

COMMUNICATION TO STAKEHOLDERS

Issue No.: HPA16-2025/26

31 March 2025

SAHPRA Engagement Portal - Application IDs

DOCUMENT HISTORY

First Publication – Version 1	06 November 2024
Version 2	TBC

This communication serves to notify applicants about the issuance of Application IDs. Following the administrative freeze (ending 31 March 2025), newly generated Application IDs will be available on the portal for each application, encompassing all strengths and multiples combined. In accordance with eCTD Specification 3.1, the Application ID serves as a unique identifier for the complete application (eCTD or eSubmission) and will be automatically generated for all new applications.

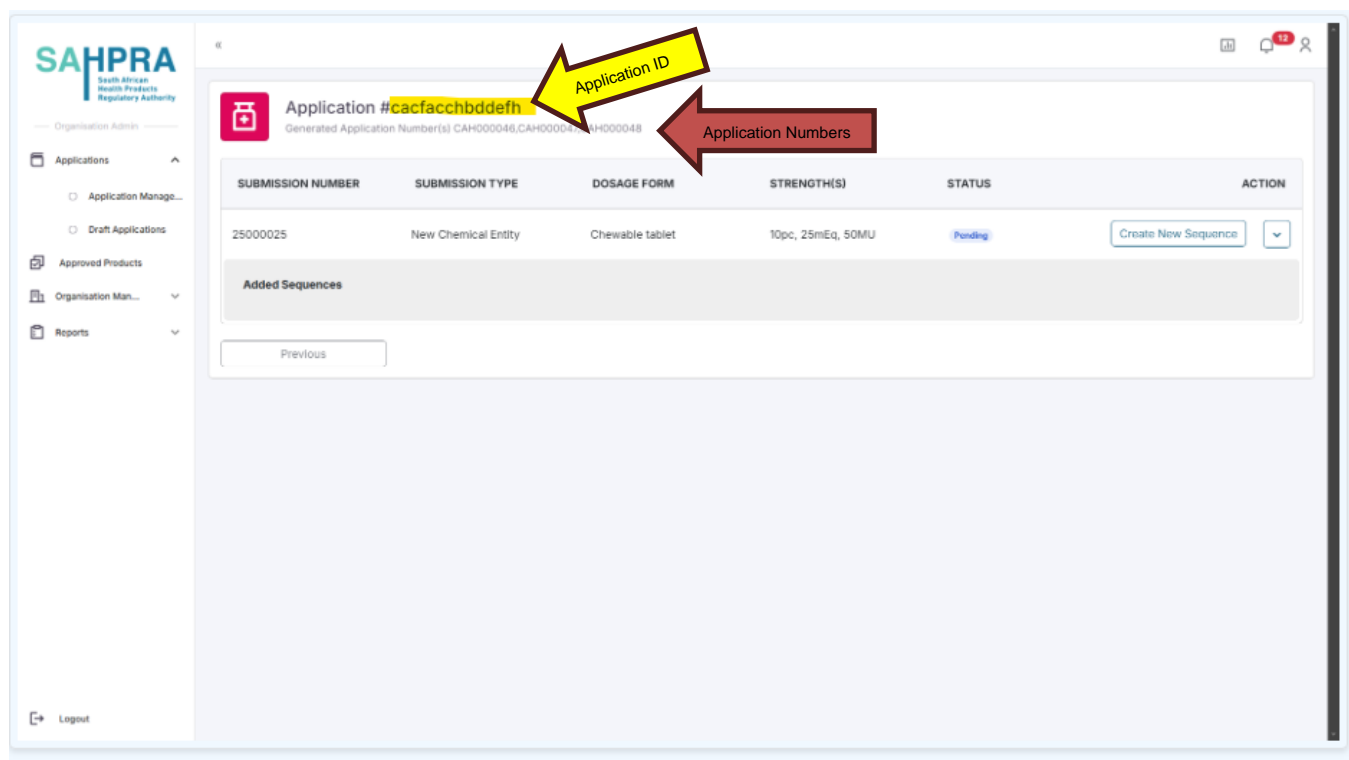
PLEASE NOTE: The Application ID **does not** replace the Application Number assigned by the South African Health Products Regulatory Authority (SAHPRA). Kindly refer to eCTD Specification 3.1 for further clarification on the distinctions between Application IDs and Application Numbers.

