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ETHICAL AND LEGAL CONSIDERATIONS CONCERNING THE ACCEPTANCE BY DOCTORS OF "INCENTIVES" OFFERED FROM PHARMACEUTICAL COMPANIES: A SOUTH AFRICAN SURVEY

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A research report submitted to the University of the Witwatersrand, Faculty of Health Sciences, Steve Biko Centre for Bioethics, Johannesburg, in partial fulfilment of the requirements for the degree of MSc Med in the field of Bioethics & Health Law

Johannesburg, 2009

DECLARATION

I, Mandisa Joyce Gwendoline Maholwana declare that this research report is my own work. It is being submitted for the degree of MSc Med in the field of Bioethics and Health Law at the Steve Biko Centre for Bioethics, Faculty of Health Sciences in the University of Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.



.....

.....03RD..... day of .....NOVEMBER....., 20.09.

DEDICATION

This work is dedicated to my husband, Kagiso. Without him the completion of my research report would still be a pipe dream. I wish to thank him for his patience, guidance and love.

I wish to thank my children, Tlotlo, Kitso and Loapi for the many nights they had to go to bed without a bedtime story and for their numerous attempts to help Mom print and staple her work.

My sisters Babalwa and Zandile for the countless occasions they had to step in and baby-sit.

A special dedication to Lynette, who looks after my children. For not complaining about the late nights and numerous weekends babysitting alone, she has really made this happen for me.

ABSTRACT

Purpose

There is limited literature available in South Africa concerning the interaction of doctors with the pharmaceutical industry. The purpose of this research report was to establish what South African doctors believe to be acceptable and appropriate incentives from the industry, highlight what they consider reasonable compensation for professional activities performed on behalf of the industry; and whether they perceive interaction with the industry's marketing apparatus to be a significant influence on their prescribing habits.

Methods

A questionnaire was emailed to all active doctors in South Africa with email addresses from the Medpages® database. The survey was conducted in March 2009 - April 2009. The desired sample size was 500 General Practitioners (GPs) and Specialists in private practice.

Results

A final sample of 400 valid responses was analysed, representing 80% of desired sample. Majority of the respondents were male (74%) with an almost equal split between GPs (51.5%) and specialists (48.5%). The study revealed that 92% of the respondents accepted branding items whilst 60% of the respondents accepted personal gifts from the industry. The results revealed that 85% of the respondents felt that doctors should be paid for speaking at CMEs, and just over

half the sample (52%) felt they wanted to be paid their own rate as opposed to the industry rate. The investigation revealed that 77% of the respondents felt that their interaction with the industry influenced their prescribing habits and suggesting that such influence to be more pervasive with their colleagues, specifically 95% felt their colleagues are influenced by their interaction with industry ($p < 0.001$). About three quarters of the respondents (73%) believe patient management may be compromised if doctors' prescribing habits are influenced by their interaction with the industry. Most respondents (72.5%) were either not aware or did not know of any regulations or guidelines with regards to acceptance of gifts by doctors from the industry.

Conclusion

This study demonstrated that perverse incentives continued to be given to doctors, and doctors have not shown a distinct aversion to accepting these perverse incentives and gifts. These perverse interactions have been shown in existing literature and in this research report to influence prescribing habits. Doctors do not seem to operate within their guidelines and legal framework, as stipulated by the HPCSA, when accepting these potentially harmful perquisites. What legal and ethical considerations are the doctors employing when accepting 'incentives' from industry is the question; and what is the doctor's role in protecting his/her patients? Ignorance of the guidelines, as the study indicates to be the case, does not justify involvement in perverse relationships. Doctors have professional and personal moral responsibilities to ensure they familiarise

themselves with guidelines regulating their professional conduct and ultimately protect the patients.

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1.0 INTRODUCTION

The pharmaceutical industry (henceforth 'the industry') plays a critical role in the development, production, and marketing of new drugs and technologies that are essential to the advancement and application of scientific and medical practice. Research and development ('R&D') of new drugs takes years and costs can run into millions of dollars before a product is available to the public. The incumbent pharmaceutical industry, dominated by a handful of listed multinational corporations, not only have to recoup development costs on patent drugs and technologies, but also achieve their target return on investments. In many instances new drugs are launched at a higher cost than established products (Brennan, *et al.*. 2006: 429; Hemphill 2006: 323-324; Brody 2005: 83; Coyle 2002: 396; Jureidini and Mansfield 2001: 95). As a strategic imperative, pharmaceutical companies launching new products need to be aggressive in market penetration and hasty in gaining market share as the competitive advantage conferred by patent protection is of limited duration.

Concerning pharmaceuticals developed for humans, a critical component of the industry's marketing strategy, as Brett, *et al.*. (2003: 2213) point out, is to acquire advocates for their products, increase public awareness through campaigns and flood the market with branded items. Coyle (2002: 397) concedes that all the

partnered activities between doctors[1] and the industry often offer important opportunities to advance medical knowledge and patient care. Coyle is, however, also concerned about the introduction of bias during these activities. This is because direct marketing to the end consumer, the patient, is forbidden for prescription drugs. Thus, the leveragability of patient product demand and ultimate consumption is achieved through the prescribing doctor. Due to information asymmetry between the doctor and patient, the swaying of doctors' preference towards a specific drug directly influences patients' choice of drugs and is the ultimate driver of sales for the industry competitors. Previously the only restraint on the pharmaceutical multinationals ('multinationals') was the size of their marketing budget, with the industry spending billions of dollars in marketing activities including free drug samples given to prescribing doctors (Morgan, *et al.*. 2006: 559; Coyle 2002:396; Jureidini and Mansfield 2001: 96).

Due to the intensity of industry competition and shrinking margins while simultaneously stronger turnover and profit imperatives are demanded, marketing practices have been perceived to be increasingly more perverse leading most governments to enforce measures aimed at curbing perversity in an effort to safeguard patient welfare (Brennan, *et al.*. 2006: 430; Brett, *et al.*. 2003: 2213; Steinman, *et al.*. 2001: 551).

[1] In the context of the pharmaceutical industry – doctor relationship, in this research report I use the terms 'doctor' and 'prescriber' interchangeably referring to a doctor who prescribes pharmaceutical products (drugs) for his or her patients.

Numerous studies, including the important contribution by Morgan, *et al.* (2006), have noted the international trend where medical professional bodies and other industry stakeholder bodies such as The American College of Physicians, the American College of Obstetricians and Gynecologists, the American Medical Association, the Pharmaceutical Research and Manufacturers of America, International Federation of Pharmaceutical Manufacturers Associations Code, and the Association of the British Pharmaceutical Industry have performed major revisions to their guidelines in order to establish more appropriate interactions between pharmaceutical companies and prescribing doctors (Morgan, *et al.* 2006: 559; Coyle 2002: 396; Steinman, *et al.* 2001: 551; Wazana 2000: 379; Gibbons, *et al.* 1998:151). Locally, South African regulatory interventions have included, *inter alia,* the amendment of the Medicines and Related Substances Act 101 of 1965, which rendered the issuing of free drug samples ('sampling') to prescribing doctors ("prescribers"); and discounts extended to wholesalers and retail distributors ("discounting") illegal (Act 90 of 1997: 5). This intervention is aimed at increasing price transparency, and promoting competition. The goal is thus the attenuation of the drug manufacture's influence on prescribers.

However, despite regulatory interventions, a perverse relationship between prescribers and the pharmaceutical industry has not been totally eradicated. Both parties appear not to be sufficiently deterred by regulatory involvement including sanctions. The lure of mutual benefits derived from such a relationship appears to be a stronger driver than are regulations which aim to shape and

influence ethical behaviour. As an example, it is conceivable that doctors receiving financial inducements fail to speak out against them. Doctors also might fail to object to the “five star” treatment afforded them by a pharmaceutical company when sponsored to attend conferences. Such prescribers might also miss the prestige and preferential treatment reserved for being the highest prescriber of ‘product X’, advocate for ‘product Y’, or key opinion leader for ‘product Z’. Conversely, the pharmaceutical industry is equally disincentivised to report their ’best advocates’, ‘highest prescribers’, etc. to professional bodies. In addition, an incentivised prescriber could conceivably resort to a type of blackmail and demand more incentives from a pharmaceutical representative to keep their improper business relationship quiet. The bottom line is that both parties involved in such practices run the risk of being implicated and sanctioned for unfair inducement or acceptance of perverse incentives.

There exists then, the possibility of a perverse relationship between a prescriber and pharmaceutical company. This potential raises many vexing legal and ethical questions. Some examples follow: Who, a doctor or a pharmaceutical representative mutually engaged in promoting unnecessary drugs carries the greatest ethical breach? In the case of a doctor requesting a “kick-back” for prescribing a particular pharmaceutical product, does the pharmaceutical representative have an ethical duty to report this? Where is the line drawn between fair compensation for professional services rendered and perverse incentives designed to influence prescribing patterns? Is it possible for the two

parties to engage in a mutually beneficial relationship – one which can be trusted to rise above self-interests – and beneficially act in the patient's best interests? Would it be deemed ethical when prescribers start "naming their price" for supporting drug A or B when prescribing patterns diverge from clinical indication – driven mostly by self-benefit?

Most pharmaceutical companies, at least in South Africa, belong to industry associations that have developed guidelines aimed at shaping the relationship between the industry and prescribers. The South African Marketing Code ('the Code'), though still in draft (January 2008), enshrines measures which ensure industry accountability and includes guidelines aimed at engendering responsible and "ethical" marketing of pharmaceutical products.

It is to be borne in mind that the main thrust and aim of professional guidelines, is patently to ensure and protect patient welfare. The pharmaceutical industry's marketing code purports to espouse the same ideals (SA Marketing Code 2008: 4). It is then most instructive to gain insight into the patient's view of the prescribing doctor-pharmaceutical industry incentives dynamic. Gibbons, *et al.* (1998: 153), conducted a survey amongst patients and doctors, and compared their respective attitudes towards industry gifts given to prescribing doctors. Patients, it was found, felt gifts were more influential than did their doctors in driving prescribing habits, and also that gifts were less appropriate than did their doctors.

There is substantive literature examining inducements and perverse incentives extended to doctors by the industry and the possible ramifications thereof (Morgan, *et al.* 2006: 559; Brody 2005: 82-83; Wazana 2000: 373). Most of these studies aimed to establish that when prescribing doctors were incentivised by the pharmaceutical companies, such practices generally were, in the main, not in the patient's best interests. This is because such doctors were likely to prescribe expensive drugs that were not necessarily the most appropriate treatment for the patient (Brody 2005: 83; Dana and Loewenstein 2003: 252-253; Steinman, *et al.* 2001: 551). Such results and many similar-theme investigations have been influential in shaping regulation worldwide aimed at curbing unethical prescriber behaviour and undesirable marketing practices by pharmaceutical companies. The result of research into this area has been successful creating public awareness of the problem. Worldwide, such responses from both medicine and industry have led to the formulation and promulgation of regulations to curb such unethical activities.

Wazana (2000: 373) and Dana and Loewenstein (2003: 252-253) contend there is general consensus that the prescribing doctor-pharmaceutical company relationship is problematic. In South Africa, the Department of Health ('DoH') has developed regulatory frameworks to assist industry players in these relationships; while the medical professional body, the Health Professionals Council of South Africa (HPCSA) has developed guidelines for doctors aimed specifically at

managing these interactions. However, it remains unclear whether such interventions have the desired twin effect of influencing ethically desirable doctor behaviour and ultimately protecting the patient.

A case cited in the South African Medical Journal (Bateman 2003: 566-567, 2002: 677-678) concerned a group of referring doctors who were heavily sanctioned by the HPCSA for receiving “kickbacks” from a radiology practice for their referrals. It was proven that many of these referrals were unnecessary / not clinically indicated but the referral group received inducements based on the numbers of patients referred. This acutely highlights the Council’s resolve to root out unethical behaviour in the broader healthcare industry. While this is different from the classical prescribing doctor-pharmaceutical industry relationship, it is similar in the placing of greed above ones duties and obligations to patients. It uses patients as a means to an end and not as ends in themselves. The grounding of this ethical directive is found in Kant’s second formulation of the Categorical Imperative which bids us to:

Act so that you treat humanity, whether in your own person or in that of another, always as an end and never as a means only (Kant [1785] 1993: 30).

The following scenario is another illustration of what Kant means.

Dr X. has an agreement with “Alpha Laboratory”. This agreement entitles Dr. X. to receive a 40% discount each month if she orders more than 100 “special blood tests”. To receive this reduction, Dr. X. consistently and knowingly orders superfluous clinically non-indicated laboratory blood tests on her patients in order to reach the discount cut-off target. Dr X uses her patients as a means to her end – the price discount – which is for her personal benefit. Her action is not motivated by the desire to achieve an outcome (end) that is optimal for the patient from an ethical holistic bio-socio-economic perspective. Kant’s Categorical Imperative remains the maxim that ideally should inform and shape the behaviour of both prescribers and the pharmaceutical industry.

Both prescribers and industry have regulations and guidelines supporting ethical practises. Since this is the case, who might be held accountable for ethical breaches? Globally, the thrust of most studies to date has been focused on the role of the pharmaceutical companies as the explanatory variable concerning perverse prescribing in the doctors-pharmaceutical industry relationship.

