South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

REQUIREMENTS FOR LODGING A COMPLAINT ON MEDICINES AND MEDICAL DEVICES

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.

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Definitions, 5.5, 5.6, 5.8 and 5.9	

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1. BACKGROUND

1.1 The South African Health Products Regulatory Authority (SAHPRA) (hereinafter referred to as the Authority) is a statutory body, established to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of 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.

1.2 The Regulatory Compliance Unit is responsible for ensuring that all complaints are investigated and closed timeously.

2. PURPOSE

2.1 This guideline outlines the information required when lodging a complaint on a medicine and medical devices, and it also facilitates the investigation process.

3. SCOPE

3.1 This guideline covers all types of complaints on medicines medical devices quality, safety and / or efficacy, and advertising of medicines, but excludes adverse reaction complaints resulting from the use of a medicine, which should be reported to the Pharmacovigilance Unit at SAHPRA.

4. DEFINITIONS

4.1 Medicines Act: Medicines and Related Substances Act, Act 101 of 1965

4.2 Medical devices: Means any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973) —

(a) intended by the manufacturer to be used, alone or in combination, for humans or animals for one or more of the following:
  (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
  (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
  (iii) investigation, replacement, modification, or support of the anatomy or of a physiological process;
  (iv) supporting or sustaining life;
  (v) control of conception;
  (vi) disinfection of medical devices; or
  (vii) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and

(b) which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means;

4.3 Medicine:

(a) means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—
  (i) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or
  (ii) restoring, correcting or modifying any somatic or psychic or organic function in humans, and

(b) includes any veterinary medicine,

5. HOW TO LODGE A COMPLAINT

A complaint should be in writing. A telephonic complaint is also acceptable but written complaints are the preferred route.

5.1 State the name of the medicine, the registration number, the batch number and the expiry date of the medicine.

5.2 In case of an unregistered medicine, state the name of the manufacturer/supplier/agent and contact details.

5.3 State the detail of the complaint.

5.4 Submit a sample of the medicine, medical device or advertising material to accompany the complaint where applicable.

5.5 Attach a photo of the complaint sample with geo-location/Pin location and business information where applicable.

5.6 Refrain from purchasing any complaint sample/s as buying an illegal product makes the buyer complicit in a crime as a result **purchasing of a complaint sample/s it is not a requirement for lodging of a complaint.**

5.7 Present all complaints in English. Advertisements that are not in English should be accompanied by an English translation.

5.8 Address all complaints (excluding adverse reactions) to the Registrar of Medicines for attention of the Director: Inspectorate & Law Enforcement at the following address:

SAHPRA
Regulatory Compliance Unit
Building A (4th Floor)
402 Kirkness Road
Loftus Park
Arcadia

complaints@sahpra.org.za

Tel: (+27)012 501 0311

5.9 Address complaints on adverse reactions resulting from the use of a medicine to:

SAHPRA
Pharmacovigilance Unit
Building A (2nd Floor)
402 Kirkness Road
Loftus Park
Arcadia

pvqueries@sahpra.org.za

Tel: (+27)012 501 0311

NB: It should be noted that the confidentiality of the information submitted to the SAHPRA is governed by section 34 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended.