satisfactory financial means.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	40	20 %
DISAGREE	93	47 %
NEITHER AGREE NOR DISAGREE	16	8 %
AGREE	40	20 %
STRONGLY AGREE	9	5 %
TOTAL	**198**	**100 %**
Q12 I prescribe generic medicines for my cash patients only.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	63	32 %
DISAGREE	92	47 %
NEITHER AGREE NOR DISAGREE	17	8 %
AGREE	21	10 %
STRONGLY AGREE	5	3 %
TOTAL	**198**	**100 %**

II. Patient and his disease:

Patient's disease profile affects the doctor's choice of medicines. This is reflected by Q18 and Q19 and is illustrated in Table11. Most of the doctors, 80 % (28 % + 52 %), disagree that generics should be confined to chronic diseases only. By implication, the other 20 % (12 % + 5 % + 3 %) do restrict the use of generics to chronic non-remitting diseases and do not use generics in acute life threatening diseases. Of interest, 41 % (24 % + 17 %) of the doctors agree that they are concerned when using generics for a patient with serious disease and would prefer, by implication, the use of ethical drugs. Conversely, 47 % (35 % + 12 %) of the doctors are not concerned when using generics for serious diseases.

TABLE 11: Analysis- Generic prescription & patient's disease profile

Q18 Generic medicines should be confined to chronic diseases.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	55	28 %
DISAGREE	103	52 %
NEITHER AGREE NOR DISAGREE	24	12 %
AGREE	10	5 %
STRONGLY AGREE	6	3 %
TOTAL	**198**	**100 %**
Q19 I am concerned when prescribing generic medicines for patients with a serious disease.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	24	12 %
DISAGREE	69	35 %
NEITHER AGREE NOR DISAGREE	24	12 %
AGREE	48	24 %
STRONGLY AGREE	33	17 %
TOTAL	**198**	**100 %**

III. Patient's attitude regarding generic medicines:

Q 20 and Q 21, as perceived by the doctor, test patients' attitudes towards generic use. Whether the patients are receptive in making a generic switch, or not, is addressed by Q 21. Here 76 % (65 % + 11 %) of the doctors found that most of their patients are receptive and willing to make a generic switch, but about 9 % of the doctors found that most of their patients disagree with the use of generic alternatives. Whether or not the doctors inform their patients, when prescribing a generic alternative, is addressed by Q 20. Surprisingly, only 53 % (43 % + 10 %) of the doctors inform their patients when prescribing a generic alternative. A significant 22 % (18 % + 4 %) of the family practitioners do not inform their patients. This is shown in Table 12.

TABLE 12: Analysis- Generic prescription & patient's attitude

Q 21 Most of my patients are receptive to a generic alternate prescription.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	0	0 %
DISAGREE	18	9 %
NEITHER AGREE NOR DISAGREE	30	15 %
AGREE	128	65 %
STRONGLY AGREE	22	11 %
TOTAL	**198**	**100 %**
Q20 I inform my patients when I am prescribing a generic alternative.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	8	4 %
DISAGREE	35	18 %
NEITHER AGREE NOR DISAGREE	50	25 %
AGREE	85	43 %
STRONGLY AGREE	20	10 %
TOTAL	**198**	**100 %**

4.2.4 Generic prescription and the family practitioner's clinical autonomy

This attitude was tested by Q13 and Q14. Here, it is clearly shown that only 55 % (46 % + 9 %) of the family practitioners agree that the active request by medical aid schemes, to use generic alternatives, is acceptable to them. But, 27 % (10 % + 17 %) of the family practitioners clearly disagree with such requests. Similarly, 51 % (42 % + 9 %) of the respondents agree with the active request by pharmacists to use generic alternatives, but 36 % (14 % + 22 %) of the doctors clearly object to such suggestions.

TABLE 13: Analysis- Generic prescription & doctor's clinical autonomy

Q 13 Active request by medical aid schemes to use generic alternatives is acceptable to me.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	20	10 %
DISAGREE	34	17 %
NEITHER AGREE NOR DISAGREE	36	18 %
AGREE	90	46 %
STRONGLY AGREE	18	9 %
TOTAL	**198**	**100 %**
Q 14 Active request by pharmacists to use generic alternatives is acceptable to me.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	28	14 %
DISAGREE	43	22 %
NEITHER AGREE NOR DISAGREE	26	13 %
AGREE	83	42 %
STRONGLY AGREE	18	9 %
TOTAL	**198**	**100 %**

4.2.5. Generic prescriptions and the Specialist's influence

Q 22 and Q 23 test this. A significant 43 % (30 % + 13 %) of the family practitioners agree that they are often disappointed when the supporting specialists prescribe the original brand drug rather than a generic, indicating higher use of ethical drugs by the supporting specialists. Moreover, 23 % (17 % + 6 %) of the doctors feel that their supporting specialists are unhappy when a switch to a generic alternative is made. This is shown in Table 14.

TABLE 14: Analysis- Generic prescription & Specialist's influence

Q 22 I am often disappointed when my supporting specialists prescribe original ethical products rather than generics.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	8	4 %
DISAGREE	44	23 %
NEITHER AGREE NOR DISAGREE	60	30 %
AGREE	60	30 %
STRONGLY AGREE	26	13 %
TOTAL	**198**	**100 %**
Q 23 My supporting specialists are usually unhappy when I switch to generic alternatives.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	12	6 %
DISAGREE	60	30 %
NEITHER AGREE NOR DISAGREE	81	41 %
AGREE	33	17 %
STRONGLY AGREE	12	6 %
TOTAL	**198**	**100 %**

4.2.6 Strategies promoting wider use of generics

Strategies promoting wider use of generics as perceived by the family practitioner are tested by Q16, Q17 and Q24. A significant 34 % (26 % + 8 %) of the doctors feel that financial incentive is necessary to promote generic usage, but 45 % (20 % + 25 %) of the doctors disagree with such suggestion. With regards to the marketing of generics, 59 % (47 % + 12 %) of the doctors feel that the marketing of generics is below par when compared with that of ethical drugs. Also, 60 % (46 % + 14 %) of the doctors feel that the formulary drawn up by the IPA/Guild is necessary to further promote the use of generic medicines, while 19 % (14 % + 5 %) of the doctors disagree with this suggestion. The results are shown in Table 15.

