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An Exploratory Study Into the Use and Pricing of Schedule Zero Medicines Post Exemption From the Single Exit Price Policy in South Africa

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Abstract

Background: South Africa, promulgated pricing legislation in 2004 for scheduled medicines except for, schedule zero medicines. The aim of this study was to explore the impact of schedule zero medicine exemption from the Single Exit Price policy in the private sector.

Objectives: The objectives of this study were to determine prescription pricing trends and whether any price differential for a basket of schedule zero analgesics existed across three economic areas; the number of brands available; and prices of over the counter and prescription medicines.

Methods: The medical scheme database was obtained for the period January to June 2014 for prescription schedule zero medicine analysis. Outlets within three economic areas in the eThekwini Municipality were identified for data sampling using a mystery shopper approach. Schedule zero analgesic prices and pack-sizes were recorded on the day of the visit, which occurred from 12 March to 11 April 2015.

Results: An analysis of 14 106 prescriptions from the medical scheme database showed significant differences ($p < 0.05$; CI 95%) when the submitted prices were compared to the cash prices. Dispensing fees were also significantly different ($p < 0.05$; CI 95%). 35 outlets were visited in which 65 schedule zero analgesics were noted. An ANOVA testing for differences between the economic areas indicated significant differences for 4 products.

Conclusion: A more extensive study should be conducted to verify the pricing of schedule zero pricing on prescriptions to ensure that they are not linked to any perverse incentives.

Keywords: analgesic pricing trend, pricing policy, schedule zero, single exit price, South Africa

1. Introduction

There have been many calls to restructure both the private and public sectors of the South African health care system (Jaques & Fehrsen, 2007). While there are many issues that required attention, it was the rising costs of healthcare (Harrison, 2009; Jaques & Fehrsen, 2007), especially the high expenditure on medicines (Bangalee & Suleman, 2015, 2016; Jaques & Fehrsen, 2007; Vogler, 2018) that was a key concern. The pricing of medicines was addressed on a number of occasions under the Apartheid government (Gray, 2009), with the Department of Health constituting Commissions of Inquiry in 1961, 1978 and 1985 to investigate the high costs of health care (Gray, 2009) and most especially high medicine prices.

In 1996, the then Minister of Health, Dr Nkosazana Dlamini Zuma, expressed dissatisfaction at medicine pricing in South Africa and spoke of a new medicines policy, at a time when the country's medicine pricing was amongst the five highest in the world (Zuma, 1997). A National Drug Policy was developed that outlined initiatives to make medicines more affordable and for prices of medicines, from the manufacturers to the point of sale to the patient, to become transparent (Zuma, 1997).

The necessary legislation was amended in 1997 and introduced two inter-related sections, i.e. Section 18A, which banned bonuses and sampling, and Section 22G, which dealt with the creation of a Pricing Committee. This committee was established within the Ministry of Health and had clearly defined functions, these were to monitor and regulate the pricing of medicines and provide for a transparent pricing system that involved the Single Exit Price (SEP) (Bangalee & Suleman, 2016; Gray, 2009). The policy stated that "such price shall be the only price at

which manufacturers shall sell medicines... to any person other than the state", with pharmacists and dispensing practitioners being allowed to charge a "dispensing fee", these provisions coming into effect in 2004 (Berger, 2004; Gray, 2009).

The SEP affects all medicines, except schedule zero medicines, which were exempt, as are veterinary medicines (Berger, 2004). Schedule zero medicines can therefore be sold at outlets other than pharmacies and by persons who were not pharmacists. There is no evidence that indicates that the exemption of schedule zero medicine from the Single Exit Pricing policy is good practice, nor whether they should be included within the policy/regulation. It is therefore necessary to know whether a permanent exemption should be provided at all.

The aim of this exploratory study was therefore to explore the impact of schedule zero medicine exemption from the Single Exit Price Policy (2004) on their use and pricing in the South African private healthcare sector.

