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UTILISATION OF OVER-THE-COUNTER MEDICINES IN MEDICAL SCHEMES IN SOUTH AFRICA

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Original published work submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in fulfilment of the requirements for the degree of Doctor of Philosophy.

Johannesburg, 2020

DECLARATION

I, Neelaveni Padayachee student number 0711983X, declare that this Thesis is my own work and that I contributed adequately towards research findings published in the articles stated below which are included in my Thesis.



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Professor Alan D Rothberg

Third Supervisor



……day of …May 28 2020

Professor Ilse Truter

DEDICATION

To my children:

Shivashen Wologanathan Padayachee

Santhan Wologanathan Padayachee

Karunya Aadhi Padayachee

ABSTRACT

In South Africa over-the-counter medicines (OTCMs) are freely available to consumers. Medical schemes allow beneficiaries to purchase OTCMs at their discretion via 'acute medicines benefits'. The primary aim of the study was to explore the utilisation of OTCMs in medical schemes. The dataset was obtained in 2015, from a large medical scheme administrator, providing data for 641 525 beneficiaries. The thesis covers three studies and an article considering ethical issues.

The first study focused on the impact of benefit design on utilisation of OTCMs. Two plans were compared, one with rich benefits, the other providing more-restricted benefits. Members accessed OTCMs from the risk pool in the high benefit plan and from a discretionary, day-to-day benefit in the low benefit plan. Pharmacists and beneficiaries showed a preference for more-expensive generic and original OTCMs, particularly in the rich benefit plan. Doctors prescribed lower-cost products and favoured generics, but also prescribed more-expensive generics or originals to patients in the rich benefit plan. The use of OTCMs did not appear to have an impact on downstream healthcare cost.

The second study explored utilisation at a product level, focusing on multi-component analgesic OTCMs, most containing combinations of codeine, paracetamol, caffeine and doxylamine. Unique contributions of this study were that larger pack sizes were dispensed by pharmacists compared to doctors, and no differences were found between doctors who were contracted to the scheme as 'designated providers' vs. those who were not. However, dispensing doctors prescribed cheaper and smaller pack sizes of analgesic OTCMs. Of particular note was the large price variation between similarly-constituted products.

The third study measured access to commonly-used OTCMs by individuals registered for the management of common chronic diseases via a disease management programme (DMP), and to consider why the medicines were accessed in addition to mainstream drugs prescribed for treatment. There was high utilisation of condition-related OTCMs, most likely to improve uncontrolled disease, or possibly for management of a side-effect of medicines prescribed for treatment of another disease. These OTCMs should be claimed via the risk pool as part of chronic disease management and not paid as 'discretionary' benefits. Results indicate that medical schemes and their DMPs are failing to deliver on their mandate.

The final paper was based on results of the three studies and considered the ethics around OTCM access: utilisation by individuals; manufacture, marketing and sales; service delivery by doctors and pharmacists; and most importantly, relevant national policies and guidelines. The

conclusion is that OTCMs are behaving as a commodity and not a right. Conclusions and recommendations are presented in the context of three important issues currently being debated in the country: National Health Insurance; the Health Market Inquiry; and amendments to the Medical Schemes Act.

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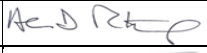
AGREEMENT BY CO-AUTHORS

By signing this declaration, the co-authors listed below agree to the use of the article by the student, N Padayachee as part of her Thesis.

Paper 1: **Over-the-counter medicine utilization by beneficiaries under Medical Schemes in South Africa**

Student is first author

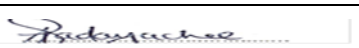
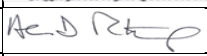
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Paper 2: **Utilisation of over-the-counter analgesics in two private medical insurance schemes in South Africa**

Student is the first author

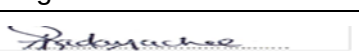
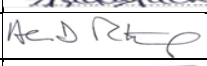
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Paper 3: **Use of over-the-counter medicines: a window into chronic disease management by medical schemes**

Student is first author

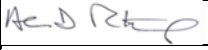
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PUBLICATIONS

Four peer-reviewed journal articles arose from this study.

CONFERENCE AND POSTER PRESENTATIONS

- 2017 podium presentation at the Therapeutic Sciences Research Day
  Schedule 0-2 medicines utilisation by patients belonging to medical schemes in South Africa.
- 2017 Poster presentation at the ISPOR conference in Sandton
- 2019 podium presentation at the Therapeutic Sciences Research Day
  Medical Schemes: Saints or Sinners when it comes to managing disease management programmes

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CONTRIBUTIONS OF AUTHORS TO THE STUDY

Within this thesis my supervisors and I contributed directly to the research design, implementation and writing of the publications herein. I hereby acknowledge their specific contributions towards the papers presented in this thesis.

The research design was primarily conceptualised by myself under the close guidance and mentoring of Professor Alan Rothberg. The analysis and design were conducted independently; however my supervisors were available for consultation whenever I required it. Dr Neil Butkow and Professor Ilse Truter assisted in the fine-tuning of the research design and provided assistance with the drafting of the publications.

I primarily drafted the structure and layout of the thesis. Professor A Rothberg reviewed and assisted with the body of the research while Dr N Butkow and Professor I Truter assisted with components of the literature review. They made recommendations on the aspects that the study should focus on to ensure that the thesis shows originality and provides clear outcomes.

The papers were primarily conceptualised and written by myself with assistance from my supervisors. Professor Alan Rothberg assisted with methodology and discussion for each paper whilst Dr N Butkow and Professor I Truter assisted with the literature review.

NOMENCLATURE

AIDS	- Acquired Immune Deficiency Syndrome
ATC	- Anatomical Therapeutic Chemical
CDL	- Chronic Diseases List
CMS	- Council for Medical Schemes
DMP	- Disease Management Programme
DSP	- Designated Service Provider
EML	- Essential Medicines List
GDP	- Gross Domestic Product
GP	- General Practitioner
GPP	- Good Pharmacy Practice
HIV	- Human Immunodeficiency Virus
HMI	- Health Market Inquiry
MMAP	- Maximum Medical Aid Price
MPR	- Medicine Price Registry
NCD	- Non-Communicable Disease
NDP	- National Drug Policy
NHI	- National Health Insurance
OECD	- Organisation for Economic Co-operation and Development
OTCM	- Over-the-Counter Medicines
PAT	- Pharmacist Assisted Therapy
PCDT	- Primary Care Drug Therapy
PHC	- Primary Health Care
PMB	- Prescribe Minimum Benefit
SA	- South Africa
SAHPRA	- South African Health Products Regulatory Authority
SEP	- Single Exit Pricing
SM	- Self-Medication
SSR	- Supply Side Regulator
STG	- Standard Treatment Guidelines
TRIPS	- Trade Related Aspects of Intellectual Property Rights
WHO	- World Health Organisation

CHAPTER ONE: INTRODUCTION AND LITERATURE REVIEW

INTRODUCTION AND LITERATURE REVIEW

The focus of this thesis is on access to and utilisation of over-the-counter (OTC)/non-prescription medicines in South Africa (SA). The ideal situation would be access for all SA citizens to affordable, appropriate, high quality OTC medicines (OCTMs), but as indicated in Figure 1.1 below, achievement of this goal would be dependent on an optimal relationship and interplay between the numerous stakeholders involved.

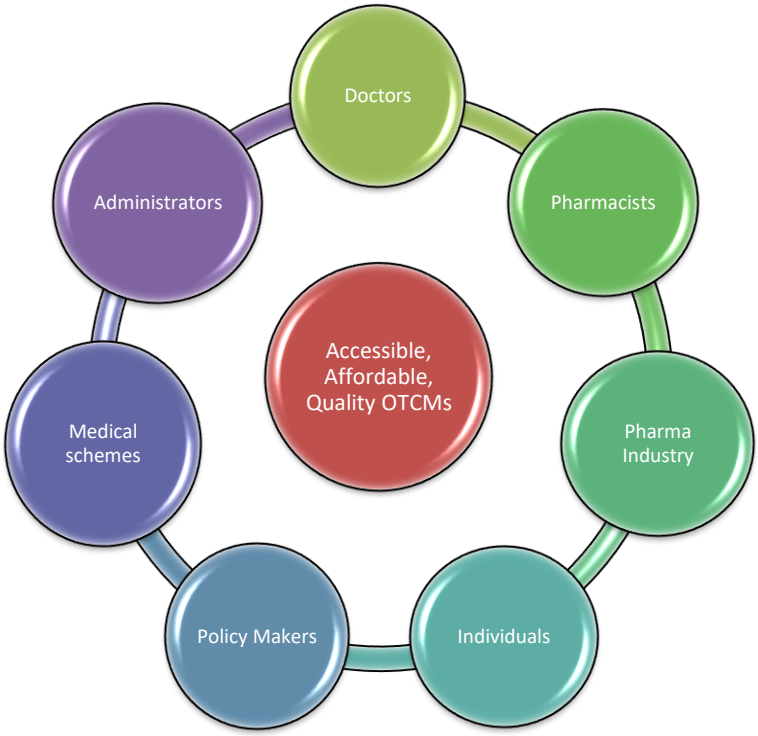


Figure 1.1: Stakeholders Involved in Utilisation of OTCMs

Before delving into the dynamics and logistics of access and utilisation it is necessary to examine the basis for access to these medicines, which is the enabling of individuals to self-medicate. This is typically for treatment of minor ailments that do not require the intervention of a doctor, but on occasion patients also access OTCMs for self-medication of an underlying chronic condition.

1.1 OVER-THE-COUNTER MEDICINES

Over-the-counter medicines are medicines that are available without a prescription. Their purchase is usually triggered by the patient and overseen by a pharmacist[1]. The difference between OTCMs and prescription medicines can sometimes be a blurred line because differentiation may be based on dosages and/or indications. For example, in

SA, doxycycline an antibiotic, is available as a Schedule 2 drug (without a prescription) for the chemoprophylaxis of malaria (in those aged 8 years and older for not longer than 4 months). However, if it is used for other infectious indications then it is regarded as a Schedule 4 drug, which requires a prescription[2]. A full explanation of scheduling of medicines is provided below, as determined by the South African Health Products Regulatory Authority (SAHPRA).

Over-the-counter medicines in SA are legislated by the Medicines and Related Substances Act 101 of 1965. Medicines are categorised according to Schedules. These Schedules range from Schedule 0 to Schedule 8, and OTCMs are covered in Schedule 0 to Schedule 2. The scheduling status is based on international guidelines in which control over access, possession and supply are considered. The overarching considerations for the scheduling status in SA are based on the SAHPRA Scheduling of Medicines Guideline[1-2].

These guidelines are extracted directly from the SAHPRA Scheduling Guidelines[2], page 10:

- evidence for the toxicity of the substance and the safety in use;
- the proposed indication for the substance;
- the need for medical diagnosis, monitoring and medical management by a healthcare professional;
- the potential for abuse and
- the need for access to the substance

<u>Schedule 0</u>

Schedule 0 (S0) medicines are considered to be safe for use and do not require the advice of a medical professional. This is the only Schedule that is unaffected by government-regulated single exit pricing (SEP), which aims to promote transparent medicine pricing in SA by legislating a single price for all medicines sold by manufacturers to distributors or dispensers[3]. Single exit pricing will be discussed in detail at a later stage. Paracetamol is an example of an S0 medicine that is available in any general store in pack sizes that do not exceed 24 tablets. Pack sizes that are greater than 24 are sold and available at a pharmacy as a Schedule 1 drug and, according to legislation, sales are required to be recorded by a pharmacist, pharmacist intern or pharmacist assistant[2].

Schedule 1 and Schedule 2

Schedule 1 medicines are considered safe but may require the advice of a medical professional and are used to treat minor illnesses and ailments such as mild pain, mild fungal infections or coughs and colds. These products are provided in legislated quantities and dosages, and if exceeded become a higher scheduled prescription-only drug. See examples below[2].

Table 1.1: Examples of Schedule 1 and Schedule 2 Medicines

Drug	Status (S1 or S2)	Schedule 3 and above
Ibuprofen	Tablets used for mild to moderate pain for a maximum of 10 days and should not exceed 1.2 grams (S2) Used for the treatment of gout and not exceeding 5 days (S2)	Exceeding 1.2 grams (S3)
Orphenadrine	When used as a muscle relaxant (S2)	Any other condition (S4)
Codeine	Oral preparations containing not more than 10mg of codeine per dosage unit and with a maximum daily dose not exceeding 80mg for a treatment period of 5 days, and limited to one pack per customer. Not intended for export (S2)	More than 10mg (S3)

Although these legislative/regulatory measures exist, enforcing and monitoring of the requirements necessitate a supply of human and other resources by the legislative bodies. Stricter control of codeine was considered via the Codeine Care Project which entailed establishing a centralised database to monitor the purchase of all codeine products sold using the individual's identity number, however, this did not materialise[4].

Schedule 3,4,5 and 6 drugs are prescription only, however, a pharmacist who has a primary care drug therapy (PCDT) license as stipulated by section 22A of the Medicines and Related Substances Act, is able to prescribe S3 and above within the scope of the PCDT licence[5]. Schedule 7 drugs are controlled substances such as cocaine, while Schedule 8 includes drugs that are strictly controlled such as amphetamine. A summary of the schedules are provided in **Table 1.2** below.

Table 1.2: Medicine Scheduling in South Africa[6]

Medicine schedule	Where is it available and what do you need to know?	Example
Schedule 0	On the shelf at a general shop	Simple analgesics like aspirin
Schedule 1	Over the counter at a pharmacy. A sale record must be kept.	Antibacterial and antifungal skin creams
Schedule 2	Over the counter at a pharmacy. A sale record must be kept.	Cough and cold preparations
Schedule 3	Prescription only; available from the pharmacy dispensary – can be repeated for 6 months.	Medicines for hypertension and diabetes
Schedule 4	Prescription only; available from the pharmacy dispensary – can be repeated for 6 months.	Anti-infectives like antibiotics and antivirals
Schedule 5	Prescription only; available from the pharmacy dispensary – repeats stipulated.	Pyscho-active medicines like sedatives and anti-depressants
Schedule 6	Prescription only; available from the pharmacy dispensary	Narcotic painkillers
Schedule 7	Controlled substances	Drugs like cannabis and heroin
Schedule 8	Strictly controlled substances	Amphetamine, dexamphetamine and nabilone

1.1.1 **Classification of an OTCM**

ing to the World Health Organisation (WHO), the basic requirements for a product to be classified as an OTCM involve three criteria. Moreover, detailed labelling should always provide the consumer with sufficient information to assist in making an informed decision as to when, how and why to self-medicate[1].

The first criterion is that the active ingredient should not be toxic at the recommended dosage. The assumption here is that individuals will understand the labelling and adhere to the dosage requirements. This issue was addressed by Trivedi et al, who showed that non-prescription medication labelling is often incomprehensible to a lay person and needs to be improved for readability[7]. Additionally, a case reported by Gunn in 2001 detailed the death of a nine-month-old baby from a mixed-drug intoxication after the ingestion of multiple doses of a cold and flu preparation that contained phenylpropolamine, acetaminophen, pseudoephedrine, dextromethorphan and chlorpheniramine. This highlights not only the “recommended dosage” component but also the ability of parents or patients to use medicines rationally[8]. Furthermore, there are questions around the quality checks on the information on OTCM labels. In SA, the regulatory body, SAHPRA, as per the regulations of the Medicines and Related Substances Act 101 of 1965, provides a clear guide to manufacturers on the requirements for the labelling of medicines[5]. In addition, SAHPRA serves as the final quality control mechanism before the product is sold[9]. Along these lines, Balbani in

Brazil discovered that important excipients were missing on OTCM labels, which could result in adverse events[10]. Clearly, if an ingredient is missing then actual information about toxicity will also be missing. The complexity of describing OTCMs is frequently the result of multiple active ingredients in one product. Whether these combinations are clinically valuable is questionable[11], however, if an individual is unaware of the multiple active ingredients, and combines the OTCM with a drug that has the same active ingredient, there could be serious adverse effects and/or toxicities[12].

The second WHO criterion states that the intended use of the medicine should be suitable for self-medication, but should not delay diagnosis and treatment of a medical condition. A study by Ducrotte showed that individuals delayed seeking treatment for potentially-precancerous gastric oesophageal reflux disease for up to 2 years, based on an assumption that OTC proton pump inhibitors (PPIs) worked effectively for heartburn and/or indigestion and could be used for months or years[13]. Inadomi, also raised concerns about the potential for PPIs to mask underlying pathology, and recommended that in the case of self-treatment for indigestion/heartburn, therapy should rather be discussed with a healthcare professional and 'personalised'[14].

Lastly, the product should not have unwanted adverse effects or require constant monitoring[1]. The term unwanted adverse effects is used loosely in this context, considering that in SA a potentially harmful product such as codeine is freely available as an OTCM, albeit in low doses. Thus, the potential for abuse exists, particularly with the ability of a patient to 'pharmacy hop' and purchase multiple packets or bottles of such products at a number of pharmacies with little or no oversight or control. This criterion will also not apply to chronic medicine users who are also regular OTCM users and should therefore be carefully monitored for potential adverse effects resulting from the combination of OTCMs and concurrently-prescribed higher-schedule medicines[15]. Also of concern is the case of theophylline, a narrow spectrum therapeutic agent that is a common ingredient in cough mixtures. Using too much, or use in combination with other drugs, may result in toxicity and even death[16].

Although these WHO criteria exist, the underlying assumption is that the consumer can either independently, or with the assistance of a pharmacist, recognise and diagnose symptoms, be cognisant of underlying chronic conditions, and understand the labelling instructions of the OTCM[1]. The WHO also defines 'rational use of medicines' and states that "patients should receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community"[17].

1.1.2 Benefits and Risks of OTCMs

Taking cognisance of the above information, to understand the position of OTCMs in the clinical treatment of a myriad of self-diagnosed diseases it is important to consider the risks and benefits of OTCMs.

Table 1.3: Benefits and Risks of OTC Medicines

Benefit	Risk
▪ Increased access to effective treatment[18-19] ▪ Reduction in physician visits[18] ▪ Increased productivity[18] ▪ Increased patient autonomy[18-19] ▪ Reduced costs to third-party payers (government and insurance companies)[18] ▪ Increased availability in populations in rural or remote areas[20]	▪ Incorrect self-diagnosis [19,21] ▪ Failure to seek appropriate medical advice promptly[19,21] ▪ Incorrect choice of therapy[19,21] ▪ Failure to recognise special pharmacological risks[21-22] ▪ Rare but severe adverse effects[21] ▪ Failure to recognise or self-diagnosis contraindications[19,21] ▪ Interactions, warnings and precautions[21] ▪ Failure to recognise that the same active substance is already being taken under a different name[21] ▪ Failure to report current self-medication to the prescribing physician(double medication/harmful interaction)[21,19] ▪ Failure to recognise or report adverse drug reactions[21] ▪ Incorrect route of administration[21] ▪ Inadequate or excessive dosage[19,21] ▪ Excessively prolonged use[21] ▪ Risk of dependence and abuse[21-22] ▪ Food and drug interactions[21]

From Table 1.3, it is apparent that risks can potentially outweigh benefits. The benefits can, however, prevail, provided that the individual has the knowledge to rationally use OTCMs independently, or under the guidance of a pharmacist or other competent health professional. For example, under benefits, “increased access to effective treatment” assumes that OTCM use is based on sound knowledge of the minor ailment and that use is rational. Failure to choose the correct medicine and use the medicine correctly, based on quantity and dosage intervals, and be cognisant of potential drug interactions, can quickly convert benefits into risks. Pharmacist interventions, advice and comprehensive record keeping on the use of OTCMs are critical to self-medication being beneficial[19].

Education on the rational use of OTCMs can prevent unnecessary and dangerous clinical hazards, as in the continuous use of medicines for dyspepsia[15]. In a study by

Westerlund almost 34% of a population sampled were uncertain about the indication for specific drugs e.g. in the case of a public domain advertisement on the dangers of using ibuprofen (which may cause heartburn), the information was misunderstood and some patients used ibuprofen for the treatment of heartburn[23]. Labelling also needs to be clear and easy to understand, as there are many misconceptions around medicines[24-27]. In SA, questions arise as to whether OTCMs are sold and managed appropriately in compliance with various policies, guidelines and legislation[5, 28-31] that specify measures such as comprehensive record-keeping and the provision of adequate advice. A clear example of why this is questionable was shown by a recent Carte Blanche television programme. The insert showed the easy accessibility of codeine at a pharmacy, the obvious lack of advice/counselling, and the absence of recording of the Schedule 2 drug information. Also shown was the absence of regulatory oversight, with a government representative explaining that pharmacies are largely expected to self-regulate[32].

1.2 MINOR AILMENTS

Minor ailments are defined as common, self-limiting or uncomplicated conditions, which can be diagnosed and managed without medical intervention[33], have a limited duration, and are non-threatening to the patient[34]. According to the Consumer Health Products Associations Clinical and Medical Committee in the United States of America, these minor ailments can be grouped into 12 broad therapeutic classes. They cover a broad array of minor, self-limiting diseases and over 80 therapeutic categories of OTCMs, which have similar prescription indications and safety profiles[35]

- Analgesics and antipyretics
- Cold, cough and allergy products
- Night-time sleep aids
- Gastro-intestinal products
- Dermatologicals
- Topical products (antifungals/anti-inflammatory)
- Ophthalmics
- Oral health products
- Minor menstrual complaints;
- Nicotine replacement
- Weight loss
- Emergency contraceptives

While the groups appear to be straight-forward in terms of an individual's ability to choose an appropriate OTCM, there is nevertheless a requirement for knowledge of these minor ailments and OTCM-related risk in the event of misdiagnosis and/or

delayed treatment. For example, Ferris et al. showed that women were frequently misdiagnosing bacterial vaginosis and trichomonous vaginitis instead of vulvo-vaginal candidiasis[36]. This has implications for treatment. Other examples of poor self-management due to a lack of knowledge is the use of a cough mixture to treat the side-effect of an angiotension converting enzyme drug prescribed for treatment of high blood pressure[37]. Also applicable to OTCMs is the requirement for the patient to have the knowledge as to whether a minor ailment is acute, or a chronic more serious one which, if left untreated, could be life-threatening.

1.3 PRESCRIPTION ONLY TO OTC

The growing demand for OTCMs due to the expansion of the self-care industry and the drive to reduce healthcare costs will likely see this market grow even more in the future. Another reason for growth is the development of many previously prescription-only medicines becoming available without a prescription. This prescription to OTC switch is the process of changing the scheduling status of an approved prescription-only medicine to OTCM status in the same dosage form and route of administration[35, 38]. A high safety margin, ease of administration, effectiveness and use in conditions that are easily recognisable are some of the factors important in the switching of a drug to an OTCM[39]. There are obvious benefits to switching, however, there are also risks. The benefits include increased access to medicines, resulting in convenience to the patient and increased autonomy. Furthermore, more costly care in the healthcare system may be reduced, as shown in a study from MacQuarie University. That analysis showed that 10.4 billion Australian dollars could be saved in the healthcare system through direct consumer access and self-care. Such a switch also has the effect of increasing profitability of pharmaceutical companies, as the switch provides additional volume of sales and may even extend the product lifecycle[40-41].

Although the benefits are many, switching prescription medicines to OTCMs can also pose risks to an individual. For example, inappropriate use of previously-switched non-steroidal anti-inflammatory drugs (NSAIDs) amongst elderly patients can result in serious adverse effects, whilst using sedating anti-histamines can increase falls[42]. Brass and Creyer raised a few risks on switching from prescription-only to OTCMs such as inaccurate self-diagnosis, delayed or suboptimal treatment of serious conditions, and inappropriate drug use[43-44].

1.4 SELF-MEDICATION (SM)

As already stated, SM is a practice whereby patients are given the autonomy to manage minor ailments with non-prescription drugs[19]. Self-medication appears to be on the

increase and has been stated to be the most widespread form of medical care on the global stage[45-48]. Furthermore, SM provides individuals with opportunities to take personal responsibility for their health by self-diagnosing and self-treating an assortment of minor illnesses[49-50]. The popularity and acceptability of OTCMs are due to the convenience of their accessibility and the decreased cost[51]**.** These factors often determine whether a patient consults a doctor or a pharmacist[52]. However, in developing countries, OTCMs' 'convenience' is often replaced by 'need' due to limited access to and availability of resources in many areas[53].

There is a large body of evidence on why individuals self-medicate. Some of the common associations with OTCM use follow: [50, 54, 55]

- Socio-economic factors
- Lifestyle
- Low severity of illness
- Knowledge of the ailment and treatment
- Time saving
- Easy access to the drugs
- Education level
- Age
- Gender
- High cost of a doctors consultations

Once again, it is important to emphasise that the taking of personal responsibility suggests/assumes that consumers are knowledgeable about their symptoms and can independently treat minor ailments. Multiple studies have shown that insufficient medicine knowledge, incorrect self-diagnosis, failure to identify drug interactions, inappropriate use and multi-ingredient OTCMs are real concerns[19, 22, 56-57].

Trusting a patients' knowledge is perilous, as discussed by Bissell who observed that individuals considered OTCMs to be of low risk with a low potential for harm. This perception of low risk may also lead to continuous or regular use of an OTCM, with or without a pharmacists' advice[58]. Further to this, individuals tend to choose OTCMs irrespective of scientific evidence for or against their use[59-60]. Although choosing a common OTCM may seem harmless, the potential for drug-interactions with prescription medicines exists[61].

In 2000, the WHO published guidelines that stated, "*It has become widely accepted that self-medication has an important place in the health care system. Recognition of the responsibility of individuals for their own health, and awareness that professional care*

for minor ailments is often unnecessary, have contributed to this view. Improvements in people's general knowledge, level of education and socioeconomic status in many countries form a reasonable basis for successful self-medication"[1]. This final sentence is disturbing in that it first makes a general statement regarding improvements in knowledge, education and socio-economic status, and then speaks of "many countries". What is vague and open to question in a country like SA is whether it is included among the many 'knowledgeable' countries with adequate education and knowledge, or whether additional measures ranging from basic health education to national policy and control are necessary.

Self–medication is more widespread in the developing than in the developed world, and is thought to be linked to the (lower) quality of a country's healthcare system[20,63]. Further to this, Ahmad and Phalke have shown that in lower economic environments such as rural India, SM practice is high amongst illiterate people[64-65]. Third world countries in Sub-Saharan regions have been shown to have an average adult literacy rate of 64%, which is one of the lowest in the world[66]. Therefore, individuals with low literacy should be provided with more guidance on the use and selection of their medicines[67]. Considering these concerns and the frequent deregulation of prescription medicines to OTCMs, there is surely a need in the domain of OTCMs to not only educate and inform, but also to monitor and control access and utilisation. To achieve this one requires the full participation of all stakeholders represented in Figure 1.1.

Examples included in this chapter allude to the frequent fine line between minor ailments and more serious ones, and how a lack of knowledge by an individual, poor oversight by a healthcare professional, and relaxed legislation can be detrimental to patients. Under such circumstances, OTCM use can become a liability and lead to wasteful expenditure, postponed treatment and poorer clinical outcomes[36].

Challenges to OTCM use exist globally. In the South African context, statistics indicate that the country has a literacy rate of 94.4% and 60% of the population have internet accessibility[68, 69]. These positive numbers suggest that the country should indeed be included among the WHO's "many" whose citizens can competently utilise OTCMs. This thesis aims to explore whether this is indeed so.

1.4.1 Global Trends in OTCMs Utilisation

Internationally the OTCM industry has grown steadily over the years, and estimations are that it will be worth 491.02 billion US dollars globally by the year 2025[70]. This trend is supposedly due to factors such as ageing populations, patients seeking to treat minor conditions on their own, and also the many switches of prescription-only medicines to OTCMs[71]. Globally, the Indian pharmaceutical industry has been ranked fourth in terms of volume of OTCM production, and thirteenth in terms of OTCMs value globally. India exports OTCMs to a value of approximately 2.6 billion US dollars, with domestic sales reaching a value of approximately 4 million US dollars[61]. In 2015, OTCM sales in the United States were approximately $40 billion, which represented a 2% increase over 2014[51]. Perhaps these estimates of the future worth of the OTCM market will also depend on how countries around the world respond to the widespread liberalisation of cannabis products. Non-pyschoactive cannabidiol in particular is gaining popularity amongst consumers and manufacturers as a product with the potential to safely treat a multitude of conditions. It is therefore possible that future inclusion of cannabidiol and possibly even low-dose psychoactive cannabis as OTCMs will significantly increase the size of the OTCM market since the legal cannabis market (medicinal and recreational) on its own has been projected to grow to 30 billon US dollars by 2025[72,73].

1.4.2 Pharmaceutical Industry in SA

Pharmaceutical companies have a powerful influence on the sales of OTCMs and many are able to set prices and compete with others based on brand awareness, packaging and stakeholder loyalty. According to a report on the global OTC drug market, SA features at number 19, 'enjoying' status as one of the leading drivers of OTCMs in the marketplace[71]. In SA the market is valued at billions of Rand. In 2015, according to the Healthcare and Lifesciences Review, a total of R39.5 billion was spent on medicines, with almost 26% (R10.2 billion) going to the OTC market[74]. A Helen Suzman Foundation report showed that in 2017 the total value had increased to R48.6 billion, 69% of which was attributable to the private sector and 31% to the public sector through its facilities that cater for around 83% of the population[75]. A sample report from Adcock Ingram, a pharmaceutical manufacturing company that is a leading manufacturer of OTC analgesics in SA, showed an OTC analgesics sales turnover increase from R761.5 million for the period ended 31 December 2015 to R884.6 million one year later[76].

In the retail sector, competition exists even though two corporate pharmacies, Dischem and Clicks, account for about 20% of the sales in the private sector. The threshold for abuse of dominance is 35% as defined by the law[77]**.** Dischem, in the year ending 2017, had a turnover of R17.3 billion with 36% of the turnover coming from the dispensary[75].

Documents and reports in the public domain reveal that there was a 13.8% increase in OTCM sales at the Clicks group dispensaries between September 2018 and February 2019, while Dischem reported that approximately 50% of their medicine sales are OTCMs[78-79]. Dischem also promotes its 'ordering app', which is essentially for management of patients' chronic medicine requirements but also promotes simultaneous ordering of OTCMs[79].

Pharmaceutical companies have two medicine arms to their businesses, ethical medicines and OTCMS. Although ethical medicines provide a bigger profit margin, the timelines to recoup costs are long and therefore OTCMs become appealing. The OTCMs produce a smaller profit margin, but timelines are shorter to achieve a profit. The Table below illustrates the differences in distribution of medicines between South Africa's private and public sectors for S1 and S2 medicines. Notably in the private sector the S1 and S2 medicines would typically include original and generic products, whereas in the public sector the tender system usually focuses on generics.

Table 1.4: Difference in Distribution of OTCMs in the Public and Private Sectors

Schedule	Private Sector (no. items)	Public Sector (no. items)
1	272	27
2	492	35

1.5 PRIVATE SECTOR IN SOUTH AFRICA AND OTCMs

A two-tiered healthcare system was what the newly-elected democratic government in SA 'inherited' in 1994. Such a system was not unique to SA, but the population sizes and socioeconomic differences between the tiers were significant and remain so to this day. The private sector, which manages approximately 17% of the population, has been well-resourced on a per-capita basis for many years when compared to the public sector which serves majority of the population. At this time the 'private sector' is considered to comprise of the privately-insured (through medical schemes) and also all South Africans who have an out-of-pocket/self-payment portion of their healthcare costs[80].

1.5.1 Background to Medical Schemes in South Africa

1.5.1.1 Definition of a medical scheme

Medical schemes provide insurance for health care in the private sector in SA. As per the Medical Schemes Act, medical schemes are defined as the business of undertaking liability in return for a contribution in order to make provision for obtaining any 'relevant health service'. Medical schemes provide financial assistance for a health service, or can provide the relevant health service directly or by agreement with health care providers[81].

The Friendly Societies Act (Act 25 of 1956) in 1889 was the initial legislation for medical schemes followed by the Medical Schemes Act (Act 72 of 1967). In 1889 De Beers Consolidated Mines was the first medical scheme that provided medical insurance for its employees. After the Second World War, medical schemes proliferated to the stage where in 1960 there were 169 schemes covering 1.6 million persons[82].

Deregulation of the medical schemes industry in the mid-1980s was mainly driven by the rampant increase in medical costs, global economic liberalisation trends, establishment of non-employment linked (open) medical schemes, and the movement towards for-profit commercial insurers[83]. The 1989 amendments to the Medical Schemes Act of 1988 allowed 'risk rating' in the management of medical schemes expenditure[84]. 'Mutuality' became more popular compared to the 'solidarity' principles. 'Mutuality' principles are common amongst the voluntary medical schemes. Here members are assessed or underwritten on application and pay based on their risk. 'Solidarity' principles on the other hand are contributions that are not linked to risk. The members' contributions may be paid equally or based on their ability to pay. The solidarity principles require the contributions to become compulsory for defined groups. In the mid-1990s, the public sector suffered the consequences of the principles of mutuality as a result of higher-risk elderly and chronically-ill patients running out of medical scheme benefits. The elderly, categorised often as high risk, were allocated insufficient funds by the schemes to manage either their chronic conditions or their day-to-day requirements. In the absence of adequate cross-subsidisation this then resulted in medical scheme members running out of funds. At this point they were typically 'dumped' onto the public sector for further care.

