

**A survey to determine the perception of registered
homoeopaths in South Africa toward the availability of
over the counter (OTC) homoeopathic medicines.**

By

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This mini-dissertation was submitted for examination in partial compliance with the requirements for the Master's Degree in Technology: Homoeopathy, in the Faculty of Health Sciences at the Durban University of Technology.

I, Tymara Catheryn Broughton, do hereby declare that this dissertation is representative of my own work, both in conception and execution.

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ABSTRACT

Introduction

Discussion among homoeopaths in South Africa provides the impression that there is a degree of misunderstanding and ignorance about homoeopathy, and opinions are varied on its application and efficacy amongst the South African public. An over the counter (OTC) medicine, is a medicine which is sold without a prescription directly to the public, which includes homoeopathic medicines. OTC medicines may be sold at any retail outlet, i.e. a pharmacy or general store. There is much evidence pointed towards the growth and rise in over the counter sales in complementary and alternative medicine, a growth of more than 17% in total, homoeopathy is a major part of the complementary and alternative medicine group, having its own growth of more than 16% over a four year period. Self-medication in the form of over the counter medicines forms the main part of this industry (Caldis, 2000).

The market was previously examined by the Mintel Group for complementary medicines and its growth in sales, in April 2003. Since then, the market has continued to expand, growing by 45% in real terms from 1999 to 2004.

Greater consumer awareness of alternative medicines, an interest in healthy lifestyles, and the willingness to self-medicate certain conditions have all contributed to the increased value of sales (Mintel, 2005).

Whenever the economic and public health benefits of self-medication are discussed, it is important to address inequalities in health. This means that not every citizen may feel sufficiently confident to practice responsible self-medication. It is also evident that not everybody has the financial means to do

so. The whole notion of responsible self-medication both in a traditional sense and in the future is based on the concept of choice. Allowing individuals certain options when they suffer minor, self-limiting or chronic diseases is the fundamental consideration behind responsible self-medication (AESGP, 2004).

Methodology

A non-experimental descriptive survey was conducted to determine the perceptions of registered South African Homoeopaths regarding the availability of over the counter homoeopathic remedies. A self-administered questionnaire was distributed and 68 anonymous responses were obtained. Raw data was analysed using descriptive statistics and the relationships between variables tested for correlations.

Results

Respondents perceived homoeopathic OTC medicine sales and their availability in health shops and pharmacies, as contributing to the promotion of the profession as well as increasing its accessibility to the public. Other benefits perceived were the cost effectiveness of homoeopathic OTC medicines and convenience for home usage.

The majority of respondents felt that there should be certain restrictions regarding the availability of OTC homoeopathic medicines, such as, the limitations regarding the availability of certain potencies. Participants also expressed concern over the degree of training held by retail outlet staff. Certain respondents felt that homoeopathic medicines should only be

available with a prescription or used under the guidance of their practitioner. Other negative aspects of over the counter homoeopathic medicines were: incorrect use of medication, overdosing, and potential negative effects the patient may experience if the OTC medicine interacts with other medication, as well as the concern over the risks of self-medicating without the advice from a practitioner.

Conclusions and recommendations

The majority of respondents were in favour of the availability of homoeopathic OTC medicines to the public, provided that they are suitably regulated to ensure patient safety and quality control. Furthermore the regulation of the relevant retail outlets including education of staff in this regard was recommended. Respondents also were in favour of the awareness of the profession that homoeopathic OTC medicines created.

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Definition of Terms

Allied Health Professions Council of South Africa (AHPCSA)

Allied Health Professions Council of South Africa is a statutory council for Natural Health, responsible for the promotion and protection of the health of the population of South Africa and will affect this by regulating and setting standards for the various professions, under act 63 of 1982 (Babaletakis, 2007).

Complementary medicine

A broad term encompassing those forms of treatment which are not widely used by the orthodox health care professions, and the skills of which are not taught as part of the undergraduate curriculum of the orthodox medical courses (Sweidan, 2007).

Food and Drug Agency of the United States of America (FDA)

FDA is the federal agency responsible for ensuring that foods are safe, wholesome and sterile; human and veterinary medicines, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe. FDA also ensures that these products are honestly, accurately and informatively represented to the public (FDA, 2008).

Good manufacturing practice (GMP)

This is a term that is recognised worldwide for the control and management of manufacturing and quality control testing of foods and pharmaceutical products (Natura, 2007).

Hahnemann

Samuel Hahnemann was the founder of homoeopathy (De Scheeper, 2001).

Health Products Association of South Africa (HPA)

The Health Products Association of South Africa, it represents the manufacturers of complementary medicines in South Africa (HPA, 2006).

Homoeopathic Association of South Africa (HSA)

The current body representing registered homoeopaths and homoeopathic students, and their interests (Babaletakis, 2007).

Homoeopathic medicine

Homoeopathic medicine is a holistic system of treatment; the name homoeopathy is derived from two Greek words, homeo (similar) and pathos (suffering). Together it means “like disease”. The system is based on the principles that substances which produce symptoms of sickness in healthy people will have a curative effect when given in much diluted quantities to sick people who exhibit those same symptoms (De Scheeper, 2001).

M.Tech.Hom (M.Tech: Homoeopathy)

A Master's Degree in Technology in homoeopathy, which is offered at Durban University of technology and the University of Johannesburg (Durban University of Technology, 2008).

Medicines Regulatory Authority (MRA)/ Medicines Control Council (MCC)

The Medicine Regulatory Authority, South Africa has developed a medicine regulatory authority with internationally recognized standing; it has been transformed in order to improve its performance and regulatory processes.

The Medicines Control Council (MCC) is a statutory body that was established in terms of the Medicines and Related Substances Control Act, 101 of 1965.

The Medicines Control Council applies standards laid down by the Medicines and Related Substances Control Act, (Act 101 of 1965) which governs the manufacture, distribution, sale, and marketing of medicines. The prescribing and dispensing of medicines is controlled through the determination of schedules for various medicines and substances (MCC, 2008).

Orthodox medicine

A system in which medical doctors and other healthcare professionals (such as nurses, pharmacists and therapists) treat symptoms and diseases using medicines, radiation, or surgery. Also called conventional medicine, western medicine and allopathic medicine (Medicinenet, 2008).

OTC homoeopathic medicine

OTC (over-the-counter): Available without a prescription. OTC homoeopathic medicines are available without a prescription, simply "over the counter." OTC homoeopathic medicines are in contrast to prescription medication that requires a doctor's order/signature (MedicineNet, 2006).

Pharmaceutical Inspection Convention (PIC)

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international associations between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP (Good Manufacturing Practice) (PIC/S, 2008).

Pilot Study

A preliminary study to assess the validity of an intended future study (Fink, 1995).

Retail

The sale of goods or commodities in small quantities directly to consumers (Natura, 2007).

CHAPTER 1

1.1 Introduction

Discussion among homoeopaths in South Africa provides the impression that there is a degree of misunderstanding and ignorance about homoeopathy, and opinions are varied on its application and efficacy amongst the South African public. There is much evidence pointed towards the growth and rise in sales of the complementary and alternative medicine industry, a growth of more than 17% in total, with homoeopathy as a part of the industry having its own growth of more than 16%, over a four year period (from 1996 to 1999), in South Africa. Self medication as an over the counter medicine forms a major part of the complementary and alternative medicine industry; this industry is thoroughly marketed in the local and international media. Use of over the counter medication is very popular as it is so widely and readily available to the public (Caldis, 2000).

Complementary therapies are well positioned as consumers become dissatisfied with conventional medicine and seek cures that also promote well-being (Datamonitor, 2001).

Historically there have been regulatory problems associated with complementary medicines. In recent years there have been influxes of a great number of herbal and other complementary health products onto the market. As there was no appropriate regulatory systems in place for these products,

the sales of these products are relatively uncontrolled resulting in a “grey market” in complementary medicines (Caldis, 2000).

Part of the problem essentially stems from the fact that the Medicines Control Council (MCC) has been faced with too many new therapies/modalities simultaneously. In addition, coming from a biomedical paradigm it meant that it was very difficult for the MCC to comprehend many of these new therapies and their respective “medicines” as they were not fully understood by the council (Caldis, 2000).

It is important to understand that in many cases these ‘new’ medicines which are coming into the South African market are not new, but are substances with demonstrated efficacy and safety for many years in other parts of the world, and that they have formed the basis of an established healthcare philosophy (Caldis, 2000). Caldís (2000) states that the requirement for double blind testing of each substance is clearly not practical or necessary considering the fact that unlike new pharmaceuticals, these substances are certainly not new.

According to Caldís (2000), the costs involved to try and begin to fund such events (double blind testing), will be millions and millions of rands. There are thousands of products from all sectors, not just homoeopathy that will require double blind testing and there are no funds to support such a task, nor is there time, to do so. The process could take many years to complete during which patients would potentially be deprived of access to such complementary

medicines, thus the completion of such a task may have negative consequences for the general public's health.

The Health Products Association of South Africa (HPA) is an association of 75 manufacturers, importers and distributors of complementary medicines or "health products". These members comprise mostly of the complementary medicines market and include representatives of individual companies. The HPA's objective is to organise all industry as a unified voice in liaison with government bodies in dealing with legislation and regulation (Caldis, 2000).

In an HPA survey, it was shown that during the period 1996 to 1999 of the general health products turnover, homoeopathic medicine (including tissue salts) had grown by 168%, from R11 million to R30 million. In this time period it was established that the growth was R6.3 million per annum (Caldis, 2000).

According to the most recent survey done by the Health Products Association (HPA) of South Africa, from a period between 2001 to 2003, homoeopathy had experienced a growth of 16.4 % being the equivalent of R61 million.

Aromatherapy and Herbals were the only two categories out of six to experience a financial decline in sales compared to the other four, which includes energy and nutritional supplements, foods and homoeopathy.

Homoeopathic medication comprised 4% of the shareholders sales in the year 2003, with nutritional supplements being the highest component at 53% (Health Products Association of South Africa market survey, 2001, 2002, and 2003).

Caldis (2000) states that other evidence to show that consumption of complementary medicine is on the increase is further illustrated by the increasing number of publications covering this topic and their increasing circulation figures. In addition, established mainstream publications are finding readers demand a higher content of articles covering complementary medicines.

The practice of Complementary and Alternative Medicine (CAM) has become increasingly popular over the past few years. Up to 58% of general practitioners use CAM to treat their patients and in 1999 five million patients consulted a complementary practitioner. By 2002 the Royal Pharmaceutical Society predicts that retail sales of herbal, homoeopathic preparations and aromatherapy oils will total £126 million in the United Kingdom (Zollman, 2004). Use of OTC medicine is by far the most common curative action consumers take. It is especially popular for cough/cold/flu complaints and allergy/sinus problems (Datamonitor, 2002).

The Mintel International Group Ltd. previously examined the market for complementary medicines in April 2003. Since then, the market has continued to expand, growing by 45% in real terms from 1999 to 2004. Greater consumer awareness of alternative medicines, an interest in healthy lifestyles, and the willingness to self-treat certain conditions have all contributed to increased value sales (Mintel, 2006).

Responsible self-medication considerably reduces the expenses of medical and healthcare costs for national economies. Based on a detailed analysis of seven European countries, total annual savings resulting from a move of 5% of prescribed medications to self-medication exceed 16 billion Euros. This demonstrates that self-medication makes a significant contribution to relieving the financial burden of the European healthcare systems (AESGP, 2004).

Doctor-related costs affect different parties in different ways depending on the healthcare system in a particular country. In some countries, doctors are paid a consultation fee by the patient. Thus the doctor loses such a fee when a patient chooses to self-medicate. In other countries, doctors are remunerated by public funds on the basis of points awarded for different forms of consultation, in which case self-medication also reduces the doctor's income (AESGP, 2004).

A public shift to self-medication would also have an impact on doctors' time. Fewer consultations on minor illnesses would free up time that could be spent on longer consultations for more serious conditions and reduce waiting time in the doctor's surgery, thus providing a real impact on the quality of care. Patients who self medicate tend to spend more money on their medication, as they do not have to contribute to the cost of the medication through medical aid on prescribed medication that are levied in certain countries (AESGP, 2004).

It has been assumed that people are absent from work for a shorter period of

time when they practice responsible self-medication than when they go to see a doctor as they generally return to work sooner without an official endorsement from a doctor that they are ill (AESGP, 2004).

Traveling to the doctor and the pharmacy involves time and transportation costs. It has been proven that patients spend less time going to the pharmacy than going to the doctor, and that travel-related costs are also higher when going to both the doctor and the pharmacy than only to the pharmacy (AESGP, 2004).

1.2 Aim of the study

The aim of this survey was to determine the perception of registered homoeopaths in South Africa toward the availability of over the counter (OTC) homoeopathic medicines, by means of a self administered questionnaire.

1.3 Objectives of the study

1. To determine the general attitudes towards the availability of OTC homoeopathic medicines.
2. To determine the proportion of registered homoeopaths using OTC homoeopathic medicines.
3. To view current trends on the dispensing and use of homoeopathic OTC medicines among registered homoeopaths in South Africa.
4. To view the relationship between the demographic and practice detail variables, and the responses given by respondents.

CHAPTER 2

Literature Review

2. Homoeopathy

2.1. Brief History of Homoeopathy

The term homoeopathy comes from the Greek words *homeo*, meaning similar, and *pathos*, meaning suffering or disease. Homoeopathy seeks to stimulate the body's defence mechanisms and processes so as to prevent or treat illness. Treatment involves giving very small doses of substances called remedies that, according to homoeopathy, would produce the same or similar symptoms of illness in healthy people if they were given it in larger doses.

Treatment in homoeopathy is individualized (tailored to each person).

Homoeopathic practitioners select remedies according to a total “holistic” picture of the patient, including symptoms but also lifestyle, emotional and mental states, and other factors such as dreams (Whorton, 1987).

The foundation of homoeopathy is “like cures like”; a principle meaning that a substance that can produce certain symptoms in healthy people can cure the same symptoms in the sick (Stehlin, 1995). In the late 1700's, Samuel Hahnemann, a physician, chemist, and linguist in Germany, proposed this new approach to treating illness (Stehlin, 1995). This was at a time when the most common medical treatments were harsh, such as bloodletting, purging, blistering as well as the use of crude forms of sulphur and mercury (Stehlin,

1995). According to Stehlin (1995) at the time, there were few effective medications for treating patients, and knowledge about their effects was limited.

Hahnemann, the founder of homoeopathy, arrived at this conclusion from firsthand experience. Hahnemann was interested in developing a less-threatening approach to medicine. The first major step reportedly was when he was translating a herbal text and read about a treatment (Cinchona bark) used to cure malaria. He took some cinchona bark and observed that, as a healthy person, he developed symptoms that were very similar to malaria symptoms. This led Hahnemann to consider that a substance that may create symptoms in a healthy person may also relieve in a sick one. This concept is called the "similia principle" or "like cures like." The similia principle had a prior history in medicine. Hippocrates known as the "father of medicine" in ancient Greece noted, for example, that recurrent vomiting could be treated with an emetic (such as Ipecacuanha) that would be expected to make the condition worse. Another way to view "like cures like" is that symptoms in a diseased patient are part of the body's attempt to heal itself e.g., a fever can develop as a result of an immune response to an infection, and a cough may develop in order to eliminate mucus thus medications should be given which support this self-healing response (Whorton, 1987).

According to Whorton (1987), it is through the use of natural substances either plant, animal or mineral, homoeopathic medicines seek to cure in accordance with natural laws of healing. Pharmaceutically prepared in very small doses, homoeopathic medicines work with the body's natural defenses

to heal itself and help maintain balance and health. These remedies are safe and effective for children and adults with no known side effects.

Hahnemann added two additional key elements to homoeopathy:

A concept that became known as "potentization", which holds that by systematically diluting a substance, with vigorous shaking at each step of dilution, a remedy is rendered more effective, by extracting the vital essence of the substance. Secondly was the concept of "dilution", if the dilution continues to a point where the substance's original molecules are no longer physically present, homoeopathy holds the "memory" of the molecules, that is, the effects they exerted on the surrounding water molecules may still be therapeutic (Stehlin, 1995).

2.2 The homoeopathic simillimum

This is the single remedy that corresponds to the totality of symptoms/the drug picture. It is the most similar remedy corresponding to the case, one covering the true totality of the patients symptoms, and when found, is always curative, and in incurable cases, it is the best possible palliative remedy. The simillimum is the remedy that best matches the patient's symptoms and is most likely to cure those symptoms based on the principle of 'like cures like' (Gaier, 1991).

2.3 The totality of symptoms

Hahnemann states that the totality of symptoms, points to the curative medicine, because that totality, the holistic aggregate, is the image which

outwardly reflects the internal disease process and the corrective reaction of the dynamis. The homoeopath should cover the majority of the patient's signs and symptoms (including non-verbal things like mannerisms and facial expressions) and find a corresponding drug picture (Yasgur, 1998).

According to Paruk (2006), the accuracy of homoeopathic prescribing is dependant upon the similarity between the characteristics of the medicine and the individual characteristics of the patient's illness. Homoeopathic prescriptions are thus individualized to the patient.

2.4 A homoeopathic remedy

The Allied Health Professions Council (1982) proposes that any substance, mixture of substances, preparation, compound, product, device or thing which is compounded and manufactured in accordance with homoeopathic principles, techniques or philosophy is considered a homoeopathic remedy. The remedy is obtained by method of successive dilution and succussion and/or trituration whether achieved manually, mechanically, or electronically including radionics or by whatever means or whatever scale of dilution.

A homoeopathic remedy, remedies a situation, it remedies symptoms which are the expression of a disease in a patient (Yasgur, 1998).

2.4.1 Simplex remedies

For the homoeopath practicing, in order for them to match an appropriate drug picture to a particular disease picture, only one medicine can ever be truly homoeopathic to the presenting illness at any one time. Therefore, single

remedies, and not combinations, should be administered to patients. This is so since remedies were proved singly and not as mixtures, and combinations of remedies may well present reactive effects which are different from their constituting medicines individually (Gaier, 1991).