This study focused on a basket of schedule zero analgesic medicines as these medicines are available from stores other than pharmacies such as supermarkets, health shops and service stations. Aspirin, low dose paracetamol and vitamins generally fall within this category (IPASA, 2016). For this study, a basket of schedule zero analgesic medicines were considered and consisted of Aspirin-only, Paracetamol-only and a combination of Aspirin and Paracetamol containing products. Furthermore, schedule zero analgesic medicines were selected as part of the study aimed to analyse a medical scheme database to see how and when these schedule zero analgesics were prescribed by medical practitioners and how these prescriptions were then handled in terms of pricing i.e. if dispensing fees were being charged or not and for which disease conditions these medicines were often co-prescribed.

The objectives of this study were: (i) to establish the manner in which a schedule zero analgesic is priced, by comparing their dispensing fees and total submitted fees when prescribed with different medicine categories to determine if there are trends associated with their pricing; (ii) to establish the number of brands available in a specific setting and from medical scheme records; (iii) to determine if there was a price differential for a basket of schedule zero analgesics when purchased over the counter between three different economic areas, and (iv) to compare the pricing of schedule zero medicines purchased over the counter and on prescription.

2. Methods

This exploratory, descriptive and comparative study used a quantitative methodology with random (outlets) and purposive sampling (economic areas) along with a database review; and descriptive and statistical analysis. Ethical approval was obtained from the University of KwaZulu-Natal Humanities and Social Sciences Research Ethics Committee (Protocol reference number: HSS/0154/013). Permission to use information from the medical scheme database was granted, and all data was coded and presented as aggregate information to ensure confidentiality was maintained.

The study setting was the South African private healthcare sector, and included supermarkets, independent community pharmacies and corporate pharmacies in the eThekwini Municipality, KwaZulu-Natal. Three areas were selected, taking into account their unemployment percentage, maximum earning per year, total population, higher education qualifications and race distributions: low-income (Umlazi), middle-income (Berea) and high-Income (Umhlanga) areas (May & Govender, 1998; STATSSA, 2011). Data was obtained from two sources, the first being the type and pricing of Schedule zero medicines from the randomly selected outlets in the three economic areas, and the second from a private medical scheme database for data on patients' claims.

2.1 Prescription Schedule Zero Analgesic Medicines

A medical scheme database was provided and included all items that were claimed from the medical scheme from January 2014 to June 2014. This showed an initial 87 847 patients who made 2 096 833 claims (including all repeat and acute prescription/claims for all patients). A filter was applied to the data to show only schedule zero medicine claims to determine the number of patients who had claimed for these medicines (12 956 patients). Using Microsoft Excel 2007, it was sorted according to the unique coded membership numbers. These 12 956 patients were analysed individually, and their chronic/acute prescriptions were extracted, which resulted in a total of 67 217 claims.

Once all the data on the patient's chronic and acute prescriptions had been obtained, the number of times the different schedule zero analgesic medicines appeared on a prescription was counted and further analysed into different Anatomical Therapeutic Chemical (ATC) categories. Variables extracted from the medical scheme database included: demographic information (age and gender); the schedule zero analgesic and the accompanying medicines on the same prescription that can be dispensed by a licensed pharmacist or a doctor. In addition, the source of payment was extracted: Acute, Chronic, Prescribed Minimum Benefit (PMB), Oncology or Savings.

Three schedule zero medicines (Panado® tablets, Ecotrin® tablets and Bayer Aspirin Cardio® tablets) that are prescribed with the various ATC categories were analysed according to the benefit group that paid for it, the dispenser (pharmacy, doctor), dispensing fees, and total submitted fees for each of the different medical scheme benefit groups. Pricing differentials were calculated for dispensing and total submitted fee within the medical scheme benefit groups (Acute, Chronic, PMB, Oncology, Savings), and the different dispensers (dispensing doctors/pharmacy). This was done to determine if there are any differences or trends in pricing when prescribed with the various ATC categories, based on the medical scheme benefit group that was responsible for payment, as well as the dispenser.

The data was analysed to determine if there was any correlation between scheduled prescription medicines and prescribed schedule zero analgesic medicines. It was also analysed to determine how schedule zero medicines are priced when they form part of a prescription (i.e. the dispensing fee charged and the difference in price when compared to being bought over the counter after adjusting for inflation).