In 1993 the Medical Schemes Act was significantly amended in order to transform the environment. The new legislation introduced a set of compulsory prescribed minimum benefits (PMBs) which all schemes were obliged to offer. The new Act prevented any form of discrimination especially based on age, medical history and health status. The cost to members could be based only on the income level and/or number of

dependants. Therefore, the potential for cross-subsidisation was not only of the elderly and ailing by the young and healthy, but also of low earners by the high earners[82].

The revised Act also provided for establishment of restricted membership (i.e. 'closed') medical schemes, with the basis of the restriction being employment or former employment in a profession, trade, industry or calling, or by a particular employer or class of employer. In contrast, an open medical scheme is one in which the medical scheme is obliged to offer cover to anyone who is eligible for membership in terms of Medical Schemes Act, the medical schemes rules and the ability to pay the required premium[85]. A member of a medical scheme is a person who is enrolled or admitted as a member and who abides by the rules of that specific scheme. A 'dependant' according to the Medical Schemes Act 131 of 1998 means the spouse or partner, dependent child/children or other members of the member's immediate family in respect of whom the member is liable for family care and support, or any other person who, under the rules of a medical scheme, is recognised as a dependant of a member[86].

1.5.1.2 **The statutory body**

In 1967, the Medical Schemes Act[86] provided for two bodies, the Council for Medical Schemes (CMS)[87] and the Registrar of medical schemes to be established to fulfil the executive functions of the Act. In the 1998 Act these functions were re-defined, further governing the functioning of the CMS.

The CMS is a statutory body established by the Medical Schemes Act (131 of 1998) to provide regulatory supervision of private health financing through medical schemes[87].

The Medical Schemes Act gives the Council a number of statutory objectives including[86]:

- To protect the interests of medical schemes and their members;
- To monitor the solvency and financial soundness of medical schemes;
- To control and co-ordinate the functioning of medical schemes in a manner that is complementary to the national health policy;
- To investigate complaints and settle disputes in relation to the affairs of medical schemes;
- To collect and disseminate information about private health care in SA;
- To make rules (that are in line with the Medical Schemes Act) with regard to its own functions and powers and

- To make recommendations to the Minister of Health on criteria for the measurement of quality and outcomes of the relevant health services provided for by medical schemes.

In the 2018/2019 annual CMS report there were 78 registered medical schemes, 19 of which were open and 59 restricted. These schemes had a total of 8 916 695 beneficiaries, comprised of 4 039 705 principal members and 4 876 990 dependants. Over the past decade the number of medical schemes decreased from 133 to 78, largely due to consolidation of small-sized restricted schemes[88].

Prior to 1994 the Medical Schemes Act did not include or apply to medical scheme brokers, medical scheme administrators or managed care organisations. The revised Act now regulates all of the above stakeholders. Corporate governance, financial and membership requirements, and provision of benefits are some of the controls that have now been placed on medical schemes by the Medical Schemes Act[82].

1.5.1.3 **Benefit design**

Medical scheme benefits are separated into 2 distinct pools: the risk pool and the discretionary pool. The risk pool is largely determined by PMBs and includes PMB-related medicines, hospitalisation and specialist and general practitioner (GP) consultations and interventions, and also relevant physiotherapy and occupational therapy services. The discretionary pool is for 'day-to-day' expenses, which usually include doctor visits, acute medicines, OTCMs and allied disciplines' consultations and treatments not related to PMBs. Dental and optical services and other interventions unrelated to medical necessity, such as cosmetic surgery, are also included in this benefit pool.

The discretionary pool, which ultimately is regarded as a member's money to be spent up to set limits, nevertheless has several models for cost-containment. The vehicle known as the medical savings account was introduced into the private health sector in 1994 after the 'down-regulation' of the Medical Schemes Act. Members access the discretionary pool via several mechanisms which may or may not involve a medical savings account. When a patient joins a plan in a medical scheme that has a savings option, the savings amount is available to the patient from the day of admission of the member to the scheme. If not used within a benefit year the funds accumulate. There are several models of savings account, all of which depend on how much the member has agreed to contribute each month:

1. The savings account pays up to the limit determined by the contribution and then stops.

2. The member pays up to a point, after which the savings account pays up to the limit.
3. A combination of 1 and 2.

In response to potentially-huge financial liability of an unrestricted fund, the medical schemes have generally focused on payment for PMB and related expenses. As such, discretionary benefits whether funded through limited access to the risk pool, or a vehicle such as a savings account, represent cost-shifting from medical scheme to the member. Where a medical scheme does not have a savings account, chronic medicines are well-funded via the risk pool, while OTCMs and acute medicines are also paid from that pool until a defined limit is reached. If a member does not use the benefit in a year, the balance reverts to the medical scheme (i.e. it accumulates to the medical scheme's reserves and belongs to all the members of the scheme rather than to a specific member).

1.5.2 **Medical Schemes and OTCMs**

The introduction of mandatory payment for high-cost PMBs has resulted in medical schemes shifting their focus onto managing quality, access and cost of communicable and non-communicable chronic diseases and the chronic medicine portfolio. Primary health care (PHC) costs, which are mainly covered by the discretionary pool, are largely left to the member to manage, whether through a limited benefit or a co-payment. Medical schemes may also introduce cost-cutting measures such as formularies, designated service providers (DSPs) and disease management programmes. Formularies may be restricted to evidence-based generic or other drugs. If the member deviates from the listed, approved drug and opts for an original drug, then the member has a co-payment. A different approach was developed by Medikredit, a registered managed healthcare business in SA, which introduced the Maximum Medical Aid Price (MMAP), which was adopted by many medical schemes. This initiative was not product specific but involved medical schemes paying a recommended maximum amount for a medicine that had generic equivalents[89]. Medical schemes can also cap the dispensing fee component that is paid to a pharmacist. This may once again result in costs shifting to individuals. Designated service providers (DSPs) are defined as individual healthcare providers or groups of healthcare providers selected by a medical scheme to offer its members the diagnosis, treatment and care of PMB and any other specified conditions[90]. They therefore provide care at a cost that is beneficial to the medical scheme, and in return DSPs enjoy increased business. Disease management programmes (DMPs) are healthcare support programmes that are offered by medical schemes and have been added into the cost framework of the risk pool. They usually provide services ranging from information leaflets/care guides on specific chronic

conditions such as hypertension or asthma, to comprehensive management of conditions such as diabetes and HIV/AIDS. The abovementioned measures are all in place to support and assist in reducing cost, often without much attention to quality of care. Primary healthcare conditions and OTCMs are typically not included with the PMBs, even in good DSP and DMP initiatives. In fact, there are few or no measures in place to educate members, to alert patients of potential harm of overuse of certain OTCMs, or for tracking the extent to which known or undiagnosed chronic patients may be using or abusing OTCMs through concurrent use.

1.5.3 Administrators and OTCMs

Administrators of medical schemes are separate entities serving medical schemes. They operate on a for-profit basis and promote institutional safety and soundness of medical schemes[87]. Their functions are varied, but their focus is to increase efficiencies by providing infrastructure for system assessments, collecting of contributions and negotiating rates with providers on behalf of the medical scheme[87]. A critical role of the administrator is to provide analysis and reports on key indicators such as the number of admissions to hospital per thousand beneficiaries, number of consultations by general practitioners and specialists per thousand beneficiaries, and the incidence of caesarean sections per scheme population covered. Administrators are engaged by medical schemes; however, this landscape has changed to some extent in recent times due to vertical integration[75]. Holding companies may not only have an interest in the medical scheme but may also include entities such as an administration company, disease management programme provider/s, and a pharmaceutical benefit management company in its portfolio[75,92]. Such relationships have the potential to create perverse incentives and significant conflicts of interest[92].

1.6 LEGISLATION, POLICY AND OTCMs

In 1996, the National Drug Policy (NDP) had set the scene on pricing and was the catalyst for many pricing interventions. The economic objectives of the NDP were to rationalise the drug pricing system in SA by introducing a non-discriminatory, regulated pricing system with complete transparency on the parts of pharmaceutical manufacturers, wholesalers and providers of services[93]. There have been several changes (Figure 1.2) to the Medicines and Related Substances Act 101 of 1965 over the last two decades in order to achieve these goals. These legislative changes were aimed at shaping the medicine-pricing environment to make medicines transparent, affordable and thus more accessible to the SA population.

Single exit pricing – Regulations relating to transparent pricing made in section 22G of the Medicines and Related Substances Act 101 of 1965[5].

Bonusing and sampling prohibited as of January 2004 as per regulations 18A and 18B of the Medicines and Related Substances Act 101 of 1965[5].

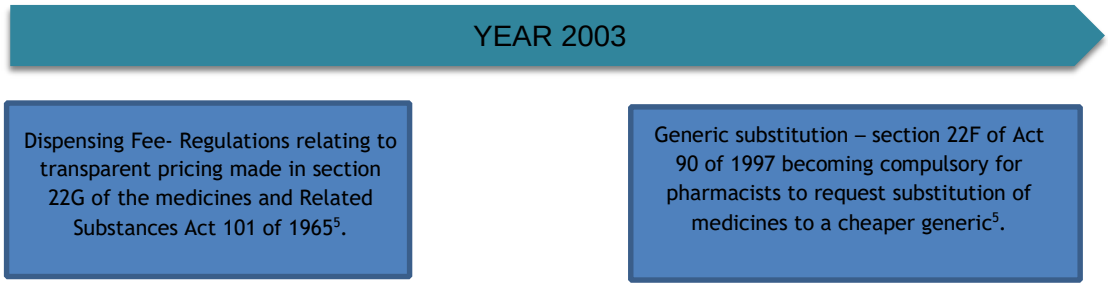


Figure 1.2: Important Legislative Changes around Pricing of Medicines

1.6.1 Single Exit Pricing

The introduction of SEP in 2004 aimed to promote transparent pricing of medicines with the exception of Schedule 0 medicines, multivitamins and veterinary medicines. The SEP consists of the manufacturer price, the logistics fee and the value added tax (15%) and is supposed to be reviewed annually. Changes to the SEP are based on recommendations from the Pricing Committee[3, 5]. Although transparent, and prices are reflected on an accessible government website, it is unclear how the manufacturer's price or the logistic fee are actually calculated. For example, if one looks at the Medicines Price Registry (MPR) for a group of medicines with the same composition, (Table 1.5), it is clear that the manufacturer price and thus SEP vary across the products. According to the MPR list there are 15 generic forms of a product that contains doxylamine, paracetamol, codeine and caffeine, all of which have varying prices[94].

Table 1.5: November 2019 Price Differences between Schedule 2 Medicines Having the Same Composition[94]

Schedule	Drug	Ingredients	Dosage Form	Pack Size	Manufacturer Price (Rand)	Logistics Fee (Rand)	VAT 15%	SEP	Unit Price (Rand)	Originator or Generic
S2	Syndol^{R}	Caffeine 30mg Codeine 10mg Doxylamine 5mg Paracetamol450mg	Tablet	18	22.60	3.05	3.85	29.49	1.64	Original
S2	Betapyn^{R}	Caffeine 30mg Codeine 10mg Doxylamine 5mg Paracetamol450mg	Tablet	18	25.15	3.39	4.28	32.82	1.82	Generic
S2	Adco-dol^{R}	Caffeine 45mg Codeine 10mg Doxylamine 5mg Paracetamol450mg	Tablet	20	13.22	1.79	2.25	17.26	0.86	Generic

S2	Resdol[R]	Caffeine 30mg Codeine 10mg Doxylamine 5mg Paracetamol450mg	Tablet	20	11.78	1.30	1.96	15.04	0.75	Generic
S2	Alpha-Dol[R]	Caffeine 30mg Codeine 10mg Doxylamine 5mg Paracetamol450mg	Tablet	20	9.07	1.60	1.60	12.26	0.61	Generic
S2	Tenso-dol[R]	Caffeine 30mg Codeine 10mg Doxylamine 5mg Paracetamol450mg	Tablet	20	9.10	0.73	1.47	11.30	0.57	Generic
S2	Nomopain[R]	Caffeine 30mg Codeine 10mg Doxylamine 5mg Paracetamol450mg	Tablet	20	12.58	1.24	2.07	15.89	0.79	Generic

***VAT Valued Added Tax**

*** SEP Single Exit Price**

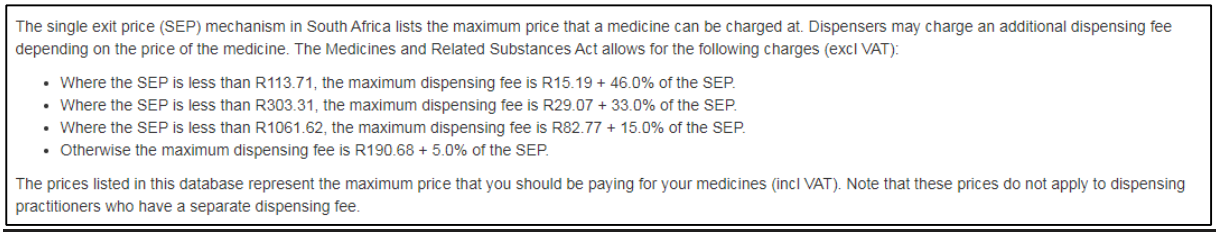
Moodley and Suleman showed that SEP legislation has indeed reduced prices since inception; however the study did not take the dispensing fee into consideration[3]. On the other hand, a Masters dissertation by Pretorius has shown that the SEP plus dispensing fee has had very little financial benefit to the patient. The study showed that when comparing the same basket of medicines across 3 pharmacy sectors (corporate group, independent and hospital pharmacies) the price difference varied, with R1183,46 being the minimum and R1711,79 the maximum. This revealed that there were marked inconsistencies between pharmacies[95], suggesting that although the SEP is there to standardise pricing of medicines, the dispensing fee may vary. Ultimately, this affects the cost to the patient. According to the same report, retail pharmacies have introduced strategic changes in order to adapt and counteract the changes in legislation. These include promoting and increasing front shop sales (e.g. of supplements and vitamins) and increasing volumes of sales of lower cost items[95]. These strategies include aggressive promotion of OTCMs. A study by Vogler covering nine European countries confirmed that regulations and economic pressures to increase turnover resulted in an increase in OTCM sales[96].

The Helen Suzman Foundation reported that the functioning of the SEP system is less rigid than was originally conceptualised. Firstly, the dependence on the initial prices provided by the manufacturers can either be accepted or rejected by the Department of Health, but they cannot be amended by it. This therefore suggests that little attention is paid to composition of medicines because the SEP for similarly constituted products may vary considerably (Table 1.5). Secondly, the logistics fee, which is a source of income for wholesalers and distributors and should be rigidly defined for each product, also varies. This fee should not vary between wholesalers and distributors for a particular product based on their scale of operations and/or geographical location[75].

For the SEP to have an impact on pricing of medicines, 'bonusing', providing samples and incentivising medicine use became illegal[5]. According to the Medicines and Related Substances Act, bonusing means an agreement or arrangement that rewards a purchaser, health care professional, hospital or funder with an inducement of bonus product in exchange for purchasing or prescribing a particular medicine, or purchasing or prescribing a certain volume of a particular medicine. Discounting is a type of incentive scheme which includes, but is not limited to, volume or bulk purchase discounts and other trade discounts, including discounts given to customers off the manufacturer's or importer's published selling price, in exchange for purchase of large quantities. Furthermore, bonus or sample deals such as additional product units, were often given to customers below the list price or even free of charge[5].

1.6.2 Dispensing Fee

The dispensing fee was legislated in 2003 in section 22G of the Medicines Act that also aimed to promote transparency in the pricing of medicines by pharmacies. The proposed first draft of the SEP had an allowable fee of 24% of the SEP with a cap of R24. This was highly contested[97]. A final dispensing fee, agreed upon in 2006, is increased annually[75]. As of 2019 November, the dispensing fee is as follows (Figure 1.3)[94]:


The single exit price (SEP) mechanism in South Africa lists the maximum price that a medicine can be charged at. Dispensers may charge an additional dispensing fee depending on the price of the medicine. The Medicines and Related Substances Act allows for the following charges (excl VAT):

- Where the SEP is less than R113.71, the maximum dispensing fee is R15.19 + 46.0% of the SEP.
- Where the SEP is less than R303.31, the maximum dispensing fee is R29.07 + 33.0% of the SEP.
- Where the SEP is less than R1061.62, the maximum dispensing fee is R82.77 + 15.0% of the SEP.
- Otherwise the maximum dispensing fee is R190.68 + 5.0% of the SEP.

The prices listed in this database represent the maximum price that you should be paying for your medicines (incl VAT). Note that these prices do not apply to dispensing practitioners who have a separate dispensing fee.

Figure 1.3: Single Exit Price November 2019[94]

Despite attempts at conformity, the dispensing fee varies across the type of pharmacy (independent, corporate or hospital) as the schedule is not adhered to[95]. While the Act is intended to standardise fees, corporate chains have the potential to charge a lower dispensing fee based on volumes, while the independent pharmacies claim that they are forced to charge a higher fee in order to survive.

1.6.3 Generic Substitution

Generic substitution was introduced by the NDP in 2003 to further contain expenditure. The NDP was committed to the use of interchangeable multisource pharmaceutical products (IMPP, generics), using the international non-proprietary name (INN) or generic name. This policy was intended to introduce generic prescribing in both the

private and public sectors[98]. In addition to this, the Medicines and Related Substances Act 101 of 1965, section 22F states that generic substitution is allowed[5], but the dispenser (pharmacist or a licensed dispensing practitioner) cannot substitute a cheaper prescribed generic medicine with a more expensive one[99]. According to the Good Pharmacy Practice, pharmacists are ethically bound to offer patients a generic medicine based on their professional expertise, and consideration given to safety, quality and efficacy[28]. Any changes to a medicine from the original to the generic or vice versa must be with the patient's approval. However, the trend may be different when it comes to OTCMs prescribed by doctors[100] because patients are generally 'brand loyal'[101].

1.7 SOUTH AFRICAN PHARMACY COUNCIL (SAPC) AND IMPACT ON OTCMs

The GPP guidelines, Code of Conduct and Ethical Rules are core regulatory documents pertaining to the scope of practice of pharmacists and pharmacy personnel. All are aligned to the Pharmacy Act 53 of 1974[28-31]. These documents succinctly describe the rules to which pharmacists are expected to adhere.

The GPP guidelines are precise on the requirements for patient-initiated treatment, stipulating that OTCM provision should include taking a complete history, followed by proper counselling and consideration of the social, legal and economic aspects of an individual's condition. Moreover, across the full scheduling range, a record of all medicines dispensed to the patient is expected to be kept at the point of supply. As per the guidelines from the GPP, page 85[28].

- The name of the medicine or scheduled substance;
- The date on which the prescription was dispensed;
- The dosage form and quantity of the medicine or scheduled substance;
- The name and address of the patient and, where applicable and
- The name of the medical practitioner, dentist or any other authorised person who issued the prescription

The intention of the recorded information is to provide insight into the medicine purchasing behaviour of the patient, and to assist the pharmacist to make clinically informed decisions on drug interactions, adverse effects and drug abuse.

In addition, the rules relating to the Code of Conduct for pharmacists, other persons, and pharmacy owners registered in terms of the Pharmacy Act 53 of 1974, provide a detailed description of their fundamental duties. Although all the rules are important, in terms of recording medicine information, the code of conduct further states that a

pharmacist should exercise proper and/or reasonable care in respect of and control over medicines[29-30].

Furthermore, ethical rules for pharmacists explicitly state that if a pharmacist omits or contravenes any of the rules, s/he will be subject to disciplinary action as per Chapter V of the Pharmacy Act, 1974[29, 31]. Chapter V states that the SAPC Board has the power to inquire into any complaint, charge or allegation of improper or disgraceful conduct of persons who fall under the scope of the Pharmacy Act 53 of 1974[29]. Unlike scheduled medicines which are only dispensed with a valid prescription from a prescriber, OTCMs do not require a prescription. The recording of S1 and S2 medicine information is dependent on the pharmacists' willingness to do so. While failure to do so is a breach of the regulatory requirements, it is rarely, if ever, prosecuted.

The Pharmacy Act 53 of 1974 provides for the appointment of officers who perform duties on behalf of the SAPC. They are legally allowed to inspect any registered pharmacy in SA under the guidance of SAPC to ensure that the pharmacy conducts its business as per the GPP guidelines[28-29]. Although inspectors have been given this mandate, the ability to provide regulatory oversight to 4480 pharmacies (community, wholesale, private, public, manufacturing, consultant and academic) in South Africa[102] is a tall order. The human resource expectation is immense, and the ability to monitor the actions of pharmacists on a daily basis is almost impossible. Therefore, the SAPC regulatory body is reliant on the conscience of pharmacists and the expectation is that they will always endeavour to promote public health and maintain the honour and dignity of the profession[30].

1.8 PUBLIC SECTOR CONTROLS ON COST, QUALITY AND ACCESS

Public sector medicine acquisition and prescribing is as per the Essential Medicines List (EML) and the Standard Treatment Guidelines (STGs)[103]. The EML was established post-apartheid as mandated by the NDP to reduce the escalating costs of medicines and to make medicines accessible, available and affordable. The WHO Expert Committee on the selection and use of essential medicines described essential medicines as "those that satisfy the priority health needs of the population". They are selected with due regard to disease prevalence, evidence of efficacy and safety, and comparative cost-effectiveness. Essential medicines are "intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford"[104]. With self-care booming and universal health coverage under consideration, the relatively small number of OTCMs in the EML is perhaps concerning.

1.8.1 Tendering

Medicines in the public sector are procured via the tender process which has been in existence since 1982. The process in essence is the bulk purchase of medicines at a fixed price for a stipulated period following a competitive bidding process. The government accepts bids from all interested parties, provided they have marketing authorisation from the national medicines authority. The quantities provided by government for the tender are based on usage rates in previous years and epidemiological forecasts. The amounts are not binding, and government may request smaller or larger amounts. The tender process is meant to stimulate competition between generic firms and decrease drug prices[105].

In 2017, the Helen Suzman report showed that six manufacturers supply more than 40 products to the public sector[75]. Historically, however, there has been evidence of collusion between manufacturers. For example, in 2008 the Competition Commission found that Adcock Ingram Critical Care, Dismed Criticare, Thusanong Health Care and Fresenius Kabi SA were colluding during a tender process to avoid competition and manipulate prices. The 'non-bidding' companies would together decide on an inflated price for the medicine and apply for the tender, with the expectation that the agreed low-bidding company would obtain the tender. While the collusive nature of such arrangements suggests that the tender would be rotated every 2 years between the companies, there is also the reality that it is difficult for a manufacturer to tool up for a large-volume, low-margin product in one year. They would have to then shut down a production facility in the event that government selects a lower cost alternative the next year[106]. An added implication of the tender system is that a successful manufacturer whose margins are squeezed may seek to recoup losses by increasing prices for the same and other medicines it sells to the private sector.

1.9 HEALTH MARKET INQUIRY

The private healthcare sector has experienced high and rising costs of medical scheme and healthcare services over the years. There were concerns within government about consumers being disempowered and uninformed, regulations being ineffective and a lack of accountability. In 2014 the Competition Commission established an investigation into the private sector[92]. This was triggered by a study conducted by the Organisation for Economic Co-operation and Development (OECD) and the WHO. The results when published showed that even though SA had the lowest Gross Domestic Product (GDP), private hospital services costs were comparable to the average costs in various OECD

countries. In terms of the purchasing power of South Africans, private healthcare was expensive and it was recommended that policies were required to control prices and ensure accessibility and quality[107]. Overall, in their final report the HMI found that the private healthcare sector has not been held accountable, is inefficient and uncompetitive, with excessive utilisation of health resources and no improvement in health outcomes.

The major finding was that the private market has highly concentrated funder and facilities markets, disempowered and uninformed consumers, a general absence of value-based purchasing, practitioners who are subject to little regulation, and failures of accountability[92]. In addition, the Department of Health has not been monitoring the private sector or using current legislative powers to properly manage the sector. A lack of regular review and failure to hold regulators accountable have resulted in the sector being inefficient and uncompetitive. In an ideal world competition should result in lower costs and prices, value-for-money for consumers, and improved delivery and funding of healthcare. This competition should occur on price, cost and quality, and not on risk avoidance. None of the latter was evident during the investigation.

The absence of a supply side regulator (SSR) was considered to have impacted the patient negatively in terms of cost and measured outcomes, and reduced competition in this market. While the WHO warned that establishing new agencies should not be a way to make up for weaknesses of existing bodies[92], the HMI nevertheless found that such a regulatory body is needed. The objective of the SSR would be a competitive and cost effective supply side within a regulatory framework that can work with the proposed NHI and provide a unified healthcare system.

The practitioner market proved difficult to measure as there were no standardised measurements for quality and health outcomes, while the public was found to be uninformed and unable to measure and compare outcomes between practitioners. The report found that there can be quasi-collusive forums between practitioners through which they share advice on charging, coding and network participation[92].

Excessive utilisation was also a concern in the HMI report, and this did not result in better care but rather in wasteful expenditure. Interestingly, where there were greater numbers of practitioners, more admissions to hospital occurred, providing evidence of supplier-induced demand.

Medical schemes have prioritised PMB coverage at the expense of PHC, resulting in the promotion of hospi-centric care. This has resulted in increased costs as members are hospitalised unnecessarily to cover the costs of treatment[92].

1.10 OTCMs IN THE CONTEXT OF HEALTHCARE AS A COMMODITY VS A RIGHT

Access to healthcare is a basic human right[108]. However, the question of whether healthcare is a commodity or a right has been robustly debated[109-110]. This is despite Article 25 of the Universal Declaration of Human Rights which states that '*Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control*'[111]. This has also been supported by publication of the Sustainable Development Goals in 2015 as adopted by the United Nations committing to ensuring 'healthy lives and the promotion of well-being to all ages'[112].

The recent HMI unequivocally places the private healthcare sector it investigated in the commodity domain, a situation made worse by the failure of markets to foster competition and drive costs down. Given the magnitude of costs of private healthcare in relation to the small percentage of the population served by this sector, it is not surprising that NHI, which is firmly grounded on the side of right to healthcare, has become a priority issue for the country.

In SA, the NDP states that essential medicines must be available and accessible to all, making such access a right[93]. This is also in keeping with the proposed universal health coverage via the NHI, which aims to provide quality healthcare to all. Marks explains that the right to healthcare depends on multiple factors, including the production, distribution and pricing of medicines, the incentives for the research and development of drugs, a functioning healthcare system and adequate infrastructure[108]. In the area of medicines, South Africa has slowly been chipping away at the inequalities of the apartheid era by introducing pricing changes, improving the healthcare system and making medicines accessible.

Looking at the commoditisation of medicines, according to Elliot an item is commoditised when it is transformed into an instrument of profit and use. This has been illustrated by the aggressive marketing of medicines[110]. The impact of patenting on medicine pricing is also of concern, particularly with pharmaceutical companies often obtaining exclusive manufacturing rights for up to 20 years. This allows them to monopolise the market[108]. The World Trade Organisation Agreement on Trade Related

Aspects of Intellectual Property Rights (TRIPS) protects this legislation[107]. However, in 2001 the Doha declaration in Qatar[113] changed the TRIPS legislation by allowing resource-limited countries to access medicines that are under patent at a cheaper price via compulsory licensing. This allows a party other than the original manufacturer to produce a patented product without the consent of the patent owner. The producer will be paid for the copies of the products made under the license, but is not allowed to export the product in order to profit from sale of their low cost product to countries that are bound to sell the protected higher-priced originator drugs[114].

Pharmaceutical companies understandably need to make a profit, considering their costs towards research and development; however, they should also have an ethical responsibility to make medicines accessible at a reasonable price[115]. In 2008 Professor J Ruggie, a United Nations special representative on Business and Human Rights, released a framework in which he claimed that the key responsibility of corporations is to respect human rights. This is represented by the Ruggie 'trinity' of protect, respect and remedy, which in essence means that pharmaceutical companies have a responsibility to avoid infringing on the right to health[116].

The right to obtain healthcare in SA is clear in the Constitution and should be independent of economic status or geographical location. However, when healthcare becomes motivated by profit it can undermine the fiduciary relationship between the patient and physician[109]. The introduction of the NHI is intended to be an important step in removing commoditisation of healthcare in SA. In essence, NHI is a financing system that will ensure that citizens in SA are provided with essential healthcare, regardless of their employment status or their ability to make a direct monetary contribution to the NHI fund[117]. The final result will likely depend on the extent to which those who are currently served by the private sector will obtain care through NHI. If private care continues as is, whether funded by medical schemes, health insurance and/or out of pocket payments, there is a risk that commoditisation will endure.

1.11 ISSUES AFFECTING OTCM ACCESS, DISPENSING AND PRESCRIBING

1.11.1 Beneficiaries

In the medical schemes environment the value of medical scheme cover arises from the benefits that are provided[118]. Benefit design is therefore pivotal to a scheme's affordability, marketability and competitiveness. These elements are determined by the extent of risk pooling within the scheme, and the rationing of and access to healthcare services as determined by each medical scheme[81]. It has been shown that formularies and benefit design such as the addition of co-payments, change prescribing behaviour

and result in a reduction in prescription drug spending[119]. However, unlike the chronic medicine benefit, PHC medicines (acute or OTCMs) are not typically governed by medical scheme formularies or lists of preferred generics. Beneficiaries who pay a higher contribution towards their medical schemes usually have a fairly generous healthcare benefit which includes OTCMs, albeit to a capped amount. Generally, in a cheaper medical scheme the medicine benefits are so low that the annual capped limit is usually reached well before year end.

1.11.2 **Doctors**

Within the OTCM or acute medicines benefit, if not 'constrained' by a contractual DSP arrangement the doctor has the freedom to prescribe any drug, prescription or OTCM irrespective of price or brand. The HMI report suggests that doctors may primarily serve themselves at the expense of patients and schemes[92]. The extent to which a medical scheme will pay the doctors is determined by its rules, but some responsibility has also been shifted to the patient to decide if the medicine dispensed should be a generic or an original drug as per the Medicines and Related Substance Act[5].

1.11.3 **Pharmacists**

Pharmacists on the other hand, have a dual responsibility of ensuring the best therapeutic option for their patient whilst also managing a business. While SEP and the dispensing fee are measures intended to reduce medicine costs, an unfortunate unintended consequence has been that pharmacies, particularly small, independent pharmacies, have closed down[120]. Amongst the independent pharmacies, the dispensing fee is charged at its maximum to support their profit margin; however, corporate pharmacies can afford to lower their dispensing fee due to the volumes, thus becoming more attractive to patients. The corporate pharmacy chains also have the ability to market loyalty programs, which have also been shown to influence medicine purchasing behaviour[121]. Pharmacists have the leeway to recommend more expensive products containing multiple ingredients, thereby adding to the cost without necessarily adding much in the way of therapeutic value[11, 122]. In terms of cost of OTCMs, the pharmacist is frequently under pressure to generate profits, whether s/he is the owner of the pharmacy or an employee. This can be done by making the product more visible in the pharmacy or promoting its use, particularly to medical scheme beneficiaries whose benefit plans cover the cost.

1.12 **PREAMBLE TO THE PUBLISHED PAPERS**

Having discussed the various stakeholders involved in the access to healthcare in general and OTCMs in particular, one may view the OTCM consumer, whether in the

private or the public sector, as being at the bottom of an inverted pyramid. Multiple layers impact on how s/he will make a decision as to where, when, how and why to access an OTCM. Of critical importance is whether individuals have the knowledge and ability to make the choices. The following chapters will explore important aspects of this dynamic.

1.12.1 **Aim of the Thesis**

To explore access to and utilisation of OTCMs within high and low benefit medical schemes in South Africa with a focus on quality and cost.

1.12.2 **Objectives**:

- To explore OTCM access and utilisation in high and low plans at benefit level, also focusing on differences between pharmacists and doctors, generics vs originals, and impact on downstream costs. (Paper 1; Title: Over-the-counter medicine utilisation by beneficiaries under Medical Schemes in South Africa. Awaiting editor decision in Drug, Healthcare and Patient Safety)
- To explore OTCM access and utilisation at product level. In addition to the above, to also focus on dispensing vs. non-dispensing, and network vs. non-network doctors (Paper 2; Title :Utilisation of over-the-counter analgesics in two private medical insurance schemes in South Africa; Published in Drug, Healthcare and Patient Safety in 2019)
- To explore OTCM access and utilisation by older beneficiaries suffering from one of the common non-communicable diseases (Title: Use of over-the-counter medicines: a window into chronic disease management by private medical insurance schemes in South Africa; Submitted to Risk Management and Healthcare Policy)
- To explore ethical issues around access to and utilisation of OTCMs by beneficiaries of medical schemes (Paper 4 Title: Ethical issues around access to Over-The-Counter medicines in South Africa, Published in SAJBL in December 2019)

CHAPTER TWO: PAPER 1

2.1 INTRODUCTION

The use of OTCMs in South Africa, particularly in the private healthcare sector, has not been researched sufficiently. The impact of the use of this important category of PHC medicines on medical schemes, healthcare professionals and members is important in order to assist in assessing the contribution of OTCMs to the health of individuals and the sustainability of medical schemes.

This initial research article represents the first component of the research, investigating how benefit design and other factors within two medical schemes influenced access to and payment for OTCMs. Access to OTCMs by individuals, and the impact on utilisation of other healthcare services were also investigated. The paper has been published in Drug, Healthcare and Patient Safety, an accredited international open access journal.

