

COMMUNICATION TO STAKEHOLDERS

Issue No.: CRO01-2025/26

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CORE BUSINESS ESCALATION PROCEDURE

INTRODUCTION

This document intends to provide clarity on SAHPRA's Core Business Escalation procedure, to enable effective and efficient communication between SAHPRA and its stakeholders. This escalation procedure communicates the Regulatory Authority's structured framework for addressing and resolving any regulatory, compliance, or operational issues in a timely and transparent manner. It defines the hierarchy of communication and responsibility — outlining specific levels of authority to engage with, as queries progress in severity or complexity. The procedure ensures that concerns related to health product approvals, safety monitoring, quality control, licensing and general enquiries are escalated to the appropriate Unit or Department, then to Managers, Senior Managers, and finally Executives, depending on the nature and urgency of the matter. This systematic approach promotes accountability, minimizes regulatory risk, and safeguards public health through prompt communication.

Please note only matters listed below may be brought to the Office of the Chief Regulatory Officer (CRO), using the escalation process outlined.

1. Medical Devices
2. Inspectorate & Regulatory Compliance
3. Pharmaceutical Evaluation Management
4. Clinical Evaluation Management
5. Radiation Control
6. Veterinary Medicines
7. Section 21
8. Clinical Trials

Matters outside the jurisdiction of the CRO need to be escalated accordingly. It must be highlighted that applicants or stakeholders are required to **first peruse the Key Contacts page¹** on the SAHPRA website to identify the Unit responsible for addressing the query. This will ensure that queries are routed to the correct Unit to avoid delays in effectively addressing matters.

¹ <https://www.sahpra.org.za/key-contacts/>

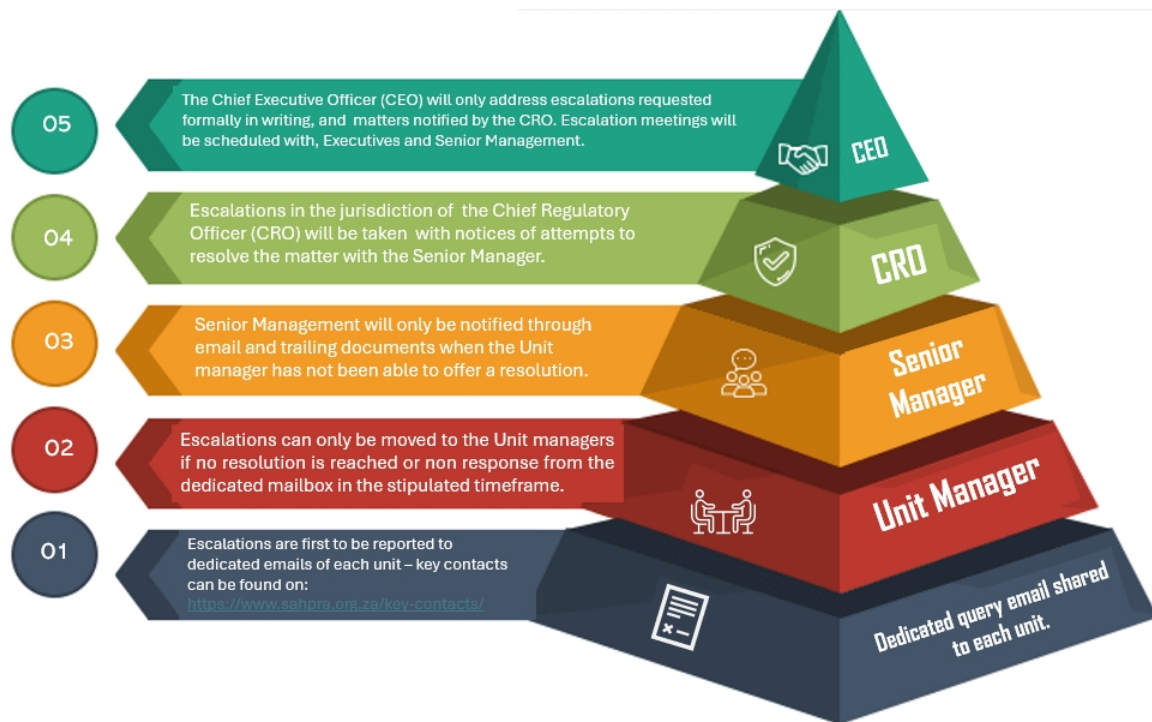


Figure 1: 5 Stages of SAHPRA Business Escalation.

Step 1

Registration and Administrative queries:

To initiate an escalation process, technical queries need to be addressed to the dedicated email addresses. Applicants should expect a response from the dedicated email addresses in **5-10 working days**.

Step 2

Escalation to the Unit Manager:

If no resolution, then the applicant can escalate to the relevant Unit Manager who ought to respond to the issue within **7 working days of receipt**. The Unit Manager will communicate the proposed response via email. Should there be no response from the Unit Manager, then the applicant can escalate the matter to the relevant Senior Manager.

Step 3

Escalation to the Senior Manager:

The Senior Manager will be notified through email and trailing documents. The Senior Manager upon receiving such email will try to resolve the escalated matter within **7 working days upon** receipt.

Step 4

Escalation to the CRO/ COO:

Only after the matter has surpassed the above timelines for resolution and there is still no satisfactory response from the Senior Manager, then the matter via email, can be brought to the attention of the Chief Regulatory Officer (CRO) or, for HPA matters escalate to the Chief Operations Officer (COO). Due to the volume of queries, always ensure the Office Manager of the CRO is in copy when escalations are sent to the CRO. Matters will be attended to within **5 working days**.

Step5

Escalation to the CEO:

Escalation to the CEO is of the highest level – this escalation will be requested formally in writing with supporting documents that no form of previous interventions and resolutions have been of any help. The Office of the CEO will not address any escalations outside of there being evidence that matters have gone through the necessary channels of protocol and escalation structure (refer **Fig. 1**).

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