2.2 Over the Counter Schedule Zero Medication

In order to assess whether the basket of medicines were available equitably, shopping Malls that contained supermarkets, corporate pharmacies and independent community pharmacies within the eThekwini Municipality were identified for inclusion in this study. The areas were divided into economic zones as there was no information available on whether access to and distribution of schedule zero medicines varied across economic zones. A sample of these outlets were randomly selected in each of these economic zones, from which the price of each medicine and the number of brands of schedule zero analgesic medicines that were available on the day of data collection were listed (as well as strength, pack size and dosage form). A mystery shopper approach was used to collect this data (Dillip et al., 2012; Bell, Camacho, & Velasquez, 2014; "ESOMAR world research," 2005), whereby the selected outlets were visited and the prices of all schedule zero analgesic medicines that were available on the shelf at the time were recorded. The pack sizes enabled a 'price per tablet' function to be calculated to compare the prices between the stores.

Data collection at these sites began on the 12th of March 2015 and continued until the 11th of April 2015, during which time thirty five outlets were visited. This included thirteen supermarkets (within seven shopping malls), sixteen independent community pharmacies and six corporate pharmacies. In the low-income area, this consisted of two supermarkets, one corporate pharmacy and five independent community pharmacies (23% of the outlets). In the middle-income area, there were four supermarkets, three corporate pharmacies and seven independent community pharmacies (40% of the outlets). The high-income area had seven supermarkets, two corporate pharmacies and four independent community pharmacies (37% of the outlets).

3. Results

The results that follow are organised in terms of the four objectives of this study, as listed at the end of the introduction.

3.1 Prescription Schedule Zero Analgesic Medicines

From the medical scheme database prescriptions of schedule zero analgesics, 14 101 prescriptions were analysed, of which 7 205 (56%) were for males and 5 751 (44%) for females, (n = 12 956 patients). The average age of patients was 61.36 years (ranging from 0 to 99 years old). Claims of the 14 101 schedule zero analgesic were as follows: 7 100 were claimed from the Acute, 851 from the Chronic, 13 from Oncology, 6 021 from PMB and 116 from Savings benefit group.

Medicines from 14 ATC categories were prescribed in conjunction with schedule zero analgesics, of which the most common categories were Blood and Blood forming organs (72.91%), Cardiovascular System (72.89%) and Central Nervous System (48.39%). (See Table 1 for all ATC categories)

Fifty-one percent (7 249) of the 14 101 prescriptions claims had no co-payments (the medical scheme had paid the total cost). The remaining 6 857 (49%) claims had co-payments that ranged from ZAR 0.01 to ZAR 64.93. Of the 14 101, claims, 4402 (31%) did not include a dispensing fee, with the remaining 9 704 claims (69%) having dispensing fees that ranged from ZAR 0.10 to ZAR 47.67. Of these 14 101 schedule zero analgesic containing prescriptions, 10 888 (77%) were provided by a dispensing pharmacist (PD), and 3 213 (23%) by dispensing doctors (DD), with the latter not charging a dispensing fee in most cases (98%; n = 3153).

Table 1. ATC categories with which schedule zero analgesics are prescribed

ATC Category	Number of Prescriptions	Percentage
Blood and Blood forming Organs	9446	72.91%
Cardiovascular System	9444	72.89%
Central Nervous System	6270	48.39%
Alimentary Tract and Metabolism	5558	42.90%
Musculoskeletal System	2895	22.34%
Respiratory System	2489	19.21%
General Anti-Infectives for Systemic use	2387	18.42%
Systemic Hormonal preparations, excluding sex hormones and insulins	1731	13.36%
Genitourinary System and Sex Hormones	1023	7.90%
Dermatological	368	2.84%
Sensory Organs	352	2.72%
Antineoplastic and Immunomodulating agents	128	0.99%
Various	108	0.83%
Antiparasitic Products	62	0.48%

Note. Prescriptions may contain one or more ATC category and that is why the percentages do not add to 100%.

3.2 Comparison of the Dispensing Fees Amongst the Different Medical Scheme Benefit Groups and ATC Categories, and Dispensers

A comparison was undertaken of the dispensing fees using the ANOVA test. This was conducted on three medications: Panado®, Ecotrin® and Bayer Aspirin Cardio®.

