

**COMMUNICATION TO STAKEHOLDERS**

Issue No.: HPA15-2024/25

**28 May 2024**

**Implementation of Regulatory Information Management System – Update on Progress**

Document History

First Publication – Version 1	06 March 2024
Version 2	26 April 2024
Version 3	26 April 2024
Version 4	27 May 2024

We are sharing a communication to provide a general update on the progress for the deployment of the Regulatory Information Management System (RIMS) that commenced at the end of March 2024.

As per the communication shared on the 26 April 2024, we would like to highlight a few issues that we have identified with the triggers files that are being submitted by applicants which are resulting in upload and processing failures/issues.

**Kindly assist with attending to these items to ensure that the upload of submissions run smoothly.**

1. The **related sequences field** – this must be populated with a value – if it’s a baseline or initial submission – the related sequence number must then be the 0000 or as relevant – as this submission is related to itself. Any responses or submissions of supplementary information should contain the relevant related sequence number.
2. **Ensure that mandatory fields are all populated** – use the drop-down lists where

relevant.

3. **Ensure that the naming convention for the trigger file is correct –**

- a. Correct (“0000-envelope” or “0006-envelope” etc.)
- b. Incorrect (“0002-envelop” or “0002-envelope-za” or “envelope-0023-za”

*Ensure that “envelope” is spelt correctly.*

4. Ensure that the **trigger file is saved as an XML file** and not a .txt file.

5. Ensure that the **naming convention of the application folder is correct** – it should just be the application number (of then the first strength).

6. Provide the submission as:

- o Application folder
  - Submission Folder
  - Submission Working Documents Folder
    - Application form folder – and then just the documents (no folder within folder please)
    - Product Information folder – and then just the documents (no folder within folder)
  - Submission trigger File

7. Quality Control the Working folder before submission – avoid uploading “temp files”, database files and any other file that should not be part of the submission. Also, ensure that the Application folder and Product information folder sequence number relates to the current sequence and not a prior sequence’s structure.

8. The naming conventions for the working documents must be in line with the guideline.

From 27 May 2024, the system will scan application folders and identify trigger file issues that will be moved into a **folder on your FTP site to a folder named - "Err"**.

Please monitor this location as applications that are moved here will have a trigger file issue that should be resolved, and the application re-uploaded once ready.

*(NB! Applicants have edit access on the FTP locations – so you can delete incorrect submissions, correct and then re-upload once ready)*

***For applications where there are no issues with the trigger file – these will be moved through for the automated systems check.***

- 1. A trigger file content check will be done – if any anomalous/incorrect values are picked up in validation – it may result in a failure during admin screening – and the Health Products Authorisation (HPA) team will send a specific communication to you in this regard.*
- 2. If no trigger file content issues are picked up, the automated business validation will be carried out – any issues picked up here will be communicated via the automated messaging system with a validation report.*
- 3. If there are no issues with the trigger file, and no issues with automated business validation – the application will progress to the admin screening process etc.*

As we continue with the implementation and data correction issues, you may be requested to provide some missing data fields as it relates to some applications, or where there are data gaps on baselines, the missing information will be requested, or where there are specific sequence folders that may be required to be re-processed in the docuBridge system that could not be retrieved from the previous data repository, the specific sequence will be requested.

The process of the roll-out does allow an opportunity to establish the completeness and accuracy of data within the new data repositories. This is critical for us as we move forward and bring online the SAHPRA portal services, which also includes the online and real-time

applicant dashboards.

We appreciate that there may be some frustration during the following 2-3 months as we phase out old trackers and bring in new trackers, and ways to provide visibility and progress of applications. We are looking forward to providing improved digital platforms as the digital projects progress throughout the year.

***Kindly note that the updated Q & A document as well as the date for the follow-on webinar will be published today.***

***An updated version of the Trigger File v2.0 will be uploaded and available for use from Tuesday, 28 May 2024 (this version includes additional submission types as per feedback/suggestions received from Industry)***

Kind regards,

  
SIGNIFLOW

**Christelna Reynecke**  
SAHPRA Chief Operating Officer (COO)

Boitumelo Semete-Makokotlela  
  
SIGNIFLOW

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