Furthermore, while eCTD Specification 3.1 states:

- “For legacy applications, the eCTD identifier previously used as the Application Folder (root node) should be used as Application ID.”
- “For legacy applications, please continue to use the previous Application Folder name as Application ID and Application Folder for all future Sequences.”

It has been decided that new Application IDs will be generated for all legacy applications, due to past confusion surrounding naming conventions for multiple applications. As a result, the above statement no longer applies and will be updated in the specifications accordingly.

Applicants will be able to retrieve their Application ID on the Portal.



The above can be found in the Training Manual of the SAHPRA Engagement Portal at the following URLs:

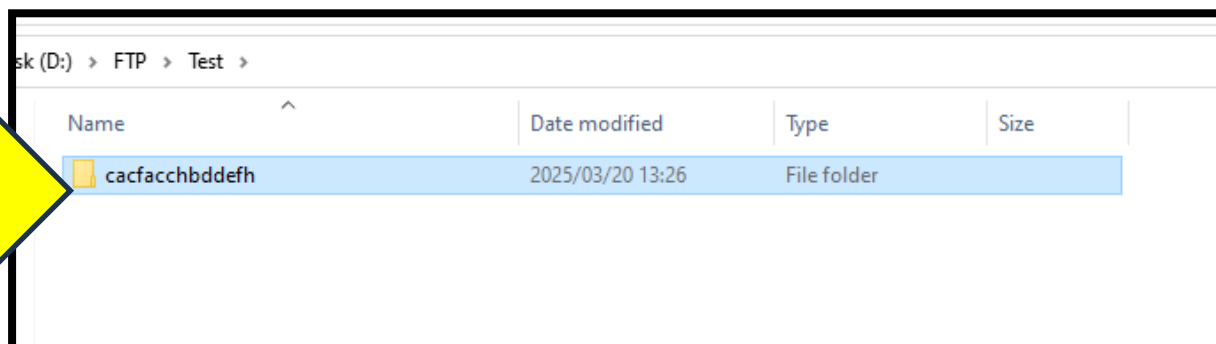
- <https://portal.sahpra.org.za> https://portal.sahpra.org.za/user-manual/_site/index.html

The Application ID will be used as follows:

1. **Envelope** – The Envelope of the eCTD Application must be updated to incorporate the newly assigned Application ID.
2. **Root Folder Naming Convention** – The folder designated for sequence submissions (root folder) should now be aligned with the newly assigned Application ID.

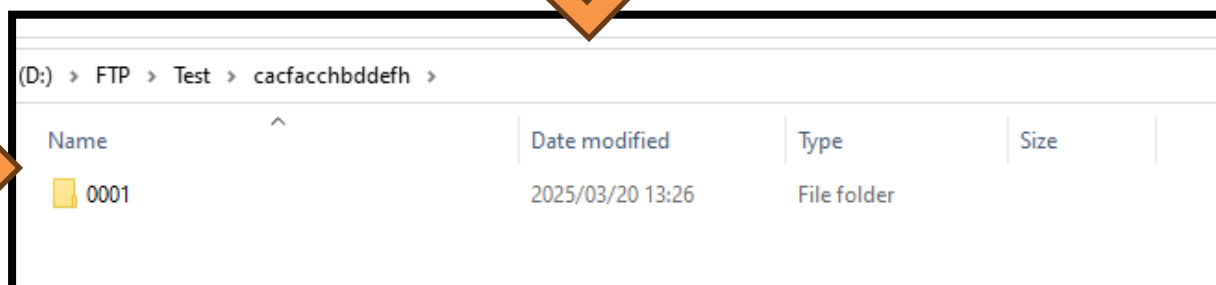
The structure of your eCTD submission should be organised as follows:

Application
ID is the root
folder



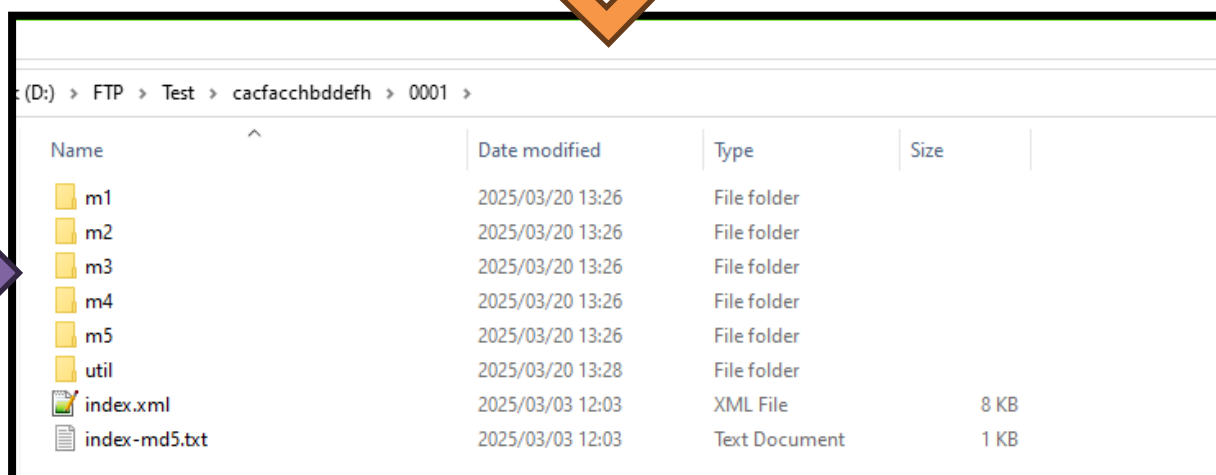
Name	Date modified	Type	Size
cacfacchbddefh	2025/03/20 13:26	File folder	