3.2.1 Panado®

The testing showed no significant differences between the benefit groups of the medical scheme when Panado® was concerned across all ATC categories. When dispensers where compared, there were significant differences in dispensing fees, with medicines being dispensed by pharmacies having a tendency to be significantly higher (113%) priced than that of those dispensed by doctors.

When ATC categories were compared, the dispensing fees differed in the total average dispensing fees for each category, and highest when prescribed with Antineoplastic and Immunomodulating agents. The dispensing fees for all ATC categories ranging from ZAR 0.00 to ZAR 0.25. The analysis also showed that there were significant differences in dispensing fees that were claimed from the acute benefit group for each ATC category.

3.2.2 Ecotrin®

There were significant differences between the benefit group of the medical scheme for Ecotrin® in five (36%) of the 14 ATC categories. The dispensing fees were higher in the Savings category. Medicines dispensed by pharmacies had a significantly higher (290% higher) price than that of those dispensed by doctors. When ATC categories were compared, the dispensing fees did not differ in any benefit group or by any of the dispensers.

3.2.3 Bayer Aspirin Cardio®

There were no significant differences in price between the medical schemes' benefit groups when Bayer Aspirin Cardio was the schedule zero analgesic, except for one of the fourteen ATC category (Alimentary tract and metabolism). There were however significant differences in dispensing fees, with pharmacies generally being significantly higher (440% higher) than doctors, almost all whom did not including a dispensing fee. Differences occurred in the dispensing fees of 12 (86%) of 14 ATC categories. When the dispensing fees of the ATC categories were compared, they did not differ in any benefit group or between dispensers.

3.3 Comparison of the Total Submitted Fees Amongst the Different Medical Scheme Benefit Groups and ATC Categories, and Dispensers

A comparison of the total submitted fees using the ANOVA test was conducted on three medications: Panado®, Ecotrin® and Bayer Aspirin Cardio®.

3.3.1 Panado®

There were no differences between the various benefit groups for the total submitted fees for each ATC category. However, 13 (93%) of the 14 categories showed significant differences when dispensers were compared. One trend was that the submitted fees claimed by pharmacies were higher than those claimed by dispensing doctors, these being higher by 4%. There were no differences for any of the benefit groups or dispensers when compared by ATC categories.

3.3.2 Ecotrin®

There were significant differences between the benefit groups for the total submitted fees in six (43%) of the 14 categories, with the claims from the Oncology benefit group having the highest average submitted pricing. There were also tendencies for significant differences when dispensers were compared with of 12 (86%) of the 14 categories being indicated. On average, the submitted fees claimed by pharmacies were higher (2% higher) than those claimed by dispensing doctors. There were no differences for any of the benefit groups or dispensers when compared by ATC categories.

3.3.3 Bayer Aspirin Cardio®

There was a significant differences between the benefit groups for the total submitted fees in five (36%) of the 14 categories, with the claims from the Savings benefit group having the highest average submitted pricing. There were also significant differences when dispensers were compared with 10 (71%) of the 14 categories being indicated. On average, the submitted fees claimed by pharmacies had a tendency to be higher (3% higher) than those of dispensing doctors. When compared by ATC categories, there were significant differences for the total average submitted fees, the PMB benefit group and when claimed by a pharmacy. On average, the claims from the General Anti-Infectives for Systemic use ATC category were the highest in the total average group, with the Various ATC category having the highest submitted fees in the PMB benefit group. There were also significant differences in the fees when submitted by a pharmacy.

Details of the information provided in the summaries above are available in Supplementary Tables 1 and 2.

3.4 Comparison of the Prices of Over-the-Counter Basket of Schedule Zero Analgesics Between Three Different Economic Areas and the Number of Brands Available

There were 65 over the counter schedule zero analgesic products, of different pack sizes in the three economic areas. The low-income area had 43 of 65 (66.15%) of these items, the middle-income area had 64 of 65 (98.46%), and 57 of 65 (87.69%) were found in the high-income area outlets.