TABLE 15: Analysis- Strategies promoting wider use of generics

Q 16 Financial incentive (direct and indirect) is an acceptable measure to promote wider use of generics.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	42	20 %
DISAGREE	49	25 %
NEITHER AGREE NOR DISAGREE	39	20 %
AGREE	52	26 %
STRONGLY AGREE	16	8 %
TOTAL	**198**	**100 %**
Q 17 Marketing of generics by Pharmaceutical companies is below par when compared to that of original products.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	14	7 %
DISAGREE	38	19 %
NEITHER AGREE NOR DISAGREE	30	15 %
AGREE	93	47 %
STRONGLY AGREE	23	12 %
TOTAL	**198**	**100 %**
Q 24 A formulary drawn up by my IPA/Guild to guide generic medicine use is very necessary.		
	FREQUENCY	**PERCENTAGE**
STRONGLY DISAGREE	10	5 %
DISAGREE	27	14 %
NEITHER AGREE NOR DISAGREE	44	21 %
AGREE	90	46 %
STRONGLY AGREE	27	14 %
TOTAL	**198**	**100 %**

4.3 RELIABILITY TEST

A measure is reliable to the degree that it yields consistent results. Reliability is concerned with estimates of the degree, to which a measurement is free of random or unstable error. Reliable instruments are robust, and work well under different conditions. This distinction of time, and condition, is the basis for frequently used perspectives on reliability—stability, equivalence, and internal consistency. Reliability analysis studies the properties of measurement scales, and the items that make them up. It does this by calculating a number of commonly used measures of scale reliability, and provides information about the relationships between individual items in the scale (Cooper D, 1998).

Cronbach's Alpha This is a model of internal consistency, based on the average inter-item correlation. It reflects the degree with which the instrument, the questionnaire, has items that are homogeneous and reflect the same underlying construct (Cooper D, 1998).

In this study, Q 1 to Q 30 from the questionnaire, were tested for reliability analysis with Cronbach's Alpha using SPSS. This revealed:

Alpha = .5260

This indicates that the data was moderately reliable.

4.4 FACTOR ANALYSIS

4.4.1 INTRODUCTION TO FACTOR ANALYSIS

Factor analysis is a means of data reduction, and is utilised to reveal the underlying factors, that account for the potential correlations between variables. In this study, it assisted in identifying the more important group of responses, affecting the generic prescription by family practitioners. The first step is to develop a set of correlations, between all the variables of interest. As the project was primarily about the attitudes and perceptions of the family practitioners, and the factors affecting their prescription, the questions concerning the individual characteristics and the personality traits of the family practitioners were left out, for the purposes of factor analysis.

In the correlation matrix, most of the data has the correlation coefficient of the value of 0.3 or above. In addition, the p value is less than 0.01, making the data highly significant. Furthermore, factor analysis of the data was deemed appropriate, as the Kaiser-Meyer-Olkin measure of sampling adequacy of 0.724, was obtained for the importance rating score. This is high on a 0 to 1 scale (Stewart, 1981:58).

TABLE 16: Kaiser-Meyer-Olkin and Bartlett's Test

Kaiser-Meyer-Olkin Measure of Sampling Adequacy		.724
Bartlett's Test of Sphericity	Approx. Chi-Square	912.776
	df	171
	Sig.	.000

The second step is to "extract" a set of initial factors, from the correlation matrix already developed. Principal component method, as well as Alpha method, of factor extraction was used. The Alpha method can interpret both variables and the extracted factors, and can be used when the list of variables is assumed to be a sample from a universe of relevant variables.

The third step is to "rotate" the initial factors, to find a solution. In order to ensure "stability" and "robust" data, a process of rotations is used in the factor analysis. Stewart (1981:59) points out that most rotational methods tend to yield similar results, for a given set of data, and this tendency was confirmed, using multiple rotational methods. Here, the Varimax and Equamax rotation are shown in Table 17, although all the different rotation and extraction methods were analysed and shown to reveal similar results. The approach was adapted from O'Neill C *et al*, (1997).

This report consists of five factors. Most factors bear resemblance to the expected attitude/perceptions constructs. It must be noted that, although one can identify specific high loadings, each factor consists of unique strengths and weaknesses of all the questions, working interdependently, to form the factor (Cooper D, 1998). In the report, however, the Alpha method explains only about 38.9 % of the total variance, as opposed to the Principal component method, which explains about 54.8 % of the total variance. As the total variance explained is only about 54.8 %, the reader must interpret it with due caution. Here, 45.2 % of the variance not explained by the five factors represents a limitation of the factor analysis.

4.4.2 SCREE PLOT

This method is suitable for an analysis that has less than 40 variables (Cooper D, 1998). The number of factors extracted, was based on the roots criterion, whereby, only factors with eigenvalues greater than 1.0 are removed. The Scree method of factor extraction was explored, and this also yielded the five factors mentioned. After the five factors, each with eigenvalue >1, very few factors actually add any substantial information (Cooper D, 1998). The scree plot below shows that after factor 5, the curve has an "elbow" as shown below.

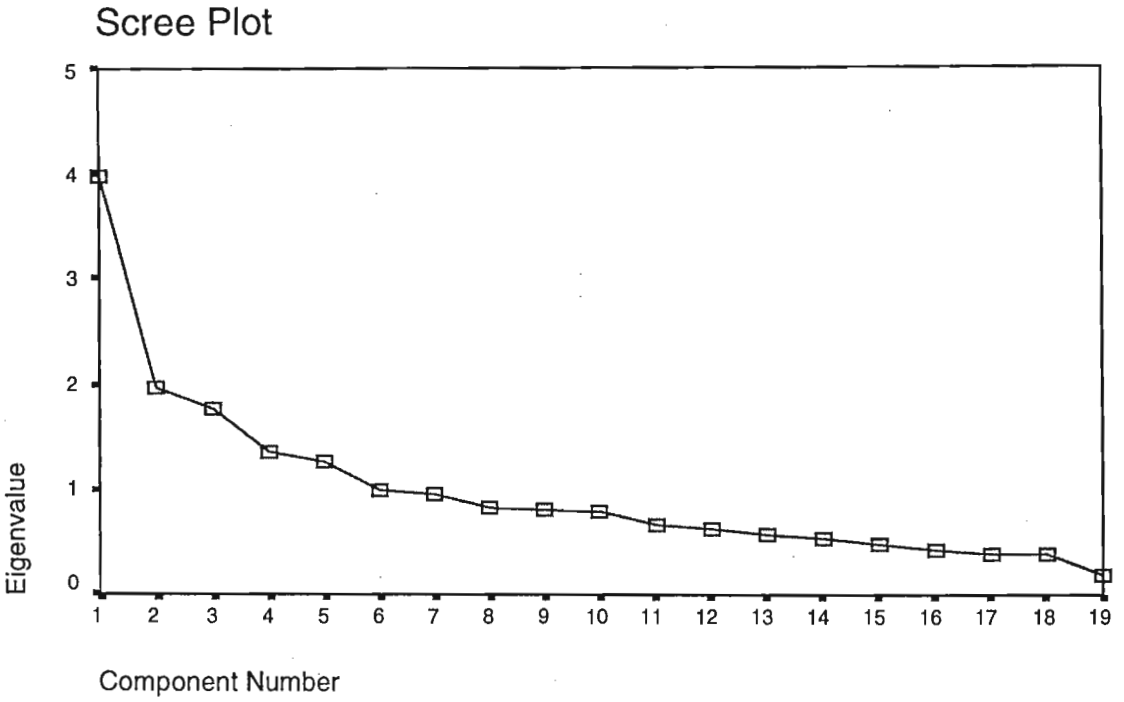

Figure: 6 Scree Plot

4.4.3 FIVE FACTORS

The five factors include doctors' attitudes/perceptions, as well as the factors affecting their prescription. The author has subjectively labelled the five factor descriptions, based on the loading, and in the order of importance. These are as follows:

1) Patient Concerns: Patient's disease pattern and his financial capacity.
2) Clinical autonomy of the doctors.
3) Strategies promoting wider use of generics: Financial incentive and the marketing of the generics.
4) Cost of medicines.
5) Specialists' opinion.