This research report intends to question this hypothesis in the South African context where admittedly, limited literature is available concerning the interaction of doctors with the pharmaceutical industry. I explore by way of a survey of South African doctors in private practice and the extent to which doctors themselves desire, and perhaps overtly demand, to be incentivised by the pharmaceutical industry. My exploration will examine the influence of doctors as

the explanatory variable on this perverse relationship. Further, this research aims to elucidate what South African doctors believe to be acceptable and appropriate incentives from the industry, highlight what they consider reasonable compensation for professional activities performed on behalf of the industry; and whether they perceive interaction with the industry's marketing apparatus to be a significant influence on their prescribing habits.

2. LITERATURE REVIEW

2.1 Ethical basis of research

In publicly swearing the Hippocratic Oath or articulating a Medical Declaration doctors enter a moral and social contract with society. Since the practice of medicine involves an intimate relationship with other persons, it becomes a moral endeavor and as such entails special ethical and moral obligations on the part of the doctor not the least of these being the placement of the patient's best interests above all others. Medicine's social contract with society is expressed in the public swearing of an Oath or declaration.

Because of the ways in which the history of medicine and the history of the pharmaceutical industry evolved, the same or similar moral obligations that doctors are held to were not placed on the pharmaceutical industry and did not play a pivotal role in its development. For example, one does not hear of pharmaceutical industry employees being given greater autonomy in exchange for service to humanity. The pharmaceutical industry is accountable ultimately to its shareholders. Its *raison d'etre* is shareholder wealth maximization. This is not to say that the pharmaceutical industry is devoid of any social responsibility. Yet the trajectories of medicine and the pharmaceutical industry are inextricably intertwined. Doctors, on the one hand, have obligations and are accountable to society for patient health maximization and welfare; while at the same time they rely most heavily on the research and development of new drug products and services from the industry. Doctors are obligated to keep updated in their

professional development which entails that they keep abreast of scientific developments e.g. new diseases, new ways of treating illnesses, and new clinical research findings. When the paths of industry and medicine engage they also seem to carry with them some type of a moral response. It is most likely that, at least arguably, social myths contribute to this: doctors are more moral and honest than ordinary citizens as opposed to business people who have no qualms whatsoever placing ‘profit over people’.

While it may have been just a historical chain of events which separated the two fields as predominately noted in Western Cultures, there is no doubt that doctors are held to higher ethical standards than are the ‘common folk’.

Apart from Oaths or declarations, foundational ethical theories such as Virtue ethics, Utilitarianism and Kantianism also lend support to the obligation of doctors to provide their patients with the best possible care.

Virtue ethics focuses on the character of the agent. As White (1993:3) puts it: “Virtue depends on character, not deeds, and our character is shaped by every action we perform”. Concerning the practice of medicine, its goals and benefits are best expressed in relationships where doctors actively exhibit a professionalism that includes the virtues of e.g. honesty and integrity, respect for patients, compassion, and the dedication to their field expressed through keeping up to date through continuing professional development (Jonsen, Siegler and

Winslade 2002:14-15). Of course, the idea of developing a good character does not apply only to one profession or one individual. In addition to those virtues already mentioned, others such as courage, good faith, and loyalty are also important factors in individual morality. Virtue ethics, as Aristotle explains is important because its focus is placed on the development of good character through practicing the virtues (*Nicomachean Ethics*, Book X, section 9). In this way of thinking, when each of us as individuals make a decision to do or not to do something we are obliged to consider if our choice (e.g. the choice between being honest or dishonest) was the virtuous choice. Our goal should be to develop the virtue of being an honest person as a foundational part of our character.

Although Virtue ethics is not unique to the practice of medicine, it has played a major role in the shaping of society's perception concerning ideas of what constitutes a "good" doctor/health care professional. This perception points to one of a person of trust who is honest, compassionate, knowledgeable, sensitive, and who importantly, places the other's best interests above his or her own.

An ethical system which upholds the doctor's duty to individual patients and society is that of Utilitarianism. Founded by Jeremy Bentham (then later reworked by James Mill and John Stuart Mill), Utilitarianism has as its first principle that of utility. This first principle is commonly stated as: "Act to promote the greatest amount of happiness/ good / pleasure for the greatest number of

people" (Frey 2000:165). This way of thinking links the ethical character of actions or policies (right or wrong / good or bad) to their overall consequences. In the context of prescribing doctors and the pharmaceutical industry, the Principle of Utility would consider that it is a right action for a doctor to prescribe only the necessary amount, clinically appropriate, and fiscally affordable drug relative to a patient's illness. If all doctors acted accordingly, then there would be a greater chance of benefit to all patients.

In this context, health economists in South Africa and globally, have identified the cost of scripted premium priced patented pharmaceutical drugs as one of the major drivers of health care costs. Clinically unsupported, prescribing of expensive drugs manifestly contributes to the increase in health care costs (Hemphill 2006: 323-325; Dana and Loewenstein 2003: 252-253; van den Heever 2002-2003: 7, Jureidini and Mansfield 2001: 95). The resultant health care inflation, which in most developed economies and in South Africa – an emerging economy – has outstripped the general Consumer Price Index ('CPI') has meant decreasing access to health for the majority, even those fortunate to have some form of health insurance. The fact of perversely incentivised prescribing habits cannot be viewed as promoting the greatest happiness/ good / pleasure for the greatest number of people. On the other hand, increased scripting clearly translates to higher earnings for the pharmaceutical companies, here the benefit is clear. But neither perverse action, be it from a doctor or the

pharmaceutical industry fulfil the requirement to benefit the greatest number of people.

The final ethical system addressed in this research report is Kantian ethics. Kantian ethics is based on the premise that moral actions are not driven by developing good character or our desires or a good outcome. Rather, moral action is driven by an agent's motive - his or her moral intent. For Kant, the only thing good is a good will, that is, one follows reason's guidance and acts from a sense of duty (Kant 1993:5). For an action to be good, Kant believed that it must not simply be conducted because of a moral law (follow a moral rule) but must be performed for the *sake of* moral law. In other words, a person does *good* not because he or she is inclined to do good as in Virtue ethics, or because the good action would have positive consequences as in Utilitarianism. For Kantians, actions classified as good, must be inherently good regardless of the ends, goals or objectives we might have. To quote Hill (2000: 228):

It is a familiar Kantian theme that they act on principle, where the governing maxim is not on the form "I will do X because as it happens X promotes Y, which I want" but rather "I will do X, regardless of its effect on what I desire.

Placing this in context, let us see how the application of one's motive / intent might play out in practice: When a doctor has been identified as Company X's highest prescriber or Company advocate for a product, what might his/her motive

be in prescribing or leveraging his/her status and influence in the medical community when advocating to colleagues a given product? Can we say for certain that the doctor's motive or intent is shaped by Kantian ethics (true belief in the good a particular product brings to his patients)? Or might it be driven by the lure of perquisites ("perks") and incentives offered to him by the drug manufacturer?

Linking these three major ethical systems, we can see some central elements that can be used in shaping the ethical character of an action. One way of thinking looks at the character of the agent, one looks at the results of the action and the latter looks at the actions themselves. Between all can be seen a wide range of internal and external factors of human actions that have ethical consequences. Although these systems of ethics differ and conflict in theory, in practice they can be said to compliment each other. This is evident in the questions Hill (ibid: 228) addresses:

Will the doctor prescribe the premium priced drug X because as it happens doing so will place him in a good position to qualify for an overseas trip the manufactures of drug X are sponsoring, a holiday the doctor wants or will the doctor prescribe the most cost effective and clinically appropriate drug regardless of the effect such prescribing action will have on his prospects to qualify for the overseas trip; which he desires. If the former course is adopted, what do such

actions reveal about the doctor's primary responsibility to the patient's health and general welfare?

Having given direction concerning three ethical systems, the question as to how doctors should fashion their behaviour in a doctor-pharmaceutical industry relationship, is addressed in Coyle (2002: 397).

Coyle examines the doctor's ethical position concerning gifts and financial relationships with the industry and proposes positions which are posited to assist doctors in making ethical decisions when interacting with the industry. She highlights that these positions are based on the medical profession's fundamental principles of Biomedical ethics (see: Beauchamp and Childress' *Principles of Biomedical Ethics* 1997). For Coyle, these include the duty of responsibility; the obligation to act in the patient's best interest (beneficence), the obligation to protect the patient from harm (non-maleficence), and the duty to respect the patient while fostering the process of informed choice (autonomy).

Coyle points out that it is a general feeling that most doctors do not regard promoting equity in health care as their responsibility. However, she poignantly argues to the contrary by contending that doctors should bear the responsibility of promoting equity in health care delivery (justice).

Deriving from ethical theories and principles, another critical ethical consideration concerns the professional duties doctors owe their patients. The Royal College of Physicians (RCP 2005) states:

At the heart of good medical care is a set of values, attitudes, and behaviour called medical professionalism.

Medical professionalism is a set of virtues, values, and behaviour that underpins the trust the public has in doctors, and the medical profession is distinguished by the need for judgment in the face of uncertainty (RCP 2005: 1; Coyle 2002: 396-397). In 1999, *the RCP began The Medical Professionalism Project* (RCP 2005). It consists in a Charter which set out three principles which doctors should always follow: patients' welfare, patients' autonomy, and social justice. The Charter also set out professional responsibilities which were expressed as ten professional commitments: competence, honesty confidentiality, maintaining appropriate relationships, improving quality of care, improving access to care, the just distribution of finite resources, scientific knowledge, maintaining trust and professional duties (RCP 2005: 6).

Concerning medical professionalism, in "Educating for Professionalism in Medicine," a position statement by the Association of American Medical Colleges (AAMC), a few definitions of professionalism is given.

The AAMC defines professionalism as altruistic which encompasses respect, compassion, ethical probity, honesty, and avoidance of conflicts of interest (Inui 2003: 12). Further, in the USA the Accreditation Council for Graduate Medical Education (ACGME) professionalism includes such virtues and values as respect: compassion, integrity, responsiveness to needs, altruism, accountability, commitment to excellence, sound ethics and sensitivity to culture, age, gender, disabilities (ibid). It is also noteworthy that doctors should evince core humanistic virtues and values (e.g. honesty, integrity, caring, compassion, altruism, empathy, respect for others and trustworthiness) and adhere to high ethical and moral standards (ibid).

A statement from this Council (ibid: 11) is particularly relevant:

In the end, it is not because we have special knowledge and technology that we can be trusted – instead, we are trusted only if this knowledge and technology is firmly attached to values that are explicit, understood, and (when push comes to shove) altruistic.

Locally, The Health Professions Council of South Africa (HPCSA) has formulated guidelines to help doctors achieve the onerous task of delivering what is best for the patient. The HPCSA's ethical and professional guidelines clearly state:

A practitioner shall not engage in or advocate the preferential use or prescription of any medicine, if any improper financial gain or valuable consideration is

derived from such preferential use or prescription or the advocacy of preferential usage by the doctor (HPCSA Booklet 2 2007: 18; HPCSA Booklet 7 2007:6).

The HPCSA guidelines on over-servicing, perverse incentives, and related matters (HPCSA Booklet 7 2007: 1) regard it as an offence to offer or accept a perverse incentive. The notion of the profession's autonomy is re-enforced by the HPCSA noting that: Health care is to a large extent self-governing and practitioners must ensure that their participation in Continuing Professional Development ('CPD') activities is in keeping with their duties towards patients and society (ibid: 10).

The HPCSA guidelines serve to assist the doctor when there is potential conflict of interest and further require that doctors should always maintain autonomy, independence and regard the clinical needs of their patients as paramount (ibid: 1).

Yet questions remain: Is it possible for doctors to remain honest and altruistic under significant material influence and inducement from the pharmaceutical industry despite the strict regulatory framework, explicit professional ethical guidelines, and the publicly pronounced pharmaceutical industry self-regulating marketing code? Does it perhaps not confound reason to expect parties in a symbiotic relationship, as exists in the perceived perverse doctor-pharmaceutical company relationship, to exercise impartial and objective oversight roles over

each other's behaviour and practices when this very act fundamentally threatens the symbiosis?

To quote Coyle (2002: 397) "while the ethics of medicine and the ethics of the business sometimes diverge, both are legitimate, and a thoughtful collaboration between physicians and industry can result in the best of patient care". Brody (2005: 83) feels that one of the doctor's ethical duties, other than serving the patient's interest, is clinical competence. He accepts that this will include accepting well-grounded medical evidence from the industry. There seems to be a consensus that the interaction between industry and the medical profession is necessary and ideally, both should be engaged to ensure that the good of the patient trumps all other wishes, dreams, and desires. To do otherwise stands in sharp contravention of the ethical systems, principles, guidelines, rules, Oaths and declarations which have and continue to ground the practice of medicine as a moral enterprise.

2.2 Legal basis of research

2.2.1 South African legal and regulatory framework

The Medicines and Related Substances Control Act 101 of 1965, as amended Act 90 of 1997 (henceforth the 'Act') is the cornerstone of the regulatory legal framework for pharmaceutical governance in South Africa. The aims of the Act were principally to lower the cost of pharmaceutical products and improve price transparency.