2.4.2 Combination Remedies/Polypharmacy

In contrast to simplex remedies, Yasgur (1991) states that a complex remedy, it is a homoeopathic product which contains more than one remedy. The administration of more than one remedy at a time either through giving a number of single remedies at the same time or giving a combination homoeopathic product. This needs to be differentiated from the other use of this term, namely when two remedies are combined into one, this new substance exhibits both constituents as well as its own characteristics. Two elements in combination may yield predictable symptoms as well as unique and unpredictable ones.

Research has shown that patent medicines (combination remedies) are more dangerous than simple drugs (a single remedy), because they are usually a throwing together of a number of remedies to cover a very large range of symptoms, and hence are more injurious because of a greater disturbance of the vital force (Yasgur, 1998).

Studies have found that pharmacists provide some homoeopathic combinations for simpler cases on an over the counter basis, prescribing them pathologically, in preference to non-homoeopathic medicines that may produce injurious reactions. There may be a problem of possible antidotal

effects between simultaneously administered homoeopathic drugs of similar action. Another predicament which may arise out of the concomitant non-individualization in such 'homoeopathic shotgun' prescriptions is the total therapeutic ineffectiveness (Gaier, 1991).

2.5 Potency

According to Gaier (1991), it is the stage of altered remedial activity to which a drug has been taken by means of a measured process of deconcentration, with succussion, or by trituration, of the medicinal substance, which is then brought to a state of diminutive infinitesimal subdivision. This process, if performed according to the prescribed homoeopathic pharmacopeias for potentization (dynamization), increases both the physical solubility and the physiological assimilability of the drug, while also changing its therapeutic activity as a homoeopathic remedy.

The lowest possible homoeopathic potency is known as the mother tincture, it is a drug solution (alcoholic, hydro alcoholic, aqueous or glyceric) prepared in accordance with homoeopathic pharmacopoeial standards. In preparing the homoeopathic mother tincture, the quantity of the original drug and the carrier/vehicle are proportioned with very few exceptions, in such a way that it should represent one tenth (1/10) of the original drug, thus mother tincture = 1D (Gaier, 1991).

The object of homoeopathic pharmacy is to prepare each substance that the whole of its reaction-eliciting qualities should be retained in a suitable form.

The resulting product, the drug base also known as the mother tincture. A

mother tincture can then be further subdivided with homoeopathic dilutes such as alcohol, aqua distillata, or by triturating it with sugar of milk (lactose).

These divisions of the substance are attenuations that, if succussed at intervals, are called potencies or dynamizations. In dynamizing there are different scales that are used: decimal, centesimal, 50-millesimal and korsakovian (Gaier, 1991).

Gaier (1991) has found that when treating a patient it is necessary to administer the correct potency with the correct remedy. The lowest useful homoeopathic potency for medicines that are practically inert in the crude state usually corresponds to the 8D, as it does for colloids and lithotherapeutic agents. It is also seen that highly toxic drugs only show alternative properties above their 'aggressive range' which is upward from about the 10D.

When producing a remedy one must take into account the use of Avogadro's Number, this is a constant number of molecules in a mole of any substance; its value 6.02252×10^{23} mol⁻¹. Mole is the amount of substance that contains as many atoms as there are atoms in 12g of ¹²C, the most abundant isotope of carbon. The Avogadro limit is reached at 12CH or 23DH potency, and in potencies that are higher than these, there is not a single molecule of the original base substance or mother tincture expected to remain in the remedy (Gaier, 1991).

Studies have shown that a remedy, when it is well indicated in terms of the law of similars, should always respond, as long as it is the appropriate remedy. Hahnemannian potencies from tinctures or base drug to 3CH or 6D

are classified as 'low'; above that up to 12CH or 24D as 'medium'; then above that up to 30CH or 60D as 'high'; and beyond that as 'very high' (Gaier, 1991).

According to Bartel (1991), limits have to be set in terms of prescribing and self-medicating with homoeopathic medicines, as the power of the medicines can be increased to a point (potency too high) where there is overstimulation for the patient. For this reason, a homoeopathic medicine may be more harmful if the dose is too large.

2.5.1 The Hahnemannian method

The Hahnemannian method requires the use of a fresh phial at every stage of dynamization (Gaier, 1991).

2.5.1.1 The Decimal scale

The decimal scale (denoted by the symbol D) means that all succeeding attenuations are prepared by adding one part of the preceding potency to nine parts of dilute alcohol and succussing it ten times at every stage (Gaier, 1991).

2.5.1.2 The Centesimal scale

The centesimal scale (denoted by the symbol C) is when a person adds 99 parts of dilute alcohol to one part of the previous level of dynamization, succussing ten times, to make the subsequent potency. All succeeding attenuations are prepared by adding one part of the preceding dynamization to 99 parts of the dilute alcohol and succussing it ten times at every stage (Gaier, 1991).

2.5.2 The Korsakovian scale

Korsakovian scale was introduced by General von Korsakoff from Russia, denoted by the symbol K. This method requires the use of just one phial throughout the dynamization process, it takes less effort, and it is inexpensive and takes up less storage space. This method has demonstrated to be inaccurate as there are considerable variations in the rate of molecular deconcentrations between potencies (Gaier, 1991).

2.6 Homoeopathic dosage forms

The administration of medicine in doses, being the administration of a definite quantity of medicine taken, or applied, all or at one time, or over a period of time is known as a dose. The dosage forms or pharmaceutical forms used in homoeopathic practice are: granules, pilules, tablets or globules – these are all forms of lactose, but they vary in size and shape. There are solutions, mother tinctures and low potency solutions (e.g. 2DH). These are usually in liquid form and are based in either aqua distillata or alcohol. Then there are creams, ointments, eyedrops, lotions, mouthwashes, liniments, injectables, peccaries, suppositories, inhalation capsules and powders; these tend to be used on a 'required' basis and are usually combined with systemic medicines (Gaier, 1991).

2.7 Prescription errors

According to Gaier (1991) if the inappropriate homoeopathic remedy is given it generally fails to elicit any response in a patient as homoeopathic remedies have been shown to have no side effects. Although there are rare occasions

when there is a patient who happens to be particularly sensitive to the remedy given, it may produce a very active response it can be anxiety-inducing in the patients, such a remedy may just bring to the surface previously suppressed symptoms.

2.8 South African legislation governing OTC medication

According to the Medicines and Related Substances Control Act (MRSCA), Act no. 101 of 1965, as amended and its regulations, no medicine may be traded unless it has a relevant marketing authorization or is compounded by a pharmacist or a suitably qualified practitioner during the normal course of their duties. Furthermore, it also schedules substances and indications into schedules from 0 to 9, based on the type of ingredients, what they are used for and the circumstances under which the product may be dispensed or sold (i.e. in health shops / by pharmacists / on prescription only).

Furthermore, the MRSCA, Act no.101 of 1965, states that pharmacists and practitioners with the relevant dispensing licenses may, according to the requirements and restrictions of their own respective acts, prepare and dispense medicines for individual patients in patient specific quantities. The provision for this type of dispensing is set in the Medicines Control Act, Act 101, which requires that practitioners have licenses in order to dispense. The requirements of the dispensing process are set annually by the Pharmacy Council and legislated in the Pharmacy Act, which controls pharmacists and the processes of manufacturing and dispensing medicines. These provisions are included in a pharmacist's normal training and laid out for homoeopathic

practitioners in a dispensing and compounding guideline. Homoeopathic practitioners are also restricted in the medicines/substances that they may prescribe or dispense by their own Acts, which is the Allied Health Professions Act. This does not relate to OTC medicines, as it is restricted to medicines prepared on a patient specific basis.

The MRSCA, Act no.101 of 1965, also proposes that medicines, which have obtained marketing authorizations from the Medicines Regulatory Authority through the medicine registration process defined in Act 101, may be sold in retail (including "OTC medicines") trade which is subject to the restrictions and stipulations of the marketing authorization. This registration process requires that the manufacturer has suitably demonstrated that the product is safe and is efficient for the indications claimed, as well as that it can be manufactured to a consistent quality under conditions defined as "Good manufacturing practices" (GMP) with all the necessary quality control and quality assurance checks. The stipulations for GMP are laid down in the South African Good Manufacturing Practices Guide, and/or the Pharmaceutical Inspection Convention (PIC) Guide, which describes all the areas, steps, processes, controls, and checks that must be followed during the process of manufacturing a medicine in order to achieve GMP approval. The actual stipulation of how the medicine must be labelled and the information which must appear on the immediate primary and secondary packaging materials and which may be allowed on advertising material is contained in Act 101, its regulations and associated guidelines.

Another proposal by this Act states that “OTC medicines”, refers to medicines within the schedules 0 – 2 which may be sold without prescription in open retail shops, i.e. pharmacies (schedule 0 in health shops and other general retail outlets) and which should have marketing authorizations from the Medicine Regulatory Authority (MRA). Complementary medicines are further divided into 9 subcategories based on the different philosophies of complementary medicine. Homoeopathic medicines form one category. However, the regulations and guidelines of this Act 101 have not been sufficiently developed to allow for the reasonable attainment of a marketing authorization. Hence, although all the above technically applies to OTC homoeopathic medicines, the MRA is unable to reasonably restrict trade simply because it cannot provide a correct regulatory process and as a result it has had to endure the marketplace being flooded with “complementary medicines” which it has been unable to control. But current reports suggest that new legislation is imminent, and these regulations will have stricter guidelines regarding the: labelling requirements, permitted wording, ingredients and claims made.

Although the content of advertisements is stipulated in Act 101 and would normally be limited by the marketing authorization granted, the Advertising Standards Authority has also laid down restrictions for OTC medicines. These are most relevant to complementary medicines, which currently do not have a system for awarding proper marketing authorization (Medicines and Related Substances Control Act, 1965).

There are currently no specific regulations and guidelines controlling any of the categories of complementary medicines, which include homoeopathic simplexes. The existing law, the MRSCA, Act no.101 of 1965, handles the channels through which a medicine may be sold through scheduling of the medicine or substance:

- Schedule 0 medicines can be sold freely in open shop, supermarkets, and health shops.
- Schedule 1 must be sold under the supervision of a pharmacist from "behind the counter".
- Schedule 2 must be sold under the supervision of a pharmacist but may be sold without a doctor's prescription.
- Schedule 3 onwards: are prescriptions only with increasing levels of control (Van Wyk, 2007).

2.8.1 Legislation regulating homoeopathic OTC medicines

Van Wyk (2007) advises that in the case of simplex OTC homoeopathic medicines, if the starting substance from which the remedy was prepared is scheduled at level 2 or higher (according to the existing schedules), then in terms of current law the sale of the OTC homoeopathic remedy would be prohibited. Thus only homoeopathic simplexes which are derived from crude substances which themselves have been scheduled are restricted from being sold OTC.

The new regulations anticipated in the forth coming years have been in development for the last 20 years (since 1986). Industry, the regulatory

authorities and all other relevant stakeholders such as government, have been actively involved in its development. It is anticipated that the new regulations will allow the retail sale of a certain range of OTC homoeopathic simplexes determined by potency. The proposed range would include safe low potencies (taking into account toxicity of very low potencies derived from toxic starting materials), up to a maximum potency of 30CH (based on the theory that these are deeper acting remedies and belong in the realm of the practitioner). While this is not yet law, it is a guideline all responsible manufacturers and distributors of complementary medicines adhere to which is why potencies above 30CH are seldom found in retail, except in combination products which were on the market prior to the proposal. Currently however there is no law prohibiting a pharmacist from dispensing an unscheduled substance of any potency to a patient (Van Wyk, 2007).

2.9 Packaging of Homoeopathic medicines

The South African guide to GMP (2004), states that packaging operations must follow clearly defined written procedures in order to produce finished products of the required quality and must comply with their authorized packaging documents as well as all legal requirements. This includes special attention must be paid to labels and labelling throughout the entire packaging cycle. This is because of their often complex and variable nature, and the number and small quantity of defined active ingredients, control of starting materials, storage and processing assume particular importance in the manufacture of homoeopathic/herbal medicinal products. Quality control

personnel should have particular expertise in herbal medicinal products in order to be able to carry out identification tests and recognize adulteration, the presence of fungal growth, infestations, non-uniformity within a delivery of crude plants. The guideline also states that only authorized personnel following an approved and documented procedure should issue packaging materials for use and that each delivery or batch of printed or primary packaging material should be given a specific reference number or identification mark. Furthermore, outdated or obsolete primary packaging material or printed packaging material should be destroyed and this disposal recorded.

In addition, this guideline highlights that finished products must be placed in quarantine in such a way that they cannot be removed for use until such time as they are released. Samples of the product taken at intervals during the packaging process must be retained for examination by the Quality Control laboratory and for retention purposes. Documentation should be reconciled, completed/and sent for a complete documentation audit by quality assurance. When all required parameters are satisfied, including the document audit, Quality Control may recommend release of the product from its quarantine status. A pharmacist should release the finished product for sale.

2.9.1 Storage of homoeopathic remedies

Potentised medicines or dilutions that may be impregnated in carriers such as alcohol or saccharose and stored in bottles may be affected in stability. In physics, coherence is the occurrence of certain, temporarily unchangeable

correlations between phases of overlapping waves. This means that these waves allow for interference of the homoeopathic medicines therapeutic effect, waves such as microwaves, cell phones etc. Experience has shown that that Camphora and any products with Menthol/Mint can counter the effects of a homoeopathic medicine, but patients are generally not informed of these facts, via leaflets or labelling in OTC packaging (Hulman, 1995).

2.10 Dispensing regulations of OTC homoeopathic medicines

The South African guide to GMP (2004) proposes that starting material should only be purchased from approved suppliers and in accordance with the registration dossier. Starting materials in the storage area should be appropriately labelled. Labels should bear at least the following information:

- (a) The designated name of the product and the internal code reference,
where applicable
- (b) A batch number given at receipt of goods
- (c) Where appropriate, the status of the contents (e.g. in quarantine, on test,
released, rejected)
- (d) Where appropriate, an expiry date or a date beyond which retesting is
necessary.

There should be appropriate procedures or measures to assure the identity of the contents of each container of starting material. Bulk containers from which samples have been drawn should be identified. Only starting materials which have been released by the Quality Control Department and which are within their shelf life should be used. Starting materials should only be dispensed by

designated persons, following a written procedure, to ensure that the correct materials are accurately weighed or measured into clean and properly labelled containers. Each dispensed material and its mass or volume should be independently checked and signed for by a pharmacist or other legally authorized person.

2.11 The use of OTC homoeopathic medicines

A survey on the use of OTC homoeopathic medicines was conducted by Reid (2002) in Manchester, Great Britain. The objective was to: obtain data on conditions treated by OTC homoeopathy; its perceived effectiveness; the length of time respondents had used OTC homeopathic medicines, whether respondents combined them with prescription medicines and their reasons for using OTC homeopathic medicines. The most frequent applications were respiratory, mental/psychological ailments and bruises/injuries. Various respondents perceived OTC homeopathic medicines to be effective for relieving these conditions. There was a trend for respondent's first using OTC homeopathic medicines over four years previously. Thirteen per cent of respondents combined it with their prescription medicines. One of the most strongly endorsed reasons for using OTC homoeopathy was that it was a natural treatment and was perceived as harmless.

According to Kayne (2001), there are three levels of dosing appropriate to homoeopathic self-treatment:

1) First aid level – this includes the first treatment given for an acute problem, as well as first aid for an injury. In this situation, one would recommend 2 tablets of the prescribed homoeopathic remedy every 15 minutes to 2 hours depending on the severity on the condition for about 6 doses. Children should be given one tablet as a dose in these cases.

2) Acute conditions - this is a condition a patient may have had for a few days (i.e. constant repetitive sneezing). For this, a homoeopathic practitioner would recommend taking 2 tablets 3 times a day for 7-10 days. If the condition is not substantially better, advice should then be sought from a homoeopathic practitioner.

3) Chronic conditions –these may be conditions that lend themselves to self-treatment, for example a person who still has a bruise after sustaining a blow to the leg six weeks ago. This however does not apply to long-term medical conditions, such as Rheumatoid Arthritis. But an appropriate dose would be 2 tablets twice daily for about 4 weeks.

With regard to homoeopathic potency, generally the more acute the condition; the higher the potency should be prescribed. This may vary depending on the individual practitioner's advice and past experience, also from what is seen in textbooks. Typically, 6CH is used for chronic conditions and 30CH is used for acute conditions (Kayne, 2001).

2.12 Legislation governing OTC medicines in the USA

The National Centre for Complementary and Alternative Medicine (2003) highlighted that the U.S. Congress passed a law in 1938 declaring that homoeopathic remedies are to be regulated by the FDA in the same manner as non-prescription, OTC medicines, which means that they can be purchased without a physician's prescription. Although currently conventional prescription medicines and new OTC medicines must undergo thorough testing and review by the FDA for safety and effectiveness before they can be sold, but this requirement does not apply to homoeopathic remedies.

Furthermore the NCCAM (2003) also states that remedies are required to meet certain legal standards according to strength, quality, purity, and packaging. In 1988, the FDA required that all homoeopathic remedies list the indications for their use (i.e., the medical problems to be treated) on the label. The FDA also requires the label to list ingredients, dilutions, and instructions for safe use.

The guidelines for homoeopathic remedies are found in an official guide, the *Homoeopathic Pharmacopoeia of the United States*, which is authored by a non-governmental, non-profit organization of industry representatives and homoeopathic experts. The *Pharmacopoeia* also includes provisions for testing new remedies and verifying their clinical effectiveness. Remedies on the market before 1962 have been accepted into the *Homoeopathic Pharmacopoeia of the United States* based on historical use, rather than scientific evidence from clinical trials (NCCAM, 2003).

Similarly to the South African process of producing homoeopathic remedies, the manufacturer has to suitably demonstrate the products safety and efficacy for the indications claimed. Stipulations concerning “good manufacturing practices” (GMP) are laid down in the South African Good Manufacturing Guide, and in the Pharmaceutical Inspection Convention Guide (PIC), these describe all the steps, processes, controls and checks to be followed in order for the approval of manufacturing the medicine (Medicines and Related Substances Control Act, 1965).

