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A comparison of the information used to populate patient information leaflets for complementary medicines with recommended references, and an analysis of the type and order of language used

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Abstract

Regulations published by the Medicines Control Council (MCC), the regulatory body that existed before the South African Health Products Regulatory Authority (SAHPRA), required Complementary and Alternative medicines to demonstrate the safety, quality and efficacy of the product. Package Inserts (PIs) and Patient Information Leaflets (PILs) needed to comply with the MCC's Guidelines. Four package inserts from four different complementary products were compared and analysed. Biral® and Calmettes Nite tablets, containing Valerian Root, and Flora Force St John's wort and Wellvita St John's wort were examined. The package inserts were evaluated for compliance to the published Guidelines for Package Inserts, and the information presented was validated according to published references in a literature review. The package inserts were compared according to active ingredient. The information available to the patient was evaluated using the principles of Critical Discourse Analysis. The findings showed there were discrepancies in compliance to the Guidelines; the Valerian Root PIs were more compliant than the St John's wort PIs. Biral® and Calmettes Nite tablets contained similar information with Calmettes presenting more clinical information. Both inserts had sections that were appropriate for the non-medical reader, and areas that are confusing. The Flora Force St John's wort PI used few full sentences and relied on medical terminology throughout the insert. It was significantly shorter than the Wellvita St John's wort PI. The Wellvita St John's wort PI was simply written, until the sections on Side Effects and Interactions, where medical terminology and abbreviations were used. All four products presented themselves as natural remedies. While the information contained in the PI can be validated in published literature, more oversight of these inserts is required from the SAHPRA.