Section 18A aspires to achieve the fundamental aims of the Act by, *inter alia*, minimizing perverse incentives given by the pharmaceutical companies to prescribers, encouraging generic medicines usage, and illegalising bulk discounts offered to pharmaceutical wholesalers and distributors (Act 90 of 1997: 5). The regulator's concern was that doctors were likely to prescribe and dispense (dispensing doctors) drugs that were discounted or prescribe drugs where they were likely to receive rebates.

The "prescribe & dispense" problem is an Apartheid legacy problem where, in the impoverished Black townships, there were no pharmacies and it was the practice for a general practitioner to keep an inventory of drugs for his or her patients. Therefore, most general practitioners, especially in the townships were also dispensing doctors. This meant they operated and owned the dispensary of the drugs they in turn prescribed. These dispensing doctors evidently had a profit

incentive from the pharmaceutical retail margin, over and above the classical prescribing doctor- pharmaceutical company relationship dynamic; which has been shown to be perverse (van den Heever 2002-2003 :18-21). The patient did not benefit from the discounted price as the discount was not passed onto the patient. In addition, because of the discount or bonus incentive, patients were to receive inappropriate drug treatment because of inventory management challenges e.g. where the doctor may have high stock levels of a given drug, but not the appropriate one.

Section 18B of the Act renders sampling of any medicine illegal (Act 90 of 1997: 5). In this situation, doctors would dispense and sometimes charge patients for samples of innovative products, which in most instances was not sustainable as the patient's financial position could not fund these more expensive drugs or medical funders refused to reimburse because there were cheaper existing alternatives. Once the samples ran out, patients had to revert to whatever medication they could afford or what the medical funder could reimburse. This type of situation was not optimal for patient management especially for chronic conditions like hypertension, diabetes, etc. To compound the problem and further compromise the patient's financial position, in some instances patients were billed by their doctors for these 'free samples'. Such samples were not for retail use but given to doctors by pharmaceutical companies as part of their market penetration strategies.

Section 18C of the Act recommended the need for a Code of Ethics for the pharmaceutical industry. This Code has been developed by the industry and is currently being reviewed by government (Act 90 of 1997: 6).

Here it is worth reiterating that the spirit of all measures outlined above strive to curb perverse marketing activities by the pharmaceutical industry; and ultimately improve patient welfare.

2.2.2 Industry Self Regulation

The South African Code of Practice for the Marketing of Medicines (SA Marketing Code)

The SA Marketing Code was finalised in January 2008 by the industry and is currently being reviewed by the Department of Health (DoH). The majority of pharmaceutical companies participated and contributed in the compilation of the Code. These companies have in principle agreed to subscribe to the Code on the principle of self-regulation (SA Marketing Code 2008: 4).

The Code aims to promote ethical marketing of medicines by the industry and also signifies the industry's commitment to ethical and professional marketing activities by all stakeholders including prescribers and advisers. The industry, through the Code, also seeks to demonstrate its desire to preserve the independence of the doctors (ibid: 4). The strength of the Code is that it will be enforced through the acceptance of accountability by all stakeholders. Moreover

and importantly, it will be enforceable through a formal process handling complaints. A Marketing Code Authority (MCA) will be established to deal with complaints from the industry stakeholders. Through this authority, an appeal or complaints body will be established to enforce corrective measures on parties that err (ibid: 32-43).

Section 18 of the Code addresses inducements, gifts, and promotional items stating:

…There shall be no personal enrichment of healthcare professionals or other healthcare providers. No gift, benefit in kind, rebate, discount, kickback or any other pecuniary advantage shall be offered or given to members of the health profession, administrative staff, government officials, or the general public as an inducement to prescribe, supply, stock, dispense, administer or buy any medicine, subject to the provisions of Clause 18.2 (ibid: 21).

Occasional gifts and promotional items would be of minimal value which will be determined by the MCA from time to time. Gifts for personal use would not be allowed except where it is a cultural courtesy gift. A maximum of one inexpensive gift per year may be given to a healthcare professional (ibid: 22).

The concern with the flexibility of the Code is the likelihood that some pharmaceutical companies would still try to find loopholes and gaps in this regulation. It poses a challenge to the rest of the industry to monitor these

activities. An additional concern is the lack of measures to record and audit frequency and monetary value of these gifts. Despite these obstacles, efforts by government and industry (The Medicines and Related Substances Control Act 101 of 1965, as amended Act 90 of 1997 and the South African Code of Practice for the Marketing of Medicines) are apparent in the hope to curb illegal and unethical practices by prescribers and industry.

2.2.3 International Law and Marketing Codes

Globally, substantial research has been carried out by various regulatory authorities and industry bodies to facilitate optimal working relations between the pharmaceutical industry and doctors. This is based on the shared position that the final outcome must be ensure the best interest of the patient and to always aim to improve the patient's overall welfare.

United States of America (USA)

In the USA, the Pharmaceutical Research and Manufacturers of America (PhRMA), code (revised in 2008) aims to encourage industry relationships with healthcare professionals that are not perceived as inappropriate by patients nor the public at large. The PhRMA code emphasises focusing on patients' medical needs and doctors' medical knowledge and experience. Company or industry interaction with doctors is perceived as professional in nature and fashioned to facilitate the exchange of medical or scientific information that will benefit patient care.

Perquisites are not outright forbidden, but guidelines on what is deemed appropriate advise, for instance, that hospitality and entertainment should be modest and occur in a manner conducive to providing scientific value (PhRMA 2008: 2-5). Items of minimal value that are relevant to the professional's practice

are allowed provided the quantity and frequency does not suggest inducement (ibid: 12).

The Food and Drug Administration (FDA) which licenses drugs in the USA, also plays an important role in monitoring the pharmaceuticals industry activities post licensing. These 'include guidelines on the use of promotional material and the qualifications of the industry speakers. Promotional material should be consistent with the FDA requirements governing such communications and speakers for the industry are required to be well trained. This is because the FDA holds companies accountable for the presentations of their speakers (ibid: 9-10).

The PhRMA code is not so rigorous as to expect doctors to render speaking services for pharmaceuticals companies, using their professional knowledge and time, for free. The code states that doctors acting as speakers on behalf of industry can be reasonably compensated, fair market value, for their time provided speaking arrangements are not inducements or rewards for prescribing products for the company (ibid).

United Kingdom (UK)

In the UK, Part IV (section 21) of the Medicines Advertising Regulations of 1994 which governs the advertising of registered medicines states that 'where relevant medicinal products are being promoted to persons qualified to prescribe or supply relevant medicinal products, no person shall supply, offer or promise to such persons any gift, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy'.

The Association of British Pharmaceutical Industry (ABPI) Code of Practice which represents the UK industry, is backed by statutory control, and aims to ensure ethical and professional promotional activities by the industry. The industry is committed to benefiting patients and wants to ensure appropriate use of medicines. The ABPI Code amongst other things addresses potential conflict for doctors with regards to provision of gifts and hospitality by the industry (ABPI 2006: 4-5).

The Code of Practice discourages gifts that are given as an inducement to prescribe, recommend or sell any medicine' but allows promotional aids of low value. Medical and educational goods for the benefit of patients are also acceptable under this Code they are branded with the corporate and not the product name (ibid: 27).

The Code continues to point out that where doctors act as service providers for the industry, their remuneration must not be linked to sales in any particular

territory or sales of a specific product (ibid: 29). This is to ensure that the doctors' motives for prescribing a given drug are not tied to the drug company's sales' (and ultimately earnings) maximization imperative. Complaints and transgressions to the ABPI code are handled by the Prescription Medicines Code of Practice Authority (ibid: 36-49).

The General Medical Council (GMC) is the regulatory body for the medical profession in the UK and is responsible for giving guidance on standards of professional conduct and medical ethics' (ibid: 31).

Paragraph 1 of the GMC Good Medical Practice (2006) captures the essence of a good doctor as:

Doctors that make the care of their patients their first concern: they are competent, keep their knowledge and skills up to date, establish and maintain good relationships with patients and colleagues, are honest and trustworthy, and act with integrity.

Paragraph 74 (GMC 2006) encourages doctors to act in their patients' best interests. The acceptance or request for gifts or inducements is highly discouraged especially where such inducements can be seen to affect the doctor's prescribing habits (ibid).

Canada

Research-Based Pharmaceutical Companies (Rx&D) represents the pharmaceutical industry in Canada. Rx&D is a member of the International Federation of Pharmaceutical Manufacturers and Associates (IFPMA) and strongly supports the missions and principles of the IFPMA code. Rx&D embraces the ideals of a fair and free society that include, amongst others, the freedom to trade and carry on commerce, and the freedom to allow science and medicine to advance their knowledge bases. The Canadian Code accepts the obligation to ensure that Canadian doctors and patients have access to education and information about the appropriate use of the industry products and services. That obligation includes using non-coercive and non-inducing means and methods of communication (Rx&D Code of Conduct 2006: 3).

The guiding principles include: modest meals and refreshments as the only acceptable form of hospitality, no monetary or other consideration is to be given to doctors for the purpose of gaining access or influence and grants or donations are never to be provided to doctors to promote specific prescription medicines (ibid: 4). Concerning "incentives" the Code (ibid: 9) states:

Industry must not offer to any health care professional or to any member of a health care professional's clinical or administrative staff, any gift – in cash or

kind, or any promotional aid, prize or reward or any other item which is intended for personal or family benefit or pecuniary advantage.

Any breach of the Code of Conduct by stakeholders is handled through the Industry Practices Review Committee ('IPRC') (ibid: 12-14).

International Federation of Pharmaceutical Manufacturers and Associates (IFPMA)

The IFPMA is a non-profit, non-governmental organisation representing industry associations and companies from both developed and developing countries (IFPMA Code 2006: 3). The IFPMA encourages participation from companies and industry associations whether local codes exist or not in the various member countries. Where there are no local codes or applicable laws the IFPMA code can be used as a default code to govern marketing activities by the industry (ibid: 2).

This Code re-emphasises industry's commitment to educational and promotional activities that benefit patients and promotional programs and collaborations that enhance the practice of medicine. It seeks to be the overarching body that oversees promotional practices worldwide, especially in countries where there are no local regulations or codes (ibid: 1). Consistent with the various country national codes, the IFPMA Code encourages reasonable reimbursement to doctors who provide genuine services as speakers or presenters and considers

practice related gifts of minimal value to be appropriate for health care professionals (ibid: 12-13).

Concerning accountability, complaints relating to the infringement of the IFPMA Code can be sent to the IFPMA secretariat. The IFPMA, in an attempt to resolve the complaint, will communicate with senior management of the company in breach of the Code (ibid: 15-22). Following procedure, the company or industry found in breach will be subject to strict penalties.

The local industry has instituted a Marketing Code which it purports to honour and agrees to abide by all applicable regulations. Yet, because the practice of doctors is asking for, expecting and in some instances, demanding inducements from the pharmaceutical companies is quite embedded in South African medical practice, it is questionable if these measures in themselves are sufficient and of such force and effect as to influence the prescribing doctor's behaviour.

All professionals should be compensated with fair market value for rendering professional service. Concerning that, there is agreement. However, questions remain e. g. What "fair price" and importantly, at what point might a patient's care and wellbeing likely be compromised when greed enters into the doctor-pharmaceutical industry relationship?

3.0 EMPIRICAL ARM OF THE REPORT

3.1 Research Objectives and Methods

3.1.1 Overall aims of the report

Industry relationships with doctors should aim to support, and be consistent with the professional responsibilities the doctors have towards their patients. The Health Professions Council of South Africa (HPCSA) guidelines outline clearly what the doctor's obligations are and how doctors should conduct themselves when interacting with the pharmaceutical industry. However, it remains debatable as to whether these guidelines have the desired effect on the profession.

The aim of this paper was to seek to understand what the respondent doctors feel is appropriate behaviour when interacting with the pharmaceutical industry. The local Marketing Code needs to encourage transparency on gifts given and payments made to healthcare professionals by the industry. An open register, which is already encouraged in the USA (Ross, *et al.*. 2007: 1216-1217), which can be audited randomly will remove barriers and difficulties in reporting perverse incentives by the industry or the healthcare professionals themselves. Healthcare professionals who bill appropriately for their services should not be embarrassed to have these figures open to public scrutiny. These efforts in no way aim to undermine the pivotal role the pharmaceutical industry plays in the healthcare value chain. The existence of the pharmaceutical industry is critical

for the advancement of medical knowledge and development of new technologies. However, the industry and the healthcare profession need to coexist in an environment that fosters educational value and advancement of medical knowledge to the benefit of the end user, the patient.

3.1.2 Study objectives

The overall objective of the study is to establish doctors' opinions on gifts and incentives offered by the pharmaceutical industry.

The primary objective was to establish

1. The prescribing doctors' opinion on the acceptance of incentives, gifts and inducements offered by the pharmaceutical industry.

The secondary objectives were to establish

1. The prescribing doctors' opinion of the influence their interaction with the pharmaceutical industry upon their prescribing habits.
2. The prescribing doctors' opinion about compensation for speaking engagements on behalf of the pharmaceutical industry.
3. The prescribing doctors' awareness of the regulatory guidelines governing their acceptance of gifts and incentives from the pharmaceutical industry.

The specific questions to address the secondary objectives aimed to

- Establish if doctors felt it was appropriate to accept branding items from the pharmaceutical industry.

