

COMMUNICATION TO STAKEHOLDERS

Issue No.: HPA16-2025/26

30 April 2025

SAHPRA Engagement Portal – Important Updates

DOCUMENT HISTORY

First Publication – Version 1	06 November 2024
Version 2	01 April 2025
Version 3	01 April 2025
Version 4	03 April 2025
Version 5	04 April 2025
Version 6	30 April 2025

The South African Health Products Regulatory Authority (SAHPRA) is providing the following key updates on the SAHPRA Engagement Portal.

1. Extension on Submissions

Response and Renewal submissions due from 1 April 2025 that have not yet been submitted due to the phased activation of submission types and recent enhancements have been granted an extension until 15 May 2025.

2. Upcoming System Release – 30 April 2025

- At 16:00 today, all older Health Product Authorisations (HPA) applications will revert to a “Legacy State”, meaning applications will appear in both the **Application Manager** and **Legacy Applications** tabs.
- **Captured Data Will Be Retained**, but assistance is required to process the necessary data fields for accurate fee calculations related to Master/Duplicates and Responses linked to a submission type.
- Legacy items in the **Legacy Applications** tab should only be updated when creating a new submission for older applications—there is no time limit for this.
- Following this reversion:
 - **Master and duplicate assignment functionality** will be available to support accurate fee calculations.
 - **Submission type data completion** will be required.

- A distinction between the following categories will be necessary for correct calculations on order forms:
 - **NCE/Biologicals/Vaccine products**
 - **Generic/Biosimilar products**
 - This applies to **Responses** and **Variation submissions** within older applications.
- Applicants are reminded to report any sequences that generated errors during invoice generation. If you have not already, please send the relevant details to portal.support@sahpra.org.za to enable the removal of affected sequences and ensure the continuation of responses.

3. Introduction of the "Release Note" Tab

A new **Release Note** tab will be added to the Portal menu, allowing users to view newly introduced features and fixes. This will provide updates on specific issues and enhancements, along with their impacts.

4. Renewals Submission Activation – 8 May 2025

The Renewals submission type will go live on **Thursday afternoon, 8 May 2025**.

Thank you for your patience as we work on enhancing the system. Thank you for your support!

Kind regards,




Christelna Reynecke
Chief Operating Officer
SAHPRA

Date: 30 April 2025