Factor 1: Patient Concerns

As identified by both Equamax and Varimax rotation, there are two items that make up factor one. Factor one has the highest variance, accounting for 18.5 % variance by Alpha extraction, and, 16.5 % by the Principal component method of extraction. The two items, together with their components, which make up factor one, are as follows:

- The patient's disease pattern:
    i. The seriousness of the disease.
    ii. The chronic nature of the disease.
- The patient's financial capacity:
    i. Prescribing generics for cash patients.
    ii. Prescribing ethical drugs for patients with satisfactory financial means.

These patient factors primarily seem to dictate the use of generic versus ethical drugs by family practitioners.

Factor 2: Doctor's clinical autonomy

This is another significant factor explaining 12.7 % of the variance for the Principle component extraction, Varimax rotation. The two items that make up this factor are as follows:

- Active requests by medical schemes.
- Active requests by pharmacists.

Most family practitioners do not like their clinical judgement to be challenged by those outside of their profession. They truly value their clinical freedom and autonomy. This is reflected by its high variance.

There are other items in both factor one and two but, because of their lower loading, are not mentioned.

Factor 3: Strategies promoting wider use of generics

This factor explains 9.1 % of the variance for the Principle component extraction, Varimax rotation. The two primary strategies to promote the wider use of generics include:

- The financial incentive (direct and indirect) to promote generics.
- The increased marketing effort by the generic pharmaceutical companies.

The family practitioners feel that these strategies should promote the wider use of generics.

Factor 4: Cost of medicines

This factor explains 8.5 % of the variance for the Principle component extraction Varimax rotation. The cost of medicines is an important factor and is reflected by two items:

- The cost of medicines is an important factor when deciding on the treatment.
- The cost of medicines is a limiting factor to providing satisfactory care.

This important factor reflects the impact of the high cost of medicines as well as the family practitioners' cost consciousness.

Factor 5: Specialists Opinion

This reflects 7.9 % of the variance in Principle component extraction, Varimax rotation category. This factor illustrates the specialists' influence on the family practitioners' attitudes, and their prescribing habits. The two items that reflect this are as follows:

- The family practitioners' disappointment when specialists do not prescribe generics.
- The specialists' disapproval when the generics are used.

TABLE17: Analysis- Factor loading scores for Varimax and Equamax rotation to analyse respondents' rating

Variable	Alpha Extraction Varimax Rotation	Alpha Extraction Equamax Rotation	Principle Component Extraction Varimax Rotation	Principle Component Extraction Equamax Rotation
Factor 1: Patient factors **Variance explained by the factor (%)**	**(18.5%)**	**(18.5%)**	**(16.5 %)**	**(15.5%)**
▪ Patient's disease pattern Generic medicines use should be confined to chronic diseases.	.576	.594	.645	.664
I am concerned when prescribing generic medicine for patients with serious diseases.	.628	.600	.678	.660
▪ Patient's financial capacity I prescribe generic medicines for my cash paying patients only.	.626	.600	.667	.683
I do not prescribe generic medicines for patients with satisfactory financial means.	.581	.593	.690	.671
Factor 2: Doctor's clinical autonomy **Variance explained by the factor (%)**	**(6.8%)**	**(6.8%)**	**(12.7 %)**	**(12.9%)**
▪ Active request by medical aid schemes to use generic alternatives is acceptable.	.631	.642	.722	.739
▪ Active request by pharmacists to use generic alternatives is acceptable to me.	.591	.606	.708	.728
Factor 3: Strategies for wider use **Variance explained by the factor (%)**	**(6.1%)**	**(6.1%)**	**(9.1%)**	**(9.3%)**
▪ Financial incentive is an acceptable measure to promote the wider use of generics	.477	.477	.643	.644
▪ Marketing of generics by pharmaceutical companies	.360	.351	.560	.544
Factor 4: Cost of medicines **Variance explained by the factor (%)**	**(3.5%)**	**(3.5%)**	**(8.5%)**	**(8.5%)**
▪ The cost of medicines limits my ability to provide satisfactory care.	.639	.640	.809	.808
▪ The cost of medicines is important factor when choosing treatment.	.664	.664	.789	.790
Factor 5: Specialists' opinion **Variance explained by the factor (%)**	**(3.9%)**	**(3.9%)**	**(7.9%)**	**(8.5%)**
▪ I am disappointed when supporting specialists prescribe ethical products.	.656	.622	.688	.722
▪ My supporting specialists are unhappy when I switch to generics.	.501	.560	.800	.770
Kaiser-Meyer-Olkin measure of sampling adequacy	.724	.724	.724	.724
Total % of variance explained	**38.9 %**	**38.9 %**	**54.8 %**	**54.8 %**

4.5 CHARACTERISTICS AND THE PERSONALITY TRAITS OF THE FAMILY PRACTITIONERS AS RELATED TO THE PERCENTAGE OF GENERICS PRESCRIBED

The chi-square cross-tabulation test was chosen to identify the individual characteristics of family practitioners that emphasise high use of generics as opposed to low use. Here, the percentage of generics, which were prescribed by an individual doctor, was compared with other characteristics of the family practitioners, such as the age of the doctor, the duration of family practice and the type of practice (dispensing vs. non-dispensing practice, and, the percentage of cash paying patients in the practice). Chi-square cross-tabulation test was chosen, as both the variables are independent. Here, a low significance value of 0.05 indicates some relationship between the variables. When this was done in this study, no significant relationship was found as the p value was greater than 0.05 in each case. This means that, in this study, there was no relationship found between the percentage of generics prescribed and the "type" of the doctor. This is shown briefly in Table18 below.