Sequence
folder



Name	Date modified	Type	Size
0001	2025/03/20 13:26	File folder	

eCTD

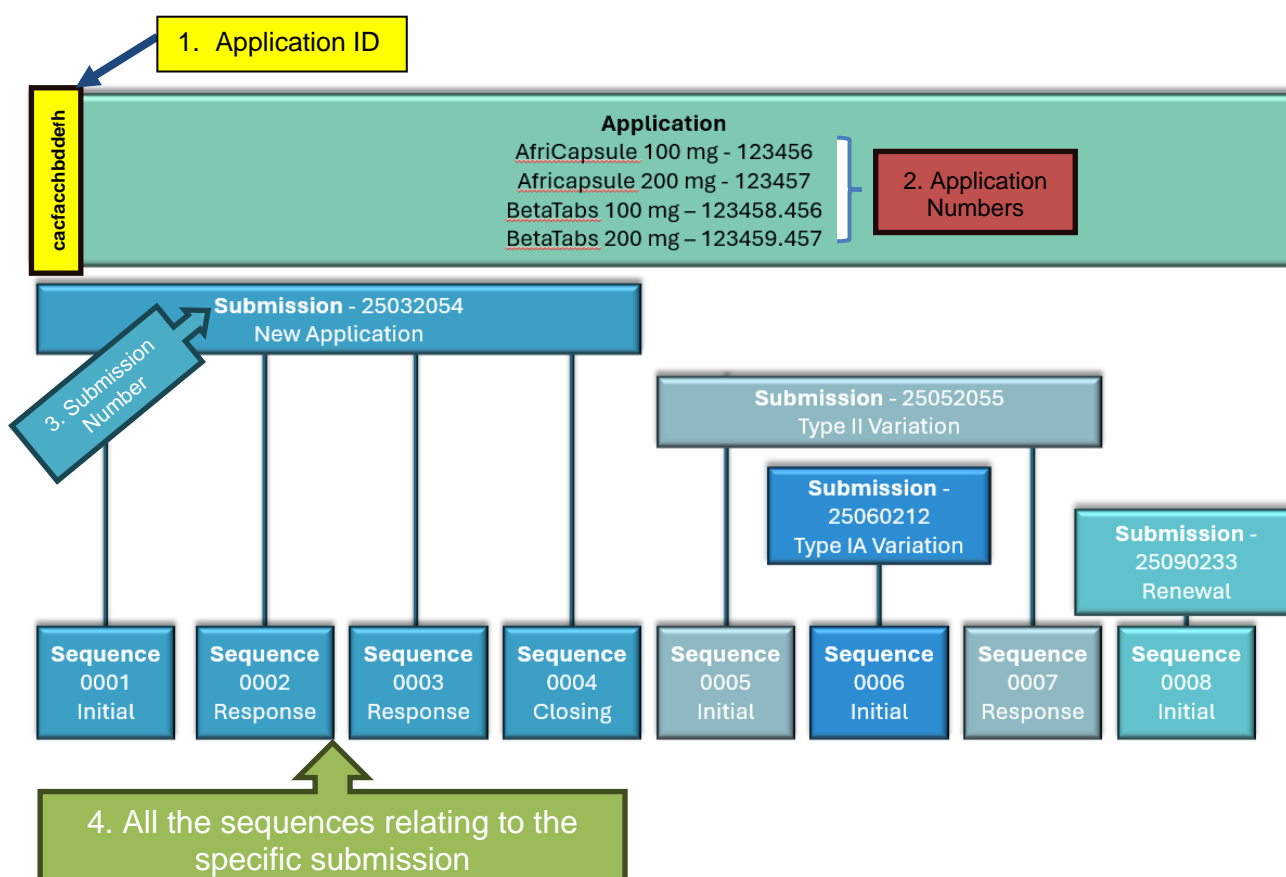


Name	Date modified	Type	Size
m1	2025/03/20 13:26	File folder	
m2	2025/03/20 13:26	File folder	
m3	2025/03/20 13:26	File folder	
m4	2025/03/20 13:26	File folder	
m5	2025/03/20 13:26	File folder	
util	2025/03/20 13:28	File folder	
index.xml	2025/03/03 12:03	XML File	8 KB
index-md5.txt	2025/03/03 12:03	Text Document	1 KB

Please note the following:

1. **NO Trigger File:** Applicants are not required to create a Trigger File; this will be generated by the Portal.
2. **DO NOT** submit a sequence folder within a sequence as it will not be processed.
3. **DO NOT** use the old naming convention of the root folder, such as the Application Number (e.g. 123456). Doing so will result in a sequence failing validation.
4. **DO NOT** include any working documents outside of the eCTD, Validation Reports, signed MD5 Checksum or any other documents not required in the root folder.

A diagram is provided below to explain the distinction between an Application ID, Application Number, Submission Number, and Sequence Number.



1. **Application ID:** Each application is assigned a single, unique Application ID.

2. **Application Numbers:** Applications may include multiple strengths or duplicates, with each strength or duplicate being assigned its own Application Number.
3. **Submissions:** An application comprises multiple submissions, each representing a regulatory activity. For example:

Pre-registration sequences grouped together as a single submission, since they pertain to the same regulatory activity (e.g., product registration).

Post-registration sequences, such as the initial sequence for a Type II major variation and the subsequent response to a query regarding the variation, are considered one submission. Each submission is assigned a Submission Number by the Portal, and all sequences within a submission will share the same Submission Number. *For detailed guidance, refer to the eCTD Specification 3.1.*

4. **Sequences:** Sequences are the units where all data is submitted. Sequences within a single submission do not have to be sequential, however, you must submit sequences sequentially, independent of the submission they belong to.

Please email Pratibha Sobrun, pratibha.sobrun@sahpra.org.za, if you have any further questions.

Kind regards,



Christelna Reynecke
Chief Operating Officer
SAHPRA

Date: 31 March 2025



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

Date: 31 March 2025