A medical scheme's appeal to consumers is based on the benefits provided. Each scheme has a number of product offerings that are marketed to consumers, with each offering having different benefit options. These options differ between medical schemes and within each scheme[118]. Schemes are able to design each benefit and therefore each option is treated as a separate risk pool. However, according to legislation each benefit option must be self-sustaining[84]. This is a requirement that ensures solidarity and the principle that the young cross-subsidise the old, and the healthy cross-subsidise the sick (Chapter 1). This security may fall away when risk pooling occurs at an option level, and may result in fragmented risk pools[81]. To get out of the 'fragmentation trap,' medical schemes may completely remove or limit the availability of certain benefits from the risk pool by transferring the risk to the member. One example is the day-to-day benefit category which provides for acute medicines and OTCMs. In a 'traditional' medical scheme this category is usually covered to a limited extent by the general risk pool, or from a discretionary sub-pool of funds. In the 'new generation' medical schemes there is often a savings account. Here members agree to have part of their contribution held in a personalised account. The member then decides how and when the money is spent. These savings are exclusively reserved for the members and there is no cross-subsidisation between members. Once the funds have been spent the member is expected to self-fund any additional services in the benefit category. This removal of funds from the general risk pool may interfere with risk pooling and the cross-subsidisation principles of solidarity[118] and furthermore, as argued by Doherty and McLeod, a savings account does not consider the potential for oversupply. For example,

once the funds are in the individual's hands there is little control of how they are used. Thus, in a fee-for-service environment there is the potential for oversupply, whether driven by the doctor or the patient [84]. Therefore, in essence the savings option individualises benefits and reduces risk pooling[118]. With this in mind, analyzing the usage of OTCMs will provide some insight into whether these medicines are being used efficiently, and could inform medical schemes and managed health care organisations about aspects that could be improved.

The Medical Schemes Act 131 of 1998 introduced PMBs as a policy instrument for provision of minimum levels of medical scheme cover. Prescribed minimum benefits must be provided for all medical scheme members and include the diagnosis, treatment and care for a designated set of 270 conditions, any emergency condition and a list of 25 chronic conditions (as per the Chronic Disease List)[87]. These benefits provide a 'safety net' for members, and ensure that they are not denied care for serious illnesses[123]. As an unintended consequence, the introduction of PMBs and their high costs has resulted in members having to manage many of their day-to-day benefits by themselves through cost-shifting strategies such as savings accounts. Medical schemes have introduced a number of 'demand-side' initiatives to assist with management of this benefit such as monetary limits, co-payments at the point of service and savings accounts, but much of the overall responsibility for efficient and cost-effective management of the benefit is dependent on the members. 'Supply-side' initiatives are also possible, for example contracting with designated doctors and/or pharmacies that provide services or medicines at preferred prices. These demand- and supply-side initiatives are meant to deter members from accessing benefits unnecessarily, but mostly in relation to costs associated with PMBs. In the case of day-to-day benefits, and OTCM usage in particular, there are few if any managed healthcare solutions that maximize the value for the members.

Herein lies the responsibility of doctors and pharmacists to provide OTCMs which are cost-effective and clinically appropriate. The perception has always been that the use of OTCMs reduces doctor visits and reduces overall healthcare costs[19,22]. Certain schemes may in fact have a specific Pharmacist Assisted Therapy (PAT) benefit to promote self-medication and therefore less dependence on General Practitioners (GPs). The impact of the PAT benefit was an element of particular interest in this first study.

For this paper, data were obtained from an administrator with several health risk management departments covering access to and utilisation of chronic medicines, and also to healthcare provider services for specific conditions such as HIV, diabetes and

renal failure. The administrator services a number of medical schemes which together covered 2.3 million lives at the time of receipt of the dataset. This represented one-third of the private healthcare market. The dataset that was provided included 12 de-identified medical schemes of differing benefit richness, size and demographics. Benefit richness is based on factors such as the average scheme rate of reimbursement; benefit limits and co-payments; whether 'new generation' or 'traditional' medical schemes; having capitated or hybrid structures; network variations; and beneficiary versus family benefits[124]. A high-benefit scheme typically has comprehensive benefits with fewer restrictions, while a low-benefit scheme focuses on PMBs, benefit limits, co-payments and the use of network hospitals and doctors. For this study, two plans were selected, one with rich benefits and the other with a lower set of benefits. The detailed dataset included OTCM utilisation patterns according to whether they were prescribed by a doctor or dispensed by a pharmacist. In terms of the data provided it was also possible to analyse the differences in patterns of prescribing between the healthcare professionals, the differences between generic and original use, the impact of chronic disease status of the patient on OTCM utilisation, and ultimately the overall costs. The differences in patterns of OTCM usage between high and low benefit medical schemes was of particular interest.

2.2 PAPER 1: OVER-THE-COUNTER MEDICINE UTILIZATION BY BENEFICIARIES UNDER MEDICAL SCHEMES IN SOUTH AFRICA

Padayachee N, Rothberg AD, Butkow N, Truter I. **Over-the-counter medicine utilization by beneficiaries under Medical Schemes in South Africa** awaiting editor decision from *Drug, Healthcare and Safety*

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OVER-THE-COUNTER MEDICINE UTILIZATION BY BENEFICIARIES UNDER MEDICAL SCHEMES IN SOUTH AFRICA

Abstract

Background: South African medical insurance schemes (known as medical schemes) cover about 17% of the population. Within these schemes access to medicines for a defined set of chronic diseases is mandated by legislation. However, much of the responsibility for treatment of minor conditions with non-prescription over-the-counter (OTC) medicines has been transferred to the individuals within the medical schemes. The overall expenditure on Pharmacist-Assisted Therapy (PAT)/OTC medicines in South Africa is considerable and medical schemes endeavor to limit amounts paid out by devising strategies that will limit their financial exposure.

Aim: To investigate how benefit design and other factors within two medical schemes influenced access to and payment for OTC medicines, and to explore whether access to OTC medicines by individuals impacted on utilization of other healthcare services.

Methods: Medical scheme data were obtained from a leading administrator for two health plans, one with comprehensive benefits covering 4 593 beneficiaries (designated HI), the other with lower benefits covering 54 374 beneficiaries (LO). Extracted data included beneficiary demographics, OTC medicines prescribed by doctors and/or dispensed by pharmacists, and monetary amounts claimed by individuals and paid by the medical schemes. Doctor consultations, costs and payments were also extracted, as were beneficiaries' records of their chronic disease/s and any episode/s requiring hospitalization.

Results: Some 60-70% of beneficiaries submitted claims for OTC medicines accessed directly or recommended by a pharmacist, and 80-90% claimed OTC medicines that were prescribed by a doctor during a consultation. Amounts claimed and percentages of original products prescribed were substantially higher when accessed directly by beneficiaries or recommended by pharmacists than when doctors prescribed the medicines. In multivariate analysis there was no clear advantage of offering access to OTC medicines in order to reduce visits to general practitioners, although in the LO plan it appeared that beneficiaries with chronic diseases made less use of the OTC benefit and more use of medical specialists.

Conclusion: Within these two plans there were higher costs and greater use of original products when beneficiaries or pharmacies accessed OTC medicines than when these

medicines were prescribed by doctors. A key question is whether access to these medicines and the costs thereof would be managed better if paid for directly by individuals and not as insured benefits through the medical scheme.

Key Words: Medical Schemes, Over-the-counter benefit, Acute medicines, Pharmacist-assisted benefit, Over-the-counter medicines.

Introduction

Healthcare services for most South Africans are provided by the public sector while the private sector services about 17% of the population. Currently some 8,78 million lives are covered by medical insurance schemes which are tax-exempt, not-for-profit entities, in principle owned by their members.[1,2] All such schemes are formally registered as Medical Schemes with the legislated national regulator (Council for Medical Schemes) and will therefore be referred to as medical schemes in this article. The value of medical scheme cover arises from the benefits that are provided.[3] Benefit design is therefore crucial to a scheme's affordability, marketability and competitiveness. These elements are determined by the extent of risk pooling within the scheme, and the rationing of and access to healthcare services as determined by each medical scheme.[4] Further explanation of these and other terms used in this article is provided in Table I.

Table I: Terminology

High benefit	A medical scheme or option within a medical scheme that has comprehensive benefits, greater access to GPs*, specialists, acute and chronic medicines, with few limitations.[5]
Low benefit	A scheme or option that focuses on prescribed minimum benefits, a chronic disease list, benefit limits, co-payments, and network hospitals, doctors and other providers.[5]
Member	The individual holding the contract with the medical scheme for him/herself and dependants.
Beneficiaries	Members and their dependants constitute beneficiaries.
Administrator	An entity responsible for managing the day-to-day operations of one or more medical schemes
General Practitioner Encounter	Individual/unique visit to the GP by a beneficiary.
Specialist Encounter	Individual/unique visit to the specialist by a beneficiary.
Account /Claimed amount	The amount claimed by the service provider (GP, specialist, pharmacy, hospital etc.).
Insured/Paid Amount	The amount paid by the medical scheme out of the risk/non-discretionary pool of funds.
Savings Account	A limited benefit set aside for payment of day-to-day needs such as acute medicines, doctor visits and dental care.
GP Tariff	The amount paid by the scheme per GP consultation.
Specialist Tariff	The amount paid by the scheme per specialist consultation.

Chronic Registration	Registration by a beneficiary for one or more chronic conditions covered by the medical scheme, usually aligned to the chronic disease list. [5]
Plan	A set or subset of benefits within a medical scheme, often referred to as an option.
Rand	South African currency. At time of study R12.6 was equivalent to 1 US Dollar.

* GP = General Practitioner

One element of benefit design is the day-to-day benefit category which typically covers out-of-hospital expenses such as GP and specialist consultations and services, dentistry and acute medicines. The latter are typically required to treat minor conditions e.g. antibiotics for an infection. Acute medicine coverage is dependent on a medical scheme's design and may be covered by the general risk pool or by a discretionary pool of funds which is capped in terms of annual maxima, and often involves a savings component. This is essentially regarded as 'member's money,' is available from day 1 of a benefit year, and covers a limited number of services that are not regarded by medical schemes as being required by law.[5] The acute medicines component covers 'non-chronic' medicines prescribed by GPs and specialists, and commonly also includes a sub-category or sub-benefit covering pharmacist-assisted therapy (PAT) which allows a pharmacist to recommend treatment, and an over-the-counter (OTC) benefit which is available to beneficiaries without input from a pharmacist. The goal of the latter is the self-treatment of minor acute conditions. The benefit provides access to Schedule 0-2 (S0-S2) medicines as determined by the national medicines regulatory body.[6] These medicines do not require a doctor's prescription but are often included in a prescription after a consultation for dispensing by a pharmacist. Detail of the scheduling is provided in Table II. Within the S0-S2 categories the amounts available to beneficiaries vary from medical scheme to medical scheme. Most do not provide much in the way of education on these benefits, even though the rationale for the PAT/OTC benefit is to allow access to immediate care, obviate the need to see a doctor for a prescription, and reduce overall costs of care.

Table II: Explanation of South African Medicine Schedules [7]

MEDICINE SCHEDULE	WHERE AND HOW MADE AVAILABLE	EXAMPLE
S0	On the shelf at a general store or pharmacy	Simple analgesics like aspirin
S1	Over the counter at a pharmacy. A sale record must be kept	Antibacterial and anti-fungal skin creams
S2	Over the counter at a pharmacy. A sale record must be kept	Cough and cold preparations
S3	Prescription only; available at the pharmacy dispensary. Can be repeated for 6 months	Medicines for hypertension and diabetes
S4	Prescription only; available at the pharmacy dispensary. Can be repeated for 6 months	Anti-infectives such as antibiotics and antivirals
S5	Prescription only; available at the pharmacy dispensary. Repeats stipulated	Psycho-active medicines like sedatives and anti-depressants
S6	Prescription only; available at the pharmacy dispensary	Narcotic painkillers
S7	Controlled substances	Drugs like cannabis and heroin
S8	Strictly-controlled substances	Amphetamine, dexamphetamine and nabilone

How the PAT/OTC benefits are managed by beneficiaries and pharmacists, and their impact on overall healthcare and costs have been reported to a limited extent in South Africa. In a recent study of S1-2 medicines utilization by beneficiaries we focused on a range of commonly-used analgesic products and found that costs were higher when medicines were accessed via pharmacies than when prescribed by doctors. Furthermore the cost of products dispensed by doctors who dispensed directly to patients was lower than when doctors wrote prescriptions that were filled by pharmacies.[8] In contrast to that study, this one focused on utilization at beneficiary level rather than product level. Consequently the purpose was to determine how, within the S0-S2 categories, the acute medicines benefit and the sub-category of PAT/OTC medicines were utilized by beneficiaries and then paid for by the medical scheme. Two types of medical schemes were selected, one offering beneficiaries a 'rich' or comprehensive set of benefits, the other operating at the lower and more-restricted end of benefit designs. The impact of the PAT/OTC benefit on utilization of other benefit categories such as access to doctors and hospitals was also assessed.

Methodology

Beneficiaries were selected from a database provided by a large medical scheme administrator. This administrator services over 3 million individuals and has been in existence for over 4 decades. This cross-sectional study used a subset of one year's data (1 January to 31 December 2015) covering 12 medical scheme plans/options with 641 525 beneficiaries in total. The medical schemes, plans, members and beneficiaries were not identifiable from the data provided. Only two plans were selected for this study, one which from review of the data was a high benefit scheme with no savings account i.e. a comprehensive set of benefits paid out of a single insured/risk pool

(designated HI). The other was identifiable from the claiming pattern as a low benefit plan with restricted benefits and a savings account for discretionary use up to specified limits (designated LO).

All beneficiaries were identified only by a unique study number. Background information provided for each beneficiary included gender, age and ethnicity. Medicines data extracted for this study included only S0-S2 medicines, irrespective of whether paid from the acute benefit or PAT/OTC sub-benefit. For the purpose of this study, S0-S2 medicines prescribed by a doctor from the acute medicines benefit are referred to as doctor-prescribed (DP) medicines, while the PAT/OTC medicines accessed directly by the beneficiary or on the recommendation of the pharmacist are referred to as beneficiary/pharmacist (BP) medicines. Each medicine claimed, whether originator or generic product, was coded according to the World Health Organization's Anatomical Therapeutic Classification (ATC) system. This system is used in drug utilization management to analyze and improve dispensing and prescribing practice, and ultimately enhance quality of drug use.[9]

The Rand amount purchased and claimed by beneficiaries (account amount),and the amount paid by the medical scheme (insured amount) for the S0-S2 medicines were captured, whether a DP medicine paid from the acute benefit or a BP medicine paid from the PAT/OTC sub-benefit. The latter also included whether the amount paid was derived from a savings account or paid out-of-pocket if there was a shortfall in payment. General practitioner and specialist encounters (i.e. consultations) were also recorded, as were costs and payments for such encounters. Each beneficiary's record of medical scheme registration for treatment and management of one or more chronic conditions was captured, as was the cost of episodes requiring hospitalization.

Analysis was carried out on the individual plans using descriptive statistics, t-tests, frequency analysis by means of chi-square (x^2) test, and multivariate regression analysis (*Statistica* Version 13.2; TIBCO Software Inc, Palo Alto, CA, USA).

Ethics

Ethics Approval was obtained from the Human Ethics Committee of the University of the Witwatersrand (certificate M160141).

Results

Descriptive Statistics

As shown in Table III, the study covered 59 327 beneficiaries distributed between the HI and LO plans. Demographics within the plans were similar, with a slight preponderance of females. Approximately half of the beneficiaries were African and one-third were Caucasian. Percentages of Mixed race and Asians were also similar. Beneficiaries within the HI group were significantly older than in LO and were registered for a greater number of chronic diseases.

Table III: Demographic profiles of beneficiaries with claims for S0-S2 medicines paid from DP or BP medicine benefit pools

	HI	**LO**	**p-value** (t=comparison of means) (x^2= comparison of groups)
Total beneficiaries (n)	4593	54734	
Gender: n (%) Female Male Unknown	 2523 (54.9) 2070 (45.1) 0	 27954 (51.4) 26356 (48.5) 64 (0.001)	p=0.571; x^2=0.32
Ethnicity: n (%) African Mixed Race Asian Caucasian Unknown	 2300 (50.1) 404 (8.8) 283 (6.2) 1606 (35.0) 0	 27745 (51.0) 5337 (9.8) 3763 (6.9) 17494 (32.2) 35 (0.001)	p=0.965; x^2=0.27
Age Band (years): n (%) ≥5 6-15 16-25 26-35 36-45 46-55 56-65 >65	 137 (3.0) 517 (11.3) 641 (14.0) 81 (1.8) 317 (6.9) 783 (17.0) 835 (18.2) 1282 (27.0)	 8878 (16.3) 7519 (13.8) 5844 (10.7) 14452 (26.6) 9152 (16.8) 4973 (9.1) 2404 (4.4) 1152 (2.1)	p<0.00001; x^2= 68.25
Mean Age (±SD)	47±24	28±17	p<0.00001; t=52.42
Registered chronic conditions per beneficiary (Mean ± SD)	2.8 ±1.8	1.7±1.01	p<0.00001; t=40.88

HI=Comprehensive benefit; LO=Restricted benefit; DP=Doctor prescribed medicines; BP=Beneficiary/Pharmacist prescribed medicines

Beneficiaries were categorized in age bands for each plan. This categorization separated out infancy/early childhood, childhood/adolescence, and various stages of adulthood, and was particularly useful for the logistic regression analysis.

Table IV: DP and BP medicine cost, payment and utilization patterns

	HI	**LO**	**p-value (t=comparison of means) (x^2= comparison of groups)**
DP Medicines – mean(SD) Account amount** Insured amount** Savings amount**	R464 (296)* R423 (185) -	R170 (88)* R2.90 (10) R141 (77)	p<0.00001; t=63.35 p<0.00001; t =145.4
% Beneficiaries accessing DP medicines	89.3%	83.1%	p<0.00001; x^2=121.54
BP Medicines – mean(SD) Account amount** Insured amount** Savings amount**	R621 (302) R582 (264) -	R275 (123) - R274* (93)	p<0.00001; t=63.46 - -
% Beneficiaries accessing BP medicines	67.9%	58.5%	p<0.00001; x^2= 154.71

***All amounts rounded to nearest Rand value**

****Average amounts claimed paid per beneficiary from various benefit pools over the year.**

HI=Comprehensive benefit; LO Restricted benefit; DP=Doctor Prescribed medicines; BP=Beneficiary/Pharmacist prescribed medicines

While the large sample sizes result in very significant differences in percentages of beneficiaries in the HI and LO plans accessing BP and DP medicines, overall the ranges show the high number of beneficiaries making use of the benefit: in the 80-90% range for DP medicines, and in the 58-68% range for the BP medicines. Differences were found in the area of costs. For both the DP and BP categories, over the one year period HI beneficiaries submitted claims that were substantially higher than for LO. Table IV also shows that in the HI group the amounts claimed were largely paid out of the insured/risk pool. In both the DP and BP categories there was a short-payment of around R40 (derived from the difference between account amounts and paid amounts) that would have been for the member to pay out-of-pocket. In LO, both DP and BP medicines were paid via the savings benefit. However, it is important to note that whereas in the DP category there was a short payment of some R30, in the BP category the medical scheme appears to have paid in full. The latter falsely suggests that the LO scheme was more generous, but in fact for such schemes the electronic claims system is set up for automatic rejection if the beneficiary has exhausted her/his annual capped benefits. This results in the beneficiary paying in full, with no payment expected from the medical scheme. Across the board, amounts reflected for BP medicines were substantially higher than for DP medicines. In other words, S0-S2 medicines prescribed

by doctors cost the plans substantially less than S0-S2 medicines recommended by pharmacists or accessed directly by a beneficiary.

Table V: Comparison of frequency and cost of generic vs. original products according to claims for DP vs BP medicines in ATC category RO5X

	HI		**LO**		**p-value**
	Number of items (%)	Average cost/item (Rand) Mean (SD)	Number of items (%)	Average cost/item (Rand)* Mean (SD)	**(t=comparison of means) (x^2= comparison of groups)**
DP medicines					<0.00001;x^2 =78.04
Generics	889 (58)	37 (17)*	9021 (69)	24 (12)*	P<0.00001;
Originals	540 (35)	62 (39)*	3441 (26)	46 (21)*	t=22.26
Unknown	101 (6.6)	23(11)*	580 (4)	19 (13)*	P<0.00001; t=9.32 P=0.0037; t=2.91
BP medicines					p<0.00001; x^2=57.93
Generics	1334 (34)	47 (23)*	10500	39 (21)*	
Originals	2529 (64)	77 (32)*	(40)	64 (33)*	P<0.00001;
Unknown	83 (2.0)	38 (23)*	15263 (58)	26 (15)*	t=12.08 P<0.00001; t=18.84
			689 (2)		P<0.00001; t=4.64

*Costs rounded to nearest Rand value

To explore possible reasons for the differences in medicine costs between the plans, the data were interrogated specifically for cost and utilization patterns in one of the commonest S0-S2 claiming categories viz. the respiratory category which relates to treatment for coughs and colds (ATC category RO5X). Table V shows that whether HI or LO, doctors prescribed generic medicines to a greater extent than original products (60-70% generics vs. 40-30% original products). In contrast, in the BP category the generic:original ratio was reversed and there was greater use of higher-priced original products. Table V also shows that whether medicines were in the DP or BP category or original vs. generic, average costs of these medicines were always higher in HI.

Table VI: Multivariate linear regression results for HI and LO plans with PAT/OTC costs as dependent variable

HI (Intercept 558.2)	**B**	**p-value**
Age (years)	4.59	<0.00008
LO (Intercept 273.8)	B	P value
Age (years)	4.24	<0.00001
Specialist Encounters (No.)	-11.98	<0.00073
Chronic Diseases Registered (No.)	-45.59	<0.00001

In Table VI results of multivariate regression analysis are shown for both plans, with PAT/OTC claimed amount as the dependent variable and a number of independent variables (age, gender, number of GP and specialist encounters, cost of DP medicines, number of chronic diseases and per-beneficiary hospital costs). Univariate analysis was first carried out for the latter variables and all with $p<0.02$ were entered into the multivariate analysis. Results showed that in both HI and LO, higher PAT/OTC costs were related to advancing age. Neither plan showed that there was less use of GPs or GP-prescribed medicines if beneficiaries accessed the PAT/OTC benefit. In the LO plan there was less use of the PAT/OTC benefit by beneficiaries who had more registered chronic diseases and/or who consulted specialists to a greater extent.

Discussion

Prior to legislative changes in 1998, medical scheme contributions/premiums were based on the risk profile of beneficiaries.[10] Thus, elderly and/or chronically ill patients paid higher contributions, were given life-long exclusions for pre-existing conditions or were denied membership completely. This resulted in medical scheme membership often becoming unaffordable to those who needed it most. Furthermore, medical schemes were empowered to impose monetary limits on benefit categories. This discriminatory scenario resulted in the drafting and promulgation of a new Act, ensuring that medical schemes could not discriminate based on risk profiles, and making it compulsory for every medical scheme to accept all eligible applicants, irrespective of age and/or ill-health. The legislation also mandated a comprehensive package of 'hospitalizable' and chronic medical conditions, identified in the Act and Regulations as Prescribed Minimum Benefits (PMBs) and the Chronic Disease List (CDL).[5] In addition, amendments to the Medicines and Related Substances Act prevented pharmacies and dispensing doctors from profiting from the production and distribution of medicines.[11] These legislative changes have impacted positively on medical schemes' expenditure.[12] However, the costly nature of the mandatory services for PMBs and the CDL has resulted in significant cost shifting towards medical scheme beneficiaries in the area of primary health care (PHC). As more money was required for funding of the prescribed (and costly) chronic conditions and services, less and less of each Rand spent on healthcare benefits went towards services provided by PHC providers such as GPs and pharmacies.[13] In addition to being allowed to place much of the burden of PHC costs on their beneficiaries, medical schemes were permitted to implement strategies for cost containment. In the case of OTC medicines these included monetary limits, co-payments at the point of service, and savings accounts in order to create incentives for beneficiaries to manage their own utilization. These so-called demand-side initiatives may deter beneficiaries from accessing services unnecessarily. Medical schemes may also add supply-side initiatives, for example contract with designated dispensing doctors

and/or pharmacies in order to obtain medicines at preferential prices. Formularies of 'approved medicines' or 'recommended price lists' may also be devised that will only cover full costs if adhered to, exposing beneficiaries to the risk of out-of-pocket payments.[14]

As reported by others, there is a complex inter-relationship between medical scheme benefit richness, demographic profile and cost of the cover.[3] This is illustrated in Table III which shows demographics of the HI and LO plans. Gender and ethnicity were similar for the two, but comment is necessary in respect of the latter. Whereas ethnicity is usually extremely important in South Africa as a marker of historical socioeconomic status, it is less relevant in the context of medical scheme membership because all beneficiaries are required to pay the same contributions. As such, most beneficiaries would be within similar socioeconomic categories, with those in the HI plan able to afford the higher contributions and vice versa.[15] The higher average age of 47yrs in the HI plan vs. 28yrs in LO no doubt had an impact on medicines utilization. Multivariate analysis showed that age was a significant determinant of PAT/OTC utilization, and because there were more older beneficiaries in HI, one would expect this to impact on overall utilization in HI. This can be seen in Table IV which shows that for both BP and DP medicines a significantly higher percentage of beneficiaries in the HI plan submitted claims vs those in LO. Along similar lines, given the younger age profile in LO and the known relationship between a medical scheme's benefit richness and its costs of membership, it is probable that the LO plan would have been selected by beneficiaries not only on the basis of affordability, but also because they were younger and healthier. This was confirmed in Table III by the significantly lower average number of chronic diseases registered by members in the LO plan.

Tables IV and V show clearly that beneficiaries in HI consistently had higher average costs for S0-S2 medicines than those in LO, whether in the DP or BP category. There are three main reasons for this. The first is that the benefit design in a HI plan operates on a 'use or lose' basis. Beneficiaries pay a higher annual contribution in HI and have fairly generous healthcare benefits. However, if benefits such as those for acute and/or PAT/OTC medicines are not used by the end of the year they are forfeited and the cycle repeats the following year. Consequently beneficiaries may opt for higher cost products rather than lose funds they could use. Doctors, pharmacists and beneficiaries are aware of the differences between HI and LO plans and as such there may be a tendency to utilize higher-priced products in HI. This leads to the second reason for the medicines cost variation between HI and LO. Table V shows clearly that generic products cost less than originals, and also that beneficiaries and the pharmacists who assisted them utilized original products to a greater extent than when doctors prescribed these S0-S2 medicines. Pharmacies are for-profit entities and their business strategies

may include opportunities to maximize profit. Regarding the third possible reason for higher costs, our previous study showed clearly the extent to which profit can be made on the S0-S2 category medicines.[8] Whether analgesics, anti-inflammatories, cough medicines or other OTC products, the marketplace abounds with large numbers of products that have similar chemical compositions but are priced very differently. Legislation exists that requires manufacturers to declare a fixed 'exit price,' but how that price is actually determined by a manufacturer is not a requirement of the law.[16] Whether the OTC products are prescribed by a doctor, selected by the beneficiary or recommended by a pharmacist, it is frequently in the pharmacist's control as to which products are actually dispensed.

The purpose of the multivariate analysis shown in Table VI was a) to explore variables related to BP costs and b) to ascertain whether there was evidence of reduction in costs of other healthcare services. Already mentioned is that for both plans it was the older beneficiaries who accessed the PAT/OTC benefit to a greater extent. The unexpected finding that PAT/OTC costs were lower for beneficiaries in the LO plan who had more chronic diseases registered with the plan and/or consulted specialists to a greater extent requires further study, but suggests that sicker beneficiaries did not 'indulge' in this benefit. Perhaps they were treated more-appropriately by specialists and received care (including chronic medicines) that would have been fully funded via the risk pool. Notably, giving beneficiaries access to an OTC/PAT benefit did not appear to reduce visits to a GP, to reduce prescriptions for S0-S2 medicines, or to be associated with lower hospital costs i.e. there was no apparent beneficial impact on so-called downstream costs.

According to the literature, direct patient access to pharmacist and/or self-prescribed medication is becoming increasingly important within healthcare systems, promoting empowerment and potentially reducing costs.[17-19] It is also stated that partnerships between stakeholders who provide education and information may maximize the value of benefits and minimize risk.[19] The present study suggested a limited ability of this PAT/OTC benefit to reduce costs. Some 60-70% of the beneficiaries accessed the BP benefit. If one multiplies the average amount paid by each beneficiary by the number of claiming beneficiaries in the HI and LO plans then overall amounts paid out for S0-S2 BP medicines over the year were substantial: R1.94m for HI and R8.74m for LO. Expressed as the cost to the plans in terms of total cost/total number of scheme beneficiaries, this then translates to about R394 per beneficiary per annum (pbpa) in HI and about R164 pbpa in LO. This derivation of a pbpa cost is routinely used by actuaries in costing annual premiums for the range of benefits offered by each medical scheme. Putting this into perspective, the Council for Medical Schemes Annual Report for the

same year as this study showed that for the total population of covered lives in the medical schemes industry, the average cost of obstetricians/gynecologists services was R189 pbpa, and for physicians was R257 pbpa.[20] These figures show that this study's widely-used BP benefit was within the range of total beneficiary access to some essential and expensive medical specialist services. The greater use of S0-S2 original vs. generic products in both plans (64% in HI and 58% in LO) and the higher average cost of the BP medicines in comparison to the DP medicines point to the cost ineffectiveness of the BP benefit when left to pharmacists and/or beneficiaries to manage. In addition, in HI there were short payments of ±R40 for BP medicines for the beneficiary to pay out-of-pocket. Not even this additional cost at the point-of-service appears to have led beneficiaries to question whether equivalent products were available at a lower price. Consequently, it would not be unreasonable for medical schemes to consider reducing annual medical scheme premiums/contributions by the relevant amounts, leaving beneficiaries completely responsible for self-medication. This could lead to greater vigilance on the part of beneficiaries and pharmacists, particularly when it comes to the type of product provided and the costs thereof.

Limitations

In addition to the abovementioned reasons for cost differences between benefit plans and BP and DP categories one should ideally also consider cost-reducing strategies such as the 'managed care' initiatives via contracted network doctors and pharmacists in the lower benefit plan. Such initiatives, which were not explored in the present study, imply contractual obligations to prescribe and dispense lower cost product equivalents.[21] There is also the possibility that costs were impacted by geographic distribution or purchasing behavior of LO vs. HI beneficiaries. For example, pharmacies servicing LO beneficiaries might have been situated in areas that operated off a lower cost base and perhaps charged lower dispensing and administration fees. Alternatively, LO beneficiaries might have made more use of corporate/chain pharmacies that were able to secure medicines at lower prices vs. HI plan beneficiaries who might have preferred to use their 'personal' community pharmacies.[22] It was not possible from the dataset to identify which OTC products were entirely selected by beneficiaries and which recommended by pharmacists.

Conclusion

Within these two medical scheme benefit plans there were higher costs and greater use of original products when beneficiaries or pharmacies accessed S0-S2 medicines via the PAT/OTC benefit than when these medicines were prescribed by doctors. In an era in which there is much criticism of the private sector and the role of doctors in driving healthcare costs up doctors appeared to be more cost-effective in providing access to

S0-S2 medicines when compared to the same range of medicines bought by beneficiaries or recommended by a pharmacist. In this study it was not possible to determine the extent to which pharmacists were driving costs in comparison to beneficiaries. This is an issue worth pursuing in the future. The richness of a benefit plan was also a factor driving costs, with S0-S2 medicines costing more when provided by the high-benefit plan compared to the lower plan. The higher cost of S0-S2 medicines in the higher benefit plan was most likely not related to better or more-effective medicines because within these schedules one is essentially dealing with similar chemical compounds, often combined in differing concentrations, but priced differently. Results of this study indicate that access to a PAT/OTC benefit did not impact on doctor encounters or hospitalization. Given that the annual expenditure by medical schemes on OTC medicines runs into the billions of Rands one must ask whether cost savings and cost-effectiveness could be improved by eliminating the benefit. This would encourage individuals to pay greater attention to the value proposition of the products they are purchasing. An alternative would be education of beneficiaries by medical schemes on the subject of OTC medicines, more in the way of supply- and demand-side interventions, and careful monitoring of benefit utilization, but medical schemes might argue that the return would not be worth the investment.

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References

1. Ncube NBQ, Solanki GC, Kredo T, Lalloo R. Antibiotic prescription patterns of South African general medical practitioners for treatment of acute bronchitis. *S Afr Med J*;2017,107:119-122.

2. Ramjee S, Vieyra T. Neither here nor there: The South African medical scheme industry in limbo. Actuarial Society of South Africa Convention, 22-23 October 2014.Department of Actuarial Science, School of Management Studies, University of Cape Town. 2014,165-179

3. Kaplan J & Ranchod S. Analysing the structure and nature of medical scheme benefit design in South Africa. In: Padarath A, King J, English R, editors. *S Afr Hlth Rev*. 2014/15:165-178.

4. McLeod H & Ramjee S. Medical schemes. In: Harrison S, Bhana R, Ntuli A, editors. Available from: http://www.hst.org.za/publications/South%20African%20Health%20Reviews/SAHR2007.pdf:47. Accessed August 23, 2019..