TABLE 18: Analysis- Chi-Square Cross-tabulations relating the percentage of generics prescribed with the characteristics of the doctor

CROSSTABS
Chi-Square Tests

	% prescriptions being generic medicines versus the doctor's age			% prescriptions being generic medicines versus Dispensing practice			% prescriptions being generic medicines versus duration of practice			% prescriptions being generic medicines versus % of cash paying patients		
	value	df	Asymp. sig (2-sided)	value	df	Asymp. Sig (2-sided)	value	df	Asymp. Sig (2-sided)	value	df	Asymp. Sig (2-sided)
Pearson Chi-Square	11.101	9	.269	3.981	3	.264	10.697	9	.297	12.630	9	.180
Likelihood Ratio	11.790	9	.225	3.468	3	.325	12.079	9	.209	13.763	9	.131
Linear-by-Linear Association	1.844	1	.175	.478	1	.489	.532	1	.466	5.658	1	.017
N of Valid Cases	198			198			198			198		

Annexure 2 contains the details of the Chi-Square Cross-tabulations (pages 80-89).

Also, similar cross-tabulations with chi square test were performed, between the percentage of generics prescribed, and the personality traits of the doctor. Whether the

doctors were "disillusioned," "self-satisfied," "over-stretched," "experimentalist" or "postgraduate", no statistically significant relationship was obtained as the p value was consistently above 0.05. This is shown briefly in Table19.

TABLE 19: Analysis- Chi-Square Cross-tabulations relating the percentage of generics prescribed with the personality traits of the doctor

CROSSTABS

Chi-Square Tests

	% prescriptions being generic medicines versus "Disillusioned"			% prescriptions being generic medicines versus "Overstretched"			% prescriptions being generic medicines versus "Postgraduate" *		
	value	df	Asymp. sig (2-sided)	value	df	Asymp. Sig (2-sided)	value	df	Asymp. Sig (2-sided)
Pearson Chi-Square	19.057	12	.087	14.880	12	.248	24.786	12	.016
Likelihood Ratio	20.006	12	.067	14.859	12	.249	20.896	12	.052
Linear-by-Linear Association	.180	1	.672	.003	1	.958	.115	1	.734
N of Valid Cases	198			198			198		

	% prescriptions being generic medicines versus "Progressive"			% prescriptions being generic medicines versus "Self Satisfied"			% prescriptions being generic medicines versus "Experimentalist"		
	value	df	Asymp. sig (2-sided)	value	df	Asymp. Sig (2-sided)	value	df	Asymp. Sig (2-sided)
Pearson Chi-Square	12.370	12	.416	12.152	12	.110	15.508	12	.215
Likelihood Ratio	12.895	12	.377	13.115	12	.053	13.266	12	.350
Linear-by-Linear Association	1.128	1	.288	.339	1	.468	.013	1	.908
N of Valid Cases	198			198			198		

Annexure 2 contains the details of the Chi-Square Cross-tabulations (pages 80-89).

*As 55 % of the cells have an expected count less than 5, the Pearson Chi-Square test, in this case, is not valid (see p.86).

Thus, from the study, one can conclude, that the individual characteristics and the personality traits of the doctor do not significantly impact on the percentage of generics prescribed by the family practitioner. Instead, the five factors, elucidated by factor analysis, are deemed critical.

4.6 PROBLEMS ENCOUNTERED BY GENERIC MEDICINES

This section was optional. About 67 % (133) of the respondents commented. Their responses were coded according to the broad categories. Once coded, frequency analysis was conducted. These qualitative responses give good insights into the problems that family practitioners face when using generic medicines.

- 67 % of the doctors who responded expressed serious concerns regarding the efficacy/effectiveness of the generics. Many of them quoted partial or even "total failure of treatment" and that generics "simply do not work." 42 % were doubtful of the quality of generics.
- 53 % of the family practitioners were concerned about the increased side effect profile experienced with the use of generics. Many doctors report that the patients are "worse off" by using generic medicines instead of the ethical drugs. In some cases, it was reported that patients actually deteriorated. This was clearly unacceptable for the family practitioners.
- The cost-effectiveness of generics was not as significant as it was originally assumed. 65 % of the family practitioners complained that the generics available are "not as cheap as they should be". The "price difference between the generics, and the ethical drugs is marginal", and "not as wide as it is perceived". This makes the switch to generic very difficult to justify, as the risks increase, but there is no significant cost saving.
- Packaging of the generic drugs is not adequate. As a result, by the time the goods reaches the ultimate consumer (the patient) tablets are often crushed/damaged.
- Lack of patient confidence in the generics remains a problem as mentioned by 35 % of the family practitioners.
- The erratic supply of generics in the market place was quoted as yet another problem faced by 24 % of the doctors.
- About 20 % of the family practitioners complained that there are "too many inferior generics" with "poorer quality formulations", available in the marketplace. They feel that there is little regulation of the quality of these generics by MCC (Medicines Control Council).

Thus, significant and valid problems were raised by the family practitioners in the study. These need to be addressed by the government, generic pharmaceutical industry and managed care organisations.

4.7 RECOMMENDATIONS BY THE FAMILY PRACTITIONERS TO INCREASE GENERIC USE

This section was also optional. Around 71 % (141) of the doctors answered this section. Their responses were coded according to the broad categories. Once coded, frequency analysis was conducted. These qualitative responses give good insights into the strategies that the family practitioners feel will increase the use of generics by doctors. Among the recommendations made by the family practitioners, the essential findings include:

- Continuing health education: About 54 % of the respondents feel that the key is to increase the awareness, and change the perceptions of all involved. This includes the health care personnel (doctors, nurses, pharmacists), and the general public.
- Research: About 64 % of the doctors want to see at least some basic published research, done by the generic pharmaceutical companies, to prove that the efficacy and bio-equivalence of the generic drugs is similar to the ethical products. This scientific proof, they feel, will restore their confidence in the quality of generics and promote their use. This should not involve the huge capital outlay like the ethical pharmaceutical companies.
- Price: About 60 % of the doctors feel that the cheaper price of generics would help increase its use. Most feel that generics are still not as cheap as they should be and the price difference between the generic and the ethical product is not significant.
- Marketing: Aggressive marketing of the generics would certainly increase its market share, according to 43 % of the doctors.
- Stricter monitoring of generics: 42 % of the family practitioners would like a controlling body like MCC (Medicines Control Council), to monitor the quality of the generics on the market more closely. Many of these doctors (35 %) feel that there are "too many generics" available on the market, with the "quality of all not being closely monitored".
- Improved presentation: About 30 % of the family practitioners suggest improved packaging and presentation of the generics so that the medication, when it reaches its ultimate consumer, the patient, is still acceptable.

- Strategies to promote generics: 40 % of the doctors admit that offering financial incentive to the doctors and pharmacists might actually increase generic usage. 10 % of the doctors feel that the formulary and/or legislation will also enforce the wider use of generics.
- Improved distribution channels: About 10 % of the doctors feel that generics are not readily available. Improving the distribution channels should ensure reliable supply of generics to the market.

CHAPTER 5: RESEARCH CONCLUSIONS AND RECOMMENDATIONS

5.1 ACHIEVEMENT OF THE RESEARCH OBJECTIVES

The primary aim of this study is to elucidate the attitudes and perceptions that family practitioners have towards the use of generic medicines. The secondary aim of the study is to evaluate the factors that affect the prescription of pharmaceuticals by family practitioners. The third aim is to research the individual characteristics of family practitioners, and their personality traits, that impact their generic prescription.