- Establish if doctors felt it was appropriate to engage in frequent relationship dinners with the pharmaceutical industry.
- Establish if doctors felt it was appropriate for them to be sponsored by pharmaceutical companies to congresses regularly.
- Establish if doctors felt it was appropriate to accept personal gifts from the pharmaceutical industry.
- Establish what the doctors felt was appropriate compensation for presenting to CME gatherings, medical aid funders and medical congresses on behalf of pharmaceutical companies.
- Establish if doctors felt the interaction with the pharmaceutical industry influences their prescribing habits.

3.1.3 Methods

A questionnaire (Appendix A) based on previous work done by Morgan *et al.* 2006: 560; Brett *et al.* 2003: 2214; Steinman *et al.* 2001: 552 and Gibbons *et al.* 1998: 152 was developed. The questionnaire was hosted by an independent internet company, *Afridesign* that specialises in setting up web-based surveys. The data was collated in an anonymous manner, the system does not store any personally identifiable information. The questionnaire was emailed as a web-link to the participants. Responses were kept electronically on the website and downloaded at the end of the survey.

The questionnaire collected the following demographics: gender, age, type of practice and the province where the doctor is based. Specifically, the demographic profiling was colour blind.

The majority of the questionnaire was quantitative as respondent doctors were required to rate their responses on a 4 point Likert scale. A minor qualitative component was introduced by the inclusion of a few open ended questions; making up only 10% of the questionnaire. The survey was conducted from March 2009 to April 2009. Weekly reminder emails were sent to all participants. The questionnaire was internet-based making it difficult to decipher who the respondents were and hence reminder emails were sent to everyone. The database was locked on the 20th of April 2009.

3.2 Study Population and sampling

Study population was general practitioners (GPs) and specialists in private practice in South Africa. Sample included all doctors with email addresses, approximately 14 000, across all provinces as per Medpages® database. The database was filtered to include all active medical practitioners, using Medical Practitioner (MP) numbers, with email addresses. Active medical practitioners were practitioners who had not retired or deceased. The filtration process however inevitably led to the inclusion of respondent doctors in the public sector as the private-public data stratification was not discernable from the email addresses. In mitigation of this implicit sampling contamination an additional

criterion to indicate whether the doctor is in the private or the public sector was included in the questionnaire. The results were filtered to include only doctors in the private sector. The desired sample size was 500 doctors; comprising both general practitioners and specialists in private practice.

3.3 Ethical Issues

The researcher has received Research Ethics Committee (REC) (Human) approval from the University of the Witwatersrand to conduct this research with general practitioners and specialists in private practice across South Africa. The Committee's research approval number is M080602 (Appendix B).

3.3.1 Confidentiality

The webpage with the questionnaire was hosted by an independent internet company. All identifiers like names or MP number were removed, and only email addresses were captured in the final sample database. The researcher was not be able to link participants and their responses to the questionnaire.

3.3.2 Informed Consent

The survey did not involve use of patient records or any form of human tissue samples, for instance blood or urine samples from patients. A participant information sheet was included to explain the objectives of the survey (Appendix C). The completion of the questionnaire by the doctor was deemed to imply consent to participation.

3.4 Data management

Data was obtained from the internet company as coded data which was analysed by the researcher, with the help of a statistician. Data security will be ensured as all research data will be kept under lock and key for a period of 5 years, after which period it will be destroyed.

3.5 Statistical analysis

The data was analysed using the following methods (Appendix D):

- Cronbach's alpha to measure internal consistency of the questionnaire.
- Frequency distribution of individual questions
- Cross tabulation between questions
- Cross tabulation between items and demographics

3.6 Study limitations and bias

The survey was limited to doctors with active email and internet access. The study was also subject to non-response bias. It has been noted that the typical response rate in surveys ranges from 35% to 60% (Morgan *et al.*. 2005: 560). Prescription bias has also been documented by Dana and Loewenstein (2003: 254) as doctors do not perceive themselves to be influenced by industry, but feel their counterparts are likely to be influenced by industry activities.

4.0. RESULTS

The database was locked on the 20th of April 2009, at which point 496 valid responses had been received. Ninety six (96) of the responses from the total response pool were from the public sector and hence were excluded from the analysis as they fell outside the sample definition. Therefore, a final sample of 400 valid respondents, comprising of both general practitioners (GPs) and specialists in the private sector were analysed. This represented 80% of the intended sample.

The study questionnaire demonstrated very good internal consistency as measured by the Cronbach alpha statistical measure. Specifically, the results yielded a Cronbach alpha of 0.820 (82%), which is comfortably above the required hurdle of 0.70 (70%).

4.1 Demographics

4.1(a) Demographics of responding doctors (see Table 1)

Results revealed a gender bias, with a majority (74.25%) male response rate. The distribution in terms of medical speciality revealed an almost equal split between GPs (51.5%) and specialists (48.5%). The mode and median age group was the 41 -50 years olds (34%); and together with the 31-40 years (31.25%) and 51-60 years (23.50%) groups comprised the majority of the respondents. Respondents <30 years accounted for 2.75% of the sample and respondents >61 years of age were 8.5% of the sample.

Geographically, the highest percentage of responses were from Gauteng (45%) followed by the Western Cape (21%) and KwaZulu Natal (14%) provinces respectively. Responses received from other provinces were as follows Eastern Cape (7%), Free State (4%), North West (3%), Limpopo (3%), Mpumalanga (2%) and Northen Cape (1%)

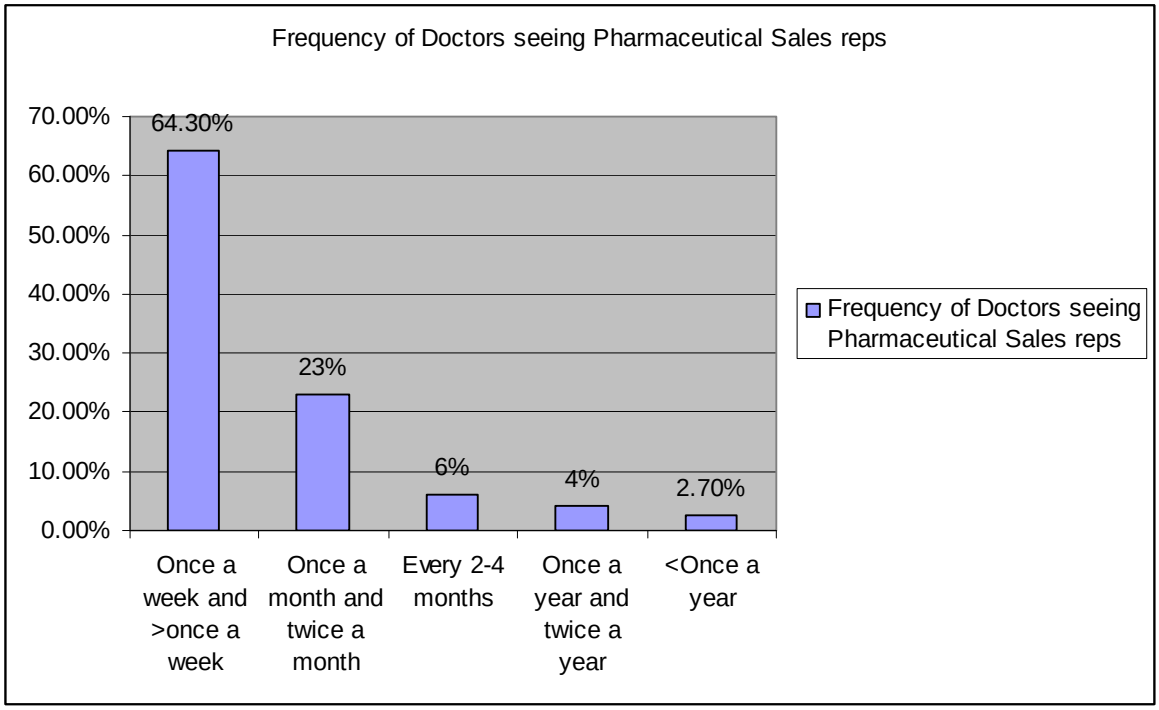
Table 1. Demographics of responding doctors n=400

Characteristics		N	%
Gender	Male	297	74.25
	Female	103	25.75
Speciality	GP	206	51.5
	Specialist	194	48.5
Age	<30 years	11	2.75
	31-40 years	125	31.25
	41-50 years	136	34
	51-60 years	94	23.5
	>61 years	34	8.5

4.1 (b) Frequency of visits from industry representatives (see Figure 1)

A very high proportion of the sample (87.3%) saw a representative a minimum of once a month. About two thirds of the respondents (64.3%) see pharmaceutical sales representatives either once a week or more than once a week, while just under a quarter (23%) saw representatives less frequently, either once a month or twice a month.

Figure 1. Frequency of Doctors seeing Pharmaceutical Sales Reps



4.2 Establishing doctors' opinions on gifts and incentives offered by the pharmaceutical industry

A 4 point Lickert scale was used to give participants varying options to express how they felt under the different interaction scenarios proposed in the questionnaire. To facilitate analysis and reporting, the responses have been grouped as follows; responses for 'Never' have been coded as 'No,' and 'Always, Often and Sometimes' as 'Yes respectively'.

Further, responses for 'Agree and Strongly Agree' have been captured as 'Agree' and responses for Disagree and Strongly Disagree' grouped as 'Disagree'.

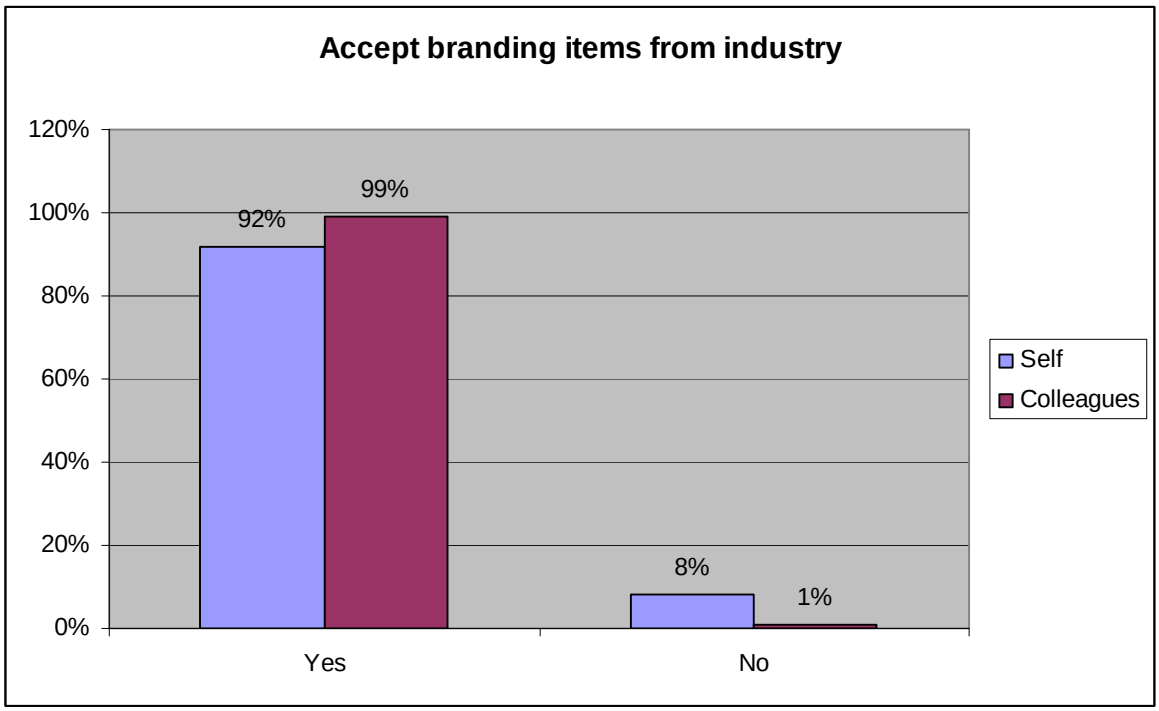
Responses for 'Inappropriate and Somewhat Inappropriate' have been captured as 'Inappropriate', and those for 'Appropriate and Somewhat Appropriate' have been captured as 'Appropriate'.

Finally, responses for 'Proper and Very Proper' were captured as 'Proper', whereas 'Improper and Very Improper' have been captured as 'Improper'.

4.2(a) Acceptance of branding items from industry (see Figure 2)

An overwhelming majority (92%) of the respondents accepted branding items from the industry and almost the entire sample (99% of the respondents) was of the opinion their colleagues were behaving likewise and accepted branding items from the industry.

