6 March 2024

Implementation of Regulatory Information Management System

Document History

First Publication – Version 1	6 March 2024

INTRODUCTION

As you are aware, SAHPRA has been focused on progressing the digital transformation of the organization over the past few years. We have different initiatives underway to digitalize our business processes.

A significant step in this journey - is the roll out of the software that will assist the Core Technical teams to manage Health Product registration application documents, lifecycle documents/updates and provide enhanced reporting and tracking capabilities.

As we are ramping up for the cut-over and go-live on the software platform, there are various activities that the team will be completing in the next few weeks. An important item is the migration of legacy data and getting all recent submissions imported.

To this end, we will be introducing an administrative freeze period as at close of business on 20 March 2024. This will allow us to complete the transfer of all applications that had been received post the First Copy Date and bring the latest submissions into the work queues.

We will then complete the migration, cut-over and embark on implementation activities between 21 March 2024 and 15 April 2024.

Please refer to the activities timetable below for the breakdown.

IMPORTANT ACTIVITIES AND DATES TO NOTE:

	Activity	Start	End
1	RIMS Industry Update and eCTD spec launch	11-Mar-24	11-Mar-24
2	Administrative Freeze **STARTS**	20-Mar-24	
	eCTD submission (new applications and Variations) via sFTP closes at 17h00		
	Variation submissions via DVP Portal closes at 17h00		
3	Migration of latest submission packages/dossiers received from 21 Feb 2024 to 20 March 2024	21-Mar-24	
4	Final Testing	25-Mar-24	27-Mar-24
5	Cut-Over to new environment	27-Mar-24	
6	Go-Live - Internal - ramping up	02-Apr-24	12-Apr-24
7	Administrative Freeze **ENDS**	15-Apr-24	
8	Submissions for New Health Product applications , **submissions for ALL Variations** and submission for Renewals via sFTP **START**	16-Apr-24	

Please note:

Detailed discussions around the requirements for submissions from 16 April 2024 will be discussed at the webinar planned for 14 March 2024 – this specifically relates the interim inclusion of a simple XML file that must be uploaded along with the eCTD zip folder submissions.

We will go through the simple XML template on the 14th of March 2024 and then all relevant documents, templates and XML how-to guide will be published for review and preparation for new submissions from the 16th of April 2024.

From 1 July 2024 – the SAHPRA portal applications process will facilitate the generation of the XML file.

All *variations* submitted from 16 April 2024 will be via eCTD through sFTP - so that all sequences are managed appropriately in the Information System.

 Legacy applications that had been made via the DVP portal up to 20 March 2024, will be processed and closed out. All NEW Variation applications submitted post the admin freeze will be required to conform with eCTD specifications and guidelines and must be submitted in eCTD format to enable lifecycle management of the application, to also prevent further duplication of submissions through different mechanisms, and eliminate missing sequences in the document flow.

Further information and documentation will be shared via follow-up communication Monday 11 March 2024 in preparation for the Webinar on 14 March 2024.

Regards

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COO