Potential cost savings from generic medicines – protecting the Prescribed Minimum Benefits

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Abstract

Background: South Africa has followed a pro-generic policy since the introduction of the National Drug Policy in 1996. The selection processes in the public and private sectors have, however, remained largely disconnected, and at times contradictory. Medicines provided outside of hospitals accounted for 17% of medical aid spend in 2006, up 8.8% from the previous year. Of particular concern to funders has been the expenditure on the 27 chronic conditions listed as Prescribed Minimum Benefits. The Medical Schemes Act (No 131 of 1998) provides for the definition of Prescribed Minimum Benefits, which stipulate a package of services or care a medical scheme must provide for in its benefit design. There is pressure to reconsider these requirements in order to increase the affordability of medical scheme coverage. This study assessed the potential savings that would be achievable by substituting generics for brand name (originator) medicines listed in the chronic disease algorithms set out by the Council for Medical Schemes (CMS).

Methods: All medicines listed in the 25 chronic diseases algorithms made available by the CMS were identified. Brand and generic versions were identified in the Monthly Index of Medical Specialties (MIMS, May 2006). Single exit prices inclusive of value added tax were obtained from the web site of the Pharmaceutical Blue Book and the cost per defined daily dose for one month was then calculated. Cost differentials, where available, were then identified for each medicine listed in the algorithms. Cost differentials for medicines within each algorithm were presented as the median of the difference between brand and generic medicines listed for that algorithm, and also as the median of differences between generic medicines for the same condition.

Results: Three of the algorithms (diabetes insipidus, haemophilia and hypothyroidism) list medicines for which no generic equivalent was available at the time of the study. The median cost differential between brand and generic equivalents for the remaining 22 chronic conditions ranged from 19.5% (for type 1 diabetes mellitus) to 97% (for Addison's disease). Across the entire chronic disease algorithm set, 80 medicines with generic equivalents were listed for 22 conditions. The median cost differential between brand and generic versions of these 80 medicines was 49.9% (interquartile range 32.0 to 78.5%). Of all generic medicines identified, 67.5% were more than 40% cheaper, per defined daily dose (DDD) per month, than the branded version. In 16 medicines the cost differentials between generic versions were 1% or less. Some correlation between the number of generics and the size of the cost differential was apparent (correlation coefficient 0.49). There were examples of high-cost differentials in highly competitive areas of the market.

Conclusions: An argument could be made for more closely aligning the process of developing the National Essential Drugs List and the development of the CMS algorithms. By being more specific about which medicines should be covered, needless expenditure on "me-too" agents of doubtful additional benefit could be avoided. Where clinically warranted, appropriate choices could be provided. Finality in respect of the pricing of medicines needs to be achieved. This applies not only to the dispensing fee but also to the proposed benchmarking process and the proposed differential between brand and generic medicines.

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Introduction

South Africa's National Drug Policy, approved by the Cabinet in 1996, committed the country to the use of generic medicines as a key cost-savings mechanism.[1] One of the stated aims of the policy was "[t]o promote the availability of safe and effective drugs at the lowest possible cost". The means to achieve this was stated as follows: "This aim will be achieved by monitoring and negotiating drug prices and by rationalising the drug pricing system in the public and private sectors, and by promoting the use of generic drugs". The detailed policy prescription went further: "The policy will aim at achieving generic prescribing in both the public and private sectors. Until this aim is achieved, generic substitution will be allowed, through legislation, in the public and the private sector". A pro-generic stance was also signalled in respect of medicines selection: "A National Essential Drugs List Committee (NEDLC), appointed by the Minister of Health, will be responsible for the selection of drugs to be used in the public sector. … The NEDLC will draw up and periodically review a National List of Essential Drugs using generic names". However, the extent to which this selection would impact on the private sector was seen as less certain. While the Essential Drugs

List would be used as the foundation for many aspects in the public sector, including "the basic health care package of the National Health System for Universal Primary Care" and "standard treatment guidelines and training in rational prescribing", its application in the private sector was left almost to chance: "The list may also be used as a model for medical aid schemes".

