

## COMMUNICATION TO STAKEHOLDERS

Issue No.: HPA15-2024/25

**26 September 2024**

# Implementation of Regulatory Information Management System – Update on Progress

### Document History

<b>First Publication – Version 1</b>	06 March 2024
<b>Version 2</b>	26 April 2024
<b>Version 3</b>	26 April 2024
<b>Version 4</b>	27 May 2024
<b>Version 5</b>	08 July 2024
<b>Version 6</b>	26 September 2024

## INTRODUCTION

This communication is intended to provide an update on the progress of the Regulatory Information Management System (RIMS) deployment at the South African Health Products Regulatory Authority (SAHPRA).

We wish to thank industry members who attended the launch of the SAHPRA Engagement Portal on 20 September 2024. We want to re-iterate a few important milestones and key dates for the activities planned for the next six (6) months.

### Kindly note the following:

- New health product submissions in version eCTD 3.1 may be submitted from **1 October 2024**, but this format will be compulsory from **1 November 2024**.

- The SAHPRA Engagement Portal User Administration will go live on **1 November 2024** allowing organisations to register their company details, the related Admin users and normal organisational users.
- A How-To online session will be held on **24 October 2024** to run through the Account Administration and Registration module. A Quick Reference Guide will be made available after the session.
- An on-site joint testing session with a small group of industry participants and SAHPRA internal users will be conducted to walk through the logging of applications for New Registrations, Renewals and Variations.
  - **Industry members who wish to participate in the Focus Group** are invited to indicate their interest via email. Please send an email to [christelna.reynecke@sahpra.org.za](mailto:christelna.reynecke@sahpra.org.za) indicating your interest in participating in the Focus Group, with the following in the subject line: SAHPRA FOCUS GROUP PARTICIPANT. The participation emails must be submitted by **18 October 2024**.
  - 5-8 applications each for “New Medicines”, “Variations”, and “Renewals” will be selected. Applications that have been submitted already can be used for the testing session.
  - Once the Focus Group participants have been identified, a planning session will be scheduled for November 2024 in preparation for the testing session in December.
- The testing session is planned for **02 to 05 December 2024**.
- Testing feedback will be consolidated and a Snag List consolidated between **06 and 13 December 2024** before the annual break.
- Trouble-shooting and refinements will be carried out between **13 January 2025 and 21 February 2025**.
- Focus group will re-convene between **24 February 2025 and 28 February 2025**.
- **28 February 2025** is the last day to request for application numbers for new medicines that will be submitted before 24 March 2025.
- A How-To online session will be held on **06 March 2025** to prepare for logging of New Medicine, Variation and Renewal applications on the Portal. A Quick Reference Guide will be made available after the session.
- No new submissions will be taken in from **24 March 2025 to 31 March 2025**. This is to allow the docuBridge application listings and the sequence-related data to be synched with the Portal. **Please ensure that your applications are submitted before 24 March 2025.**


Data cleansing and normalisation activities are ongoing, and your assistance will be required during October 2024 to March 2025 to verify data sets available for your organisation and product portfolio.

**Go-Live for Health Product Applications (new, variations and renewals) is planned for 1 April 2025.**

**Note:** We are currently looking at creating a playpen environment which will be made available post **06 March 2025** for industry to practise. This component will be confirmed in a follow-up communication.

Thank you for your patience and ongoing support.

Kind regards,

  
SIGNIFLOW

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**SAHPRA Chief Executive Officer (CEO)**