

**THE EXTENT OF COMPLIANCE WITH INTERNATIONAL
FEDERATION OF PHARMACEUTICAL MANUFACTURERS AND
ASSOCIATIONS (IFPMA) CODE AND MARKETING PRACTICES OF
PHARMACEUTICAL COMPANIES IN KENYA**

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Declaration

This management research project is my original work and has never been presented for the award of a degree in any other university or institution of learning.

Signed.......... Date .. 15/11/2010

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This management research project has been submitted for examination with my approval as the university supervisor.

Signed.......... Date .. 16/11/2010

Dedication

This research project is dedicated to my children Dylan and Carla for their understanding especially when I had to be away from home during special occasion attending school and to my husband for always being there for me and supporting me in every way throughout this period.

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Special appreciation goes to the following for their invaluable input to this project.

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God bless you all.

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ABSTRACT

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) is a non-profit, non-governmental Organization (NGO) representing national pharmaceutical associations and companies from both developed and developing countries. The member companies of the IFPMA are research-based pharmaceutical, biotech and vaccine companies. The Federation was founded in 1968 and was admitted into official relations with the World Health Organization in 1971.

The IFPMA Code sets out standards for the ethical promotion of pharmaceutical products to healthcare professionals to ensure that member companies' interactions with healthcare professionals are appropriate and perceived as such.

IFPMA also seeks to preserve the independence of the decisions taken by healthcare professionals in prescribing medicines to patients. Industry relationships with healthcare professionals must support, and be consistent with, the professional responsibilities healthcare professionals have towards their patients. IFPMA member companies are accountable for addressing and correcting infringements under relevant codes. They should also ensure that internal structures and procedures (including adequate training of employees) are created to ensure responsible and ethical promotional activities.

This project objective was to find out the extent of compliance with IFPMA code and marketing practices of pharmaceutical companies in Kenya. This was guided by two specific objectives.

First was to establish the extent to which the pharmaceutical companies in Kenya have complied with the International Federation of Pharmaceutical Marketing Association Code on their marketing practices and then to identify the marketing practices applied.

To undertake the study, a descriptive research design was used. The data was analyzed by employing descriptive statistics (percentages) and factor analysis.

The findings of the study are that to a large extent pharmaceutical companies comply with the international federation of pharmaceutical manufacturers and associations IFPMA codes.

The code greatly affects their marketing practices as it dictates what they can and cannot do. It ensures that marketing practices are ethical and put the interests of patients first. It also ensures that promotional items are not of significant value and gifts of a personal nature are discouraged.

ABBREVIATIONS AND ACRONYMS

ARIPO	:African Regional Industrial Property Organization
COMESA	:Common Market for Eastern and Southern Africa
DRC	:Democratic Republic of Congo
DTC	:Direct-To-Consumer
EAC	: East African Community
FDA	:Federal Drugs Agency
GDP	: Gross Domestic Product
IFPMA	:International Federation of Pharmaceutical Manufacturers & Associations
KEBS	:Kenya Bureau of Standards
KEMSA	:Kenya Medical Suppliers Agency
MNCs	:Multi National Corporations
MoH	:Ministry of Health
NGO	:Non-Governmental Organization
NHSSP	:National Health Sector Strategic Plan
OTC	:Over the Counter
PSK	:Pharmaceutical Society of Kenya
R&D	:Research & Development
SPSS	:Statistical Package for Social Sciences
UK	:United Kingdom
US	: United States
USA	:United States of America
WHO	:World Health Organization
WTO	:World Trade Organization

CHAPTER ONE: INTRODUCTION

1.1: Background of the Study

The regulations governing the pharmaceutical industry have been refined through time and are intended to ensure the availability of safe and effective drugs on the market (LaFrancis Popper and Nason, 1994). Marketers in the pharmaceutical industry need to take into account regulatory constraints, if that is they wish to implement an ethical marketing strategy. LaFrancis Popper and Nason (1994), have identified a number of categories of regulations affecting the introduction of drugs, and have shown that the type of regulation did have an effect on the timing of a new product introduction. Marketers working for a global pharmaceutical company need to bear in mind the fact that the long lead time involved in bringing a new drug to the market means that income generation needs to take into account the investment in future research and development projects (Sapienza, 1993). Hence, marketers working for a pharmaceutical company need to fully understand the strategic and tactical planning implications associated with quantifiable potential risks, and need to develop contingency plans in order to counteract the actions of competitors.

Porter (1985) has made it clear that innovative products create opportunities for erecting competitive barriers and pharmaceutical companies can, through strategic positioning, establish entry barriers that keep substitute products out of the market. The pharmaceutical industry generally classifies individual drugs according to product groups called therapeutic categories. These categories may be viewed as a set of drugs that have similarities in the diseases treated and in the character of treatment. Yeoh (1994) provides two reasons as to why pharmaceutical companies specialize in specific areas of drug therapy. First, the chemical properties of drugs in one therapeutic category differ from the chemical properties of drugs in another category. Second, marketers in pharmaceutical companies can ensure that research competence in particular therapeutic categories are developed and exploited and this is easier to achieve than the company incurring high

learning costs and additional costs associated with failure as a result of entering unfamiliar therapeutic categories. Thomas (1988) has paid attention to the costs associated with pharmaceutical marketing activities and has concluded that most companies concentrate their sales efforts on specific therapeutic categories.

Competitive advantage (Porter, 1980, 1985) can be associated with a company developing and exploiting internal technology (Grant, 1995). Licensing represents an option that enables a company to extend its geographic reach, as well as fill gaps in a product line for example. Sapienza (1993) has made reference to internal development and the erection of entry barriers, and Yeoh (1994) has suggested that a commitment to internal research and development is necessary in order to develop successful new pharmaceutical products for the global market. Senior managers in pharmaceutical companies are paying attention to such issues as increasing research and development costs; and the increasing levels of competition (Little, 1989). It is because of the constant threat of competition, that senior marketing staff in pharmaceutical companies has adopted a global perspective to the market.

1.1.1: Pharmaceuticals Marketing

The pharmaceutical industry today, as with many other industries, is under intense pressure to meet ambitious growth objectives. Net sales growth of 20 per cent per annum is a typical target for major players, whilst “single digit growth” is regarded as unacceptable by the financial markets. In order to meet these ambitious sales targets and to maintain the output of the stream of innovative products, the pharmaceutical industry is one of the biggest spenders on R&D. For instance, British pharmaceutical companies are estimated to have spent 15 per cent of sales revenues on R&D in 1998, a growth of 10 per cent on the previous year (Osborne, 1999).

A lot of efforts go into sales and marketing and over time ethics of pharmaceutical companies have been questioned by the media. Gift giving has been associated with enticement to prescribe drugs. Beyond gift giving, other marketing practices have raised ethical questions. For example, Pharmaceutical companies have “redefined” a disease to treat more patients. Depression went from an incidence of 50 per million in 1950 to 100

per million today, far beyond epidemiologic projections. Could this be the result of increased pharmaceutical marketing for new antidepressants (Healy, 2000)? Another marketing strategy that is recognized as an ethical issue is lowering thresholds for therapy to sell drugs to more patients (Moynihan and Cassels, 2005).

The distinguishing characteristic and all-pervasive influence on the pharmaceutical business is the pharmaceutical pricing system (Larsen and Schaumann, 1990). Prices for new products are determined under two systems. In the first system, the majority of prices are determined by comparison with prices for existing therapies for the same disease or condition. Standard clinical trial practice is to compare new products against active controls, as discussed earlier. Therefore, a crucial part of a company's product development strategy is to choose control products that offer an attractive target for evidence of efficacy and have a comparatively attractive price. The second price-setting mechanism is used when no comparative product is available. It is based on the cost of production and comparative worldwide prices, if available (Larsen and Schaumann, 1990). This second mechanism has been used infrequently. However, with the greater variety of new product types available, many generated from biotechnology techniques, the use of this second system is expected to increase.

1.1.2: IFPMA Code of Pharmaceutical Marketing Practices

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) is a non-profit, non-governmental Organization (NGO) representing national industry associations and companies from both developed and developing countries. Member companies of the IFPMA are research-based pharmaceutical, biotech and vaccine companies. The Federation was founded in 1968 and was admitted into official relations with the World Health Organization in 1971. The main objectives of IFPMA are: to encourage a global policy environment that is to innovation in medicine, both therapeutic and preventive, for the benefit of patients around the world; to contribute industry expertise and foster collaborative relationships and partnerships with international organizations, national institutions, governments and non-governmental organizations that are dedicated to the improvement of public health, especially in developing and

emerging countries; and to assure regular contact and experience-sharing and coordinate the efforts of its members towards the realization of the above objectives.

The IFPMA Code and the operating procedure of the IFPMA Code apply directly in territories where no national code has been adopted by the respective member association. The IFPMA Code and its operating procedure also apply in all cases where a member company commits a breach of the IFPMA Code in territories where there are national codes adopted by the respective member association but the member company in alleged breach is not a member of that association.

The IFPMA Code sets out standards for the ethical promotion of pharmaceutical products to healthcare professionals to ensure that member companies' interactions with healthcare Professionals are appropriate and perceived as such. For the purposes of the IFPMA Code: "pharmaceutical product" means all pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) which are intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which are intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body.

"Promotion" means any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all media, including the internet. "Healthcare professional" means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product. "Member Company" means any company that is a member of IFPMA (direct member) or a member of any association that is a member of IFPMA (indirect member). "Company" can refer to national companies and/or the worldwide parent company. "Member association" means any association that is a member of IFPMA.

The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and marketing new medicines.