Medicines dispensed outside of hospitals (by pharmacists and dispensing practitioners) accounted for 17% of medical scheme benefits paid out in 2006. This reflected an increase of 8.8% over the previous year, totalling R8.7 billion.[2] Of particular concern to funders has been the expenditure on the 27 chronic conditions listed as Prescribed Minimum Benefits (PMBs). The Medical Schemes Act (No 131 of 1998) defines PMBs as a package of services or care a medical scheme must provide for in its benefit design.[3] The PMB package was extended with the introduction of a chronic disease list (CDL) and an accompanying set of prescribed treatment algorithms (for 25 conditions) in late 2003.[4] The CDL was expanded later to include HIV/AIDS and bipolar mood disorder, but no algorithms were provided for these two conditions. Only the algorithm for multiple sclerosis has been amended.[5] In terms of HIV/AIDS, the injunction is that a medical scheme should provide at least those services and treatments that are provided by the state. Medical schemes have to provide benefits and pay for the full management of the 27 conditions with no co-payments. In order to contain the costs incurred by providing PMBs for the chronic conditions and to ensure that schemes can financially cover their members who need this benefit, the Regulations to the Medical Schemes Act have allowed certain measures to be introduced by the medical schemes.[6] Schemes are, for example, permitted to draw up a list of safe and effective medicines (known as a formulary) to treat certain conditions. Many of these medicines would be expected to be generics and if a brand name medicine were prescribed and dispensed, the scheme would have the right to limit coverage to the cost of a referenced generic version. Despite these measures, the costs of providing PMB cover remain a concern. In the Council for Medical Schemes (CMS) 2006/2007 Annual Report it was stated that proposed rule amendments to their benefit options submitted by 41% of open medical schemes were initially rejected. One of the reasons listed for initial rejection was "inadequate provisions being made for Prescribed Minimum Benefits".[2] A recent newspaper article has cited three medical scheme industry priorities for the future.[7] In order to attract new members, industry commentators felt that there needed to be changes made to the PMB legislation, greater use of contracted provider networks and better benefit design for low-income medical schemes.

Protecting the PMBs, as a key element of the new community-rated medical schemes environment, is therefore vital. One way to do this would be to limit the costs of medicines provided for the management of chronic conditions listed in the PMBs. This study assessed the potential savings that would be achievable by substituting generics for brand name (originator) medicines listed in the chronic disease algorithms set out by the CMS.

Methods

Ethics approval was obtained for this research project. A census was conducted of the 25 chronic diseases for which algorithms were made available by the CMS. All medicines listed were then sought in the South African Medicines Formulary (7th edition). Where a pharmacological class rather than a specific medicine was listed in the algorithm, all examples of the class listed in the South African Medicines Formulary were included. Brand and generic versions were identified in the most accessible form available to medical practitioners, namely the Monthly Index of Medical Specialties (MIMS). The May 2006 issue was used. Brand versions were those initially registered by an innovator or research-based pharmaceutical manufacturer, whereas generic versions were those of the same strength and dosage form, registered after patent expiry or as licensed by the patent-holder.

Single exit prices (SEPs), inclusive of value added tax, were obtained from the web site of the Pharmaceutical Blue Book (http://www.pbb.co.za/). All SEPs were obtained prior to the increases allowed from January 2007. The cost per defined daily dose (DDD) for one month (defined as 30 days) was then calculated. DDDs were obtained from the web site of the World Health Organization (WHO) Collaborating Centre for Drug Statistics Methodology (http://www.whocc.no/atcddd/). This site defines a DDD as follows: "The DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults". DDDs may not, however, bear any direct relation to the actual doses prescribed nor match the most appropriate clinical dose. They are, nonetheless, a standard applicable to utilisation studies and allow comparison across different care settings. Given the uncertainty in the market relating to dispensing fees, these were not included in cost calculations. The listing of medicines as "non-substitutable" by the Medicines Control Council was also not taken into account, as each of these could potentially be prescribed as the generic version, if available, based on an individual's assessment. While, in this case, substitution by the pharmacist is proscribed, the prescriber would have the option of choosing a generic, either initially or for a patient who has previously been treated with a branded version. Cost differentials, where available, were then identified for each medicine listed in the CMS algorithms. Cost differentials for medicines within each algorithm were presented as the median of the difference between brand and generic medicines listed for that algorithm, and also as the median of differences between generic medicines for the same condition.