Figure 2. Percentage of respondents that accept branding items from industry: Self vs. Colleagues

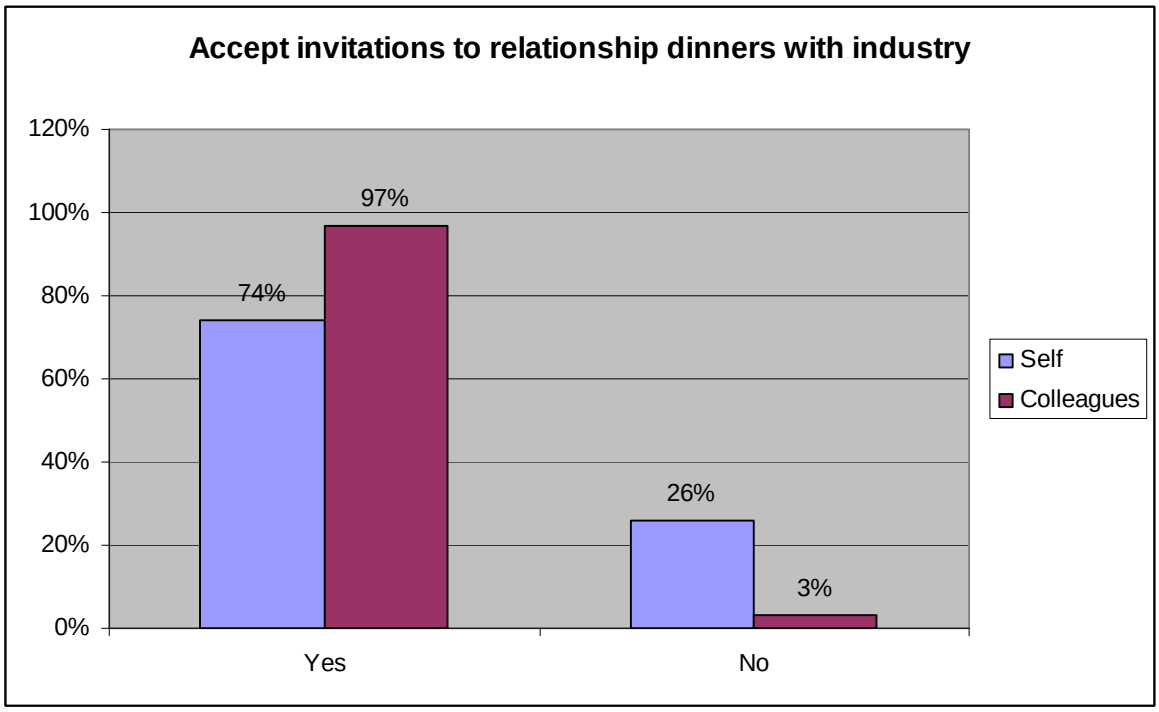


A statistically significant 85% of respondents who did not accept branding items felt their colleagues, exhibited behaviour to the contrary, and actually did ($p<0.001$).

4.2(b) Acceptance of invitations to relationship dinners with industry (see Figure 3)

Whereas about three quarters (74%) of the respondents accepted invitations to relationship dinners with the industry, 23% more thought their colleagues accepted invitations to relationship dinners with industry.

Figure 3. Percentage of respondents that accept invitations to relationship dinners with industry: Self vs. Colleagues.

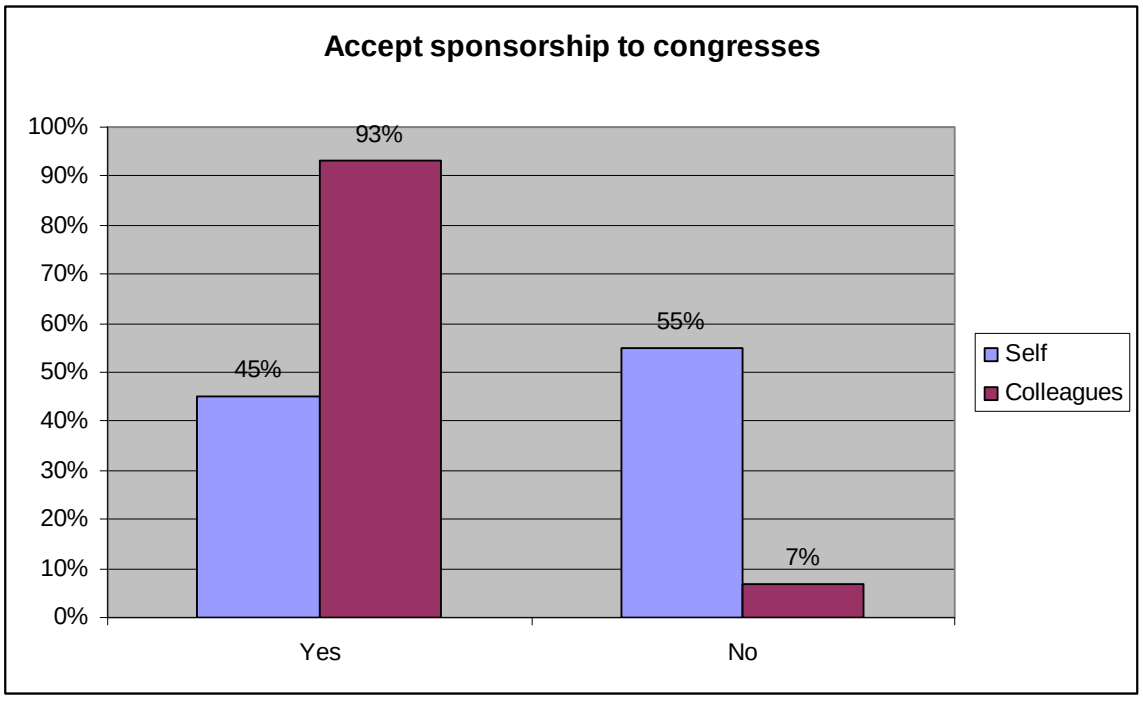


Again, the proportion of respondents who claimed not to accept invitations to relationship dinners, but felt their colleagues did was high (87.5%) and statistically significant with $p<0.001$.

4.2(c) Acceptance of sponsorship to congresses (see Figure 4)

Although just under half the sample (45%) claimed to accept regular sponsorship to congresses from the same company, more than twice this number (93%) thought their colleagues accepted regular sponsorship to congresses from the same company.

Figure 4. Percentage of respondents that accept regular sponsorship to congresses from the same company: Self vs. Colleagues



A third (33.5%) of GPs versus 58% of specialists accepted regular sponsorship to congresses from the same company ($p<0.001$); while 88% of respondents who did not accept regular sponsorship to congresses from the same company felt

their colleagues did ($p<0.001$). Both these findings were found to be statistically significant as demonstrated by the level of significance indicated above.

The study revealed that 60% of the respondents accepted personal gifts from the industry. Further, on a 4 point Lickert scale the respondents were asked to indicate if they found it ethical to receive certain perquisites from pharmaceutical companies and most (75%) found it inappropriate to accept a personal gift to the value of R1, 000.

Also, in descending order of deemed appropriateness the respondents felt it was proper to accept branding items (85%), tickets to sporting events (60%) and spa vouchers (57%), while only 16% indicated it was proper to accept a free weekend away with a spouse as a reward or inducement.

4.2(d) Interpretation of 'gift' by the respondents

The respondents were probed via an open-ended question to give their interpretation of what they perceived to be a gift from a pharmaceutical company. After collating and coding the questionnaire responses in the following categories emerged:

- 25% of the respondents felt branding items like pens and mugs, were gifts.
- 25% felt personal items like vouchers, perfumes or any items not relevant to the practice were gifts.

- 17% felt any item of high value i.e. >R200 whether personal or related to practice were gifts. For example, though a pen is relevant to the doctor's practice, expensive pens like Watermans® were seen as gifts.
- 11% of the respondents felt that activities like dinners, sponsorship to congresses, expensive practice equipment including laptops would be gifts as these are intended to 'bribe' the doctor.
- 20% of the respondents felt that anything from the industry, from a pen or lunch to congress sponsorship or equipment donation were gifts.

As to how the sample doctors would react if the pharmaceuticals stopped extending perquisites to them, 90% said they would still be willing to see pharmaceutical representatives if the industry stopped giving branding items and 86% even if sponsoring of doctors to congresses ceased.

4.2(e) Respondents' opinion on appropriate compensation for presentations on behalf of industry

The study also attempted to gain insight into the remuneration dynamics around the relationship between respondent doctors and the pharmaceutical industry, specifically in respect of making medical presentations. The areas probed include presentations at Continuing Medical Education ('CMEs') - including medical congresses- and presentations to medical funders on behalf of pharmaceutical companies. The results revealed that 85% of the respondents

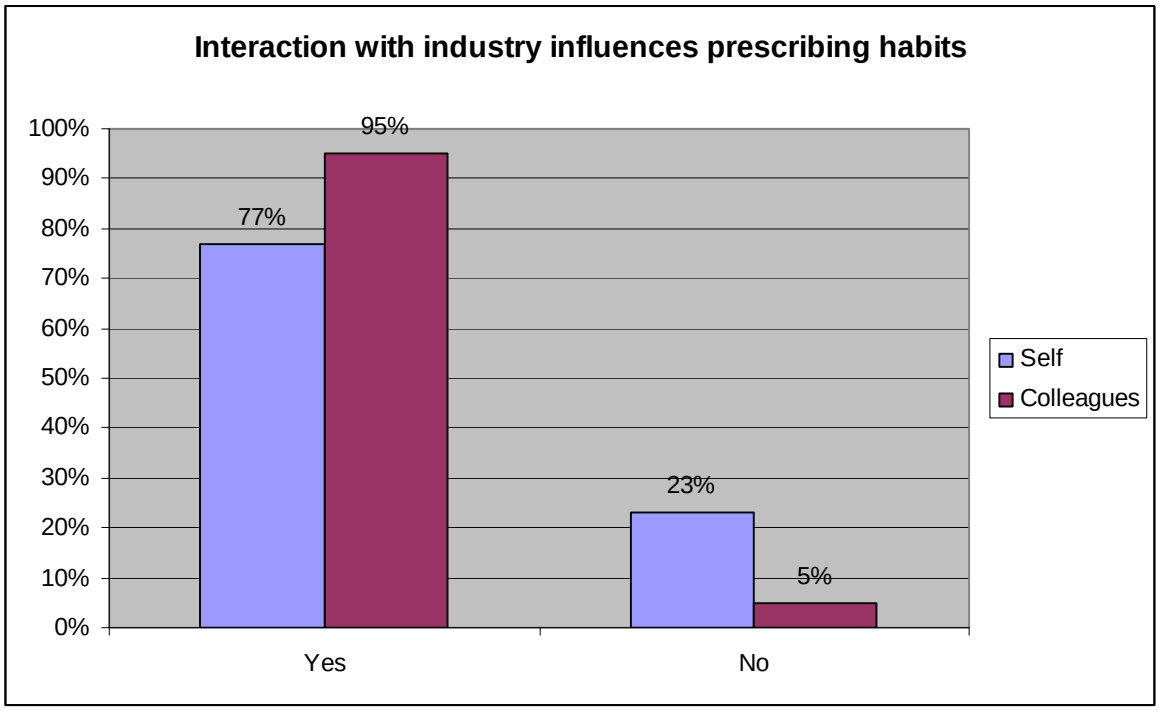
felt that doctors should be paid for speaking at CMEs, and just over half the sample (52%) felt they wanted to be paid their own rate, while 48% were happy with being paid the industry rate. Suggested payments were mostly in the range R1, 000 to R5, 000 per presentation. It is interesting to note that the remuneration band was suggested by the sample in response to open ended, unstructured questions where no grading was suggested by the researcher. Around 40% of the sample felt this band appropriate - with 41% of the respondents indicating this range acceptable for presenting at CMEs, 40% suggesting acceptability for presentations to medical aids and 39% indicating it acceptable for presenting at medical congresses. Only 7% of the respondent felt doctors should be paid more for presenting at medical congresses, suggesting a remuneration band of between R7, 501 and R10, 000.

4.2(f) Respondents' opinion on whether interaction with industry influences the doctors' prescribing habits (see Figure 5)

The study next turned to the investigation of the possible influence of the doctor's relationship with the pharmaceutical industry on his/her choice of pharmaceutical therapeutic interventions; and the effect of this relationship on the ultimate standard and quality of care delivered by the doctor to his/her patient.

The investigation revealed that 77% of the respondents felt that their interaction with the industry influenced their prescribing habits and suggesting that such influence to be more pervasive with their colleagues, specifically 95% felt their colleagues are influenced by their interaction with industry ($p < 0.001$) see Figure 5 below.

Figure 5. Percentage of respondents that feel interaction with industry influences prescribing habits: Self vs. Colleagues



About three quarters of the respondents (73%) believed patient management may be compromised if doctors' prescribing habits are influenced by their interaction with the industry. GPs (75%) felt more strongly about the possible harm to patient compared to specialists (68%) if doctors' prescribing habits are influenced by their interaction with industry $p<0.05$.

4.2(g) Respondents' opinion on appropriate 'gifts' from the pharmaceutical industry

Having focused on possibly perverse perquisites extended by the industry to the doctor, the questionnaire probed respondents for what they considered appropriate gifts from the industry; and then finally investigated the respondents' awareness of the regulatory framework governing the interaction between doctor and industry.

Respondents were given an opportunity to list up to ten (10) gifts. No list was provided by the researcher from which the respondents could choose.

