

COMMUNICATION TO STAKEHOLDERS

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Regulatory Information Management System – Cancellation of Health Product Registrations for non-eCTDs

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INTRODUCTION

This communication aims to provide an update to applicants regarding a South African Health Products Regulatory Authority (SAHPRA)-initiated grace period for cancelling the registration of health products not in eCTD format.

Post the implementation of eCTD 3.1 submissions process, SAHPRA has started to receive communication from applicants seeking to cancel the registration of products that are either not marketed or are being discontinued. These requests highlight that the dossiers that are not in eCTD format cannot be cancelled in accordance with ZA-SAHPR eCTD Specifications v3.1.

SAHPRA acknowledges the challenges faced by applicants in converting to the eCTD format. **The following temporary solution will be allowed for the cancellation of registrations for non-eCTDs exclusively during the period from 1 April 2025 to 31 May 2025:**

- A formal cancellation request, including the reasons for cancellation must be submitted to the dedicated mailbox: cancellations@sahpra.org.za
- The request must be signed by the Responsible Pharmacist and include a certified copy of the registration certificate or an affidavit if you are not in possession of the original registration certificate.
- SAHPRA will issue a letter to confirm the cancellation of the health product.

Following this period, applicants must adhere to the Application Withdrawal process as outlined in Section 4.5.2.1 of ZA-SAHPR eCTD Specifications v3.1.

Please note: Annual retention fees for the year ending 31 December 2024 remain applicable for products being cancelled in 2025. The above process does not mean products on the register as at the end of 2024 are now exempted from the retention fee payment. These cancellations will apply to this year's retention fees payable on or before June 2025.

Please email Pratibha Sobrun, pratibha.sobrun@sahpra.org.za, if you have any questions.

Kind regards,




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