5. Medical Schemes Act 131 of 1998, Regulations. Available from: https://www.gov.za/sites/default/files/a131-98.pdf. Accessed 18 July, 2019

6. South African Health Products Regulatory Authority. Consolidated Schedules. Available from: https://www.sahpra.org.za/documents/f6bf8a532016_Consolidatedschedules20082009201120122013201420 15March_May2016(includingprescribers).pdf Accessed October 20, 2019

7. The Innovation Pharmaceutical Association of South Africa (IPASA) Available from https://www.google.com/search?q=schedule+02+ipasa&rlz=1C1GCEU_enZA832ZA832&sxsrf=ACYBGNRSj8VgLkJ1MjGwKnoSZHI9RQyYOQ:1571903385214&source=lnms&tbm=isch&sa=X&ved=0ahUKEwjfj5a3tLTlAhWFXhUIHfukAJEQ_AUIEigB&biw=1600&bih=740#imgrc=OSLtYvqI5ZfKXM: Accessed October 20, 2019

8. Padayachee N, Rothberg AD, Truter I, Butkow N. Utilization of over-the-counter analgesics in two private medical insurance schemes in South Africa. *Drug, Healthcare and Patient Saf*. 2019;11:37.

9. World Health Organisation. The Anatomical Therapeutic Chemical Classification System with defined daily doses. Available from: http://www.who.int/classifications/atcddd/en/. Accessed October 12, 2019

10. Wayburne L, Bradley E. Maintaining a balance: The impacts of ageing on the age cross-subsidy in medical scheme contributions. 2013, Actuarial Society of South Africa Conference. http://actuarialsociety.org.za/convention/convention2013registration/papers/12-821cd3c7ba1745dca4a75f334159954c.pdf. Accessed August 23, 2019.

11. Medicines and Related Substances Act 101 of 1965. Available from: https://www.gov.za/sites/default/files/41762_gon703.pdf. Accessed August 21, 2019

12. Council for Medical Schemes. Available from: http://www.compcom.co.za/wp-content/uploads/2018/01/CMS-PMB-Review-consultative-doc.pdf . Accessed October 23, 2019

13. Doherty J, McLeod H. Medical Schemes. *S Afr Hlth Rev*. 2002; 1:41-66.

14. Kaplan J & Ranchod S. An actuarial perspective on medical scheme benefit design. Actuarial Society of South Africa 2015. Available from: http://137.158.155.94/handle/11427/16692. Accessed July 23, 2019

15. Edwards T. Socio-demographic determinants of health-seeking behaviour among the South African population: An analysis of NIDS. Masters' Thesis. 2016. Available from: https://www.datafirst.uct.ac.za/dataportal/index.php/citations/6022. Accessed October 20, 2019

16. Bangalee V, Suleman F. Towards a transparent pricing system in South Africa: trends in pharmaceutical logistics fees. *S Afr Hlth Rev*. 2016 Jan 1;2016(1):221-31.

17. Saba H, Shivananda KS, Jayan M, Hussain CA. Prevalence of self-medication practices and its associated factors in rural Bengaluru, Karnataka, India. *Int J Comm Med Pub Hlth*. 2017, 3:1481-1486.

18. Bennadi D. Self-medication: A current challenge. *J Basic Clin Pharm*. 2014; 5:19-23.

19. Hughes CM, McElnay JC, Fleming GF. Benefits and risks of self-medication. *Drug Safety*. 2001; 24:1027-1037.

20. Council for Medical Schemes, Annual Report 2013-2014 Available from: https://www.medicalschemes.com/files/Annual%20Reports/AR2013_2014LR.pdf. Accessed August 23, 2019.

21. Making health insurance work for the low-income market in South Africa. Cost drivers and strategies Available from: https://cenfri.org/wp-content/uploads/2009/08/Making-health-insurance-work-for-the-low-income-market-in-South-Africa_Cenfri-FinMark-Trust-Elixir-Fifth-Quadrant_August-2009.pdf. Accessed July 23, 2019

22. Capetalk. Available from: http://www.capetalk.co.za/articles/12197/independent-community-pharmacies-unite-to-fight-bulling-by-medical-aids. Accessed October 24, 2019

2.3 CONCLUSION

The recent HMI report raised concerns about the escalating costs in the private sector and the role of doctors in driving healthcare costs up, it was therefore encouraging to see that doctors appeared to be more cost-effective in providing access to S0-S2 medicines when compared to the same range of medicines bought by beneficiaries or recommended by a pharmacist. However, one must bear in mind that pharmacists have been hard-pressed to survive after the introduction of the SEP, controls on bonusing and sampling, removal of bulk discounts, CDL algorithms, reference price lists, MMAP and generic substitution[5,87,89].Therefore selling more expensive OTCMs has likely become an avenue for increasing revenue. The results from this paper also showed that Schedule 0-2 medicine costs were driven by the richness of the plan. The costs of Schedule 0-2 medicines were higher in the richer benefit compared to the lower benefit plan, which is similar to the results obtained by Otto et al[125].

While this first study provided useful insights, the dataset did not allow exploration of other elements such as a comparison of dispensing practices between corporate and independent pharmacies. Another opportunity for future research lies in further investigation of the questions raised by the multivariate analysis which showed that elderly members with chronic conditions in the LO plan purchased fewer OTCMs when compared to members in the HI plan, but visited specialists more often. The assumption here is that due to the low monetary value in the OTCM/acute benefit, these members visited specialists in order to obtain appropriate care. This needs to be explored further using a different dataset with all the necessary details.

The paper has suggested that OTCMs are relatively 'unnoticed' within medical schemes due to their relatively low cost and limited impact on the mandatorily-funded risk pool. However, these medicines are growing in popularity and their overall costs are considerable. The OTCM benefit is not a mandatory requirement and therefore could be removed by schemes, however this may reduce a schemes' appeal and marketability. Therefore, medical schemes should perhaps consider strategies aimed at educating members on the better use of the benefit.

Overall, the paper assessed OTCMs at a benefit level, either from a risk pool or from a plan that had a savings account which was used at the discretion of the member. A component of the study focused on respiratory medicines in the RO5X ATC group. The sub-analysis of this particular ATC group provided the stimulus for the next paper which would focus on OTCM utilisation at a product level. The RO5X ATC analysis revealed that pharmacists, when compared to doctors, prescribed generic or original products that were generally more expensive. It thus became important to explore another category in greater detail. The next study was developed with an emphasis on analgesics because they featured as one of the top ATC groups in the plans assessed in this first study. This was also important because, as shown in Table 1.5 within the analgesic OTCM category many products had similar chemical compositions at equivalent dosages, but at varying prices. In addition, codeine-based OTCMs featured prominently, which added to the interest in exploring this ATC group.

CHAPTER THREE: PAPER 2

3.1 INTRODUCTION

Over-the-counter medicine usage has become popular due to increasing global economic pressures to manage escalating healthcare costs[126]. Although OTCMs are beneficial they do come with a multitude of risks (Table 1.3). For the consumer to benefit from OTCMs they must be taken responsibly. This responsibility is dependent on a doctor prescribing rationally, pharmacist prescribing/dispensing and advising appropriately, and lastly, the patient using the medicines as directed by the healthcare professional, and/or following the labelling information provided by the pharmaceutical company.

Upon investigating the RO5X ATC group in the previous paper it was evident that at a product level there were distinct differences between the prescribing behaviour of doctors and the dispensing practices of pharmacists in terms of costs and product choice. To investigate this further a detailed analysis of the NO2BE51 ATC group was undertaken. This ATC group includes analgesics that featured amongst the top ATC groups in the two previously-investigated plans. Pain has been shown to be one of the main symptoms for which patients seek treatment, either from a healthcare professional or by accessing an OTCM. In 2017, the global analgesic market was valued at 24.9 billion dollars, with an expected 7.2% growth between 2018 and 2023[120]. Between the period of 2012 and 2017, the Middle East and Africa had the second fastest growing analgesic market[76]. There is a plethora of OTC analgesic medicines available in SA such as NSAIDs, codeine and acetaminophen. Often OTC analgesics are combined with anti-histamines to provide a wider range of symptom coverage. However, the benefits of these combinations are uncertain, such as the value of using low dose codeine in OTC preparations[127-128]. In addition, codeine abuse has become a global concern. Some countries have banned the substance completely, while others have reduced the concentration of codeine that is accessible to patients[129-130]. Codeine is unavailable in the EML but freely accessible at differing strengths, dosage forms, combinations and quantities in the private sector (Chapter 1). The easy access of codeine to patients, and the regulatory body's difficulty in monitoring consumers' purchasing behaviour, make the drug a target for abuse[32].

Codeine itself has low intrinsic activity and low affinity at the opioid receptor. As such it requires the enzyme P450 2D6 to convert it to morphine for the analgesic effects. The rate at which this conversion occurs is dependent on the genetics of individuals. Slow metabolisers do not experience the full effects of codeine as it is not converted to morphine. This can often result in patients increasing the dose and therefore being

exposed to more side-effects such as constipation and respiratory depression[128]. Healthcare professionals need to be vigilant, and patients should be educated on the potential harms of codeine when used excessively, or for a longer duration than required. In this regard, medical schemes could play an important oversight role because access to OTCM benefits allows members to purchase these drugs easily with little recourse or monitoring. Members can purchase these drugs using their registered beneficiary details, but co-payments and monetary limits are actually the only restrictions. Overall, in the context of accessing OTCMs, medical schemes regard the discretionary benefit as the member's money. This facilitates the opportunity for oversupply by both the patient and the supplier, whether a doctor who prescribes or a pharmacist who dispenses.

3.2 PAPER 2 : UTILISATION OF OVER-THE-COUNTER ANALGESICS IN TWO PRIVATE MEDICAL INSURANCE SCHEMES IN SA

Padayachee N, Rothberg AD, Butkow N, Truter I. **Utilisation of over-the-counter analgesics in two private medical insurance schemes in SA** Published in *Drug, Healthcare and Patient Safety*

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ORIGINAL RESEARCH

Utilization of over-the-counter analgesics in two private medical insurance schemes in South Africa

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Introduction: In South Africa there is an easy access to over-the-counter (OTC) medicines and expenditure is high. Certain OTC products are available to the public in general stores, while others may only be available at pharmacies. It is also common for OTC medicines to be prescribed by a doctor for treatment of minor illnesses. Individuals with medical insurance usually have cover for these products, but typically only to a limited extent.

Aim: To investigate the utilization patterns in two medical insurance schemes of OTC analgesic products in the Anatomical Therapeutic Chemical (ATC) category N02BE51 which includes medicines containing paracetamol and varying combinations of codeine, caffeine and antihistamines.

Methodology: Data were obtained for two benefit plans, one with generous, high benefits (HI), the other with lower benefits (LO). Data covered utilization of OTC medicines in the N02BE51 group, indicating whether the medicines were purchased at a pharmacy or dispensed by a doctor. Doctors were further categorised as contracted/network or non- network providers. Product costs and volumes were analysed according to access directly by the beneficiary, recommendation by a pharmacist, or prescription from a doctor.

Results: Compared to doctors, pharmacists issued more-expensive products. Average costs were higher in the HI plan compared to the LO plan. Pharmacists showed a preference for dispensing larger and more expensive pack sizes. Doctors showed better cost containment: the average cost of products in HI was twice that of LO. Doctors dispensing directly to patients issued smaller pack sizes and lower-priced products. Contracted network doctors did not appear to impact on costs.

Conclusion: Among the privately-insured individuals studied, the availability, cost and formulation of N02BE51 OTC products appeared to be poorly regulated, whether by the consumer, pharmacist, medical insurance scheme or legislation. Doctors demonstrate better cost containment by prescribing less costly, smaller pack-size alternatives compared to pharmacists.

Keywords: paracetamol, codeine, anti-histamines, pharmacists, doctors, cost, pack size

Introduction

By definition, “ethical medicines” are medicines that can only be accessed by patients on a doctor’s prescription. Over-the-counter (OTC) medicines are not subject to such control and, being more available, contribute significantly to South Africa’s annual healthcare expenditure. According to reliable industry infor- mation, in 2015 R39.5bn was spent on all medicines (R=South African Rand; in 2015 R12.6=1US Dollar). The OTC market accounted for almost 26% of the total amount (R10.2bn)[1] One particular manufacturer featured as the leader in OTC sales, an achievement highlighted in the company’s 2018 annual report which showed OTC market growth of 7.6% (calculated at R1.898bn).[2]

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The ease of access to OTC medicines by consumers has resulted in a perception that the products are harmless and do not pose health or other risks.[3] These medicines, available without a prescription, are categorised by the national accreditation and registering body as Schedule 0,1 or 2 medicines.[4] Schedule 0 medicines are available at general stores and supermarkets, while Schedule 1 and 2 medicines (S1,S2) are kept behind the counter at pharma- cies but can still be purchased without a prescription.[4] Many OTC products are "poly-pharmaceuticals" and con- tain mixtures of various Schedule 1–2 medicines, but the evidence base for their effectiveness is generally lacking. Most have "flown under the radar" in terms of safety with the exception of ephedrine, pseudoephedrine and codeine. In the latter cases the Medicines and Related Substances Act 101 of 1965 was amended to limit the milligram quantity of these substances in OTC preparations and restrict the number of packs that an individual is able to purchase.[5-7] While placing the above restrictions on access to codeine, the legislation is less prescriptive about the poly-pharmaceutical formulations of OTC medicines. Freely available to the public via cash payments, OTC medicines are also available to medically-insured benefi- ciaries via their "medical aid schemes", whether accessed directly by the beneficiary, recommended by a pharmacist or prescribed during a doctor's consultation for treatment of a minor illness. In South Africa private health insurance is provided by not-for-profit medical aid schemes. In 2015 there were 87 medical aid schemes registered with the Council for Medical Schemes (CMS), the Government regulatory body.[8] Each one offers access to a range of medical, dental, optical, paramedical and medicinal ser- vices known as "benefits." Benefit combinations vary between medical aid schemes, with each combination termed a "plan" or "option". Health plans are purchased by "beneficiaries" on the basis of affordability and health- care needs. Where healthcare is accessed within the public sector which serves more than 80% of the population, S1, S2 medicines are prescribed and dispensed according to the South African Essential Medicines List (EML) which is a formulary with a limited number of OTC medicines, typically only includes single-compound products and does not include combination medicines.[9]

An additional issue with OTC medicines is that the combination and concentration/strength of ingredients may be identical or differ only marginally between products, yet prices vary markedly without sound basis. However, it is not only the varying cost of the products themselves, but also the potential costs of their adverse effects that are important. For example, a study by Friedman showed that cheaper, "old generation" sedating antihistamines were easily accessible for allergic conditions, but the long- term cost impact of the adverse effects of these drugs had not been considered.[10] In terms of potential costs of adverse outcomes, the codeine-containing medicines represent a category that raises or should raise concerns in the country. As a result of legislation, OTC medicines are restricted to 10mg of codeine per dose.[7] While this is restrictive, it does not limit the risk of addiction.[11] Codeine abuse is currently receiving attention globally, with Australia removing codeine-containing OTC preparations and "up-scheduling" them to the "prescription only" category,[12] while measures to restrict access are also being considered in the United States and Canada.[13,14]

Council for Medical Schemes annual reports indicate that a high percentage of covered beneficiaries access the OTC benefit, irrespective of whether they have restricted or generous benefits.[8] Furthermore, as shown by others, it appears that the higher the available benefit, the more tends to be spent on an event, despite the fact that spend- ing more-carefully would extend the value of the benefit.[15] Medical aid schemes provide little in the way of member education and also have few, if any, cost-containment initiatives within the OTC benefit.[8] This may be because schemes have limited interest in how the benefit is used. It is typically capped in one way or another and structured in such a way that it functions as a debit card account, to be used at the discretion (or indiscretion) of the beneficiary concerned.

Access to care, cost of care and quality are key elements in any discussion around a health system. The aim of the present study is to investigate the utilization patterns in two South African medical aid schemes of a high-impact set of OTC products. As such the focus was on analgesic products in the Anatomical Therapeutic Chemical (ATC) N02BE51 category which includes med- icines containing paracetamol and varying combinations of codeine, caffeine and antihistamines. The study addresses individual products and explores costs, volumes and elements of quality, the latter mainly related to reg- ulatory oversight of pricing and formulation of products in the ATC category under review. We also discuss find- ings in relation to the current national debate around costs in the private sector in general, and the intended transition to universal, affordable access to quality healthcare.

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Methodology

Beneficiaries were selected from a 2015 database provided by a large medical aid scheme administration company in South Africa. Administration companies take on the day- to-day operational activities of one or more medical aid schemes. Services range from enrolment of members to payment of claims, actuarial services and production of management reports. The administrator who provided our data has been in existence for over 40 years and serves more than 3 million lives within a number of medical aid schemes. The various medical aid schemes, their specific benefit options/plans and beneficiaries were not identifi- able; as such all data were confidential. One year's data was provided for analysis covering 12 plans with 641 525 beneficiaries in total. Only two plans were selected for this study, one within a high benefit medical aid scheme with a comprehensive set of generous benefits (designated HI), the other offering a lower benefit plan (designated LO). In both plans there was access to OTC medicines up to specified limits.

Beneficiaries were identified only by a unique study number. Background information provided for each bene- ficiary included gender, age and ethnicity. Medicines data extracted included only S1,S2 medicines. Those prescribed or dispensed by a doctor are referred to as doctor-pre- scribed (DP) medicines, while those accessed directly by the beneficiary or on the recommendation of the pharma- cist are referred to as beneficiary/pharmacist (BP) medi- cines. In the South African context all medically-qualified and registered practitioners are referred to as doctors, whether general practitioners, specialists or sub-specialists in the various medical and surgical disciplines.

Actual indication for the medicines could not be ascer- tained because of the frequent use of a non-specific diag- nostic ICD10 code such as in the Z76 category which covers "Persons encountering health services in unspeci- fied circumstances."[16] Each medicine claimed was coded according to its ATC classification.[17] Within the ATC system medicines are grouped into five levels (anatomical main group, therapeutic subgroup, pharmacological sub- group, chemical subgroup and chemical substance). One of the most-frequently accessed categories, N02BE51, covers N: the nervous system, 02 represents analgesics, BE and 51 cover paracetamol and its combination with various ingredients, excluding psycholeptics. In South Africa this ATC category includes a large number of products, most of which have varying combinations of a relatively limited number of ingredients. Products may be original or generic and be priced very differently, in many cases for identical formulations.[18]

This ATC category was selected not only because its overall utilization was high in both HI and LO plans, but also because of the potential for products in this category to present with adverse drug reactions.[19] For both HI and LO plans the top 10 N02BE51 products were selected based on volume, whether accessed via the DP or BP route. The contribution of each product to the total cost within the ATC was calculated, together with the average cost of each product as submitted to and paid by the medical aid scheme. To establish whether the HI and LO plans selected for this study were representative of utiliza- tion in other plans, five other plans were randomly selected from the database of 12 plans. A correlation analysis was performed for the top products of the five against the products accessed within the two plans used in this study. Results showed correlation coefficients that ranged between 0.84 and 0.99, with *p*-values ranging from <0.005 to 0.000. Statistical analysis was carried out using Statistica (Version 13.2 TIBCO Software Inc., Palo Alto, CA, USA) which was also used for descriptive statistics and frequency analysis. Significance was set at $p<0.05$.

In the DP option in both plans, the top 10 medicines by volume were further separated, based on whether they were prescribed by a formally-registered dispensing doctor (who stocks medicines within her/his practice) or a non- dispensing doctor (who writes a prescription for dispen- sing by a pharmacist). An additional level of service provision and DP-prescribing explored the involvement of contracted, preferred/designated service providers (DSPs), alternatively referred to as "network doctors". This applied only to the LO plan as it was not a managed care strategy employed by the HI plan.

Ethics approval was obtained from the Human Ethics Committee of the University of the Witwatersrand (certi- ficate M160141).

Results

Table 1 shows the ranking of 14 branded products in the NO2BE51 ATC by composition and volume in the HI plan, whether BP-dispensed or DP-prescribed. Six products were common to both DP and BP. The generic use within both DP and BP categories was similar. Of the top 10 in both BP and DP categories, seven of the products have the same chemi- cal composition, yet prices ranged between R7.54 and

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Table 1 Top 10 branded products coded by contents and ranked by volume in the N02BE51 ATC for BP and DP (HI plan)

BP	Number of claims	Avg cost per product (Rand)	DP	Number of claims	Avg cost per product (Rand)
A1	688	66.86	A1	146	46.24
A2	287	96.33	B2	83	25.02
A3*	146	110.08	A2	67	90.81
B1	60	42.17	E1*	36	16.59
A4	57	79.74	A6	31	7.54
B2	57	24.12	A3*	28	90.71
A5	50	38.95	A4	27	80.53
C1	41	114.46	A7	27	54.47
D1	31	48.52	D2	24	25.12
E1*	30	47.45	B3	22	10.26
Total spend in category N02BE51: R117 580 Top 10 spend in N02BE51: R107 737 (91.63%) Average cost of top 10: R66.87 % volume of generics: 87.84			Total spend in category N02BE51: R29 946 Top 10 spend in N02BE51: R22 756 (76.0%) Average cost of top 10: R44.73 % volume of generics: 86.97		

Notes: *Original; [A1-A7]Paracetamol, codeine, caffeine and doxylamine tablets. [B1-B3]Paracetamol, codeine and promethazine syrup. [C1]Paracetamol, codeine, caffeine and diphenhydramine tablets. [D1-D2]Tripolidine, pseudoephedrine and paracetamol syrup. [E1]Codeine, caffeine and phenyltoloxamine tablets
Abrreviations: BP, beneficiary/pharmacist accessed; DP, doctor prescribed; HI, high benefits.

R110. The average cost for the top 10 in the BP category was R66.82 in contrast to R44.73 in the DP category.

Table 2 shows volume and cost comparisons for identical products prescribed by non-dispensing and dispensing doc- tors. When comparing identical products dispensed by the two doctor groups it is clear that the dispensing doctors showed better cost containment. For the non-dispensing doc- tors the medicine costs were almost twice as high as those of the dispensing doctors. Two products (A1,A2) have similar ingredients but costs ranged between R28.08 and R109.96. Some of the large price differences could be the result of differing pack sizes. This is explored below (Table 3).

Table 3 compares the frequency with which smaller and larger pack sizes of the two most commonly utilised products (A1, A2) were dispensed between three groups: dispensing doctors, non-dispensing doctors and pharmacists. Frequency analysis showed that there was significantly more dispensing of large packs by pharmacists, while dispensing doctors were significantly less inclined to do so. This had an impact on costs reflected in Tables 1 and 2.

Table 4 shows the ranking of 15 branded products by composition and volume in the N02BE51 ATC in the LO plan. Five products were common to both DP and BP categories, with almost complete use of generics in both. Eight products contain similar ingredients. The average product price in the BP category was more than double

Table 2 Cost comparisons for identical Top 10 products pre- scribed by dispensing vs non-dispensing doctors in ATC N02BE51 in HI plan

Non-dispen- sing Dr	Avg cost (Rand)	Dispensing Dr	Avg cost (Rand)
A1	60.03	A1	28.08
B2	27.61	B2	13.28
A2	109.96	A2	34.48
E1*	23.77	E1*	12.02

Notes: *Original; [A1-A2]Paracetamol, codeine, caffeine and doxylamine tablets. [B2]Paracetamol, codeine and promethazine syrup. [E1]Codeine, caffeine and phenylto- loxamine tablets.
Abrreviations: ATC, Anatomical Therapeutic Chemical; HI, high benefits.

Table 3 Pack sizes for two commonly- utilised products accord- ing to service provider in HI plan

HI Plan	A1 Number of packs dispensed	A2 Number of packs dispensed
	Pack Size 20	Pack Size 18
Non-dispensing Dr	34*	16
Dispensing Dr	21*	162
Pharmacist dis- pensed (OTC)	219*	148
	Pack Size 100	Pack Size 100
Non-dispensing Dr	42*	21
Dispensing Dr	8*	0
Pharmacist dis- pensed (OTC)	428*	109

Notes: [A1-A2]Paracetamol, codeine, caffeine and doxylamine tablets. *Chi-square for comparison of dispensing of pack sizes by different providers: $p<0.001$.
Abrreviations: OTC, over-the-counter; HI, high benefits.

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Table 4 Top 10 branded products coded by contents and ranked by volume in the N02BE51 ATC for BP and DP (LO Plan)

BP	Number of claims	Avg cost per Product (Rand)	DP	Number of claims	Avg cost per Product (Rand)
A1	4632	49.74	B2	1302	16.47
A2	1256	68.25	A1	1109	26.03
B2	1037	17.36	D	943	21.35
D3	854	18.96	2	840	10.26
D2	547	23.44	B3	685	17.64
A8	537	38.57	D	559	13.58
A5	505	38.98	3	420	17.08
A4	432	57.67	B4	411	45.08
D1	416	39.82	B5	374	15.01
A3*	357	71.50	A2	312	9.45
			A9		
			A6		
Total spend in category N02BE51: R522 199 Top 10 spend in N02BE51: R475 023 (90.97%) Average cost of top 10: R42.43 % volume of generics: 96.62			Total spend in category N02BE51: R193 867 Top 10 spend in N02BE51: R132 988 (68.60%) Average cost of top 10: R19.19 % volume of generics: 100		

Notes: *Original; [A1-A6 A8-A9]Paracetamol, codeine, caffeine and doxylamine tablets. [B2-B5]Paracetamol, codeine and promethazine syrup. [D1-D3]Tripolidine, pseudoephedrine and paracetamol syrup.
Abbreviations: ATC, Anatomical Therapeutic Chemical; BP, beneficiary/pharmacist accessed; DP, doctor prescribed; LO, low benefits.

that of the DP category (R42.43 vs R19.19). The use of smaller pack sizes is detailed below (Table 6), but the choice of cheaper generics by doctors and proportionally lower dispensing fees may also have distorted the average cost in favour of the doctors.

Table 5 shows the cost differences for products com- mon to both non-dispensing and dispensing doctors. For four of the six common products the costs were very close, however once again for the two generics that contain paracetamol, caffeine, doxylamine and codeine there was a substantial difference. This is shown below as a possible manifestation of pack size differences (Table 6).

Table 6 shows frequency of dispensing by dispensing doctors, non-dispensing doctors and pharmacists. In com- parison with the HI plan there appeared to be more

Table 5 Cost comparisons for identical Top 10 products prescribed by dispensing vs non-dispensing doctors in ATC N02BE51 in LO

Non-dispensing Dr	Avg cost (Rand)	Dispensing Dr	Avg cost (Rand)
A1	37.04	A1	17.37
A2	60.48	A2	33.20
B2	17.68	B2	14.63
B5	19.73	B5	16.44
D2	23.87	D2	20.65
D3	19.18	D3	17.16

Notes: [A1-A2]Paracetamol, codeine, caffeine and doxylamine tablets.[B1-B2, B5]Paracetamol, codeine and promethazine syrup. [D2-D3]Tripolidine, pseudoephedrine and paracetamol syrup.
Abbreviations: ATC, Anatomical Therapeutic Chemical; LO, low benefits.

"balanced" use of smaller and larger pack sizes, but fre- quency analysis showed again that pharmacists, and to an extent non-dispensing doctors, resorted to larger pack sizes than dispensing doctors. There was an impact of pack size dispensing on costs as reflected in Tables 4 and 5.

Table 7 shows costs attributable to different doctor categories. Network doctors are doctors who have ser- vice-level and payment agreements with medical aid schemes. These doctors were further categorised as either dispensing or non-dispensing doctors. There was not much

Table 6 Pack sizes for two commonly- utilised products accord- ing to service provider in LO plan

LO	A1 Number of packs dispensed	A2 Number of packs dispensed
	Pack size 20	Pack size 18
Non-dispensing Dr	265*	91
Dispensing Dr	448*	116
Pharmacist dispen- sing (OTC)	2097*	774
	Pack Size 100	Pack size 100
Non-dispensing Dr	126*	27
Dispensing Dr	1*	0
Pharmacist dis- pensed (OTC)	2214*	302

Notes: [A1-A2]Paracetamol, codeine, caffeine and doxylamine tablets.*Chi-square for comparison of dispensing of pack sizes by different providers: $p<0.001$.
Abrreviations: OTC, over-the-counter; LO, low benefits.

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Table 7 Cost comparisons for identical products provided by network doctor vs non-network doctors in the non-dispensing and dispensing doctor categories

Non-dispensing Dr	Avg cost (Rand)	Dispensing Dr	Avg cost (Rand)
A1		A1	
Network Dr Non-network Dr	35.74 45.56	Network Dr Non-network Dr	17.47 14.19
A2		A2	
Network Dr Non-network Dr	58.75 70.66	Network Dr Non-network Dr	16.44 20.56
B2		B2	
Network Dr Non-Network Dr	17.49 18.63	Network Dr Non-network Dr	33.20 30.01
B5		B5	
Network Dr Non-network Dr	19.64 20.23	Network Dr Non-network Dr	17.16 15.20
D2		D2	
Network Dr Non-network Dr	23.72 25.04	Network Dr Non-network Dr	14.66 13.42
D3		D3	
Network Dr Non-network Dr Average cost (All products)	19.37 18.00 31.06	Network Dr Non-network Dr Average cost (All products)	20.65 20.67 19.47

Notes: [A1-A2]Paracetamol, codeine, caffeine and doxylamine tablets.[B2, B5]Paracetamol, codeine and promethazine syrup.[D2, D3]Tripolidine, pseudoephedrine and paracetamol syrup.

difference in costs between network and non-network doc- tors, irrespective of whether they dispensed directly to patients or wrote prescriptions for dispensing by a phar- macy. However, as shown in previous Tables, the average cost remained higher for the non-dispensing doctors com- pared to the dispensing doctors (R31.06 vs R19.47).

Discussion

This study focused on 14 branded products in the N02BE51 ATC category representing 'top 10' expenditure in the HI plan and 15 products in the LO plan. Overall, 50 mostly-parace- tamol-based and codeine-containing products were dis- pensed in the NO2BE51 category, with variable prices but limited differences in terms of their composition. South Africa has “single exit price” legislation that compels all manufacturers to declare the price of each product and seeks to ensure that prices are not inflated at points of sale.[20] However, as shown in this study, there is no requirement for manufacturers to justify prices or show how they were derived. This results in identically-formulated products hav- ing markedly differences prices. This aspect is confirmed and covered in detail in a recent report which showed that two- thirds of 6613 products across the ATC categories were formulated identically to one or more others.[18] The use of several generic products in this study raises the question of whether similarly-constituted products are always and reli- ably clinically equivalent. This is an important issue that has been reviewed by others who note that particularly in emer- ging economies and developing countries there is variability between drug batches, between generic and originator pro- ducts, and impurities may be present.[21]

The cost differentials for identical products according to how they are accessed also indicates that legislation that is intended to regulate dispensing fees and the handling costs of medicines is also failing.[22] Costs to the medical aid schemes were related to the available benefits; the higher the available benefit the greater the cost even for identical products. This is in accordance with published data.[15]

The cost of OTC products accessed by beneficiaries or recommended by pharmacists was higher than when pre- scribed by a doctor. This has been reported for Schedule 0 medicines in South Africa but to our knowledge has not been studied for S1 and S2 OTC medicines.[23] Furthermore, non-dispensing doctors appeared to be more cost-effective than dispensing doctors, and network contracts between the medical aid schemes and doctors did not appear to generate OTC medicines savings. These findings accord with other local research.[24,25]

In some cases the cost differentials appeared to be related to provision of larger pack sizes by pharmacists and non-dispensing doctors (whose prescriptions are ulti- mately dispensed by pharmacists). Further investigation is required to assess the extent to which dispensed quantities might differ from what was prescribed. In this regard recent changes to legislation[5] prevent the sale of large pack sizes, but this does not necessarily prevent pharma- cists from dispensing multiple boxes of a smaller quantity. It is possible/likely that pharmacies have higher overhead costs than dispensing doctors, and that they dispense accordingly in order to maximise returns. While regulated by government,[22] the variable application of dispensing fees may be a factor in the cost differentials. This was not measurable in this study.

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Several ingredients within the S1,S2 category, for example ephedrine, pseudoephedrine and codeine are sub- ject to legislative restrictions.[6,7] In the ATC category under review, codeine is included in several products up to the specified maximum concentration. While codeine is a weak opioid, despite these safeguards the drug has the potential for abuse and dependence. Furthermore, seda- tion, and euphoria are common side effects that may impair function.[26] Simply decreasing the codeine quantity accessible to an individual consumer is also not an effec- tive control because in the medical aid schemes environment it is possible for one beneficiary to access additional OTC quantities by simply using another family member's benefit. In fact, research has shown that in this country 43% of codeine abusers accessed codeine-containing pro- ducts through their medical aid schemes.[27] A recent inves- tigative report has also highlighted poor oversight by government and poor compliance in the dispensing of codeine-containing products by pharmacists.[28]

Billions are spent annually on OTCs in South Africa, apparently not in a cost-effective manner. It is therefore appropriate to consider whether free market principles should prevail or interventions introduced that would bet- ter regulate access to and the cost and quality of OTCs. For the BP category, in order to reduce costs medical aid schemes could enhance managed care interventions, per- haps restrict access to lower cost products by following strategies such as the Maximum Medical Aid Price (MMAP)[29] or a medical aid scheme-specific recom- mended price list that would only cover products at the lower end of the cost spectrum.[30] Medical aid schemes could also do more to develop evidence-based OTC formularies and educate beneficiaries in the use thereof. Benefits could be restructured in order to create greater awareness of cost implications, although research has shown that "brand awareness" does not change in response to such initiatives.[31] Alternatively, the benefit could be abolished completely, leaving beneficiaries to self-medi- cate according to affordability, but in this regard research has shown that while "price shopping" may be supported in theory, consumers are limited in their ability to effect change.[32] In the DP category, medical aid schemes could pay more attention to the potential value of doctors, pre- dominantly general practitioners but dispensing doctors in particular, who appear to be more aware of costs in their prescribing of OTCs to patients.