Respondents felt the following items were ethically acceptable gifts to doctors from the pharmaceutical companies:

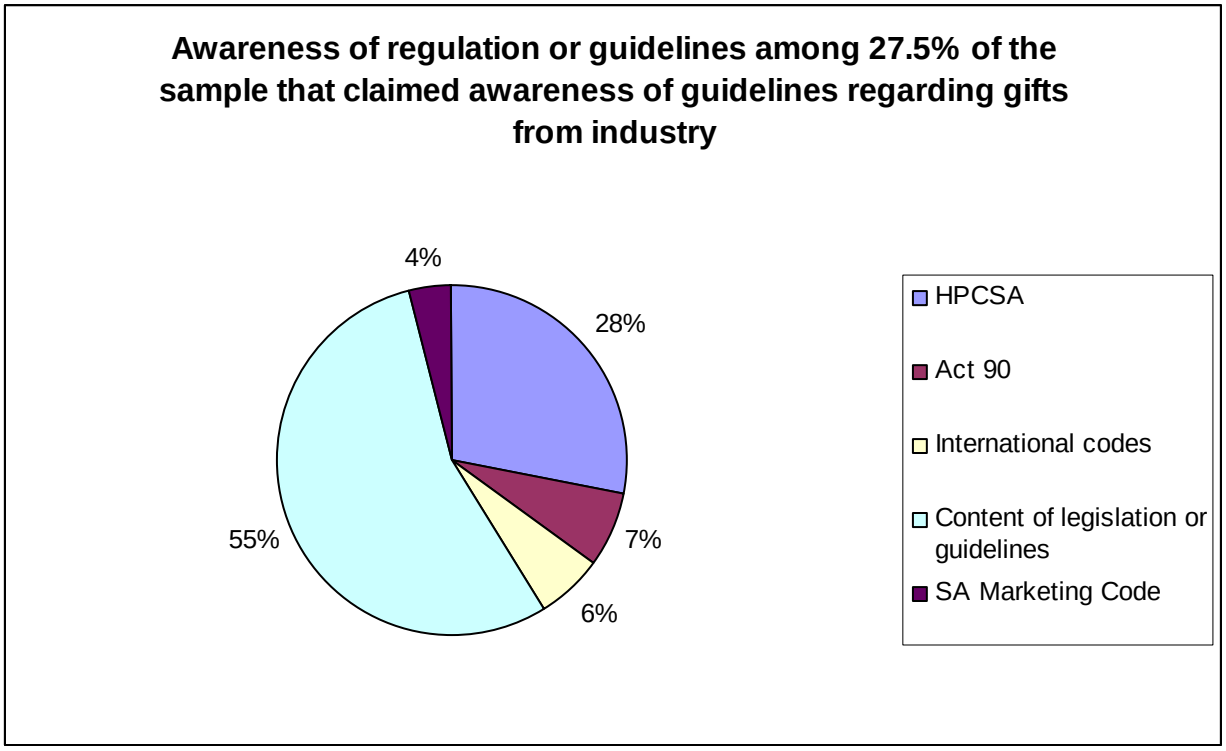
- 67% suggested branding items were acceptable
- 20% thought textbooks, educational materials for patients and medical journals were appropriate
- 16% felt sponsorship to congresses and CME activity should continue
- 27% would like personal items like vouchers, wine, lunch and branded T-shirts
- 3% did not want any give-aways at all
- 5% still wanted drug samples despite the legislation

4.2(h) Awareness of regulations or guidelines on acceptance of gifts from industry (see Figure 6)

Most respondents (72.5%) were either not aware or did not know of any regulations or guidelines with regards to acceptance of gifts by doctors from the industry.

Of the 27.5% that either knew or were aware of the guidelines; only 28% were specifically aware of the local HPCSA guidelines, a mere 7% knew of Act 90 (Medicines and Related Substances Control Amendment Act 90 of 1997, hereafter referred to as Act 90), and only 6% mentioned international codes like UK GMC, PhRMA, RCP, AMA guidelines.

Figure 6. Awareness of regulation or guidelines among 27.5% of the sample that claimed awareness of guidelines regarding gifts from industry.



Notably, only 4% of all respondents in this sub-set of 27.5% were aware of the South African Marketing Code.

More than half of these respondents (55%), although claiming familiarity with regulations and guidelines, could not explicitly name any guideline. It is interesting to note however, that all respondents that were familiar with regulations and guidelines (whether or not they could name them), were also aware of the different types of unprofessional or unethical behaviour that the guidelines intend to contain. For instance, these respondents indicated that drug samples were illegal, no perverse incentives were allowed, give-aways should be

of minimal value and relevant to the practice and no entertainment of partners at scientific meetings should be allowed.

5.0 DISCUSSION AND CONCLUSIONS

5.1 Introduction

The main objective of the study was to establish doctors' opinions on gifts and incentives offered by the pharmaceutical industry. The secondary objectives were to establish if these incentives or interaction with the industry influenced their prescribing habits; establish doctors' opinion of the influence their interaction with the pharmaceutical industry had upon their prescribing habits and establish doctors' awareness of the regulatory regime governing their acceptance of gifts from the industry.

5.2 Discussion of Study Findings

The findings of the study are highlighted in the discussion that follows. The findings are presented to mirror the priority and sequence of the research questions as outlined above.

- ***The study indicates that doctors generally accept incentives from the industry, and they to some extent feel justified in so doing as they feel that the industry should give them some 'payment in kind' for the opportunity cost of seeing re*****ps.**

The perceived appropriateness of this acceptance of gifts and incentives did, however, appear to exist within certain bounds which are influenced by the dollar

value of the incentive. This was evidenced by the fact that 75% of respondents felt it was inappropriate to accept a gift of R1, 000, while 92% of the respondents felt that it was appropriate to accept branding items. 60% of respondents felt it was appropriate to accept personal gifts from industry which in the main are not related to medical practice. However, regardless of the value of the branding items or any other gifts received from industry, these can still be perceived as inducements even when the doctor believes otherwise, as shown by Gibbons, *et al.* (1998: 153) that patients felt gifts were less appropriate than did their doctors.

The results further show, and with statistical significance, that doctors were of the opinion that their counterparts were more likely to accept gifts and other 'incentives' from industry than they themselves. This suggests that individual doctors hold themselves in higher moral and ethical esteem as compared to their colleagues.

Despite doctors' general acceptance of gifts as highlighted above, it is interesting to note that the majority of the respondents indicated they would be willing to see representatives in the absence of gifts and incentives. This may indicate that beside the perverse aspect of the interaction, doctors still perceived some value add from the industry in their interaction with pharmaceutical representatives.

- ***Majority of the respondents felt that interaction with industry influenced their prescribing habits***

The results indicate, with statistical significance, that doctors believed their colleagues (their prescribing habits that is) were more likely to be influenced than themselves; again expressing a less favourable opinion of their counterparts' ethical and professional standards.

Further, the majority of the respondents felt that patient management may be compromised if doctors' prescribing habits are influenced by their interaction with industry. More GP's (75%) than specialists (68%) felt patient management may be compromised if interaction with industry exerted perverse influence on their prescribing habits. Statistical testing revealed this difference in number between GPs and specialists to be statistically significant.

- ***Majority of the respondents felt that doctors should be paid for speaking engagements on behalf of industry; and the suggested payment per engagement was mostly in the band between R1, 000 and R5, 000.***

A minority (7%) felt that doctors should be paid more for presenting at congresses and the suggested compensation band was R7, 500 to R10, 000 per speaking engagement which typically lasts between half an hour to two hours at the very most. It is interesting to compare this "asks" with the current reported R50/hour compensation for public sector doctors; especially in light of the current

more than one month old strike of public sector doctors at public hospitals in the various provinces.

Although no industry compensation rate was defined in the study, nor declared by the respondents, the sample was split in the middle with half proclaiming to be satisfied with the going industry rate and the other half indicating they would prefer to “name their price”.

- ***Only 28% of the respondents were aware of “any guidelines or regulations” governing acceptance of gifts by doctors, with again just 28% of this cohort mentioning the HPCSA guidelines***

The majority of respondents appeared not to be aware of what the industry is trying to achieve with the Marketing Code, as shown by a lack of awareness of the Marketing Code

5.3 Areas of future research

The insights gained from the study have served as a platform from which we make recommendations for areas of possible future research. The researcher has distilled three areas that are considered worthy of future research attention

- Whereas this study focussed on the opinions of doctors in respect of the ethics around their acceptance of perverse incentives and gifts from the pharmaceutical industry, it would be of interest to establish from industry if doctors are indeed asking for incentives and gifts. The objective being to illicit the extent to which industry believes doctors' behaviour is instrumental in encouraging them (industry) to behave unethically by extending perverse incentives and gifts. Fundamentally, the question would be: 'to what extent do doctors consciously and actively requests gifts and incentives from industry, hence actually perpetuate the perverse relationship?'
- The research indicates that doctors' inclination to accept gifts, and their perceived appropriateness of such acceptance, bears a somewhat inverse relationship to the monetary value of the gift or incentive. A future research question is to explore if a dollar threshold that serves as an ethical boundary and informs the doctor when a gift is appropriate and when it is not exists. The natural evolution of this line of inquiry would be to further investigate the predictive variables of such a threshold (if indeed it exists).

- Doctors have a responsibility towards their patients. It would be interesting to explore what doctors believe to be their ethical and legal responsibilities when perverse incentives and gifts are offered to them.

5.4 Recommendations

Personal responsibility for ethical behaviour by the medical practitioner is fundamentally the responsibility of the doctor and one that cannot, and should not, be delegated to third parties. The two most important organs that practically have sufficient leverage to curb unethical behaviour and perverse relationships are the HPCSA and the Pharmaceutical Industry's Associations e. g. Innovative Medicines South Africa (IMSA) and Pharmaceutical Industry Association of South Africa (PIASA) to name a few.

- The HPCSA has made a resolve to root out perversity in the healthcare profession as shown in recent cases where doctors were heavily sanctioned for their involvement in such activities. Recommendations are for the HPCSA to engage in a nationwide comprehensive, and structured, education campaign on its guidelines to inform doctors of their guidelines. Specifically, doctors should be educated not only on the need and rationale for the guidelines aimed at curbing perverse relationships, but also of the penalty and sanction for breaching of the guidelines. The education campaign evidently will need to be ongoing if it is to shape and

change attitudes and behaviour that is chronic among adult individuals. Also a preventative approach would be for the HPCSA to engage with medical schools to ensure that these guidelines are an inherent part of ethics education especially at undergraduate level where interaction with the pharmaceutical marketing machinery is minimal and attitudes (and behaviour) are still malleable.

- The pharmaceutical industry, through IMSA, PIASA and other industry associations, should also engage in an education campaign to educate doctors about the “Code” that govern their behaviour so doctors can be made aware of the type of ethical conduct expected of the industry. It is possible that it would be easier for doctors to identify, and hopefully desist from being party to, perverse and unethical behaviour initiated by the industry if they had clarity of mind about what constitute industry perverse behaviour; and that it is their duty and responsibility to report such behaviour to the both the HPCSA and the MCA. It is interesting that in South Africa, to date, no case has ever been taken up to the HPCSA that implicates the industry.
- Improvements to the Marketing Code itself are recommended. Specifically, the local Marketing code needs to encourage transparency on gifts given and payments made to doctors, and other healthcare professionals, via the implementation of an open register which can be randomly audited. This transparency, it is posited, will minimise requests for inflated payments and inappropriate inducements and perquisites.

5.5 Conclusion

The pharmaceutical industry and the healthcare profession need to converge at some point, and their respective strategic imperatives of maximization of return on investments (industry) and optimisation of the quality and standard of health-care (doctor) need to find confluence.

From a marketing point of view, all available strategies to gain market share must be employed by the organisation; but to the extent that the pursuit for profit could lead to the death of patients there need to be boundaries and guidelines. In addition, while the doctor may seek to enjoy certain perquisites offered by the industry, it is important to bear in mind that this could cloud clinical judgement to the patient's detriment. Furthermore, this is the moment when the principle of non-maleficence would be eroded. Hence, ethical boundaries need to be drawn.

This study demonstrated that perverse incentives continue to be given to doctors, and doctors have not shown a distinct aversion to accepting these perverse incentives and gifts. These perverse interactions have been shown in existing literature and in this research report to influence prescribing habits. The trust that society places on the medical profession is eroded by such behaviour, especially when self interest supersedes patient interest.

Doctors do not seem to operate within their guidelines and legal framework, as stipulated by the HPCSA, when accepting these potentially harmful perquisites. What legal and ethical considerations are the doctors employing when accepting 'incentives' from industry is the question; and what is the doctor's role in protecting his/her patients?

Ignorance of the guidelines, as the study indicates to be the case, does not justify involvement in perverse relationships. Doctors have professional and personal moral responsibilities to ensure they familiarise themselves with guidelines regulating their professional conduct as put out by the professional bodies and councils in the country. Moreover, the HPCSA is a statutory council as per the Health Professions Act No. 56 of 1974 and therefore, any policy and guideline documents emanating from this body would have quasilegal standing. It is imperative that doctors understand this.

Will it be business as usual for the industry, or will they conduct business in a more responsible way according to the letter and spirit of their own Code? The Code and the HPCSA guidelines will not by themselves eradicate the problem of perverse relationships between the industry and the doctor. The time has come for doctors to start taking personal responsibility for their actions and for the industry to be true to its stated moral and ethical standards in its marketing initiatives.