Results

Three of the CDL algorithms list medicines for which no generic equivalent was available at the time of the study. These were diabetes insipidus, haemophilia and hypothyroidism. The median cost differential between brand and generic equivalents for the remaining 22 chronic conditions ranged from 19.5% (for type 1 diabetes mellitus) to 97% (for Addison's disease). Of these, three conditions involved the use of only one generic equivalent and, therefore, a comparison between two or more generics was not possible. These were diabetes type 1, glaucoma and Parkinson's disease. The median cost differentials between brand and generic versions and between generic versions per algorithm are shown in Figure 1.

Across the entire CDL algorithm set, 80 medicines with generic equivalents were listed for 22 conditions. The median cost differential between brand and generic versions of these 80 medicines was 49.9% (interquartile range 32.0 to 78.5%). Of all generic medicines identified, 67.5% were more than 40% cheaper, per DDD per month, than the branded version.

Cost differentials between generic medicines were not always as large as may have been expected. Table I shows a list of 16 medicines for which cost differentials of 1% or less were seen.

Figure 1: Median cost differentials per CDL algorithm

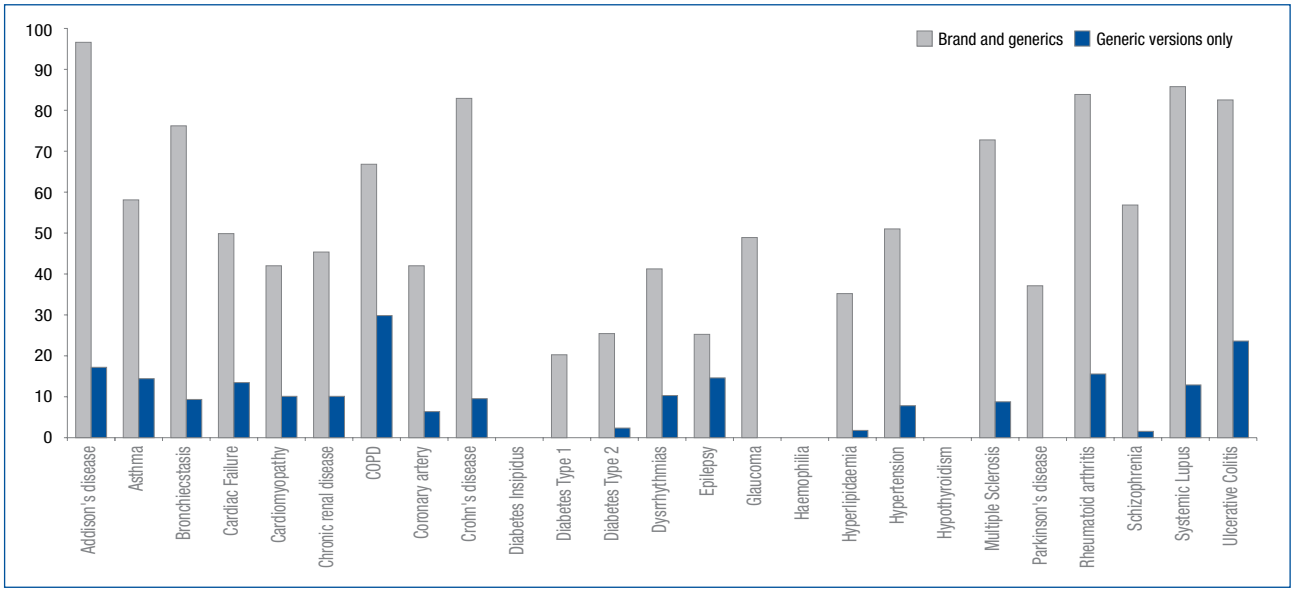

Figure 2: Number of generic versions available versus cost differential between brand and generic medicine