To a large extent managed care initiatives are in effect in the public sector through processes such as the State's tender system (which manages the cost aspect) and formul- aries such as the EML (which restricts access to a limited range of products and also affects quality by excluding most multi-ingredient products).[9] Extension of State control to the private sector's access to OTC medicines would almost certainly impact on overall costs and quality through regulation in areas of pricing, product composition and poly- pharmacy. On the other hand, up-scheduling of an ingredient such as codeine would likely lead to an increase in costs through additional consultations with doctors and also financial disadvantage to pharmacies.[33]

The results of this analysis and the list of possible interventions should also be considered within the context of current debates around private sector healthcare in South Africa. Three documents are under consideration: the National Health Insurance (NHI) Bill, the interim report of the Health Market Inquiry (HMI), and the Medical Schemes Amendment (MSA) Bill.[34-36] The NHI Bill is focused on the future, while the HMI report is directed towards the existing private healthcare system with an emphasis on the roles of private hospitals, medical aid schemes, administrators and doctors in driving the costs of private healthcare. Pharmaceutical companies, manufacturers and distributors of OTCs were not covered by the HMI, but recommendations in the interim report certainly apply and are consistent with the interventions proposed above based on results of the present study. These include the need to introduce value-based purchas- ing, effectively control costs, educate disempowered and uninformed medical aid scheme beneficiaries, and use DSPs with obligations to provide cost-effective quality healthcare.

The proposed amendments to the Medical Schemes Act include ten major changes of which two are particu- larly relevant to this study: revising the current acute benefit package to include primary health care (PHC) medicines and care, and ensuring that the comprehensive benefit package is covered in full without co-payments. In terms of OTCs, if the amendments become law then in future the medical aid schemes would likely include within the PHC benefit the common ATC categories and the poly-pharmaceuticals discussed in this paper. According to the NHI Bill these would then have to be covered in full with no co-payments. Without attention being given to access and cost controls, the lack of formularies, DSPs, networks and guaranteed prices, there is thus a risk that the proposed MSA amendments would actually result in higher expenditure on OTCs in the future.

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Conclusion

Within the medical aid schemes industry, access to and costs of OTC medicines are poorly managed, whether by the benefici- aries, medical aid schemes/administrators, pharmacists or State. On the positive side, doctors (particularly doctors who dispense from their consulting rooms) show better cost containment compared to pharmacists, who appeared to favour more-expensive products in larger pack sizes. The recommen- dations emanating from this study are consistent with those that appeared in the recent interim report of the Health Market Inquiry,[35] demonstrating that cost drivers that apply to hospi- tals, administrators and doctors apply similarly in the OTC market, with stakeholders endeavouring to drive costs up rather than down.

Disclosure

The authors have no conflicts of interest in this work.

References

1. Healthcare and Lifesciences Review. 2016. Available from: https:// pharmaboardroom.com/pharmareport/south-africa-pharma-report. Accessed September 26, 2018
2. Concern over rising medicine prices in SA as Adcock Ingram profit soars. 2018 Available from: https://businesstech.co.za/news/business/ 267957/concern-over-rising-medicine-prices-in-sa-as-adcock-ingram- profit-soars. Accessed November 12, 2018.
3. Markotic F, Jurisic D, Curkovic M, et al. Sharing of prescription analgesics amongst patients in family practice: frequency and asso- ciated factors. *Eur J Pain*. 2018;22(4):716–727. doi:10.1002/ejp.1157
4. South African Health Products Regulatory Authority. Scheduling of Medicines. Available from: https://www.sahpra.org.za/documents/a56714ff2.36_Scheduling_of_Medicines_Jun14_v1.pdf. Accessed September 26, 2018.
5. Gray A, Vawda Y. Health Policy and Legislation. Padarath A, Barron P editors. *South African Health Review 2017*. Durban: Health Systems Trust; 2017: 52. Available from: http://www.hst.org.za/publications/South%20African%20Health%20Reviews/HST%20SAHR%202017%20Web%20Version.pdf. Accessed 27 September, 2018.
6. South African Health Products Regulatory Authority. Medicines and Related Substances Act, 1965 (Act 101 of 1965) Schedules. Available from: http://www.sahpra.org.za/documents/ca12c1aeGov_Gazette_31010_25April2008_Scheduling_of_pseudoephedrine_BZP.pdf. Accessed September 26, 2018
7. South African Health Products Regulatory Authority. Consolidated Schedules. Available from: https://www.sahpra.org.za/documents/f6bf8a532016_Consolidatedschedules2008200920112012201 320142015March_May2016(includingprescribers).pdf. Accessed September 26, 2018
8. Council of Medical Schemes. Available from: https://www.medicalschemes.com. Accessed April 29, 2019
9. Standard treatment guidelines and Essential Medicines List for South Africa. 2013. Available from: http://www.kznhealth.gov.za/pharmacy/PaedsSTG2013LR.pdf. Accessed September 26, 2018.
10. Friedman RL. Allergic rhinitis prescription - where to now in South Africa? *Current Allergy Clin Immunol*. 2006;4(19):180–185.
11. Carney T, Wells J, Parry CD, McGuinness P, Harris R, Van Hout MC. A comparative analysis of pharmacists' perspectives on codeine use and misuse – a three-country survey. *Subst Abuse Treat Prev Policy*. 2018;13(1):12. doi:10.1186/s13011-018-0149-2
12. McCoy J, Bruno R, Nielsen S. Attitudes in Australia on the upscheduling of over-the-counter codeine to a prescription-only medication. *Drug Alcohol Rev*. 2018;37(2):257–261. doi:10.1111/dar.12568
13. ABC News. Available from: https://www.abc.net.au/radionational/programs/breakfast/canada-moves-to-ban-over-the-counter-codeine-sales/9364194 Accessed April 28, 2019
14. US Food and Drug Administration. Available from: https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-restricts-use-prescription-codeine-pain-and-cough-medicines-and Accessed April 28, 2019
15. Otto M, Armeni P, Jommi C. Variations in non-prescription drug consumption and expenditure: determinants and policy implications. *Health Policy*. 2018;122(6):614–620. doi:10.1016/j.healthpol.2018.01.012
16. ICD-10. Available from: www.icd10data.com/ICD10CM/CodesZ00- Z99 Accessed May 2, 2019
17. World Health Organisation. The Anatomical Therapeutic Chemical Classification System with defined daily doses Available from: http://www.who.int/classifications/atcddd/en. Accessed November 12, 2018
18. The Supply of Pharmaceuticals in South Africa. Helen Suzman Foundation. 2018. Available from: https://hsf.org.za/publications/special-publications/pharmaceuticals-in-south-africa/pharma-report-2018.pdf Accessed November 12, 2018
19. Schmiedl S, Rottenkolber M, Hasford J, et al. Self-medication with over-the-counter and prescribed drugs causing adverse-drug-reaction-related hospital admissions: results of a prospective, long-term multi-centre study. *Drug Saf*. 2014;37:225–235. doi:10.1007/s40264-014-0141-3
20. Single Exit Pricing. Department of Health. Available from: http://www.health.gov.za/index.php/2014-03-17-09-09-38/legislation/joomla-split-menu/category/121-reg2004. Accessed April 29, 2019
21. Johnston A, Holt DW. Substandard drugs: a potential crisis for public health. *Br J Clin Pharmacol*. 2014;78(2):218–243. doi:10.1111/bcp.12298
22. Dispensing Fee. Available from: https://www.gov.za/sites/default/files/gcis_document/201409/326851053.pdf. Accessed June 6, 2019.
23. Perumal-Pillay VA, Thereshen Reddy SF. An exploratory study into the use of pricing of schedule zero medicines post exemption from the single exit price policy in South Africa. *Global J of Health Sc*. 2019;11(3):23–31. doi:10.5539/gjhs.v11n3p23
24. Trap B, Hansen EH, Hogerzeil HV. Prescription habits of dispensing and non-dispensing doctors in Zimbabwe. *Health Pol and Plan*. 2002;17(3):288–295. doi:10.1093/heapol/17.3.288
25. Modi BH The comparative cost of treating medical aid and non-medical aid patients attending private general practitioners. Master of Medicine Dissertation, 2013. University of the Witwatersrand, Johannesburg.
26. Nielsen S, Van Hout MC. Over-the-counter codeine –from therapeu- tic use to dependence, and the grey areas in between. *Curr Top Behav Neurosci*. 2016;34:59–75.
27. Dada S, Burnhams NH, Van Hout MC, Parry CDH. Codeine misuse and dependence in South Africa- learning from substance abuse treatment admissions. *South Afr Med J*. 2015;105(9):776–779. doi:10.7196/SAMJnew.8172
28. Carte Blanche Investigation, M-net DSTV. Available from: https://m-net.dstv.com/show/carte-blanche/news/codeine-addictions-signs-and-symptoms-carte-blanche/news Accessed November 11, 2018
29. Boyce D, Bartlett G. The maximum medical aid price programme: A review of the concept and of its ability to reduce expenditure on medicines. *South Afr Med J*. 1990;78(8):147–151.
30. Rothberg AD, Blignault J, Serfontein CB, et al. Experience of a medicines reference-pricing model. *South Afr Med J*. 2004;94(3):183–188.

31. Parente ST, Feldman R, Chen S. Effects of a consumer driven health plan on pharmaceutical spending and utilisation. *Health Serv Res*. 2008;43(5p1):1542–1556. doi:10.1111/j.1475-6773.2008.00857.x
32. Semigran HL, Gourevitch R, Sinaiko AD, Cowling D, Mehrotra A. Patients' views on price shopping and price transparency. *Am J Manag Care*. 2017;23(6):e186–e192.
33. Gudin J, Lee AJ. The downside of upscheduling. *Pain Med*. 2013;14 (11):1628–1629. doi:10.1111/pme.12257_3
34. National Health Insurance Bill. 2018. Available from: http://www. health.gov.za/index.php/gf-tb-program/398-national-health-insur ance-bill-2018. Accessed November 12, 2018.
35. Health Market Inquiry: Provisional findings and recommendations. 2018. Available from: http://www.compcom.co.za/wp-content/uploads/2018/07/Health-Market-Inquiry-1.pdf. Accessed November 12, 2018.
36. Medical Schemes Amendment Bill. 2018. Available from: https://www. gov.za/sites/default/files/41726_gon636s.pdf Accessed November 12, 201

3.3 CONCLUSION

Medicine costs are rising globally and several cost cutting measures have been attempted by many countries. South Africa is no different. The introduction of compulsory generic substitution and SEP are examples of those measures in SA (Chapter 1). However, results of this second analysis of OTCM access and utilisation by medical scheme beneficiaries strongly suggests that these measures are failing. Generic prescribing and dispensing have yet to be completely embraced by all healthcare professionals and, as shown in the results, pharmacists seem inclined to dispense larger pack sizes when given the opportunity. On the other hand, dispensing doctors appear to be more frugal. Once again this is evidence that contrary to the findings of the HMI, certainly in the PHC domain of OTCMs, doctors do not appear to be manipulating the system to their advantage. The tendency to use more-expensive OTCMs in the HI benefit, especially by pharmacists, was further confirmed in this component of the study.

Although SEP has been in existence for more than a decade, the price differences between products that contain the same ingredients is alarming and suggests that the legislative process should involve more than simply having manufacturers declare an exit price without also justifying that price. The SEP legislation has indeed reduced medicine pricing over the years[3], however, how these medicines are priced by the manufacturer is questionable. As shown in this study, medicines that have the same active ingredients vary widely in price and in general appear to be more expensive than those shown in Table 1.5. While important to review why similarly-constituted products are priced differently, it is also relevant to ask whether there is actually value in the polypharmaceutical combinations. Polypharmaceutical combinations of paracetamol, caffeine, paracetamol,codeine and doxylamine are common in the private sector OTC market. However they are not included in the EML as they are regarded as unnecessary. Combination analgesics are commonly used for the management of pain, however, the risk of adverse effects exists if there is a lack of close monitoring, especially if the combined analgesics are unknowingly used together with acute or chronic medications, for example cold preparations that may also contain analgesics which could result in toxicity[131-132].

It is also within the power of the medical scheme administration systems to explore patterns of OTCM usage. This has the potential to yield relevant clinical information about the user such as the presence of underlying chronic conditions (e.g. asthma), and result in improved health of the beneficiary and also possible savings to the scheme. Interestingly, during the analysis it was noted that PMB drugs such as Ecotrin^{R} and aspirin featured prominently. This suggested that members were accessing ‘chronic-type’ medicines via this benefit. According

to the MSA and related CDL algorithms, when accessed by a beneficiary who has registered her/his chronic disease/s, these drugs should be claimed and paid in full from the PMB risk pool and not paid as OTCMs via one or other limited ‘discretionary’ benefit.Questions were therefore raised around why beneficiaries were purchasing these drugs outside of the PMB benefit, and importantly, where were the CDL-related managed healthcare interventions that medical schemes were being paid to provide for beneficiaries who have actually registered for disease management. This led to the development of the third paper.

CHAPTER FOUR: PAPER 3

4.1 INTRODUCTION

The WHO global action plan for the prevention and control of non-communicable diseases (NCDs) aims to reduce premature mortality from these conditions by 25% by 2025. According to WHO, NCD burden can be reduced if appropriate preventive and curative actions and interventions are effectively implemented[133-134].

South Africa is facing the challenge of a quadruple burden of disease i.e. the HIV/AIDs – tuberculosis epidemic, high prevalence of mother and child mortality, violence and injury, and a growing burden of NCDs[135]. In 2010, a national burden of disease study showed that 39% of deaths were due to NCDs, making them one of the top causes of death in SA[136]. Additionally, the private sector showed that the top 10 CDL conditions in 2015 were hypertension, hyperlipidaemia, Type 2 diabetes, asthma, hypothyroidism, coronary artery disease, cardiomyopathy, epilepsy, bipolar mood disorder and glaucoma[137]. Therefore, identifying individuals at risk and preventing the progression of disease in those with exisiting NCD conditions, could be key to reducing morbidity, mortality and healthcare costs.

The private sector in SA is mandated to treat and cover the costs of 25 chronic conditions (Chapter 1)[87]. In order to achieve this, medical schemes may implement disease management programmes that are responsible for mitigating clinical and financial risk. This is accomplished by preventing, diagnosing and treating conditions appropriately. The three essential elements of disease management are: a knowledge base that quantifies the economic impact of the disease problem and determines care guidelines; a delivery system that incorporates all levels of care; and a quality improvement system to audit performance against evolving standards[138].

Disease management programmes (DMPs) have become important tools within medical schemes. Multidisciplinary, multicomponent programmes ideally integrate in a proactive approach, focusing on the whole course of a chronic disease, using evidence-based standards of care[139].

The costs of DMPs are incorporated into the medical scheme members' monthly premium on the understanding that for those who are registered for management, their chronic disease will be managed optimally in order to reduce hospitilisations, disease progression, morbidity and overall cost[140-141]. This cost to the beneficiaries should therefore provide

comprehensive care and include measurable outcomes. However, from the many benefit guides that are accessible in the public domain, DMPs provide disease management that is highly variable. The care ranges from the provision of simple care guides and health brochures for hypertension, hyperlipidemial and asthma, to comprehensive management for specific conditions such as diabetes, HIV/AIDS and renal failure[142-143]. There has even been a concern that pharmaceutical companies influence the scope of a DMP, based on the 'drug of interest' for that company, for example supporting an asthma programme because the company specialises in asthmatic drugs[138]. The CMS plays an important role in registering, accrediting and regularly reaccrediting DMPs. Accordingly, if the DMPs are not performing based on stipulated outcomes, then accreditation should be refused.

Within the medical schemes, treatment of the specified conditions is guided by treatment algorithims[86]. Certain OTCMs may play an important role in improving clinical outcomes, such as the use of aspirin in the prevention of cardiovascular complications of diabetes[144] or the use of short-acting beta-2 agonists in the prevention and control of asthma[145]. To fulfill the role of reducing financial and clinical risk, utilisation patterns of OTCMs may also be used as a guide for DMPs to identify individuals who require chronic disease management. The following study was undertaken to gain insight into OCTM access by beneficiaries or prescription by doctors for beneficiaries registered with the medical schemes DMP for management of one of the country's common chronic conditions.

4.2 PAPER 3: USE OF OVER-THE-COUNTER MEDICINES: A WINDOW INTO CHRONIC DISEASE MANAGEMENT BY PRIVATE MEDICAL INSURANCE SCHEMES IN SOUTH AFRICA

N Padayachee, AD Rothberg, N Butkow, I Truter in review at *Risk Management and Healthcare Policy*

USE OF OVER-THE-COUNTER MEDICINES: A WINDOW INTO CHRONIC DISEASE MANAGEMENT BY PRIVATE MEDICAL INSURANCE SCHEMES IN SOUTH AFRICA

Abstract

Background

In South Africa (SA) privately-insured individuals have easy access to over-the-counter (OTC) medicines. For patients registered with the insurer for management of a chronic disease through a disease management programme (DMP), the manner in which OTCs are accessed may provide insight into how well the disease is controlled and also how well the DMP is performing.

Objective

The study aimed to measure access to commonly-used OTC products by individuals registered for management of prevalent chronic diseases, and to consider why the medicines were selected in addition to mainstream drugs usually prescribed for treatment.

Methodology

Data were extracted from a large corporate database. Individuals of interest were aged ≥40 years and registered for management of one of the prevalent non-communicable diseases. Utilisation of aspirin, inhaled corticosteroids and bronchodilators was assessed.

Results

The study population included 4 149 individuals registered for management of hypertension, hyperlipidaemia, Type 2 diabetes, asthma, chronic obstructive pulmonary disease, bronchiectasis, coronary artery disease, cardiomyopathy, cardiac failure, arrhythmia, vascular disease or glaucoma, and 12 105 controls without any of the chronic conditions. The conditions were grouped together as metabolic, respiratory, cardiovascular or glaucoma. Whether accessed directly by individuals or prescribed by doctors, there was high utilisation of bronchodilators in the respiratory group, likely for supplementary management of disease. Bronchodilators were possibly accessed for management of side effects of medicines prescribed for treatment of cardiovascular disease. Bronchodilator access was also high among control subjects, possibly indicating that this group included those with asymptomatic or undiagnosed disease. Aspirin appeared to be appropriately utilised for management of cardiovascular and metabolic disease. All the OTC medicines were inappropriately funded out of the acute medicines benefit pool instead of being funded from the chronic medicines pool.

Conclusions

Disease management programmes are an integral part of managed care, which itself is written into legislation as a tool to mitigate clinical and financial risk within privately-funded medical insurance schemes. Analysis of OTC medicines accessed by DMP-registered individuals strongly suggests that DMPs are falling short in both clinical and financial areas. Routine system-driven claims analysis would enable insurers to develop performance-enhancing interventions.

Introduction

In South Africa private health insurance is provided by 78 entities known as medical schemes. Most provide cover for employees of corporate entities or employee groups such as trade unions, while a few are open to the general public. The industry covers some 8.9 million lives and is regulated by the government-constituted Council for Medical Schemes (CMS). Covered individuals are referred to as beneficiaries. In 1998 in order to ensure mandatory cover for all beneficiaries the South African Government promulgated Medical Schemes Act 131 and its associated Regulations.[1] Managed care principles are embedded in the Act and applied in various ways by the medical schemes. Included in the legislation is a set of Prescribed Minimum Benefits (PMBs) that guaranteed funding for the diagnosis, treatment and ongoing care of 270 conditions considered urgent in nature, require hospitalisation, represent 'a threat to life or limb' and are regarded as treatable within the local context.[1] The associated Chronic Disease List (CDL) covers 26 chronic conditions and is prescriptive in terms of management, the emphasis being on treatment algorithms and drug therapy.[1] A key feature of the PMBs and CDL is the requirement for medical schemes to fund the designated services in full out of the risk pool, without co-payment.

In a comprehensive review that highlighted South Africa's quadruple burden of disease, Mayosi et al[2] pointed out that much needed to be done to and for the country's health systems in order to strengthen primary healthcare, integrate care of chronic diseases and attend to risk factors.[2] Their comments largely apply to the country's public health system which covers >80% of the population, but in fact within the privately-funded medical schemes these elements exist to a greater or lesser extent in disease management programmes (DMPs). A major focus of DMPs is on non-communicable diseases, with the aim of preventing, diagnosing and treating conditions which range from highly-prevalent hypertension to haemophilia at the bottom end of the prevalence spectrum.[3] As shown in a 2018 analysis of medical scheme beneficiary data routinely submitted to the CMS, the top 10 CDL conditions in 2015 were hypertension, hyperlipidaemia, Type 2 diabetes, asthma, hypothyroidism, coronary artery disease, cardiomyopathy, epilepsy, bipolar mood disorder

and glaucoma.[3] Medical scheme beneficiaries with one or more CDL conditions register with their medical scheme's relevant DMP in order to obtain a range of healthcare services (known as 'benefits') and funding for their disease/s. Benefit guides in the public domain reveal that disease management provided by DMPS is highly variable, ranging from simple access to advice, care guides and health brochures for hypertension, hyperlipidaemia and asthma[4], to comprehensive management of specific conditions such as diabetes, Human Immunodeficiency virus /Acquired Immunodeficiency syndrome(HIV/AIDS) and kidney failure.[5] One particular programme puts particular effort into managing beneficiaries with multiple chronic diseases, employing staff to assist with access to appropriate care, and providing educational material to promote healthy lifestyle changes.[6] The cost of DMPs is factored into the monthly contributions/premiums of all beneficiaries, this on the grounds that well-managed disease among affected individuals maintains their health, reduces morbidity and hospitalisation, and ultimately achieves savings for all.[7,8] As is the case with PMBs, services and care within the various DMPs are expected to be paid from the risk pool.[9]

For CDL conditions the mainstay of drug treatment is doctor-prescribed medicines as per treatment protocols[1]. The medicines typically appear as Schedule 3-6 drugs as defined by the South African Health Products Regulatory Authority (SAHPRA), the entity established by government to oversee the regulation of health products, including all medicines and controlled substances.[10] The higher the schedule, the greater the restriction to access. Over-the-counter (OTC) medicines in lower schedules (0-2) may also be indicated for the CDL conditions. Whether in lower or higher schedules, when used for management of chronic diseases these medicines should be accessible via the risk pool and not paid for out of other 'funding pools' that typically have monetary limits and/or co-payments, and cover 'day-to-day' benefits such as out-of-hospital doctor consultations and services, and acute medicines. The acute medicines component includes OTC medicines prescribed by doctors or accessed by beneficiaries for purposes of self-medication.

Medical scheme beneficiaries access large quantities of OTC medicines, and utilisation patterns and costs differ according to whether products are accessed by beneficiaries or prescribed by doctors.[11] The focus in this analysis is on older, DMP-registered beneficiaries who were eligible for management of one of the CDL conditions and also for full funding of appropriate medicines via the risk pool. Our particular objective was to identify common OTC products accessed by these beneficiaries, and to consider why the lower-scheduled medicines might be selected. Literature exists from other countries showing the extent to which chronic disease patients access non-prescription medicines, sometimes in support of their care but often to their detriment.[12]

Methodology

Beneficiaries were selected from a database provided by a large South African medical scheme administration company. Such companies typically administer a number of medical schemes and are responsible for their operational needs, ranging from enrolment to call centre services, claims processing and actuarial services. De-identified demographic and claims data for 641 535 beneficiaries were provided for a 12-month period (January – December 2015) by the company, which services a number of medical schemes that together cover over 3 million beneficiaries. Benefits vary between medical schemes, with each combination of medical, dental, hospital, medicines and other benefits constituting a 'plan' or 'option'. For the purposes of this study the beneficiaries of interest were drawn from four 'comprehensive' benefit plans with similarly rich/generous benefits in terms of scope, funding and access to health providers and services.

The CMS list of top CDL conditions was reviewed, and treatment algorithms and guidelines[1] studied to identify OTC medicines that had a place in the management of the conditions. This resulted in the inclusion of 12 conditions that were assigned to one of four groups: metabolic syndrome/metabolic (hypertension, hyperlipidaemia, Type 2 diabetes); respiratory (asthma, chronic obstructive pulmonary disease, bronchiectasis), cardiovascular (coronary artery disease, cardiomyopathy, cardiac failure, arrhythmia, vascular disease) and glaucoma (Table 1). The specific diagnosis for each beneficiary as registered on the relevant DMP was directly extracted from the database. Only beneficiaries ≥40 years of age were included, the age cut-off applied so as to also include early-onset chronic disease. Beneficiaries registered for more than one of the selected chronic conditions were excluded to eliminate 'overlap' as to why a particular OTC medicine might have been accessed. Beneficiaries aged ≥40 years not registered for any of the chronic diseases formed the control group. Based on treatment algorithms and guidelines [1] the OTC medicines for further study were aspirin, bronchodilators and inhaled glucocorticoids. Use of these products was extracted from the database as captured i.e. according to the Anatomical Therapeutic Chemical (ATC) classification which groups all products according to active substances, organ or system on which they act, and therapeutic, chemical or pharmacological properties.[13] In the case of glaucoma the OTC medicines of interest were products containing anti-histamines which, according to guidelines, may aggravate the condition and should be avoided[14]. Additional information extracted for each beneficiary included gender, age, ethnicity and the cost of the OTC medicines as submitted to the medical schemes for payment.

At medical schemes level all medicine claims are captured according to how they were accessed by beneficiaries and paid by the medical scheme. It was thus possible to identify

whether the OTC medicines were prescribed by a doctor or accessed directly by beneficiaries. For purposes of this study the doctor-prescribed medicines are referred to as DP medicines, and those accessed by beneficiaries are referred to as BP. Data were then analysed for the four chronic disease groups and the control group. Access to the medicines of interest was assessed for each group, whether from the DP or BP category. Statistical analyses, carried out using Statistica (Version 13.2 TIBCO Software Inc., Palo Alto, CA, USA), included descriptive statistics, comparison of means, and frequency analysis. Significance was set at $p<0.05$

Results

Details of the study population and the five groups are shown in Table 1. One-quarter (25.5%) of the beneficiaries were formally registered for management of their chronic disease through a DMP. This is higher than the 20.1% reported by the CMS for the same set of conditions within the total population of medical scheme beneficiaries,[3] and is likely the result of this study focusing on beneficiaries aged >40 years. The breakdown by ethnicity is quite different from that reported by Statistics South Africa in 2018 [15] which showed that 72% of whites, 49% Asians, 20% mixed race and 10% of Black Africans belonged to a medical scheme. Differences are likely due to the nature of the medical schemes and beneficiaries selected for this study.

Table 1: Characteristics of the Study Population

Age: years (SD)	
Respiratory Group (n=247)	55.2 (11.7)
Metabolic Group (n=3638)	57.7 (13.1)
Cardiovascular Group (n=200)	61.6 (15.5)
Glaucoma Group (n=87)	63.8 (17.1)
Control Group (n=12108)	53.9 (11.6)
Gender: n (%)	
Male	7 500 (46.1%)
Female	8 753 (53.9%)
Ethnicity: n (%)	
Black African	2 812 (17.3%)
Mixed race	4 975 (30.6%)
Asian	1 416 (8.7%)
White	7 007 (43.1%)
Beneficiaries with one chronic disease: n (%)	4 149 (25.5%)
Controls: n (%)	12 105 (74.5%)

The specific medical conditions recorded on the medical schemes database and their contributions to the four chronic disease groupings are shown in Table 2. Also shown are the OTC medicines selected for study, and the sources that served as the basis for their selection. Aspirin-containing OTC products of interest fell into ATC category B01AC06, fluticasone was the only OTC inhaled glucocorticoid (ATC R01AD08), while OTC bronchodilators were identified in three ATC categories: salbutamol (R03AC02) and theophylline (R03DA20 and R03DA54). Theophylline represented 82.4% of the accessed bronchodilators.

Table 2: Groups, Chronic Conditions and OTC Medicines of Interest

Chronic group	Chronic diseases (% contribution to group)	OTC medicine/s of interest
Metabolic (n=3638)	Hypertension (69%); Type 2 diabetes (14%); Hyperlipidemia (13%)	Aspirin[18]
Respiratory (n=247)	Asthma (90%); Chronic Obstructive Pulmonary Disease/Bronchiectasis (8%)	Fluticasone, Theophylline, Short-acting β_2 agonists [1]
Cardiovascular (n=200)	Ischemic heart disease (31%); Congestive heart failure (31%); Vascular disorders (31%); Arrhythmia (5%)	Aspirin[18] Short-acting β_2 agonists, Theophylline [1]
Glaucoma (n=87)	Glaucoma	Anti-histamines[14]

For each of the chronic disease groups the breakdown by gender showed that males were affected to a greater extent than females for all except the cardiovascular group (Figure 1). Disease rates were highest for white beneficiaries and lowest for Black Africans. Prevalence of respiratory disease was almost three times higher for Asians than for Black Africans. It is important to note that these figures for prevalence were not based on population-based surveys or screening programmes and as such may hide significant numbers of asymptomatic and/or undiagnosed disease.

Fig. 1 Beneficiaries per chronic disease group by gender and ethnicity

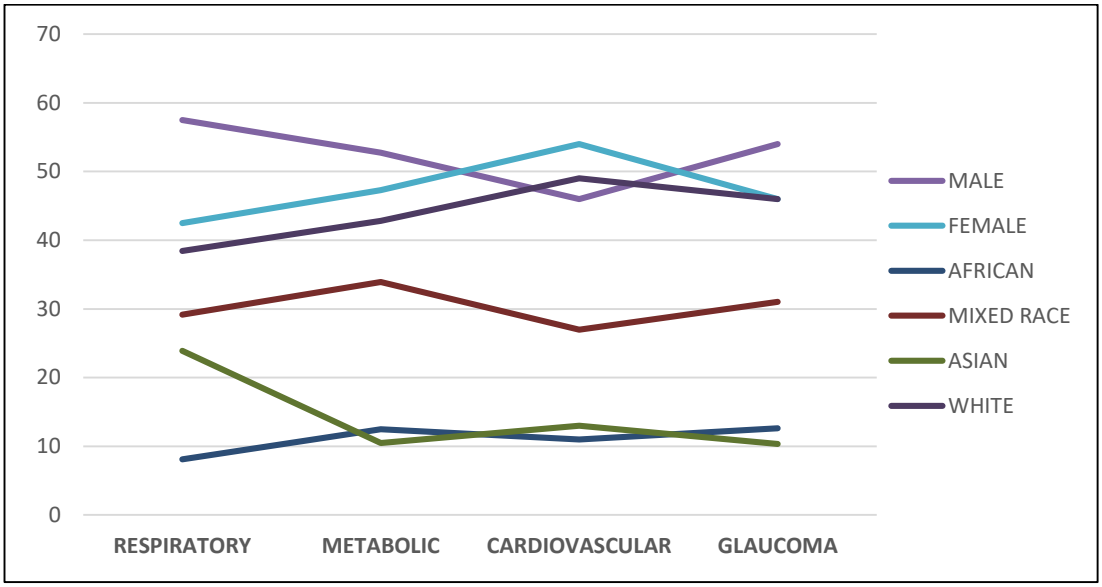
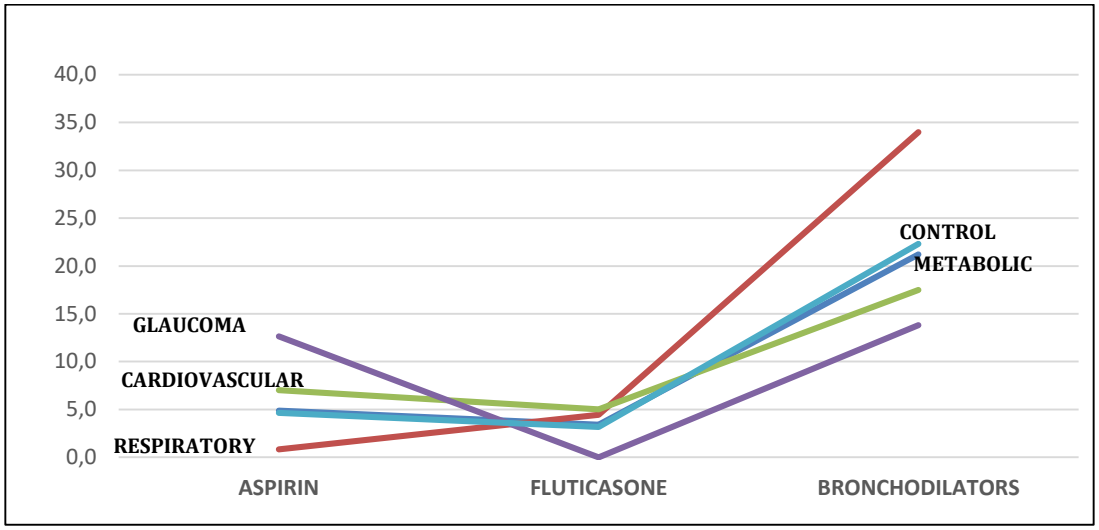


Figure 2 shows the percentage of beneficiaries within the four chronic disease categories and the control group. Among glaucoma patients the use of antihistamines was indeed significantly lower than in the control group (41.3% vs. 54.5%; $p<0.02$) but there was also clear indication that these medicines were not avoided as per recommendations.[14] Of particular interest was the use of aspirin and bronchodilators by patients with glaucoma. Both medicines were accessed by almost 15% of the group. Beneficiaries within the respiratory group showed almost no use of aspirin, while bronchodilators were accessed by more than one-third of patients. Beneficiaries within the metabolic, cardiovascular and control groups showed very similar profiles of fairly low use of aspirin, similar access to fluticasone, and use of bronchodilators by about 20%. The latter finding raises the question of whether the control group was indeed representative of beneficiaries without any of the chronic diseases under review. For this study beneficiaries within the four chronic disease categories were identified on the basis of registration with one of the medical scheme DMPs; it therefore follows that beneficiaries with undiagnosed disease might have accessed medicines to the same extent as those with DMP-registered disease, but were not reflected/recorded on the database as suffering from one of the index conditions.