APPENDICES

Appendix A

Survey Questionnaire

Mandisa Maholwana™

PARTICIPANT INFORMATION SHEET

"Ethical and legal considerations concerning the acceptance by doctors of "incentives" of
- A South African Survey

You have been invited to participate in the survey. >>

+ **1 Gender** ◯ Male ◯ Female
+ **2 Sector** ◯ Public sector practice ◯ Private sector practice
+ **3 Specialty** ◯ GP ◯ Specialist
+ **4 Age** ---------- ▢
+ **5 Region** ---------- ▢

+ **6 How often do you see pharmaceutical sales representatives?**
---------- ▢

+ **7 Do you accept branding items from pharmaceutical sales representatives?**
Always ◯ Often ◯ Sometimes ◯ Never ◯

+ **8 Do you think your colleagues accept branding items from pharmaceutical sales representatives?**
Always ◯ Often ◯ Sometimes ◯ Never ◯

+ **9 Do you accept invitations to relationship building dinners with pharmaceutical companies?**
Always ◯ Often ◯ Sometimes ◯ Never ◯

+ **10 Do you think your colleagues accept invitations to relationship building dinners with pharmaceutical companies?**
Always ◯ Often ◯ Sometimes ◯ Never ◯

+ **11 Do you accept regular sponsorship to congresses from the same pharmaceutical company?**
Always ◯ Often ◯ Sometimes ◯ Never ◯

+ **12 Do you think your colleagues accept regular sponsorships to congresses from the same pharmaceutical companies?**
Always ◯ Often ◯ Sometimes ◯ Never ◯

+ **13 Do you think interaction with a pharmaceutical sales representatives influences your prescribing habits?**
Always ◯ Often ◯ Sometimes ◯ Never ◯

+

14 Do you think other practitioners' prescribing habits are influenced by their interaction with pharmaceutical sales representatives?

Always ◯ Often ◯ Sometimes ◯ Never ◯

15 Do you feel patient management may be compromised, if doctors' prescribing habits are influenced by the pharmaceutical industry

Always ◯ Often ◯ Sometimes ◯ Never ◯

16 What is your interpretation of a 'gift' from a pharmaceutical company?

17 Do you accept personal gifts from pharmaceutical sales representatives?

Always ◯ Often ◯ Sometimes ◯ Never ◯

18 Do you feel a personal gift from a pharmaceutical sales representative, say to the value of R1000.00, is appropriate?

Very appropriate ◯ Somewhat appropriate ◯ Somewhat inappropriate ◯ Very inappropriate ◯

19 I would still be willing to see pharmaceutical sales representatives, if the industry stopped giving branding items.

Strongly agree ◯ Agree ◯ Disagree ◯ Strongly disagree ◯

20 I would still be willing to see pharmaceutical sales representatives, if the industry stopped sponsoring individuals to congresses.

Strongly agree ◯ Agree ◯ Disagree ◯ Strongly disagree ◯

21 Do you feel doctors should be paid for speaking at CMEs?

Strongly agree ◯ Agree ◯ Disagree ◯ Strongly disagree ◯

22 How much do you feel doctors should be paid for presenting, the same presentation, at CMEs (*exclude initial preparation time*)?

R .00

23 How much do you feel doctors should be paid for presenting, the same presentation, on behalf of pharmaceutical companies to me (*exclude initial preparation time*)?

R .00

24 How much do you feel doctors should be paid for presenting at congresses including preparing the presentation?

R .00

25 Do you feel it is ethical for doctors to accept branding items from the pharmaceutical industry?

Very proper ◯ Proper ◯ Improper ◯ Very improper ◯

26 Do you feel it is ethical for doctors to accept tickets sponsored by a pharmaceutical company to a sporting event?

Very proper ◯ Proper ◯ Improper ◯ Very improper ◯

27 Do you feel it is ethical for doctors to accept a spa voucher sponsored by a pharmaceutical company whilst attending a congress?

Very proper ◯ Proper ◯ Improper ◯ Very improper ◯

28 Do you feel it is ethical for doctors to accept a free weekend away with a spouse or partner for being the highest prescriber of a pro

Very proper ◯ Proper ◯ Improper ◯ Very improper ◯

29 Do you think doctors should be paid their own rates or industry rate for speaking on behalf of pharmaceutical companies at CMEs?

Own rate ◯ Industry rate ◯

30 In your opinion, please list what you feel are ethically acceptable gifts that doctors may receive from the pharmaceutical companies

i. ii. iii. iv. v.
vi. vii. viii. ix. x.

31 Are you aware of any guidelines regarding acceptance of gifts, by doctors, from the pharmaceutical industry?

Yes ◯ No ◯

If Yes, please name them.

i.
ii.
iii.
iv.
v.

CLICK HERE TO SUBMIT

Thank you for taking the time to fill in this questionnaire.

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Appendix B

Ethics Committee Clearance

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Maholwana

CLEARANCE CERTIFICATE **PROTOCOL NUMBER M080602**

PROJECT Ethical and legal considerations concerning acceptance by doctors of incentives offered by pharmaceutical companies: A South African Survey

INVESTIGATORS Dr MJG Maholwana

DEPARTMENT Med Bioethics and Health Law

DATE CONSIDERED 08.06.27

DECISION OF THE COMMITTEE* Approved subject to completing the ethics application
in full

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 08.06.30 **CHAIRPERSON** ..... (Professor P E Cleaton Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Prof D von Bogaert

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix C

Participant Information Sheet

Mandisa Maholwana™

PARTICIPANT INFORMATION SHEET

I am Mandisa Maholwana, a postgraduate student at the University of Witwatersrand. I am conducting a survey amongst general practitioners and specialists in private practice in partial fulfillme degree of MSc Med (Bioethics & Health Law), Steve Biko Centre for Bioethics, Faculty of Health Sciences.

My research report is titled

"Ethical and legal considerations concerning the acceptance by doctors of *"incentives"* offered by pharmaceutical compan
- A South African Survey

You have been invited to participate in the survey. >>

BEFORE YOU START:
Before agreeing to participate, it is important that you read and understand the following explanation of the purpose of the study, the study procedures, benefits, risks, discomforts, and precautions as well as the alternative procedures that are available to you, and your right to withdraw from the study at any time.This information leaflet is to help you to decide if you would like to participate. You should fully understand what is involved before you agree to take part in this study.

CONTACT:
If you have any questions, do not hesitate to contact me via email at drmands@vodamail.co.za or call me on **082 852 4797**

AGREEMENT:
You should not agree to take part unless you are satisfied about all the procedures involved.

COMPLIANCE:
Please be completely truthful with me regarding the information requested in the questionnaire.

CONSENT:
Completion of the survey will be regarded as consent to participate in the survey.

PURPOSE OF THE SURVEY:
The purpose of this study is to establish doctors' opinion on gifts and incentives offered by the pharmaceutical industry

LENGTH OF THE SURVEY AND NUMBER OF PARTICIPANTS
The survey will be conducted across the country and will be sent to approximately 500 GPs and Specialists in private practice.

The survey will take approximately 25 minutes to complete

RISKS AND BENEFITS OF PARTICIPATING IN THE SURVEY:
There are no risks or benefits to you, Information will be stored by a third party and given to me as coded data and therefore there is no risk of linking participants to their responses.

RIGHTS AS A PARTICIPANT IN THIS SURVEY:
Your participation in this study is entirely voluntary and you can decline to participate, or stop at any time, without stating any reason.

REIMBURSEMENT FOR PARTICIPATION:
You will not be paid to participate in this survey.

ETHICS APPROVAL:
This research protocol has been submitted to the University of the Witwatersrand, Human Research Ethics Committee (HREC) and written approval has been granted by that committee. If you want any information regarding your rights as a research participant, or complaints regarding this research study, you may contact Prof. Cleaton-Jones, Chairperson of the University of the Witwatersrand, Human Research Ethics Committee (HREC), which is an independent committee established to help protect the rights of research participants at (011) 717 2301.

CONFIDENTIALITY:
This questionnaire is being emailed by a third party that has a database of GPs and Specialists in private practice with email addresses. Responses will be converted to coded data by the third party. Once a participant has responded or refused to participate in the survey, they will be taken off the sample list. I will be completely blinded to the names of participants on the survey. All information obtained during the course of this survey will be kept strictly confidential. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this survey.

DEFINITIONS:
Branding Items – items of minimal value pens, torches that are branded with co product logo

Personal gifts – Items of higher value normally not branded with product or com e.g. shopping vouchers, gift hampers

Industry rate for CMEs – Remuneration an average fee paid by most pharr companies for CMEs

If you decline to participate, please CLICK HERE TO EXIT

If you agree to participate please CLICK HERE TO CONTINUE

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Appendix D

Statistical Analysis

18 Variables: QQ7 QQ8 QQ9 QQ10 QQ11 QQ12 QQ13 QQ14 QQ15
QQ17 QQ18 QQ19 QQ20 QQ21 QQ25 QQ26 QQ27 QQ28

n = 400

Simple Statistics

Variable	N	Mean	Std Dev	Sum	Minimum	Maximum
QQ7	400	2.06500	0.95617	822.00000	1.00000	4.00000
QQ8	400	1.79250	0.74890	717.00000	1.00000	4.00000
QQ9	400	2.92250	0.82959	1169	1.00000	4.00000
QQ10	400	2.40750	0.64224	963.00000	1.00000	4.00000
QQ11	400	3.39000	0.78066	1356	1.00000	4.00000
QQ12	400	2.52500	0.71108	1010	1.00000	4.00000
QQ13	400	2.97250	0.72668	1189	1.00000	4.00000
QQ14	400	2.64000	0.62158	1056	1.00000	4.00000
QQ15	400	2.01250	0.81486	805.00000	1.00000	4.00000
QQ17	400	2.98000	0.97312	1192	1.00000	4.00000
QQ18	400	3.22000	1.01695	1288	1.00000	4.00000
QQ19	400	3.36250	0.72967	1345	1.00000	4.00000
QQ20	400	3.28000	0.79887	1312	1.00000	4.00000
QQ21	400	1.74250	0.88212	697.00000	1.00000	4.00000
QQ25	400	1.99500	0.70443	798.00000	1.00000	4.00000
QQ26	400	2.37750	0.89834	951.00000	1.00000	4.00000
QQ27	400	2.41750	0.91394	967.00000	1.00000	4.00000
QQ28	400	3.38000	0.88462	1352	1.00000	4.00000

Cronbach Coefficient Alpha

Variables	Alpha
Raw	0.819971
Standardized	0.812768

$\approx 0{,}820 = 82{,}0\%$

Cronbach Coefficient Alpha with Deleted Variable

	Raw Variables		Standardized Variables	
Deleted Variable	Correlation with Total	Alpha	Correlation with Total	Alpha
QQ7	0.538842	0.802750	0.544571	0.794941
QQ8	0.465772	0.808313	0.468526	0.799547
QQ9	0.569664	0.801783	0.572637	0.793222
QQ10	0.358744	0.813987	0.375521	0.805075
QQ11	0.360846	0.813759	0.363803	0.805764
QQ12	0.295880	0.816870	0.319467	0.808352
QQ13	0.275320	0.817931	0.285755	0.810303
QQ14	0.173053	0.821791	0.189872	0.815772
QQ15	0.184946	0.823456	0.176545	0.816523
QQ17	0.504393	0.805066	0.493229	0.798059
QQ18	0.610016	0.797356	0.592102	0.792023
QQ19	0.160937	0.823508	0.163253	0.817269

Analysis all questions

Private

nq1	Frequency	Percent	Cumulative Frequency	Cumulative Percent
F	103	25.75	103	25.75
M	297	74.25	400	100.00

nq2	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Private	400	100.00	400	100.00

nq3	Frequency	Percent	Cumulative Frequency	Cumulative Percent
GP	206	51.50	206	51.50
Specialist	194	48.50	400	100.00

nq4	Frequency	Percent	Cumulative Frequency	Cumulative Percent
31-40yrs	125	31.25	125	31.25
41-50yrs	136	34.00	261	65.25
51-60yrs	94	23.50	355	88.75
<30 yrs	11	2.75	366	91.50
>61yrs	34	8.50	400	100.00

nq5	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Eastern Cape	26	6.50	26	6.50
Free State	17	4.25	43	10.75
Gauteng	179	44.75	222	55.50
KwaZulu Natal	56	14.00	278	69.50
Limpopo	11	2.75	289	72.25
Mpumalanga	9	2.25	298	74.50
North West	13	3.25	311	77.75
Northern Cape	4	1.00	315	78.75
Western Cape	85	21.25	400	100.00

nq6	Frequency	Percent	Cumulative Frequency	Cumulative Percent
< once a year	11	2.75	11	2.75
> once a week	168	42.00	179	44.75
every 2 months	15	3.75	194	48.50
every 3 months	4	1.00	198	49.50
every 4 months	5	1.25	203	50.75
once a month	45	11.25	248	62.00
once a week	89	22.25	337	84.25
once a year	7	1.75	344	86.00
twice a month	47	11.75	391	97.75
twice a year	9	2.25	400	100.00

nq7	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Always	139	34.75	139	34.75
Never	33	8.25	172	43.00

