FACTORS INFLUENCING THE SALES OF GENERIC DRUGS: A CASE STUDY OF SOUTH WESTERN KENYA

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DECLARATION AND RECOMMENDATION

This Research Project is my original work and has not been presented for a degree or any other award in any other University.

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This Research Project has been submitted for examination with our approval as University supervisors.

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DEDICATION

This Research Project document is dedicated to my wife Judy and our sons Jamey and Eddy for the encouragements and support they gave me throughout my MBA degree programme.

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ABSTRACT

Medicine is an essential item in our day-to-day lives. Conventional medicine, which is used commonly, is divided into generic and branded categories. The branded type is always first to get into the market because the original innovator company is protected by patent. It is for this reason that they are expensive and sometimes unavailable. Once the patent elapses, generics are manufactured and are marketed alongside the branded ones. This leads to competition for market share.

Studies have shown that over the recent past, the size of generic pharmaceutical market has been growing steadily. This study, therefore, looked at the factors influencing this growth in the South Western Kenya as well as the prescribers' attitudes on generic market growth.

The objective of the study was to investigate and establish the factors that influence the sales of generic drugs in the region. The study concentrated on the three towns: Kisii, Kericho, and Migori. Data collection was through personal interviews and observations where structured questionnaires were administered to doctors, pharmacists and selected patients. Fifteen registered pharmacies were selected from these towns and used for the study. The data collected was analyzed using both qualitative and quantitative techniques that include frequency distribution tables, measures of variability, and percentages. The results are expected to be of importance to all pharmaceutical companies, Ministry of Health of the Kenyan government and other health policy handlers, academicians and marketing firms.

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LIST OF ABBREVIATIONS

POM: Prescription Only Medicine, which can only be dispensed upon producing a prescription (written request) by a registered medical practitioner.

OTC: Over-the-counter medicine can be dispensed without the prescription of a doctor.

LDC: Less developed countries.

MO: Medical Officer

CO: Clinical Officer

GP: General Practitioner

WHO: World Health Organization

UNDP: United Nations Development Program

R&D: Research and Development

US: United States

WTO: World Trade Organization

EU: European Union

AIDS: Acquired Immuno Deficiency Syndrome

ARV's: Antiretroviral

IP: Intellectual Property

GSK: GlaxoSmithKline.

IMS: International Market Survey of America

USD: United States Dollar

South Western Region: Kisii, Kericho and Migori.

DEFINITION OF TERMS

Generic: Arbitrarly term for a drug produced and marketed by a company other than the original innovator when the patent expires.

Branded Generic: Differentiated drug by some marketers in order to create brand royalty among physicians and pharmacists by identifying their range of generic drugs by a common trade marked name followed by the generic name.

Conventional medicine: Industrially manufactured drugs with synthetic and or organic derivatives as active ingredients.

Traditional medicine: Herbal preparations

Bioavailability: The rate and extent to which the active substance is absorbed from a pharmaceutical form and becomes available at the site of action.

Bioequivallence: Two medicinal products are bioequivalent if they are pharmaceutically equivalent and if their bioavailabilities after administration in the same molar dose are similar to such degree that their effects, with respect to both efficacy and safety, will be essentially the same.

Pharmaceutical equivalence: Medicinal products are pharmaceutically equivalent if they contain the same amount of the same active substance(s) in the same dosage forms that meet the same or comparable standards.

Pharmacy: Is a store or retail outlet managed by a pharmacist or chemist stocked with drugs and dispensed upon prescriptions.

Original or Branded drugs: That which is produced and marketed by the Innovator Company and has some patent rights.

Interns: Medical students who are on attachment.

Technology-intensive Companies: Those that engage in research of new drugs; otherwise, known as the original innovators.

CHAPTER ONE

1.0. INTRODUCTION

1.1 Background to the study.

Over the years, provision of good and affordable healthcare to citizens of any country like Kenya has been a major priority. However, this has been constrained by lack of funds.

The branded drugs are both expensive and unavailable to source. Hence, the less developed nations resort to using substitute generic drugs, which are low –priced and are as effective as the branded one.

Generic drugs have been a feature of modern pharmaceutical industry from its early beginnings in the 1890's. As Barrie (1990) contends, generic drugs made up a large share of the market comprising mainly naturally occurring and unpatented substances until the large scale break-through in innovation of synthetic compounds occurred in the 1940's.

A recent study by IMS (International Market Survey) of America journal (1976) indicated that, for five years in a row, 1975 through 1979, the total number of retail pharmacy prescriptions for branded drugs had declined, while the number of generic prescriptions handled in retail pharmacy had increased. This growth of generic drugs sales in the pharmaceutical industry offers a number of challenges to the companies engaged in manufacturing branded medicine.

One of the most striking features of this study is that the generic challenge has not been addressed effectively by the industry (Luciani, 1996). It is probable that in addition to the particular circumstances of individual firms, there are a number of more complete and subtle factors influencing the industry's response to generic competition.

1.1.1 The Historical profile of Generic Drugs

During the mid-1970's, the market in several countries for many categories of consumer goods and other specialty like drugs, was subject to competition from a new form of the product called generic product (Statman, 1979).

This new form of competition was revolutionary. Generic products were in direct competition in markets traditionally dominated by specialty products where branding had been used as a strategy to differentiate basically similar products.

Unlike most marketing innovations, generic consumer products originated in Europe and were later adopted in the US and then the rest of the third world countries including China, India, Brazil, Egypt, South African and then Kenya. These products are low-priced austerely packaged goods of standard quality unsupported by brand advertising. Burrie (1990) has pointed out that a number of social, political, economic, technological factors are at play and that for the pharmaceutical industry to be effective, strategic decisions must reflect the realities of the predominantly societal rather than industrial role of the industry.

As Faria (1989) points out, the generic competition to branded medicine, is a success due to a failure to devise effective counter- strategies by the technology intensive pharmaceutical companies who rely heavily on the revenue of patent lapsed specialties. However, as Dietrich (1978) observes, one of the major management problems presented by the growth of generic drugs sales to the technology –intensive pharmaceutical companies has been how to meet the many challenges, which generics pose to current and future business operations.

This study addresses such factors that influence the sales of generics and also provides a basis for developing ideal strategies for pharmaceutical companies that manufacture branded drugs for responding to the generic competition according to specific market circumstances. This study dealt, specifically, with the pharmaceutical market in Kisii, Kericho and Migori towns in Kenya.

1.2 Statement of the problem

On the introduction of generic drugs into the market, the original branded drugs begin to lose market share as a result of increased competition from these generics. Even though the branded drugs continues to retain a large share of the market due to previously attained brand loyalty (as a result of patent protection), generic drugs do gain some grounds in the pharmaceutical industry in terms of market share. The generic drugs market growth is of significant importance in the pharmaceutical industry as it offers a number of challenges to the manufacturers of branded medicine. Given this scenario, therefore, there is need to understand the factors that have influenced these growths in the industry.

