South African Health Products
Regulatory Authority
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GUIDELINE ON HOW TO LODGE A COMPLAINT ON MEDICINES AND MEDICAL DEVICES

This document has been prepared to serve as a guidance document regarding SAHPRA requirements for lodging a complaint on Medicines and Medical Devices – Regulatory Compliance Unit.

Document History

Final Version	Reason for Amendment	Effective Date
1	First issue, public comments incorporated and published for implementation	September 2006
2	Change of Telephone and Fax numbers	June 2010
3	Change to the new SAHPRA format, addition of Background, Scope, Definitions, 5.5, 5.6, 5.8 and 5.9	September 2021
4	- Updated on the latest guideline template - Old document number 5.09 replaced with the new unique document number (SAHPGL-INSP-RC-12, see the footer of this document)	November 2022

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Glossary

Abbreviation/ Term	Meaning
IVDs	*In-Vitro* Diagnostics
RCU	Regulatory Compliance Unit
SAHPRA	The South African Health Products Regulatory Authority

1. INTRODUCTION

Any person suspecting that the quality, safety and/or efficacy or advertising of medicine and medical devices may be compromised and that the use of these medicines or medical devices may affect the health of the intended end user, must report these complaints to SAHPRA for investigation to ensure that all medicine and medical devices are safe, efficacious and meet the quality standards as required to be administered to patients in South Africa.

1.1 Purpose

This guideline outlines the process to follow, and information required when lodging a complaint on medicine and medical devices. The lodging of complaints initiates and facilitates the investigation process by SAHPRA.

1.2 Scope

This guideline covers all types of complaints relating to the quality, safety and / or efficacy and advertising of medicines and medical devices. Adverse reactions resulting from the use of a medicine are excluded from this guideline and should be reported to the Vigilance Unit at SAHPRA.

2. LEGAL PROVISION

The South African Health Products Regulatory Authority (SAHPRA) (hereinafter referred to as the Authority) is mandated to monitor, evaluate, regulate, investigate, inspect, register and control medicines, Scheduled substances, clinical trials and medical devices, IVDs and related matters in the public interest according to section 2A of the Medicines and Related Substances Act, Act 101 of 1965, as amended (Medicines Act). The Authority must ensure health products and medicines registered or authorised by the Authority, during the entire life cycle, comply with the information that has been evaluated and approved by the Authority through section 2B(1)(c) of the Act. The Regulatory Compliance Unit (RCU) is responsible for ensuring that all complaints are investigated and closed timeously.

3. HOW TO LODGE A COMPLAINT

Any person that becomes aware of a suspected substandard or potential counterfeit medicine or medical device must lodge a complaint relating to medicine and medical devices by accessing the Whistleblower function on the SAHPRA website indicated below:

Whistleblower - SAHPRA

The electronic form consists of fields whereby the relevant information pertaining to the complaint relating to the medicine or medical device can be entered. The sections and subsections are indicated below. Fields

marked with an * are mandatory and it is recommended to fill in all fields to enable SAHPRA to provide feedback to the reporter/complainant.

3.1 Reporter's Details should be as follows:

- Reporter's full name;
- Reporter's e-mail address;
- Reporter's contact number; and
- Date that the complaint was reported.

  NOTE: This information is not mandatory and the complainant may choose to remain anonymous.

3.2 Company/ Product Information:

- Name of Company/Manufacturer/Distributor/Wholesaler;*
- Where is the company/if you have the address please write; *
- Name of the person involved/responsible and contact details if available;*
- Name/s of Product/s;*
- If applicable, list the product batch number/s;
- If applicable, list the product expiry date/s;
- Describe the complaint/concerns and indicate dates where possible; and
- Reason for the complaint.

3.3 Any supporting pictures or other documentation can be uploaded and then the complaint can be submitted.

4. REFERENCES

None

5. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the old guideline 5.09 for the Requirements & Guidelines on How to lodge a complaint on Medicines and Medical Devices. It will be reviewed on this timeframe or as and when required.