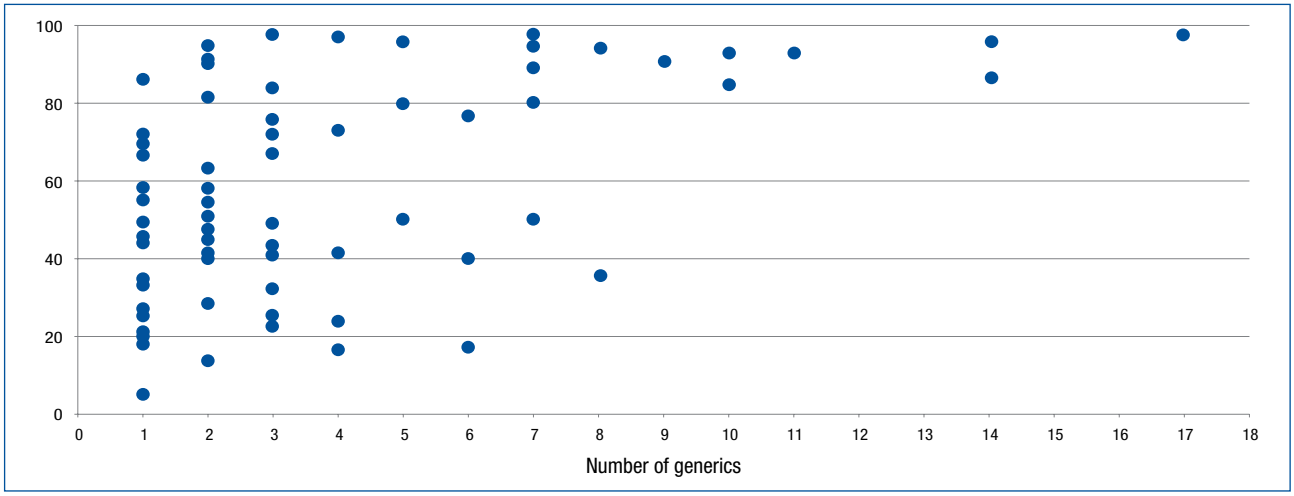

Table I: Medicines for which the cost differential between generic versions was 1% or less

Medicine	Cost differential between generic versions (%)
Amoxicillin capsules 500 mg	0.1
Doxycycline tablets 100 mg	0.9
Enalapril tablets 20 mg	0.0
Ramipril capsules 10 mg	0.0
Ciprofloxacin tablets 500 mg	0.9
Metronidazole infusion 500 mg/100 ml	0.0
Glimepiride tablets 4 mg	0.0
Amiodarone tablets 200 mg	0.0
Pravastatin tablets 40 mg	0.1
Indapamide tablets 2.5 mg	1.0
Spironolactone tablets 25 mg	0.0
Oxybutynin tablets 5 mg	0.5
Sulpiride capsules 50 mg	0.0
Clozapine tablets 100 mg	0.0
Clomipramine tablets 25 mg	0.1
Dosulepin tablets 75 mg	0.1

Competition theory would seem to support a contention that the cost differential between the branded and the lowest priced generic version would be related to the number of generic equivalents on the market. The maximal cost differentials are often only achieved when at least nine such products are on the market. In order to test this contention, within the narrow sample of medicines used in the management of chronic conditions, the cost differentials were plotted against the corresponding number of generic equivalents (Figure 2).

A weak correlation between the number of generics and the size of the cost differential was apparent (correlation coefficient 0.49). There were examples of high-cost differentials in highly competitive areas of the market. For example, 17 generic versions of metronidazole were identified, and the cost differential between the brand and generic versions was 96.9%. There were, however, exceptions. While only one generic version of imipramine was identified, the cost differential compared to the brand version was 85.4%. The median cost differentials associated with different numbers of generic versions are shown in Table II.

Table II: Cost differentials associated with different numbers of generic versions

Number of generic versions identified	Total number of medicines represented	Median cost differentials between brand and generic versions (%)
1	25	35.0
2	17	50.9
3	12	45.8
4	5	41.5
5	3	79.5
6	3	39.4
7	5	88.4
8	3	35.2
9	1	90.4
10	2	88.3
11	1	92.4
14	2	90.6
17	1	96.9

Discussion

This study has shown that, for the medicines listed (either as individual medicines or as pharmacological groups) in the CDL algorithms, which form the basis for the Prescribed Minimum Benefits that have to be provided by all medical schemes, a substantial number are available as both brand and generic versions. Of the 25 CDL conditions for which specific algorithms were provided by the CMS, all but three listed medicines for which a generic version was available. An important limitation of this study was that only those generic versions listed in MIMS were identified. It is probable that more generic versions were on the market at the time of the study, but neither listed in MIMS, nor easily identified in the pricing source used. It is also possible that these unidentified generic versions were priced even lower than were those listed in MIMS. If that were the case, then the cost differentials calculated would have represented an under-estimate of the possible savings.