1.3 Objectives of study

The main objective of this study is to investigate and establish the factors that influence the sales of generic drugs in the Western region of Kenya (that is Kisii, Kericho and Migori).

The specific objectives of the study are;

1. to establish the market share in terms of sales volume of generic and branded medicine in the recent past;
2. to find out the factors influencing the preference of generics by patients to branded medicine; and
3. to identify the factors contributing to prescriptions of generic drugs by doctors and clinical officers.

1.4 Research questions

The following research questions guided the study.

1. Are the generic drugs manufacturing companies more aggressive in the marketing and promotion of their products than their counterparts involved in the manufacturing of branded medicine?
2. Do the sales volume of generic drugs compare favourably with those of branded medicine?
3. What are the patients' attitudes to generic drugs?

4. Do the levels of income affect the sales of generic drugs?
5. Are the medical practitioners major players in the selection of the drugs to be used?

1.5 Research Hypotheses

To put the proposed study in focus and to achieve the study objectives, the following hypotheses were postulated.

1. There is no significant difference between the sales volume of generic drugs and branded ones.
2. Patient's awareness of the two types of formulation in the pharmacy is independent of preference

1.6 The Research Assumptions

The study was based on the following assumptions.

1. The prescribers (consultant doctors, the clinical officers and general practising doctors) are aware of the various formulations of drugs available in the market.
2. Not all generic drugs have perfect match or are a substitute to original drugs.
3. Poverty levels amongst the patients in the region under study has led to high generic drug competition.
4. That there will be only two types of drugs, that is: generics and branded ones.

1.7 Significance of the study

The findings of this study are hoped to be of significant importance to many people. Firstly, it is expected that the management of pharmacies and chemists will use the research findings to improve their business and offer quality service.

Secondly, manufacturers of branded drugs commonly referred as originals will be able to understand clearly the competition offered by generic drugs manufacturing firms and the

underlying factors, which have contributed to the current sales situations and be able to develop an effective generic drugs counter-strategies within the constraints outlined. Thirdly, the government and especially the Ministry of Health will benefit greatly in formulating an effective and workable National Policy regarding drugs and general healthcare. Fourthly, academicians, marketing departments of several firms, researchers and management consultants will use the research findings as a source of knowledge and reference.

Finally, the findings and recommendations of the study would be of use as a background for further research and will assist future researchers to identify issues that are to be addressed in the pharmaceutical industry, especially, the generic drug market and its implications.

1.8 The Scope and limitations of the study

1.8.1 The scope of study

A list of registered Pharmacies within Kericho, Kisii and Migori Municipalities indicated that there are 35 dully-registered pharmacies in this region. The study covered 15 chemists and focused on the factors influencing the sales of generic drugs. A number of practising doctors and Clinical Officers were interviewed on their preference on prescriptions within this region and a host of selected patients were also interviewed.

1.8.2 Limitations of study

The following impediments were experienced during the research period.

1. Non-response or withholding of some information considered to be confidential or as against the firm's policy to release such information.
2. Financial constraints, time and climatical factors were limiting factors too.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

Generic medicine is a copy of an original brand name product whose patent has expired. It may be marketed either as a brand or unbranded (in which case it is identified by its internationally approved proprietary 'generic', scientific name), in accordance with patent law. Most governments believe they can save on healthcare costs by creating a more favourable environment for generics, which are considerably less expensive than brand name drugs.

2.2 Background

Generics are considerably less expensive than the original medicine because their manufacture does not incur the risks and costs associated with the research and development of innovative medicines. Since generics contain well-known, safe and effective substances, pre-clinical tests and clinical trials can be replaced by simple bioequivalence studies (www. EuActiv.com)

A new drug can take up to USD 50 million to develop (Fanucci et al, 1980) so it must sell in millions to recoup the expensive research outlay. Thus, the drug original innovator company (the manufacturing market leader) exercises the monopoly power through protecting its brand-name products with patents, hence, high prices and intense promotion. Although medicines may be intended to promote health, any idea that companies making drugs operate differently from those producing cars, oil or military equipment should be forgotten. The ethics and commercial objectives are more or less the same; expansion, security and above all market control (Wells, 1985). As such, costs and profits in the industry are high – which incidentally don't benefit the consumer.

The size of the generic market differs widely in various nations of the world. The EU's generic market today is worth 7 billion Euro, compared to around 70 billion Euro for the total pharmaceutical market value. In contrast, generic medicine in the US alone accounts for 40% of all prescribed medicine while in the third world countries of Africa, Latin America India and parts of South East Asia excluding China it accounts for over

(EU's www. Market forces: consumers power in today's world – N1 147 – the drug industry).

These differences are mainly as a consequence of the different policies that surround;

1. market conditions for new medicines,
2. pricing structures,
3. prescribing/dispensing structures,
4. requirements, and
5. the existence of specific incentives to encourage generic drugs use.

For instance, regarding the regulatory framework and intellectual property protection policy, the EU set up a commission that proposed a comprehensive reform of the legislative framework on medicinal products. The commission emphasized the importance of achieving a balance between encouraging and rewarding the development of innovative medicines by providing sufficient intellectual property protection, and creating a genuine market in generic medicines, through the introduction of a Bolar provision(www.EuActiv.com).

2.2.1 Bolar provisional

The "Bolar exemption" is a policy that allows generic manufacturers to prepare production and regulatory procedures before patents expire, so that products can be ready for sale as soon as the patent ends, rather than having to go through the lengthy preparatory process only after the patent period is over. This exemption is in agreement with the WTO rules on trade – related aspects of intellectual property rights.

In Kenya, generic drugs must be registered with the Pharmacy and Poisons Board. This is a government agency concerned with the regulations and control of the activities of the pharmaceutical industry.

Such activities include:

- registration of businesses involving drugs, chemists, pharmaceutical manufacturing companies, private hospitals, Clinics among others;
- registration of pharmacists and issuance of practising licenses;
- inspection and regulation; and

– registration of all drugs in the Kenyan market among other functions.

The recent events by the Kenyan parliament to reverse an amendment to the industrial property Act that blocked commercial importation of cheaper medicine was a welcome idea especially in relation to cheaper Anti-retroviral drugs (ARVs). The change made it possible for generics to be imported into Kenya.

This amendment followed another policy shift in which WTO agreed to allow developing nations with no pharmaceutical industries to ignore patent rights and import cheaper generic medicines to fight cases of national emergencies, like the AIDS pandemic. This policy is called the IP – intellectual property law.

The IP Act was later changed requiring potential importers or producers of generics to seek explicit permission from the patent holder. Following this changes, a Kenyan firm, Cosmos Limited, successfully negotiated with the giant firm. GlaxosmithKline, GSK, and Ingelham Boehringer to Manufacture and sell cheaper ARVS, whose patent rights are still in existence. This was done in September 2003

2.3 Market development

Patterns of company entry into the drug market are both numerous and complex and the route chosen would appear to depend on a variety of factors. As Barrie (1990) writes, the patterns of business entry can be classified by the basic business mission of the company. That is, technology – intensive or generic entries.

