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Full Length Article

Maximum potential cost-savings attributable to generic substitution of antipsychotics 2008 to 2013

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ABSTRACT

Background: Schizophrenia is a costly illness to treat, especially during a time of escalating medicine inflation costs, putting a large economic strain on patients, their families and the community. Treatment, however, can become more affordable through generic substitution.

Objective: To determine the maximum potential cost-saving through generic substitution for both originator and more expensive generic items while observing the prescribing patterns of antipsychotics.

Method: Antipsychotic medicine usage was analysed retrospectively during the study period 2008 to 2013 using data obtained from a nationally representative Pharmaceutical Benefit Management Company. The study population consisted of 4410 patients with ICD-10 codes (F20-F20.9) who had paid claims for an antipsychotic reimbursed from their prescribed minimum benefits. Active ingredients were identified using the MIMS classification system. Maximum potential cost savings were determined by substituting all originator and more expensive generic antipsychotic items with the cost of the least expensive generic antipsychotic item available.

Results: Through generic substitution, a total potential cost-saving of ZAR4 642 685.45 could be possible from 2008 to 2013. Average cost per items increased from ZAR600.53 ± ZAR435.00 (median ZAR 539.82) in 2008 to ZAR1 196.59 ± ZAR 942.16 (median ZAR 940.72) in 2013 and had a significant effect on patients' contribution, which increased with 726.94% from 2005 to 2008. Psychiatrists prescribed the majority of antipsychotics. Although generic items claimed increased by 60.31% during the study period, psychiatrists still favoured non-generic prescribing (40.63%).

Conclusions: Potential economic benefits can be generated with generic substitution.

Abbreviations: GDP, gross domestic products; PMB, Prescribed Minimum Benefits; NDP, National Drug Policy; WHO, World Health Organization; MIMS, monthly index of medicines speciality; SEP, single exit price; NRF, National Research Foundation.

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1. Introduction

Neuropsychiatric conditions are ranked third in their contribution to the burden of disease in South Africa, after HIV/AIDS and other infectious diseases (Bradshaw, Norman, & Schneider, 2007; Lund et al., 2008). A study conducted by Williams et al. (2008) revealed that 16.5% of all South Africans suffer from common mental disorders, including, *inter alia*, depression, anxiety and somatoform disorders. This figure, however, did not include schizophrenia and bipolar mood disorder (Williams et al., 2008). When costs of treatment for psychiatric illnesses are compared, schizophrenia is the most costly illness to treat (Emsley & Booysen, 2004). Without healthcare coverage, treatment for schizophrenia can become unaffordable, even if generic medicines are used (Lehman et al. 2004). A rapid increase was observed in the percentage of medical expenditures in association with prescription drugs (Fischer & Avorn, 2003). In 2011, $12.6 billion was spent on 54 million prescriptions issued for antipsychotics in the United States of America (Leonhauser, 2012). Irrespective of its economic strain on patients themselves, this disease also puts a large economic burden on families, societies and healthcare systems (Emsley & Booysen, 2004). For example, according to Emsley and Booysen (2004), it could cost a family of a schizophrenic patient approximately ZAR 498 771.00 per year to take care of such an individual, while spending approximately 15 h a week taking care of these members.

South Africa spends 8.9% of its gross domestic product (GDP) on health, which is relatively high compared to the 5% recommended by the World Health Organization (WHO) (WHO, 2016; Department of Health, 2011). According to the South African National Treasury (2015), a total of ZAR 121 billion was spent on health for 2012/2013 (Department of Health, 2011). Regardless of this rather high expenditure, health outcomes compared to more or less the same middle-income countries, remain poor (Department of Health, 2011).

In order to control healthcare costs in the private sector of South Africa, a number of regulations, policies and pricing interventions were put in place by the South African Government, *inter alia*, the National Drug Policy (NDP), the Medicines and Related Substances Control Amendment Act (No 90 of 1997), Good Pharmacy Practice (GPP) and Good Marketing Practice (GMP) rules, a transparent pricing structure and certain pricing interventions such as mandatory generic substitution, the establishment of the Single Exit Price (SEP) for all medicine, and the Prescribed Minimum Benefits (PMBs) and Chronic Disease List. The goal of the National Drug Policy, published in 1996, was to "ensure an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens of South Africa, and the rational use of drugs by prescribers, dispensers and consumers" (South Africa, 1996). The Medicines and Related Substances Control Amendment Act No 90 of 1997, tabled in Parliament in May 1997, was designed for the provision of more affordable medicines (Deroukakis, 2007; South Africa, 1997). In Section 22F of this act, which was implemented on 2 May 2003, generic substitution was promulgated and states that a pharmacist is required to dispense the generic alternative of a prescribed medicine, unless the patient or the prescribing doctor explicitly refuses the substitution, or if the price of the generic product is higher than that of the branded or originator product (Black, 2013; Deroukakis, 2007; South Africa, 1997). The Medicines and Related Substances Act, Good Pharmacy Practice (GPP) and Good Marketing Practice (GMP) rules furthermore ensure that medicines are of good quality, that medicines are safe and effective, that marketing takes place according to a code of marketing and that medicine prices are transparent and in accordance with single exit price (SEP) regulations (Black, 2013). The Prescribed Minimum Benefit (PMB) conditions listed by Council of Medical Schemes (CMS) (CMS, 2009) is a set of well-defined benefits to make sure that all medical scheme members have access to certain minimum health services, regardless of the benefit option they have selected, in order to be provided with continuous care, to improve the health and well-being of a patient, to make healthcare more affordable and to prevent restriction of access to health insurance for high-risk individuals (CMS, 2010). Medical aid schemes are obligated to cover diagnosis, medical costs as well as cost of care of patients registered on the chronic disease list of the PMB, provided that the prescribed therapeutic algorithm is followed (CMS, 2009; Department of Health, 2003). Schizophrenia is listed as one of these 27 chronic disease disorders in South Africa.

The single exit price in South Africa is set according to benchmark prices of other international countries that follow pricing systems closest to the system that is used in South Africa. Department of Health (2015). New Zealand, Australia, Canada and Spain were chosen as benchmarking countries (Department of Health, 2015). The SEP may be applied to products that are priced below the international benchmark and may be increased up to the international benchmark, but the SEP may not exceed the price of the benchmark (Department of Health, 2015). The annual increase of SEP for 2008 was 6.5%; in 2009 SEP increased with 13.2%; and in 2010 SEP increased with 7.4% (Council for Medical Schemes, 2014). In 2011, there was no increase in SEP (South Africa, 2011). An annual adjustment was made in 2012 for the SEP of medicines and scheduled substances where the South African Minister of Health stated that SEP may only be applied to a maximum of 2.14% as last stated on 9 December 2011 (South Africa, 2012). In 2013, a maximum of 5.8% was applied as last stated in 23 December 2012 (South Africa, 2013). In 2013, medicine expenditure increased by 2% for cost per item from 2011 (Mediscor, 2013). A total of 42.2% of manufacturers that represent approximately 83.3% of products sold in South Africa took a 4% increase in SEP for January to May in 2013 (Mediscor, 2013). This increase in cost puts a large economic strain on patients during a time of spiralling medication inflation (Mediscor, 2013).

According to the WHO (2010), a generic drug is a pharmaceutical product or medicine item that is manufactured without a licence from the innovator company and marketed after the patent right of the specific drug has expired. These generic medicines should be of the same formula (including, *inter alia*, the same amount of active ingredient and the same route of administration) while giving the same therapeutic effectiveness than that of the originator medicine (Borgherini, 2003). Originator products have a higher cost than their generic versions, which produce the same therapeutic effect