In the low-income area, Paracetamol (Panado®) 500mg tablets (pack size of 24's) was the most commonly found product, (at six of the eight outlets; 75%), with an average price per tablet of ZAR 1.04. Aspirin (Disprin® Extra strength 24's) tablets were the most common in the middle-income area (available in 13 of the 14 outlets; 93%) outlets, with an average price per tablet of ZAR 1.70. Paracetamol and Aspirin (Med Lemon®) sachets of eight, and Paracetamol (Panado®) 24 tablet pack of 500mg tablets were the most frequently found schedule zero analgesic in the high-income area (found at 10 of the 13 outlets ;77%), with an average price of ZAR 4.55 and ZAR 0.99 per sachet and tablet, respectively. The most frequently found schedule zero analgesic among the three income areas was Panado® 500mg tablets (pack size of 24's), found in 27 of the 35 (77%) outlets in all three income areas.

Using SPSS, a one sample t-test was used to determine if there were any differences in the prices of medicines within a single income area. The individual prices were compared to the average price for that medicine within the income area, and there were no significant differences ($p > 0.05$; CI 95%). The ANOVA test was used to determine if there were any statistical differences between the average prices of the medicines among the three different income areas. The ANOVA tested a null hypothesis (with a 95% confidence interval) that the mean of each medicine for each area was the same, with only 4 medicines of the 65 (6.15%) showing significant differences ($p < 0.05$; CI 95%). These items were:

- Grandpa® tablets (Paracetamol and Aspirin - pack size of 38's), prices were highest in the high-income area and lowest in the middle-income area;

- Clicks Paracetamol® tablets (Paracetamol - pack size of 24's), prices were highest in the middle-income, lowest in the high-income area and not found in the low-income area;
- Bayer Aspirin Cardio® tablets (Aspirin - pack size of 30's), prices were cheapest in the low-income area and highest in the high-income area;
- Anadin® Extra tablets (Aspirin - pack size of 30's), prices were highest in the low-income area and the same price in the middle- and high-income area.

3.5 Comparison of Over the Counter and Prescription Prices for Schedule Zero Analgesic Medicines

A comparison of the schedule zero analgesic medicines acquired on prescription with those bought privately with cash was undertake to detect any price differences. A total of 68 brands of schedule zero analgesic medicines were claimed from the medical scheme, of which 28 were also available at the over the counter sites (supermarkets, independent community pharmacies and corporate pharmacies).

The costs of the schedule zero analgesic medicines submitted to the medical scheme consisted of ingredient price, the dispensing fee and the calculated tax for the submitted ingredient price. This total submitted price was then compared to the purchase price of the schedule zero analgesic when obtained at over the counter outlets that were initially visited. The low-income area had 23 of the 28 common medicines, with 27 and 23 common medicines in the middle- and high-income areas respectively.

The prices submitted to the medical scheme were then compared to the price of the medicine at the outlets in the different economic areas. Using SPSS version 23, a one sample t- test was performed to compare the submitted price (via medical scheme) to the prices in the low-income area. One of the 23 (4.35%) medicines resulted in a p value of less than 0.05, indicating that their prices were significantly different. The same test showed that eight of the 27 (29.62%) medicines for the middle-income and seven of the 23 (30.43%) for the high-income area had a p value of less than 0.05, indicating that their prices significantly differed. On average, the prices submitted to the medical scheme had a tendency to be higher (23.91% higher) when compared to average prices in the low-income area, 0.66% lower for the average prices in the middle-income area, and 7.3% higher for the average prices in the high-income area when compared to those purchased over the counter.

The average medical scheme submitted price was then compared to the average prices of the different economic areas combined for the common schedule zero medicines, and showed that eight of the 28 (28.57%) medicines had significantly different prices ($p < 0.05$, CI 95%). The average medical aid submitted prices showed a tendency to be 1.5% higher than that bought over the counter for all economic areas combined.

Details of the information provided in the summaries above are available in Supplementary Tables 3 and 4.

4. Discussion

There were many brands of the over the counter schedule zero analgesic medicines, available and evenly distributed throughout the three areas that were analysed, with little difference in prices among them. The highly competitive nature of business may have had an effect on the pricing of these medicines, this being the reason for similar prices.