2.3.1 Technology – intensive company entry

The main factor here is whether the entry was made on the basis of a conscious decision, that is, whether the entry passively occurred or was actively planned (IMS market monitor: Europe 1980). Since all product patents are time limited and the majority of companies continue marketing products after the lapse of the patent, a large number of products marketed by the technology – intensive companies are defacto branded generics. This constitutes the passive entry.

Active entry or planned entry has four main directions.

1. Branded generics- where several companies have introduced a line of branded generics that are distinct from their regular line of products.
2. Commodity generics – where sales are made directly to pharmacists using special deals and rebates to induce pharmacists to stock and dispense them.
3. Hybrid – branded generic operations which have branded generic products mixed into a line of internally derived mature products, transitional generics and new developed products.
4. Toll manufacturing – here some companies manufacture for some generic marketers.

2.3.2 Generic Entry

Generic company activity in the generic market is extremely complex ranging from specialization in one area to participation in almost all faces of production and marketing as Slatter (1984) asserts.

Generic drug companies have widely differing concentrations, operating characteristics and marketing techniques; however, they can be grouped into three main areas of specialization – manufacturers, manufacturers and marketers and marketers. (Op. Cit.)

2.4 Business strategy in the pharmaceutical industry

Unlike many industries, there is little explicit data published on the types of strategies adopted by pharmaceutical companies (Hall, 1980). This situation is due partially to the highly visible nature of the industry's product line.
Drugs are divided into sectors like antibiotics, vitamins, antifungals, antiarthritics etc. Companies can choose few sectors to dominate but giant multinationals are multifaceted in their concern.

When a company invents a new drug even though the third world markets consumes only about 15% of the world's pharmaceutical, the multinationals target this market because the potential for growth is much greater than in the west. This means that

the poorest people in the poorest countries end up buying the most expensive medicines, even though cheaper alternatives exist.

How is this done? This is by skilful advertising, which promises health and a better life to people living in poverty, 'and by shaping doctors' prescribing habits. Product launches are often accompanied by conferences which the companies claim are important for spreading scientific information. But of course, there are also pleasant perks for the medics who come away with a special regard for the company's product.

In the developing countries doctors have virtually nothing other than what a drug company chooses to tell them about a product and the promotion techniques maybe crude (Barrie 1990). Making sure that doctors prescribe their products is important to the companies. But making sure that government doesn't act against their interests is vital.

It is important anyway for any government to act responsibly to control their manipulation of consumers, doctors and itself to promote a free market economy.

2.5 Marketing and sales

Kotler (2000) contends that more people and more countries, are convinced that markets works better under relatively free conditions where buyers can decide what and where to buy and competition economies produce more health than highly regulated or planned economies. The three developments in the recent past of –globalization, technological advances and deregulations- spell endless opportunities.

With the expiry of patent rights of some drugs manufacturing companies, and with the emergency of generic competition, a brilliant disguised opportunity is opened for those engaged in generic drugs manufacture with the market response bring overwhelming. Similarly a study by International Resource Development (1982) concludes that the period from 1963 to 1979 when generics were being introduced was marked by increasing government attention to regulation and public and private concern over health care costs with these two factors in play that is the government attention and the costs factors, the generic market offered a solution to the government as well as to its citizens and the marketing concept that Kotler postulates played a significant role.

2.6 Factors influencing the sales of generic drugs

- **Expirations of patent**

The US patent law provides investors with protection from unauthorized use of their patented invention for a period of 17 years (Kitch, 1973).

There are three types of patents; Product, Use and Process; applicable to pharmaceuticals. The most effective and common form of patenting is the products patent since this claims as invention the chemical formula of the drug.

The loss of patent protection on products with large sales volume provided an economic inducement for other companies to market generic copies of the original patented drug.

- **Cost structures**

Here a patient manages to reduce the cost of medication by substituting with generics hence, leads to saving. Pharmacists who dispense generics get a high return on their investment.

- **Look a-like products**

In terms of packaging, colour and even naming e.g. Septrimed compared with Septrin and Cannox and Amoxyl etc.

- **Technological environment**

Like the issue of drug equivalence expressed in terms of bioavailability and bioequivalence. The generics are bioequivalent to branded drugs in terms of absorption rate, potency, and purity, integration time, dissolution time and in various other characteristics.

- **Life style changes**

Thus better career prospects for all (especially women), improved contraception legalized abortion and planned/unplanned childless marriages or delays in child bearing alter the patterns of medical needs and this impacts on the intensity of usage of drugs.

- **The income levels**

Low income earners who seek medication in the LDC's prefer affordable yet effective medicines and this can only be through generic drugs.

- **Raw material availability**

The companies that specialized in supply of raw materials to larger pharmaceutical companies find growth opportunities as they expand their outlet for excess productive capacity to generic drugs manufacturing ones further increasing competition.

- **Consumerism**

As part of the contemporary growth in consumer advocacy, consumer groups have been active in promoting the increased use of generic drugs to lower the consumer's cost of health care.

- **Relaxed regulation**

This includes the WHO policy on the management of health care costs, WTO directives through the IP Act, the government legislation and control among others. These relaxed regulations lead to more volume in terms of manufacturing and sales.

- **Substitution**

The pharmacists' "right to generic substitution" is a policy under which pharmacists are free to override the decision of doctors and dispense generic drugs, even where doctors have specified in the prescription the brand he prefers, without consulting the patients or the doctor (Commerce and Industry Journal No. 49, 2005).

- **Prescribers' attitude**

Professionals including pharmacists and doctors in the industry can react favourably or unfavourably towards a generic drug.

- **The marketing strategies**

(as explained in section 2.4 above of this document)

2.7 The conceptual framework

The research identified the following variable as the ones that impact on the sales of generic drugs in the region.

1. Independent variables are cost of medicine, number of patients and income levels.
2. Dependent variable is the sales of generic drugs.
3. The intervening variables include: the effort of the medical sales representatives employed by drug manufacturing companies, the technological level, the prescribers attitude and perception and the government.

The government through its agencies or departments regulates the sale of generics as well as branded ones. Thus, the availability of branded generics will depend on the licensing by the government to a manufacturing company for production and sale.

