

## COMMUNICATION TO STAKEHOLDERS

Issue No.: HPA15-2025/26

**22 January 2025**

# Implementation of Regulatory Information Management System – Information on eCTD 3.1 Module 1 – Document Matrix

### Document History

First Publication – Version 1	06 March 2024
Version 2	26 April 2024
Version 3	26 April 2024
Version 4	27 May 2024
Version 5	08 July 2024
Version 6	25 September 2024
Version 7	24 October 2024
Version 8	28 October 2024
Version 9	16 January 2025
Version 10	22 January 2025

## INTRODUCTION

This document is intended to provide an update on the document matrix to be utilised by all applicants submitting applications for the Renewal of the certificate of registration from 22 January 2025. The Document Matrix location is as follows: <https://ectd.sahpra.org.za/>.

Reference is made to ZA-SAHPRA eCTD Specification, SAHPGL-HPA - Renewal of Human and Veterinary Medicines Requirements and Process and GLF-HPA-04A - ECTD Validation And Technical Screening For Renewals.

**Note:** Applicants should ensure that the web browser's cache is cleared so that the latest version of the document matrix can be viewed.

**Please take note of the following critical updates to the document matrix for Renewal applications:**

1. Note to Evaluator 1.0.2 updated to "NV" currently "P"
2. Meeting information 1.0.5 updated to "XE" currently "P"
3. Additional Annexes 1.2.2 A updated to "NV" currently "P"
4. Checklists, Validation templates 1.2.5 updated to "E" currently "W"
5. Reference Product – Local 1.3.1.2.1 updated to "NV" currently "XE"
6. Other references 1.3.1.2.2 updated to "NV" currently "XE"
7. Braille 1.3.4 updated to "NV" currently "P"
8. Foreign Prescribing and Patient Information updated to "NV" currently "P"
9. Artwork and Pictures of Samples 1.3.6.2 updated to "E" currently "XE"
10. Affidavit by Responsible Pharmacist 1.5.2.3 updated to "E" currently "XE"
11. Additional Types of Applications Specific Requirements 1.5.A updated to "E" currently "XE"
12. Inspection Reports or Equivalent Document 1.7.2 updated to "P" currently "W"
13. SAPC Registration 1.7.7 updated to "E" currently "XE"
14. Registration with Registrar of Companies 1.7.8 updated "XE" currently "W"
15. Quality Overall Summary 2.3 updated to "NV" currently "W"
16. Module 3 Quality updated to "P" currently "XE"

For any further clarification, feel free to reach out to SAHPRA.

Kind regards,



*Reynecke*

SIGNIFLOW

Christelna Reynecke  
**SAHPRA**  
Chief Operating Officer (COO)



Boitumelo Semete-Makokotlela  
*Boitumelo Semete-Makokotlela*

SIGNIFLOW

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