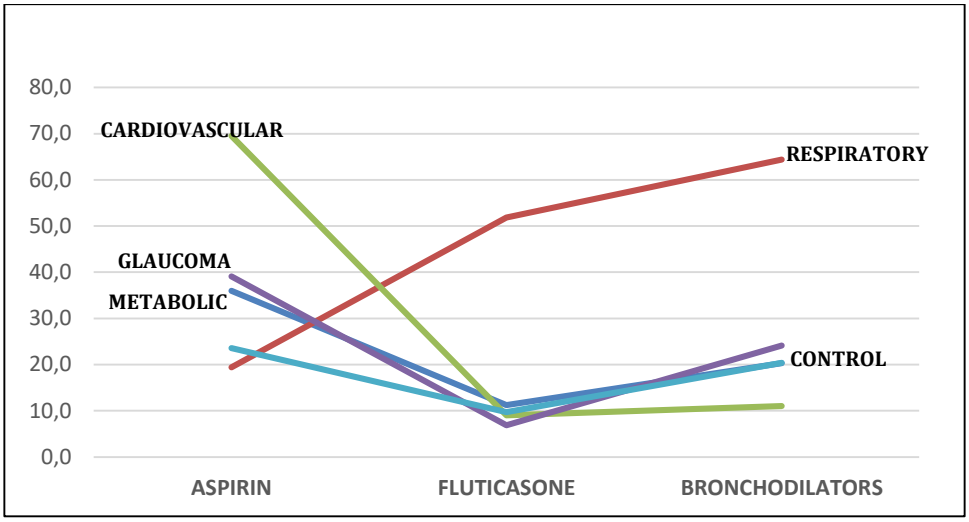
Fig. 2 OTC Medicines accessed directly by beneficiaries (BP category)



As shown in Figure 3, utilisation rates of OTC medicines in the doctor-prescribed category were higher than when beneficiaries accessed on their own (also shown in Table 3). Patients in the cardiovascular group had the lowest prescription rate for bronchodilators but the highest for aspirin. This rate for prescription of aspirin is similar to that identified by the Health Quality Assurance organization (HQA) that monitors performance of medical schemes and healthcare providers[16] and is also in accordance with international guidelines for management of the conditions that are included in the category.[17] In the respiratory group >60% of patients received OTC bronchodilators and >50% received fluticasone. The moderate prescription

rate of aspirin for patients in the metabolic group is also in line with international guidelines that recommend aspirin for patients at increased risk for cardiovascular events.[17] In the glaucoma group aspirin was prescribed for some 40% and bronchodilators for 20%. As already discussed for the BP medicines, similar utilisation of the medicines by the control, metabolic and respiratory groups raises the question of whether beneficiaries in the control group did indeed have one of the chronic diseases but were not registered on the medical scheme DMP. At medical scheme level they would have been regarded as free of chronic disease, while at doctor level they may have been diagnosed and treated.

Fig. 3 OTC Medicines included in a doctor's prescription (DP category)



When all the OTC medicines of interest are combined, as shown in Table 3 there were significantly higher numbers of beneficiaries who accessed OTC medicines via a doctor's consultation and prescription than on their own ($p<0.0001$).

Table 3: Percentage of Beneficiaries in Chronic Disease and Control groups Accessing OTC Medicines Directly vs. via a Doctors' Prescription

Group	% Beneficiary-accessed (BP)	% Doctor-prescribed (DP)
Chronic Disease (n=4172)	30.0	72.5
Controls (n=12108)	30.1	53.7

Discussion

Access to OTC medicines is often presented as a cost-saving mechanism that allows members of the public to self-treat minor ailments rather than consult a doctor;[18] However, there are also roles for various of these medicines in the management of chronic diseases. In the present study the focus was on utilisation of OTC medicines applicable to the management of a selection of chronic diseases prevalent among medical scheme beneficiaries ≥40 years of age, formally registered with an appropriate DMP. As shown in Table 2, 22.5% of beneficiaries were in the metabolic category, 1.5% were categorised as respiratory, 0.12% as cardiovascular and 0.5% as glaucoma. This distribution is similar to that reported by CMS for the same conditions.[3]

The analysis of chronic disease group according to gender and ethnicity (Figure 1) showed results at odds with national data. The higher rate of females in the cardiovascular group differs from that shown in the CMS report which reflected a male:female ratio of 1.4:1,[3] while the prevalence of diseases among ethnic groups differs from national statistics.[15] It is important to note that the various disease prevalence rates were not based on surveys or screening programmes that would have identified actual prevalence rates and/or asymptomatic/undiagnosed disease. Furthermore, recording of chronic diseases in the medical schemes environment is typically influenced by health-seeking behaviour of different groups. This has been studied in the South African context, showing that female gender, higher levels of education and ethnicity (whites in particular) are directly related to access to health services and treatment.[19] Also important is that this study focused on DMP-registered chronic conditions; in the absence of registration the condition would not have been identified and recorded.

Utilisation of OTC medicines accessed directly by beneficiaries is shown in Figure 2. In keeping with their disease, 5% of respiratory patients accessed fluticasone and one-third accessed bronchodilators. The latter is of some concern since theophylline (the dominant bronchodilator in this study) is not regarded as mainstream treatment for asthma, although it might have a role in disease that is difficult-to-control.[20] Aspirin was accessed by a very small percentage of respiratory patients, possibly reflective of avoidance because of the effect of aspirin as a trigger for asthma.[21] Between 17 and 22% of patients with diagnosed metabolic and cardiovascular conditions accessed bronchodilators. Here there is the possibility that they accessed the medication for self-treatment of a side-effect of treatment for their underlying disease. A beta-blocker prescribed for a cardiovascular patient with heart failure or arrhythmia is known to cause bronchoconstriction in some, resulting in use of a bronchodilator for management of the symptom.[22-23] Bronchodilators contained in ‘cough mixtures’ may also have been accessed by hypertensive patients in

the metabolic group who had a cough resulting from treatment with an angiotensin-converting-enzyme (ACE) inhibitor.[24] The similar utilisation between subjects in the metabolic and control groups has raised the question of undiagnosed disease in the latter. This is highly likely given that all three conditions within the metabolic group (hypertension, Type 2 diabetes and hyperlipidaemia) are known to be undiagnosed on a large scale, both nationally and globally. In this regard, studies in the Sub-Saharan region have shown a 15-76% rate of undiagnosed hypertension, while globally 45.8% have undiagnosed diabetes.[25-26] Around 15% of glaucoma patients accessed aspirin and bronchodilators. While neither medicine has a place in mainstream management of glaucoma, data have shown that the

different types of glaucoma may benefit from these medicines.[27-29] Several thousand beneficiaries in this study had a chronic disease registered for management by a medical scheme DMP which should have overseen all elements necessary for disease control, including funding of OTC/acute medicines. These requirements are detailed in legislation[1] and in the CMS Accreditation Standards for Managed Care Organizations.[9]

Prescription of OTC medicines by doctors for beneficiaries in the four groups is shown in Figure 3. In the respiratory group there was again high prescription of fluticasone and bronchodilators. Both medicines should have been funded from the risk pool, and one must question what the DMP was actually managing. Higher-scheduled medicines are the mainstay of treatment for the respiratory conditions,[1] therefore the resort to OTC medicines, theophylline in particular, suggests that disease control might have been inadequate. In comparison with the minimal aspirin utilisation rate when patients self-medicated, the 20% prescription rate by doctors was fairly high, particularly since there is the known role for aspirin as an asthma trigger.[21] This is worthy of further investigation. However in the cardiovascular group there was appropriately-high prescription of aspirin, consistent with guidelines for secondary prevention in conditions such as ischaemic heart disease, vascular disease and arrhythmias.[17] Despite its low cost, aspirin should also have been funded as a chronic medication. The prescription of aspirin to almost 40% of patients in the metabolic group was also in line with guidelines, for example for diabetics with risk factors for cardiovascular disease.[17] The prescription of bronchodilators for 20% of metabolic group patients could again have been for treatment of side effects such as an ACE-inhibitor cough.[24] The control group had a 40% prescription rate for aspirin and 22% rate for bronchodilators, possibly for ‘undiagnosed’ disease, but in this category of doctor-prescribed medicines it is more likely that doctors were treating a condition that had been diagnosed but not registered with the medical scheme. The high prescription rate of aspirin and 20% rate of bronchodilators to glaucoma patients were possibly for the reasons already mentioned for the beneficiary-accessed medicines.

A number of concerns arise out of this study, the first being that OTC medicines were accessed for the treatment of DMP-registered conditions and not fully funded out of the chronic medicines benefit. In some cases the OTC medicine was entirely appropriate (e.g. aspirin for cardiovascular patients), in others it was perhaps less-appropriate (e.g. theophylline for asthma patients who could/should have been better managed with first-line drugs), and in a third category it might have served as a ‘flag’ warranting further investigation (aspirin for glaucoma patients). The CMS is clear on the criteria for accreditation of managed care organizations and their DMPs,[9] but precisely how these programmes

operate is variable.[4-6] Diabetes management is typically multi-dimensional with programmes offered by medical schemes or outsourced to a dedicated service provider that enrols patients, schedules regular access to doctors, nurses, nutritionists and biokineticists, and provides medicines and laboratory tests relating to diabetes control.[8] On the other hand, hypertension is the most prevalent condition but DMP management is usually limited to approval of chronic medicines, access to brochures, and the occasional telephone call from the medical scheme.[4] Whether a comprehensive or a more-basic DMP it is well within the capability of medical scheme administrators and their DMPs to interrogate claims data and maximise the value[30,31]. Claims for medicines other than the mainstream higher-scheduled drugs would be identified and if linked in any way to the particular chronic condition a call could be made as to whether disease was inadequately controlled or medicines administered to treat side effects of other drugs. Beneficiaries and/or their doctors could also be contacted for information as to why particular OTC medicines were being accessed, whether for supplementary disease control or to treat side effects such as cough or wheezing. Interrogation of the use of aspirin and bronchodilators by and for glaucoma patients might shed interesting light on the condition and its management, while a review of OTC claiming patterns in apparently-healthy beneficiaries would likely alert and inform medical schemes of the need to screen for undiagnosed conditions such as hypertension and diabetes. Table 3 condenses data from the study into various categories, showing whether OTC medicines in this study were accessed directly by beneficiaries or prescribed by a doctor, and whether beneficiaries were DMP-registered or apparently free of the chronic conditions studied. The 30% of beneficiaries with a registered disease who directly accessed OTCs were likely those whose disease was under-treated or were self-medicating for side effects of recommended treatment. The 72.5% for whom OTC medicines were prescribed by doctors were likely in similar categories (under-treated or treated for side-effects). In both cases the DMPs were falling short in their responsibilities, while the CMS should also be held to account for poor oversight of DMPs that they have accredited. The 30.1% of control beneficiaries who directly accessed OTCs likely included those with undiagnosed disease. This category should be managed by medical schemes through ‘wellness days’ that offer screening for common conditions such as diabetes, hypertension, hyperlipidaemia, asthma and cardiac dysfunction. For the 53.7% of control beneficiaries for whom the OTC medicines were prescribed by doctors one may speculate that the doctors were aware of the various conditions, but between themselves and their patients had failed to have the diseases registered with the medical schemes. Recognizing that DMPs are paid for by beneficiaries, management failures such as the above are breaches, not only of trust but also of contracts between beneficiaries and their medical schemes.

Limitations

This study involved beneficiaries of a subset of medical schemes administered by one administration company. Results and observations may therefore not be applicable to the broader industry. In the interpretation of the data some postulates are presented, for example OTC bronchodilators accessed or prescribed to treat side effects of mainstream drugs used for cardiovascular disease**.** Evidence supports such postulates,[22-24] but it was not possible to confirm the associations in this study because the beneficiary database was limited to OTC medicines. No such limitation exists at medical scheme level and all associations could be explored with the potential to yield both clinical and financial benefits.

Conclusion

Disease management programmes are an integral part of managed care which itself is written into legislation as a tool to mitigate clinical and financial risk within medical schemes.[1] Our analysis of OTC medicines accessed by DMP-registered beneficiaries strongly suggests that DMPs are falling short in both clinical and financial areas. Routine system-driven claims analysis would enable medical schemes to develop performance-enhancing interventions.

List of abbreviations

DMP - Disease management programme
OTC - Over-the-counter
CMS - Council of Medical schemes
PMB - Prescribed Minimum Benefits
CDL - Chronic Disease List
SAHPRA - South African health products regulatory authority
ATC - anatomical therapeutics chemical
ACE - Angiotensin- converting Enzyme
BP - Beneficiary purchased
DP - Doctor prescribed
HIV - Human Immunodeficiency Virus
AIDs - Acquired Immunodeficiency Disease

Ethics: Ethics approval was obtained from the Human Ethics Committee of the University of the Witwatersrand (certificate M160141).

Consent for publication: Not Applicable

Availability of data and materials: The data that support the findings of this study are available from the administrator but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of the administrator.

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References

1. Medical Schemes Act 131 of 1988. https://www.gov.za/sites/default/files/gcis_document/201409/a131-98.pdf (accessed 24 June 2019)

2. Mayosi BM, Flisher AJ, Lalloo UG et al. The burden of non-communicable diseases in South Africa. The Lancet. 2009;374(9693):934-947. https://doi.org/10.1016/s0140-6736(09)61087-4

3. Govuzela M et al. Prevalence of chronic disease in the population covered by medical schemes in South Africa. Council of Medical Schemes. https://www.medicalschemes.com (accessed 24 June 2019)

4. Disease Management. Government Employees Medical Scheme https://www.gems.gov.za/en/members/programmes/disease-management (accessed 24 June 2019)

5. Chronic Illnesses and other medical conditions. Discovery Health Medical Scheme https://www.discovery.co.za/medical-aid/chronic-illnesses-other-medical-conditions (accessed 24 June 2019)

6. Beneficiary Risk Management. Medscheme. http://www.medscheme.com/products-and-services/health-administration/integrated-disease-management/(accessed 20 June 2019)

7. Aid for AIDS. http://www.aidforaids.co.za/about.php(accessed 19 June 2019)

8. Core Concepts in Diabetes Mellitus. Centre for Diabetes and Endocrinology http://web.cdediabetes.co.za/about-cde/our-history(accessed 21 June 2019)

9. Accreditation Standards for Managed Care Organisations. Council of Medical Schemes. https://www.medicalschemes.com/files/Guidelines%20and%20Manuals/Standard%20doc%20managed%20care%20final%2022%20Oct%2003.pdf (accessed 24 June 2019)

10. Consolidated Schedules. South African Health Products Regulatory Authority. https://www.sahpra.org.za/documents/f6bf8a532016_Consolidatedschedules20082009201120122013201420142015March_May2016(includingprescribers).pdf (accessed 22 June 2019)

11. Padayachee N, Rothberg AD, Truter I, Butkow N. Utilization of over-the-counter analgesics in two private medical insurance schemes in South Africa. Drug Healthcare Patient Saf. 2019;11:37-45.

12. Qato DM. Alexander GC, Conti RM et al. Use of prescription and over-the-counter medications and dietary supplements among older adults in the United States. JAMA. 2008; 300(24):2867-2878. https://doi.org/10.1001/jama.2008.892

13. Anatomic and Therapeutic Classification. World Health Organisation. https://www.who.int/medicines/regulation/medicines-safety/toolkit_atc/en/(accessed 19 June 2019)

14. Is it safe to take anti-histamines if you have glaucoma. The Glaucoma Foundation. https://www.glaucomafoundation.org/info_new.php?id=156&cat=11#173 (accessed 24 June 2019)

15. Mid-year population estimates 2018. Statistics South Africa. https://www.statssa.gov.za/publications/P0302/P03022018.pdf (Accessed 24 June 2019)

16. Health Quality Assessment Newsletters. Health Quality Assessment. https://www.hqa.co.za/newsletters

17. Cardiovascular disease and risk management: standards of medical care in diabetes. American Diabetes Association. Diabetes Care. 2018;41(Supplement 1):S86-104. https://doi.org/10.2337/dc18-s009

18. Dalton K, Byrne S. Role of the pharmacist in reducing healthcare costs: current insights. Integr Pharm Res Prac. 2017;6:37. https://doi.org/10.2147/iprp.s108047

19. Abaerei, Admas Abera. Factors affecting health-care seeking behaviour, and assessment of the population's perception of the major health problems in Gauteng province, South Africa 2013. MSc Dissertation, University of the Witwatersrand http://wiredspace.wits.ac.za/handle/10539/21533(accessed 17 June 2019)

20. Barnes PJ. Theophylline. Am J Resp Crit CareMed 2013;188(8):901-6. https://doi.org/10.1164/rccm.201302-0388pp

21. Narayanankutty A, Reséndiz-Hernández JM, Falfán-Valencia R, Teran LM. Biochemical pathogenesis of aspirin exacerbated respiratory disease (AERD). Clin Biochem. 2013;46(7-8):566-578. https://doi.org/10.1016/j.clinbiochem.2012.12.005

22. Lewis RV, Lofthouse C. Adverse reactions with β-adrenoceptor blocking drugs. Drug Saf. 1993;9(4):272-279. https://doi.org/10.2165/00002018-199309040-00005

23. Carvedilol side effect:cough. eHealthMe. https://www.ehealthme.com/ds/carvedilol/cough (accessed 24 June 2019)

24. Simon SR, Black HR, Moser M, Berland WE. Cough and ACE inhibitors. Arch Int Med. 1992;152(8):1698-1700. doi:10.1001/archinte.1992.00400200128023

25. Ataklte F, Erqou S, Kaptoge S, et al. Burden of undiagnosed hypertension in sub-Saharan Africa: a systematic review and meta-analysis. Hypertension. 2015;65(2):291-298. https://doi.org/10.1161/hypertensionaha.114.04394

26. Beagley J, Guariguata L, Weil C, Motala AA. Global estimates of undiagnosed diabetes in adults. Diabetes Res Clin Prac. 2014;103(2):150-60. https://doi.org/10.1016/j.diabres.2013.11.001

27. Attarzadeh A, Hosseini H, Nowroozizadeh S. Therapeutic potentials of aspirin in glaucomatous optic neuropathy. Med hypotheses. 2006;67(2):375-7. https://doi.org/10.1016/j.diabres.2013.11.001

28. Zimmerman TJ. Topical ophthalmic beta-blockers: a comparative review. J Ocul Pharmacol Ther. 1993;9(4):373-84. https://doi.org/10.1089/jop.1993.9.373

29. Waldock A, Snape J, Graham CM. Effects of glaucoma medications on the cardiorespiratory and intraocular pressure status of newly diagnosed glaucoma patients. Br J Ophthalmol 2000;84(7):710-3.

30. Rothberg AD, Matshidze PK. Perimenopausal wrist fracture--an opportunity for prevention and management of osteoporosis. S Afr Med J. 2000;90:1121-4

31. Rothberg AD, Matshidze PK. Monitoring and management of bone status in patients on chronic glucocorticoid treatment--the Medscheme experience. S Afr Med J. 2000; 90:1125-9

4.3 CONCLUSION

It is apparent that DMPs are failing in their role of mitigating clinical and financial risk. Patients with a registered chronic condition are accessing relevant OTCMs directly or are seeking additional OTCM treatment from doctors. Both paths suggest inadequate disease control. Furthermore, patients may be taking OTCMs or receiving them from doctors to treat side effects of mainstream drugs prescribed for their underlying chronic conditions. Whatever the underlying reason for access to these OTCMs, they should be funded as part of their chronic benefit. In some cases there could be a case for changing the mainstream, higher-scheduled medicines. Furthermore, some of the ‘control’ patients in the study may have had undiagnosed disease and were accessing OTCMs on a pharmacist’s advice or a doctor’s prescription. Either way, such patients could have been identified via the medical scheme’s administration systems, tested for the relevant chronic disease, and if positive referred to an appropriate DMP. Along these lines, schemes should also be capable of reviewing data to find beneficiaries who, for example, are accessing multiple doses of an OTC bronchodilator and may have asthma. Such individuals would likely be uncontrolled and require an intervention. Furthermore, considering aspirin is contra-indicated in most

asthmatics, schemes could be reviewing data and investigating why one in five respiratory patients was obtaining aspirin from their doctor.

The OTCM use by glaucoma patients is something that schemes could have reviewed if they were truly interested in managed care. For example, why were high numbers of glaucoma patients taking antihistamines when the medication is contraindicated and, as has been suggested in the literature[146], were they taking aspirin and bronchodilators because they experienced an unexpected benefit from the medication?

Even though Rand amounts for the OTCMs under review were small (e.g. aspirin), the schemes should be funding the OTCMs out of the risk pool. Unfortunately, administration systems are not designed to automatically pick up the error, and members probably do not think it worth their while to argue with the medical scheme because of the negligible cost. However, if managed care is truly serious about 'the right care at the right time for the right condition in the right place, at the right price', then its manifestation in the form of DMPs is not delivering.

The results of the three papers thus far brought to the fore the shortcomings of medical schemes' DMPs, the schemes themselves in overseeing the DMPs, and the CMS as the body that accredits both schemes and DMPs. The shortcomings manifest at a number of levels, starting with the patient/medical scheme beneficiary, through to pharmacies/pharmacists, OTCM manufacturers, medical schemes and the various legislative bodies. Healthcare is a human right but when it comes to OTCMs there are many barriers that impinge on the ability of individuals to enjoy that right. These barriers are discussed in greater detail in the fourth article as published in the South African Journal of Bioethics and Law.

CHAPTER FIVE: PAPER 4

5.1 INTRODUCTION

There are multiple roleplayers involved in the access to, quality of and cost of OTCMs in SA. Each is unique in its role in ensuring that the public has access to quality OTCMs. However, in providing access, maintaining ethical clarity often becomes challenging. This paper discusses ethical issues affecting patients/beneficiaries, ranging from a lack of knowledge about OTCMs to a lack of interest in conserving their savings/PAT/OTCM benefit. Pharmaceutical manufacturers have a strong commitment to maximise profits and satisfy their shareholders, while independent pharmacies/pharmacists are under pressure to remain sustainable, and large corporates devise strategies to satisfy shareholders. Policy-makers make policies with good intentions, however, these are frequently difficult to implement and/or enforce, while medical schemes do not deliver on their mandates and fail to educate their beneficiaries.

5.2 PAPER 4: ETHICAL ISSUES AROUND OVER-THE-COUNTER MEDICINES IN SOUTH AFRICA

N Padayachee, AD Rothberg, N Butkow, I Truter published in the *South African Journal of Bioethics*

ARTICLE

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Ethical issues around access to over-the-counter medicines in South Africa

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South Africa is engaged in a heated debate around how to achieve universal healthcare (UHC) that will be accessible to all, affordable for the country and of high quality. Essentially, this discourse frames UHC as a right, yet there is strong evidence that certainly in the privately funded sector, healthcare functions as a commodity within a failing market system. Research has shown these failures to affect the highest cost elements of hospital, specialist and chronic disease care. In this review, we show that commoditisation also affects the primary healthcare market, specifically in the area of over-the-counter (OTC) medicines. The segment represents a multibillion-rand contribution to the economy, with stakeholders – ranging from government, pharmaceutical manufacturers and pharmacists to medical schemes and their members – driving the costs of OTC medicines up rather than down.

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Some years back, a cartoon appeared showing a swarthy Mafia caricature in a suit, seated behind an executive desk in a plush office. The caption: 'I used to deal illicit drugs until I realised there was more money selling ethical medicines.' This cynical but prescient comment on the costs of one of the most important elements of healthcare is particularly disturbing because it relates to cost and price manipulation of ethical medicines, which, typically, are regu- lated, i.e. subject to national drug registration and/or scheduling systems; require a doctor's prescription; and are restricted in terms of access to the public. If price and cost elasticity exist for 'ethical' products, what is the situation for over-the-counter (OTC) medicines, which are not regulated to the same extent, are directly accessed by consumers, are enthusiastically produced by numerous competing manufacturers and are aggressively sold by pharmacies?

In the South African (SA) public sector (covering healthcare for ~85% of the population), OTC medicines are managed by the tender system and the Essential Medicines List (EML).[1] These two initiatives enable the state to limit the number of available products, and fix the prices of OTC medicines for the population that it serves at primary healthcare (PHC) level. The EML predominantly includes single-ingredient products, so recipients have limited access to numerous higher-priced multi-ingredient OTC medicines (which in general do not have a sound evidence base[2]). In the private sector, there are several stakeholders in the OTC value chain (Fig. 1), many with conflicts of interest and all exposed to perverse incentives that could influence their ability or willingness to achieve access to affordable, high-quality OTC medicines, as a goal. Herein lies an important assumption: viz., that access to affordable high-quality medicines is indeed the goal.

This assumption also introduces the key question of whether healthcare is a commodity or a right.[3]

The commodity argument proposes that the marketplace governs demand, supply and the cost of healthcare while consumers/patients rationally make choices according to needs. Society benefits as costs decline through market competition, and quality improves through competitive advantage. The argument that healthcare is a right posits that healthcare is a need and not a choice, and that profit motives undermine the doctor-patient relationship. It argues that government should regulate standards of care that could be vulnerable to compromise (e.g. if insurers try to minimise costs), and should act to reduce the information asymmetry that precludes patients from behaving as informed consumers.[3] The current debate around National Health Insurance (NHI)[4] in SA is firmly based on access to healthcare being a right, but certainly within the private sector, the preliminary findings of the Health Market Inquiry,[5] which focused on private hospitals, specialists and medical schemes, indicate that healthcare is commoditised. If healthcare is performing as a commodity at the top end of the cost spectrum, what is the situation for OTC medicines in the PHC domain? Economists would probably argue that if OTC medicines are a commodity, then stakeholders, from manufacturers, distributors, medical schemes and healthcare providers all the way through to consumers, would endeavour to drive costs down. Our previous research[6] has shown that this is not the case: parties on the supply side appear to prioritise profit, while consumers on the demand side show little interest in quality or value. These behaviours call into question the ethical and moral values of stakeholders.

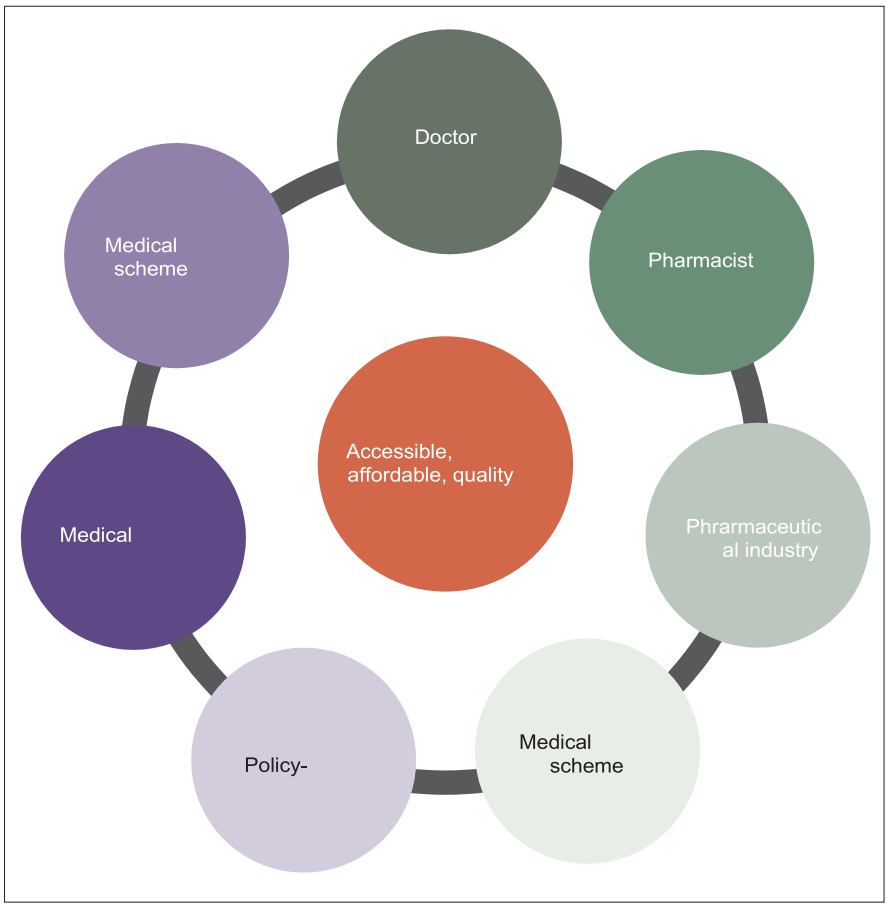


Fig. 1. Stakeholders involved in the access, affordability and quality of over-the-counter (OTC) medicines supply and demand chains in the private sector.

We have previously studied utilisation of the OTC medicine benefit in two medical scheme plans, one offering a set of comprehensive benefits at the top end of the range, the other offering more-restricted access to benefits.[6] In the present article, the research findings are applied to the various stakeholders in the OTC supply and demand chains, and are discussed in terms of stakeholder behaviour as it relates to access to medicines as well as their quality and costs.

Methodology

The empirical data referred to in this review were extracted from a database of medical schemes' OTC medicines claims, and analysed for a PhD submission. Publicly available sources relevant to the privately funded healthcare sector were also reviewed, as were guidelines from professional bodies and relevant Acts and regulations pertaining to the costs and quality of and access to OTC medicines.

Pharmacists and pharmacies

Our research has shown that medical scheme expenditure on OTC medicines in two high-volume disease categories (covering minor respiratory ailments, i.e. coughs and colds, and ailments requiring analgesia/ mild sedation, respectively) appears to be higher when pharmacists recommend or dispense medicines than when doctors prescribe or dispense for the same set of ailments. Pharmacists have added leeway to recommend more expensive products and products containing multiple ingre- dients, thereby adding to the cost without necessarily adding much in the way of therapeutic value.[2,7] The costs are also higher if the customer belongs to a medical scheme with more generous benefits.[6] Also shown in our research was that average cost differentials were very different for two multi-ingredient analgesic products, both containing paracetamol, codeine, caffeine and doxylamine, where product A is the original and B the generic version (Table 1).

In these examples, 'cost' refers to the amount claimed by the service provider (i.e. the price), and not the amount actually paid by the medical schemes.

Perhaps the starting point for understanding the factors that drive or direct the behaviour of pharmacists is an examination of professional guidelines. According to the SA Pharmacy Council's applicable code of conduct,'the pharmacist's goal in the provision of medicine therapy should be to achieve appropriate therapeutic outcomes that contribute towards patient health and quality of life. The attitudes, behaviours, commitments, concerns, ethics, functions, knowledge, responsibilities and skills of the pharmacist should therefore be focused on primarily benefiting the patient and the public as a whole.'[8] While noble in intent, the code of conduct grants latitude in the provision of OTC medicines, and much is left to the individual pharmacist. The 'Good pharmacy practice' (GPP) guidance document[9] provides a set of minimum standards for practising pharmacists in SA. Within the GPP, the 'Pharmacist-assisted therapy (OTC medicines) minimum standard' states that medicines must be selected based on quality, efficacy and safety. For the pharmacist, there is often a conflict between applying the guidelines and his or her autonomy and relative freedom to provide advice and guidance.[10] In terms of the cost of OTC medicines, the pharmacist is frequently under pressure to generate profits, whether (s)he is the owner of the pharmacy or an employee. This can be done by making a particular product more visible in the pharmacy, or promoting its use, particularly to medical scheme beneficiaries whose benefit plans cover the cost. Furthermore, many pharmacies are owned by large corporations whose goal is to deliver profits to shareholders. These factors may influence the ethical and professional judgement of pharmacists.[11]

From the above, it is clear that guidelines and codes of conduct are not prescriptive, and there is some reliance on the conscience of the pharmacist. From the perspective of legislation, a number of Acts and their regulations have the potential to affect provision of OTC medicines (Table 2), but again the legislation is relatively weak. Consequently, pharmacists may generally be in compliance, but as shown in Table 1,

Table 1. Average cost in ZAR of two versions of a multi-ingredient OTC product according to high- v. low-benefit medical scheme plan and pharmacist v. doctor as provider

Product	High-benefit plan		Low-benefit plan	
	Recommended by pharmacist	Prescribed by doctor	Recommended by pharmacist	Prescribed by doctor
A	110.08	90.81	71.50	-*
B	66.86	46.24	49.74	R16.47

OTC = over-the-counter.
*Product rarely prescribed by doctors treating patients in the low-benefit plan.