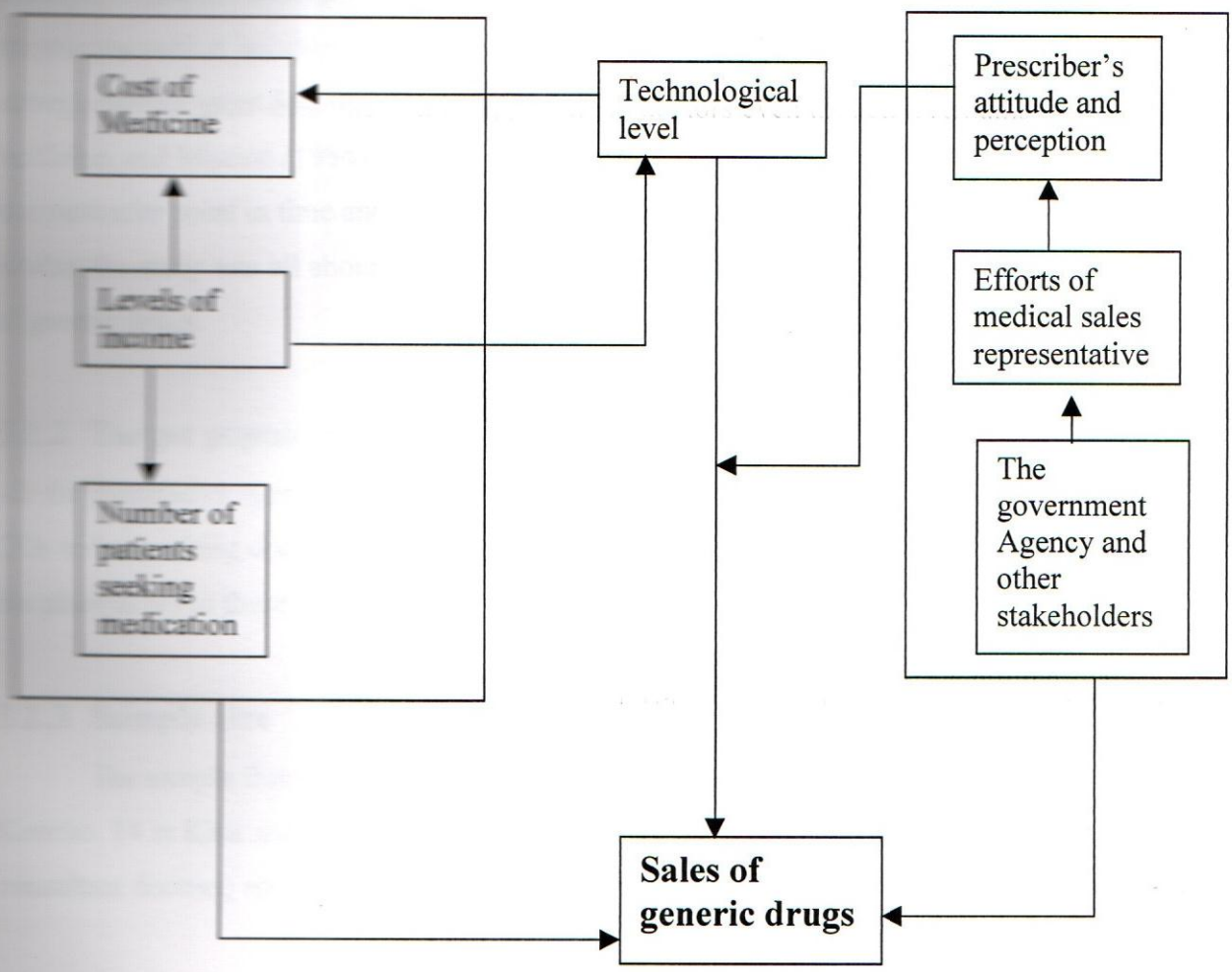
Before licensing to manufacture generics the expiry of patent to the original drug must have occurred. However according to the latest regulations under the World Trade Organization (WTO), the patent rights for medicine can be waived in cases of national emergencies, like the AIDS pandemic in Kenya and the LDC in general, to make the use of cheaper generics possible – (www: generics in Kenya. htm).

Once a drug is available in the market, the manufacturing companies engage on sales promotion through medical sales representatives who visit prescribers who in turn promise to support their brand through prescription.

The level of technology impacts on both cost and the prescriber's attitude. Thus,well packaged and shaped medicine will be appealing to doctors even though it remains expensive.

The number of chemists stocking the drugs encourages immensely the medical representatives to double their effort so as to improve the stock levels. The level of income too will matter.

These factors can be related diagrammatically as below:



Source (Author, 2005)

CHAPTER THREE

3.0 RESEARCH METHODOLOGY

3.1 Introduction

This chapter discusses the study design, explains the study population and the sampling procedures. It also discusses research instruments and the data analysis.

3.1.1 Research design

The study is a descriptive survey research. Abagi (1995:16) argues that a descriptive research attempts to describe what was or what is in a social system such as in the pharmaceutical industry. The use of survey was appropriate for this study because surveys provide great deal of information, which is accurate (Kerlinger, 1973). As Cohen and Manion (1994) observe, the intention of a survey research is to gather data at a particular point in time and use it to describe the nature of existing conditions which is what the study was all about as it seeks to investigate the factors influencing the sales of generic drugs.

3.1.2 Target population

All the pharmacies operating in Kisii, Kericho and Migori Municipalities, all GPs, MOs, COs and consulting doctors therein and all the patients visiting the prescribers above and the pharmacies in these towns.

3.1.3 Sample size

The sample frame constituted of 35 pharmacies operating in this region (12 in Kericho, 14 in Kisii and 9 in Migori), 38 registered doctors (combines MOs, GPs, and consultant doctors) and 51 COs in the specific towns (Ministry of Health records 2003)

From the sampling frame, stratified random sampling technique was be used to select 15 chemists (six from Kisii, six from Kericho and three from Migori) according to criteria of size (wholesale or retail or both), staff size, and area of operation.

The prescribers were selected on the basis of their specialization e.g. surgeon, pediatrician, physician, obstetrician, gynaecologist. Thus, a total of 12 doctors and 18 chemists were selected. This presented approximately 30% of the total population, which Kothari (1985) recognizes as an adequate sample for the descriptive research and presents a fairly representative size. Ninety respondents were interviewed of which forty-five patients, fifteen pharmacists and thirty prescribers were given a questionnaire each to complete. The patients were randomly sampled at chemists and hospitals that the researcher visited during the research period.

3.3.4 Instruments for data collection

Primary and Secondary data were collected. Primary data were collected using structured questionnaire with both open and closed questions being used. Warwick and Linger (1975) states that researchers should settle on instruments which provide high accuracy, generalizability and explanatory power with low cost, rapid speed and a minimum of management demands with high administrative convenience. The open-ended qualitative data such as perception and feelings of patients and doctors will be obtained through interviews and observations as well as journals, publications and other relevant sources.

As Prasad and Reddy (1983) contends, observation is one of the most important and extensively used methods of data collection. Thus general observation will be used to capture a general sales trend and the pharmacists' practice in some pharmacies.

3.3.5 Data analysis

Data was analyzed using both descriptive and quantitative statistics where possible. Frequency distribution tables were prepared from the questionnaire responses and then measures of central tendency (mean, mode and median) used. Percentages and general descriptive statistics were used to draw conclusions to the study.

CHAPTER FOUR

4.0 DATA PRESENTATION, ANALYSIS AND DISCUSSION

4.1 Overview

This chapter gives the interpretation and presentation of responses obtained from the questionnaires and observational procedures as given in chapter three. It presents the information as provided by pharmacists, prescribers and patients selected from the three towns of Kericho, Kisii and Migori, where the study covered.