Ethical promotion helps to ensure that healthcare professionals have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients (International Federation of Pharmaceutical Manufacturers Associations (IFPMA), 2006). The pharmaceutical industry has an obligation and responsibility to provide accurate information and education about its products to healthcare professionals in order to establish a clear understanding of the appropriate use of prescription medicines. Industry relationships with healthcare professionals must support, and be consistent with, the professional responsibilities healthcare professionals have towards their patients. Pharmaceutical companies must maintain high ethical standards when conducting promotional activities and comply with applicable legal, regulatory and professional requirements. Through the promotion of the Code, IFPMA seeks to ensure that ethical promotional practices are established worldwide. The IFPMA Code sets out standards for the ethical promotion of pharmaceutical products to healthcare professionals to ensure that member companies' interactions with healthcare professionals are appropriate and perceived as such.

IFPMA also seeks to preserve the independence of the decisions taken by healthcare professionals in prescribing medicines to patients. Industry relationships with healthcare professionals must support, and be consistent with, the professional responsibilities healthcare professionals have towards their patients. IFPMA member companies are accountable for addressing and correcting infringements under relevant codes. They should also ensure that internal structures and procedures (including adequate training of employees) are created to ensure responsible and ethical promotional activities.

The IFPMA code does not seek to regulate the following activities: Promotion of prescription only pharmaceutical products directly to the general public (i.e. direct to consumer advertising); promotion of self-medication products that are provided "over the counter" without prescription; pricing or other trade terms for the supply of pharmaceutical products; the engagement of a healthcare professional to provide genuine consultancy or other genuine services to a member company; the conduct of clinical trials; and the provision of non-promotional information by member companies.

1.1.3: The pharmaceutical industry in Kenya

Kenya spends about 8% of its GDP on health. Per capita expenditure per person stood at about US\$ 11 per person in 2003. Out of this, US\$ 6 came from budgetary resources, which also included donor contributions and the balance of about US \$5 came mainly from out-of-pocket expenditure (Economic Survey, 2004). This expenditure fell far below the WHO's recommended US\$34 per capita. Out-of-pocket expenditure thus accounted for 53% of the total cost of healthcare, with the remainder being Government contributions from general taxation (25%), Social Health Insurance (15%), private prepaid health plans (5%) and non-profit institutions expenditure at 2%. The above scenario means the current healthcare financing system depends mainly on out-of-pocket expenditure and therefore 75% privately financed (Kenya's Pharmaceutical Industry, 2005).

The pharmaceutical industry in Kenya consists of manufacturers, distributors and retailers, who all actively support the Ministry of Health and other key players in developing the health sector. The pharmaceutical sector consists of about 30 licensed concerns include local manufacturing companies and large Multi National Corporations (MNCs), subsidiaries or joint ventures. Most are located within Nairobi and its environs. These firms collectively employ over 2,000 people, about 65% of who work in direct production. The industry compounds and packages medicines, repackaging formulated drugs and processing bulk drugs into doses using predominantly imported active ingredients and excipients. The bulk of locally manufactured preparations are non-sterile, over-the-counter (OTC) products. The number of companies engaged in manufacturing and distribution of pharmaceutical products in Kenya continue to expand, driven by the Government's efforts to promote local and foreign investment in the sector.

The Kenya Medical Suppliers Agency (KEMSA), a division of the Ministry of Health, largely carries out the distribution of pharmaceutical products in Kenya. It distributes drugs to government public health facilities and private health facilities. KEMSA has been an autonomous body since 1st July 2003. Its policy is to make available essential drugs and equipment primarily but not exclusively, to public facilities. KEMSA competes with other suppliers, e.g. the mission based medical supply facility (MEDS) and private

wholesalers. Pharmaceutical products in Kenya are channeled through pharmacies, chemists, health facilities and shops. There are about 700 registered wholesale and 1,300 retail dealers in Kenya, manned by registered pharmacists and pharmaceutical technologists. The drugs on sale in Kenya are sold according to the outlet categorization, which can be described as free-sales/OTC, pharmacy technologist dispensable, or pharmacist dispensable/prescription only (Statistical Abstract, 2003).

Control of the profession of pharmacy and the trade in pharmaceutical products is administered by the Ministry of Health (MoH), through the Pharmacy and Poisons Board, as provided for by Chapters 244 (The Pharmacy and Poisons Act) and 245 (The Dangerous Drugs Act) of the Laws of Kenya. Kenya largely imports medicinal and pharmaceutical products from sources such as Great Britain, India, Germany, France, the USA and Switzerland. Importers are expected to meet legal requirements, which include: Provide samples to the Kenya Bureau of Standards (KEBS) for quality checks and registration; Meet the regulations of the national policy, which has been adopted by the MOH; This includes an essential drugs list, using WHO guidelines, whose objective is to promote the availability of quality pharmaceutical products at affordable prices; and Pass regulatory quality control, monitoring and market surveillance as stipulated by the Pharmacy and Poisons Board and the National Drug Quality Control

The Pharmacy and Poisons Board was established by the Pharmacy & Poisons Board Act. The Act also confers, to the Board, the right to declare an epidemic. Breaking of any of the Boards' rules is illegal and criminal under the Act. The Pharmacy and Poisons Board ensures: For Manufacturers: Manufacturers register their premises; the products are registered with the Board Product labeling in English or Kiswahili; and Ensures Batch Number, Date of manufacture, Expiry Date and Address of Manufacture is labeled. For Pharmacists: All pharmacists have practicing licenses; Register their premises with the Board; Employ qualified personnel; and observe the laid down professional ethics

1.2: Statement of the problem

The pharmaceutical industry today, as with many other industries, is under intense pressure to meet ambitious growth objectives. Net sales growth of 20 per cent per annum

is a typical target for major players, whilst “single digit growth” is regarded as unacceptable by the financial markets (Osborne, 1999). Gift-giving, even gifts of negligible value, by drug companies can influence physicians’ prescribing behavior and be a conflict of interest (Katz *et al.*, 2003; Blumenthal, 2004). Nurses working in physicians’ offices have been influenced by gifts (Edmunds, 2004). Although much of the literature is about ethical issues in the developed countries; the pharmaceutical industry’s involvement in provocative issues is a global phenomenon (Ornellana, 2002). The IFPMA code is currently being used by companies as a guide in order to ensure that physicians get accurate information on drugs for the benefit of patients. It also tries to ensure that physicians’ decisions on prescriptions are independent, informed and free of undue influence.

The code’s seeks to preserve the independence of the decisions taken by healthcare providers in prescribing medicines to patients. In a country where not everyone follows the code, some companies get undue advantage over others. Restrictions on marketing practices, eg journal subscriptions means whereas some companies can get subscriptions on medical journals for doctors to use in their daily practice ,others cannot. Physicians therefore are likely to view those who cannot as not adding value to their practice. Sponsorships is also an area of concern. The code allows companies to give part sponsorships to physicians for medical meetings and conferences that are usually very costly but very educational. This ensures that what is given cannot be viewed as enticement and is not luxurious .This means several companies get the opportunity to sponsoring the same physician therefore no greater influence. The code also states that a give away cannot be of a greater value that ten dollars and accomodation if offered has to be in an area or a hotel that the physician can afford. Therefore companies that comply with the code find restrictions where others are not affected at all hence undue advantage.

The issue of concern is marketing restrictions and sales incentives. It pertains to any regulations or guidelines that can potentially impact marketing or sales practices, such as providing gifts or incentives to physicians, promotion of drug benefits or off-label use of an approved drug. Pharmaceutical companies need to take action to address the negative effects of the IFPMA Code of Marketing. There is scarcity of literature on the effects of

some of the ethical restrictions to marketing of pharmaceutical products in the developing countries, especially Kenya.

Studies undertaken in Kenya in the pharmaceutical industry include the following: Obado (1991) studied the influence of perceived organizational climate on Kenya's pharmaceutical sales forces motivation; Lesiew (1992) undertook an analysis of sources of finance for Eldoret based pharmaceutical outlets; Munyiri (2000) undertook a survey of the use of business process reengineering approach in the Kenyan pharmaceutical manufacturing industry; Muiva (2001) undertook a survey of the use of competitive intelligence systems in the Kenyan pharmaceutical industry; Naikuni (2001) undertook an empirical investigation of the application of promotional mix elements within multinational pharmaceutical companies in Kenya; Opiyo (2006) focused on the responses of pharmaceutical importers to the challenge of illegal trade in pharmaceuticals; Kamau (2006) undertook an empirical investigation of the strategies used to market generic pharmaceutical products, focusing on respiratory infections drugs in Kenya; and Muchelule (2006) studied the multinational pharmaceutical firms' adaptation to the challenge of parallel importation of drugs in Kenya.

None of the above studies focused on the effect of International Federation of Pharmaceutical Marketing Association Code on Marketing Practices of pharmaceutical companies in the Kenya. The current study seeks to understand more thoroughly the impact of the IFPMA Code on the pharmaceutical industry. This study will attempt to bridge the knowledge gap by seeking answers to the question "What is the extent of compliance with the International Federation of Pharmaceutical Marketing Association Code and Marketing practices of pharmaceutical companies in Kenya?"

1.3: Objective of the Study

The following are the objectives of the study:

The study seeks to examine the extent of compliance with International Federation of pharmaceutical manufacturers and associations (IFPMA) code and marketing practices of pharmaceutical companies in Kenya

The study will be guided by the following specific objectives:

- (i) To establish the extent to which the pharmaceutical companies in Kenya have complied with the International Federation of Pharmaceutical Marketing Association Code on their marketing practices.
- (ii) To identify the marketing practices applied by Pharmaceutical companies in Kenya as a result of the IFPMA code.

1.4: Significance of the Study

The study aims to address regulators, enforcers and the academy, presenting reflections on some research-driven innovative approaches, strategies and tools used to cope with the effects of IFPMA Code on Marketing Practices by pharmaceutical companies in Kenya, with reference to some instances of concrete application deriving from the experience and know-how of other countries.