2.13 Safety of homoeopathic OTC remedies

According to NCCAM (2003), homoeopathic medicines in high dilution, taken under the supervision of trained professionals, are considered safe and unlikely to cause severe adverse reactions. Some patients report feeling worse for a brief period of time after starting homeopathic remedies.

Homoeopaths interpret this as the body temporarily stimulating symptoms while it makes an effort to restore health. Liquid homeopathic remedies can contain alcohol and are permitted to have higher levels of alcohol than conventional medicines for adults. This may be of concern to some consumers. However, no adverse effects from the alcohol levels have been reported either to the FDA or in scientific literature. Homoeopathic remedies are not known to interfere with conventional medicines; however, if patients are considering using homoeopathic remedies, patients should consult with their healthcare practitioner before self administration of OTC homoeopathic medicine. Similarly to all medicines, allopathic and homoeopathic, a patient is best advised to:

Contact their health care provider if their symptoms continue for more than 5 days. To keep the remedy out of the reach of children. To consult a health care provider before using the product if the user is a woman who is pregnant or nursing a baby.

2.14 Positive and negative effects of OTC homoeopathic medicines

Wilber (2004) indicated that homoeopathic medicines comprise of infinitesimal doses of the crude/original substances, and so side-effects are very unlikely. Other advantages of homoeopathy are that many people realize that the human body is an incredible being and that; it has the ability to heal itself.

Monks (2001) highlighted that a reason for the growing acceptance of homoeopathic remedies is that consumers have become more responsible and involved in their own health care and have become more educated in living a healthy lifestyle. Consequently, many are discovering that conventional OTC medicines often lead to unwanted side effects or are contraindicated for use together with other medicines they may already be taking and so they are using homoeopathic products in an effort to avoid such consequences. One of the best examples of the problems consumers encounter with conventional drugs is the use of sleep aids. Consumers who require sleeping aids commonly suffer from other conditions/complaints simultaneously. This often requires them to take other medications along with the sleeping aids which may result in undesirable drug interactions. Homoeopathic sleep aids, do not present such problems and are increasingly

being recommended by pharmacists to patients looking for something to help them rest.

Secondly, BioRight International Inc. (2000) indicates that consumers are finding that conventional OTC medicines are simply not effective for some conditions. "Surveys conducted have shown that consumers are least satisfied with products available for conditions such as coughs and colds."

Monks (2001) advises that many of the concerns, which influence consumer's choice of homoeopathic remedies over orthodox medications, are compounded in paediatric cases. Parents are interested in sourcing products to treat their children's ailments without creating negative consequences. Offering products that can allay parents' concerns and attract a wider audience to their OTC departments is also appealing to retailers.

2.15 The growth of homoeopathic OTC medicines

According to the Health Products Association of South Africa (HPA) (2007), the complementary medicines industry market size in South Africa was estimated to be approximately 2 billion Rand in May 2007.

Complementary medicines reach the market predominantly through direct sales (43%), 25% through retail pharmacy/ health shops and 16% supermarkets. A maximum of 2% is distributed through practitioners. The remaining channels include wholesalers; export sales and online internet sales. In a survey conducted by the *Homoeopathic Products Association* (2000) it was noted that 5% of the total market size of complementary medicines were homoeopathic medicines. The Homoeopathic annual markets

growth average was 15% between the years of 1998 to 2000 (Caldis, 2000; Tomlinson, 2007).

If the total market share of homoeopathy was taken and further divided in categories, it would be seen that homoeopathic remedies hold the highest percentage of 78%, followed by homoeopathic creams of 16% and tissue salts of 6% (Caldis, 2000).

In a market survey carried out on complementary medicine by the HPA (2003) between 2001 to 2003, all major stakeholders in the industry were assessed, including homoeopathy, nutritional supplements and herbal medicines. Homoeopathy had an annual growth of 16.4 % over the three years; its industry (complementary medicines) size in 2001 was R49 million, it grew to the industry size of R61 million in 2003. It was noted that, out of the R61 million, R23.9 million was attributed to Homoeopathy.

Courage (2007) points out that with the complementary medicines industry being an almost unregulated industry. Smaller markets, like homoeopathy, which require specialized knowledge are less easy to enter but are generally niche markets that they do not offer huge profitability. Given the single exit pricing system which was introduced for allopathic medicines, many of the multinational pharmaceutical giants are now looking towards complementary medicines, where pricing is not regulated, as a means of profitable growth. This has lead to acquisitions of smaller complementary medicine manufacturers by the pharmaceutical giants. Many of the pharmaceutical

giants have significant advantages through economies of scale and are able to compete with cost advantage (Courage, 2007).

The demand for homeopathic medicines is expected to continue building, according to manufacturers and retailers. Future growth will take place as the marketplace becomes more educated. Publicity about alternative therapies, which homoeopathy is considered to be, will continue to be a subject of mass media interest, and the continued press coverage of homoeopathy will create interest and make consumers aware of the benefits of self-medicating with homeopathic products. Unlike an alternative such as herbal products, where publicity about a particular product can create voracious demand, publicity about homoeopathy tends to be more general in nature and of a more stable demand (Troy, 1995).

Wilber (2004) declares that without a doubt, U.S. consumers are starting to embrace the benefits of homeopathic medicines. Traditional retailers such as pharmacies are starting to meet this demand as homoeopathy grows beyond its early roots in health food stores, and homeopathic practices. At the same time, "More and more suppliers are getting into selling homoeopathy because they can see that consumers are interested in safe, natural medicines for their entire family".

With today's prevalent trend of people wanting safe, effective and low-risk medicines for the management of their chronic self-care complaints, homoeopathy is showing consistent growth in the retail market. However, there remains resistance to recommending homeopathic medicines. The confusion, which haunts homeopathic product use in the United States,

seems to lie with healthcare professionals who don't understand it. Indeed consumer, retailer and healthcare professions education is key to the continued growth of the homeopathic medicines in pharmacies (Wilber, 2004).

2.16 Survey methodologies

Statistical surveys are used to collect quantitative information about items in a population. Surveys of human populations and institutions are common in political polling and government, health, social science and marketing research. A survey may focus on opinions or factual information depending on its purpose, and many surveys involve administering questions to individuals. When the questions are administered by a researcher, the survey is called a structured interview or a researcher-administered survey. When the questions are administered by the researcher, the survey is referred to as a questionnaire or a self-administered survey (Abramson, 1999).

2.16.1 Mail administered surveys:

There is usually an average response rate of 5% - 30% in such surveys. The questionnaire may be handed to the respondents or mailed to them, but in all cases they are returned to the researcher via mail. The cost is very low, as bulk postage is mostly cheap in South Africa. There are however long time delays, often several weeks, before the surveys are returned and statistical analysis can begin. It is not suitable for very complex issues as there is no interviewer bias introduced. A large amount of information can be obtained: some mail surveys are as long as 50 pages.

A survey is a research tool, which uses structured and well-formed questions to gather information from a sample group of people, of any size; it takes less effort and is inexpensive, compared to other techniques of data collecting. Surveys are also used to assess people's emotions, beliefs, attitudes and self-behaviour. Researchers can then use the information gathered to describe behaviour and develop causal hypotheses, which can be tested in experiments, although surveys cannot by themselves establish causality (Abramson, 1999 and Mitchell and Jolley, 1992).

Advantages of surveys are that they can be used to investigate problems in realistic settings, and they also allow researchers to examine a large number of variables that can be analysed with the help of multivariable statistics (Cooper and Schindler, 2001).

Disadvantages of surveys are that independent variables cannot be manipulated as in experimental research, and the reliability and validity cannot always be easy to ensure. One of the major weaknesses in surveys is that the information's quality and quantity depends heavily on the willingness and ability of the respondents to cooperate. The respondents may fail to see the value in participation, or in paper surveys, respondents might interpret the questions differently from what the researcher intended, as well as respondents may intentionally mislead the researcher by giving false information. Thus, a survey response should be accepted for what they are, a statement made by others that reflects varying degrees of truth (Cooper and Schindler, 2001).

2.16.2 Advantages of self-administered questionnaires

- They are less expensive than interviews.
- They do not require a large staff of skilled interviewers.
- They can be administered in large numbers at one place and time.
- Anonymity and privacy encourage more candid and honest responses.
- Lack of interviewer bias.
- Speed of administration and analysis.
- Suitable for computer based research methods.
- Less pressure on respondents

Care should always be taken when designing a questionnaire as to make sure that it is the correct length, that the questions are clear and do not lead in any form. This should be done as to avoid biased answers and vague responses. It may be prevented by doing a pilot study on the questionnaire before finalising the survey (Doman, 1993).

2.17 Related Research

- Courage (2006) completed a survey on subject failure and delays in qualification of DUT graduates from 1994 to 2004. Her study was to investigate the certain difficulties that the DUT homoeopathic graduates may have had during their education process. The study done by Courage (2006) uses a similar sample group as used in this study, participants who graduated from DUT and were registered as homoeopaths with the AHPCSA. The research design and the

methodologies of this study are based on the same methodologies and design that Courage (2006) used in her study.

- Babaletakis (2006) assessed the career choices and paths taken by the graduates from DUT between 1994 and 2004. The sample group used by Babaletakis (2006) is similar to the sample group used in this study, participants whom attended DUT who were graduates, are now registered homoeopaths; registered homoeopaths were used as participants in this study. The research design and methodologies for this study was based on the same methodologies used by Babaletakis (2006).

CHAPTER 3: Methodologies

3.1 Study Population

All homoeopaths in South Africa registered with the Allied Health Professions Council of South Africa (AHPCSA) were asked to participate in this survey. The survey was conducted by means of a self-administered questionnaire.

The population consisted of 504 registered Homoeopaths; a minimum of 20-30% was required of the total group in order for statistical analysis to be viable.

3.1.1 Inclusion criteria

All practitioners had to be registered with the Allied Health Professions Council of South Africa and therefore their names appeared on the AHPCSA register, from which the contact details of participants were derived.

3.1.2 Exclusion criteria

Registered homoeopaths that did not have South African addresses, or that had no current addresses or contact details were not included.

3.2 The design and development of the questionnaire

A new questionnaire was designed for the purposes of this study (Appendix A). It consisted of two parts, part A the demographic section and part B comprising opinion and perception related questions about the availability of homoeopathic OTC medicines. Both part A and part B were to be completed by all participants. A definition of OTC, self-medication and a 'homoeopathic remedy' was drawn up for the purpose of this study; this ensured that all participants understood these terms correctly.

A pilot study was conducted in which 6 registered homoeopaths participated. The group was selected because of their similarity to the respondents who would eventually participate in the survey. The questionnaire was distributed to the individuals for their comments and input regarding clarity, understanding and possible ambiguity of the questions. After the assessment of the questionnaire, any suggestions or changes were reviewed and then appropriate changes were made.

The aim of the pilot study was to determine:

- If the questionnaire provided the needed information.
- Were certain questions redundant or misleading.
- Were the questions appropriate for the participants being surveyed.
- How consistent is the information obtained by the survey.
- How accurate is the information obtained by the survey.

3.3 Data collection

3.3.1 Telephonic contact and confirmation of addresses

The registered homoeopaths were contacted telephonically, to introduce them to the researcher and the research proposal.

The participant's contact details were confirmed as well as their willingness to participate in the study. It was also important to establish how the participants wanted to receive their questionnaires i.e. via e-mail, post or hand delivery. Any registered homoeopaths that could not be contacted were automatically excluded from the survey.

3.3.2 Distribution and collection of questionnaires

Convenient methods of response:

To encourage participation in the study, it was important to make the methods by which participants could respond as flexible and convenient as possible. Hence, each participant was offered 3 methods by which they could respond and could do so according to whichever method best suited him/her.

Methods that were used to distribute and collect questionnaires:

- Post
- E-mail
- Hand delivery

All responses (completed questionnaires) were received by an independent party, who had no direct association with the homoeopathic profession.

The independent person ticked off the names of respondents against a list of registered homoeopaths so that a list of those who had responded could be made. Only once identification of the respondents was removed did the researcher and supervisor have access to the questionnaire.

3.3.3 Response time

The researcher allowed a two-week time lapse, for a response to be received. After this time the participants were contacted again to confirm that they had received the questionnaire, and were reminded to complete and return it. A further four weeks were allowed for the return of questionnaires, after which the non-complying candidates were excluded from the study. The researcher then considered the data capture complete and could then proceed with the data analysis.

3.4 Data storage

All answered questionnaires were deemed confidential documents, so once the names had been deleted from the questionnaires they were stored in a locked filing cabinet in custody of the researcher. Only the researcher and the research supervisor had access to the files. In the case of e-mailed replies, the e-mail was printed and then deleted, with no traceable address or name

appearing on the printed copy. The hard copy was then stored in the locked filing cabinet.

3.5 Critical pathways in this survey

3.5.1 Tracing potential participants

Reliable and accurate contact details from the AHPCSA (Allied Health Professions Council of South Africa) were necessary to facilitate contact with the potential participants.

3.5.2 Response rate

3.5.2.1 Role of the Information Letter

In trying to ensure compliance of the participants, it was imperative to thoroughly inform the registered homoeopaths of the proposed research and to emphasise the importance of the information. Much care was taken in the presentation of the questionnaire to avoid the notion that the survey was simply a “marketing” ploy or that the information would be used against the participant. A careful explanation of the intention of the study was laid out in the Information Letter, which each potential participant received. The Information Letter also clearly explained the measures, which were taken to ensure the confidentiality of the responses, to avoid responses that may have been given because they sounded proper, rather than truthful.

3.7.2.2 Time constraints of participants

A concern that the researcher was faced with was that, due to the nature of the sample group, participants might be reluctant to spend valuable time on completing the questionnaire. Therefore the questionnaire was limited to only the essential questions pertaining to pertinent areas, which were identified by the researcher and confirmed, by the pilot study, and research supervisor.

The questionnaire was structured so that there were a variety of well-distributed questions, which required writing of some basic details. This was done as to avoid the questionnaire seeming boring and of no use. Many questions allowed the participants to comment further if they wished. Each potential participant was also informed of the estimated time taken to complete the questionnaire, which according to the pilot study would be between 10 and 20 minutes.

3.6 Data Analysis

The raw data were processed and analysed in the following steps:

3.6.1 Procedure 1:

Raw data were inputted into an Excel spreadsheet form. The raw data were then manipulated into correct form and frequency counts were performed. The frequency counts were used to generate the descriptive statistics (graphs and tables). These included: demographics (gender, age category, ethnic group, homeopathic and other qualifications), practice details (length of time in

practice, practice location, type of practice and whether practice includes its own dispensary), and attitude and opinions towards homoeopathy.

3.6.2 Procedure 2:

The raw data were inputted into XPSS for further analysis.

3.6.3 Procedure 3:

The raw data were analysed using the XPSS Crosstabs procedure. This returned Phi and Kendall's Tau correlation co-efficients. The following correlations were tested:

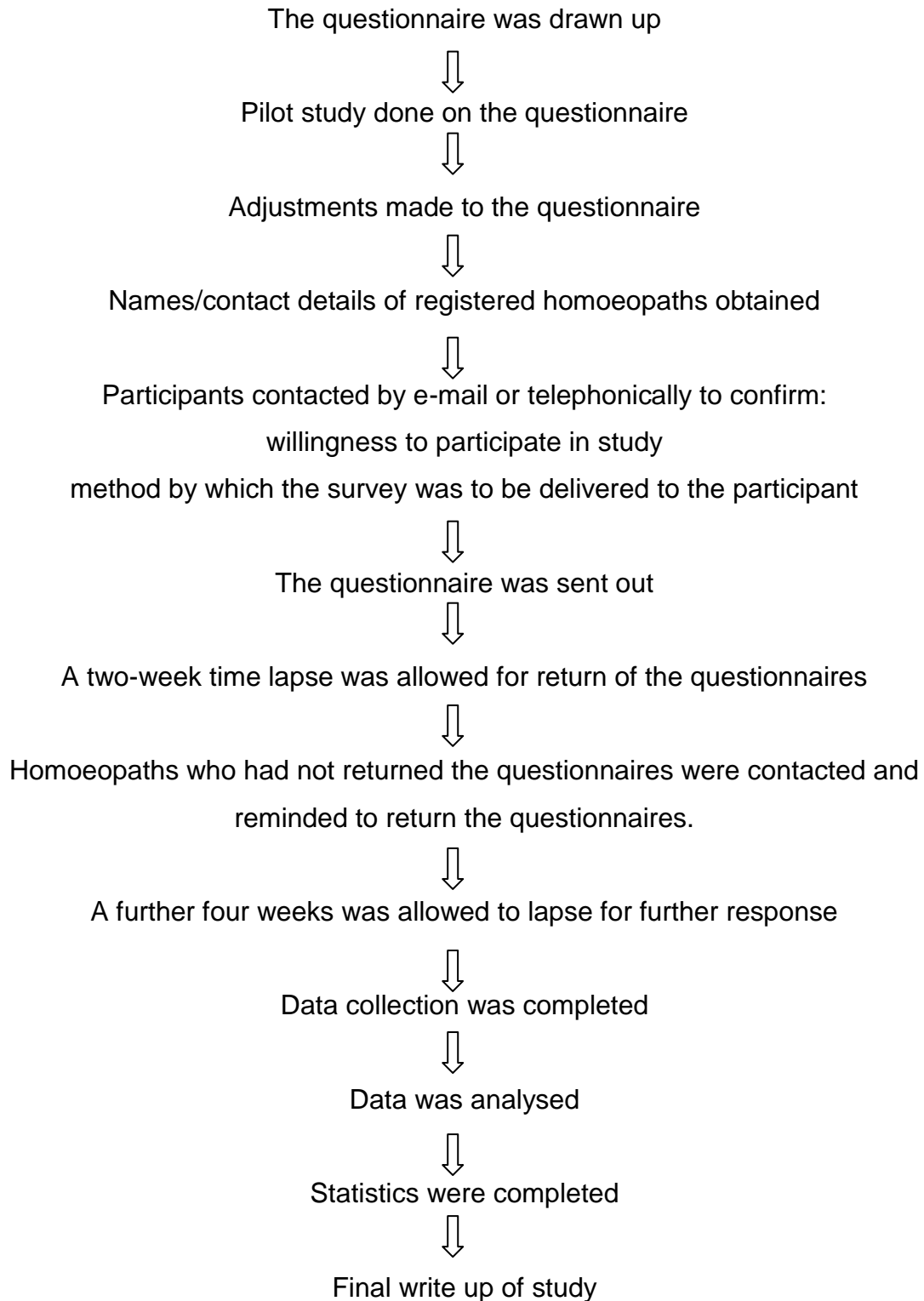
- Demographic variables against Part 2 (Questions describing the respondents attitudes to and opinions of homoeopathic OTC preparations)
- Practice status variables against Part B (Questions describing the respondents attitudes to and opinions of homoeopathic OTC medicines)

3.6.4 Procedure 4:

The raw data was analysed using SPSS Hierarchical Cluster analysis procedure. This returned the dendrograms showing the relationship between responses within variables. The following variables were assessed in this way:

- The perceived benefits of homoeopathic OTC medication
- The perceived negative effects of homoeopathic OTC medication

3.8 Flow chart of processes



CHAPTER 4: Results

4.1 Introduction

Following the methodology described in Chapter 3, the study produced raw data in the form of completed questionnaires. These were obtained by following a convenience sampling method. Qualified and registered practitioners were approached with a view to completing the questionnaire.