The data were presented and analyzed descriptively using simple frequency tables and percentages for purposes of illustrations. This was followed by discussions of the findings.

It is important to note that all percentages in this chapter and subsequent ones are reported in brackets.

Ninety respondents were interviewed in which forty five patients, fifteen pharmacists and thirty prescribers were given a questionnaire each to complete. Of the forty five questionnaires administered to patients only thirty six fully completed were collected, all the fifteen questionnaires administered to pharmacists were collected and only twenty six out of the thirty questionnaires administered to prescribers, were collected. In total, seventy seven questionnaires out of ninety given out were collected.

4.2 The Respondents' Personal Information

4.2.1 Prescribers

The prescribers were categorized into two: Clinical Officers (COs) and Medical doctors who included general practitioners (GPs) and consultant doctors.

The total number of prescribers interviewed and responded was 26, of which (65.4)were (Clinical) (34.6) were medical doctors of different specialization.

Most of these prescribers examined more than 20 patients on a daily basis. Again, it was noted that most presribers interviewed had a work experience of over five years and that majority of them were government employees.

4.2.2 Patients

The patients in general are the end users of the drugs stocked in a pharmacy. Thirty six patients responded. Out of this (83.3) were aware of the existence of both generic drugs and original branded medicine. Only (16.7) indicated that they were not aware. Again (30.6) of the patients interviewed indicated that they received their medical examination at private clinics, (66.7) were attended at the government hospital and that (2.7) was attended at a company medical institution.

4.2.3 Pharmacists

Fifteen pharmacists responded. Out of this (40) had a degree in pharmacy, (20) had a diploma, (20) had a certificate, (13.3) had other professional qualification while (6.7) had no professional qualification.

All the practising pharmacists had more than five years experience in this business.

4.3 The market share of generic drugs – general sales.

From the questionnaire administered to the pharmacist who stock and dispense/sell medicine, all pharmacist, 15, indicated that the sales have been generally high. Of this (40.0) put the approximate percentage at about 55%, (46.7) at

approximately 60% while (13.3) put the high sales volume at about 70%. This trend was possible because most patients (83.3) who use the medicine were aware of the existence of both generic drugs and original branded medicine and that (75.0) of them indicated that they don't mind being dispensed with any of the two types of drugs available.

Again, the stock levels influenced greatly the market share of the generic drugs over the branded original medicine. Most pharmacist/stockists (53.3) indicated that they stocked more original branded medicine (about 60%) than generic drugs.

4.4 Levels of income

The income level is very important in any economy as it reflects on the buying power of its citizens. In this study the researchers sought to know from the patients how their buying capacity was and to what extent it affected their choice of medication. (63.9) of the patients interviewed earned below Ksh. 10,000, (19.4) earned between Kshs 10,000-20,000 while only (13.9) earned above Kshs.20,000.

Since majority earned less than Kshs. 20,000 they choose a substitute medicine whenever the one prescribed was way beyond their reach. (75.0) choose substitute medication while (25.0) did not. Thus since generic drugs are low priced and work as effective as the original branded ones, The low level of income has greatly influenced the high sales trend of generics.

4.5 The number of patients seeking medication.

The number of patients being attended to by prescribers and pharmacists constitutes a great deal in the industry since these are the end users of a drug. Thus the higher the number the high the sales volume and vice versa.

Disease prevalence is generally on the increase due to increase of poverty level. Emergence of incurable disease like HIV/AIDS, ALS (amyotrophic lateral Sclerosis) also known Lou Gehrig's disease among others, emergence of resistance disease causing pathogens which were hitherto preventable are factors that have led to more patients seeking medication.

4.6 Prescribers (COs, consultant doctors, General Practising doctors)

These are the persons who do diagnosis and prognosticate on the medical condition of the patients. They play a very important role in influencing the sales pattern of the drugs available in the chemists. Many prescribers (38.4) preferred generics (30.8) branded and (30.4) preferred both generics and branded.

Table 4.1 The Prescribers' Type

Description	Frequency	Percent
Generic	10	38.4
Branded	8	30.8
Both	8	30.8

The prescribers gave a number of reasons as to why they prescribed the medicine in that pattern. Table 4.2 below summarizes the reasons given by the prescribers and an attempt has been made to calculate the weighted mean of the reason and an analysis thereafter.

Table 4.2 Reasons why prescribers prefer generic drugs

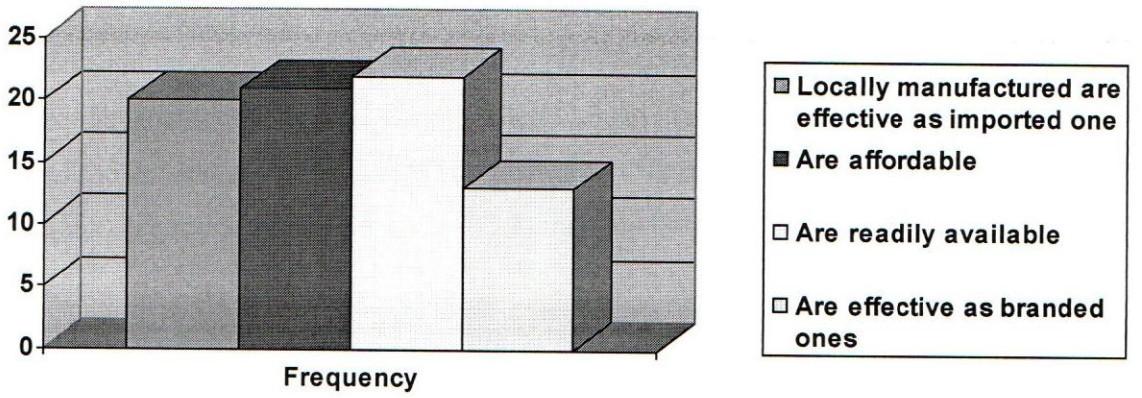
Reasons why Prescribers use generic drugs	Weights (w)			Σf	Σwf	Σwf / Σf
	Quite influencing	Influencing	Least influential			
	3	2	1			
Efficacy	26	-	-	26	78	3.00
Availability	6	12	8	26	50	1.92
Packaging	5	9	12	26	45	1.73
Patient choice/selection	7	9	10	26	49	1.88
Bioequivalence	24	2	-	26	76	2.92
Cost	14	12	-	26	66	2.54

From the table analysis above, efficacy of the drug prescribed had the highest weighted mean of 3.0 and it meant that the prescribers went for it first as they did to bioequivalence and then cost. Packaging style leas influenced the prescribers in their prescription pattern even though it played a significant role that cannot be ignored in the industry.

4.6.1 The opinion of prescribers on generics

The researcher sought to know what opinion did the prescribers have on generic drugs. (80.8) affirmed that they were affordable than the branded ones, (76.9) agreed that both locally manufactured and the imported ones works the same i.e. there is no one superior than the other, (50.0) indicted that cheaper generics are equally potent as the expensive ones and that (84.6) agreed that the generics are readily available even at the remotest area than the brands.

