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Has the increase in the availability of generic drugs lowered the price of cardiovascular drugs in South Africa?

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ABSTRACT

Background: This research focuses on pharmaceutical competition in South Africa where concurrent pricing legislation is being implemented without monitoring the consequences on generic drug competition and usage.

Objective: To examine the relationship between originator drug prices and the number of generic brands within the cardiovascular class of drugs and to compare South African prices with international reference prices.

Method: Data on private sector drug prices was sourced from the *South African Medicine Price Registry*. The relationship between the median proportional price and the number of brands in the therapeutic class was analysed using correlation analysis. International reference prices were obtained from the *Management Sciences for Health International Drug Price Indicator Guide* (2012 edition).

Results: A weak correlation between originator and generic drug prices and the number of available brands was observed, the exception being diuretic drugs. The median prices per strength of the originator generic were still higher than the most expensive generic version manufactured by any other company, the exception being telmisartan. Comparison of price ratios between the originator drug, lowest priced generic and international reference price values revealed that the originator drug prices had a median price ratio of 20.99 (interquartile range 7.31–53.46) and the lowest priced generics had a median price ratio of 4.28 (interquartile range 2.10–8.47).

Conclusion: Increased generic competition is not a predictor of lower drug prices. The study also concludes that the current South African pharmaceutical policies have not yet achieved the lowest prices for drugs when compared internationally.

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1. Introduction

Access to therapeutic drugs forms an integral part of any successful healthcare system (Bangalee, 2015). The high cost of therapeutic drugs, which has often been cited as a barrier to accessibility to essential medicines, has led to the promotion of generic drug consumption in South Africa.

The restructuring of the South African public health sector post-1994 led to the development and implementation of the National Drug Policy (NDP) in 1996. The economic objective of the NDP was to decrease the cost of therapeutic drugs in both the private and public sectors (Department of Health, 1996). In May 1997, The Medicines and Related Substances Control Amendment Act 90 (hereinafter referred to as "the Act") was tabled at parliament (Deroukakis, 2007). It was implemented to allow government to undertake a variety of actions in order to reduce drug prices and improve the affordability of medicines in line with the economic objectives of the NDP. The Act, implemented on 2 May 2003, mandates pharmacists to inform all private patients buying prescribed medicines about the benefits of generic alternatives (Deroukakis, 2007).

In addition to the mandatory offering of generic substitution, the 1997 amendments to the South African Medicines and Related Substances Act, in terms of section 18A, banned "bonusing" (preventing pharmaceutical manufacturers from offering discounts and/or rebates to patients or healthcare providers) and with section 22G this led to the formation of a "pricing committee" which was tasked with constructing "transparent pricing mechanisms" (Nicolosi & Gray, 2009). The high levels of discounting and payment of incentives within the pharmaceuticals supply chain had raised serious concerns in the Department of Health (DOH) as these practices did not pass the savings on to the consumer. Retail pharmacies and dispensing doctors on the other hand were able to capitalise on these incentives while consumers continued to pay the official manufacturers' "listed" price (Hawkins, 2011). This also countered the effect of generic substitution as evidence revealed that in many cases doctors and pharmacists were not always agreeable to substituting the lower priced generic but would rather dispense the more profitable product (Hawkins, 2011). This lack of transparency in prices in the supply chain as well as the loss of benefits to consumers led to the prices of pharmaceutical drugs being regulated by the single exit price (SEP) legislation in 2004. This meant that drug manufacturers could only sell their products at one price to all their customers, regardless of the nature of the customer's order size and consumption levels (Republic of South Africa, 1997). The implementation of SEP in the private sector resulted in a significant shift from a free market to a regulated one in order to ensure transparent pricing practices for the industry. However, there is very little research on whether the implementation of this pricing policy has impacted on the use of generic drugs, and this study attempted to look into this area by selecting a particular group of drugs to investigate.

Globally, cardiovascular diseases (CVD) are responsible for 30% of all deaths, with the greater majority (80%) of these deaths occurring in developing countries (van Mourik, Cameron, Ewen, & Laing, 2010). Although HIV/AIDS remains the leading overall cause of mortality in sub-Saharan Africa, cardiovascular disease is the second leading killer and is first among individuals over the age of 45 years (Lopez, Mathers, Ezzati, Jamison, & Murray, 2006). Thus, "in South Africa approximately 195 people die per day due to CVD, representing about 20% of the daily deaths due to HIV/AIDS" (Steyn, 2007). There is currently minimal information on the cost of CVD treatment in South Africa; however, the use of generic drugs could potentially address the need to reduce treatment costs. Furthermore, the growth of the South African generic pharmaceutical market is set to rapidly accelerate owing to the expiry of a number of patents especially in the cardiovascular category (Moorad, 2012). While previous studies revealed the price-lowering effect of generic competition with respect to the number of sellers in the overall market (Cook, 1998; Fatokun, Ibrahim, & Hassali, 2011), very little data is available on this concept within a specific drug therapeutic class, let alone in South Africa, which has the additional policy of the SEP.

1.1. *Aims of the study*

The aim of this study was to examine the relationship between originator drug pricing and the number of available generic brands within the cardiovascular drug class in the context of SEP legislation, and to compare South African drug prices with international drug prices.

2. Research method and design

The quantitative study design was a secondary data analysis based on data collected on the five classes of cardiovascular drugs listed in the abridged *South African Hypertension Guidelines of 2011* (Seedat & Rayner, 2012). These classes were ACE-inhibitors, beta blockers, calcium channel blockers, diuretics and angiotensin II antagonists. All drugs listed under each class were categorised according to their classification in the *South African Medicines Formulary*, 10th edition (Division of Clinical Pharmacology, 2012).

Data on South African private sector prices of originator and generic drugs was sourced from the South African Medicine Price Registry which is the official website that communicates drug prices as approved by the Pharmaceutical Economic Evaluation Unit of the Department of Health (South African Medicine Price Registry). The number of registered brands as at 10 June 2013 for each drug preparation was obtained from the registry. Drugs chosen under each medication were only included if there was a generic drug and originator price available. Combination preparations were excluded as they tend to alter the classification of the drug.

Originator pharmaceutical products were those initially registered by the innovator research-based pharmaceutical manufacturer on the basis of the documentation of their efficacy, safety and quality, whereas generic drugs were those usually intended to be interchangeable with the originator brand product, of the same strength and dosage form, registered after patent expiry or as licensed by the patent holder. Originator generic drugs were defined as generic drugs that were manufactured by the company that also manufactured the originator drug. Due to the differences in pack sizes