The specific objectives of the analysis were as follows:

- (1) To describe the demographic characteristics of individuals sampled.
- (2) To describe the current perceptions of homoeopathic OTC medication
- (3) To determine any statistically significant correlations between demographic or other characteristics and perceptions towards OTC medications (as reflected in the completed questionnaires).

The analysis of the data was done using SPSS® for Windows™ and Excel® XP™.

4.2 Overview of Results Chapter

4.2.1 Descriptive data

4.2.1.1 Demographics

These comprised distribution tables and graphical depiction of the demographic data (gender, age category, ethnic group, homeopathic and other qualifications).

4.2.1.2 Practice Details

These comprised distribution tables and graphical depiction of the data related to geographical location and practice type (length of time in practice location, type of practice and whether practice includes its own dispensary).

4.2.1.3 Attitude and Opinions

These comprised distribution tables and graphical depiction for the data related to the respondents attitudes to and opinions of homeopathic OTC medication.

4.2.3 Analysis

Non-parametric statistical tests were used to determine the presence and significance of correlations between demographic descriptors, and respondent's attitudes to and opinions of homeopathic OTC medication.

4.2.4 Comments

This comprised a description of the comments made by respondents. Further discussion of these in light of the above statistical analysis follows in Chapter 5.

4.3 Abbreviations

Respondent = individual satisfying inclusion criteria who completed the questionnaire

H_0 = null hypothesis

H_1 = alternative hypothesis

S.D. = standard deviation

Z = standardised z value for statistical measurements

P = two tailed probability of equalling or exceeding $z/2$

N.S. = no statistically significant difference

S = statistically significant difference

If $p < 0.05$ then a significant difference was concluded (5% level of significance)

If $p > 0.05$ then no significant difference was concluded (5% level of significance)

4.4 Descriptive statistics

4.4.1 Demographics

The data used for the following analyses were derived from Questions 1 to 8 of Part A of the completed questionnaires. In terms of the objectives described in the introduction, the respondents' demographic characteristics were described.

Table 4.1 Table Showing Gender Distribution of Sample

Gender	Number of Respondents	Percentage of Respondents
Male	27	50.04%
Female	26	49.06%

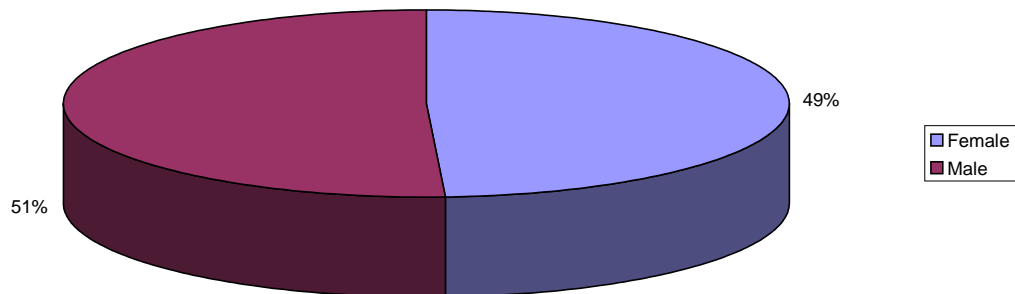


Figure 4.1 Chart Showing Gender Proportions of the Sample

The gender proportions of the respondents were fairly even.

Table 4.2 Table showing Age Distribution of Sample

Age Category	Number of Respondents	Percentage of Respondents
20-25 Years	2	3.77
26-35 Years	18	33.96
36-45 Years	6	11.32
46-55 Years	3	5.66
>55 Years	24	43.40

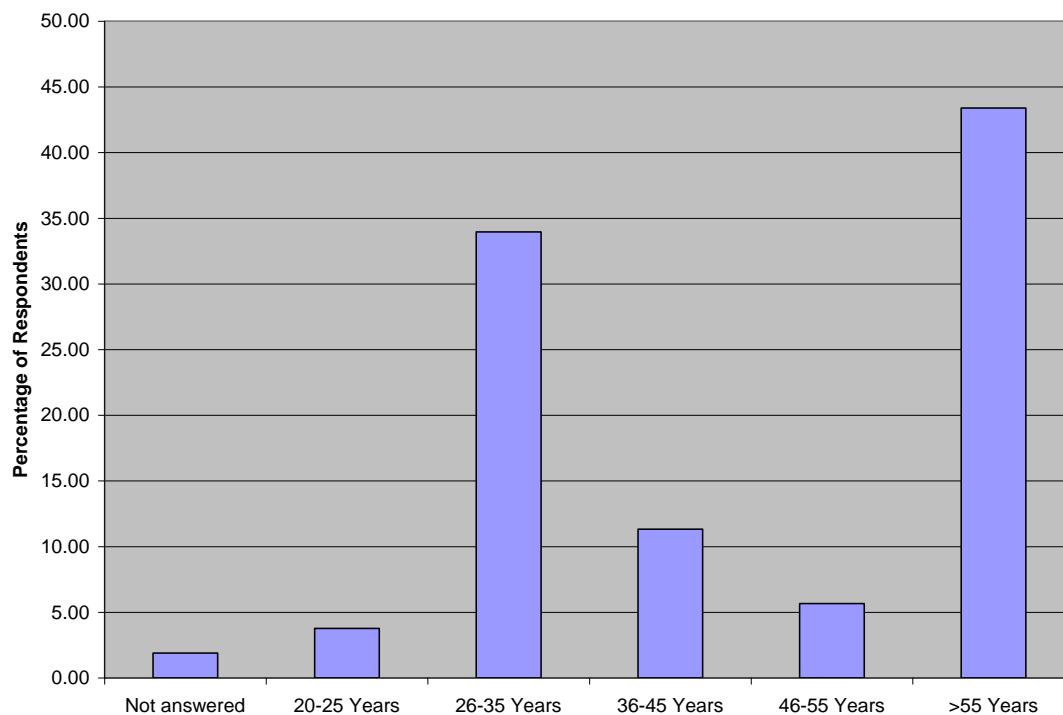


Figure 4.2 Graph Showing Age Distribution of Sample

The age group distribution demonstrates a higher peak in the 26 – 35 age group as well as for the 55+ year age group.

Table 4.3 Ethnic Composition of Sample

Ethnic Group	Number of Respondents	Percentage of Respondents
Not Answered	1	1.89
White	43	81.13
Indian	3	5.66
Black	1	1.89
Coloured	1	1.89
Other	4	7.55

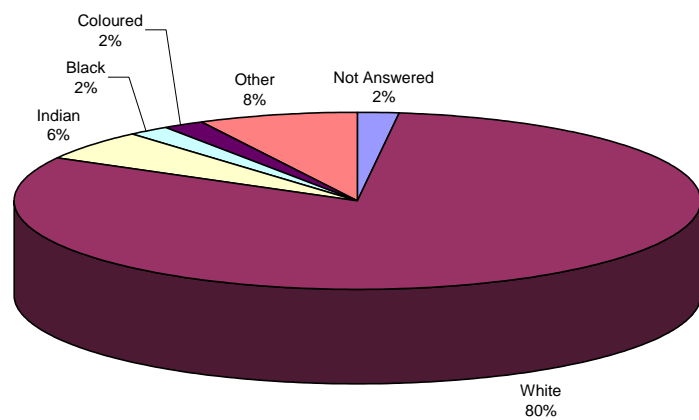


Figure 4.3 Graph Showing Ethnic Composition of Sample

The majority of the ethnic population was White with 80%, 'Other' was the next largest group, Indian 6% and then Black and Coloured both 2%.

4.4.2 Practice Status

The data used for the following were derived from Questions 1.2, 1.5, 1.6, 1.7 and 1.8 of Section A of the completed questionnaires. In terms of Objective 2 in the introduction, the respondents' demographic practice details were described.

Table 4.4 Table showing location of practice by province

Location of practice	Number of respondents	Percentage of respondents
Kwa-zulu Natal	14	26.42
Gauteng	16	30.19
Western Cape	9	16.98
Eastern Cape	2	3.77
Northern Cape	1	1.89
Limpopo	4	7.55
Northern Province	2	3.77
Free State	3	5.66
Mpumalanga	2	3.77
Other	0	0.00

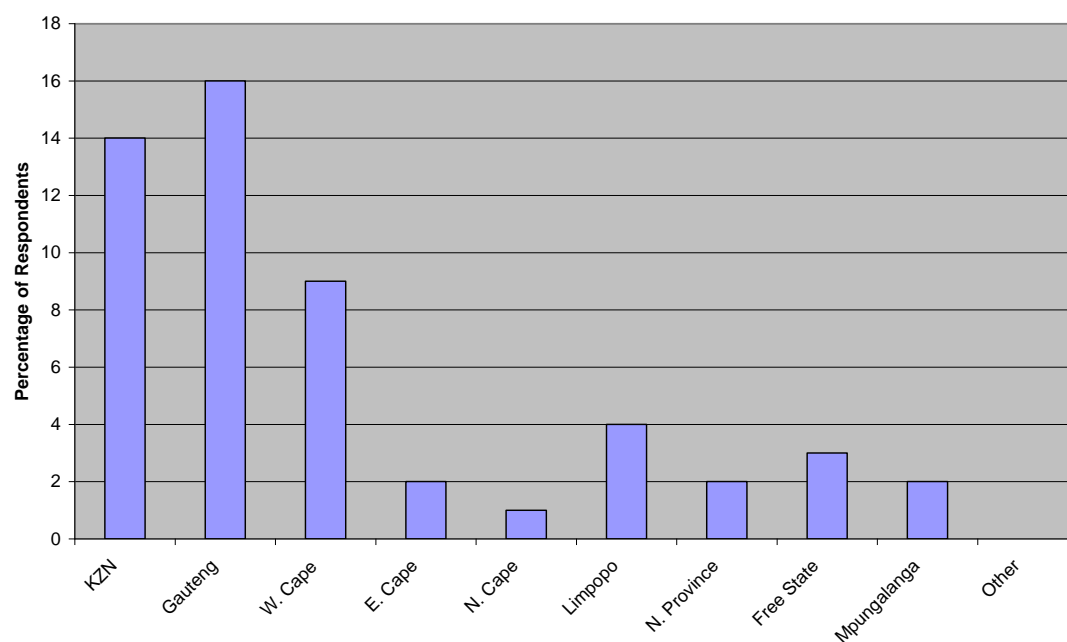


Figure 4.4 Graph showing the demographic location of respondent's practices by province

The figure above reflects the predominance of homeopaths in the major population centres of the country- Johannesburg, Pretoria, Durban and Cape Town, these city centres located in Gauteng, KZN and Western Cape.

Table 4.5 Table showing respondents type of practice.

Type of practice	Number of respondents	Percentage of respondents
Sole Practice	47	88.68
Partnership	3	5.66
Hospital	0	0.00
Clinic	3	5.66
Other	0	0.00

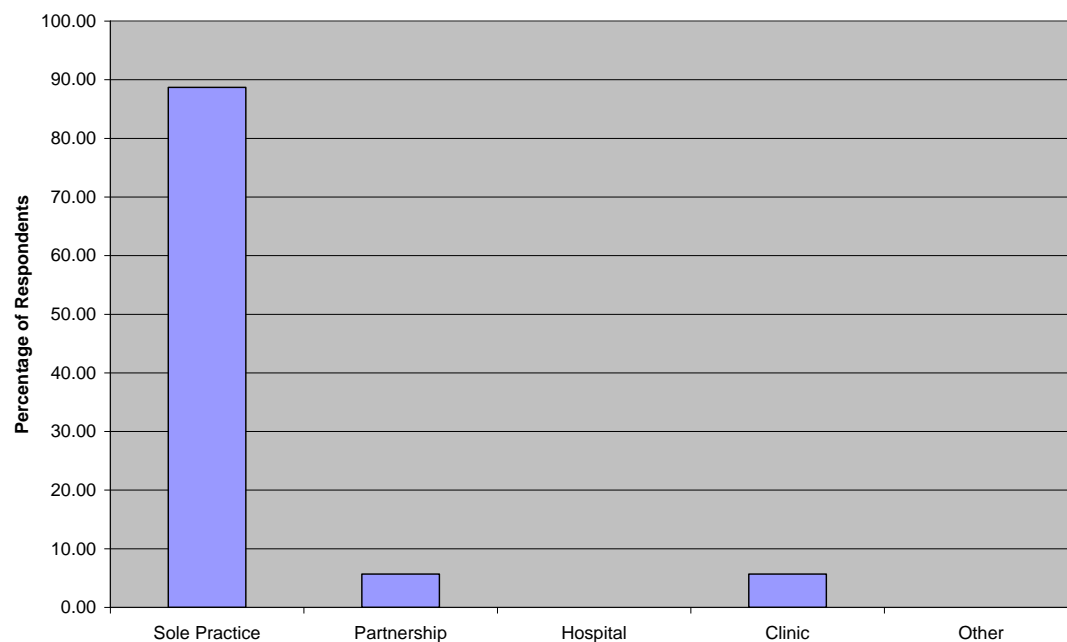


Figure 4.5 Graph showing respondents type of practice

Most of the respondents are in sole practice.

Table 4.6 Table showing length of time respondents have been in practice

Length of time in practice	No of respondents	Percentage of respondents
0 - 2 Years	5	9.43
3 - 5 Years	11	20.75
6 - 8 Years	3	5.66
9 - 12 Years	7	13.21
>12 Years	5	9.43
Other	22	41.51

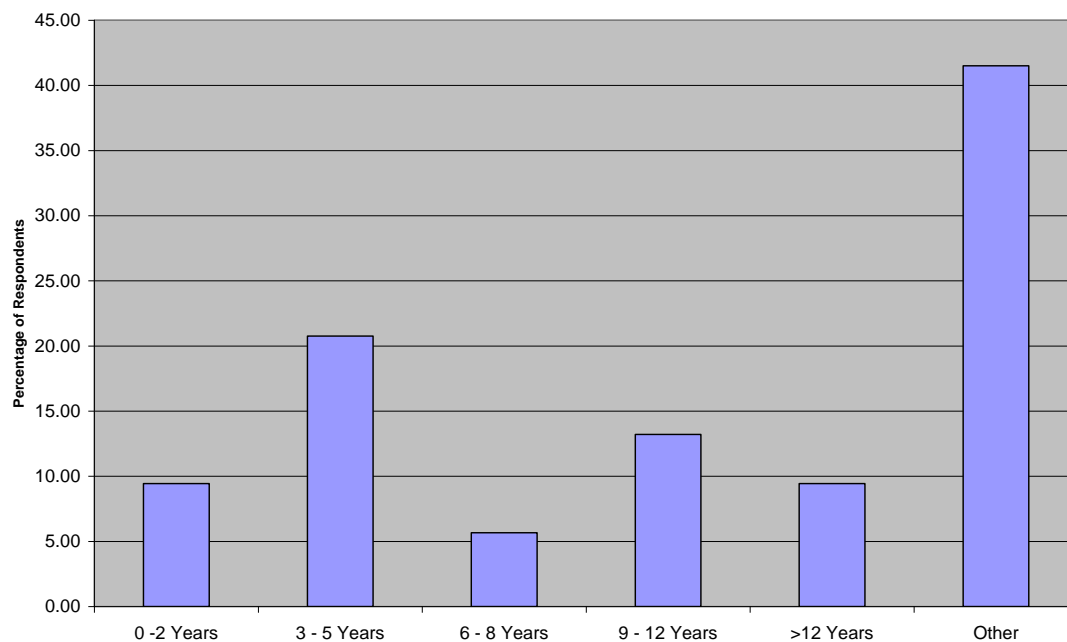


Figure 4.6 Graph showing length of time in practice

The response offered by “Other” is not entirely clear. This lack of clarity (what did the respondents mean when choosing “Other”) makes it impossible to analyse this variable in terms of the objectives described in Section 1 of demographics.

Table 4.7 Table showing whether respondents practice includes its own dispensary

Practice includes dispensary	No of respondents	Percentage of respondents
Yes	49	92.45
No	4	7.55

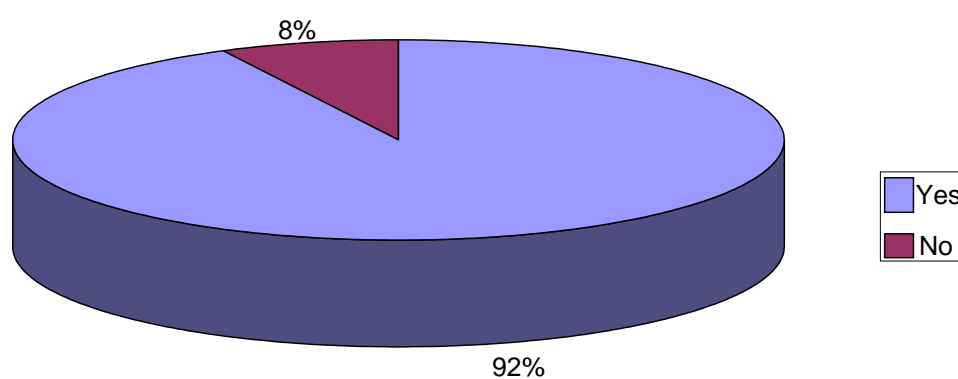


Figure 4.7 Graph showing whether respondents practice includes its own dispensary

The majority of respondents had their own dispensary.