Fig 4.1 Bar Graph Opinion of prescribers on generics



4.7 The effort of Medical sales representatives

Medical sales representatives commonly known as "Med reps" act as a link between the manufacturers and the prescribers. They give information to the prescribers about the new drugs in the market and the brand name in which it is selling. Since most medical training course cannot exhaust all the medicines in the market, they actually give current updates of information about the drugs in the market.

All the 26 prescribers appreciated the work or the effort of "Med reps". This shows that they are very important in the industry. (50.0) prescribers gave support to "Med reps" by prescribing the drug promoted by its brand name, (23.1) prescribed by the active ingredient, (19.2) prescribed the active ingredient then manufacturer and (7.7) other method.

The medical sales representatives influence the prescription pattern of many prescribers in this region. And since many generic manufacturing Companies have many "reps" operating in this region than the original innovator Companies, they influence the sales pattern too. (69.2) of the prescribers agreed that "med reps" influenced their pattern of prescription, (26.9) strongly agreed while (3.8) disagreed.

Medical "reps" do not influence the prescribers only. They too influence the pharmacists on the type of drugs to stock. Since their terms of service is favourable and their goods/ drugs are being prescribed, the rate of turnover is higher than the "original" branded one. (73.3) of the pharmacists indicated that generics have a high profit margin than (26.7) who indicated that branded original medicine have better margin. (66.7) agreed that the persuasion of "Med reps" influenced the stocking of generic drugs while (33.3) indicated otherwise. (66.7) showed that because of the influence of "med reps" on prescribers there are a higher number of prescriptions on generic medicine while (33.3) indicated otherwise.

4.8 The government

4.8.1 The government as a shareholder.

Governments the world over, are the greatest consumers of many products. The government hospitals, dispensaries and clinics are in great numbers. Thus, they consume more when compared with the private clinics. Since generics are cheaper in sourcing the government prefers generics to original branded medicines as a way of lowering the cost of health care.

4.8.2 The government as an agency.

The government's body concerned with the registration and regulation of the pharmaceutical industry is called the Pharmacy and Poisons Board. It is the one that determines which drug will be available in the market and who will be the players in the industry.
The researcher sought to know how the board has been fairing on in its core activities. Thus, (53.3) pharmacists felt strongly that it is corrupt, (66.7) indicated that it has not checked and rooted out malpractices in the industry, (66.7) showed that it has not advised the government adequately on a policy regarding drugs and health care in general.

Table 4.3 below summarizes the pharmacists' opinions on the regulatory body i.e. the Pharmacy and Poisons' Board.

Table 4.3 The pharmacists opinion on the Pharmacy and Poisons' Board

Opinion on the Board by Pharmacist	Weights (w)			Σf	Σwf	$\frac{\Sigma wf}{\Sigma f}$
	Strongly agree	Agree	Disagree			
	3	2	1			
The Board is corrupt	8	7	0	15	38	2.53
Has not yet rooted out mal-practices in the industry	5	7	3	15	32	2.13
Has not adviced the government adequately	3	10	2	15	31	2.06
Needs to be overhauled	5	6	4	15	31	2.06

The corruption practices or allegations and inability to root out any malpractices in the industry have met the Board to be viewed negatively by the very people who are its subjects. The corruption allegations weighted mean was highest at 2.53 while other opinions scored above the mean of 2.0 which means that the Board was generally below its expected performance.

4.9 The patients' attitude on generic drugs.

The researcher sought to know what opinion did the patients themselves have on generic drugs. This was of importance because the user must accept the drug he is about to use and that this will be reflected on the willingness to buy it even in the face of equally cheaper original branded medicine.

(66.7) patients indicated that the cheaper drugs work as effective as the expensive ones. Original branded (27.8) showed that they are less effective while (5.6) showed strongly that they were not potent. Again (52.8) patients indicated that serious ailments need not necessarily be managed with expensive medicines, (27.8) noted that they should be managed by expensive drugs while (19.4) showed strongly that cheaper drugs cannot manage serious ailments.

These opinions again reflect that generic drugs have gained ground as very affordable medicines which work as effective as the branded original ones. It is on this background that today the generic ARVs manufactured by the local firm Cosmos Ltd are gaining ground and are prolonging life at an affordable cost as much as the original do. This, then, influences the sales trend and that many patients now could prefer them (generics) to the branded ones.

The table below gives a summary of the patients' attitude on generic drugs.

Table 4.4 The patients attitude on generic drugs

Patients opinion on generic drugs	**Weights (w)**			**Σf**	**Σwf**	**Σwf / Σf**
	Strongly agree	**Agree**	**Disagree**			
	3	**2**	**1**			
Cheaper drugs work as effective as the expensive ones	24	10	2	36	94	2.61
Clinical Officers prescribe cheaper drugs always	17	12	7	36	83	2.31
Well organized chemists have "good" drugs	17	15	4	36	85	2.36
Very severe ailment is to be treated with expensive drugs	7	10	19	36	60	1.67

From Table 4.4 analysis above it is clear that patients don't mind the cost as they agreed generally that cheaper drugs (which are mainly generics) worked as effective as expensive one (mainly branded original drugs). The cost factor scored 2.61 of the mean weighted average against the 1.67 mean weighted average of treating severe ailment with expensive drugs on a scale of 3.

4.9.1 The pharmacists opinion

The researcher sought to know from the pharmacists whether if, they were patients, what type of preparation they would prefer. (60.0) of the pharmacists interviewed indicated that they would prefer generics for simple reasons of efficacy potency and costs while (400) indicated that they could prefer branded original ones because they work more effectively than generics and that they did not have faith in generic drugs.

4.9.2 Prescribers' opinion

The findings showed that (34.6) preferred generics, (26.9) preferred original while (38.5) preferred both.

In all, the above instances, it is important to note that generics were preferred more than branded ones. And it is against this background that the researcher felt that the generic drugs have an upper hand in this region in terms of sales than the branded ones.

4.10 The role of prescribers and pharmacists in sales and selection of drug(s) to be used.

The researcher sought to know how the prescribers influenced the choice of a drug and that of the pharmacists. Most of the prescribers interviewed were COs. Majority of them worked with the government. Incidentally, most patients visit the government hospitals than they do to private clinics and hospitals. (93.3) pharmacists interviewed noted that COs generated most prescriptions. (66.7) indicated that consultant doctors generated some good number of prescriptions while (73.3) indicated that GPs, MOs and interns generated the same.

Table 4.5 The role of prescribers in sale and selection of drug.

The prescriber type	Weights (w)			Σf	Σwf	Σwf / Σf
	Generates most prescriptions	Generates a few prescriptions	Generates least prescriptions			
	3	2	1			
Clinical Officers (COs)	14	2	-	15	44	2.93
Consultant doctors	2	10	3	15	29	1.93
Others (GPs, MOs, and CO interns)	1	11	3	15	28	1.86

From Table 4.5, the analysis shows, that COs by virtue of their large numbers (and therefore more patients at their disposal for examinations), influence greatly the sales of generic drugs. COs influence scored a mean of 2.93 out of the possible mark of 3.0 meaning that they contributed greatly in the selection of a drug.

