

COMMUNICATION TO STAKEHOLDERS

Issue No.: HPA15-2025/26

26 February 2025

Implementation of the Regulatory Information Management System– Status updates on the SAHPRA Engagement Portal

DOCUMENT HISTORY

First Publication – Version 1	06 March 2024
Version 2	26 April 2024
Version 3	26 April 2024
Version 4	27 May 2024
Version 5	08 July 2024
Version 6	25 September 2024
Version 7	24 October 2024
Version 8	28 October 2024
Version 9	16 January 2025
Version 10	22 January 2025
Version 11	24 February 2025

INTRODUCTION

Reference is made to HPA15-2024/25, version 5 and 6.

This document serves to inform applicants about the upcoming launch of the SAHPRA Engagement Portal on 01 April 2025.

SAHPRA wishes to thank applicants for the validation of data points and to re-iterate the significance of the portal on our regulatory processes. This centralised platform will streamline the facilitation of submissions for Health Product Applications by providing a unified interface for all new, variation and renewal submissions which will interface with eCTD.

To ensure the smooth transition, please take note of the following important dates:

No.	Activity Description	Start	End	Status
1	Health Product Submissions in eCTD 3.1 Go-live	01 November 2024	n/a	Done
2	SAHPRA Engagement Portal User Administration Go-live	01 November 2024	n/a	Ongoing
3	Testing session	05 December 2024	05 December 2024	Done
4	Troubleshooting and refinements	13 January 2025	21 February 2025	Done
5	Focus group testing	10 February 2025	11 February 2025	Done
6	Application number requests (cut-off date)	28 February 2025	31 March 2025	Ongoing
7	Administrative freeze – do not submit applications for new products, variations, renewals, response to queries	18 March 2025	31 March 2025	Ongoing
8	DVP closure*	18 March 2025	n/a	Ongoing
9	Industry webinar	19 March 2025	19 March 2025	Ongoing
10	SAHPRA Engagement Portal go-live	01 April 2025	n/a	Ongoing

*The DVP remains available until 31 August 2025 to allow applicants to download documents. From 01 September 2025, the DVP will be decommissioned.

From 01 April 2025, the administrative freeze is lifted, and we resume activities as normal using the SAHPRA Engagement Platform.

Thank you for your patience and ongoing support. Please email Pratibha Sobrun, pratibha.sobrun@sahpra.org.za, if you have any questions.

Kind regards,




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