The study explores themes and issues to which the international community is becoming increasingly sensitive, and which would certainly benefit from innovative vision and approach. The ideas and solutions expressed surely need further development, test and discussion, but they are bound to become part of the most significant prospective challenges occasioned by IFPMA Code on Marketing Practices.

1.4.1: The Pharmaceutical Companies

The study will also make managerial contributions for players in the pharmaceutical industry, in that it provides a basis for the various companies to better understand the effects of IFPMA Code on Marketing Practices and could use the information to identify the shortcomings of the process and improve on it. In addition, innovative strategies will be formulated to overcome the effects of the Code.

1.4.2: The regulatory bodies and the Government

The research findings shall also aid in the improvement of the already formulated policies and enforcement of the same in order to facilitate full implementation and in conformity with the IFPMA Code.

1.4.3: Academic Researchers

The study will make a significant contribution to the growing body of research on the effects of IFPMA Code on Marketing Practices of pharmaceutical companies. The findings may also be used as a source of reference for other researchers. In addition, other academic researchers may need the study findings to stimulate further research in this area of pharmaceutical marketing and as such form a basis of good background for further researches.

CHAPTER TWO: LITERATURE REVIEW

2.1: Introduction

This chapter presents a review of the literature related to the purpose of the study. The chapter is organized according to the specific objectives in order to ensure relevance to the research problem. The review was undertaken in order to eliminate duplication of what has been done and provide a clear understanding of existing knowledge base in the problem area. The literature review is based on authoritative, recent, and original sources such as journals, books, thesis and dissertations.

2.2: Marketing of Pharmaceutical Products

Pharmaceutical products include both prescription and non-prescription over-the-counter (OTC) drugs. OTC products are somewhat similar to consumer goods. Our focus is on prescription (ethical) drugs, which share some characteristics with industrial goods and other characteristics with consumer goods. The similarities with industrial goods are due to the multi-party aspect of the buying process. For prescription drugs, the following different buying parties can be identified (Corstjens, 1991): prescriber - doctor; influencer - hospitals, nurses, professors, reimbursement agencies (government); consumer - patient; and financier - partly patient, partly government or third party (varies by country), managed health care organizations (hospitals, HMOs). Sales and marketing practices in the industry are areas of potential ethical transgression and are addressed extensively in literature. As primary interfaces between pharmaceutical companies and patients, physicians are the target of marketing and sales efforts. For example, gift-giving, even gifts of negligible value, by drug companies can influence physicians' prescribing behavior and be a conflict of interest (Katz et al., 2003; Blumenthal, 2004). Nurses working in physicians' offices have been influenced by gifts (Edmunds, 2004).

Interestingly, despite the literature coverage and publicity in newspapers, physicians are still prone to the enticement of gifts according to a recent national survey (Brett et al.,

2003). But the ethical compromise does not stop there. The literature suggests gift-giving leads to more compromising relationships, such as writing treatment guidelines that will shape the prescribing behavior of other physicians (Studdert et al., 2004; Goozner, 2005). Other instances include prescribing drugs that a patient does not need and switching a patient to a new drug just to increase the sale of that new drug (Kmietowicz, 2004; Kassirer, 2005). They are also far-ranging and encompass working with medical students and advertising directly to patients with direct-to-consumer (DTC) marketing (Sierles et al., 2005). DTC advertising is an area of particular concern due to its potential to mislead patients (Chandra and Holt, 1999). Banned until 1980, the use of DTC advertising by pharmaceutical companies has increased, though there are guidelines to advertise on television (Pinkus, 2002).

2.2.1: Research & Development

The importance of research and innovation for competition among major pharmaceutical firms places the ethical drug industry in a select grouping of high-technology industries. The most distinctive feature of pharmaceutical innovation lies in the spending strategies of the major firms: high rates of investment in R&D expenditures (as a percentage of sales and profits), and relatively high rates of spending for basic research. The research and development process in the pharmaceutical industry is usually very long, taking, on average, between ten and 15 years to discover, develop, and fully test a new drug. The process is also very expensive, averaging between 10 and 15 per cent of sales for research-intensive drug companies.

Currently, the cost of bringing a new drug through the necessary trials is estimated at \$230 million in the USA, \$150 million in Europe, and \$125 million for major Japanese manufacturers (Bezold and Knabner, 1994). Federal Drugs Agency (FDA) testing and trial requirements are more extensive and longer in duration causing much of this extra cost. Corstjens (1991) identified three specific reasons to explain the higher research and development costs in the pharmaceutical industry. First, increased government regulations regarding new drug approvals have increased the need and cost of testing. Second, the complexity of new DNA research into the human genome have added new costs as well as substantially expanded growth opportunities.

And, third, the therapeutic transition from R&D for acute therapies to chronic and long-term therapies has increased the need for drug-testing over a longer period of time.

2.2.2: Government regulations

The pharmaceutical industry provides products which can significantly influence the overall productivity, aggregate demand, and consumer behavior in terms of use of discretionary income. Therefore, through exercising regulatory policy national governments as well as supragovernmental authorities such as World Health Organization (WHO) and now the World Trade Organization (WTO) are acting to disseminate more broadly pharmaceutical products as a general concern for world health welfare and the relief of technical and trade barriers impeding world trade. National governments basically regulate in four different ways to influence the drug industry: in the introduction of new products; in the pricing of drugs; in the trade of drugs; and in patents and trademarks.

The role of the government, and especially the Ministry of Health, cannot be overlooked by (foreign) manufacturers of pharmaceutical products. From before the start of manufacturing a new drug until the post-marketing stage, there are many laws and regulations for pharmaceutical firms to comply with. To manufacture or import pharmaceuticals in Kenya, an approval by the Ministry of Health is required. Licenses are granted based on data submitted by the applicant, and the Ministry of Health is responsible for reviewing each item in terms of name, contents, volume per dosage, usage, number of dosages, effectiveness, effect, performance, side effects, etc. in order to control the quality, effectiveness, and safety of the drug (JETRO, 1992). The standard review period for new ethical drugs is 18 months (but two years for generics) (Larsen and Schaumann, 1990). This relatively short period of review, which would exclude by its brevity primate testing, would be considered excessively liberal in contrast with US FDA regulations and, of course, explain a large difference in the R&D cost of bringing new pharmaceuticals to the market. Post-marketing surveillance plays an integral and significant role in the approval process. Each new product is, in effect, provisionally approved for a period of six years, at the end of which time the manufacturer must apply for re-examination.

2.2.3: Distribution

Distribution systems are highly complex in practically all consumer product markets, and the pharmaceutical industry is no exception. Obtaining adequate distribution has been a key barrier for firms wishing to enter, or expand, in the industry, and is currently the main issue of strategy (re)evaluations for many firms. The practice of simply viewing wholesaling as an extension of the manufacturer's business activities, rather than as a service to buyers, has begun to change only recently. Still, in comparison to Western practices, a superior level of service is provided to customers. Wholesalers often make at least two runs a day on standard delivery routes and will provide same-day service on most orders (Larsen and Schaumann, 1990).

2.2.4: Promotion

Personal selling is the most important aspect in promoting pharmaceutical products. This extra product support may be in part due to cultural differences in dealing with physicians or it may simply be that services are being performed other than those offered elsewhere, such as the promotion of non-traditional remedies. In addition, about 35,000 wholesaler sales representatives are competing for the physician's time. This total of 77,000 is almost equivalent to one person promoting pharmaceuticals to only 2.5 practising physicians. The comparable figure for the USA is one salesperson for every ten physicians; in the UK the ratio is well over ten (Larsen and Schaumann, 1990).

Next to personal selling, promotional tools for marketing pharmaceutical products are either underdeveloped or relatively underused. Journal advertising is done, but traditionally more often for the public relations value with the particular medical association producing the journal than for actual product promotion. There are several general medical magazines published by leading publishers as well as a growing number of single-sponsor journals (Larsen and Schaumann, 1990).

2.2.5: The pricing mechanism

The distinguishing characteristic and all-pervasive influence on the pharmaceutical business is the pharmaceutical pricing (Larsen and Schaumann, 1990). Prices for new products are determined under two systems. In the first system, the majority of prices are determined by comparison with prices for existing therapies for the same disease or condition. Standard clinical trial practice is to compare new products against active controls, as discussed earlier. Therefore, a crucial part of a company's product development strategy is to choose control products that offer an attractive target for evidence of efficacy and have a comparatively attractive price. The second price-setting mechanism is used when no comparative product is available. It is based on the cost of production and comparative worldwide prices, if available (Larsen and Schaumann, 1990). This second mechanism has been used infrequently. However, with the greater variety of new product types available, many generated from biotechnology techniques, the use of this second system is expected to increase.

2.2.6: Market Segmentation

Pharmaceutical companies, in general, segment their target users on the basis of their behavior and decision-making process. This marketing dichotomy of industrial/consumer goods in their formulation of marketing strategies has long been discussed among marketing scholars. The Industrial Marketing Committee Review Board (American Marketing Association, 1960) and some scholars differentiated consumer goods marketing from industrial goods marketing according to main distinctions in the ultimate user/buyer's behavior. Sheth (1973) in his theory of family buying decisions implicitly recognized the similarity between industrial and household buying behavior. Later, Wind (1978) showed the similarity in the consumer and organization segmentation concepts by demonstrating that the buying centers have been moving from individuals to multi-persons.

In the pharmaceutical industry, ethical products are considered to be organizational buying, whereas over-the-counter (OTC) preparations are categorized as consumer buying. Although the patient is generally the ultimate end user, regardless of whether

ethical or OTCs are concerned, medical practitioners have a rather unique and often multiple role in the purchasing process of pharmaceutical products. They may be the deciders who make the buying decision for their patients when prescribing ethicals, or they may play the role of influencer and/or gatekeeper in the case of OTCs or hospital dispensaries. In countries such as Hong Kong, where medical practitioners are permitted to dispense ethical products in their clinics, their buying motives can be even more complex and buying behavior becomes consumer buying. It is therefore understandable that the bulk of marketing efforts is directed toward medical practitioners.