5.1.1 ATTITUDES OF FAMILY PRACTITIONERS TOWARDS GENERICS AND FACTORS AFFECTING ITS PRESCRIPTION

Using factor analysis, this study identifies five important features that affect the attitudes, perceptions and the prescribing habits of the family practitioners. These are as follows:

1) Patient Concerns: Patient's disease pattern and his financial capacity.
2) Clinical autonomy of the doctors.
3) Strategies promoting wider use of generics: Financial incentive and marketing of generics.
4) Cost of medicines.
5) Specialist's opinion.

Factor 1: Patient Concerns

The study clearly demonstrates that most family practitioners put their patients' interests first. The patient factors, as identified by factor analysis, are the patient's financial capacity and his disease pattern. These, primarily, dictate what the family practitioners prescribe. In this study, (TABLE 11, page 46), 41 % of the family practitioners were concerned, when using generics for a patient with serious disease and would prefer, by implication, the use of ethical drugs. This implies that ethical drugs, despite being more expensive, have doctors' trust because of their proven research and performance track records. Family practitioners prescribe what they feel is best for their patients.

Moreover, as the newer drugs are discovered, "purer" forms of drugs, with improved efficacy, and fewer side effect profiles, become available. Often, then there is little justification to prescribe older drugs, especially in the patients with serious disease (Mehl B, 1998). An example of a similar argument is the use of Cox-2 drugs, where safety is important. More than 20 million patients have severe arthritis. Some 13 million use ibuprofen and other nonsteroidal anti-inflammatory drugs regularly. Of those, 2 % to 4 % have severe stomach problems; 15 % have milder side effects such as nausea and heartburn; up to 17 000 die from drug complications annually. "The numbers are small, but why take a chance?" says Bevra Hahn, President of the American College of Rheumatology (Toma T, p. 670, 2000).

Patient's financial capacity is also an important consideration. This study shows that 25 % of the doctors (TABLE 10, page 45) do not prescribe generics for patients with satisfactory financial means. These two factors seem to primarily dictate the use of generics versus ethical drugs by the family practitioners.

Factor 2: Doctors' clinical autonomy

Dr. B. Jan, a family practitioner in Los Angeles, feels that it is "impossible to practice good medicine, if you are punished, for prescribing what you think is best for the patient" (Mehl B, p. 135, 1998). Doctors' clinical autonomy is a very significant factor, and where this has not been respected, it has not been surprising to find that the managed care has not been successful. One of such places includes southern Africa. Discovery Medical Aid CEO, Adrian Gore, in a recent newspaper article, (Survey: Managed Health Care: Little satisfaction. page 8, Sunday Times, Business Times, April 29, 2001) admitted, "...by and large managed health care has not worked in South Africa." The patients (customers), too, are not very satisfied, either. They, too, complain about their medical schemes regarding inadequate benefits, and inefficient payments despite high monthly membership fees.

Many family practitioners (TABLE 13, page 48) do not like the interference by pharmacists, or medical aids, and do not readily accept their active request. This is seen to be questioning doctors' clinical decisions, without assuming being legal responsibility for these decisions and its consequences. Another reason is the lack of trust and transparency by medical aids. Indeed, a newspaper report suggested, that medical schemes are holding pharmaceutical companies at ransom, and have threatened to remove drugs off their essential list of medicines /formularies, unless the pharmaceutical industry companies pay them "substantial kickbacks." (Cameron J, 2001).

Yet another reason the family practitioners are dissatisfied with managed health care is because they feel that they are grossly underpaid by the medical schemes and their yearly increase has consistently been below the inflation rate. It has been quoted that the payment to family practitioners by medical aids have actually decreased by 3 % from the period of 1989-1999, in contrast to the benefits to the specialists, and hospitals that have increased by 82 % and 500 % respectively in the same period. (du Preez, 2001).

These issues need to be addressed to allow family practitioners, managed care organisations, government, and generic pharmaceutical industry to work together to promote generics.

Factor 3: Strategies promoting wider use of generics

The strategy of providing the financial incentive (direct and indirect) to the family practitioner may help promote wider use of generics. It has been reported by Monane M *et al,* (1998), that managed care organisations either penalise doctors for not sticking to formularies/generic drugs, or alternatively, reward them for using the correct drugs. This, however, raises ethical issues. The Ethics SA survey, done in October 2000, shows that 73 % of the responding doctors believe that South African doctors are ethical in their professional conduct, and 91 % believe that the practice of medicine imposes a higher standard of moral integrity than other professions (http://www.ethicsa.org/report1.html).

Ethic S.A CEO, Prof. Willem Landman , reports that doctors, however, are getting increasingly frustrated, and constrained, by the unrealistic medical scheme benefits, government demands and intervention, and the conflicting interests of the role stakeholders, such as managed care and pharmaceutical industry companies. His impression is that the profession is caught between its traditional commitment to ethically sound practice, on the one hand, and growing demands of the financial survival on the other (http://www.ethicsa.org/report1.html). In this study, (TABLE 15, page 50), 45 % of the doctors disagree with the financial incentive, whereas 34 % of the doctors are willing to accept financial incentive to promote the use of generics. Noting similar situations, Fredrick J, (2000), advises that financial incentives be formally given to the pharmacists and doctors, as it will still be a cheaper route to promote generics and to cut costs. This needs to be considered instead of the enforced legislation.

Aggressive marketing by the generic pharmaceutical industries is yet another strategy that the family practitioners feel, will lead to the wider use of generic medicines. One of the most significant determinants of a drug's sales is the amount of promotion it receives, as this creates consumer demand (Beckman M, 1995). Marketing then takes the form of detailing (sales representation), direct mail, sampling (free samples provided to doctors), medical journal advertising, sponsorship of continuing medical education, public media advertising and the promotion of disease management programmes (Beckman M, 1995). Some of the family practitioners suggest that the generic industry, like the ethical drug industry, follow some of these strategies to actively market their generic products. In this study, (TABLE 15, page 50), 59 % of the doctors feel that the marketing by generic pharmaceutical industry is below par; and improving its marketing effort will certainly increase its market share. At present, marketing by the generic pharmaceutical industries is insignificant, and often the family practitioners are often unaware about the availability of the generics.

Factor 4: Cost of medicines

Alger A, (p. 130, 1999), found that physicians tend to be brand loyal, and tend to prescribe higher-priced drugs, even when an identical copy, the generic, is available at a significant saving. He states that generics accounted for 40 % of prescriptions, but could be 75 %, if they were prescribed as often as could be. He observed, the "... generics wouldn't even get 40 % of the market, if it were not for the laws that permit pharmacists to substitute for the brand names."

