

COMMUNICATION TO STAKEHOLDERS

Issue No.: HPA15-2025/26

12 June 2025

Regulatory Information Management System – Technical Files – Website Upload

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
Version 11	24 February 2025
Version 12	11 March 2025
Version 13	12 June 2025

The South African Health Products Regulatory Authority (SAHPRA) has issued important updates impacting the technical files located in the SAHPRA eCTD repository and found in the following location, <u>SAHPRA eCTD</u>.

Please ensure your software is updated to reflect the following changes:

New values added and **existing values revised** for the following metadata fields: application-type, evaluation-path, sequence-type, submission-type, and submission-lead.

The document matrix has also been updated to incorporate the changes related to submission-type.





Kind regards,

Christelna Reynecke

SAHPRA

Chief Operating Officer (COO)

Date: 12 June 2025