

## COMMUNICATION TO STAKEHOLDERS

Issue No.: HPA16-2025/26

**1 April 2025**

### SAHPRA Engagement Portal – Launch Update

#### DOCUMENT HISTORY

First Publication – Version 1	06 November 2024
Version 2	01 April 2025
Version 3	01 April 2025

Applicants are hereby notified that the South African Health Products Regulatory Authority (SAHPRA) Engagement Portal is set to launch at midday on 01 April 2025.

**PLEASE NOTE:** Administration users to update FTP Login Details as outlined below. This must be completed prior to creating applications that require an eCTD upload to the SAHPRA FTP server.

SAHPRA Engagement Portal Applicants Training Manual

The **Draft Applications** sub-tab contains all draft applications not yet submitted to SAHPRA to easily continue building your application. Once the application has passed the payment upload step, it will move to the Applications Manager.

The **Approved Products** tab will have any applications with approved applications/ products located in the tab.

The **Organisation Management** tab (Only applicable to Organisation Administrators) allows the user to see and edit their **Organisation Details**, manage and invite users that are part of the organisation under **User Management** and management of the organisation **Subdivisions**.

On this page:  
Login & Logout Procedures  
Login  
Logout  
Navigating the Portal  
Password Management

Edit Organisation

- Note: FTP details must be set under your Organisation Details before attempting to create applications that require eCTD uploads to the SAHPRA FTP Server. The system will warn that a upload could not be verified if the FTP details are not filled in when trying to "Confirm FTP Upload" on a sequence.
- Your profile can be accessed via the profile icon in the top right where personal account details can be managed and changed.

During this phased implementation, the Automator will operate once per day with validation reports available from 18:00 onwards. **If you do not receive a validation outcome within 48**

hours of your submission, kindly contact [eCTD.validation@sahpra.org.za](mailto:eCTD.validation@sahpra.org.za) and cc Pratibha Sobrun, [pratibha.sobrun@sahpra.org.za](mailto:pratibha.sobrun@sahpra.org.za).

For any outstanding missing sequences from the activity of 10 March 2025, the process will resume next week with an updated communication to follow.

Please email Pratibha Sobrun, [pratibha.sobrun@sahpra.org.za](mailto:pratibha.sobrun@sahpra.org.za), if you have any further questions.

Kind regards,



Christelna Reynecke

**Chief Operating Officer**

**SAHPRA**

Date: 01 April 2025