

## COMMUNICATION TO STAKEHOLDERS

Issue No.: HPA15-2024/25

**28 October 2024**

# 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

### INTRODUCTION

This document is intended to provide an update on the document matrix to be utilised by all applicants from 01 November 2024 (eCTD 3.1 go-live date). The Document Matrix location is as follows: <https://ectd.sahpra.org.za/>.

Please take note of the following critical updates to the document matrix:

1. Tabulated schedule of amendments 1.5.2.1 was “Error” for Submission type New Generic
2. Validation template 1.2.5, should be “Error” currently blank
3. Change in applicant 1.2.3.1 updated to XE for NCE and New Generic, currently “P”
4. PI annotated 1.3.1.1.3 “Error” for NCE & New Generic
5. PIL annotated 1.3.2.3 “Error” for NCE & New Generic
6. BTIF 1.5.6.1 “Error” for variations Type Iain, IB & II Clinical
7. Data set similarities 1.10.4.1 “Error” for NCE & New Generic
8. Declaration of sameness 1.10.4.2 “Error” for NCE & New Generic
9. RRA Reports 1.10.5 “Error” for NCE & New Generic

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

Kind regards,

  


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

Boitumelo Semete-Makokotlela

  


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