

GUIDELINE FOR APPEALS AGAINST REGULATORY DECISIONS

April 2022

This guideline is intended to provide guidance to applicants wishing to submit an appeal against all regulatory decisions which are administrative in nature.
Any person aggrieved by the decision of the Authority may appeal against such decision by notifying the Chief Executive Officer within thirty (30) days of becoming aware of such decision of his or her intention to appeal and setting out the full grounds of appeal. The Authority is committed to ensure that appeals are acknowledged and dealt with fairly, efficiently, and effectively.

Document History

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List of abbreviations and definitions

Abbreviation / Term	Meaning
Act/Medicines Act	The Medicines and Related Substances Act, 101 of 1965
Appeal	Process of lodging a grievance against the decision of the Authority
Appeal Committee	Committee constituted by the Minister to hear an appeal emanating from a grievance that was referred to the CEO by an appellant, but could not resolved in a meeting between the appellant and the CEO
Appellant/applicant	Persons aggrieved by the decision of the Authority
CEO	Chief Executive Officer

1. Introduction

1.1 Purpose

The purpose of this guideline is to outline the principles and process to be followed when submitting an appeal against the decision taken by SAHPRA.

1.2 Scope

This guideline applies to all regulatory decisions of SAHPRA that are administrative in nature. Appeals will only be processed if they meet the following criteria:

Table 1: details the matters that can be considered section 24A.(1) of the Medicines Act .

Authority's decision relating to	Appealable	Not Appealable
Decision on standard of quality, safety and efficacy		X
Contravention of the Medicines and Related Substances Act		X
Non-compliance with timeframes	Depending on the circumstances such appeal maybe considered	
Submission of incomplete dossier		X
Failure or delay in respond to a query	X	
Failure to submit a required report	X	

The appeals letter must have the following information/ details, such as:

- Name of person who wrote the letter,
 - name of the company that is complaining (if applicable); and
 - contact details like phone numbers, address and valid e-mail address.
- A letter of appeal must set out full grounds of appeal, and where possible supporting evidence/ documents must be attached thereto.
 - The appeal must be submitted within thirty (30) days of becoming aware of the decision of the Authority.

2. Legal Provision

Medicines and Related Substances Act, Act 101 of 1965

Section 24A. Appeal against decision of Authority. —

- (1) Any person aggrieved by the decision of the Authority may appeal against such decision by notifying the Chief Executive Officer within 30 days of becoming aware of such decision, of his or her intention to appeal and setting out the full grounds of appeal.
- (2) Upon being notified, the Chief Executive Officer shall meet with the appellant within 30 days of being so notified in the absence of legal representatives to try to resolve the matter, especially if the appeal involves administrative matters.

- (3) Should the Chief Executive Officer and the appellant fail to resolve the matter as contemplated in subsection (2), the appellant shall within 30 days of being notified by the Chief Executive Officer of the failure to resolve the matter and upon payment of a prescribed fee, request the Minister in writing to convene an appeal committee.

3. Appeals Process

- 3.1 Any person who is aggrieved by the decision of the regulator may lodge an appeal with the CEO.
- 3.2 All appeals should be submitted to the CEO via Email to CEOoffice@sahpra.org.za
- 3.3 An appeal must be lodged within thirty **(30) days** of becoming aware of the decision of the Authority.
- 3.4 The CEO must within **30 days** of receipt of the appeal meet and hear the applicant's grievance, in the absence of legal representatives, to try and resolve the matter.
- 3.5 The CEO shall consider the applicant's submission and take the decision.
- 3.6 The CEO shall inform the applicant of the outcome of the appeal.
- 3.7 The CEO may uphold or reject an appeal, and in the event the appeal is rejected, the CEO must provide the applicant with written reasons thereof.
- 3.8 If the matter remains unresolved, the applicant has **30 days** of being informed of the CEO's decision, to request the Minister in writing to constitute an Appeal Committee.
- 3.9 In the event the appellant refers an appeal to the Minister, the appellant shall pay the prescribed fee into SAHPRA's banking account.
- 3.10 The Appeal Aommittee shall have a chairperson who has the knowledge of the law. The is appointed by the Minister, and two persons nominated by the appellant and the other two persons nominated by the CEO, these nominated persons must have knowledge of the subject matter.
- 3.11 The appellant and the CEO may be legally represented in the proceedings of the Appeal Committee.
- 3.12 The Appeal Committee shall hear and make its decision within 30 days of its first meeting to hear the appeal.
- 3.13 Should any party feel aggrieved by the decision of the Appeal Committee, such party may approach the High Court for a judicial review.

Amendment History

Version	Date	Reason for amendment
V1	April 2022	New Guideline