With regard to schedule zero analgesic medicines prescription review from the medical aid database, most analgesics were claimed from the Acute benefit group, indicating that physicians considered them to be short term treatments for those pain related ailments. Half of the claims had no co-payments and slightly less than one-third had no dispensing fee attached, these being from doctors.

With regard to the comparison of submitted fees across ATC categories, benefit groups and the dispensers of schedule zero medicines on prescription, a higher fee was noted for pharmacy submissions than doctors. Submitted prices also had a tendency to differ between ATC groups and benefit groups. Total submitted fees included dispensing fees amongst other costs, as doctors were not charging this fee their total submitted fee was lower. Doctors generally charge a consultation fee plus the claim from the medical schemes for the medicines that have been prescribed, whereas pharmacists do not charge a consultation fee but only for the submission to a medical scheme. The differences in submitted fees between ATC categories and benefit groups may indicate that medical schemes may deem schedule zero medicines more important or more useful when prescribed with certain ATC categories or when it's paid by different medical scheme benefit groups than others. However, this would require further research to validate the above statement.

Prices of schedule zero medicines on prescription tended to be higher, due to the fact that over the counter schedule zero medicines will not include dispensing fees as opposed to these medicines on prescription. A prescription must be filled by a trained health care professional (pharmacist or doctor) and hence the higher price when they are

compared. This means that schedule zero medicines are subjected to a dispensing fee, with no regulation of this fee due its exemption from the Single Exit Price policy. It is unknown whether a higher dispensing fee arrangement has been negotiated for schedule zero medicines on prescriptions with medical schemes as part of the overall negotiations for lower dispensing fees for other medicines that are included within SEP. Further research on the calculation of dispensing fees for schedule zero medicines is required including the proportion of the dispensing fee to the total cost of prescription. In addition, it is not known whether the dispensing fee changes during the course of the year, as the price of the schedule zero product is changed, or if that fee is static. These are all unintended consequences due to the exemption from the Single Exit Price policy, which is intended to control and make transparent the pricing of medicines along with controlling dispensing fees.

Research of this nature has not been published in South Africa before, making it difficult to compare the findings of this study on the effects of the schedule zero medicines exclusion from Single Exit pricing policies. A literature search also indicated that research only on schedule zero medicines has not been published elsewhere. Studies done by Sun et al. (2008) in China and by Nguyen et al. (2010) in Vietnam indicate their methods of controlling medicine prices as a whole, not schedule zero level medicines only. In Vietnam, the methods of controlling medicine prices included a modified free market pricing structure, and the Pharmaceutical Law No 34/2005/QH11 stated that medicine suppliers and distributors are free to set prices of their products based on market forces, subject to stabilization by the State (Nguyen, Knight, Mant, Cao, & Brooks, 2010). These prices had to be deemed reasonable (not to be higher than prices of medicines of the same categories) when compared to prices of the same medicines in comparable countries (however, which price that needs to be reasonable, i.e. ex-factory, wholesale, retail, before or after tax price was not specified) (Nguyen et al., 2010).

In China, the National Development and Reform Commission (NDRC) issued many policies on drug pricing, some of which set maximum retail prices for medicines that are included in the essential medicine list of the urban basic medical insurance (BMI). The maximum retail prices were based on a mark-up above the average production cost declared by manufacturers, with all other medicine prices being market based (Sun, Santoro, Meng, Liu, & Eggleston, 2008).

Schedule zero medicines, due to exemption, could be subjected to perverse incentive arrangements (Berger, 2004). However, this would need to be investigated in a separate study.

In Bolivia, a National Drug Policy was implemented recently and is based on two main pillars: firstly, the National System for Monitoring and Medicine Control of Drugs was introduced and is supported by the country's Medicines Act and accompanying regulations. This allows the government to regulate the importing, production, distribution, sale advertisement and surveillance of drugs in order to protect the population from the harmful effects of fraudulent products/activity that occur in the pharmaceutical supply chain. Secondly, the Unified National Supply System, which led to the creation of the Center of Procurement and Supply, ensures that all essential drugs are easily accessible to the country's network of public health institutions at a reasonable price. This Center established standards for criterion that must be met for suppliers as well as best practices for procuring medicines through state owned and run institutions. It also provides technical and quality requirements for the various types of procurement contracts. However, the process that is used to determine a 'reasonable' price is unclear (Kohler, Mitsakakis, Saadat, Byng, & Martinez, 2015).

