South African Health Products
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GUIDELINE 7.04: COMPLEMENTARY MEDICINES - HEALTH SUPPLEMENTS SAFETY AND EFFICACY

To all stakeholders

The purpose of Guideline 7.04 (*Complementary Medicines - Health Supplements Safety and Efficacy*) is to provide clear guidance with regard to the safety and efficacy (SE) requirements for registration of Health Supplements as a subset of complementary medicines in South Africa in the Common Technical Document (CTD) format. The intent of this document is to ensure that the levels of evidence for SE are rigorous enough to protect public health and maintain consumer confidence, while providing a clearly defined pathway to register health supplements.

The guideline represents the South African Health Product Regulatory Authority's (SAHPRA) current thinking on the quality, safety, and efficacy of these medicines. Annexures associated with this guideline have been published for public comment prior to implementation. In the interest of focus, only the proposed additional Annexures are included to amend the guideline.

In assessing the safety, efficacy and quality of health supplement and preparations the attached Annexures M and N have been developed to guide the use of the substances listed therein when used in Complementary Medicines as Health Supplements. The following **Annexures M - N** to the Guideline 7.04 are now published for implementation.

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