2.3: Ethical issues in the pharmaceutical industry

There is currently an organized movement by individuals and groups to change how the pharmaceutical marketplace provides safe, effective, and affordable medicine. This movement is not new. It has been around since the beginning of the modern pharmaceutical industry, periodically intensifying and diminishing throughout the years. Revitalized in recent years, movement supporters assert that the current pharmaceutical system is broken and major changes are necessary (Angell, 2004; Avorn, 2004; Goozner, 2004) They allege that the pharmaceutical industry makes excessive profits by taking advantage of perverse incentives in a market where consumers rely on third parties (i.e. physicians) to choose drugs for them and prescription drug insurance coverage (often provided by employers or the government) to shield consumers from the full cost of paying for those drugs. The distorted economics of the market therefore permits the industry to succeed by marketing new, expensive drugs that are often no better than cheaper alternatives currently on the market. Those high priced drugs are supported by tax incentives and Federal investment in research and development. Furthermore, promotional efforts by drug companies encourage inappropriate prescribing by physicians, incorrect drug use and unreasonable expectations by patients, and wasteful expenditures on drugs and other health care.

During the last half century, studies on ethical issues such as the polio vaccine shortage and subsequent law suit against Cutter Pharmaceutical for negligence in 1958 started from that has grown to the present day, addressing issues like marketing practices, clinical study design and pricing of prescription medicines (Offit, 2005). Prior to coverage in the peer-reviewed literature, newspapers carried stories about drugs

overstating their therapeutic capabilities as far back as the 1850s when the first sales representatives began to call on physicians (Pepin, 1996). Although much of the literature is about ethical issues in the US, the pharmaceutical industry's involvement in provocative issues is a global phenomenon (Ornellana, 2002).

Another area of attention in the literature concerns clinical data, the link between science and business. Clinical data must support the approval for sale of new drugs (Marsa, 1997). Reports describe practices of questionable ethics such as deliberately miscoding data to minimize a side effect, enrolling healthy children in pediatric studies and aggressively diagnosing medical problems in healthy volunteers to aid in recruiting patients, as was the case in the ketamine trials (Tishler and Gordon, 1999; Healy, 2003; Koren, 2003). The date when the final treatment is given to a patient under a study protocol (time-to-last-treatment) is always a milestone in clinical studies and efforts to achieve it faster have led to ethical dilemmas. Examples from the literature are treating the homeless in exchange for basic rewards, such as food and medical care (Beauchamp et al., 2002). Other examples include using clinical research organizations (CROs), whose mission is to run clinical studies for pharmaceutical companies, primarily because they have an existing network of clinical trial sites; or using ghostwriters to “hoodwink” medical journals and publish favorable study results faster (Schieppati et al., 2002; Wagena and Knipschild, 2005).

Concerns about drug pricing have been covered extensively in the literature and newspapers, dating back over 30 years (Walker, 1971; Maitland, 2002). Another issue is patent exclusivity and the opposition of pharmaceutical companies to any actions that could make additional sources of product available before patent expiration, resulting in restricted patient access to drugs. Another issue is regulatory attempts to impede marketing, production or use of drugs, which has led to a doctrine that approves the use of a drug that is life saving but has side effects that can cause injury – a doctrine that is not allowed for other products (Masek, 2000).

The literature also represents the pharmaceutical industry favorably in many cases. Publications note that patients enter clinical studies without coercion and get access to a drug that cures their illness when approved drugs are unable to do so (Pepin, 1997). One of the eight myths about the drug industry's ethics identified by Spilker (1984) is that

consumer advocates provide the public with unbiased truths about the drug industry. According to Spilker (1984), in addition to being unfairly represented by consumer advocates, pharmaceutical companies are often the focal point of hostility because they are one of the most well-known components of healthcare delivery.

Other components of health care delivery are payers, policy makers and providers, like doctors and hospitals, who have also been accused in the literature of ethical transgressions. Examples are HMO physicians obligated to cut costs, a physicians' conference refusing to sell space to an anti-pharma group, or the conflict of interest that can result from partnering between medical organizations and pharmaceutical companies (Veatch, 1985; Lenzer, 2005; Kerridge et al., 2005). Pharmaceutical companies also get maligned for the transgressions of clinical trialists who fail to provide appropriate treatment or full safety to patients (Barrett and Jay, 2005).

CHAPTER THREE: RESEARCH METHODOLOGY

3.1: Introduction

This chapter covers a description of the study design, target population, sample design and size, data collection instruments and procedure.

3.2: Research Design

To undertake the study, a descriptive research design will be used. This is a scientific study done to describe a phenomena or an object. This kind of study involves answering research questions. This method was preferred as it permits gathering of data from the respondents in natural settings. In this case, it will be possible for the researcher to administer the data collection tools to the respondents in their workstations, which is relatively easy, with high likelihood of increasing the response rate.

3.3: Population of the Study

The population of study consisted of the International Pharmaceutical Companies operating in Kenya, whose number stood at 45 as at December 2008. (Appendix I). The respondents in each of the companies were the Head of the marketing function. A Census of all the 45 companies was undertaken.

3.4: Data Collection

Primary data was collected from the Heads of the Marketing functions of the various organizations using a semi-structured questionnaire. The questionnaire consisted of two sections, Section I and section II. Section I consisted of items pertaining to profile of the respondents while section II consisted of items pertaining to the area of study. The sets of questionnaires were pre-tested on ten randomly selected respondents which necessitated adjustments in order to make them more suitable and minimize bias in responses.

The questionnaires were administered to the companies whose offices are in Nairobi by hand delivery. Once completed, the researcher personally collected the questionnaires from the respondents. In addition, the researcher made telephone calls to the respective

respondents for further explanation of the purpose of the study and set a time frame for the completion of the questionnaires.

3.5: Data Analysis

The data was analyzed by employing descriptive statistics (percentages, mean scores and standard deviations) and factor analysis. Factor analysis was used in reducing the predetermined statements/variables into fewer and meaningful factors. This was done by grouping statements into factors using a factor loading of 0.5. Statistical Package for Social Sciences (SPSS) and excel spread sheet were used as an aid in the analysis. The two packages were preferred because of their ability to cover a wide range of the most common statistical and graphical data analysis. The analysis were presented frequencies in tables, charts and bar graphs and discussed as per the objectives and research questions of the study.

CHAPTER FOUR: DATA ANALYSIS AND FINDINGS.

4.1: Introduction

The research objectives were: examine the extent of compliance with International Federation of pharmaceutical manufacturers and associations (IFPMA) code and marketing practices of pharmaceutical companies in Kenya. The study was guided by the following specific objectives; to establish the extent to which the pharmaceutical companies in Kenya have complied with the International Federation of Pharmaceutical Marketing Association Code on their marketing practices and to identify the marketing practices applied by Pharmaceutical companies in Kenya as a result of the IFPMA code. The data was collected from the population of 45 International Pharmaceutical Companies operating in Kenya. The findings are presented in percentages and frequency distributions, mean and standard deviations.

4.2: General information.

This section covers general information obtained from the respondents in terms; response rate, number of operation years by organization in Kenya, number of full time employees, membership of IFMA and the kind of membership to IFPMA code of pharmaceutical marketing practices.

4.2.1: Response rate

A total of 45 questionnaires were issued out. The completed questionnaires were edited for completeness and consistency. Of the 45 questionnaires used in the sample, 42 were returned. The remaining 3 were not returned. The returned questionnaires represented a response rate of 93%, which the study considered adequate for analysis

Figure 4.1: Response rate

Response rate	Frequency	Percent
Returned	42	93
Not Returned	3	7
Total	45	100

4.2.2: Length of operation in Kenya

The respondents were to state the number of years their respective organizations have been operating in Kenya. As shown in table 4.2.1, majority of the organizations (64%) have been operating in Kenya for 16 and above years, while the remaining 34% have been in operation for a period ranging from 11 to 15 years.

Table 4.2.1: Length of operation in Kenya (years)

	Frequency	Percent	Cumulative Frequency
11 to 15 years	15	36	36
16 years and above	27	64	100
Total	42		

4.2.3: Number of full time employees

The findings presented in table 4.1 show that, 45% of the organizations employed above 26 employees on full time basis, 38% had 21 to 25 employees on full time basis, 7% had 16 to 20 full time employees while 10% had less than 10 employees on full time basis.

Table 4.1: Number of full time employees

No of employees	No of companies	Percent
Less than 10	4	10
16-20	3	7
21-25	16	38
25 and above	19	45
Total	42	100

4.2.2: Membership of IFPMA code of pharmaceutical marketing practices

The respondents were to state whether their respective organizations are members of IFPMA. The analysis in figure 4.2 shows that 83% of the organizations are members of IFPMA while only 17% were not members of IFPMA

Table 4.2: Membership of IFPMA

Membership	Frequency	Percent
Members	35	83
Non Members	7	17
Total	42	100

4.2.3: Type of membership

An organization can be members of IFPMA code of pharmaceutical marketing practices in two ways, that is, direct membership or a member of an association that is a member of IFPMA (indirect membership). The finding shows that of the thirty five organizations who were members of IFPMA, 69% had direct membership and the rest 31% were member of an association that is a member of IFPMA

Table 4.3: Type of membership

Type of membership	No of companies	Percent
Direct	24	69
Indirect	11	31
Total	45	100

4.3: Extent of compliance with the IFMA code of pharmaceutical marketing practices

This section covers findings from the specific questions posed to the respondent's to determine the extent of compliance with the IFMA code of pharmaceutical marketing practices in pharmaceutical companies in Kenya. Mean, standard deviation and factor analysis were used to analyze the data.

