

COMMUNICATION TO STAKEHOLDERS

Issue No.: Vet Unit 01-2023/24

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[ACCESS TO UNREGISTERED VETERINARY MEDICINES]

INTRODUCTION

This document provides guidance on access to unregistered medicines for animal use through the provisions of Section 21 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

Applicants are required to comply with the provisions of the Act and Regulations.

The Section 21 application and process

In addressing the challenges faced by applicants and delays in processing such applications, SAHPRA has developed a set of guidelines: SAHPGL-PEM-VET-01_v4 Guidelines on Access to Unregistered Veterinary Medicines.

The guideline outlines the process to be followed and clarifies the mandate, and scope when requesting a medicine through Section 21.

SAHPRA has also developed templates and application forms that must be completed by the applicant when requesting use of unregistered medicines for individual patients and for bulk orders when necessary.

GLF-PEM-VET-01A_v2 Veterinary Medicines Section 21 Application Form: Strictly for completion for use for individual patients. The application forms must be completed in full, signed and dated.

GLF-PEM-VET-01C_v2 Section 21 Emergency Medicines Bulk Application Form: Strictly for use by companies that will keep the product as bonded stock under recommended storage conditions before distribution to veterinarians whose applications have been approved by SAHPRA.

GLF-PEM-VET-01B_v3 Progress Report Form After Use of An Unregistered Product: The authorisation permit **allows you a once-off six (6) months' supply** of the imported product.

You are required to furnish SAHPRA with a written report on the use of the product 6 monthly and /or at the end of treatment. Failure to submit a progress report may negatively influence future applications for further authorization.

Contact details and turnaround times:

All application forms and guidelines are available on the SAHPRA website: [Veterinary Medicines - SAHPRA](#)

Hours of operation: The Veterinary Medicines Unit operates 8 hours a day (8.00 am to 4.00 pm) during the week only.

Turnaround time: All applications will be processed with 3 working days if all the required information has been submitted.

Application submission: Please use the following email address for submission and enquiries: pervetS21@sahpra.org.za

Alice Sigobodhla



 SIGNIFLOW*

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SAHPRA**