Table 2. Regulatory organisations, policies and legislation, and impact on OTC medicines

Regulatory body	Policy/regulation/legislation (MRSA)[12]	Impact/effect
NDoH and SAHPRA	Guidelines, section 22A and 37A	Guidelines emphasise importance of proper counselling on and recording of OTC and other medicines, e.g. access to codeine is limited to 10 mg per tablet/capsule. However, more than the stipulated quantity is possible if recording practices are poor or one member of a family accesses medicines on another's card.
NDoH	Single exit price, section 22(G3)	Promotes transparent pricing, i.e. product sold to all pharmacies at the same price (but OTC costs may nevertheless vary for same product, influenced by variable application of dispensing and logistics fee).
NDoH	Dispensing fee, section 22(G1b)	Pharmacists and dispensing doctors charge a fee over and above the cost of the medicine (while subject to maximum amounts, dispensing of more expensive medicines results in a higher. dispensing fee, as fees are proportional to cost of product)
NDoH	Dispensed quantity, section 22(M)	Quantity of medicines dispensed should not exceed or be less than 25% of the amount on prescription, but pharmacists appear to be going beyond the specified limits
NDoH	Generic substitution, section 22(F)	With patient approval, medicines dispensed by pharmacist or dispensing doctor are subject to generic substitution, unless 'no substitution' is stated by the prescribing doctor. Similarly constituted generics may vary in price.

OTC = over-the-counter; MRSA = Medicines and Related Substances Act No. 101 of 1965, as amended in Government Gazette May 2017; NDoH = National Department of Health; SAHPRA = South African Health Products Regulatory Authority.

there are significant opportunities for price manipulation and income generation. Furthermore, as shown in a recently aired investigative report[13] into the ease with which codeine abusers acquire quantities of codeine-containing cough mixtures, compliance with legislation may be less than ideal, and regulatory oversight may be weak. In the context of healthcare as commodity v. right, the evidence suggests that OTC medicines are squarely in the commodity court, but if the goal of commoditisation is a free market in which forces endeavour to drive costs down, then the market is failing, and not providing the most appropriate medicines of the highest quality at the lowest cost.

Medical schemes/administration companies

According to the Medical Schemes Act No. 131 of 1998,[14] managed healthcare strategies may be employed by medical schemes. Managed care itself is defined as 'clinical and financial risk assessment and management of healthcare, with a view to facilitating appropriateness and cost-effectiveness of relevant health services within the constraints of what is affordable, through the use of rules-based and clinical management-based programmes.'[15] This aligns with the three pillars of managed healthcare, viz. control of cost, quality and access. However, little is being done by medical schemes or their administrators to curb the costs and/or maintain the quality of OTC medicines. Rather, the focus of the schemes and their administrators is the management of prescribed minimum benefits (PMBs), a legislated set of benefits for specified conditions that must be accessible to all medical scheme beneficiaries.[13] Primary healthcare is barely covered within the list of PMBs, and if an individual has PHC cover as a listed benefit, it is either only partially funded out of the risk pool or funded out of a 'savings' pool that is left to the beneficiary to manage. This is an unfortunate situation, since medical schemes and their administrators are in possession of substantial amounts of data that could be utilised to enhance health. In this regard, medical scheme beneficiaries could be informed that a higher price for one OTC product does not equate to better quality than found in another lower-priced product with identical ingredients. Education could extend to the actions of the various ingredients; for example, the addiction risks of prolonged ingestion of codeine.[16] Our research has shown that codeine-based analgesic OTC medicines are widely accessed,[17] and when used to treat minor ailments may lead to addiction, or they may simply be abused by individuals for recreational purposes.[6] Furthermore, because medical schemes have data at the level of an individual beneficiary, they have the potential to monitor not only what is being used for treatment of minor ailments, but also the background against which there may be repeated use. For example, a frequent user of cough medicines

who has a history of multiple visits to a doctor for wheezing could be identified by the scheme's administrator, and encouraged to be assessed for asthma and possible enrolment into a disease-management programme.

Beyond education on the contents and costs of OTC medicines, medical schemes and administrators could further influence expenditure on OTC medicines by applying system-driven 'filters' such as a maximum medical aid price (MMAP)[18] or a reference price list (RPL)[19] that would only permit payment for approved medicines on an authorised cost-per-combination basis. Engaging with doctors and pharmacies on a contractual basis also has the potential to manage the prescribing and dispensing of OTC medicines.[20] There is also a role for the Council for Medical Schemes (CMS), the regulatory body responsible for oversight of medical schemes and the protection of their members. The CMS prides itself on the production of educational and informative material in electronic and hard-copy format, but the majority of its efforts are directed towards the PMBs, and are not related to PHC.[21] Overall, there appears to be little enthusiasm within the medical schemes environment for value-additive interrogation of data, or for spending money in order to save money.

Pharmaceutical manufacturers and distributors

Pharmaceutical manufacturers have a powerful influence on the sale of OTC medicines, as they are able to set the prices and compete with others based on branding, packaging and stakeholder loyalty. Legislation has been promulgated to provide a base cost for various products and facilitate the determination of dispensing fees for each product.[12] However, while such single-exit-price legislation requires notification of the price of a product, it is silent on how a particular price is derived. Consequently, products of similar composition may have vastly different exit prices. This can be seen in Table 1, where for product B, there can be a four-fold difference between the average cost as submitted to the medical scheme by a pharmacist, and when prescribed by a doctor. In addition, legislation covering dispensing fees allows pharmacies the latitude to promote more expensive OTC products and in turn to generate higher dispensing fees (Table 2). Vertical integration may also be an issue, e.g. where a holding company has various businesses that individually manufacture OTC medicines, distribute medicines to patients or provide management systems that enable pharmacies to maximise profit. Medical scheme administration companies may be part of the vertically integrated package, opening the door to particular product(s) manufactured by a sister company being included in a medical scheme's list of recommended medicines.[5] The multi-year HMI exercise into cost drivers within the medical schemes administration and private hospital environments delved into the complex interactions between stakeholders, ultimately concluding that there are indeed issues that are resulting in market failure and rampant escalations in costs.[5] It is clear that similar issues affect the OTC market.

Medical scheme members/beneficiaries

Towards the end of each year, the medical schemes send beneficiaries the CMS-approved amendments to the following year's benefits and contributions.[22] This facilitates a review of the appropriateness of benefits provided and, because contributions typically increase at a rate above general inflation, encourages beneficiaries to carefully consider factors such as affordability, and/or the need to change to a lower- or higher-cost benefit plan. In general, little attention is directed towards the OTC benefit, which ultimately is a 'nice-to-have' benefit not covered by the risk pool, and in effect is directly funded by the beneficiary, often with a co-payment. In the absence of consumer awareness, and a common belief that medical schemes profit from unutilised benefits, our research indicates that users of the OTC benefit pay little attention to the cost or appropriateness of OTC medicines. There appears to be a willingness to exhaust the benefit rather than extend its value by accessing equivalent but lower-cost products.

Policy-makers

Table 2 shows how government and various related entities have crafted policy, guidelines and legislation designed to regulate acquisition of OTC medicines by members of the public. However, as shown in the comment column, and very clearly shown in the recently televised investigative report into the ease of access to codeine-containing cough mixtures,[13] these efforts to control cost, quality and access leave much to be desired.

The determination of government to implement UHC in SA is closely tied to the view that privately funded care via medical schemes is grossly discriminatory, exploitative, inefficient, unaffordable and unsustainable. The extent to which NHI will reduce the number of medical schemes and/or privately insured citizens is debatable, but it is likely that whatever the final offering in a medical scheme benefit package, access to OTC medicines will not be curtailed. For patients accessing public sector PHC facilities, the EML or a derivative/derivatives thereof would continue to control access to and cost and quality of OTC medicines. One may therefore speculate that government would have little interest in redrafting OTC-related legislation in order to influence utilisation in a (dwindling) privately funded sector of the population. On the other hand, there is support for the notion that government intervention would benefit a wider population: a recent corporate report gave the value of the annual OTC market in SA as ZAR10.2 billion.[23] Extrapolation of our research data suggests that the privately funded element is only around ZAR3.4 billion (33%) of that figure. The significant balance of R6.8bn thus represents out-of-pocket expenditure on OTC medicines by the general public, who would likely benefit from policy interventions.

Doctors

On the basis of the research conducted, doctors appeared to be the only stakeholders who impact positively on the cost of OTC medicines, by prescribing lower-priced products and promoting the use of generics. This is reassuring news for this often-maligned category of private healthcare providers. Within the 'doctor' category were both dispensing and non-dispensing doctors. The latter only prescribe for subsequent dispensing via a pharmacy, while the former have a licence to buy, prescribe and dispense medicines from within their practice. Of note here is that dispensing doctors, who could potentially benefit by prescribing more expensive OTC medicines, and their associated higher dispensing fees,[24] appear to be the group prescribing most cost-efficiently (Table 3). Our research also showed that in general, there was excellent prescribing of generic products by doctors, and doctors tended to select cheaper generics than pharmacists.[6] A good example is reflected in Table 1, where it is shown that doctors treating patients in a low-benefit plan rarely

Table 3. Average cost in ZAR of multi-ingredient OTC product B (generic) according to high- v. low-benefit medical scheme plan and dispensing v. non-dispensing doctor

Product	High-benefit plan		Low-benefit plan	
	Prescribed by dispensing doctor	Prescribed by non-dispensing doctor	Prescribed by dispensing doctor	Prescribed by non-dispensing doctor
B	28.08	60.03	17.37	37.04

OTC = over-the-counter.

prescribe the original (product A), and use the far less expensive, chemically equivalent generic.

Conclusion

The moral and ethical issues around OTC medicines involve a number of stakeholders who share the responsibility of providing medicines that are accessible, affordable and of good quality. In practice, the majority of stakeholders disappoint. Pharmacists favour more expensive OTC medicines over cheaper generics, medical schemes show little interest in managing these medicines from a cost and therapeutic perspective, beneficiaries lack interest in quality or cost, pharmaceutical companies bask in weak legislation and government apparently lacks the will to engage meaningfully on the topic.

The HMI was an initiative of the Competition Commission.[5] Established in 2015 with input from local and international experts, its mission was to gain insight into the drivers of unsustainable increases in the costs of private healthcare in SA. The focus was on medical schemes, administrators, private hospitals and medical and surgical specialists. Interim findings published in 2018 drew attention to uninformed and disempowered consumers, a lack of value-based purchasing and little interest among medical schemes and administrators in reducing supplier-induced demand. The conclusion was that serious market failure exists in this environment.[5] The results of our studies into access to and provision of OTC medicines are indicative of similar market failure in this area,[6] and show that commoditisation[3] also extends to the lower end of privately funded healthcare. Government intends to reverse this through NHI, which aims to ensure that access to affordable quality healthcare is a right. Perhaps conflicting with this intention is the ruling party's recently announced 2019 election manifesto, which identifies the manufacture of pharmaceuticals as an opportunity for growth and economic empowerment for historically disadvantaged and disempowered South Africans.[25]

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1. National Department of Health, South Africa. Standard Treatment Guidelines and Essential Medicines List. Pretoria: NDoH, 2015. http://www.health.gov.za/index. php/standard-treatment-guidelines-and-essential-medicines-list (accessed 4 December 2018).
2. Murnion BP. Combination analgesics in adults. Austral Prescriber 2010;33(4):113-115.
3. Aggarwal NK, Rowe M, Sernyak MA. Is healthcare a right or a commodity? Implementing mental health reform in a recession. Psychiatr Serv 2010;61(11):1144- 1145. https://doi.org/10.18773/austprescr.2010.056
4. National Department of Health, South Africa. National Health Insurance. Pretoria: NDoH, 2016. https://www.gov.za/sites/default/files/gcis_document/201908/ national-health-insurance-bill-b-11-2019.pdf (accessed 4 November 2019)

5. Health Market Inquiry, Provisional Findings and Recommendations. 2018. http:// www.compcom.co.za/wp-content/uploads/2018/07/Health-Market-Inquiry-1. pdf (accessed 10 January 2019).
6. Padayachee N, Rothberg AD, Truter I, Butkow N. Utilization of over-the-counter analgesics in two private medical insurance schemes in South Africa. Drug Healthc Patient Saf 2019;11:37.
7. Benson A, Cribb A, Barber N. Understanding pharmacists' values: A qualitative study of ideals and dilemmas in UK pharmacy practice. Soc Sci Med 2009;68(12):2223-2230. https://doi.org/10.1016/j.socscimed.2009.03.012
8. South African Pharmacy Council. BN 108 of 24 October 2008: Rules relating to Code of Conduct (Government Gazette No. 31534). Pretoria: SAPC, 2008. https:// www.mm3admin.co.za/documents/docmanager/3C53E82B-24F2-49E1-B997-5A35803BE10A/00133607.pdf (accessed 2 February 2019).
9. South African Pharmacy Council. Good pharmacy practice. Pretoria: SAPC, 2010. http://apps.who.int/medicinedocs/documents/s19633en/s19633en.pdf (accessed 15 January 2019).
10. Rodríguez JV, Juričić Ž. Perceptions and attitudes of community pharmacists toward professional ethics and ethical dilemmas in the workplace. Res Soc Adm Pharm 2018;14(5):441-450. https://doi.org/10.1016/j.sapharm.2017.05.010
11. Wingfield J, Bissell P, Anderson C. The scope of pharmacy ethics – an evaluation of the international research literature, 1990 - 2002. Soc Sci Med 2004;58(12):2383- 2396. https://doi.org/10.1016/j.socscimed.2003.09.003
12. South Africa. Medicines and Related Substance Act No. 101 of 1965, as amended in Government Gazette May 2017. https://www.sahpra.org.za/documents/abdb 0bc7MedicinesandRelatedSubstancesAct101of1965,asatMay2017.pdf (accessed 4 November 2019).
13. Carte Blanche Investigation. Codeine addiction: Signs and symptoms. M-net, DSTV, 11 November 2018. https://m-net.dstv.com/show/carte-blanche/news/ codeine-addictions-signs-and-symptoms-carte-blanche/news (accessed 10 January 2019).
14. South Africa. Medical Schemes Act No. 131 of 1998. https://www.medicalschemes. com/files/Acts%20and%20Regulations/MSACT19July2004.pdf. (accessed 15 February 2019).
15. Council for Medical Schemes. Managed health care policy document. Pretoria: CMS, 2003. http://www.medicalschemes.com/files/Guidelines%20and%20 Manuals/Managedhealthcare_Policy_doc_2003.pdf (accessed 4 November 2019).
16. Ricardo Buenaventura M, Rajive Adlaka M, Nalini Sehgal M. Opioid complications and side effects. Pain Physician 2008;11:S105-S120.
17. Foley M, Harris R, Rich E, et al. The availability of over-the-counter codeine medicines across the European Union. Public Health 2015;129(11):1465-1470. https://doi.org/10.1016/j.puhe.2015.06.014
18. Boyce D, Bartlett G. The maximum medical aid price programme: A review of the concept and of its ability to reduce expenditure on medicines. S Afr Med J 1990;78(8):147-151.
19. Rothberg, AD, Blignault, J, Serfontein CB, Valodia B, Eekhout S, Pels LM. Experience of a medicines reference-pricing model. S Afr Med J 2004;94(3):183-188.
20. Fairfield G, David JH, Mechanic D, Rosleff F. Managed care: Implications of managed care for health systems, clinicians and patients. BMJ 1997;314(7098):1895. https:// doi.org/10.1136/bmj.314.7098.1895
21. Council for Medical Schemes. Consumer assistance. http://www.medicalschemes. com/Content.aspx?17 (accessed 4 November 2019).
22. Council for Medical schemes. Contribution and benefit changes. http://www. medicalschemes.com/files/Circulars/Circular_34_of_2006_Contribution_and_ Benefit_Changes.pdf (accessed 4 November 2019).
23. Healthcare and Lifescience Review. South Africa Pharma Report. HLR, 2016. https://pharmaboardroom.com/pharmareport/south-africa-pharma-report (accessed 10 March 2019).
24. Trap B, Hansen EH, Hogerzeil HV. Prescription habits of dispensing and non- dispensing doctors in Zimbabwe. Health Pol Plan 2002;17(3):288-295. https:// doi.org/10.1093/heapol/17.3.288
25. African National Congress. Let's grow South Africa together. 2019 election manifesto: A people's plan for a better life for all. https://voteanc.org.za/assets/ manifesto-summaries/A5_Manifesto_English.pdf (accessed 4 November 2019).

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26.

5.3 CONCLUSION

Clearly, there are multiple ethical challenges when it comes to OTCMs. This category of PHC drugs is key to treating minor ailments and could assist in reducing the burden to the healthcare system. However, pharmacists are dispensing more-expensive OTCMs, while medical schemes are providing little support in educating members on the cost-effective use of these medicines. Although, policy makers are providing relevant and robust legislation and policies there is little engagement on the topic. Pharmaceutical companies are driven by profit, and consumers lack insight and knowledge on how to cost-effectively use these medicines. Furthermore, it is apparent that OTCMs are a commodity in a failing market. Role players such as pharmacists, pharmaceutical companies and even members seem to be driving costs up by encouraging the use of more expensive OTCMs. Ideally, these medicines should be a right, making them accessible, cost effective and of good quality to all. Overall, discussions must be had on how to make these medicines accessible to all South Africans at a reasonable cost, without compromising any ethical principles.

CHAPTER SIX: CONCLUSION

6.1 CONCLUSION

This has been a fascinating journey of discovery, albeit disappointing because the OTCM healthcare benefit that has the potential to add value in terms of cost, quality and access, is complicated by so many deficiencies. What started out as a project aimed at establishing whether medical schemes that promoted access to OTCMs did in in fact achieve better health and cost outcomes, fairly rapidly evolved into so much more after preliminary review and analysis of the variables requested from the medical schemes' administrator.

The timing of the research was fortuitous as it intersected with three milestones in the South African private healthcare environment in the form of two Bills that were presented to Parliament in 2019, and the conclusion of the Competition Commission's Health Market Inquiry[86,92,117]. All three centred around the then-Minister of Health's drive to introduce universal healthcare via a National Health Insurance scheme. At the time of writing, the NHI Bill is before Parliament and subject to comment from all interested parties[117]. The same Minister was instrumental in driving the HMI that would investigate cost drivers in the private sector, and serve to strengthen the case for an affordable alternative that would serve all South Africans and not only the privileged minority. As already discussed in this thesis (Chapter 1), the HMI focused on private sector practitioners, hospitals, administrators, medical schemes and brokers. Practitioners and hospitals were found to control much of the healthcare expenditure, while funders make it difficult for existing or potential members to make comparisons between medical schemes due to convoluted benefit designs and rules. Ultimately the HMI report concluded that there is definite market failure, wasteful expenditure and no clear measures of cost-effectiveness. Medicines were not specifically included within the scope of the HMI, and the Inquiry also excluded PHC and its related OTCMs. The latter omissions beg the question of whether the market failure that was evident in the management of the 'top end' of healthcare involving PMBs, hospitals and specialist care, also extends to PHC and OTCMs. The results shown in this thesis strongly suggest that such market failure is pervasive.

One of the main recommendations of the HMI was the establishment of yet another regulatory entity, the Supply Side Regulator, in order to better manage the range of stakeholders identified as contributing to market failure in the private healthcare sector[92]. It is highly debatable whether Government will heed this or the other recommendations, because it is fairly clear from the current Bill covering amendments to the Medical Schemes Act, that

the intention is to weaken the appeal of medical schemes as a form of health insurance[86]. In fact the Bill clearly states that medical schemes may not offer any benefits that are provided through the NHI. The implication of this amendment is that medical schemes may only offer top-end and expensive benefits. For example, if NHI offers radical prostatectomy and brachytherapy as treatments for prostate cancer, then the medical scheme offering would likely be along the lines of more expensive robotic surgery. This would considerably increase the costs of medical scheme membership, almost certainly beyond the reach of many who are currently covered. Medical schemes would no doubt seek out strategies that would make their offerings more attractive. In the context of this thesis, polypharmaceutical OTCMs would probably find their way into post-NHI benefit packages, offering potential and existing beneficiaries easy access to questionably-effective and unnecessarily-expensive medicines. The amendments to the MSA also seek to outlaw co-payments for healthcare services. As such, contributions into discretionary pools such as medical scheme savings accounts would increase so that the OTCMs could be paid in full. Access to and cost of covering OTCMs would therefore increase, while the new dispensation would have little or no impact on quality. The example of OTCMs being introduced into benefit packages can probably be applied to other benefit categories as well, risking the introduction of questionably-effective medicines, procedures and care plans that are not in the NHI package, and are promoted simply to enhance marketability and attract clients.

One might argue that the OTCM-related findings of this thesis are less relevant precisely because of the implications of the HMI Report and the NHI and MSA Bills [86,92,117]. Government thinking could be that once the legislative processes have taken their course there will no longer be as viable a private sector. The universal healthcare vision is that within that sector all South Africans would be able to obtain comprehensive care in the revamped public sector. OTCM prices would be controlled by whatever replaces the tender system, and quality would be controlled by the EML. However the reality is that Schedule 0-2 OTCMs in general, and polypharmaceuticals in particular, will likely continue to be accessed by the majority of South Africans, whether covered by NHI and paying out-of-pocket, or members of medical schemes and paying via their discretionary funding pools[75].

Before proceeding to recommendations it is necessary to revisit comments made in the introduction to this thesis. The first is the WHO guideline on self-medication:
"*It has become widely accepted that self-medication has an important place in the health care system. Recognition of the responsibility of individuals for their own health, and awareness that professional care for minor ailments is often unnecessary, have contributed to this view. Improvements in people's general knowledge, level of education and*

socioeconomic status in many countries form a reasonable basis for successful self-medication"[1].

While medical scheme beneficiaries were not canvassed as to their ability to rationally and responsibly self-medicate with OTCMs, review of information provided to beneficiaries by their medical schemes indicates that where such information exists it relates to the cost of OTCMs rather than the quality. For example, which ones will be paid, which not, from which funding pool and what the Rand limit will be per beneficiary and per family. It is therefore likely that consumers, whether in the private or public sector, will rely on pharmacists, marketing material, word-of-mouth and package inserts for their knowledge as to what, when, how often and how much is required for self-treatment. The diversity of the South African population, starting with the number of official languages, makes it likely that reliance on the four abovementioned sources of information is a recipe for communication failures and knowledge gaps. This conclusion aligns with one of the important conclusions of the HMI, namely that consumers are generally uninformed and disempowered, and unlikely to be able to make the best decisions in relation to their health.

Healthcare is generally regarded as a human right. Within this right is access to OTCMs and, as stated in the opening sentences of this thesis, all SA citizens should have access to affordable, appropriate, high quality OTCMs. Achievement of this goal is dependent on an optimal relationship and interplay between the numerous stakeholders involved. If the beneficiary/patient/consumer is indeed not in a strong position to make the necessary decisions regarding self-medication, then it is incumbent upon the other stakeholders involved in the process to play their part. Figure 6.1 once again defines the players, and the following text summarises the shortcomings identified in the elements contributing to this thesis.

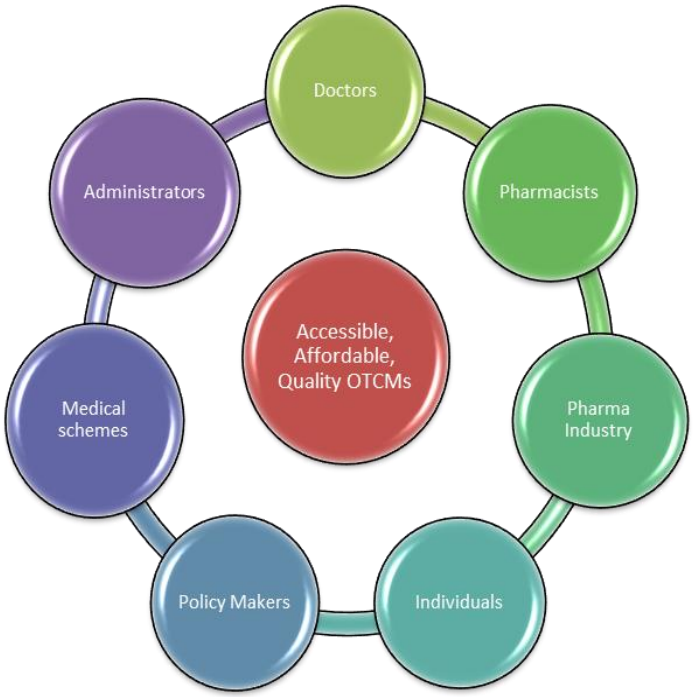


Figure 6.1: Stakeholders Involved in Utilisation of OTCMs

6.2 STAKEHOLDER SHORTCOMINGS AND FAILURES

6.2.1 Individuals

Having already made the case for many individuals not being sufficiently informed in order to make the best self-medication choices, there is also the 'use-it-or-lose-it' mentality around the OTCM benefit. Evidence from this thesis suggests that medical scheme beneficiaries had little desire to use the OTCM benefit cost-effectively in the achievement of better clinical outcomes.

6.2.2 Policy Makers

There are various levels at which important policies are determined, such as government via the NDOH that is responsible for relevant legislation, entities such as the SAPC that is responsible for registration of pharmacies and pharmacists and ensuring good pharmacy practice, and the CMS that is responsible for registration of medical schemes, administrators and brokers, and has a specific mandate to ensure that medical scheme beneficiaries are protected. The CMS has some programmes and initiatives that are directed towards consumer education, but most of the CMS activities are directed towards monitoring and evaluating medical scheme and administrator performance and compliance[87]. Analyses carried out for this thesis indicated that there are many loopholes. Legislation governing the

SEP appears to be fundamentally flawed, and related to that is the large number of available generic OTCMs. Consequently, neither price nor quality appeared to be controlled by the legislation. Variations in application of logistic fees and mark-ups by pharmacies also indicated that standardisation is sub-optimal. Guidelines published by the SAPC and CMS did not appear to be adhered to, and there are questions as to the extent that misconduct by providers is dealt with by the authorities. As an example, the CMS has detailed requirements for accreditation of DMPs, but there are large gaps in the delivery of the programmes, yet accreditation does not appear to be forfeited. Similarly, the Carte Blanche programme showed that the regulators are under-resourced and unable to monitor transgressions[32].

6.2.3 **Medical Schemes**

In general, medical schemes claim to be focused on the health of the millions of clients they enrol, yet the evidence is that most of their efforts are directed towards cost containment rather than quality of care. The OTCM benefit, whether funded via the risk pool or a discretionary pool, is intended to support self-managment of minor ailments, but little appears to be done to educate beneficiaries on effective use of the benefit, especially from a quality perspective.

6.2.4 **Administrators**

The relationship between medical schemes and administrators is a tight one, whether scheme and administrator are within the same organisation, or the administrator has a third-party arrangement with the scheme. Consequently medical schemes are always aware of the range of services that can be provided by the administrator in terms of data capture, data mining and analysis. Data from this thesis suggested that little was done to maximise the potentially-rich OTCM databases. A specific example is the ease with which an administrator could identify a beneficiary who is not registered for a DMP but is repeatedly accessing one or more OTCMs for management of a chronic cough. This cough could be symptomatic of chronic obstructive pulmonary disease or asthma. Identification of the underlying condition would not only benefit the patient, but also probably lead to long-term cost savings through appropriate rather than haphazard management.

6.2.5 **Pharmaceutical Industry**

Opportunities abound for manufacturers in the OTCM market because they are mainly governed by the requirements for producing, marketing and selling generic medicines. There are no requirements for research expenses or clinical trials, and so-called ‘me too’ products proliferate, albeit priced very differently. Branding, marketing and various incentives determine sales volumes. None of this is illegal, which essentially means that in a free

market environment in which access is mostly uncontrolled, any interventions aimed at cost and quality will have to come from the other stakeholders.

6.2.6. **Pharmacists and Pharmacies**

While registered with the SAPC and supposedly adherent to the Council's guidelines, pharmacists operate in a competitive environment[28-31]. Whether self-employed, employed in an independent pharmacy or by a corporate chain, there will always be an eye on the returns. As shown in this study, pharmacists dispensed more-expensive generics or originals, particularly in high benefit schemes. They also showed a preference for larger pack sizes.

6.2.7 **Doctors**

While doctors, particularly dispensing doctors, performed better than pharmacists and generally prescribed cheaper OTCMs, they also prescribed OTCMs that were more expensive when the member belonged to a rich-benefit plan. In the defined area of OTCMs for chronic diseases, there were situations in which doctors appeared to be deficient, for example not ensuring that a patient with a chronic disease was registered with the medical scheme's DMP, or not paying sufficient attention to the fact that a member who was registered with a DMP was having to utilise valuable OTCM benefits that should have been paid via the chronic medicines benefit.

6.2.8 **Recommendations**

It is well within the powers of all stakeholders in the OTCM 'value' chain to change the current modus operandi; the question is whether there is the political and economic will to do so. Several arguments could be presented for doing nothing: for example medical scheme beneficiaries could say it is effectively their money and they should be free to choose what they want; medical schemes would likely also argue that payment comes from discretionary funding pools and as such does not affect the more-important risk pool. Medical schemes would likely also ask whether the cost of any additional interventions would be justified, because they would add to administration costs; Government might argue that the issues around OTCMs will disappear once NHI has been implemented and controls such as the EML are in effect for all who who are covered by NHI. On the economic front there is also the reality that manufacture of OTCMs is seen as an opportunity for emerging entrepreneurs. In fact, the ruling party in South Africa used the occasion at which its election manifesto was released to explicitly state that pharmaceuticals represented a growth opportunity for the future[147].

Although a framework exists to regulate OTCMs, the implementation is weak. Policy-makers have implemented mechanisms such as SEP, however the SEP fundamentals are weak and the monitoring is poor. Prices for OTCMs that have multiple generics should be fixed and regularly monitored. Generic substitution should be tightened up by government, possibly by implemeting tools such as the MMAP[89]. Loopholes allowing variations in logistic fees, mark-ups and handling costs should be closed, and tighter control measures should be put in place to monitor large deviations. Self-medication is growing, and with more people taking responsibility for their health the OTCM industry is set to grow even more. Government needs to take cognisance of this trend and consider that even with NHI, the general public will seek OTCMs to self-medicate.

The SAPC provides elaborate guidelines on the code of conduct and ethical rules for a pharmacist. With more than 13 000 pharmacists currently in SA, the ability to effectively monitor compliance is almost impossible.Pharmacists need to abide by legislation and dispense within the law, and the SAPC must act effectively against pharmacists who do not comply. Removal from the register should be a reality, particularly after multiple offences.

The CMS is ideally positioned, through its own offices or via its registered medical schemes, to educate beneficiaries in simple layman's terms on benefits that are self-managed. According to the Consumer Protection Act[148], consumers must be provided with information that is clear and interpretable. The CMS regularly posts information on its website and has awareness drives on health- and benefit-related issues, but these services are poorly publicised. As an important benefit, OTCMs should become a standard educational feature. The CMS should also have transparent, standardised, measurable outcome matrices for all DMP programmes. The provision of DMPs should not vary between medical schemes, and a benchmark guideline should be established for uniformity.

Medical schemes and administrators should also do more in terms of quality of OTCMs. Consideration should be given to what was bought, not only at a beneficary level but also at option level, how often it was bought, and the implications for safety. Monitoring should also be carried out on the use of polypharmaceuticals, and the possible use of OTCMs to treat side-effects of a registered chronic disease. Several of these functions also fall into the domain of doctors, who could do more to make the OTCM benefit a valuable contribution, not only to the management of minor ailments, but also to enhanced and cost-effective control of chronic disease/s.

For OTCMs to change from a commodity to a right, genuine will and commitment are of paramount importance. However, even if OTCMs remain as a commodity, then as per HMI recommendations everything must be done to ensure that the market failure is addressed. All the relevant forces must operate to ensure access to quality OTCMs, effective competition between manufacturers and providers, and consumer value in the form of cost reduction.

6.2.9 **Limitations**

An important question is whether the results of this thesis can be extrapolated to the broader medical schemes environment. The first paper compared a traditional medical scheme with a new generation scheme. In the second study, in order to confirm that the results for a specific ATC group in the same two medical schemes were similar to others in the database, additional analysis was carried out and showed congruence. Lastly, the third paper applied to all the beneficiaries >40 years in the total database. Since the administrator concerned and the medical schemes represented in the database were and continue to be representative of the broader industry, on balance it is reasonable to assume that results may indeed be representative.

REFERENCES

1. World Health Organisation (WHO) Drug Information. 2000. Volume 14. Number 1. https://apps.who.int/medicinedocs/pdf/h1462e/h1462e.pdf. Accessed 11 December 2019

2. South African Health Products Regulatory Authority. Consolidated Schedules. Available from: https://www.sahpra.org.za/documents/f6bf8a532016_Consolidatedschedules2008200920112012201320142015March_May2016(includingprescribers).pdf. Accessed October 20, 2019

3. Moodley R, Suleman F. Evaluating the impact of the single exit price policy on a basket of originator medicines in South Africa from 1999 to 2014 using a time series analysis. BMC Health Services Research 2019;19(1):576.

4. SMASA Codeine Care Initiative South Africa 2014 [homepage on the Internet]]. Available from: http://selfcare247.co.za/247-codeine-care-initiative

5. Medicines and Related Substances Act 101 of 1965. Available from: https://www.gov.za/sites/default/files/41762_gon703.pdf. Accessed 12 August 2019.

