South African Health Products
Regulatory Authority
Building A
Loftus Park
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11 October 2024

GUIDELINES FOR APPEALS AGAINST REGULATORY DECISIONS

These guidelines are intended to provide guidance to appellants wishing to submit an appeal against regulatory decision regarding products and/or issues relating to SAHPRA regulated products.
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

Final Version	Reason for Amendment	Effective Date [dd Month yyyy]
1	Final Guideline for implementation	03 March 2022
2	Appeal Guidelines	March 2023
3	Appeal Guidelines	October 2024

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Glossary

Abbreviation/ Term	Meaning
Appeal	Process of lodging a grievance against the decision of the Authority
Appeal Committee	Committee constituted by the Minister to hear a grievance that was not resolved in an appeal by the appellant to the CEO
Appellant	Person aggrieved by the decision of the Authority
CEO	Chief Executive Officer

1. INTRODUCTION

1.1 Purpose

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

1.2 Scope

These guidelines apply to all regulatory decisions of SAHPRA, and these guidelines are meant to speedily resolve appeal process.

- Each appeal will be decided on its merits:
- An appeal must meet the following criteria

Table 1: Details of the matters that can be considered for appeal in terms of section 24A.

Authority's decision relating to	**Appealable**	**Not Appealable**
Decision on standard of quality, safety and efficacy	Only appealable where new information not considered before is made available	
Contravention of the Medicines and Related Substances Act	Where new evidence is made available to prove that the Act was not breached	
Non-compliance with timeframes	Depending on the facts of each case some appeals maybe considered	
Submission of incomplete dossier		X
Failure or delay to respond to a query	X	
Failure to submit a required report	X	

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

- Name of person who wrote the letter/appealing,
- Name of the company that is appealing (if applicable), and
- Contact details such as phone numbers, address, and valid e-mail address.

The 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

3.2 Any person who is aggrieved by the decision of the regulator may lodge an appeal with the CEO.

3.3 All appeals should be submitted to the CEO via Email to CEOOffice@sahpra.org.za

3.4 An appeal must be lodged within thirty **(30) days** of becoming aware of the decision of the Authority.

3.5 The Chief Executive Officer 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.

3.6 The Chief Executive Officer shall consider the applicant's submission and take the decision.

3.7 The Chief Executive Officer shall within 30 days of section 24A(2) meeting inform the appellant of the outcome of the appeal.

3.8 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.

3.9 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.

3.10 In the event the appellant refers an appeal to the Minister, the appellant shall pay the prescribed fee.

3.11 The appeal committee shall have a chairperson who has the knowledge of the law.

3.12 The chairperson is appointed by the Minister and two persons nominated by the appellant and the other two persons are nominated by the CEO, these nominated persons must have knowledge of the subject matter of the appeal but must not have a financial or business interests in the affairs of the parties to the appeal.

3.13 The appellant and the CEO may be legally represented in the appeal committee.

3.14 The Appeal committee shall hear and make its decision within 30 days of its first meeting to hear the appeal.

3.15 Should any party feel aggrieved by the decision of the appeal committee, such party may approach the High Court for a judicial review.

4. REFERENCES

The following related documents are referenced:

The Medicines and Related Substances Act;

The General Regulations

The Medical Devices Regulations

5. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision. It will be reviewed on this timeframe or as and when required.

6. General Complaints process

In terms of the complaints process, stakeholders can send through complaints via:

- Website: General Enquiries – online web form

- Enquiries mailbox: enquiries@sahpra.org.za
- Queries/complaints come through various email addresses across operational units.
    - These queries/complaints are then uploaded onto the ServiceDesk (Quantum) after the back-end process is being managed by the units.
- Complaints relating to medicine and medical devices: https://www.sahpra.org.za/complaints-relating-to-medicine-and-medical-devices/
    - There are some instances where stakeholders complain here under the Whistleblower section: https://www.sahpra.org.za/report-fraud-corruption-and-unethical-behaviour/

Approved by

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20 August 2024