Another important limitation is that no account was taken of the prevalence of the conditions included. The CMS has included a listing of the percentage prevalence of the 25 CDL conditions as a group, and for the 10 most prevalent of these conditions, but has also expressed concern about the quality of the data submitted by medical schemes.[2] However, even these figures do not allow for the prevalence of use of individual medicines in each algorithm to be determined with any certainty. Previous studies in South Africa have addressed this problem in different ways, and have provided quite different estimates of the potential costs savings that might accrue from increased use of generics. Based on a random sample of prescriptions taken from 10 pharmacies, Abdool Karrim et al estimated that a cost savings of 9.9% would have been possible if generic equivalents were substituted in those cases where the brand name products were specifically prescribed.[8] This was broadly consistent with a far older study, which had estimated that cost savings of about 9.3% (based on 1989 data) would be possible if a maximum medical aid price (MMAP) system were to be introduced, in terms of which a specified maximum price would be paid for off-patent products that had generic equivalents.[9] More recently, Djolov has used total private sector sales of the 200 most-sold medicines (in 2001) as the basis for calculating the potential costs savings if the least expensive version of the 46 products for which a generic was available (identified from MIMS) was supplied instead.[10] Potential savings (6.1%) were represented as the percentage of the total sales for the top 200 products, which represented 53% of the private sector sales value of all "ethical" medicines in 2001. This author argued that the mandatory nature of the state's intervention in this area would not only achieve little in the way of savings, but would also reduce innovation and, perhaps, increase the risk of innovator manufacturers leaving the local market. Our study has shown potential costs savings in particular CDL conditions may be far higher. These include CDL conditions listed by the CMS as being the 10 most prevalent, based on available data. The 10 most prevalent CDL conditions reported were hypertension, hyperlipidaemia, asthma, ischaemic heart disease, cardiomyopathy, cardiac failure, hypothyroidism, type 2 diabetes mellitus, epilepsy and type 1 diabetes mellitus. The potential savings have been reported in percentage terms, based on the cost per DDD per month. As mentioned previously, this is an artificial measure, designed for pharmacoepidemiological studies. Assessing the exact cost implications in a particular patient is complicated by the differences in doses actually prescribed. Some indication, however, can be gleaned from the following examples. The single exit price of 50 tablets beta-blocker propranolol 40 mg at the time of this study ranged from R135.39 for the brand version to R6.78 for the lowest priced generic (a differential of 95%). Similarly, the difference between the single exit price for atenolol 100 mg 30s was 88% (R204.06 for the brand and R25.02 for the generic version). A lower differential of 42% was seen for carvedilol 25 mg 30s (R99.84, compared with R58.40). An analogous situation could be seen in relation to the angiotensin converting enzyme inhibitors: captopril 25 mg 60s (R153.38 for the brand version; R20.98 for the generic; 86%), analapril 10 mg 28s (R39.62; R28.49; 28%), and ramipril 5 mg 30s (R155.53; R90.97; 42%).

Some of the CDL conditions illustrate a particular problem with the algorithms, as currently stated. Where a pharmacological class is stated (such as the angiotensin converting enzyme inhibitors), this would include not only the earlier members of the class, for which generic versions may have been developed, but also later patented, and thus patent-protected, versions, some of which may have marginal benefits, if any.[11] Such "me-too" medicines may add to the average costs of applying the algorithm, without adding any clinical benefit. Where no preference is explicitly stated in the algorithm, the onus is on the scheme to develop a more detailed formulary or reference pricing system in order to avoid increased expenditure. In contrast, the public sector standard treatment guidelines (STGs) follow the convention of the WHO's Model Essential Medicines List. An example from a class such as the angiotensin converting enzyme inhibitors would be listed, but each provincial service would be expected to procure only one from the class, and not necessarily make available a selection. Other pharmacological classes that could be problematic in this regard are the sulphonylureas, the inhaled corticosteroids, the inhaled anticholinergics, the oral beta-blockers, and the hydroxy-methylglutaryl-coenzyme A reductase inhibitors (statins). The inhaled anticholinergics provide a particular challenge. This class is represented by two very different products, ipratropium and tiotropium, which vary in many regards, including price. At times, the CMS algorithms differ markedly from the public sector STGs. Examples include the inclusion of the angiotensin receptor blockers in hypertension, prostaglandin analogues in glaucoma, and the broad range of products provided for in schizophrenia. It is beyond the scope of this

study to comment on the applicability of each of these inclusions. As with the use of broad pharmacological classes instead of identified medicines or exemplars of a class, some justification may be possible, on the basis of high quality evidence. However, the CMS algorithms provide no evidentiary basis for any inclusions or exclusions.