6. The Innovation Pharmaceutical Association of South Africa (IPASA) Available from https://www.google.com/search?q=schedule+02+ipasa&rlz=1C1GCEU_enZA832ZA832&sxsrf=ACYBGNRSj8VqLkJ1MjGwKnoSZHI9RQyYOQ:1571903385214&source=lnms&tbm=isch&sa=X&ved=0ahUKEwjfj5a3tLTlAhWFXhUIHfukAJEQ_AUIEigB&biw=1600&bih=740#imgrc=OSLtYvqI5ZfKXM: Accessed October 20, 2019

7. Trivedi H, Trivedi A, Hannan MF. Readability and comprehensibility of over-the-counter medication labels. Renal Failure. 2014;36(3):473-477.

8. Gunn VL, Taha SH, Liebelt EL, Serwint JR. Toxicity of over-the-counter cough and cold medications. Pediatrics. 2001;108(3):e52

9. South African Health Product Regulatory Authority. https://www.sahpra.org.za/documents/1d9c57df2.01_General_information_Jul12_v8_showing_changes.pdf. Accessed 11 December 2019.

10. Balbani AP, Stelzer LB, Montovani JC. Pharmaceutical excipients and the information on drug labels. Brazilian journal of otorhinolaryngology. 2006;72(3):400-6.

11. Murnion BP. Combination analgesics in adults. Australian Prescriber. 2010;33:113-115.

12. Wolf MS, King J, Jacobson K, Di Francesco L, Bailey SC, Mullen R, McCarthy D, Serper M, Davis TC, Parker RM. Risk of unintentional overdose with non-prescription acetaminophen products. Journal of General Internal Medicine. 2012;27(12):1587-1593.

13. Ducrotté P, Liker HR. How do people with gastro-oesophageal reflux disease perceive their disease.Results of a multinational survey. Current Medical Research and Opinion. 2007;23(11):2857-2865.

14. Inadomi JM, Fendrick AM. PPI use in the OTC era: who to treat, with what, and for how long?. Clinical Gastroenterology and Hepatology. 2005;3(3):208-215.

15. Sihvo S, Klaukka T, Martikainen J, Hemminki E. Frequency of daily over-the-counter drug use and potential clinically significant over-the-counter-prescription drug interactions in the Finnish adult population. European Journal of Clinical Pharmacology. 2000;56(6-7):495-499.

16. Bahner DR, Frenia ML, Augenstein WL. Theophylline toxicity from an over-the-counter preparation. Journal of Emergency Medicine. 1993;11(4):427-430.

17. World Health Organisation rational use of medicines. WHO rational use of medicine https://apps.who.int/iris/bitstream/handle/10665/67438/WHO_EDM_2002.3.pdf. Accessed 20 December 2019.

18. Noone J, Blanchette CM. The value of self-medication: summary of existing evidence. Journal of Medical Economics. 2018; 21(2): 201-211.

19. Hughes CM, McElnay JC, Fleming GF. Benefits and risks of self-medication. Drug Safety. 2001;24(14):1027-1037.

20. Jain S, Malvi R, Purviya JK. Concept of self medication: A review. International Journal of Pharmaceutical and Biological Archives. 2011;2(3):831-836.

21. World Health Organisation guidelines to self medication Guidelines for the regulatory assessment of medicinal products for use in self-medication. Geneva, Switzerland: World Health Orgnanization 2000:1–31.

22. Ruiz ME. Risks of self-medication practices. Current Drug Safety. 2010;5:315-323.

23. Westerlund LT, Marklund BR, Handl WH, Thunberg ME, Allebeck P. Nonprescription Drug-Related Problems and Pharmacy Interventions. Annals of Pharmacotherapy. 2001;35(11):1343-1349.

24. Gottlieb H. Medication nonadherence: finding solutions to a costly medical problem. Medscape Web site. www.medscape.com/viewarticle/409940 . Accessed July 19, 2010.

25. Guidelines for the regulatory assessment of medicinal products for use in self-medication. Geneva, Switzerland: World Health Organization. 2000:1-31.

26. Nathan JP, Zerilli T, Cicero LA, Rosenberg JM. Patients' use and perception of medication information leaflets. Annals Pharmacother. 2007;41(5):777-782.

27. Liu GG, Christensen DB. The continuing challenge of inappropriate prescribing in the elderly: an update of the evidence. Journal American Pharmaceutical Association. 2002;42(6):847–857

28. South African Pharmacy Council. Good pharmacy practice http://apps.who.int/medicinedocs/documents/s19633en/s19633en.pdf. Accessed 11 December 2019

29. South African Pharmacy Council. Pharmacy Act 53 of 1974 https://www.mm3admin.co.za/documents/docmanager/0c43ca52-121e-4f58-b8f6-81f656f2fd17/00010723.pdf Accessed 12 December 2019

30. South African Pharmacy Council. Code of conduct. https://www.mm3admin.co.za/documents/docmanager/3C53E82B-24F2-49E1-B997-5A35803BE10A/00133607.pdf. Accessed 12 December 2019.

31. South African Pharmacy council. Ethical rules. https://www.pharmcouncil.co.za/media/default/documents/Acts_or_omissions_which_can_lead_to_disciplinary_action_(1989).pdf. Accessed 13 December 2019

32. Carte Blanche television program. https://m-net.dstv.com/show/carte-blanche/news/codeine-addictions-signs-and-symptoms-carte-blanche/news. Accessed 11 December 2019.

33. Paudyal V, Watson MC, Sach T, Porteous T, Bond CM, Wright DJ, Cleland J, Barton G, Holland R. Are pharmacy-based minor ailment schemes a substitute for other service providers?: A systematic review. British Journal of General Practice. 2013;63(612): 472-481.

34. Winfield AJ, Richards RME. Pharmaceutical practice. 2nd ed. Hong Kong. Churchill Livingstone, 1998:532

35. Schneider H, Roehrig RC, Coppolecchia R, Ming D, Garwin J, Qi D, Starkey P, Hemwall E, Chaponis R, Paredes-Diaz A, Biesbrock A, Bhatti A. White paper on the benefits of OTC medicines in the United States: Report of the Consumer Healthcare Products Association's Clinical/Medical Committee. Pharmacy Today. 2010;20: 68-79.

36. Ferris DG, Nyirjesy P, Sobel JD, Soper D, Pavletic A, Litaker MS. Over-the-counter antifungal drug misuse associated with patient-diagnosed vulvovaginal candidiasis. Obstetrics & Gynecology. 2002;99(3):419-425.

37. Yılmaz İ. Angiotensin-Converting Enzyme Inhibitors Induce Cough. Turkish Thoracic Journal. 2019;20(1):36.

38. US Food and Drug Administration (FDA). Regulation Overview: Rx-to-OTC Switch. (Available from: https://search.fda.gov/search?utf8=%E2%9C%93&affiliate=fda1&query=switching+from+prescription+to+otc&commit=Search. Accessed 20 January 2020.

39. Kartha SS, Kulyadi GP, Bhat K, Sathyanarayana MB. Switching Drugs from Rx to OTC status – A Regulatory Perspective. Journal of Young Pharmacists. 2017;9(1):3-7

40. Yuen CW, Chong DW. Rx-to-OTC Switch - An Overview and its Implications to Public Health. Entering a Season of Gratitude. 2018:110

41. MacQuarie University The MacQuarie Centre for the Health Economy. The value of OTC medicines in Australia. 2014. https://www.mq.edu.au/research/research-centres-groups-and-facilities/prosperous-economies/centres/centre-for-the-health-economy/documents/FINAL20WEB20COPY20ASMI_ValueStudy_A4.pdf. Accessed 3 February 2020

42. Francis SA, Barnett N, Denham M. Switching of prescription drugs to over-the-counter status. Drugs & Aging. 2005;22(5):361-370.

43. Brass EP. Changing the status of drugs from prescription to over-the-counter availability. New England Journal of Medicine. 2001;345(11):810-816.

44. Creyer EH, Hrsistodoulakis I, Cole CA. Changing a drug from Rx to OTC status: the consumer behavior and public policy implications of switch drugs. Journal of Product & Brand Management. 2001;10(1):52-64.

45. Chewning B, Sleath B. Medication decision-making and management: a client-centered model. Social Science & Medicine. 1996;42:389-398.

46. Arute JE, Adje UD, Akonoghrere R, Omuta MC. Self-medication practices in Odo Ado community of Ado Ekiti. International Research Journal of Pharmacy and Pharmacology. 2013;3(4):53-57.

47. Sherazi BA, Mahmood KT, Amin F, Zaka M, Riaz M, Javed A. Prevalence and measure of self medication: a review. Journal of pharmaceutical Sciences and Research. 2012;4(3):1774-1778

48. Covington TR. The pharmacist as nonprescription drug therapy manager: let's seize the opportunity. Journal of American Pharmaceutical Association (wash). 2002;42(3); 518-19.

49. World medical association. https://www.wma.net/policies-post/wma-statement-on-self-medication.Accessed 12 December 2019

50. Galato D, Galafassi LD, Alano GM, Trauthman SC. Responsible self-medication: review of the process of pharmaceutical attendance. Brazilian Journal of Pharmaceutical Sciences. 2009;45(4):625-633.

51. Consumer Health Products Association. https://www.chpa.org/MarketStats.aspx. Accessed 10 January 2010

52. Thomas DHV, Noyce PR. The interface between self-medication and the NHS. British Medical Journal. 1996;312:688-91.

53. World Self-Medication Industry (WSMI). Responsible Self-Care and Self-Medication: A Worldwide Review of Consumer Surveys. Ferney-Voltaire: WSMI; nd. https://www.selfcarefederation.org/resources. Accessed 9 November 2019.

54. Aljadhey H, Assiri GA, Mahmoud MA, Al-Aqeel S, Murray M. Self-medication in Central Saudi Arabia: community pharmacy consumers' perspectives. Saudi Medical Journal. 2015;36(3):328.

55. Suleman S, Ketsela A, Mekonnen Z. Assessment of self-medication practices in Assendabo town, Jimma zone, southwestern Ethiopia. Research in Social and Administrative Pharmacy. 2009;5(1):76-81.

56. Abosede OA. Self-medication: an important aspect of primary health care. Social Science & Medicine. 1984;19(7):699-703.

57. Wood DM, English E, Butt S, Ovaska H, Garnham F, Dargan PI. Patient knowledge of the paracetamol content of over-the-counter (OTC) analgesics, cough/cold remedies and prescription medications. Emergency Medicine Journal. 2010;27(11):829-33.

58. Bissell P, Ward PR, Noyce PR. The dependent consumer: reflections on accounts of the risks of non-prescription medicines. Health:2001;5(1):5-30.

59. Bevan M, Ng YC, Cooper J, Robertson J, Walkom E, Chiu S, Newby DA. The role of evidence in consumer choice of non-prescription medicines. International Journal of Pharmacy Practice. 2019;27(6): 501-509.

60. Hanna LA and Hughes CM. First, Do No Harm': Factors that Influence Pharmacists Making Decisions about Over-the-Counter Medication. Drug Safety. 2010;33(3):245-255.

61. Sharma A, Madaan A, Nagappa AN. Medication storage and self medication practice among the youth in Karnataka region, India. International Journal of Pharmaceutical Sciences and Research. 2012;3(8): 2795-2800.

62. Guidelines for the Regulatory Assessment of Medicinal Products for Use in Self-Medication. 2000. https://apps.who.int/medicinedocs/en/d/Js2218e/. Accessed 22 January 2020

63. Carvalho RS, Kara-José N, Temporini ER, Kara-Junior N, Noma-Campos R. Self-medication: initial treatments used by patients seen in an ophthalmologic emergency room. Clinics. 2009;64(8):735-41.

64. Ahmad A, Patel I, Mohanta GP, Balkrishnan R. Evaluation of self medication practices in rural area of town Sahaswan at Northern India. Annals of Medical and Health Sciences Research. 2014;4(8):73-8.

65. Phalke VD, Phalke DB, Durgawale PM. Self-Medication Practices in Rural Maharashtra, Indian Journal of Community Medicine. 2006;31(1): 34-5.

66. United Nations Educational, Scientific and Cultural Organisation (UNESCO) http://uis.unesco.org/sites/default/files/documents/fs45-literacy-rates-continue-rise-generation-to-next-en-2017.pdf. Accessed 10 January 2020.

67. Parekh N, Ali K, Davies K, Rajkumar C. Can supporting health literacy reduce medication-related harm in older adults? Therapeutic Advances in Drug Safety. 2018;9(3):167-170.

68. Statistica. https://www.statista.com/statistics/572836/literacy-rate-in-south-africa/. Accessed 12 December 2019.

69. Eye Witness News. https://ewn.co.za/2018/02/05/nearly-60-of-south-africans-now-have-access-to-the-internet. Accessed 21 August 2019.

70. OTC Drug Market survey report2019 along with statistics, Forecasts till 2025. 2019. Marketwatch.Marketwatch.com/press-release/otc-drug-market-survey-report-2019-along-with-statistics-forecasts-till2025-2019-11-29?mod=mw_quote_news. Accessed 10 January 2020.

71. Cision PR Newswire. https://www.prnewswire.com/news-releases/over-the-counter-drugs-market-to-hit-185-billion-by-2025-global-market-insights-inc-300805621.html. Accessed 12 December 2019.

72. Medical Cannabis Network. https://www.healtheuropa.eu/medical-cannabis-pharma-industry/92589. Accessed 12 December 2019

73. Forbes online. https://www.forbes.com/sites/irisdorbian/2019/09/24/new-cannabis-report-predicts-legal-sales-to-reach-nearly-30-billion-by-2025/#5b825c861121. Accessed 12 December 2019.

74. Pharmaboard room. https://pharmaboardroom.com/pharma_report/south-africa-pharma-report. Accessed 26 September 2019].

75. Helen Suzman Foundation. https://hsf.org.za/publications/special-publications/pharmaceuticals-in-south-africa/pharma-report-2018.pdf/. Accessed 12 December 2019.

76. Insight Survey B2B Market Research. https://www.insightsurvey.co.za/wp-content/uploads/2018/07/SA-Analgesics-Industry-Landscape-Report-Brochure-2018.pdf. Accessed 10 January 2019.

77. Competition Commission. http://www.compcom.co.za/. Accessed 24 January 2020.

78. Clicks. https://www.clicksgroup.co.za/IRDownloads/InterimResults2019/clicks_analyst_apr_2019_screen.pdf. Accessed 12 December 2019.

79. Dischem.https://thevault.exchange/?get_group_doc=6262/1557985934-FY2019resultspresentation.pdf Accessed 12 December 2019.

80. UnderstandingHealthcareFinancing. http://ipasa.co.za/Downloads/Policy%20and%20Reports%20-%20General%20Health/NHI/Understanding%20Healthcare%20Financing/Introduction%20to%20Healthcare%20Financing.pdf. Accessed 12 December 2019.

81. Mcleod H, Ramjee S. Medical schemes: pooling of resources and purchasing of health care. South African Health Review. 2007: 47-70.

82. Pearmain D. Impact of changes to the Medical Schemes Act: chapter 8. South African Health Review. 2000:183-200.

83. Econex. https://econex.co.za/wcontent/uploads/2016/09/Econex_private_health_sector_study_12122013-1.pdf. Accessed 12 December 2019.

84. Doherty J & McLeod H. Medical schemes: framework for transformation. South African health review. 2002:40-1.

85. Söderlund N, Schierhout G, Van den Heever A. Private Health Care in South Africa: Technical Report to Chapter 13 of the 1998 SA Health Review. Health systems trust, 1998.

86. Medical Schemes Act 131 of 1998, Regulations. Available from: https://www.gov.za/sites/default/files/a131-98.pdf. Accessed 18 July 2019.

87. Council of Medical schemes. Role of the CMS. https://www.medicalschemes.com/Content.aspx?84. Accessed 12 December 2019.

88. Council of Medical Schemes Annual report 2018/2019. https://www.medicalschemes.com/files/Annual%20Reports/CMSAR2018-19_Annexures_V9.pdf. Accessed 12 December 2019.

89. Boyce D, Bartlett G. The maximum medical aid price programme: A review of the concept and of its ability to reduce expenditure on medicines. South African Medical Journal, 1990;78(8):147-51

90. Council of medical schemes. CMS script. Designated service providers. https://www.medicalschemes.com/files/CMScript/CMScript_20081112.pdf. Accessed 12 December 2019.

91. Council of Medical Schemes Annual report 2013/14. https://www.medicalschemes.com/files/Annual%20Reports/AR2013_2014LR.pdf/. Accessed 12 December 2019.

92. Health Market Inquiry, 2019. http://www.compcom.co.za/wp-content/uploads/2014/09/Health-Market-Inquiry-Report.pdf. Accessed 12 December 2019.

93. National Drug Policy. http://apps.who.int/medicinedocs/en/m/abstract/Js17744en/. Accessed 12 December 2019.

94. South African Medicines Price Registry. http://www.mpr.gov.za/ Accessed 12 December 2019.

95. Pretorius D. http://ipasa.co.za/Downloads/Policy%20and%20Reports%20-%20Medicines/Single%20Exit%20Price/Impact%20of%20implementation%20of%20SEP%20for%20pharmaceuticals%20SA.%20D%20Pretorius%202011.pdf

96. Vogler S, Habimana K, Arts D. Does deregulation in community pharmacy impact accessibility of medicines, quality of pharmacy services and costs? Evidence from nine European countries. Health Policy. 2014;117(3):311-27.

97. Andrews A. The dispensing fee for medications: the negative effects of pricing uncertainty on pharmacy practise in SA. Aids and society research unit. Centre for social science research. September 2009. Open.uct.ac.za/bitstream/item/22564/Andrews_dispensing_fee_for_2009.pdf?sequence=1 Ref. Accessed 10 January 2020.

98. Gray A, Santa-Ana-Tellez Y, J Wirtz V. Impact of the introduction of mandatory generic substitution in South Africa: private sector sales of generic and originator medicines for chronic diseases. Tropical Medicine & International Health. 2016;21(12):1504-12.

99. Gray A, Suleman F. Pharmaceutical prices in the 21st century. Chapter 14. Zaheer-Ud-Din Babar. Springer International Publishing Switzerland. 2015;251-267.

100. Shrank WH, Liberman JN, Fischer MA, Girdish C, Brennan TA, Choudhry NK. Physician perceptions about generic drugs. Annals of Pharmacotherapy. 2011;45(1):31-38.

101. Halme M, Linden K, Kääriä K. Patients' preferences for generic and branded over-the-counter medicines. The Patient: Patient-Centered Outcomes Research. 2009;2(4):243-255.

102. Gray A, Riddin J, Jugathpal J. Health care and pharmacy practice in South Africa. The Canadian Journal of Hospital Pharmacy. 2016;69(1):36.

103. Essential Medicines and Standard Treatment Guidelines.http://www.health.gov.za/index.php/component/phocadownload/category/197. Accessed 12 December 2019.

104. World Health Organisation. Essential Medicines. https://www.who.int/medicines/services/essmedicines_def/en/. Accessed 12 December 2019.

105. Wouters OJ, Sandberg DM, Pillay A, Kanavos PG. The impact of pharmaceutical tendering on prices and market concentration in South Africa over a 14-year period. Social Science & Medicine. 2019;220:362-370.

106. Mail and Guardian. https://mg.co.za/article/2008-02-11-pharmaceutical-companies-accused-of-collusion Accessed 12 December 2019.

107. Lorenzoni L; Roubal T. International comparison of south African private hospital price levels. OECD health working papers, 85, OECD publishing, Paris.

108. Marks SP. Access to essential medicines as a component of the right to health. Realizing the right to health. Zurich, Switzerland: Rüfer and Rub. 2009:82-101.

109. Aggarwal NK, Rowe M, Sernyak MA. Is health care a right or a commodity? Implementing mental health reform in a recession. Psychiatric Services. 2010;61(11):1144-45

110. Elliot C. Medicine as a commodity Chapter 14 (2016). The Routledge Companion to Philosophy of Medicine. New York. 1st edition: 519-28.

111. Universal declaration of human rights. https://www.ohchr.org/EN/UDHR/Pages/language.aspx?LangID=eng. Accessed 22 December 2019.

112. United Nations Sustainable Developmental Goals. https://www.un.org/development/desa/disabilities/envision2030.html. Accessed 12 December 2019.

113. WHO.The Doha Declaration on the TRIPS Agreement and public health. https://www.who.int/medicines/areas/policy/doha_declaration/en. Accessed 12 December

114. World Trade Organisation. Compulsory licencing. https://Wto.org/English/tratop_e/trips_e/public_health_faq_e.htm. Accessed 12 December 2019.

115. Lee JY, Hunt P. Human rights responsibilities of pharmaceutical companies in relation to access to medicines. The Journal of Law, Medicine & Ethics. 2012;40(2):220-33.

116. United Nations. https://www.business-humanrights.org/sites/default/files/reports-and-materials/Ruggie-protect-respect-remedy-framework.pdf. Accessed 21 December 2019

117. Department of Health. NHI. https://Health.gov.za/index.php/nhi. Accessed 12 December 2019.

118. Kaplan J & Ranchod S. Analysing the structure and nature of medical scheme benefit design in South Africa. In: Padarath A, King J, English R, editors. South African Health Review. 2014/15:165-178.

119. Joyce GF, Escarce JJ, Solomon MD, Goldman DP. Employer drug benefit plans and spending on prescription drugs. Journal of American Medical Association. 2002;288(14): 1733-1739

120. Bizcommunity. https://www.bizcommunity.com/Article/196/188/23693.html. Accessed 12 December 2019.

121. Lewis M. The influence of loyalty programs and short-term promotions on customer retention. Journal of Marketing Research. 2004;41(3):281-92

122. Benson A, Cribb A, Barber N. Understanding pharmacists' values: A qualitative study of ideals and dilemmas in UK pharmacy practice. Social Science & Medicine. 2009;68(12):2223-2230.

123. Still L (2014). Health Care in South Africa. 2014. Houghton Estate. Profile Media

124. QED Actuaries. http://qedact.com/category/insights/page/3/. Accessed 10 January 2020

125. Otto M, Armeni P, Jommi C. Variations in non-prescription drug consumption and expenditure: determinants and policy implications. Health Policy. 2018;122(6):614-20.

126. Stosic R, Dunagan F, Palmer H, Fowler T, Adams I. Responsible self-medication: perceived risks and benefits of over-the-counter analgesic use. International Journal of Pharmacy Practice. 2011;19(4):236-245.

127. Van Hout MC, Norman I. Misuse of non-prescription codeine containing products: Recommendations for detection and reduction of risk in community pharmacies. International Journal of Drug Policy. 2016;27:17-22.

128. Iedema J. Cautions with codeine. Australian Prescriber. 2011;34(5):133-35.

129. Foley M, Harris R, Rich E, Rapca A, Bergin M, Norman I, Van Hout MC. The availability of over-the-counter codeine medicines across the European Union. Public Health. 2015;129(11):1465-70.

130. MacKinnon JI. Tighter regulations needed for over-the-counter codeine in Canada. Canadian Pharmacists Journal/Revue des Pharmaciens du Canada. 2016;149(6):322-4.

131. Barkin RL. Acetaminophen, aspirin, or ibuprofen in combination analgesic products. American Journal of Therapeutics. 2001;8(6):433-42.

132. De Broe ME, Elseviers MM. Over-the-counter analgesic use. Journal of the American Society of Nephrology. 2009;20(10):2098-2103.

133. Global Action Plan for the Prevention and Control of NCDs 2013-2020 a. https://www.who.int/nmh/events/ncd_action_plan/en/. Accessed 3 January 2020

134. Sixty-Sixty World Health Assembly. https://www.who.int/nmh/events/ncd_action_plan/en/ Accessed 3 January 2020.

135. Bradshaw D, Groenewald P, Laubscher R, Nannan N, Nojilana B, Norman R, Pieterse D, Schneider M, Bourne DE, Timæus IM, Dorrington R. Initial burden of disease estimates for South Africa, 2000. South African Medical Journal. 2003;93(9):682-688.

136. Nojilana B, Bradshaw D, Pillay-van Wyk V, Msemburi W, Laubscher R, Somdyala NI, Joubert JD, Groenewald P, Dorrington RE. Emerging trends in non-communicable disease mortality in South Africa, 1997-2010. South African medical journal. 2016;106(5):477-484.

137. Govuzela M, Thsehla E, de Villiers A. Prevalence of chronic disease in the population covered by medical schemes in South Africa. Council of Medical Schemes. https://www.medicalschemes.com. (accessed 24 June 2019)

138. Council of Medical Schemes. https://www.medicalschemes.com/files/Board%20of%20Trustee%20Material/Clinical_Governance_Module.pdf. Accessed January 2020.

139. Velasco-Garrido M, Busse R, Hisashige A. Are disease management programmes (DMPs) effective in improving quality of care for people with chronic conditions. Copenhagen: WHO Regional Office for Europe. 2003:1-23.

140. Aid for AIDS. http://www.aidforaids.co.za/about.php(accessed 19 June 2019)

141. Core Concepts in Diabetes Mellitus Centre for Diabetes and Endocrinology http://web.cdediabetes.co.za/about-cde/our-history(accessed 21 June 2019)

142. Disease Management Government Employees MedicalScheme https://www.gems.gov.za/en/members/programmes/disease-management. Accessed 24 June 2019.

143. Chronic Illnesses and other medical conditions. Discovery Health Medical Scheme https://www.discovery.co.za/medical-aid/chronic-illnesses-other-medical-conditions. Accessed 24 June 2019.

144. Seidu S, Kunutsor SK, Sesso HD, Gaziano JM, Buring JE, Roncaglioni MC, Khunti K. Aspirin has potential benefits for primary prevention of cardiovascular outcomes in diabetes: updated literature-based and individual participant data meta-analyses of randomized controlled trials. Cardiovascular Diabetology. 2019;18(1):70.

145. Price AH, Clissold SP. Salbutamol in the 1980s. Drugs. 1989;38(1):77-122.

146. Glaucoma.org. https://www.glaucoma.org/g-a/why-are-allergy-medications-contraindicated-for-people-with-glaucoma.php. Accessed 10 January 2020.

147. African National Congress. Let's grow South Africa together. 2019 election manifesto. A people's plan for a better life for all. https://voteanc.org.za/assets/manifesto-summaries/A5_Manifesto_English.pdf. Accessed 10 January 2020.

148. Consumer Protection Act. https://www.gov.za/documents/consumer-protection-act. Accessed 25 January 2020

APPENDIX A

- **ETHICAL CLEARANCE CERTIFICATES | HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL) M160141**

R14/49 Ms Naelaveni Pacayachee

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160141

NAME: (Principal Investigator)	Ms Naelaveni Padayachee
DEPARTMENT:	Pharmacy and Pharmacology
PROJECT TITLE:	To Evaluate the Utilization of Over the Counter Drugs in the Savings and Acute Medicines Benefit in Certain Medical Aids in South Africa
DATE CONSIDERED:	29/01/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Neil Butkow
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	05/08/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004, 10th floor, Senate House/2nd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in January and will therefore be due in the month of January each year.

Principal Investigator Signature

Date 05/08/16

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX B

- **DATA COLLECTION TOOL FOR DATA MANAGEMENT**

Patient ID	Gender	Ethnicity	Age	Age band	RUB	GP enco(networ)	GP tariff	GP act	GP risk
					Resource utilisation band	GP encounter			

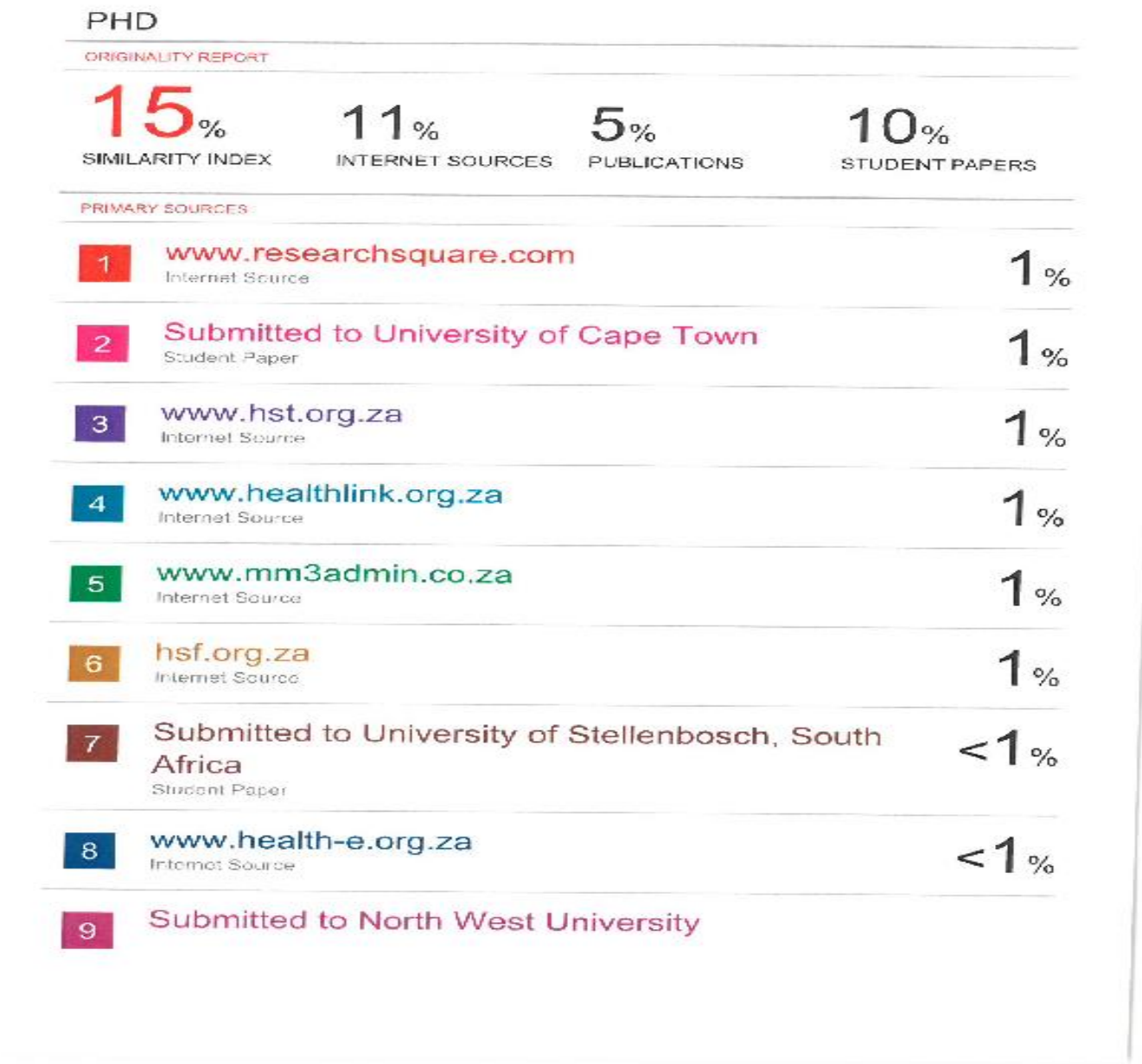
GP saving	GP encoun(nonnet)	Med acuteacc	Med acutexc	Med accpat	Med excpat	Med inspat	Med acc chr	Med insure chr
	Encounter GP non net	Acute account (claimed)	Acute excess	PAT claimed	PAT excess	Insured PAT	Claimed Chronic	Insured chronic

Ahw en	Ahw tar	Ahw acct	Ahw risk	Ahw saving	Sp enco	Spe tarrif	Spec acc	Spec risk	Spec sav	Hospital cost
Allied health workers					Specialist visit		Specialist claimed			Hospital costs

number of chronic conditions

APPENDIX C

Turn-it-in report



PHD

ORIGINALITY REPORT

15%	11%	5%	10%
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6	hsf.org.za Internet Source	1%
7	Submitted to University of Stellenbosch, South Africa Student Paper	<1%
8	www.health-e.org.za Internet Source	<1%
9	Submitted to North West University	

APPENDIX D

APPROVAL FROM DOVEPRESS TO REPRINT JOURNAL ARTICLE UTILISATION OF OVER-THE-COUNTER ANALGESICS IN TWO PRIVATE MEDICAL INSURANCE SCHEMES IN SOUTH AFRICA

RDove Medical Press update on your published paper - Request for information

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Best regards
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APPENDIX D

- **APPROVAL FROM SAJBL EDITOR FOR REPRINT OF ARTICLE ETHICAL ISSUES AROUND ACCESS TO OVER-THE-COUNTER MEDICINES IN SOUTH AFRICA**

Fw: Copyright

From: Ames Dhai <Ames.Dhai@wits.ac.za>
Sent: Sunday, January 26, 2020 9:50 AM
To: Neelaveni Padayachee <Neelaveni.Padayachee@wits.ac.za>
Cc: Claudia Naidu <ClaudiaN@samedical.org>
Subject: RE: Copyright

Dear Veni,
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Good luck going forward.
Ames Dhai
Editor SAJBL

From: Neelaveni Padayachee <Neelaveni.Padayachee@wits.ac.za>
Sent: Monday, 20 January 2020 09:21
To: Ames Dhai <Ames.Dhai@wits.ac.za>
Subject: Copyright

Dear Prof Dhai

How are you? Happy 2020 and wishing you all the best. How is the new edition to the family? I am sure you are enjoying the time.

Please can you advise. I am adding the publication into my dissertation . Do I need to obtain approval from you before this happens?

Thanks
veni