This was not reflected by the current study. This study (TABLE 9, page 44), confirms cost consciousness of the family practitioners, as they are aware of the exorbitant cost of medicines, and its impact in limiting their care. Majority of the doctors (78 %) feel that the wider use of generic medicines is a cost-effective measure. They, however, point out that the "price difference between the generics and the ethical product is not as wide as it should be." They also feel that "generics are almost as expensive as the ethical drugs" but feel that the "price reduction of generics will lead to its increased use." It is important to realise this, as further price reduction on generics, is likely to yield its increased market share.

Factor 5: Specialists Opinion

This factor highlights the specialists' influence on the family practitioners' attitudes, and his prescribing habits. A significant 44 % of the family practitioners (TABLE 14, page 49) concur that they are often disappointed when their supporting specialists prescribe original brand drug, rather than a generic. This typifies higher ethical medicine use by the supporting specialists. This is partly because the specialists are better informed, regarding the subtle differences present between the different drugs, and the significant effect it may have on the patient's disease profile.

The family practitioner respects the specialist's view. The ethical pharmaceutical industry targets the specialists as they realise this and the "snowball" effect of this strategy. In 1991, in the USA, it was estimated that the ethical pharmaceutical industry spent approximately US$1 billion more on marketing and advertising, than on research internationally, or an excess of US$ 8000 per annum, per specialist, on promotion of the pharmaceuticals (Mehl B *et al*, 2000). Specialist education, therefore, seems to be a priority in the cost cutting exercise.

5.1.2 CHARACTERISTICS AND PERSONALITY TRAITS OF THE FAMILY PRACTITIONERS AS RELATED TO THEIR GENERIC PRESCRIPTION

It was found in the literature survey (Corstjens M, 1991), that younger doctors were more price-sensitive and therefore more likely to use generics, as opposed to the older, more established doctors, who tend to prefer ethical products. However, this study shows no statistically significant differences between the age of the doctor and duration of his practice, type of practice or even the personality traits of the family practitioners when related to the percentage of the generics prescribed by them (TABLE 18, page 57; TABLE 19, page 58; Annexure: 2). One possible explanation for this is that the circumstances facing doctors in Southern Africa, is different to the circumstances facing doctors in the U.K., where the original study was conducted. In the first world countries, the factors affecting the prescription of generics are often very different. Some of these factors include: subsidisation of medication by the government [for example by NHS (National Health Service), in the United Kingdom]; enforced legislation as in Spain and Romania, where the doctors are forced to prescribe generics; and in Canada and New Zealand, where the generics are much more easily available, than the ethical drugs because of the government policies (Mehl B *et al*, 2000).

5.2 LIMITATIONS OF THE STUDY

This research was conducted over a two-month period, and reflects a single "snap-shot" in time. Due to the dynamic, changing environment of the health care industry in South Africa, especially where family practitioners are concerned, this research would have to be repeated at regular intervals, in order to gain a more complete "motion-picture" assessment, and also to detect some of the less obvious trends. Some specific limitations of the research should be noted.

- Most of the doctors were from urban and semi-urban settings. Those from rural areas were not adequately represented in the study.
- All doctors were combined into one sample population. No distinction was made between the doctors from different cities and the doctors from different countries. Rather, this analysis adopted a broad perspective of the situation facing doctors as a whole.
- The sample is a convenience sample.

5.3 MANAGEMENT IMPLICATIONS AND RECOMMENDATIONS

The following recommendations can be made from the study:

❖ For the generic pharmaceutical industry, it is recommended:

- ➢ The generic pharmaceutical industry performs and publishes some basic research to prove similar efficacy to that of ethical drugs. This should signal the commitment of the generic pharmaceutical industry towards producing reliable medications and win doctors' confidence.
- ➢ Most family practitioners want to use good quality, efficacious medications, without increased risks/side-effect profile. The generic pharmaceutical industry must satisfy this need. Improved quality of generics, together with better packaging, will increase its use by family practitioners.
- ➢ With the high cost of medicines affecting their clinical practice, most doctors are price-sensitive. Decrease in the price of the generics, should increase its use and its market-share.
- ➢ Increased marketing effort, by the generic pharmaceutical industry, should increase its market penetration. It is important to make doctors aware of the availability of a specific generic version of an ethical drug.

- It is also recommended that the generic pharmaceutical industry actively participate in the continuing medical education of the health-care personnel and the public.
- Reliable supply/distribution channels for the generic medicines are necessary.

- For the managed care organisations, it is recommended that:
  - Managed care executives need to work with the doctors, respecting their professionalism and clinical autonomy. Family practitioners put their patients first. Any attempt to force doctors, into prescribing any particular group of drugs will not work. It is important to realise this.
  - Financial reward schemes: It is recommended that appropriate and legitimate incentives be offered to pharmacists and dispensing doctors for promoting generics, as it will still be a cheaper route to reduce the overall pharmaceutical expenditure.
  - Increased transparency of the managed care organisations is necessary. This will increase the doctors', and the public's trust in their medical aid schemes.
  - It is also recommended that all the stakeholders in the health care system—the government, the generic pharmaceutical industry, the managed care organisations, and the medical profession work together to find a common solution. Trust is vital to working together to find a solution.

- Perceptions of the specialists, medical health professionals and the public regarding the generics need to be improved by continuing health education.

- Further price reduction of generic medicines is necessary. Price reduction of generics should be further subsidised by generic pharmaceutical companies, government, or by managed care organisations, either together or singly, so that generics become truly affordable. This will further promote its use.

- It has been suggested that MCC, play a more scrutinising role in the registration of generics. The quality, efficacy and bio-equivalence of generics should be closely monitored, and the results be made known to the medical fraternity.

There are very few industries that have experienced the same level of fundamental change, as the health industry since independence in South Africa. Different stakeholders in the industry need to act synergistically, to bring about a reduction in healthcare cost.

5.4 AREAS FOR FURTHER RESEARCH

- Scientific and clinical research needs to be conducted regarding the efficacy of generics available in the market.
- Further research also needs to be conducted to ensure that generic medicines are really cheaper over a long term as claimed to be.
- The means to achieve further price reduction of generics can be researched.
- The study could be repeated with random sample, nationwide, with a bigger number of doctors surveyed.
- Further research needs to be conducted, with a scientific sample, to ascertain attitudes and perceptions of specialists, pharmacists, patients, and the general public. This should provide further insights into the problems facing the market for generic medicines.
- The means of reducing overall cost of health care in the developing country like South Africa can be researched.
- High levels of change can become dysfunctional for the industry. Research needs to be conducted in a way whereby different stakeholders come together, and manage the change process. Although international models, can serve as a template, the approach will have to be individualised to suit local conditions, expectations, market forces, and the established prescribing patterns. Therefore, a thorough research needs to be done before International Guidelines are accepted and adapted to the South African scenario.

