

## COMMUNICATION TO STAKEHOLDERS

Issue No.: HPA16-2025/26

**5 May 2025**

# SAHPRA Engagement Portal – Variation, Renewal and Response Applications

## 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
Version 7	05 May 2025

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

We acknowledge that some challenges persist with submissions for variations, renewals, and responses.

To accommodate time-sensitive applications, we will implement a parallel process starting on 06 May 2025. New health product applications will continue to be submitted through the portal, while submissions for variations, renewals, and responses may be completed via FTP using the previous trigger file system.

This approach ensures the continued receipt and processing of applications while we resolve the calculation module for variations, renewals, and responses. It also provides the industry with an additional opportunity to review and correct legacy data, ensuring the proper assignment of all TOA products, submission of any missing legacy sequences or baselines, and other necessary adjustments.



We will conduct a daily manual import of these applications into docuBridge throughout May 2025. The staggered re-activation of submissions for variations, renewals and responses will commence

gradually during May 2025, with further details on the phased rollout to be communicated in due course. The re-activation will occur in controlled stages over the first four weeks of June to ensure a structured process and allow for focused issue resolution within specific submission categories.

The extension for responses (refer to Communication to Stakeholders HPA16-2025/25, Version 6) remains in effect until 15 May 2025. However, once the FTP submission process is activated tomorrow at 08:00, you may begin submitting responses and renewals that are ready for processing.

We appreciate your continued patience as we work through these initial challenges and look forward to ongoing constructive engagement.

Kind regards,

Christelna Reynecke

**Chief Operating Officer**

**SAHPRA**

Date: 05 May 2025