

**Comparison of Prescribing Information
Between
South Africa and International Reference Countries
for
Widely-Used Medicines**

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Science in Medicine in Pharmacotherapy.

Johannesburg, 2007

Declaration

I, Elizabeth Filby, declare that this research report is my own work. It is being submitted for the degree of Master of Science in Medicine in the branch of Pharmacotherapy, at the University of the Witwatersrand, Johannesburg.

It has not been submitted before for any degree or examination at this or any other university.

Elizabeth Filby

___ day of _____, 2007

Dedication

To my mother, Joan Morrison (88 yrs),
who has always been and continues to be,
my greatest champion.

Abstract

A recent World Health Organisation study conducted in 26 countries found substantial disagreement in the prescribing information available in those countries, as well as significant disparity between brands within the same country. This appears to be a common experience in other countries. This may mislead prescribers, patients and those comparing drug-use patterns across countries, and have serious safety implications.

This study was carried out to investigate the variability of prescribing information currently available within South Africa, comparing generic and originator brands. It also investigated the extent of variability between the Standardised Package Insert (SPI) mandated by the Medicines Control Council, versus internationally approved prescribing information for given drug substances.

Five drug substances were selected that are widely used in South Africa. The package inserts of the originator product were compared in terms of the indications, dosage, cautions, side-effects and drug interactions versus five generic brands of each drug substance registered in South Africa, using a comprehensive method adapted from the WHO study. The SPI was also compared against the South African originator brand package insert and those approved in four international MCC Reference Countries (ie. USA, EU, Canada & Australia) for each drug substance.

Substantial disagreement was found between the originator and generic products for each drug substance, which may be due, in part, to the absence of a mandatory periodic updating requirement for package inserts in the post-registration phase in South Africa. This may result in divergence between materials from companies that voluntarily submit safety updates over the life of the product, and those that do not.

There was also substantial disagreement between the SPI and the originator and international reference country materials. The reason is less simple to explain. The SPI project is in its early stages, and requires validation to ensure that the texts are in fact, entirely in line with latest best clinical practice and with the reference countries with which MCC aligns itself.

These findings are comparable with those found in international WHO study.

Regulatory authorities have key responsibility in ensuring that prescribing information is current and consistent across originator, generic and international materials.

It is recommended that the MCC implement a mandatory updating requirement for all registered medicines with specified timelines. Secondly, a validation step should be introduced in the MCC SPI project to ensure consistency with international materials. Additional recommendations are made to improve the quality and practicality of prescribing information to ensure that it remains relevant in the South African and regional context.

Acknowledgements

My grateful thanks to:

The staff of the Department of Pharmacy and Pharmacology, University of the Witwatersrand.

My supervisor, Dr. GJ Lowndes, for his assistance and guidance.

Claire Ducharme and Anne Bell, respectively, for their kind assistance in obtaining Canadian prescribing information approved by Health Canada, and Australian prescribing information approved by the Therapeutic Goods Agency.

Dr. S. Olorunju from the Medical Research Council of South Africa for his guidance in understanding the statistical model and its application.

My husband and family, and my work colleagues, for their unfailing support and encouragement.

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