4.4.3 Attitudes and opinions regarding homoeopathic OTC medication

These comprised distribution tables and graphical depictions of the data related to respondents attitudes to and opinions of homoeopathic OTC medication. These were as reflected in Part B of the completed questionnaires.

Table 4.8 Table showing the extent to which respondents were in favour of homoeopathic OTC medicines

Extent to which respondents were in favour of homoeopathic OTC medicines	Number of respondents	Percentage or respondents
Strongly Agree	10	18.87
Agree	12	22.64
Slightly Agree	12	22.64
Disagree	8	15.09
Strongly Disagree	11	20.75

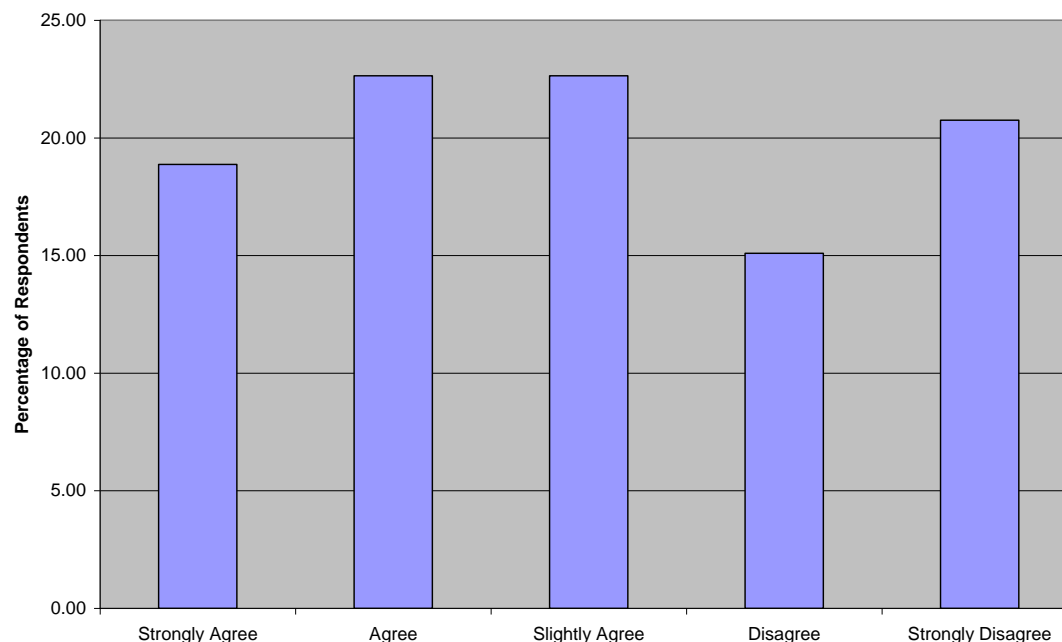


Figure 4.8 Graph showing extent to which respondents were in favour of homoeopathic OTC medicines

The responses are very evenly spread across the range between strongly agree and strongly disagree.

Table 4.9 Table showing agreement and disagreement with benefits/dangers of OTC homoeopathic medicines

Issue	Not answered	Agree	Disagree
<i>Positive aspects</i>			
Advertising for homoeopathy	15.09	54.72	30.19
A form of promoting homoeopathy	13.21	64.15	22.64
Cheaper form of medicating- more disadvantaged	15.09	56.60	28.30
More accessible for home usage	11.32	69.81	18.87
<i>Negative aspects</i>			
Incorrect use of medication	5.66	79.25	15.09
Overdose	9.43	49.06	41.51
Potentially harmful of the OTC interacts negatively with other medication	9.43	56.60	33.96
Self medicating without advice from a practitioner	7.55	69.81	22.64

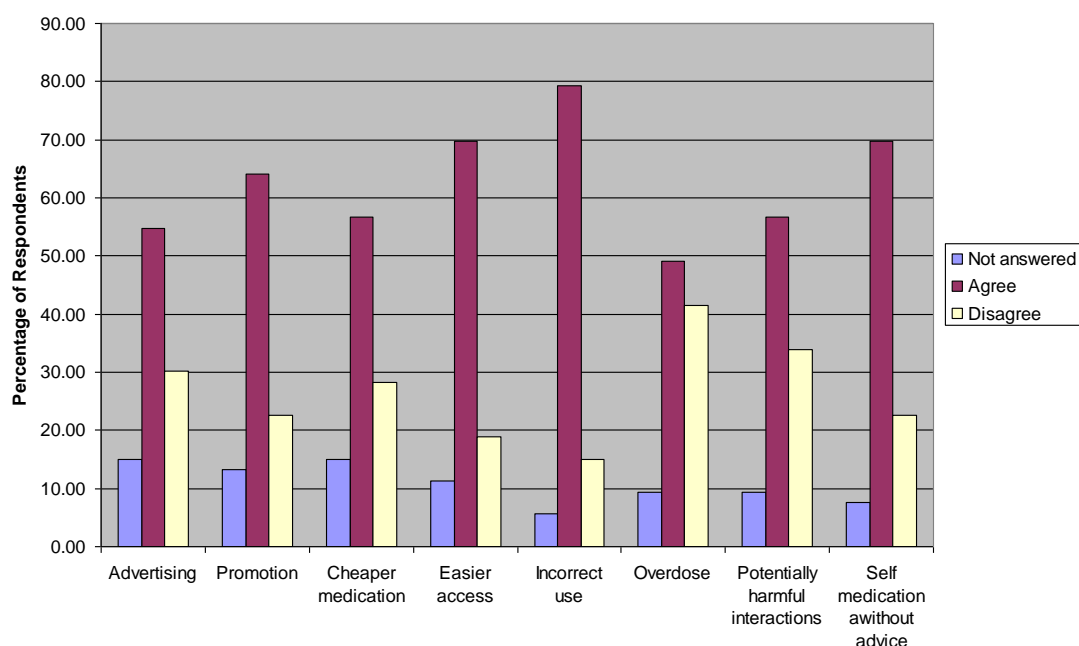


Figure 4.9 Graph showing agreement and disagreement with benefits/dangers of OTC medicines

The majority of respondents agree with the statements of possible benefits and dangers of homeopathic OTC medicines. Interesting to note is the high percentage (79%) that views incorrect usage of medication as a potential danger. Far fewer respondents feel that overdose is a danger of OTC medicines. Promotion of homeopathy, ease of access and affordability are uniformly seen as benefits of homeopathic OTC preparations.

Table 4.10 Table showing opinion of whether availability of OTC medicines should be subject to restrictions

Availability of OTC's should be subject to restrictions	Number of respondents	Percentage of respondents
Yes	49	92.45
No	4	7.55

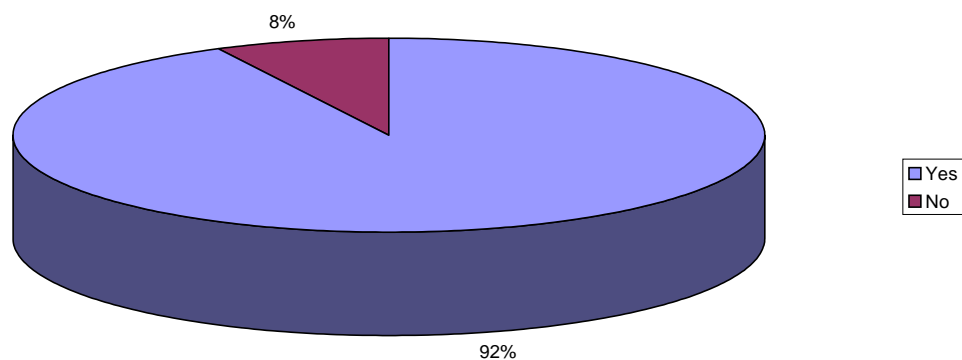


Figure 4.10 Graph showing opinion of whether availability of OTC homeopathic medicines should be subject to restrictions

Most respondents felt that the availability of homeopathic OTC preparations should be subject to restrictions.

Table 4.11 Table showing respondent's opinion of whether potency of homoeopathic OTC medicine should be subject to restrictions

Potency of OTC available should be subject to restrictions	Number of respondents	Percentage of respondents
Yes	47	88.68
No	6	11.32

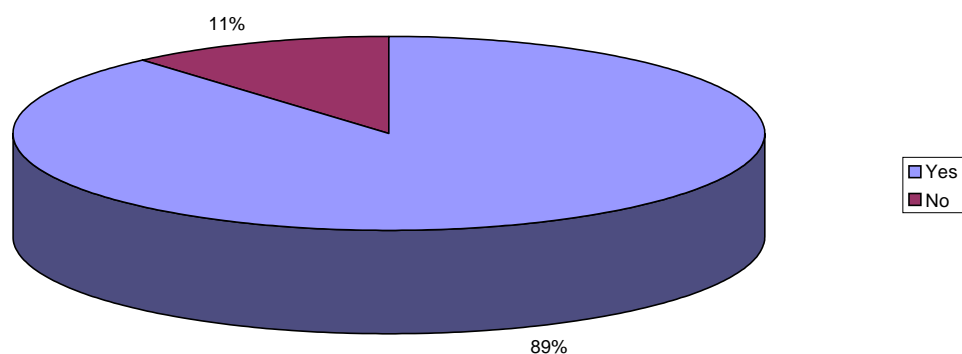


Figure 4.11 Graph showing respondent's opinion of whether potency of OTC medicines should be subject to restrictions

Similarly to the availability of OTC medicines, most respondents felt that the potency range available OTC should be restricted.

Table 4.12 Table showing respondent's opinions of whether the broad availability of homoeopathic OTC medications poses risks to patients' health

OTC medicines availability poses risks to patients health	Number of respondents	Percentage of respondents
Yes	28	52.83
No	25	47.17

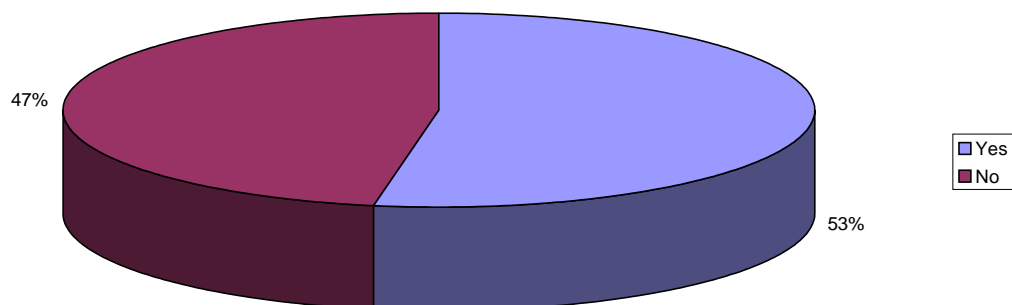


Figure 4.12 Graph showing respondent's opinions of whether the broad availability of OTC medications poses risks to patients' health

Respondents felt that the broad availability of OTC medications could pose a risk to patient's health.

Table 4.13 Table showing whether respondents dispensed medication that is also available OTC

Respondents who dispensed OTC medication	Number of respondents	Percentage of respondents
Not answered	1	1.89
Yes	36	67.92
No	16	30.19

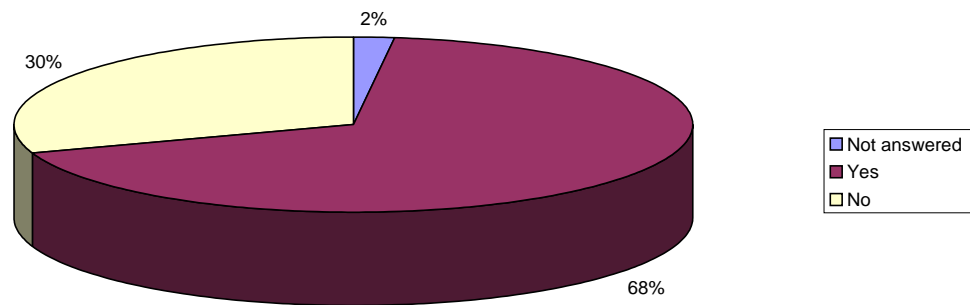


Figure 4.13 Graph showing whether respondents dispensed medication available OTC

A majority of respondents use and prescribe medication that is also commercially available over the counter.

Table 4.14 Table showing whether respondents refer patients to a retail outlet to source OTC medication

Respondents refer patients to a retail source	Number of respondents	Percentage of respondents
Not answered	1	1.89
Yes	34	64.15
No	18	33.96

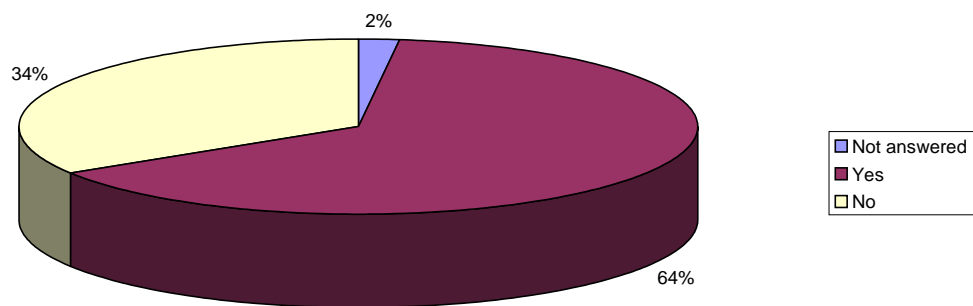


Figure 4.14 Graph showing whether respondents refer patients to a retail outlet to source OTC medication

Most respondents refer or have referred patients to a retail outlet to source OTC medication.

Table 4.15 Table showing reasons for not holding OTC medication in stock

Reason for not stocking OTC medication	Number of respondents	Percentage of respondents
Not answered	32	60.38
Too expensive	13	24.53
Not enough space in dispensary	5	9.43
No dispensary	3	5.66
Other	0	0.00

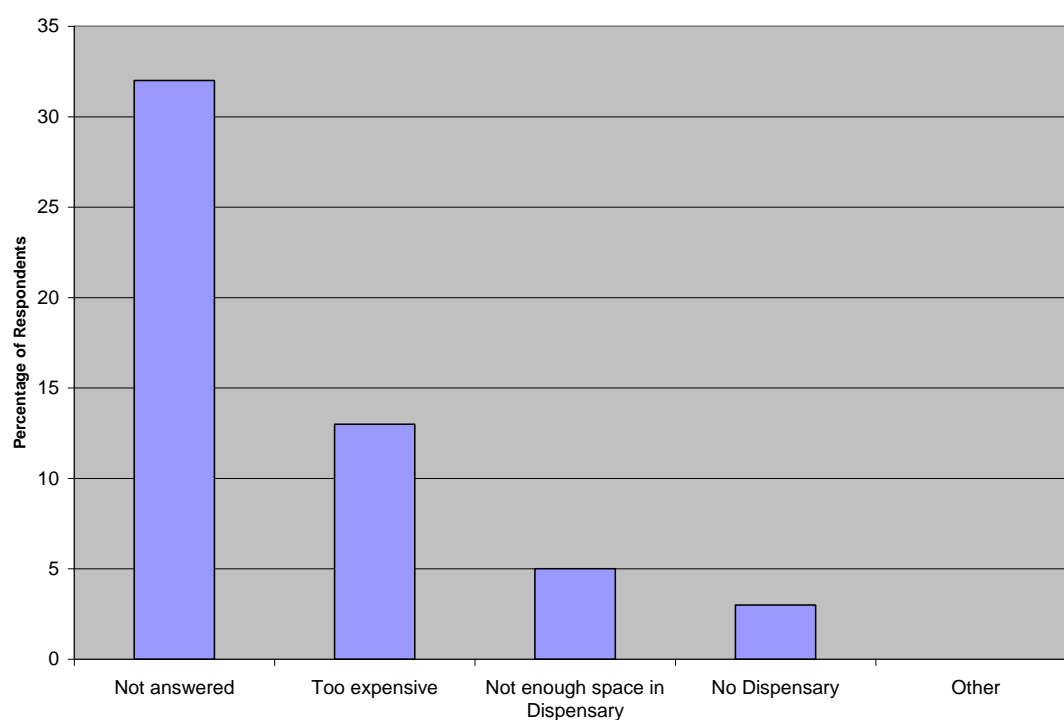


Figure 4.15 Graph showing reasons for not stocking OTC medication

While most respondents did not answer, the primary reason for not stocking OTC medicine was quoted as expense. This relates directly to the wide variety of OTC preparations available. Most respondents that did not answer were assumed to have their own dispensaries and did not think it applicable to state a reason for not holding the OTC medicines in stock.

