

## COMMUNICATION TO STAKEHOLDERS

Issue No.: HPA16-2024/25

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### ZA-SAHPRRA CTD eSubmission Specification (June 2024; v3.0) – Document out for comment

#### DOCUMENT HISTORY

July 2019 v1.0	First publication for implementation.
v2.0	Skipped to align versioning with the eCTD 3.0.
June 2024 v3.0	Initial version as updated from v1.0. Major restructuring of the document and updates to both files required and a new trigger file to collect Envelope information. Most of the content is now referencing the eCTD specification.

#### INTRODUCTION

The document, ZA-SAHPRRA CTD eSubmission Specification June 2024, v3.0 is out for applicant comment with a response deadline of Wednesday, 03 July 2024.

ZA-SAHPRRA CTD eSubmission Specification (June 2024; v3.0), provides guidance on the structure of a South African CTD eSubmission Application and guidance on creating and validating a South African CTD eSubmission Sequences. The CTD eSubmission Specification is a temporary solution for certain applications (e.g., veterinary and complementary) to be used while companies time to implement an Electronic Common Technical Document (eCTD) solution.

A half-day industry workshop will be scheduled towards the end of July 2024 to engage with specific sectors (e.g. veterinary and complementary) to clarify details.



Boitumelo Semete-Makokotlela

**Dr Boitumelo Semete-Makokotlela**  
SAHPRA Chief Executive Officer (CEO)