Table 4.3.1: Extent of compliance with the IFMA code of pharmaceutical marketing practices

	Mean	Std. Deviation
<ul style="list-style-type: none"> Pharmaceutical companies should be committed to educational and promotional efforts that benefit patients 	4.2381	.90553
<ul style="list-style-type: none"> Commitment to patients and collaborations that enhance the practice of medicine 	4.5000	.63438
<ul style="list-style-type: none"> Obligation and responsibility to provide accurate information and education about the company's products to healthcare professionals in order to establish a clear understanding of the appropriate use of prescription medicines 	4.5000	.63438
<ul style="list-style-type: none"> Maintenance of high ethical activities and compliance with applicable legal, regulatory and professional requirements 	4.5952	.62701
<ul style="list-style-type: none"> Internal structures and procedures (including adequate training of employees) are created to ensure responsible and ethical promotional activities 	4.5000	.77302
<ul style="list-style-type: none"> Pharmaceutical companies are prohibited from providing or offering financial benefits or benefit – in-kind to healthcare professionals in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. 	4.3095	.86920
<ul style="list-style-type: none"> Pharmaceutical companies are prohibited from providing anything in a manner or on conditions that would have an inappropriate influence on healthcare professional's prescribing practices. 	4.2619	.73450
<ul style="list-style-type: none"> The company engages in promotional activities that encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their practices 	4.4048	.76699
<ul style="list-style-type: none"> In the course of preparing promotional materials, all laws, local regulations and industry codes should be observed by pharmaceutical companies and they should take the responsibility to check local requirements 	4.2619	.73450
<ul style="list-style-type: none"> The company's promotional activities (which include clinical assessments, post marketing surveillance and experience programmes and post authorization studies) are not disguised. 	4.3571	.75938
<ul style="list-style-type: none"> All materials relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by the company clearly indicate by whom it has been sponsored 	4.2619	1.25055

The findings in table 4.3.1 above show that all statements had a mean ranking of above 4. Specifically; Maintenance of high ethical activities and compliance with applicable legal, regulatory and professional requirements (mean of 4.5952), Commitment to patients and collaborations that enhance the practice of medicine (mean of 4.5000), Obligation and responsibility to provide accurate information and education about the company's products to healthcare professionals in order to establish a clear understanding of the appropriate use of prescription medicines (mean of 4.5000) and Internal structures and procedures (including adequate training of employees) are created to ensure responsible and ethical promotional activities (mean of 4.5000) were the requirements which organizations complied with to a very great extent. There was very low variation in the opinion of the respondents as indicated by the values of the standard deviations

Table 4.3.2: Total Variance Explained

Component	Initial Eigen values			Extraction Sums of Squared Loadings		
	Total	% of Variance	Cum %	Total	% of Variance	Cum %
1	7.914	71.947	71.947	7.914	71.947	71.947
2	1.653	15.026	86.974	1.653	15.026	86.974
3	.966	8.782	95.756			
4	.264	2.399	98.155			
5	.155	1.413	99.567			
6	.048	.433	100.000			
7	6.129E-16	5.572E-15	100.000			
8	3.110E-16	2.827E-15	100.000			
9	8.946E-17	8.132E-16	100.000			
10	-2.083E-16	-1.894E-15	100.000			
11	-5.606E-16	-5.096E-15	100.000			

Extraction Method: Principal Component Analysis.

The result indicates that 11 variables were reduced into 2 factors. The two factors explain 86.974% (Cumulative percentage) of the total variation, the remaining 9 factors together account for 13.026% of the variance. The explained variation 86.974% is greater than 70% and therefore, factor analysis can be used for further analysis. The model with two factors will therefore be adequate to represent the data.

Table 4.3.3: Rotated Component Matrix

	Component		
	1	2	
<ul style="list-style-type: none"> Pharmaceutical companies should be committed to educational and promotional efforts that benefit patients 	X ₁	.530	.729
<ul style="list-style-type: none"> Commitment to patients and collaborations that enhance the practice of medicine 	X ₂	.851	.137
<ul style="list-style-type: none"> Obligation and responsibility to provide accurate information and education about the company's products to healthcare professionals in order to establish a clear understanding of the appropriate use of prescription medicines 	X ₃	.735	.641
<ul style="list-style-type: none"> Maintenance of high ethical activities and compliance with applicable legal, regulatory and professional requirements 	X ₄	.926	.224
<ul style="list-style-type: none"> Internal structures and procedures (including adequate training of employees) are created to ensure responsible and ethical promotional activities 	X ₅	.273	.844
<ul style="list-style-type: none"> Pharmaceutical companies are prohibited from providing or offering financial benefits or benefit –in-kind to healthcare professionals in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. 	X ₆	.567	.798
<ul style="list-style-type: none"> Pharmaceutical companies are prohibited from providing anything in a manner or on conditions that would have an inappropriate influence on healthcare professional's prescribing practices. 	X ₇	.828	.415
<ul style="list-style-type: none"> The company engages in promotional activities that encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their practices 	X ₈	.792	.557
<ul style="list-style-type: none"> In the course of preparing promotional materials, all laws, local regulations and industry codes should be observed by pharmaceutical companies and they should take the responsibility to check local requirements 	X ₉	.828	.415
<ul style="list-style-type: none"> The company's promotional activities (which include clinical assessments, post marketing surveillance and experience programmes and post authorization studies) are not disguised. 	X ₁₀	.952	.051

<ul style="list-style-type: none"> All materials relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by the company clearly indicate by whom it has been sponsored 	X ₁₁		
		-.058	.915

Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization. Rotation converged in 3 iterations.

A factor loading of 0.5 has been used to determine the variable belonging to each factor.

$$F1 = 0.851X_2 + 0.735X_3 + 0.926X_4 + 0.828X_7 + 0.792X_8 + 0.828X_9 + 0.952X_{10}$$

$$F2 = 0.729X_1 + 0.844X_5 + 0.798X_6 + 0.915X_{11}$$

4.4: Effects of IFPMA Code on the marketing strategies of Pharmaceutical companies in Kenya.

This section covers findings from the specific questions posed to the respondent's to determine the respondents agreed with the predetermined statements on effects of IFPMA Code on the marketing strategies of Pharmaceutical companies in Kenya

Figure 4.4.1: Pre-approval Communications and Off-Label Use

Pre-approval	Frequency	Percent
Yes	34	81
No	8	10
Total	42	100

As indicated in Table 4.4.1 above 81% of the respondents were of the opinion that IFPMA Code which states that no pharmaceutical product shall be promoted for use in a specific country until the requisite approval for marketing for such use has been given in that country affects their marketing strategies. Specifically, firms do not promote products for any off label uses and all products must be registered and approved appropriately with Pharmacy and Poison Board. On the other hand only 19% of the respondent's organizations were not affected by the code. Of those whose organizations were affected by the code, 70% felt that the impact was on a very great extent and the remaining 30% rated the extent to be great.

4.4.2: IFPMA states that national laws and regulations should dictate the format and content of the product information communicated on labeling, packaging, leaflets, data sheets and in all promotional material.

Table 4.4.2 shows that a greater number of respondents 81% were of the opinion that the statement ‘IFPMA states that national laws and regulations should dictate the format and content of the product information communicated on labeling, packaging, leaflets, data sheets and in all promotional material’ very great/greatly affects their organizations marketing strategies, that is, local regulations supersedes international regulations as registration is sort locally so products have to meet theses requirements, national laws also limits the shelf life products should have irrespective of the manufacturers recommendations and it is also a requirement by Pharmacy and Poison Board

Table 4.4.2: labeling, packaging, leaflets, data sheets and in all promotional material.

Labeling, Packaging etc	Frequency	Percent
Yes	34	80
No	8	20
Total	42	100

4.4.3: IFPMA Code states that promotional information should be based on an up-to-date evaluation of all relevant evidence and reflects that evidence clearly

As indicated in Table 4.4.3, 91% of the respondents were of the opinion that their marketing strategies are affected by IFPMA Code which states that promotional information should be based on an up-to-date evaluation of all relevant evidence and reflects that evidence clearly. Organizations do continually update their information on products with new evidence and make appropriate changes where necessary and organizations representatives also use clinical data which gives clear evidence of their claims.,

Table 4.4.3: Up to-date evaluation of all relevant evidence

Up to date evaluation	Frequency	Percent
Yes	38	85
No	4	15
Total	42	100

4.4.4: Events involving foreign travel

The analysis in table 4.4.4 shows that 83% of the respondents were in agreement that their marketing strategies are affected by IFPMA Code which states that no company may organize or sponsor an Event for healthcare professionals that takes place outside their home country unless it is appropriate and justified to do so from the logistical or security point of view. Organizations only sponsor international travel if they are organized from other markets and are relevant to their local needs.

Table 4.4.4: Events involving foreign travel

Foreign Travel	Frequency	Percent
Yes	35	83
No	9	17
Total	42	100

4.4.5: IFPMA Code prohibits pharmaceutical companies from paying any costs associated with individuals accompanying invited healthcare professionals at sponsored events

The findings in figure 4.4.5, show that majority (74%) of the organization marketing strategies are affected by IFPMA Code that prohibits pharmaceutical companies from paying any costs associated with individuals accompanying invited healthcare professionals at sponsored events corporations.

Figure 4.4.5: Prohibition of catering cost for other persons

Prohibition	Frequency	Percent
Yes	31	74
No	11	26
Total	42	100

4.4.6: Prohibition of payments in cash or cash equivalents

From the findings 57% of the respondents stated that the prohibition of payment in cash or cash equivalents to health professionals affect their marketing strategies, while 43% were of the opinion that the code does not affects their marketing strategies, that is, all payments are made directly to service provider and not the medical practitioner.

Table 4.4.1: Prohibition of payments in cash or cash equivalents

Frequency	Frequency	Percent
Yes	24	57
No	18	43
Total	42	100.0

4.4.7: IFPMA Code states that gifts for personal benefit of healthcare professionals (including, but not limited to, music, CDs, DVDs, sporting or entertainment tickets, electronic items) must not be provided or offered.