Table 4.16 Table showing respondents response to issues of quality control with respect to OTC medication

	OTC medicine packed and sealed		OTC medicine repacked and labelled	
	Number of respondents	Percentage of respondents	Number of respondents	Percentage of respondents
Not answered	3	5.66	3	5.66
Yes	47	88.68	5	9.43
No	3	5.66	45	84.91

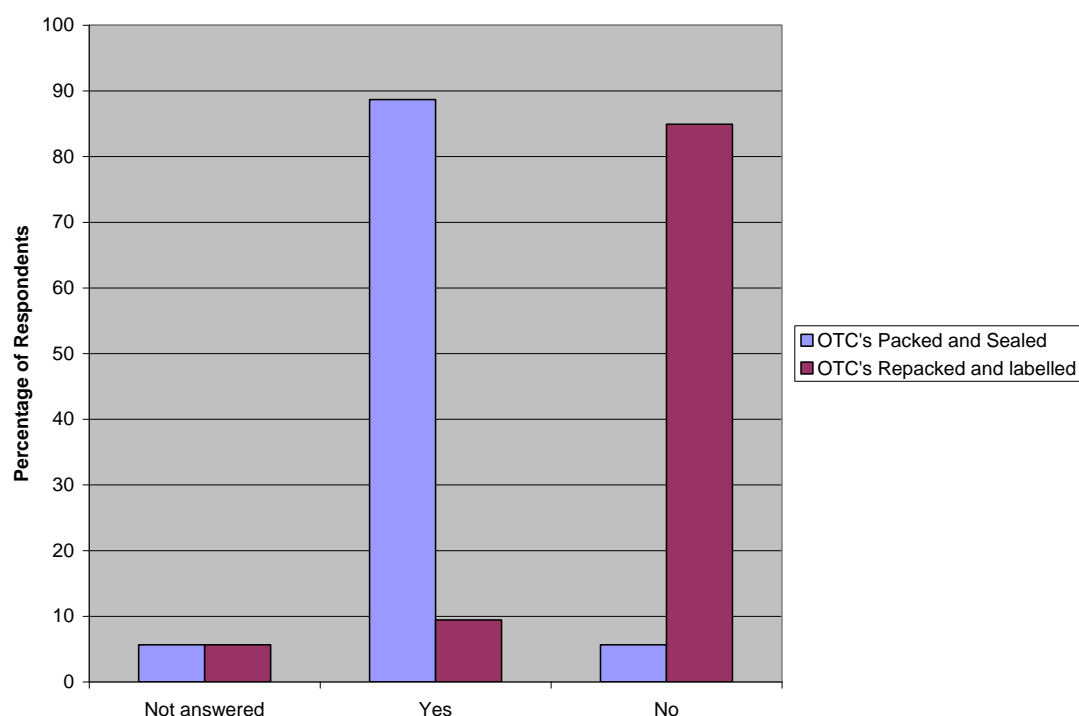


Figure 4.16 Graph showing respondents response to issues of quality control with respect to OTC medication

Most practitioners were firm on quality control issues. OTC medications should be packaged and labelled for individual sale, and should not be sold in bulk for re-packaging and labelling at the point of sale.

Table 4.17 Table showing respondents' opinions on limitations to pricing of OTC medication

Limitations placed on pricing of OTC medication	Number of respondents	Percentage of respondents
Not answered	4	7.69
Yes	32	59.62
No	17	32.69

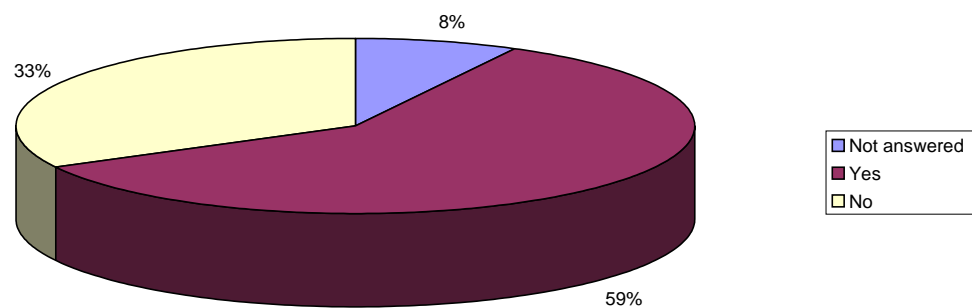


Figure 4.17 Graph showing respondents' opinions on limitations to pricing of OTC medication

Most respondents were in favour of price limitation of homeopathic OTC medicines.

Table 4.18 Table showing respondents most preferred manufacturers

Manufacturer preferred	Number of responses	Percentage of responses
Natura	32	42.67
Heel	20	26.67
Weleda	3	4.00
Reckeweg	8	10.67
Bioforce	3	4.00
Pharma Natura	2	2.67
Boiron	2	2.67
Vogel	2	2.67
Sanukehe	1	1.33
Homoeoforce	1	1.33
Bioallers	1	1.33

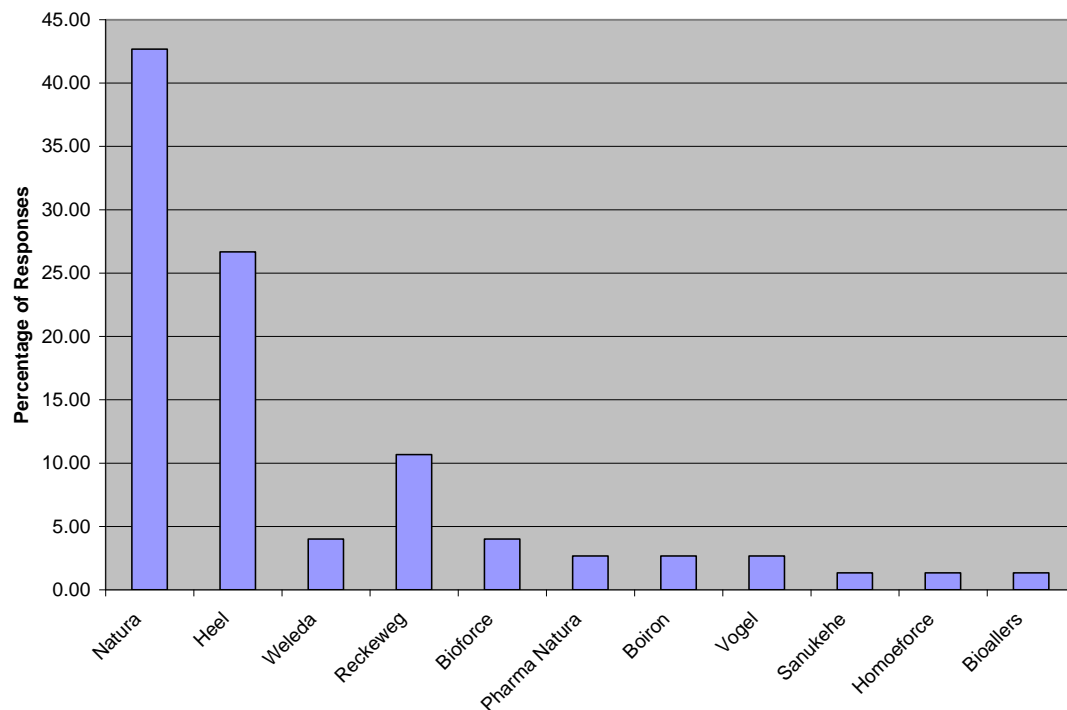
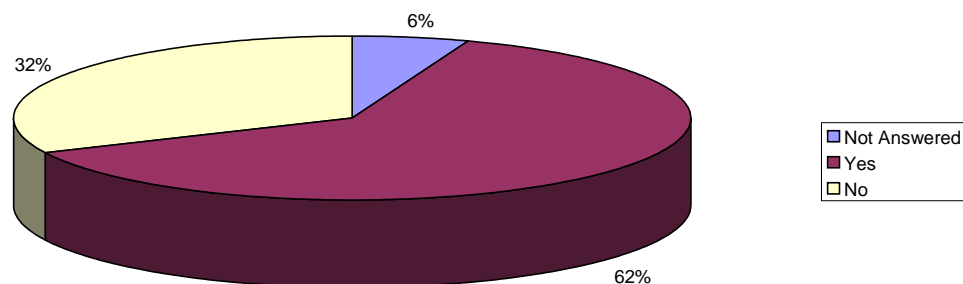


Figure 4.18 Graph showing the preferred manufacturer

The majority of responses seem to indicate a reliance on Natura and Heel products.

**Table 4.19 Table showing whether respondents would like to have OTC
homoeopathic medicines**

Respondents would like to have OTC homoeopathic medicines	Number of respondents	Percentage of respondents
Not Answered	3	5.66
Yes	33	62.26
No	17	32.08



**Figure 4.19 Graph showing whether respondents wanted homeopathic
OTC medicines**

As a summary statement, most respondents felt that they do want homeopathic medications and preparations to be available over the counter.

4.5 Correlation Analyses

In terms of the objective described in the Introduction, the relationship between the demographic and practice detail variables and the responses given was explored. This was done by hypothesis testing using the Phi Correlation Co-efficient and Kendalls Tau Correlation Co-efficient. The level of significance was set at 5% i.e. $p \leq 0.05$.

4.5.1.1

Hypothesis testing- Demographic variables against Part 2 (Questions describing the respondent's attitudes to and opinions of homoeopathic OTC preparations)

Null hypothesis 1: There was no significant correlation between any of the Demographic variables (as described by one of age, gender, and ethnic group) and respondent's attitudes to and opinions of homoeopathic OTC preparations (as described by the questions in Part 2).

Alternative hypothesis 1: There was a significant correlation between one or more of the Demographic variables (as described by one of age, gender, ethnic group) and respondents attitudes to and opinions of homoeopathic OTC preparations (as described by the questions in Part 2).

Correlations between Demographic variables (as described in age, gender, ethnic group) and the following variables/factors were assessed:

- Question 2.1: I am in favour of homoeopathic OTC medications
- Question 2.2.1: Benefits of OTC homoeopathic medicines- Advertising for Homoeopathy
- Question 2.2.2: Benefits of OTC homoeopathic medicines- A form of promoting Homoeopathy
- Question 2.2.3: Benefits of OTC homoeopathic medicines- Cheaper form of medication
- Question 2.2.4: Benefits of OTC homoeopathic medicines- More accessible for home use
- Question 2.2.5: Disadvantages of OTC homoeopathic medicines-
Incorrect usage of a medicine
- Question 2.2.6: Disadvantages of OTC homoeopathic medicines-
Overdose potential
- Question 2.2.7: Disadvantages of OTC homoeopathic medicines-
Potentially harmful interactions
- Question 2.2.8: Disadvantages of OTC homoeopathic medicines- Self medicating without advice
- Question 2.3: Should there be any restrictions on availability of OTC homoeopathic medicines
- Question 2.3.1: Should there be any restrictions on the potency of OTC homoeopathic medicines available

- Question 2.4: Do you think the broad availability of homeopathic OTC medicines poses a risk to patients' health
- Question 2.6: Do you use or dispense homeopathic medicines which are available commercially
- Question 2.7: Do you ever refer patients to a retail outlet to source OTC homeopathic medicines
- Question 2.7.1.2: Why don't you stock homeopathic OTC medicines in your dispensary
- Question 2.8.1: Quality control: OTC homeopathic medicines should be packed and sealed by a registered homeophaemaceutics company in individual units for resale.
- Question 2.8.2: Quality control: Repackaging and labelling of bulk OTC homeopathic medicines by retail outlets should be permitted.
- Question 2.9: Do you think there should be limitations or restrictions on the pricing of OTC homeopathic medicines
- Question 2.10.1: Which company or brand do you most recommend
- Question 2.12: Do you want homeopathic medicines to be available over the counter.

Significant correlations were established i.e. 'Ho' was rejected for certain categories. The significant correlations are shown in Table 4.20.

Significant correlations are indicated by marking z- and p-values; if not noted, either no correlation was noted or the correlation was not statistically significant.

Table 4.20 Table showing correlations between demographic variables describing respondent's attitudes to and opinions of homoeopathic OTC medicines

Variables	Statistical Measures			Nature of Relationship
	Pearson Chi Square (p- Value)	Significance Value (Z Values)	Value of Asymmetric Measure (Phi)	
Ethnic group* Refer patients to retail sector to purchase OTC medicines	18.497	0.047	0.591	Strong correlation. Indian respondents were slightly more likely to refer patients to purchase OTC medication than expected.
Ethnic group*Quality control (Repackaging should be allowed)	18.571	0.046	0.592	Strong correlation. White respondents were slightly more likely to disagree with the idea that repackaging should be allowed.
Gender* Availability of OTC's should be limited	4.166	0.041	0.280	Moderate correlation. Male respondents were slightly less likely to agree that OTC availability should be limited, while female respondents were slightly more likely to agree than expected.

4.5.1.2

Hypothesis testing- Practice status Variables against Part B (Questions describing the respondents attitudes to and opinions of homoeopathic OTC medicines)

Null hypothesis 2: There was no significant correlation between any of the Practice status Variables (as described in Practice location, Length in practice, Practice type, Own dispensary) and their attitudes to and opinions of homoeopathic OTC medicines (as described by the questions in Part B).

Alternative hypothesis 2: There was a significant correlation between any of the Practice status Variables (as described in Practice location, Length in practice, Practice type, Own dispensary) and their attitudes to and opinions of homoeopathic OTC medicines (as described by the questions in Part B).

Correlations between Practice status Variables and the following variables/factors were assessed:

- Question 2.1: I am in favour of homoeopathic OTC medications
- Question 2.2.1: Benefits of OTC homoeopathic medicines- Advertising for Homoeopathy
- Question 2.2.2: Benefits of OTC homoeopathic medicines- A form of promoting Homoeopathy
- Question 2.2.3: Benefits of OTC homoeopathic medicines- Cheaper form of medication
- Question 2.2.4: Benefits of OTC homoeopathic medicines- More accessible for home use

- Question 2.2.5: Disadvantages of OTC homoeopathic medicines-
Incorrect usage of a medicine
- Question 2.2.6: Disadvantages of OTC homoeopathic medicines-
Overdose potential
- Question 2.2.7: Disadvantages of OTC homoeopathic medicines-
Potentially harmful interactions
- Question 2.2.8: Disadvantages of OTC homoeopathic medicines- Self
medicating without advice
- Question 2.3: Should there be any restrictions on availability of OTC
homoeopathic medicines
- Question 2.3.1: Should there be any restrictions on the potency of
homoeopathic OTC medicines available
- Question 2.4: Do you think the broad availability of OTC homoeopathic
medicines poses a risk to patients' health
- Question 2.6: Do you use or dispense homoeopathic medicines which
are available commercially
- Question 2.7: Do you ever refer patients to a retail outlet to source
OTC homoeopathic medicines
- Question 2.7.1.2: Why don't you stock homoeopathic OTC medicines
in your dispensary
- Question 2.8.1: Quality control: OTC homoeopathic medicines should
be packed and sealed by a registered homeopaemaceutics company
in individual units for resale.
- Question 2.8.2: Quality control: Repackaging and labelling of bulk OTC
homoeopathic medicines by retail outlets should be permitted.

- Question 2.9: Do you think there should be limitations or restrictions on the pricing of OTC homoeopathic medicines
- Question 2.10.1: Which company or brand do you most recommend
- Question 2.12: Do you want homoeopathic medicines to be available over the counter.

Significant correlations were established i.e. H_0 was rejected for certain categories. The significant correlations are shown in Table 4.21.

Significant correlations are indicated by marking z- and p-values; if not noted, either no correlation was noted or the correlation was not statistically significant.

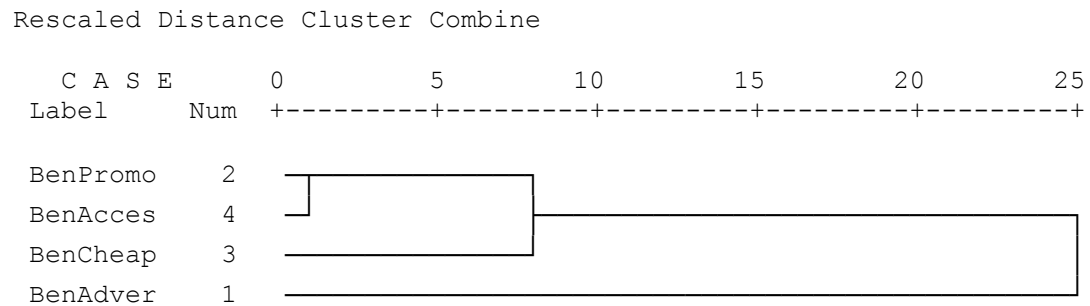
Table 4.21 Table Showing Correlations between Practice status variables and variables describing respondent's attitudes to and opinions of homoeopathic OTC medicines

Variables	Statistical Measures			Nature of Relationship
	Pearson Chi Square (p- Value)	Significance Value (Z Values)	Value of Asymmetric Measure (Phi)	
Area of Practice Location * Availability of OTC homoeopathic medicines should be limited	21.778	0.005	0.641	Strong correlation. Respondents from Gauteng, KZN and Western Cape were more unanimous in their indication that the availability of OTC homoeopathic medicines should be limited.
Area of Practice Location * Potency availability should be limited	18.137	0.020	0.585	Strong correlation. Respondents from Gauteng, KZN and Western Cape were more unanimous in their indication that potency availability should be limited.
Area of Practice Location * QC- OTC homoeopathic medicines should be labelled and packaged by manufacturer	26.636	0.046	0.709	Strong correlation. Respondents from Gauteng, KZN and Western Cape were more unanimous in their indication that strict quality control be enforced by only allowing packaging and labelling by the manufacturer.

4.5.3 Correlations within variables

For questions where respondents could choose more than one response, Hierarchical Cluster analyses were performed. This allows the identification of clustered themes within responses e.g. respondents answering one question would be more likely to indicate an answer to another question.

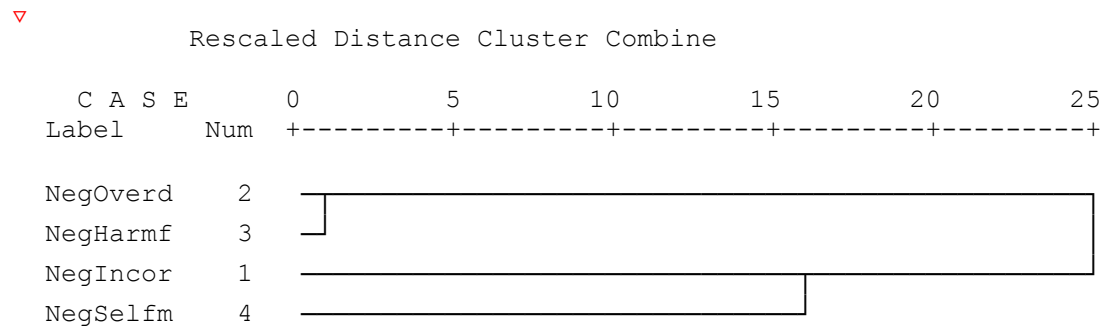
Figure 4.20 Dendrogram showing hierarchical clusters of responses to Question 2.8 – the perceived benefits of homoeopathic OTC medication.