Similarly, most patients indicated that COs prescribed less expensive drugs (which in most cases are generic drugs) while consultants prescribed expensive ones. (47.2) noted strongly that COs prescribed less expensive drugs. (33.3) agreed too while (19.s4) disagreed.

This is significant because most prescriptions reaching pharmacists is for generic medicines and that this reflected positively on the general sales of said drugs.

Pharmacists too are very crucial in the selection of the drug. The pharmacist can substitute a prescription with or without the consent of the doctor. (66.7) substitute prescriptions without doctor's consent. (26.7) with doctor's consent while (6.7) do not substitute.

With the pharmacists stocking more generic drugs than the branded original ones and with the Bolar provision at play, the patient can heed to the pharmacist view of substituting the doctor's prescription.

Again, (66.7) pharmacists do not dispense drugs designated as POM against (33.3) who indicated that POM (prescriptions only medicine) medicines are dispensed upon producing a prescription. Most pharmacists argued that process of getting examined by a doctor is long and tedious and that is why they prescribe or dispense without necessarily getting a prescription.

This trend of substituting and or dispensing POM without prescriptions is also witnessed by the patients who do not seek medical advice always whenever sick. (55.6) patients indicted that they do not seek medical advice always while (44.4) indicated that they do.

CHAPTER FIVE

5.0 SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter presents a summary of research findings, conclusions, recommendation of the study and suggestions for further research.

5.2 Summary

The objective of the study was to investigate and establish the factors that influence the sales of generic drugs in the SouthWestern Region of Kenya; that is Kisii, Kericho, and Migori.

The need to investigate on these factors arose from the recent trends in the pharmaceutical industry in which generic drugs seem to be gaining some grounds in terms of popularity as well as sales.

Data was collected from a sample of seventy-seven respondents who included fifteen pharmacists, twenty-six prescribers and thirty-six patients. A stratified and then a random selection of respondents were used. The instrument for data collection was mainly the questionnaires and observation.

Three different questionnaires: the researcher developed one for prescribers, the other for pharmacist and the other for patients. The data was collected and analyzed for basic descriptive statistics.

From the data collected, it was found that the generic drugs market has grown considerably over the recent past. The sales volume of the generic drugs is generally higher than the branded

original medicine. They have gained popularity amongst patients patients, prescribers and more so the pharmacists who dispense these medicine.

Several factors influenced this finding. Top on the list is the accessible. The income level of most patients in this region is generally low and the cost of living is high. Thus, anything that could give the anticipated results positively and yet at a lowest cost, is what one will go for.

Another important factor is the prescribers. Most patients visit district hospital, which are government facilities. Here they meet Clinical Officers who prefer giving prescriptions that are affordable and available. These are generic drugs. Hence high market share. The pharmacists preferred generic medicines to original branded ones for reasons of high profit margins, high sales volume (high rate of turnover), high number of prescriptions generated and the favourable terms of business with the supplying firms.

The prescribers also preferred generic drugs for reasons of affordability and the persuasions from medical representatives who happen to be many from generic drugs manufacturing firms as compared with the original innovator companies. Others argued that generic drugs are as effective as the original and that because of the poverty level of clientate it is reasonably good to consider them.

5.3 Conclusions

The central purpose of the present study was to establish the factors that influence the sales of generic drugs in southWestern region of Kenya. From the study, a number of conclusions have emerged.

- Generally, generic drugs are more popular than original branded ones in this region and that their sales volume is high. Most patients are aware of the existence of both generics and originals and that they don't mind any of the two.

- Clinical Officers otherwise known as CO's generate the highest number of prescriptions and they prefer generics to original ones. This is because the type of clientale they attend to be low-income earners.
- Medical representatives play crucial role in influencing the prescription pattern of the prescribers and the amount of or quantity of medicine to be stocked by pharmacists.
- The government agency concerned with regulating the pharmaceutical industry is not doing a good job. Most pharmacists feel it is generally not effectively regulatory.
- The low level of income of most patients in this region coupled with the low cost of generic drugs has led to high sales volume of these drugs.
- Lastly, manufacturers of original branded medicines can still improve their sales and compete favourably with generics in this region if they double their marketing effort and make their drugs affordable and available. This is because majority of patients trusts them and regards them highly than generics.

5.4 Suggestions for further Research

It has to be acknowledged that the current study has not exhausted the factors at play in the pharmaceutical industry concerning the generic market. The following are areas that need further research in the study area:

(i) the relationship between training qualifications and the prescription pattern of the prescribers i.e CO are diploma holders while consultant doctors are degree holders;

(ii) the marketing activities of the medical representatives and the impact of these activities on the sales of respective products;

(iii) improvement of the operations of the Pharmacy and Poisons' Board.

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APPENDIX ONE

The pharmacies selected for study from the three municipalities.

1.	Tealands chemists	)	
2.	Sujis Pharmacare	)	
3.	Tegat Pharmacy	)	
4.	Mid-rift Chemist	)	Kericho Region
5.	Litein chemist	)	
6.	Gerysen pharmacy	)	
7.	Jacks Pharmacy	)	
8.	Kendrug Chemist	)	
9.	Getembe Pharmacy	)	Kisii Region
10.	Borabu Medicals	)	
11.	Gucha Pharmacy	)	
12.	Meridian Four Pharmacy	)	
13.	Kisao Pharmacy	)	
14.	Spase Chemist	)	Migori Region
15.	Nyamaharanga Chemist	)	

APPENDIX TWO

Introductory letter to the respondents

I am a MBA student of the Faculty of Commerce of Egerton University and am currently carrying a research on the factors influencing the sales of generic drugs in Kenya especially in the Western region of Kisii, Kericho and Migori.

This questionnaire is aimed at eliciting information that will be useful in the already mentioned research. I have chosen you to furnish me with information, which I promise to strictly use for academic purpose only, and will treat it with utmost confidentiality. Please answer the questions as truthfully as possible.

Your co-operation is highly appreciated.

Thank you.

OBWOCHA JOHN NDEGE

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APPENDIX THREE

(Questionnaire for the pharmacist and pharmacy assistant).

SECTION A – PERSONAL DATA

1. Sex Male ☐ Female ☐
2. Education level
   a) Secondary ☐
   b) University ☐
   c) Post-graduate ☐
   d) Other specify _____
3. Which is your professional qualification if any
   a) Degree in pharmacy ☐
   b) Diploma in pharmaceutical technology ☐
   c) Certificate in pharmacy ☐
   d) Other (specify)_____
4. How long have you been practicing dispensing? _____

PART B

Please answer the following questions as briefly as possible

5. For the time you have practised are your clients especially patients aware of the availability of both generics and branded drugs in the market?
   a) Most of them, know ☐
   b) A few know ☐
   c) Majority don't know ☐

6. Do you strictly dispense on prescription the drugs designated as Prescription Only Medicine (POM)?

Yes ☐ No ☐

If the answer is NO please give reasons _____

_____

_____

7. (a) From the prescriptions that you receive on daily basis what proportion will you award the prescribers below in terms of prescriptions generated?

		generates most prescriptions 3	generates a few prescriptions 2	generates least prescriptions 1
(i)	Clinical Officers	☐	☐	☐
(ii)	Consultant Doctors	☐	☐	☐
(iii)	General Practitioners	☐	☐	☐
(iv)	Interns	☐	☐	☐

(b) What is the prescription preference among these prescribers (either prefer branded or generic type).

