



Mandatory substitution successful

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There is a complex interaction between public health and private health care in South Africa. Only 14.1% of the population has comprehensive access to private-sector health care on a regular basis, through medical aid schemes. Yet private health care is the dominant vehicle for both the financing and provision of health care in the country.¹ Generic substitution in this sector, therefore, has the potential to cut medication costs significantly.

The Medicines and Related Substances Control Amendment Act No. 90 of 1997 (hereinafter referred to as 'The Act') was tabled in Parliament in May 1997.² It was designed to enable the government to undertake a variety of actions in order to provide a supply of more affordable medicines.³ This study examines only one of the repercussions of the law, namely generic substitution of a branded drug. Although generics are the first choice in the public sector, the beneficiaries of medical aid schemes, as medical consumers, have the option whether or not to choose a generic medicine.

Mandatory generic substitution

The Act, implemented on 2 May 2003, states that pharmacists are to inform all private patients buying medicines by prescription about the benefits of generic alternatives. The pharmacist is required by law to dispense the generic, unless the patient (or the patient's doctor) expressly refuses the substitution, or the price of the generic is higher than that of the branded product.

The implementation of the Act required the assistance of many role players, including the Department of Health, medical practitioners, pharmacists, and administrators of medical aid schemes.

Implications of generic substitution

Generic substitution is a contentious matter because it has ethical and economic implications. According to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, patents for medicines are treated in the same way as those for any other merchandise or commodity.⁴ Patents provide the brand drug manufacturer with the legal means to prevent others from making, using or selling the invention and are used to provide incentives for research and development into new ideas.

The government has the delicate role of striking a balance

between protecting the intellectual property of the developers of blockbuster drugs, and ensuring affordable medication. However, in order that pharmaceutical companies continue to invest in research and development in South Africa, economic viability needs to be ensured. Without patent protection there is little incentive for the pharmaceutical industry to develop new drugs.⁵ This places the health of future generations in jeopardy, not only because of the lack of research and development, but also because of the drain of resources that will accompany it.⁵

However, the Act should be seen in context. South Africa is not comparable with the rest of the developed world owing to differences in infrastructure, budgets and health policy, as well as the burden of disease profiles. Cheaper drugs are not necessarily equated with better health care. Supporting structures such as medical doctors, nurses, hospitals and researchers, not to mention general infrastructure influences (such as electricity and water) also have a bearing on the extent to which minimising drug costs can contribute to lower health care costs.

Materials and methods

Tenormin was chosen as the study drug because it has been on the market since 1970.⁶ As a beta-blocker, used for the treatment of hypertension, it benefits from widespread use across all population groups in South Africa and is taken on a daily basis. It was compared with three generics, namely, Ten-Bloka, Rolab Atenolol and Adco-Atenolol.

Discovery Health was used as the medical aid scheme because it is the largest open medical aid scheme in the country, with 22.8% of the market share.⁷ A year prior to the implementation of the Act was chosen as the starting point of the study because a trend in the claiming patterns could be ascertained within this time period. The time frame under study ended on 30 April 2004, just before the implementation of the new pricing policies.

Because of the fact that all the medicines being studied have been on the market for at least 10 years, it can safely be presumed that they have become established in that segment of the market. By obtaining a figure of the market segment thus secured, a true reflection of any effects on the market could be illustrated.

Results

The results were initially studied using descriptive statistics. Thereafter, statistical models were applied to determine the significance of the changes.

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Fig. 1. illustrates the following information: (i) Tenormin had already lost a great deal of its market share a year before the implementation of the law; (ii) Ten-Bloka is the market leader in providing Atenolol in the private sector, both before and after implementation of the law; (iii) the market share of Rolab-Atenolol remained low over the 2-year period examined; and (iv) visually, there appears to be a change in trend at the end of 2002.

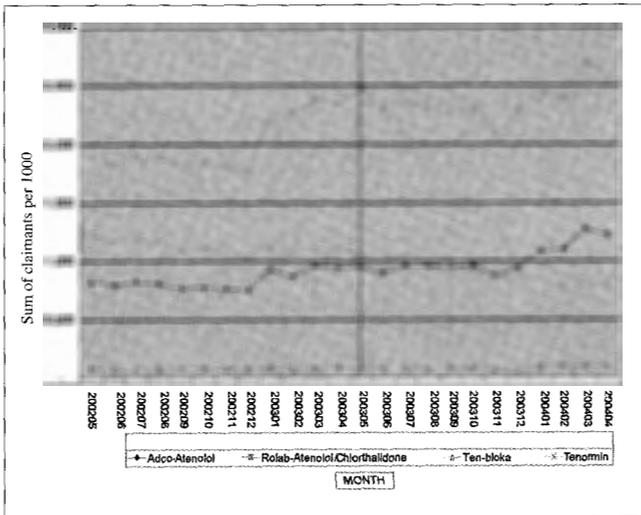


Fig. 1. The trend in claiming patterns from May 2002 to April 2004 for Tenormin and three generics.

The first step in the treatment of the data consisted of calculating the ratio of branded to generic drugs claimed at the medical aid scheme. This captured the true nature of the trend and allowed for changes in member numbers. In addition, it allowed for the overall impact of the generic law to be ascertained since generics as a whole were compared with the branded drug. Using the Auto Regressive Integrated Moving Averages (ARIMA) model, a significant change in drug-claiming patterns occurred between December 2002 and January 2003, 4 months before promulgation of the law. The probability that the change in claiming patterns was due to chance is very low ($p = 0.0002$).

In their support for generic substitution Discovery Health introduced a new policy in January 2004. According to this policy the 10% levy would be waived on the medication bill of beneficiaries who opted for generic drugs. This aimed to increase the use of generic drugs in an effort to diminish health care costs. Because of the fact that this was a known intervention, the ARIMA model was applied to the data at that point. The analysis revealed that the intervention was not significant ($t = 1.71$; $p = 0.56$). However, owing to the fact

that the analysis of the effect of the intervention of Discovery occurred over a short period of time, the results were not entirely conclusive.

Discussion

The road to the implementation of the Act was tumultuous since nearly 7 years elapsed between the time it was tabled and the time it was implemented. The draft regulations of the Act were published in the South African *Government Gazette* on 1 June 2001.⁸ Between this time and October 2002 discourse took place between the government and the pharmaceutical industry. By October 2002 the law had been finalised, and no further requests for commentary were made. On 28 March 2003, the Medicines and Related Substances Control Amendment Act was signed by President Thabo Mbeki.⁹

Owing to the protracted course of the implementation of the law, it is surmised that the premature increase in generic claims was due to the certainty that the law would be implemented. Nevertheless, generic substitution did continue to increase after the law was implemented. However the intervention by Discovery Health to promote generic substitution did not affect claiming patterns, and was subsequently withdrawn.

Conclusions

The aims of the Act have been fulfilled. The greatest increase in medical aid claims for generic drugs occurred prematurely, in anticipation of the implementation of the law. However, the support offered by Discovery Health to deter members from buying branded drugs did not yield significant results.

This study was conducted at the University of the Witwatersrand Medical School towards an MSc (Med) in Pharmacotherapy.

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