Variable name	Question number
BenPromo	Perceived benefit of homeopathic OTC medication- promotion of homoeopathy
BenAccess	Perceived benefit of homeopathic OTC medication- increased access to homoeopathy
BenCheap	Perceived benefit of homeopathic OTC medication- cheap form of prescribing
BenAdver	Perceived benefit of homeopathic OTC medication- advertising homoeopathy

The above dendrogram suggests that the promotional benefit and the ease of access are closely related in respondent's perceptions. The cost benefit is slightly less clustered, with advertising benefits perceived as a separate concept.

Figure 4.21 Dendrogram showing hierarchical clusters of responses to Question 2.8 – the perceived negative effects of homeopathic OTC medication



Variable name	Question number
NegOverd	Perceived negative effects of homeopathic OTC medication- overdose
NegHarmf	Perceived negative effects of homeopathic OTC medication-Harmful effects of interaction with other medication
NegIncor	Perceived negative effects of homeopathic OTC medication-Incorrect usage of medication
NegSelfm	Perceived negative effects of homeopathic OTC medication- self medication without advice from a practitioner

The above dendrogram suggests the following: Overdose and harmful interactions with other medications are perceived by respondents as similar in respondent's minds, as are incorrect usage and self-medication without advice. These two concept clusters are fairly discrete as far as respondent's perceptions are concerned.

CHAPTER 5: Discussion

Introduction

In this chapter, three aspects relating to homoeopathy will be discussed and how it affects registered homoeopaths in South Africa and future homoeopathic graduates. The aspects to be discussed are:

- 1) The demographic characteristics of the registered homoeopaths sampled.
- 2) The current attitudes of the registered homoeopaths towards the availability of OTC homoeopathic medicines.
- 3) Any correlations between the demographic characteristics and the attitudes towards the availability of OTC homoeopathic medicines. These various issues will be discussed using the statistical data derived from chapter four.

5.1 The respondents

The population group that the research aimed to target comprised of all the registered homoeopaths in South Africa (504 listed). The relevant names were derived from the Allied Health Professions Council's register of 2006. Of the 504, 40 homoeopaths were unable to respond, as they did not reside in South Africa. 167 homoeopaths were emailed, of which only 10 (6%) responded, this may be due to errors within the register or outdated email addresses contained therein as many emails were returned with error messages. Of the 297 homoeopaths contacted by standard post, 58

questionnaires were obtained, a 20% response. The total sample group was 68 responses and the total response rate was 15%. A possible explanation for the low response may be due to errors within the register such as incorrectly typed addresses, a change of address of the homoeopath or a lack of interest to participate in the survey. In contrast to other research conducted their sample group was a lot smaller, as this research had a much larger sample group, this may be a reason as to the lower response rate. Babaletakis (2006) had a population group of 134 graduates, of which 87 responded, the response rate obtained was 64%. Courage (2006) had a population group of 134 graduates, of which 54 responded, the response rate obtained was 40%.

5.2 Demographics

This section analyses information gained from all the respondents. The profile includes: gender, age, ethnicity, practice status and geographical distribution. This is contrasted with the practice status of the respondents.

5.2.1 Gender

It has been seen that in the homoeopathic community there is a greater proportion of female homoeopaths in South Africa and worldwide (Babeletakis, 2005). It is seen in this research that the response between females and males was fairly even, almost a 50/50 response. This discrepancy may be due to the low response rate that this survey received, skewing the data accordingly. Babaletakis (2006) had received a 66%

response from the female graduate homoeopaths and Courage (2006) had received a 65% response from the female graduates. Traditionally it has been seen over the years that the homoeopathic course attracts more female students than male students (Courage, 2006). This may be a reason that Babaletakis (2006) and Courage (2006) received higher female responses than male responses, and an additional variable that could have effected the results was that they only recruited DUT graduates, as in this survey, all graduates were recruited.

5.2.2. Age/Maturity

In 1974, the homoeopathic register opened in South Africa and closed 6 months later; it then re-opened in 1985 at which time the Allied Health Professions Council of South Africa was established. A new registration of homoeopaths then re-commenced in 1985; therefore homoeopathy has only been operational in its full capacity for some 22 years in South Africa (Caldis, 2000).

Almost half of the respondents of the total sample group were over the age of 55 years, making up 43%. The next large sample group making up 34% were between the ages of 26-35 years. The former group is most likely comprised of those homoeopaths who were educated and registered prior to the closure of the homoeopathic register thus a higher response is noted in the age group. The latter group most likely comprises those homoeopaths who were educated since the reopening of the register in 1985; they are thus most likely graduates of the M.Dip.Hom/M.Tech.Hom courses, which commenced at

Technikon Natal (now DUT), in 1989 and Technikon Witwatersrand (now UJ) in 1994. Of the other age groups that responded, the lowest was 3% at ages 20-25 years. This may indicate that the young homoeopaths that have not registered with the council or that they may not be in practice as of yet.

5.2.3 Ethnic Group

The analysis of the ethnic composition of the sample of respondent's shows that the White and Indian groups dominate, comprising 81% and 6% of the total respectively. These figures may reflect the fact that during the last 10 years, the students who have applied for the homoeopathic course have largely been derived from these two racial groups, with the Black and Coloured group forming the minority, with both comprising 2% of the total group composition. The group 'other' and the group 'not answered' were 8% and 2%, respectively, reasons given by the respondents for being in such groups was that they did not see the relevance of the question of ethnicity. In the study done by Babaletakis (2006) the majority of graduates were White, comprising of 87% and the next largest group was Indian at 11%. Courage (2006) had the majority group comprising of White, 63% and the Indian group being 31%. Ethnicity is a valuable tool to assess and re-assess, as noted in South Africa it is seen to change constantly in race groups and ratios of those groups. It is important to view the changing patterns of ethnicity, since the formalisation of homoeopathic education in South Africa.

5.2.4 Geographical distribution

The majority of homoeopaths seem to reside/practice in the most densely populated provinces of South Africa, Gauteng (30%) and Kwazulu Natal (KZN) (26%). The reason for the high percentages may be that only two homoeopathic educational institutions exist in South Africa which is located in Durban (KZN) and Johannesburg (Gauteng), i.e. these institutions are the Durban University of Technology and the University of Johannesburg. This has seen saturation or clustering of homoeopaths in these areas with other areas in the country poorly represented. The Western Cape comprises the third highest percentage being 17%; this may be due to the wide acceptance and practice of homoeopathy in the province, plus the aesthetic appeal of this province. The majority of the other provinces varied between 3-5%, this may be a result of their distances from the major South African centres, such as Cape Town, Durban and Johannesburg, as well as being more rural with relatively smaller patient population. Babaletakis (2006) noted that in her distribution of respondents that there was clustering to the three larger centres in South Africa, 46% response from Kwa-zulu Natal, 18% from Gauteng and 10% from the Western Cape.

5.2.5 Practice status

The majority of the respondents had a sole practice, (89%). This may be as the result of homoeopaths being unable to practice along side orthodox practitioners, as well as homoeopaths being unable to practice or treat

patients in orthodox medical facilities and hospitals in South Africa. It may also be due to the lack of acceptance of homoeopathy generally in the allopathic field of medicine. The Health Professions Act, 56 of 1974, currently restricts free communication between complementary health professionals and medical professionals. This limits the interaction between the general medical community and homoeopaths which effectively isolates homoeopaths. This is an issue to be addressed by the homoeopathic profession as a whole. Only 6% are in partnership and 6% have their practices located within a clinic. Partnerships are usually formed with other complementary practitioners such as chiropractors and clinics are mostly rural which the homoeopaths have established as they have seen the necessity of providing good health care in these areas.

Time in practice: A misinterpretation of the questionnaire resulted in the majority of the respondents answering 'other'. 'Other' was interpreted to mean more than 12 years in practice, but was not stated in the questionnaire as such. 'Other' was answered by 42% of the respondents to mean they had been in practice for more than 12 years. This correlates with the large percentage of the respondents, being over the age of 55 years. The group that had been practicing for between 3-5 years formed the next highest percentage (21%) this correlates with the age group 26-35 years, (34%).

Dispensary: The majority of respondents had their own dispensary (92%). This is most likely due to the absence of homoeopathic pharmacies in South Africa and relatively poorly stocked orthodox pharmacies. Practitioners may also

want to be sure of the nature and quality of remedies dispensed as well as the patient receiving the correct information regarding the dosage and posology of the remedies. Dispensing and compounding of a practitioners own medicines (non-proprietary) may also ensure that patients will return to the original source practitioner in order to obtain a repeated medicine; and so the financial benefits of a practitioner owning their own dispensary is a possible contributing factor. Individually compounded medicines also allow the practitioner to individualise prescriptions for each patient's symptom picture.

5.3 The attitudes of the registered homoeopaths regarding the availability of OTC homoeopathic medicines

A divided response was obtained from the sample regarding whether or not homoeopathic remedies should be available OTC. 19% of the respondents strongly agreed that homoeopathic medicines should be available OTC. Another 23% also 'agreed', and a further 23% 'slightly agreed'. The reasons being that certain orthodox medicines were available OTC, and so these respondents stated that homoeopathic medicines should also be available, further OTC medicines allow consumers access to homoeopathic medicines to those who may not have access to a homoeopath. The percentage of respondents that 'strongly disagreed' with the availability of OTC homoeopathic medicines was 21% and another 15% 'disagreed'.

5.3.1 Perceived benefits of homoeopathic OTC medicines

65% of the responses obtained, were positive i.e. in favour of OTC homoeopathic medicines. A significant number of practitioners did indicate that if they were away from their dispensaries and required medicines for themselves or their patients they would definitely recommend or use OTC homoeopathic medicines. The positive aspects of OTC homoeopathic medicines mentioned by respondents were: advertising, promotion of homoeopathy, a cheaper form of homoeopathic medication and easier accessibility for home usage. Many respondents said that homoeopathic OTC medicines were cost effective and that it made the public more aware of homoeopathy. Respondents also stated that homoeopathic OTC medicines allow the general public to be exposed to homoeopathy and it promotes accessibility to all members of society. Various other respondents said that OTC homoeopathic medicines had a positive impact on their business as it made the public aware of homoeopathy and more open to homoeopathic medicines and its uses. Some practitioners felt that some patients should not have to pay a consultation fee if they know what remedy they want or need, and so should be able to purchase the remedy from a retail outlet. One respondent was, quoted as saying, ‘can’t take every cough to a doctor’.

5.3.2 Perceived negative effects of homoeopathic OTC medicines

The negative aspects of OTC homoeopathic medicines mentioned were: incorrect use of medication, overdosing, and potential harmful effects if the

OTC medicine interacts negatively with other medication as well as concern over the risks of self-medicating without the advice from a practitioner.

Interestingly 79% of the respondents viewed that incorrect usage of homoeopathic medicines posed a danger to patients, while only 49% felt that there was a risk of overdosing. 69% of the respondents also felt that it was dangerous to self-medicate without a practitioner's advice. Many felt that ailments could be misdiagnosed and therefore mistreated with OTC medicines.

Homoeopathy is a medical science based on individualising the prescription choice to suite the specific needs of each patient, it is possible therefore that a broad spectrum OTC product such as a complex could fail to act or possibly cause an aggravation in the patient. Many practitioners said that if consumers were self-medicating themselves, a serious condition could be misdiagnosed, and that homoeopathic mother tinctures if available OTC could pose possible toxic effects if not used correctly. Another respondent said that they feared their patients using combination remedies, as taking more than one remedy at one time, may pose a risk on that patient's health. Some practitioners were concerned that OTC medicines allow dose, potency and repetition to be uncontrolled; which may lead to the patients having harmful reactions. A concern that many practitioners mentioned was that consumers who were self-medicating may merely be treating their condition superficially/palliatively which may be inherently dangerous, e.g. one of the respondents reported that they had a patient who was treating themselves with cold and flu OTC

homoeopathic medicines, when the flu did not seem to resolve, the patient consulted the practitioner and he was diagnosed with TB.

Thus in an ideal situation a patient should always consult a homoeopathic practitioner, as the in-depth consultation and physical examination will determine the most appropriate diagnosis and intervention. In the light of the above, when the respondents were asked if they thought that the broad availability of OTC homoeopathic medicines posed a risk to a patient's health, 53% agreed that it would. Their reasoning stated that if a patient is self-diagnosing their condition, they may diagnose wrongly and therefore treat wrongly, which may impact on the patient's health causing side effects, or the medication may fail to act.

Besides the clinical implications of OTC homoeopathic medicines on a patient's health/well-being, the impact of OTC medicines on ones business is also debateable; respondents were divided on this question, some said that the availability of OTC medicines resulted in a loss of profit to the practitioner and a portion of respondents did not perceive homoeopathic OTC medicine as a major marketing tool for the profession. A respondent commented that the building in which his practice was located had two health shops within it, he had said that they were very busy and he was not, he said that people felt it more convenient to source alternative healthcare via the health shops i.e. to purchase products OTC.

Concerns over the degree of competency/training of pharmacy and health shop staff were also raised, namely that staff should be formally trained before they should be permitted to recommend homoeopathic OTC remedies. Certain respondents said that selling homoeopathic medicines OTC was undermining the profession and its practitioner. These respondents also indicated that only a homoeopath has the responsibility and knowledge regarding safety and accuracy in prescribing the correct remedy to the patient, so remedies should only be available from a homoeopath.

5.3.3 Opinions regarding restrictions on OTC homoeopathic medicines

The majority of respondents (92%) felt that there should definitely be restrictions regarding the availability of OTC homoeopathic medicines. Some respondents felt that homoeopathic medicines should only be available with a prescription or used under the guidance of their practitioner, as they were medicines not just sweet tasting tablets. Many said that only basic remedies, such as tissue salts and first aid remedies, or low potency simplexes should be available OTC. Some said that OTC medicines must be produced by a reputable company, with clear instructions provided within the packaging.

5.3.3.1 Restrictions/ regulation regarding potency and OTC formulation/ composition

88% of the respondents felt that the potency range available OTC should be restricted. According to participants, OTC potencies must be low (not above 30CH) and only mainstream (polycrest) simplexes of low homoeopathic

potency (maximum 30CH) should be available OTC. Many of the respondents were concerned with any OTC available that contained high potencies, (over a 200CH), as they said that they would be concerned about the drug interactions if they were taking orthodox medicines. There was no limit suggested by the respondents regarding the availability of homoeopathic mother tinctures OTC. This is concerning as mother tinctures although the lowest available homoeopathic potency, do contain crude doses of the original substance and so has the potential to cause significant adverse drug interactions with resultant harmful effects. Possible reasons for respondents not commenting in this regard could be due to them viewing a homoeopathic mother tincture as herbal remedies (a common error/misconception), further the questionnaire did not explicitly query the respondents on their opinions regarding homoeopathic mother tinctures.

Some practitioners were concerned with the availability of complex remedy products; they felt that they should be controlled at least, as a patient could purchase a combination, for one ailment, a different combination for another ailment and end up taking a combination of 10-20 remedies at one time.

Other respondents said that only first aid and simple acute remedies should be available to the public, as the public needs to learn how to trust homoeopathy at a basic level, which would benefit the industry and profession as a whole.

5.3.3.2 Restrictions/ regulation regarding storage and quality control

Participants felt that the storage needs of homoeopathic medicines were different to other medicines and that products might become inactivated if storage and dispensing requirements were not met by retailers. Most practitioners were very firm on the issue of quality control, 89% indicated that OTC medications should only be sold pre-packaged and labelled by the manufacturer (as proprietary medicines), and should not be sold in bulk for re-packaging and labelling at a retail outlet. Many felt that only a suitably qualified homoeopath should be permitted to compound and dispense, and that they must have completed the Compounding and Dispensing licence. This indicates the high regard respondents hold in homoeopharmaceutics and quality control, as homoeopaths who completed their M.Tech in Homoeopathy, have studied homoeopharmaceutics extensively. In the absence of chemical testing procedures for validity of homoeopathic potencies, quality control is the primary assurance of reliable and safe medication. Practitioners felt that staff at pharmacies and health shops were not properly trained in homoeopathy and did not necessarily have the adequate knowledge and training in order to store the OTC remedies correctly. Respondents experienced concern over how in certain instances remedies were stacked on or near computers, in direct sunlight or near essential oils; these are factors that may potentially negatively influence the activity of a homoeopathic remedy. Some respondents said that it would be beneficial to have homoeopathic pharmacies in existence, like Weleda Pharmacies, which employed qualified individuals to advise patients on

homoeopathic remedies. 85% of respondents were strongly against homoeopathic OTC medicines being repacked/dispensed or labelled outside of a formal, licensed practice environment.

5.3.3.3 Restrictions/ regulation of training and practices of staff at retail outlets

Some participants said that the homoeopathic OTC medicines should only be sold by a homoeopathic practitioner, as they understand potency, dose and repetition. Practitioners felt that giving an incorrect remedy, which is incorrectly administered, may activate in a sensitive individual, a latent miasm, or a chronic condition or cause an aggravation. Practitioners felt that staff at pharmacies and health shops were not properly trained in homoeopathy and did not necessarily have the adequate knowledge and training to prescribe, dispense OTC remedies correctly. Currently most products have no instructions or guidelines that state a patient should only take one combination remedy. Normally product consulting would usually be conducted by a pharmacist, however many pharmacists do not understand the negative impacts of taking more than one combination could have for a single individual. Other practitioners noted that some patients tended to go back to the same health shop or pharmacy to purchase repeats of the same medicines. This occurs without any formal documentation or records being made, this uncontrolled repetition of OTC homoeopathic medication could negatively affect the consumer as they may begin to prove the remedies.

5.3.3.4 Regulations on pricing of OTC homoeopathic medicines

Many respondents felt that when they compared prices of OTC homoeopathic medicines with corresponding orthodox OTC medicines; they found that homoeopathic OTC medicines were in fact not a cheaper form of medication.

Thus most respondents, (59%) were in favour of there being regulations and limitations to pricing of OTC homoeopathic medication, although the main concern was that the medicines should be affordable. Many respondents felt that the pricing should be regulated by an official body such as government, council, or medical aids, in order for pricing to be similar between brands and companies. Respondents indicated that prices should be uniform, and standardised, so that the public is not exploited, so that homoeopathy does not become an elite form of medicine which only the wealthy can afford. Although regulation of pricing wasn't favoured by some 32% of the respondents, it was said that good quality products did cost a little more to produce and so they did not want limitations on pricing to influence the quality of medicines produced or to inhibit healthy competition between manufacturers.