		Branded	Generic
(i)	Clinical Officers	☐	☐
(ii)	Consultant Doctors	☐	☐
(iii)	General Practitioners	☐	☐
(iv)	Interns	☐	☐

8. In your stocks of medicine, approximately what is the percentage representation of brands and generics in total (please assign either 1 or 2 or 3)

Type	Above 60% 3	Between 40% -60% 2	Below 40% 1
Generics			
Branded			

9. What are the motivating factors that influence your preference in stocks available nce: (please tick the options below)

		Generics	Brands
(i)	High profit margin	☐	☐
(ii)	High number of prescriptions generated	☐	☐
(iii)	Favourable terms of business with the Supplying manufacturing firms.	☐	☐
(iv)	Availability in terms of sourcing	☐	☐
(v)	Persuasions from medical sale representatives	☐	☐
(vi)	High sales volume	☐	☐
(vii)	Low sales volume	☐	☐

(viii)Any other specify _____

_____

10a) For the time you have practised could you say that the sales of generics has been high or low as compared to the branded one.

High ☐ Low ☐

b) If the answer is high, approximately how in percentage form.

(i) about 55% ☐

(ii) about 65% ☐

(iii) about 70% ☐

(iv) more than 75% ☐

11. Do you substitute some prescriptions?

a) Yes with consent of doctor ☐

b) Yes without consent of doctor ☐

c) No ☐

12 a). If you were a patient, with this knowledge you have about medicine , which type of medicine would you like the doctor to prescribe?

(v) Generic ☐

(vi) Branded/Original ☐

b) Give reasons for the above answer.

_____

_____

_____

11. The government agency concerned with registration and regulations of the pharmaceutical industry has not been doing a good work. According to your opinion which factors do you think have led to this situation?

		Strongly agree 3	Agree 2	Disagree 1
(i)	It is corrupt in its practices	☐	☐	☐
(ii)	It has not checked and rooted out malpractice in the industry by importers, manufacturers distributors, wholesalers, and retailers	☐	☐	☐
(iii)	Has not advised the government adequately/effectively on a national policy regarding drugs	☐	☐	☐
(iv)	Any other reason (specify)_____			

If in your observation the agency has been doing a good work, please give any reasons_____

_____

_____

Thank you for your response.

Questionnaire for the prescribers (COs, MOs, GPs and Consultant Doctors)

SECTION A:

Personal information

1. Gender

   Male ☐ Female ☐

2. Professional qualification

   (State for example clinical officer, medical officer, paeditrician, surgeon etc

   _____

   _____

3. Are you a private practitioner or a Government employee?

   (Delete appropriately)

4. For how long have you practiced?

   a) Two years ☐

   b) Three years ☐

   c) Four years ☐

   d) Over 5 years ☐

SECTION B:

5. By estimating how many patients do you attend to on daily basis?

   a) between 5 and 10 ☐

   b) between 10 and 15 ☐

   c) between 15 and 20 ☐

   d) more than 20 ☐

6. Which type of preparation do you prefer in your prescription?

   Generic ☐

   Branded ☐

   Both ☐

7. Give reasons for your answer in question (6) above

(v) It is more effective ☐

(vi) It is readily available ☐

(vii) Patients/clients like the type ☐

(viii) I don't have faith in others ☐

(ix) Any other reason (specify)_____

_____

_____

8. Do you appreciate the effort by medical representatives you meet?

Yes ☐ No ☐

9. If the answer is yes, how do you prescribe the drugs they promote?

a) by the brand name ☐

b) by the active ingredient ☐
(the molecule)

c) by the active ingredient ☐
then manufacturer

d) Any other way
(specify)_____

_____

_____

10. Other than the cost of the drugs and the efficacy, what are other factors you consider when you prescribe a generic preparation. Please tick.

i) Bioequvalence ☐

ii) Packaging type ☐

iii) Availability ☐

iv) The patient himself ☐

v) Any other (specify)_____

_____

11. What is your opinion on generic drugs

(i) They are effective ☐

(ii) They are affordable ☐

☐

(iii) They are readily available for many patients

(iv) They are a big step towards provisions of good health care ☐

(v) Any other (specify)_____

_____

_____

_____

12. Tick (✔) one box for each of the statements given below about generics.

		Strongly agree 3	Agree 2	Disagree 1
i)	Locally manufactured generics Are more effective than the Imported ones	☐	☐	☐
ii)	Some of the marketing and Promotion effort by medical Representatives is influencing The prescription pattern of doctors	☐	☐	☐
i)	Cheaper generics are less Potent than expensive ones	☐	☐	☐
ii)	'Quacks' or unqualified persons who handle medicine have complicated the treatment schedule pushing the cost of medication to high levels	☐	☐	☐

Thank you for your response.

Questionnaire for the patients

Section A:

Personal information

1. Age (specify) _____
2. Sex Male ☐ Female ☐
3. Educational level
   (i) Primary ☐
   (ii) Secondary ☐
   (iii) University ☐
   (v) Others (specify) _____
4. Level of income (Kshs)
   (i) 5,000 and below ☐
   (ii) Between 5,000 and 10,000 ☐
   (iii) Between 10,000 and 20,000 ☐
   (iv) Above 20,000 ☐

PART B

5. Who attended to your medical examination
   (i) Clinical Officer ☐
   (ii) Medical Officer ☐
   (iii) Consultant Doctor ☐
   (iv) Others specify _____
6. Where were you attended/examined at
   (i) Private clinic ☐
   (ii) Government hospital ☐
   (iii) Others specify _____
7. Are you aware that we have generic and branded medicine?
   Yes ☐ No ☐
8. If the answer is yes, do you mind any of the two?
   Yes ☐ No ☐

9. Do you seek medical advice always before buying a drug?

Yes ☐ No ☐

10. When you find out that the drug the doctor has prescribed is expensive do you seek for an alternative that is affordable?

Yes ☐ No ☐

11. Tick (✔) one box for each of the statements given below.

		Strongly Agree 3	Agree 2	Disagree 1
i)	Less expensive drugs works as effective as expensive ones.	☐	☐	☐
ii)	Medical persons at the government hospitals especially the COs prescribe less expensive Drugs than those at private clinics especially consultants who prefer expensive drugs.	☐	☐	☐
iii)	The well organized chemists have 'good' medicine	☐	☐	☐
iv)	A serious ailment is only managed well with expensive medicine and the less threatening one with cheaper one	☐	☐	☐

Thank you for your response.