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ANNEXURE:1 THE RESEARCH QUESTIONNAIRE

Study Number

Dear Colleague,

I am Dr J.R. Purohit, a medical doctor doing a dissertation with the University of Natal. Your participation in my project on **generic medicines in family practice** is appreciated.
Phone: (031) 4021363 Fax : (031) 4021678 Cell: 082 880 1325

My practice is in ..... Suburb ..... City

Kindly mark answers by a tick (√) or cross (X).

1) AGE (Years)

≤ 30	31- 40	41 -50	≥ 51
1	2	3	4

2) ARE YOU A DISPENSING DOCTOR?

Yes	No
1	2

3) HOW LONG HAVE YOU BEEN IN FAMILY PRACTICE?

0-5 Years	6-10 Years	11 - 15 Years	> 15 Years
1	2	3	4

4) WHAT PROPORTION OF YOUR PRACTICE ARE CASH PAYING PATIENTS?

≤ 25%	26- 50%	51- 75%	≥ 76%
1	2	3	4

5) WHAT PERCENTAGE OF YOUR TOTAL PRESCRIPTIONS ARE GENERIC MEDICINES?

≤ 25%	26-50%	51-75%	≥ 76%
1	2	3	4

Responses to Q6 –30 are Likert scale (i.e 1= strongly disagree and 5 = strongly agree)

	Strongly disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
6) The cost of medicines limits my ability to provide satisfactory care.	1	2	3	4	5
7) The cost of medicines is an important factor when choosing/prescribing treatment.	1	2	3	4	5
8) I believe a wider use of generic medicines is an important cost effective measure.	1	2	3	4	5
9) I do not prescribe generic medicines for patients with satisfactory financial means.	1	2	3	4	5
10) I view prescription of generic drugs as being without evidence base.	1	2	3	4	5
11) I believe that use of a generic medicine is an acceptable compromise.	1	2	3	4	5
12) I prescribe generic medicines for my cash paying patients only.	1	2	3	4	5
13) Active request by medical aid schemes to use generic alternatives is acceptable to me.	1	2	3	4	5
14) Active request by pharmacists to use generic alternatives is acceptable to me.	1	2	3	4	5
15) I believe generic medicine efficacy is very comparable to the original brand product.	1	2	3	4	5
16) Financial incentive (direct and indirect) is an acceptable measure to promote wider use of generics.....	1	2	3	4	5
17) Marketing of generics by Pharmaceutical companies is below par when compared to that of original product.....	1	2	3	4	5
18) Generic medicines use should be confined to chronic diseases.	1	2	3	4	5
19) I am concerned when prescribing generic medicine for patients with a serious disease	1	2	3	4	5
20) I inform my patients when I am prescribing a generic alternative.	1	2	3	4	5

	Strongly Disagree	Disagree	Neither agree or disagree	Agree	Strongly Agree
21) Most of my patients are receptive to a generic alternate prescription.	1	2	3	4	5
22) I am often disappointed when my supporting specialists prescribe original brand product rather than generic.	1	2	3	4	5
23) My supporting specialists are usually unhappy when I switch to a generic alternative.	1	2	3	4	5
24)) A formulary drawn up by my IPA/Guild to guide generic medicine use is very necessary.	1	2	3	4	5

25 – 30
The following features best describe myself as Family Practitioner :

25. Disillusioned by the Medical profession	1	2	3	4	5
26. "Overstrectched" (feel overworked and demotivated)	1	2	3	4	5
27. "Postgraduate" (Keen on formal education methods to develop)	1	2	3	4	5
28. "Experimentalist" (confident to try new Therapies)	1	2	3	4	5
29. "Progressive" (broad minded and keen on clinical trials)	1	2	3	4	5
30. "Self Satisfied" (not keen on further formal education)	1	2	3	4	5

31) I have encountered the following problems with the use of the generic medicines in my practice.

i) .....
ii) .....

32) I believe the following strategies will result in a wider use of generic medicine.

i) .....
ii) .....

Thank your for your participation
Jigna Purohit

ANNEXURE :2 CHI-SQUARE CROSSTABULATIONS

CHI-SQUARE CROSSTABULATION OF PERCENTAGE PRESCRIPTIONS BEING GENERIC DRUGS VERSUS THE AGE OF THE DOCTOR

Age of the doctor in years	% prescriptions being generic drugs				Total
	≤25%	25 %- 50 %	51 %-75 %	≥76%	
≤30	0	4	6	2	12
31- 40	3	9	27	22	61
41 -50	2	13	29	23	67
≥51	1	13	15	29	58
Total	6	39	77	76	198

	% prescriptions being generic medicines versus the doctor's age		
	value	df	Asymp. sig (2-sided)
Pearson Chi-Square	11.101[a]	9	.269
Likelihood Ratio	11.790	9	.225
Linear-by-Linear Association	1.844	1	.175
N of Valid Cases	198		

a. 7 cells (43.8 %) have a expected count less than 5. The minimum expected count is less than .36

CHI-SQUARE CROSSTABULATION OF PERCENTAGE PRESCRIPTIONS BEING GENERIC DRUGS VERSUS THE DISPENSING DOCTOR

	% prescriptions being generic drugs				Total
	≤ 25%	25 %- 50 %	51 %-75 %	≥ 76%	
Dispensing doctor	3	30	64	59	**156**
Non dispensing doctor	3	9	13	17	**42**
Total	**6**	**39**	77	**76**	**198**

	% prescriptions being generic medicines versus the dispensing doctor		
	value	df	Asymp. sig (2-sided)
Pearson Chi-Square	3.981[a]	3	.264
Likelihood Ratio	3.468	3	.325
Linear-by-Linear Association	.478	1	.489
N of Valid Cases	198		

a. 2 cells (25 %) have a expected count less than 5. The minimum expected count is less than 1.27

CHI-SQUARE CROSSTABULATION OF PERCENTAGE PRESCRIPTIONS BEING GENERIC DRUGS VERSUS THE DURATION OF FAMILY PRACTICE

Duration of family practice in years	% prescriptions being generic drugs				Total
	≤ 25%	25 %- 50 %	51 %-75 %	≥ 76%	
0-5	1	9	17	7	34
6-10	0	9	17	24	50
10 -15	2	4	12	9	27
≥ 15	3	17	31	36	87
Total	6	39	77	76	198

	% prescriptions being generic medicines versus the duration of family practice		
	value	df	Asymp. sig (2-sided)
Pearson Chi-Square	10.697[a]	9	.297
Likelihood Ratio	12.079	9	.209
Linear-by-Linear Association	.532	1	.466
N of Valid Cases	198		

a. 4 cells (25 %) have a expected count less than 5. The minimum expected count is less than .82