As indicated below 57% of the respondents organizations were not affected by the Code states that gifts for personal benefit of healthcare professionals must not be provided or offered.

Table 4.4.6: Gifts for personal benefits of health care professionals.

Personal gifts	Frequency	Percent
Yes	24	57
No	18	43
Total	42	100

4.4.8: IFPMA Code states that promotional aids or reminder items may be provided or offered to healthcare professionals and appropriate administrative staff, provided the gift is of minimal value and relevant to the practice of the healthcare professional.

The results in table 4.4.2, indicates that 64% of the organizations marketing strategies are affected by Code states that promotional aids or reminder items may be provided or offered to healthcare professionals and appropriate administrative staff, provided the gift is of minimal value and relevant to the practice of the healthcare professional. On the

other hand 36% of the organizations are not affected by this code, that is, some organizations do give pens and pads to nurses for use in daily work

Table 4.4.2: Promotional aids

Promotional aids	Frequency	Percent
Yes	27	64
No	15	36
Total	42	100.0

4.4.9: IFPMA Code states that items of medical utility may be offered or provided free of charge provided that such items are of modest value and are beneficial to the provision of medical services and for patient care

The results presented in table 4.4.8 shows that 67% of the respondent organizations marketing strategies are affected by the IFPMA Code states that items of medical utility may be offered or provided free of charge provided that such items are of modest value and are beneficial to the provision of medical services and for patient care. Significant 33% of the respondent's organizations marketing strategies are not affected by the code.

Figure 4.4.9: Provision of medical utility

Medical utility	Frequency	Percent
Yes	28	67
No	14	33
Total	42	100

CHAPTER FIVE: SUMMARY, CONCLUSION AND RECOMMENDATIONS.

5.1: Summary

The findings from the questions posed to respondents regarding maintenance of high ethical activities and compliance with applicable legal, regulatory and professional requirements of the IFPMA code shows that 83% of the pharmaceutical companies are members and therefore follow the rules of the code. Only 17% of the 42 companies are not signatories to the code.

The Code which states that no pharmaceutical product shall be promoted for use in a specific country until the requisite approval for marketing for such use has been given in that country and marketing strategies of organization had 81% agreeing to it. Firms do not promote products for off label uses (new indications) and all products have to be registered and approved appropriately by the pharmacy and poisons board. 19% of the respondents felt they are not affected by this code. Of the respondents affected by this code 70% felt that the impact was very great on their marketing strategies while 30% rated the extent as great.

IFPMA code which states that national laws and regulations should dictate the format and content of the product information communicated on labeling, packaging, leaflets, datasheets and in all promotional material and marketing strategies of organization. 81% of the respondents were of the opinion that their marketing strategies were greatly affected by this code, that is, local regulations supersede international regulations as registrations are sort locally so products have to meet these requirements. National laws also limit the shelf life products should have irrespective of the manufacturers' recommendations and is also a requirement of the pharmacy and poisons board.

IFPMA Code which states that promotional information should be based on an up-to-date evaluation of all relevant evidence and reflects that evidence clearly, greatly affected 91% of the respondents. Organizations do continually update their information on products with new evidence and make appropriate changes where necessary and organizations representatives also use clinical data which give clear evidence of their claims.

IFPMA Code which states that no company may organize or sponsor an Event for healthcare professionals that take place outside of their home country unless it is appropriate and justified to do so from the logistical or security point of view shows that

83% of the respondents were in agreement that it greatly affects their marketing strategies. Organizations only sponsor international travel if they are organized from other markets and are relevant to their local needs. 17% of the respondents were unaffected by this code.

IFPMA Code which prohibits pharmaceutical companies from paying any costs associated with individuals accompanying invited healthcare professionals at sponsored events shows that majority (74%) of respondents are greatly affected by this code. The remaining 26% of the respondents sometimes pay for costs associated with persons accompanying an invited professional to a sponsored event.

IFPMA Code which states that items of medical utility may be offered or provided free of charge provided that such items are of modest value and are beneficial to the provision of medical services and for patient care greatly affects 67% of the respondents marketing strategies. 33% felt that this code did not affect them as they are not able to provide items of medical utility due to cost implications.

Whereas IFPMA Code which prohibits payments in cash or cash equivalents (such as gift certificate) to healthcare professionals affected 57% of respondents as they have to pay directly to service providers like hotels and airlines as opposed to 43% who are not affected and are able to give cash payments directly to healthcare providers.

IFPMA Code which states that gifts for personal benefit of healthcare professionals (including, but not limited to, music, CDs, DVDs, sporting or entertainment tickets, electronic items) must not be provided or offered greatly affected 57% of respondents who cannot offer such gifts as marketing items. A significant 33% are able to offer gifts for personal benefit.

IFPMA Code which states that promotional aids or reminder items may be provided or offered to healthcare professionals and appropriate administrative staff, provided the gift is of minimal value and relevant to the practice of the healthcare professional affect 64% of the respondents marketing strategies. However 36% of the organizations are not affected by this code, that is, they are able to give promotional aids of high value to healthcare professionals and administrative staff.

5.2: Conclusions

To a large extent pharmaceutical company comply with the international federation of pharmaceutical manufacturers and associations (IFPMA) code. The code greatly affects their marketing practices as it dictates what they can and cannot do.

The code ensures that the interests of patients are put first and the relationship between pharmaceutical companies and healthcare providers is purely professional and doctors are not unduly influenced by gifts and sponsorships.

The code gives all its members a level playing ground so that the big pharmaceutical companies who can afford big marketing budgets and are capable of sponsoring unnecessary overseas meetings and purchase of expensive medical equipment which can be used to influence tender awards are not able to do that.

The code ensures that all members practice evidence based medicine by ensuring that registration for all drug indications are done prior to marketing for the safety of patients and to avoid unnecessary prescriptions and local regulations take precedence over international ones because different regions experience different disease manifestations and epidemiology.

Critics of pharmaceutical industry marketing practices have always had a big issue regarding sponsorships as it has always been felt that inducement can be disguised as medical information sponsored events. To a large extent the code ensures that unnecessary sponsorships in exotic locations are avoided and persons accompanying (spouses and partners) sponsored healthcare providers are not catered for by pharmaceutical companies.

The code ensures that promotional items are of value to a doctor's practice and are not of significant value. Gifts for personal use are not allowed and this greatly affects the marketing practices of pharmaceutical companies as promotional items that can be given to healthcare providers must be of value to patients too.

5.3: Recommendations

The following recommendations are given to both the policy makers and researchers;

5.3.1. Recommendations on policy on marketing strategies

The following recommendations are made for policy makers such as the pharmacy and poisons board and the pharmaceutical manufacturers association.

The IFPMA code helps regulate pharmaceutical companies marketing ethics therefore these policy makers should ensure that all pharmaceutical companies become members of the IFPMA to create a level playing ground for all.

There have been lots of accusations on unethical practices by some pharmaceutical companies which gives the whole industry a bad name therefore pharmacy and poisons board should find a way of ensuring that their rules are in line with those of the code so that firms who are not members of the code do not get leeway to unethical practices thereby tarnishing the larger Pharma community.

Pharmaceutical companies should closely watch one another so that patients do not suffer as a result of unethical practices like off label marketing and gifts to healthcare providers that may influence their prescribing patterns.

5.3.2. Recommendations on use of IFPMA codes

The codes are beneficial for those who use them and act as a guide for marketers in the pharmaceutical industry as well as ensuring that the interests of patients are in the forefront all the time.

There are direct and indirect members. It was observed that the indirect members do not follow the code as strictly as the direct ones yet they form a significant 31% of the membership. A way should be found out to ensure both direct and indirect members adhere to the code on an equal level. The different levels should be closely monitored.

Giving local regulations an upper hand over IFPMA is good since different regions have specific drug requirements and priorities, however in instances where for example there is an outbreak (e. g swine flu) that is affecting one region and is likely to spread to others then as a precaution off label promotion should be allowed.

It would be beneficial if some aspects of the code were tailored to local scenario as different markets in different regions around the world experience different challenges that are unique to particular instances.

5.3.3. Recommendations for Further Research

Further research can be carried out to find out to what extent pharmaceutical companies that comply with IFPMA code are advantaged or disadvantaged compared to those who do not in as far as marketing efforts are concerned.

5.4 Limitations of the study

The pharmaceutical industry in Kenya is large with many players but this study looked at the marketing practices of international ones only, leaving out local manufacturers who form a large part of the total pharmaceutical industry in Kenya and is still growing.

REFERENCES

- Aaker, D.A. (1995), *Strategic Market Management*, John Wiley & Sons, Chichester. .
- Aaker, D.A. and Weinberg, C.B. (1975), "Interactive marketing models", *Journal of Marketing*, Vol. 39 No.43, pp.16-23.
- American Marketing Association, Committee on Definitions (1960), *Marketing Definitions: A Glossary of Marketing Terms*, American Marketing Association, Chicago, IL.
- Angell, M. (2004). *The Truth About the Drug Companies: How They Deceive Us and What to Do About It*, 1st ed., Random House, New York, NY, .
- Avorn, J. (2004), *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs*, 1st ed., Knopf, New York, NY, .
- Barrett, J., Jay, P. (2005), "Clinical research fraud: a victimless crime?", *Applied Clinical Trials*, Vol. 12 No.2, pp.44-6.
- Beauchamp, T.L., Jennings, B., Kinney, E.D. (2002), "Pharmaceutical research involving the homeless", *Journal of Medical Philosophy*, Vol. 27 No.5, pp.547-64.
- Bezold, C., Krabner, K. (Eds) (1994), *Healthcare 2010: Health Care Delivery, Therapies and the Pharmaceutical Industries*, Springer-Verlag, Berlin, .
- Blumenthal, D. (2004), "Doctors and drug companies", *New England Journal of Medicine*, Vol. 351 No.18, pp.1885-90.
- Boulden, J.B., Buffa, E.S. (1970), "Corporate models: online, real-time systems", *Harvard Business Review*, Vol. 48 No.4, pp.65-83.
- Brett, A.S., Burr, W., Moloo, J. (2003), "Are gifts from pharmaceutical companies ethically problematic? a survey of physicians", *Annals of Internal Medicine*, Vol. 139 No.18, pp.2213-9.
- Brown, M., Askew, M., Baker, D., Denvir, H and Millett, A. (2003). 'Is the National Numeracy Strategy Research-Based?' *British Journal of Educational Studies*, 46, 4. 362-385 (A review of the evidence for and against the numeracy strategy)
- Chandra, A., Holt, G.A. (1999), "Pharmaceutical advertisements: how they deceive patients", *Journal of Business Ethics*, Vol. 18 No.4, pp.359-66.
- Corstjens, M. (1991), *Marketing Strategy in the Pharmaceutical Industry*, Chapman & Hall, London.
- Economic Survey (2004), by Central Bureau of Statistics and Ministry of Planning.