Other types of medicine pricing control are reference pricing (WHO, 2015) as a cost-containment method. Reference pricing is a policy strategy used by the United States (Lee, Fischer, Shrank, Polinski, & Choudhry, 2012) to set a standard price or reimbursement level for a group of therapeutically interchangeable drugs, and is often based on the lowest cost member of the class. The different manufacturers of the drugs within this class can choose to price their products above or below the reference level set. This method of price regulation should be rolled out and controlled by the government and should be legislated, it should also be used together with other cost containment methods (WHO, 2015). The dispenser can offer the patient brands that fall within or outside the reference price. The patient is then responsible for any costs above the reference level. This is also sometimes known as the 'maximum allowable cost' (MAC) programme in USA (Lee et al., 2012). A study by Lee et al. (2012) in the USA showed that four out of nine reference price policies they reviewed had resulted in a significant reductions in the price of targeted drug classes, with a mean reduction of 11.5% (range 7%–24%).

The use of generic medicines is another method for medicine pricing (WHO, 2015) . Generic medicines are a vital instrument for governments to maintain their health care systems and control pharmaceutical expenditure. Generic medicines provide an opportunity to obtain similar treatments at a lower cost to patients and payers, their use being endorsed by the World Health Organisation (Simoens, 2012:8). A study by Simoens compared the international pricing of generic medicines in ambulatory care in 2005. The prices were compared between nine European

countries (Belgium, Denmark, France, Germany, The Netherlands, Norway, Spain, Sweden and UK) and with India. The study showed that the prices at which a pharmaceutical company sells generic medicines significantly varied between these European countries (Simoens, 2012). This indicates that the problem of varying medicine prices from the manufacturers is not unique to South Africa, but occurs globally.

Limitations of the study included time, which necessitated restricting the study areas to three economically identifiable spaces within the municipality. A number of the private retail outlets had stock-outs of some drugs at the time of data collection, which may have affected the overall results. However, the data that was collected was considered to show a number of significant differences, and this limitation is not considered to have affected the results substantially. An analysis of the medical scheme database over a longer time period may have provided different results, but the consistency in trends suggests that the results are an indication of the current status of prescribing and pricing practices.

Of concern is higher prices being submitted to medical schemes for payment of schedule zero analgesic medicines, which can lead to a depletion of the Savings benefit group or result in the maximum for any benefit group being reached earlier than if they had been paid for over the counter. This depletion can lead to the patient having to pay out-of-pocket for these medicines, or even other prescribed medicines or services that those funds could have been used had there not been the additional costs. While this could potentially impact on adherence to chronic medication, more research is required to confirm this.

5. Conclusion

This study has indicated that pricing variations exist for schedule zero analgesic medications that has implications for the patients who use them. As this study was limited to three geographic areas in one urban municipality and one medical aid, a more expansive study should be conducted that includes both rural and urban areas in the country, a greater number of outlets, and other medical scheme databases for a longer time period. This would corroborate the findings of this study and support the need to consider including these medicines into the country's medicine pricing policies.

This study, being the first of its kind in South Africa, can serve as a basis for future studies regarding schedule zero medicines. Additional research is recommended on a number of issues, such as establishing the effects of depleting medical scheme Savings or other benefits due to irregular pricing on adherence to chronic medications. Whether pharmacists allow these medicines to be paid for separately at a lower price or process them on a prescription and charge accordingly. In addition, studies are needed to determine if the consumers are given options to buy them as an OTC product.

The legislation regarding medicine pricing was put in place to ensure that people not only have access to the medication that they need, but that it is affordable throughout the country. Medication forms an important part of health care and ensuring that people live a good quality of life. In a world where there are millions of people suffering with many types of ailments which require medication, the availability and affordability of these medicines across all economic statuses is paramount. With medicines being available and affordable it may well increase the quality of life for many, which at the end is the goal that needs to be achieved by all governments and health care practitioners.

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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