Often	133	33.25	305	76.25
Sometimes	95	23.75	400	100.00

nq8	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Always	157	39.25	157	39.25
Never	5	1.25	162	40.50
Often	174	43.50	336	84.00
Sometimes	64	16.00	400	100.00

nq9	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Always	19	4.75	19	4.75
Never	104	26.00	123	30.75
Often	97	24.25	220	55.00
Sometimes	180	45.00	400	100.00

nq10	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Always	21	5.25	21	5.25
Never	13	3.25	34	8.50
Often	208	52.00	242	60.50
Sometime	158	39.50	400	100.00

nq11	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Always	11	2.75	11	2.75
Never	219	54.75	230	57.50
Often	41	10.25	271	67.75
Sometime	129	32.25	400	100.00

nq12	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Always	25	6.25	25	6.25
Never	26	6.50	51	12.75
Often	166	41.50	217	54.25
Sometime	183	45.75	400	100.00

nq13	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Always	7	1.75	7	1.75
Never	93	23.25	100	25.00
Often	90	22.50	190	47.50
Sometime	210	52.50	400	100.00

nq14	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Always	11	2.75	11	2.75
Never	20	5.00	31	7.75
Often	142	35.50	173	43.25
Sometime	227	56.75	400	100.00

nq15	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Always	21	5.25	21	5.25
Never	109	27.25	130	32.50
Often	72	18.00	202	50.50
Sometime	198	49.50	400	100.00

Q16	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	101	25.25	101	25.25
2	98	24.50	199	49.75
3	66	16.50	265	66.25
4	43	10.75	308	77.00
5	79	19.75	387	96.75
6	13	3.25	400	100.00

nq17	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Always	49	12.25	49	12.25
Never	136	34.00	185	46.25
Often	46	11.50	231	57.75
Sometime	169	42.25	400	100.00

nq18	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Somewhat appropriate	64	16.00	64	16.00
Somewhat inappropriate	76	19.00	140	35.00
Very appropriate	36	9.00	176	44.00
Very inappropriate	224	56.00	400	100.00

The FREQ Procedure

nq19	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Agree	165	41.25	165	41.25
Disagree	30	7.50	195	48.75
Strongly agree	195	48.75	390	97.50
Strongly disagree	10	2.50	400	100.00

nq20	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Agree	159	39.75	159	39.75
Disagree	42	10.50	201	50.25
Strongly agree	184	46.00	385	96.25
Strongly disagree	15	3.75	400	100.00

nq21	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Agree	147	36.75	147	36.75
Disagree	33	8.25	180	45.00
Strongly agree	192	48.00	372	93.00
Strongly disagree	28	7.00	400	100.00

Q22

	Cumulative	Cumulative

nq25	Frequency	Percent	Frequency	Percent
Improper	41	10.25	41	10.25
Proper	259	64.75	300	75.00
Very improper	19	4.75	319	79.75
Very proper	81	20.25	400	100.00

nq26	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Improper	106	26.50	106	26.50
Proper	180	45.00	286	71.50
Very improper	53	13.25	339	84.75
Very proper	61	15.25	400	100.00

nq27	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Improper	114	28.50	114	28.50
Proper	168	42.00	282	70.50
Very improper	57	14.25	339	84.75
Very proper	61	15.25	400	100.00

nq28	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Improper	99	24.75	99	24.75
Proper	40	10.00	139	34.75
Very improper	238	59.50	377	94.25
Very proper	23	5.75	400	100.00

nq29	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Industry rate	192	48.00	192	48.00
Own rate	208	52.00	400	100.00

Q30_1	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	76	19.00	76	19.00
1	267	66.75	343	85.75
2	21	5.25	364	91.00
3	13	3.25	377	94.25
4	9	2.25	386	96.50
5	12	3.00	398	99.50
6	2	0.50	400	100.00

Q30_2	Frequency	Percent	Cumulative Frequency	Cumulative Percent
2	59	33.33	59	33.33
3	37	20.90	96	54.24
4	73	41.24	169	95.48
6	8	4.52	177	100.00

Frequency Missing = 223

Q30_3	Frequency	Percent	Cumulative Frequency	Cumulative Percent
3	13	26.53	13	26.53

4	27	55.10	40	81.63
6	9	18.37	49	100.00

Frequency Missing = 351

nq31	Frequency	Percent	Cumulative Frequency	Cumulative Percent
N	290	72.50	290	72.50
Y	110	27.50	400	100.00

Q32_1	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	30	28.04	30	28.04
2	7	6.54	37	34.58
3	4	3.74	41	38.32
4	63	58.88	104	97.20
5	3	2.80	107	100.00

Frequency Missing = 293

Q32_2	Frequency	Percent	Cumulative Frequency	Cumulative Percent
2	3	27.27	3	27.27
3	5	45.45	8	72.73
4	1	9.09	9	81.82
5	2	18.18	11	100.00

Frequency Missing = 389

Q32_3	Frequency	Percent	Cumulative Frequency	Cumulative Percent

Frequency Missing = 400

Analysis Q6

Q6	Private
Once a week - > once a week	257 (64.3)
Once a month – twice a month	92 (23.0)
Every 2 – 4 months	24 (6.0)
Once a year – twice a year	16 (4.0)
< once a year	11 (2.7)
Total	**400 (100)**

Analysis Q22, 23 and 24

Private

nq22	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	58	14.61	58	14.61
10000	24	6.05	82	20.65
1-1000	145	36.52	227	57.18
1001-2500	106	26.70	333	83.88
2501-5000	57	14.36	390	98.24
5001-7500	2	0.50	392	98.74
7501-10000	5	1.26	397	100.00

Frequency Missing = 3

nq23	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	68	17.22	68	17.22
10000	25	6.33	93	23.54
1-1000	134	33.92	227	57.47
1001-2500	82	20.76	309	78.23
2501-5000	75	18.99	384	97.22
5001-7500	2	0.51	386	97.72
7501-10000	9	2.28	395	100.00

Frequency Missing = 5

nq24	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	119	30.05	119	30.05
10000	24	6.06	143	36.11
1-1000	62	15.66	205	51.77
1001-2500	59	14.90	264	66.67
2501-5000	96	24.24	360	90.91
5001-7500	7	1.77	367	92.68
7501-10000	29	7.32	396	100.00

Frequency Missing = 4

CROSS TABULATION DEMOGRAPHICS AND ITEMS

The FREQ Procedure

Table of Q3 by nnq11

Q3(Q3)	nnq11		
Frequency Row Pct Col Pct	No	Yes	Total
GP	137 66.50 62.56	69 33.50 38.12	206
Specialist	82 42.27 37.44	112 57.73 61.88	194
Total	219	181	400

Statistics for Table of Q3 by nnq11

Statistic	DF	Value	Prob
Chi-Square	1	23.6896	<.0001
Likelihood Ratio Chi-Square	1	23.9155	<.0001
Continuity Adj. Chi-Square	1	22.7214	<.0001
Mantel-Haenszel Chi-Square	1	23.6304	<.0001
Phi Coefficient		0.2434	
Contingency Coefficient		0.2365	
Cramer's V		0.2434	

Fisher's Exact Test

Cell (1,1) Frequency (F)	137
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	8.447E-07
Table Probability (P)	5.450E-07
Two-sided Pr <= P	1.304E-06

Sample Size = 400

The FREQ Procedure

Table of Q3 by nnq15

Q3(Q3)	nnq15		
Frequency Row Pct Col Pct	No	Yes	Total
GP	46 22.33 42.20	160 77.67 54.98	206
Specialist	63 32.47 57.80	131 67.53 45.02	194
Total	109	291	400

Statistics for Table of Q3 by nnq15

Statistic	DF	Value	Prob
Chi-Square	1	5.1861	0.0228
Likelihood Ratio Chi-Square	1	5.1970	0.0226
Continuity Adj. Chi-Square	1	4.6870	0.0304
Mantel-Haenszel Chi-Square	1	5.1731	0.0229
Phi Coefficient		-0.1139	
Contingency Coefficient		0.1131	
Cramer's V		-0.1139	

Fisher's Exact Test

Cell (1,1) Frequency (F)	46
Left-sided Pr <= F	0.0151
Right-sided Pr >= F	0.9916
Table Probability (P)	0.0068
Two-sided Pr <= P	0.0249

Sample Size = 400

CROSS TABULATION BETWEEN QUESTIONS

The FREQ Procedure

Table of nnq7 by nnq8

nnq7	nnq8		
Frequency, Row Pct, Col Pct	No	Yes	Total
No	5 15.15 100.00	28 84.85 7.09	33
Yes	0 0.00 0.00	367 100.00 92.91	367
Total	5	395	400

Statistics for Table of nnq7 by nnq8

Statistic	DF	Value	Prob
Chi-Square	1	56.3099	<.0001
Likelihood Ratio Chi-Square	1	25.6858	<.0001
Continuity Adj. Chi-Square	1	44.7042	<.0001
Mantel-Haenszel Chi-Square	1	56.1692	<.0001
Phi Coefficient		0.3752	
Contingency Coefficient		0.3513	
Cramer's V		0.3752	

WARNING: 50% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Fisher's Exact Test

Cell (1,1) Frequency (F)	5
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	2.852E-06
Table Probability (P)	2.852E-06
Two-sided Pr <= P	2.852E-06

Sample Size = 400

The FREQ Procedure

Table of nnq9 by nnq10

nnq9	nnq10		
Frequency, Row Pct, Col Pct	No	Yes	Total
No	13 12.50 100.00	91 87.50 23.51	104
Yes	0 0.00 0.00	296 100.00 76.49	296
Total	13	387	400

Statistics for Table of nnq9 by nnq10

Statistic	DF	Value	Prob
Chi-Square	1	38.2429	<.0001
Likelihood Ratio Chi-Square	1	36.2940	<.0001
Continuity Adj. Chi-Square	1	34.3709	<.0001
Mantel-Haenszel Chi-Square	1	38.1473	<.0001
Phi Coefficient		0.3092	
Contingency Coefficient		0.2954	
Cramer's V		0.3092	

WARNING: 25% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Fisher's Exact Test

Cell (1,1) Frequency (F)	13
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	1.382E-08
Table Probability (P)	1.382E-08
Two-sided Pr <= P	1.382E-08

Sample Size = 400

The FREQ Procedure

Table of nnq11 by nnq12

nnq11	nnq12		
Frequency, Row Pct, Col Pct	No	Yes	Total
No	26 11.87 100.00	193 88.13 51.60	219
Yes	0 0.00 0.00	181 100.00 48.40	181
Total	26	374	400

Statistics for Table of nnq11 by nnq12

Statistic	DF	Value	Prob
Chi-Square	1	22.9824	<.0001
Likelihood Ratio Chi-Square	1	32.8133	<.0001
Continuity Adj. Chi-Square	1	21.0705	<.0001
Mantel-Haenszel Chi-Square	1	22.9250	<.0001
Phi Coefficient		0.2397	
Contingency Coefficient		0.2331	
Cramer's V		0.2397	

Fisher's Exact Test

Cell (1,1) Frequency (F)	26
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	7.718E-08
Table Probability (P)	7.718E-08
Two-sided Pr <= P	9.169E-08

Sample Size = 400

The FREQ Procedure

Table of nnq13 by nnq14

nnq13	nnq14		
Frequency, Row Pct, Col Pct	No	Yes	Total
No	19 20.43 95.00	74 79.57 19.47	93
Yes	1 0.33 5.00	306 99.67 80.53	307
Total	20	380	400

Statistics for Table of nnq13 by nnq14

Statistic	DF	Value	Prob
Chi-Square	1	60.7364	<.0001
Likelihood Ratio Chi-Square	1	51.1886	<.0001
Continuity Adj. Chi-Square	1	56.5776	<.0001
Mantel-Haenszel Chi-Square	1	60.5845	<.0001
Phi Coefficient		0.3897	
Contingency Coefficient		0.3631	
Cramer's V		0.3897	

WARNING: 25% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Fisher's Exact Test

Cell (1,1) Frequency (F)	19
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	3.203E-12
Table Probability (P)	3.165E-12
Two-sided Pr <= P	3.203E-12

Sample Size = 400

The FREQ Procedure

Table of nnq17 by nnq18

nnq17	nnq18		
Frequency, Row Pct , Col Pct	appropri,ate	inapprop,riate	Total
No	10 7.35 10.00	126 92.65 42.00	136
Yes	90 34.09 90.00	174 65.91 58.00	264
Total	100	300	400

Statistics for Table of nnq17 by nnq18

Statistic	DF	Value	Prob
Chi-Square	1	34.2246	<.0001
Likelihood Ratio Chi-Square	1	39.6366	<.0001
Continuity Adj. Chi-Square	1	32.8134	<.0001
Mantel-Haenszel Chi-Square	1	34.1390	<.0001
Phi Coefficient		-0.2925	
Contingency Coefficient		0.2807	
Cramer's V		-0.2925	

Fisher's Exact Test

Cell (1,1) Frequency (F)	10
Left-sided Pr <= F	4.237E-10
Right-sided Pr >= F	1.0000
Table Probability (P)	3.612E-10
Two-sided Pr <= P	5.392E-10

Sample Size = 400

Appendix E

Abbreviations and Acronyms

AAMC – Association of American Medical Colleges
ABPI – Association of British Pharmaceutical Industry
ACGME – Accreditation Council for Graduate Medical Education
AMA – American Medical Association
CME – Continuing Medical Education
CPD – Continuing Professional Development
DoH – Department of Health
ERC – Ethics Review Committee
GMC – General Medical Council
HPCSA – Health Professions Council of South Africa
IMSA – Innovative Medicines South Africa
MCA – Marketing Code Authority
PhRMA – Pharmaceutical Research and Manufacturers of America
PIASA – Pharmaceutical Industry Association of South Africa
RCP – Royal College of Physicians
SAMA – South African Medical Association

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