- Edmunds, M. (2004), "Confusing ethical guidelines dampen pharmaceutical support", *Nurse Practitioner*, Vol. 29 No.8, pp.16.
- Goozner, M. (2004), *The \$800 Million Pill: The Truth behind the Cost of New Drugs*, 1st ed., University of California Press, Berkeley, CA, .
- Goozner, M. (2005), "Doctors who write guidelines often have ties to the drug industry", *British Medical Journal*, Vol. 331 pp.7523-82.
- Grant, R. (1995), *Contemporary Strategy Analysis: Concepts, Techniques, Applications*, Blackwell Publisher Inc., Oxford, .
- Healy, D. (2000), "Good science or good business?", *Hastings Center Report*, Vol. 30 No.2, pp.19-22.
- Healy, D. (2003), "In the grip of the python: conflicts at the university-industry interface", *Science and Engineering Ethics*, Vol. 9 No.1, pp.59-71.
- International Federation of Pharmaceutical Manufacturers Associations (IFPMA), 2006 <http://www.ifpma.org/>
- Kamau, J.N. (2006), an empirical investigation of the strategies used to market generic Pharmaceutical products. The case of respiratory infections drugs in Kenya: Unpublished MBA Research Project, University of Nairobi.
- Kassirer, J. (2004), *On the Take: How Medicine's Complicity with Big Business Can Endanger Your Health*, Oxford University Press, New York, NY, .
- Kassirer, J.P. (2005), *On the Take: How Medicine's Complicity with Big Business Can Endanger Your Health*, Oxford University Press, New York, NY, .
- Katz, D., Caplan, A.L., Merz, J.F. (2003), "All gifts large and small: toward an understanding of the ethics of pharmaceutical industry gift-offering", *American Journal of Bioethics*, Vol. 3 No.3, pp.39-46.
- Kerridge, I., Maguire, J., Newby, D., McNeill, P.M., Henry, D., Hill, S., Day, R., Macdonald, G., Stokes, B., Henderson, K. (2005), "Cooperative partnerships or conflict-of-interest? A national survey of interaction between the pharmaceutical industry and medical organizations", *International Medical Journal*, Vol. 35 No.4, pp.206-10.
- Kmietowicz, Z. (2004), "Second drug firm found guilty of 'switching' patients to new drugs", *British Medical Journal*, Vol. 329 No.741, pp.875.

- Koren, G. (2003), "Healthy children as subjects in pharmaceutical research", *Theoretical Medicine and Bioethics: Philosophy of Medical Research Practice*, Vol. 24 No.2, pp.149-59.
- LaFrancis Popper, K.M., Nason, R.W. (1994), "The drug lag: a 20-year analysis of six country markets", *Journal of Public Policy and Marketing*, Vol. 13 No.2, pp.290-9.
- Larsen, J.S. and Schaumann, L. (1990), *Pharmaceutical Industry Perspectives: Japan at the Crossroads*, SRI International, Menlo Park, CA., .
- Lenzer, J. (2005), "Doctors refuse space to group fighting drug company influence", *British Medical Journal*, Vol. 331 pp.7518-653.
- Lesiew, R.K. (1992), Analysis of sources of finance for Eldoret based pharmaceutical outlets: Unpublished MBA Research Project, University of Nairobi.
- Lilien, G.L., Kotler, P., Sridhar Moorthy, K. (1992), *Marketing Models*, Prentice-Hall International Inc., Englewood
- Little, A.D. (1989), "Forces driving change in the US pharmaceutical industry", *Spectrum*, pp.47-55.
- Maitland, I. (2002), "Priceless goods: how should life-saving drugs be priced?", *Business Ethics Quarterly*, Vol. 12 No.4, pp.451-80.
- Marsa, L. (1997), *Prescription for Profits: How the Pharmaceutical Industry Bankrolled the Unholy Marriage between Science and Business*, Scribner Publishing, New York, NY, .
- Masek, L. (2000), "The doctrine of the double effect: deadly drugs and business ethics", *Business Ethics Quarterly*, Vol. 10 No.2, pp.483-95.
- Moynihan, R., Cassels, A. (2005), *Selling Sickness: How the World's Biggest Pharmaceutical Companies are Turning us all into Patients*, Avalon Publishing Co., Bound Brook, NJ, .
- Muchelule, S.E. (2006), multinational pharmaceutical firms adaptation to the challenge of parallel importation of drugs in Kenya: Unpublished MBA Research Project, University of Nairobi.
- Muiva, C. (2001), A survey of the use of competitive intelligence systems in the Kenyan pharmaceutical industry: Unpublished MBA Research Project, University of Nairobi.
- Munyiri, S.R. (2000), A survey of the use of business process reengineering approach in the kenyan pharmaceutical manufacturing industry: Unpublished MBA Research Project, University of Nairobi.

- Naikuni, S.R. (2001), an empirical investigation of the application of promotional mix elements within multinational pharmaceutical companies in Kenya: Unpublished MBA Research Project, University of Nairobi.
- Obado, P.B.O. (1991), The influence of perceived organizational climate on Kenya's pharmaceutical sales forces motivation: Unpublished MBA Research Project, University of Nairobi.
- Offit, P.A. (2005), *The Cutter Incident: How America's First Polio Vaccine Led to the Growing Vaccine Crisis*, Yale University Press, New Haven, CT, .
- Opiyo, J.O. (2006), responses of pharmaceutical importers to the challenge of illegal trade in pharmaceuticals: Unpublished MBA Research Project, University of Nairobi.
- Orellana, C. (2002), "German doctors' links with drug firm investigated", *The Lancet*, Vol. 359 No.9311, pp.1039.
- Pepin, J.F. (1997), "An englehardtian analysis of interactions between pharmaceutical sales representatives and physicians", *Journal of Medical Philosophy*, Vol. 22 No.6, pp.623- 41.
- Pinkus, R.L. (2002), "From Lydia Pinkham to Bob Doyle: what the changing face of direct-to-consumer advertising reveals about the professionalism of medicine", *Kennedy Institute of Ethics*, Vol. 12 No.2, pp.141-58.
- Porter, M.E. (1980), *Competitive Strategy: Techniques for Analyzing Industries and Competitors*, The Free Press, New York, NY, .
- Porter, M.E. (1985), *Competitive Advantage: Creating and Sustaining Superior Performance*, Free Press, New York, NY, .
- Sapienza, A. (1993), "Assessing the R&D capability of the Japanese pharmaceutical industry", *R&D Management*, Vol. 23 No.1, pp.3-16.
- Sheth, J.N. (1973), "A model of industrial buying behavior", *Journal of Marketing*, Vol. 37 pp.50-6.
- Schieppati, A., Perico, N., Remuzzi, G. (2002), "Conflict of interest as seen from a researcher's perspective", *Science and Engineering Ethics*, Vol. 8 No.3, pp.337-42.
- Sierles, F.S., Brodkey, A.C., Cleary, L.M., McCurdy, F.A., Mintz, M., Frank, J., Lynn, D.J.,
- Chao, J., Morgenstern, B.Z., Shore, W., Woodard, J.L. (2005), "Medical students' exposure to and attitudes about drug company interactions: a national survey", *Journal of the American Medical Association*, Vol. 294 No.9, pp.1034-42.

Statistical Abstract (2003), by Central Bureau of Statistics and Ministry of Planning.

Spilker, B. (1984), "Myths and misconceptions about drug industry ethics", *International Journal of Applied Philosophy*, Vol. 2 pp.1-12.

Studdert, D.M., Mello, M.M., Brennan, T.A. (2004), "Financial conflicts of interest in physicians' relationships with the pharmaceutical industry – self-regulation in the shadow of federal prosecution", *New England Journal of Medicine*, Vol. 35 No.18, pp.1891-900.

Thomas, L.G. (1988), "Multifirm strategies in the US pharmaceutical industry", in Mowery, D.C. (Eds), *International Collaborative Ventures in US Manufacturing*, Ballinger Press, Cambridge, MA. .

Thomas, L.G. (1988), "Multifirm strategies in the US pharmaceutical industry", in Mowery, D.C. (Eds), *International Collaborative Ventures in US Manufacturing*, Ballinger Press, Cambridge, MA. .

Tishler, C.L., Gordon, L.B. (1999), "Ethical parameters of challenge studies inducing psychosis with ketamine", *Ethics Behavior*, Vol. 9 No.3, pp.211-7.

Trim, P.R.J. (1994), "Strategic marketing models and competitive advantage", Working Paper, No. 25, Canterbury Business School, University of Kent, Canterbury, .

Veatch, R.M. (1985), "Case study: the HMO physician's duty to cut costs – a commentary", *Hastings Center Report*, Vol. 15 pp.13-14.