Conclusion

The CMS announced in its 2006/2007 Annual Report that the process of obtaining comment on the CDL algorithms had been completed, and that revisions were in the process of being prepared. Given the problems identified in this study, an argument could be made for more closely aligning the process of developing the National Essential Drugs List (which is derived from the STGs applicable at various levels) and the development of the CMS algorithms for the PMB CDLs. By being more specific about which medicines should be covered, needless expenditure on "me-too" agents of doubtful additional benefit could be avoided. Where clinically warranted, appropriate choices could be provided (for example, based on adverse effect profiles or the propensity to interact with concomitant medication).

Lastly, finality in respect of the pricing of medicines needs to be achieved. This applies not only to the dispensing fee but also to the proposed benchmarking process.[12] The proposed 40% differential between brand and generic names carries the risk that this will become the norm, rather than the minimum. The impact on the affordability, and thus the longer-term viability, of the Prescribed Minimum Benefits could be considerable.

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References

1. Department of Health. National Drug Policy for South Africa. Pretoria; 1996. Available http://www.doh.gov.za/docs/policy/drugsjan1996.pdf (Accessed 20/11/2007).
2. Council for Medical Schemes. 2006/2007 Annual Report. Available http://www.medicalschemes.com/publications/ZipPublications/Annual%20Reports/Annual_Report_2006-7_1.zip (Accessed 20/11/2007).
3. Republic of South Africa. Medical Schemes Act (No. 131 of 1998), as amended. Available http://www.medicalschemes.com/publications/ZipPublications/Acts%20and%20Regulations/MSACT19July2004.pdf (Accessed 20/11/2007).
4. Minister of Health. Amendment to the Regulations made in terms of the Medical Schemes Act, 1998 (No. 131 of 1998). Government Notice No. R.1397. Government Gazette No. 25537, 6 October 2003. Government Printer, Pretoria. Available http://www.medicalschemes.com/publications/ZipPublications/Acts%20and%20Regulations/Regulations%206%20October%202003.pdf (Accessed 20/11/2007).
5. Minister of Health. Regulations made in terms of the Medical Schemes Act, 1998 (No. 131 of 1998). Therapeutic Algorithms for Chronic Conditions. Notice No. 1110. Government Gazette No 27236, 11February 2005. Government Printer, Pretoria. Available http://www.medicalschemes.com/publications/ZipPublications/Acts%20and%20Regulations/Regulations%20therapeutic.pdf (Accessed 20/11/2007).
6. Minister of Health. Regulations made in terms of the Medical Schemes Act, 1998 (No. 131 of 1998), as amended. Available http://www.medicalschemes.com/publications/ZipPublications/Acts%20and%20Regulations/GNR1262%20of%2020%20October%201999.pdf (Accessed 20/11/2007).
7. Jackson D. Living with a changing environment. Business Times 18 November 2007; Available http://www.thetimes.co.za/PrintEdition/BusinessTimes/Article.aspx?id=614972 (Accessed 20/11/2007).
8. Abdool Karrim SS, Pillai G, Ziqubu-Page TT, Cassimjee MH, Morar MS. Potential savings from generic prescribing and generic substitution in South Africa. Health Pol Plan 1996;11(2):198–205.
9. 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(3):147–51.
10. Djolov GG. Savings from generic drug substitution in South Africa – an arithmetical view. S Afr Med J 2003;93(8):583–4.
11. Garattini S. Are me-too drugs justified? J Nephrol 1997;10(6):283–94.
12. Minister of Health. Regulations relating to a transparent pricing system for medicines and scheduled substances. Methodology for international benchmarking of the prices of medicines and scheduled substances in South Africa. Government Notice No. R. 1211. Government Gazette No 29443, 1 December 2006. Government Printer, Pretoria. Available http://www.info.gov.za/gazette/regulation/2006/29443b.pdf (Accessed 20/11/2007).