CHI-SQUARE CROSSTABULATION OF PERCENTAGE PRESCRIPTIONS BEING GENERIC DRUGS VERSUS THE PERCENTAGE OF CASH-PAYING PATIENTS

% of cash-paying patients	% prescriptions being generic drugs				Total
	≤ 25%	25 %- 50 %	51 %-75 %	≥ 76%	
≤ 25%	4	19	25	29	77
25 %- 50 %	1	14	32	23	79
51 %-75 %	1	5	13	10	20
≥ 76%	0	1	7	14	22
Total	6	39	77	76	198

	% prescriptions being generic medicines versus the % of cash-paying patients		
	value	df	Asymp. sig (2-sided)
Pearson Chi-Square	12.630[a]	9	.180
Likelihood Ratio	13.763	9	.131
Linear-by-Linear Association	5.658	1	.017
N of Valid Cases	198		

a. 5 cells (31.3 %) have a expected count less than 5. The minimum expected count is less than .67

CHI-SQUARE CROSSTABULATION OF PERCENTAGE PRESCRIPTIONS BEING GENERIC DRUGS VERSUS THE "DISILLUSIONED" DOCTOR

Description of "disillusioned" doctors	% prescriptions being generic drugs				Total
	≤ 25%	25 %- 50 %	51 %-75 %	≥ 76%	
Strongly Disagree	3	2	16	9	**30**
Disagree	0	14	19	22	**55**
Neither agree or disagree	0	3	6	14	**23**
Agree	2	12	24	22	**60**
Strongly Agree	1	8	12	9	**30**
Total	**6**	**39**	**77**	**76**	**198**

	% prescriptions being generic medicines versus the "disillusioned" doctor		
	value	df	Asymp. sig (2-sided)
Pearson Chi-Square	19.057[a]	12	.087
Likelihood Ratio	20.006	12	.067
Linear-by-Linear Association	.180	1	.672
N of Valid Cases	198		

a. 6 cells (30 %) have a expected count less than 5. The minimum expected count is less than .70

CHI-SQUARE CROSSTABULATION OF PERCENTAGE PRESCRIPTIONS BEING GENERIC DRUGS VERSUS THE "OVERSTRETCHED" DOCTOR

Description of "overstretched" doctors	% prescriptions being generic drugs				Total
	≤25%	25 %- 50 %	51 %-75 %	≥76%	
Strongly Disagree	0	3	4	5	12
Disagree	4	4	22	14	44
Neither agree or disagree	0	6	11	11	28
Agree	1	17	29	36	83
Strongly Agree	1	9	11	10	31
Total	6	39	77	76	198

	% prescriptions being generic medicines versus the "overstretched" doctor		
	value	df	Asymp. sig (2-sided)
Pearson Chi-Square	14.880[a]	12	0.248
Likelihood Ratio	14.859	12	.249
Linear-by-Linear Association	.003	1	.958
N of Valid Cases	198		

a. 8 cells (40 %) have a expected count less than 5. The minimum expected count is less than .36

CHI-SQUARE CROSSTABULATION OF PERCENTAGE PRESCRIPTIONS BEING GENERIC DRUGS VERSUS THE "POSTGRADUATE" DOCTOR

Description of "postgraduate" doctors	% prescriptions being generic drugs				Total
	≤25%	25 %- 50 %	51 %-75 %	≥76%	
Strongly Disagree	0	1	0	1	2
Disagree	1	1	1	0	3
Neither agree or disagree	2	3	11	12	28
Agree	3	18	47	50	118
Strongly Agree	0	16	18	13	47
Total	6	39	77	76	198

	% prescriptions being generic medicines versus the "postgraduate" doctor *		
	value	df	Asymp. sig (2-sided)
Pearson Chi-Square	24.786[a]	12	*.016
Likelihood Ratio	20.896	12	.052
Linear-by-Linear Association	.115	1	.734
N of Valid Cases	198		

a. 11 cells (55 %) have a expected count less than 5. The minimum expected count is less than .06

* As 55 % of the cells have a expected count less than 5, the Pearson Chi-Square test is not valid.

CHI-SQUARE CROSSTABULATION OF PERCENTAGE PRESCRIPTIONS BEING GENERIC DRUGS VERSUS THE "PROGRESSIVE" DOCTOR

Description of "progressive" doctors	% prescriptions being generic drugs				Total
	≤ 25%	25 %- 50 %	51 %-75 %	≥ 76%	
Strongly Disagree	0	0	0	2	2
Disagree	1	0	3	4	8
Neither agree or disagree	2	5	8	9	24
Agree	2	23	49	48	122
Strongly Agree	1	11	17	13	42
Total	6	39	77	76	198

	% prescriptions being generic medicines versus the "progressive" doctor		
	value	df	Asymp. sig (2-sided)
Pearson Chi-Square	12.370[a]	12	.416
Likelihood Ratio	12.895	12	.377
Linear-by-Linear Association	1.128	1	.288
N of Valid Cases	198		

a. 12 cells (60 %) have a expected count less than 5. The minimum expected count is less than .06

CHI-SQUARE CROSSTABULATION OF PERCENTAGE PRESCRIPTIONS BEING GENERIC DRUGS VERSUS THE "SELF-SATISFIED" DOCTOR

Description of "self-satisfied" Doctors	% prescriptions being generic drugs				Total
	≤ 25%	25 %- 50 %	51 %-75 %	≥ 76%	
Strongly Disagree	2	9	28	23	67
Disagree	4	18	37	38	97
Neither agree or disagree	0	4	7	4	15
Agree	0	5	3	10	18
Strongly Agree	0	3	2	1	6
Total	6	39	77	76	198

	% prescriptions being generic medicines versus the "self-satisfied" doctor		
	value	df	Asymp. sig (2-sided)
Pearson Chi-Square	12.152[a]	12	.110
Likelihood Ratio	13.115	12	.053
Linear-by-Linear Association	.339	1	.468
N of Valid Cases	198		

a. 10 cells (50 %) have a expected count less than 5. The minimum expected count is less than .18

CHI-SQUARE CROSSTABULATION OF PERCENTAGE PRESCRIPTIONS BEING GENERIC DRUGS VERSUS THE "EXPERIMENTALIST" DOCTOR

Description of "experimentalist" doctors	% prescriptions being generic drugs				Total
	≤ 25%	25 %- 50 %	51 %-75 %	≥ 76%	
Strongly Disagree	1	1	0	2	4
Disagree	0	4	9	7	20
Neither agree or disagree	2	7	9	16	34
Agree	2	20	48	40	110
Strongly Agree	0	4	6	4	14
Total	5	36	72	69	198

	% prescriptions being generic medicines versus the "experimentalist" doctor		
	value	df	Asymp. sig (2-sided)
Pearson Chi-Square	15.508[a]	12	.215
Likelihood Ratio	13.266	12	.350
Linear-by-Linear Association	.013	1	.908
N of Valid Cases	198		

a. 10 cells (50 %) have a expected count less than 5. The minimum expected count is less than .11