5.3.4 Practitioners use and choice of OTC homoeopathic medicines

64% of respondents do refer or have referred patients to out source OTC homoeopathic medicines at a retail outlet. This may indicate that the practitioner feels that at times the patient does require a commercially

available OTC preparation and that the practitioner in reality would be unable to stock every OTC medicine that is available. The practitioner may also refer a patient to a retail outlet if the patient has travelled and is unable to consult their practitioner directly. Reasons given by respondents for not stocking OTC medicines were that financially it was not viable as there are so many ranges and varieties available. The respondents that had dispensaries said that there would not be enough storage space in their dispensary to keep stock of all the OTC homoeopathic medicines. The practitioners were also asked whether they dispensed OTC homoeopathic medicines in their own practice, 68% said that they did, and they used and prescribed them daily. This indicates that practitioners consider certain OTC's products and preparations useful and effective medicinal interventions.

Practitioners were asked directly which company or brand of OTC homoeopathic medicines they mostly recommended, *Natura* and *Heel* were the two brands that most practitioners preferred. *Natura* was the most recommended (42%), with *Heel* (26%) - a distant second. This may reflect the dedication that each company has towards the homoeopathic profession and homoeopathic practitioners, as well as their constant promoting of homoeopathy and homoeopathic products. *Reckeweg* was the third most preferred company with 10% of the respondents recommending it. In the survey there was a much-divided response between the respondents about other companies, eight other companies were recommended, which included *Pharma Natura*, *Weleda* and *Vogel*.

5.4 Correlation Analysis

5.4.1 The influence of demographics on practitioner's opinions of OTC homoeopathic medicines

A correlation was found between the ethnic group of respondents and whether they refer patients to the retail sector to purchase OTC's, there was a strong correlation found between the Indian group of respondents as they were more likely to refer a patient to purchase OTC medication.

When the ethnic groups were measured regarding their opinion on quality control, a higher proportion of respondents from the white group were found to have disagreed with the idea of compounded/repackaging and labelling of OTC homoeopathic products by retail outlets.

Gender was measured against the opinion of the availability of OTC homoeopathic medicines, it was noted that female respondents were more likely to agree that OTC homoeopathic medicines should not be limited or restricted.

5.4.2 The influence of practice status on practitioner's perceptions of OTC homoeopathic medicines

Results were skewed regarding the geographic location of practitioners as the majority of respondents practiced in three demographic regions corresponding to three major South African cities; correlations however are still mentioned as follows:

The area/location of the respondents practice was measured against what the respondents thought about the availability of OTC homoeopathic medicines and if they should be limited. Respondents located in the Gauteng, KZN, and Western Cape provinces were unanimous in that the availability of OTC homoeopathic medicines should be limited and regulated. This strong correlation may be due to the high number of practising registered homoeopaths and the high numbers of 'retail outlets' (potentially seen as competitors) in these areas, thus a higher degree of perceived competition. This factor of competition may play a role when choosing the correct location for a homoeopathic practice.

In contrast to respondents opinions from the smaller provinces on potency, the respondents opinions from the larger provinces of Gauteng, KZN, and Western Cape; agreed unanimously that the potency of OTC homoeopathic medicines should be limited.

Similarly respondents from Gauteng, KZN and the Western Cape province who were firm on their opinions, stated that there should be strict quality control enforcing only manufacturers to handle the homoeopathic OTC medicines. They felt that only the manufacturers should package and label any homoeopathic OTC medicines.

CHAPTER 6: Conclusion and Recommendations

Conclusion:

The major concerns expressed by participants regarding the availability of OTC homeopathic remedies included:

- Lack of regulation of the potency of commercially available remedies.

Legally there are laws that restrict the availability of alternative health products, such as OTC homoeopathic medicines; but a literature review has found major loop holes. These inadequacies/insufficiencies in these laws, highlight that there is currently no legal restriction regarding the availability of homoeopathic ranges of potencies available OTC.

- The lack of suitable training of retail outlet staff.

Currently the level of knowledge of retail outlet staff is not regulated and thus the degree of knowledge of such staff is inconsistent. Thus the potential for misdiagnosis of a condition or an incorrect remedy choice is high. Unsuitably trained staff also has negative implications regarding storage and thus quality assurance of the products.

Answers highlighted that the effects for the patient's health as well as their perceptions of the effectiveness of homoeopathic remedies is reduced because of the misuse of homoeopathic OTC remedies by consumers.

- Risks to quality control of homeopathic OTC remedies at retail outlets.

Most respondents felt that OTC homoeopathic medicines should be quality controlled in that it would be more reliable and safer to be packaged and labelled for individual sale and not sold in bulk for re-packaging and labelling at the point of sale. Quality control is the primary assurance of reliable and safe medication.

- Lack of pricing regulations of OTC homoeopathic remedies.

Most respondents felt that there was a lack of restriction regarding the pricing of OTC medications. They implied that consumers may be exploited and the cost-effectiveness of the remedies could be jeopardised. A practitioner's business practice may also be jeopardised.

- Potential negative impact of commercially available homoeopathic remedies on the business of the homoeopathic practitioner.

Some respondents perceived the availability of homoeopathic remedies without limitation and regulation at retail outlets to negatively influence the commercial viability of their practices.

Respondents perceived the following as benefits of the availability of homeopathic remedies OTC:

- Improving awareness of homoeopathy as a profession and as an alternative to orthodox treatment.

Respondents identified commercially available homoeopathic remedies as a method of promoting awareness among the general public.

- Facilitation of consumer access to homoeopathy.

Commercially available homoeopathic remedies afford the consumer the choice of an alternative form of treatment for their ailments.

Summary

The majority of respondents were in favour of the availability of homoeopathic OTC medicines to the public, provided that they are suitably regulated to ensure patient safety and quality control. Furthermore the regulation of the relevant retail outlets including education of staff in this regard was recommended. Respondents also were in favour of the awareness of the profession that homoeopathic OTC medicines created.

Recommendations:

- The Homoeopathic Association of South Africa (HSA), Allied Health Professions Council of South Africa, and Pharmacy Council should collaborate to review current legislation (or the lack thereof) in the light of the responses provided in this study in order to address the key areas of concern.
- Steps to ensure that staff at retail outlets are suitably trained and educated in order to safely and suitably recommend homoeopathic remedies to consumers. A way of controlling this is to introduce new regulatory legislation.
- Further studies of this nature should ensure that the opinions regarding availability of each individual form of homeopathic remedies are determined including homoeopathic mother tinctures.
- Steps to ensure an increased response rate in future studies should be taken; as in two previous studies conducted (Babaletakis, 2006) and (Courage, 2006) locating and contacting members of the target population (registered homoeopaths) was met with difficulty due to poor record keeping/outdated databases of the contact details of each registered homoeopath. It is recommended that the AHPCSA actively pursue the updating of the register. A way of controlling this may be to introduce student registration from first year until their qualification is

obtained, therefore ensuring available records of students and practitioners. This process was brought into action this year 2008.

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APPENDIX A

QUESTIONNAIRE

This survey takes about 10 minute to complete. The data will only be identified by code numbers and no names and contact details will be connected to them ensuring confidentiality.

INSTRUCTIONS:

- All Homoeopaths are requested to fill in Part A - Demographics
- All Homoeopaths are requested to fill in Part B- Questionnaire
- Fill the answer numbers where appropriate
- When an option is given for other please specify in the space provided.

PART A: DEMOGRAPHIC DATA

Personal Details:

Question 1.1

First Names	
Surname	
Date of birth	
Race	
Age (in years)	

(Removed by independent third party prior to passing onto researcher)

Question 1.2

City/ Town of Practice:

Question 1.3

Gender:

Female		Male	
--------	--	------	--

Question 1.4.1

What are your formal Homoeopathic Qualifications?

Question 1.4.2

Do you posses any other Qualifications, which may not be related to Homoeopathy?

Question 1.5

How long have you been in practice?

0-2 years	
3-5 years	
6-8 years	
9-12 years	
>13 years	
Other	

Question 1.6

In what area do you practice?

Kwa-zulu Natal	
Gauteng	
Western Cape	
Eastern Cape	
Northern Cape	
Limpopo	
Northern Province	
Free State	
Mpumalanga	
Other	

Question 1.7

What is your type of practice?

A sole practice	
A partnership	
Hospital	
Clinic	
Other	

Question 1.8

Do you have your own dispensary?

Part B- Questionnaire

The definition of OTC: Over the Counter- these medicines are sold directly to the public with no prescription needed. OTC medicines may be sold at any retail outlet, i.e. a Pharmacy or general store.

For the purpose of this study the definition of a homoeopathic medicine/ remedy is: a remedy is produced according to Homeopathic principles, i.e. serial dilution and succussion, it is prescribed according to the Law of Similars. The medicine could comprise of a single or a combination of homoeopathic remedies.

Self-medication: the self-selection and consumption of medicine not prescribed by or recommended by a Healthcare Provider.

Question 2.1

I am in favour of the availability of Homoeopathic medicines Over the Counter?

Strongly Agree	
Agree	
Slightly Agree	
Disagree	
Strongly Disagree	

Elaborate _____

Question 2.2

Do you agree or disagree with some of the possible benefits or negative effects of OTC homoeopathic medicines below, please elaborate on your choice:

Benefits:	Yes	No	Negative Effects:	Yes	No
Advertising for homoeopathy			Incorrect usage of a medicine		
A form of Promoting			Overdose		

Homoeopathy					
A Cheaper form of medicating, for a more disadvantaged patient.			Potentially harmful if the OTC interacts negatively with other medication.		
More accessible for home usage. E.g. self-medicating			Self-medicating without advice from a practitioner.		

Other _____

Elaborate _____

Question 2.3

In your opinion should there be any limitations or restrictions regarding the availability of OTC homoeopathic remedies?

Yes		No	
-----	--	----	--

Elaborate _____

Question 2.3.1

In your opinion should there be any limitations or restrictions regarding the specific potency available OTC?

Yes		No	
-----	--	----	--

Question 2.3.1.1

If yes to question 2.3.1, what would you recommend?

Question 2.3.1.2

With regards to question 2.3.1.1 why?

Question 2.4

Do you think that the broad availability of OTC Homoeopathic medicine poses a risk to a patient's health?

Yes		No	
-----	--	----	--

Elaborate _____

Question 2.5

What are the impacts (if any) of the availability of OTC Homoeopathic medicines on your practice (business)?

Question 2.6

Do you use or dispense Homoeopathic Medicines, which are also commercially available OTC?

Yes		No	
-----	--	----	--

Question 2.7

Do you ever refer your patients to a retail outlet in order to source any OTC homoeopathic medicines?

Yes		No	
-----	--	----	--

Question 2.7.1

If yes to question 2.7, in what situation or under what circumstances would you refer your patients to these retail outlets (sources that are not from your dispensary)?

Question 2.7.1.2

If yes to question 2.7, why don't you stock the OTC homoeopathic medicines in your dispensary?

It is too expensive	
---------------------	--

There is not enough space in my dispensary	
I do not have a dispensary	

Other _____

Question 2.8

With regard to quality control of OTC homoeopathic medicines:

	<u>Yes</u>	<u>No</u>
OTC's should be packed and sealed by a registered homoeopharmaceutics company in individual units for resale by retail outlets.		
Repacking and labelling of bulk OTC's by retail outlets should be permitted.		

In your opinion, should OTC homoeopathic medicine be subject to any other regulations regarding sale?

Question 2.9

Do you think that there should be any limitations or restrictions on the pricing of OTC homoeopathic medicines?

Yes		No	
-----	--	----	--

Question 2.9.1

If yes to question 2.9, what would you recommend? _____

Question 2.9.2

With regards to question 2.9, why?

Question 2.10.

Which OTC homoeopathic medicine do you mostly recommend or prescribe (if any)?

Question 2.10.1

What company or brand do you mostly recommend?

Question 2.11

Are there any specific homoeopathic over the counter medicines that you find particularly useful in your daily homoeopathic practice?

Question 2.11.1

Are there any specific homoeopathic over the counter medicine that you think should not be available over the counter?

Question 2.12

Do you want Homoeopathic medicines to be available over the counter?

Yes		No	
-----	--	----	--

Additional Comments:

Appendix B

Information Letter

Date:

Dear _____ Doctor of Homoeopathy _____

Title of Research Project:

A survey to determine the perception of registered homoeopaths in South Africa toward the availability of over the counter (OTC) homoeopathic medicines.

Name of Supervisor: Dr.David Naude (Mtech (Hom)).

As part of the completing the Masters Degree in homoeopathy, our academic programme extends over a five-year period, including one year's clinical practice as well as a doing a research dissertation. I have chosen to undertake a qualitative study; I am conducting a survey amongst all registered homoeopaths in South Africa to determine their perceptions towards the availability of over the counter homoeopathic medication in South Africa. I would like to ask you to please participate in the study, I understand that you are very busy and have many things to attend to daily.

Participation will involve completing a Questionnaire, which may take up to 10 minutes of your time in total.

As you are probably aware, the selling and use of homoeopathic medicine over the counter is a very controversial topic, plus there are many questions about self-medication with homoeopathic over the counter products and the safety to our patients.

I realise that your time is valuable and thus each Questionnaire has been limited to only the most crucial information, yet still including enough questions to ensure that the study provides meaningful information.

Please note that each practitioner will be assigned a practitioner number, ensuring anonymity.

The procedure will be as follows:

1. Once the Questionnaire is completed please may you return send your completed letter/email Questionnaire to the following email address kayack@cybertrade.co.za, return address: 5 Floralwood, 17 Inanda rd, Hillcrest, Kzn, 3610. (Addressed to Tymara)
2. The Questionnaire is addressed to an independent third party, once they have received the email/letter, your name will be marked off and deleted, and you will then only be known by a number, this is to ensure confidentiality.

3. Once you have received the Questionnaire together with this letter, there is a two-week time lapse in which you must please return it.
4. If the Questionnaire has not been sent by the two-week period, the researcher will contact you as a reminder to complete and return the document.
5. Then a further two weeks will be allowed for the return of the Questionnaire, after which time non-complying candidates will be considered 'drop-outs' of the study.

The benefits of this study for you as practitioner will be:

- The views or consensus on various issues that homoeopathic practitioners are faced with daily.
- As a homoeopathic community, what practitioners feel about certain factors involving the various issues around OTC homoeopathic medicines.

The researcher and participants will receive no remuneration for undertaking and participating in the study. The cost of the study will be in the hands of the Durban University of Technology.

If you have any queries or you are faced with any problem at any time please do not hesitate to contact:

Tymara Broughton at: 0834451628 or during the day at 0313124812

When the dissertation is complete, an abstract and table of contents will be sent to you. A copy of the full dissertation will be available for loan to you if you are interested from the D.U.T. library.

I believe that this study will provide valuable and vital information regarding Homoeopathy in South Africa, and it may contribute to developing the Homoeopathic profession as a whole, due to the importance of the various issues asked in the Questionnaire of which we are faced with daily. Your co-operation is greatly appreciated.

Yours sincerely

Tymara Broughton

Research Student

Appendix C

Thank you Letter

Date: _____

Dear _____ Doctor of Homoeopathy.

Thank you for your participation in the research study on the perceptions of registered homoeopaths in South Africa toward the availability of over the counter (OTC) homoeopathic medicines.

The information supplied has been valuable to the ongoing education and training as well as to the realistic economic viability of the Homoeopathic Profession in South Africa.

Please do not hesitate to contact us should you have any further questions. A copy of the research study will be available at the Durban University of Technology (DUT) library.

I wish you all the success in the future.

Sincerely

Tymara Broughton
Research Student

Dr. D. Naude M.Tech:(Hom)
Supervisor

Appendix D

Pilot Assessment Form

A survey to determine the perception of registered homoeopaths in South Africa toward the availability of over the counter (OTC) homoeopathic medicines.

Dear Assessor

Thank you for agreeing to assist in the piloting of the questionnaire to be used in the above mentioned research.

You are requested to please read the attached questionnaire, once you have reviewed the questionnaire you are required to fill out the following assessment form.

Additional comments can also be written on the questionnaire itself. All the gathered information will be used to ensure that the intended results of the survey are achieved.

Please answer and elaborate on the following:

1. Time taken to complete the questionnaire _____
2. Do you feel the time taken to complete the questionnaire was too long?

3. Is the presentation and layout of the questionnaire appropriate?

4. Were the instructions easy to follow?

5. Were the questions clear?

6. Did they follow a logical sequence?

7. Were any questions irrelevant?

8. Any additional
Comments _____

Thank you for your cooperation.

Yours Sincerely

Tymara Broughton
Research Student

Dr.D.Naude
Supervisor

Appendix E

Practitioner Informed Consent Document

Title of Research Project

A survey to determine the perception of registered homoeopaths in South Africa toward the availability of over the counter (OTC) homoeopathic medicines.

Name of Supervisor: Dr. D. Naude (M.Tech (Hom))

Date: _____

Please circle the appropriate answer:

Have you read the research information sheet?	Yes	No
Have you had an opportunity to ask questions regarding the study?	Yes	No
Have you received satisfactory answers to your questions?	Yes	No
Have you had an opportunity to discuss this study?	Yes	No
Have you received enough information about this study?	Yes	No
Do you understand the implications of your involvement in this study?	Yes	No
Do you understand that you may withdraw from the study: a. At any time. b. Without having to give any reason	Yes	No
Do you agree to voluntary participate in this study?	Yes	No

If you have answered 'No' to any of the above, please obtain the necessary information before signing.

I, _____ hereby agree to participate in the study that will look at Homoeopathic practitioner demographics, and opinions and perceptions regarding Over the counter homoeopathic medication.

I am aware that this involves answering certain questions regarding my views and opinions as a qualified Homoeopath.

Please print in block letters:

Practitioners name: _____ Signature: _____

Witness name: _____ Signature: _____

Research Student name: T.Broughton Signature: _____