SAHPRA
South African
Health Products
Regulatory Authority

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COMMUNICATION TO STAKEHOLDERS

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Regulatory Information Management System – *Application Withdrawal*

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INTRODUCTION

This communication is intended to provide an update to applicants on the process for the cancellation of registered health products in Specification 3.1 and as of 01 November 2024.

Reference is made to ZA-SAHPRA eCTD Specification and Guidance for Module 1 and Regional Information, July 2024, v3.1, 4.5.2 Life Cycle Operations for a Withdrawal, 4.5.2.1 Application Withdrawal.

When withdrawing an entire product life cycle history, the following process must be adhered to:

- The submission type should be set to "Application Withdrawal"
- The sequence type should be set to "Initial"
- The sequence description should be set to "Cancellation"

Application withdrawal is considered a new submission; therefore, the sequence and related sequence should be set to the next available sequence.

A letter of application should be included as "New" explaining the reasons for the eCTD application being withdrawn.

Applicants requiring a cancellation where no baseline in eCTD is available must still follow the process as per Specification 3.1. An acceptable baseline with minimum information only, i.e. Module 1, Module 2, Module 3.2.P and Module 3.2.S followed by the Application withdrawal submission type will be accepted.

For any further clarification, feel free to Pratibha Sobrun, pratibha.sobrun@sahpra.org.za.

Kind regards,

Christelna Reynecke
SAHPRA
Chief Operating Officer (COO)

21 January 2025

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22 January 2025