Wagena, E.J., Knipschild, P. (2005), "Do drug firms hoodwink medical journals? Or is something wrong with the contribution and integrity of declared authors?", *Journal of Medical Ethics*, Vol. 31 No.6, pp.307.

Walker, H.D. (1971), *Market Power and Price Levels in the Ethical Drug Industry*, Indiana University Press, Bloomington, IN, .

Wind, Y. (1978), "Issues and advances in segmentation research", *Journal of Marketing Research*, Vol. 15 No. August, pp.317-37.

Yeoh, P.L. (1994), "Speed to global markets: an empirical prediction of new product success in the ethical pharmaceutical industry", *European Journal of Marketing*, Vol. 28 No.11, pp.29-49.

APPENDIX I: LIST OF REGISTERED INTERNATIONAL PHARMACEUTICAL COMPANIES IN KENYA

- 1 Abbott Laboratories
- 2 Assia
- 3 Astra Zeneca
- 4 Bayer Healthcare AC
- 5 Boehringer Ingelheim Gmbh
- 6 Bristol –Myers Squibb
- 7 C. Mehta & Co
- 8 Cadilla Pharmaceuticals
- 9 Cosmos Limited
- 10 Dawa Limited
- 11 Eli Lilly & co Chemicals
- 12 Framin Kenya
- 13 Galaxy
- 14 GlaxoSmithKline Limited
- 15 Globe
- 16 Goodman Agencies
- 17 Harley's limited
- 18 Laborex
- 19 Joshansen & Soehne
- 20 Johnson & Johnson
- 21 Lords Healthcare
- 22 Menarini S.A
- 23 Merc & co ltd
- 24 Metro pharmaceuticals
- 25 Norbrook Kenya Limited
- 26 Novartis Pharma Services
- 27 Pan Pharmaceuticals
- 28 Pharmaceuticals Manufacturing Company
- 29 Phillips
- 30 Population services International
- 31 Regal

- 32 Sai
- 33 Sanofi Aventis
- 34 Schering Plough corp
- 35 Servier
- 36 Synermed Pharmaceuticals
- 37 Unicorn Pharma
- 38 Unisupplies Limited
- 39 Universal Corporation
- 40 Wessex Pharmaceuticals
- 41 Wockaine International Limited
- 42 Wockhardt Limited
- 43 Wyeth
- 44 Pfizer Labs Limited
- 45 Roche

APPENDIX II: QUESTIONNAIRE

This questionnaire has been designed to collect information from Heads of the Marketing function of selected Pharmaceutical companies in Kenya and is meant for academic purposes only. The questionnaire is divided into two sections. Section I seeks to capture the profile of respondents while section II will capture issues pertaining to the area of study. Please complete each section as instructed. Do not write your name or any other form of identification on the questionnaire. All the information in this questionnaire will be treated in confidence.

SECTION I: BACKGROUND INFORMATION

1. Name of Pharmaceutical company (Optional) _____

2. For how long has your organization been in operation in Kenya? (Tick as appropriate)
 - (a). Less than 1 year []
 - (b). 1 to 5 years []
 - (c). 6 to 10 years []
 - (d). 11 to 15 Years []
 - (e). 16 years and above []

3. How many full time employees does the organization have in Kenya (Pleas tick as appropriate)?
 - (a) Less than 10 []
 - (b) 11 to 15 []
 - (c) 16 to 20 []
 - d) 21 to 25 []
 - (e) 26 and above []

4. Is your organization a member of the IFPMA Code of Pharmaceutical Marketing Practices (Pleas tick as appropriate)?
 - (a) Yes
 - (b). No.

If the answer to Q4 is Yes, Please indicate the type of membership (Tick as appropriate)

- (a) Direct membership to IFPMA Code of Pharmaceutical Marketing Practices
- (b) A member of an Association that is a member of IFPMA (Indirect membership)

SECTION II: THE EXTENT OF COMPLIANCE WITH THE IFPMA CODE ON MARKETING PRACTICES OF PHARMACEUTICAL COMPANIES IN KENYA

5. Listed below are some of the requirements of the IFPMA Code on marketing practices. With respect to your organization, please indicate the extent to which your organization has complied with each of the requirements (Tick as appropriate)

Requirements of the IFPMA Code on marketing practices	Very great extent (5)	Great extent (4)	Moderate extent (3)	Low extent (2)	Very low extent (1)
Pharmaceutical companies should be committed to educational and promotional efforts that benefit patients					
Commitment to patients and collaborations that enhance the practice of medicine					
Obligation and responsibility to provide accurate information and education about the company's products to healthcare professionals in order to establish a clear understanding of the appropriate use of prescription medicines					
Maintenance of high ethical activities and compliance with applicable legal, regulatory and professional requirements					
Internal structures and procedures (including adequate training of employees) are created to ensure responsible and ethical promotional activities					
Pharmaceutical companies are prohibited from providing or offering financial benefits or benefit –in-kind to healthcare professionals in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so.					
Pharmaceutical companies are prohibited from providing anything in a manner or on conditions that would have an inappropriate influence on healthcare professional's prescribing practices.					

Requirements of the IFPMA Code on marketing practices	Very great extent (5)	Great extent (4)	Moderate extent (3)	Low extent (2)	Very low extent (1)
The company engages in promotional activities that encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their practices					
In the course of preparing promotional materials, all laws, local regulations and industry codes should be observed by pharmaceutical companies and they should take the responsibility to check local requirements					
The company's promotional activities (which include clinical assessments, post-marketing surveillance and experience programmes and post authorization studies) are not disguised.					
All materials relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by the company clearly indicate by whom it has been sponsored.					
Others (Specify)					

6. Effects of International Federation of Pharmaceutical Marketing Association Code on the marketing strategies of Pharmaceutical companies in Kenya.

(i) Pre-approval Communications and Off-Label Use

IFPMA Code states that no pharmaceutical product shall be promoted for use in a specific country until the requisite approval for marketing for such use has been given in that country.

Would you say that the statement above affects the marketing strategies of your organization? (Please tick as appropriate)

(a) Yes

(b) No.

Please explain your answer

If yes, to what extent

- A. Very Great B. Great C. Moderately
D. Low E. Very low

(ii)IFPMA states that national laws and regulations should dictate the format and content of the product information communicated on labeling, packaging, leaflets, data sheets and in all promotional material.

Would you say that the statement above affects the marketing strategies of your organization? (Please tick as appropriate)

- (a) Yes (b). No.

Please explain your answer

If yes, to what extent

- A. Very Great B. Great C. Moderately
D. Low E. Very low

(iii)IFPMA Code states that promotional information should be based on an up-to-date evaluation of all relevant evidence and reflects that evidence clearly

Would you say that the statement above affects the marketing strategies of your organization? (Please tick as appropriate)

- (a) Yes (b). No.

Please explain your answer

If yes, to what extent

- A. Very Great B. Great C. Moderately
D. Low E. Very low

(iv) Events involving foreign travel (The IFPMA Code states that no company may organize or sponsor an Event for healthcare professionals that takes place outside of their home country unless it is appropriate and justified to do so from the logistical or security point of view.

Would you say that the statement above affects the marketing strategies of your organization? (Please tick as appropriate)

- (a) Yes (b). No.

Please explain your answer

If yes, to what extent

- A. Very Great B. Great C. Moderately
D. Low E. Very low

(v) IFPMA Code prohibits pharmaceutical companies from paying any costs associated with individuals accompanying invited healthcare professionals at sponsored events.

Would you say that the statement above affects the marketing strategies of your organization? (Please tick as appropriate)

- (a) Yes (b). No.

Please explain your answer

If yes, to what extent

- A. Very Great B. Great C. Moderately
D. Low E. Very low

(vi) Gifts and Items of Medical Utility

(a) IFPMA Code prohibits payments in cash or cash equivalents (such as gift certificate) to healthcare professionals.

Would you say that the statement above affects the marketing strategies of your organization? (Please tick as appropriate)

- (a) Yes (b). No.

Please explain your answer

If yes, to what extent

- A. Very Great B. Great C. Moderately
D. Low E. Very low

(b) IFPMA Code states that gifts for personal benefit of healthcare professionals (including, but not limited to, music, CDs, DVDs, sporting or entertainment tickets, electronic items) must not be provided or offered.

Would you say that the statement above affects the marketing strategies of your organization? (Please tick as appropriate)

- (a) Yes (b). No.

Please explain your answer

If yes, to what extent

- A. Very Great B. Great C. Moderately
 D. Low E. Very low

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Please explain your answer

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Please explain your answer

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If yes, to what extent

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If yes, to what extent

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Would you say that the statement above affects the marketing strategies of your organization? (Please tick as appropriate)

- (a) Yes (b). No.

Please explain your answer

If yes, to what extent

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Would you say that the statement above affects the marketing strategies of your organization? (Please tick as appropriate)

- (a) Yes (b). No.

Please explain your answer

If yes, to what extent

- A. Very Great B. Great C. Moderately
D. Low E. Very low

(c)IFPMA Code states that promotional aids or reminder items may be provided or offered to healthcare professionals and appropriate administrative staff, provided the gift is of minimal value and relevant to the practice of the healthcare professional.

Would you say that the statement above affects the marketing strategies of your organization? (Please tick as appropriate)

- (a) Yes (b). No.

Please explain your answer

If yes, to what extent

- A. Very Great B. Great C. Moderately
D. Low E. Very low

(vii)IFPMA Code states that items of medical utility may be offered or provided free of charge provided that such items are of modest value and are beneficial to the provision of medical services and for patient care.

Would you say that the statement above affects the marketing strategies of your organization? (Please tick as appropriate)

- (a) Yes (b). No.

Please explain your answer

If yes, to what extent

- A. Very Great B. Great C. Moderately
D. Low E. Very low