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

GUIDELINE FOR RELEASE OF IMPORT HEALTH PRODUCTS AT PORTS OF ENTRY

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This document has been prepared to serve as a guidance document regarding SAHPRA requirements for release of import health products at Ports of Entry - Regulatory Compliance Unit.

Document History

Version	Date	Reason for amendment
1	10 October 2021	Guideline for implementation consolidating industry comments
2	June 2022	New Template Document change number from 5.10 to SAHPGL-INSP-RC-11

BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER

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List of abbreviations and definitions

Table 1: List of Abbreviations

Abbreviation	Complete name
AWB	Air Waybill
SAHPRA	The South African Health Products Regulatory Authority
CM	Complementary Medicine
IVD	In Vitro Diagnostic (medical device)

Table 2: List of Definitions

Term	Definition
AWB	Number for tracking parcel as provided by the courier or airway service provider
Invoice	a list outlining name of each product, strength, quantity with a statement of the sum due for these detailing the country of origin, exporting company with relevant official details
Ports of Entry	There are seven health products Ports of Entry ORTIA, King Shaka International Airport, Durban Harbour, Cape Town International Airport, Cape Town Harbour, Port Elizabeth Airport and Port Elizabeth Harbour.
Pharmacist	Means a person registered as such under the Pharmacy Act, 1974.

Introduction

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, 1965 (Act 101 of 1965), as amended (Medicines Act). The Authority must ensure health products and medicines registered or authorized 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 health products at Ports of Entry meet importation requirements in terms of the Medicines Act and the general regulations whether for personal or commercial purposes.

1.3 This guideline is intended to assist importers, agents, shippers, travellers and visitors on what relevant documents and processes are required for imported health products to obtain permission in South Africa.

1. Purpose

This guideline applies to import of health products and medicines requiring release and clearance at the Ports of Entry. Either for commercial, personal, animal health, or any other purpose by importers.

The scope includes special authorisation application process, applicable fees and the turnaround time for finalizing an application.

2. Background

This document has been prepared to serve as a guidance document regarding SAHPRA requirements for release of import health products at Ports of Entry - Regulatory Compliance Unit.

3. Requirements for Release

3.1. Supporting Documents for Release of Imports

3.1.1. Imported medicines and health products must be accompanied by the Licence issued by SAHPRA i.e. Section 22C (1)(b):

3.1.1.1. For Medical Devices, the licence should include list of such products.

3.1.1.2. For complimentary products, the Port Technicians would advise based on the existing legislation (liaison for release outcome between Regulatory Compliance and Complementary Medicines unit)

3.1.2. Imported health products must be accompanied by the Certificate of registration in respect of such medicines issued by SAHPRA in terms of Section 15 or Authorisation in terms of Section 21 in case of unregistered products;

3.1.2.1. Applicable to certain Medical Devices such as COVID-19 related products;

3.1.2.2. Not yet applicable to Complementary medicines although the complementary guideline 7.02 is applicable;

3.1.2.3. a certified copy of recording/registration in terms of the Pharmacy Act for scheduled medicines;

3.1.2.4. a certified copy of a licence in respect of premises in terms of the Pharmacy Act for scheduled medicines.

3.1.3. In addition to 3.1.1 and 3.1.2 narcotics and psychotropic substances, i.e. schedule 5, 6, 7 and 8 products can only be imported with a permit issued in terms of Section 22A (9) and 22(A)(11).

3.1.4. Shipping documents must correspond with the SAHPRA approvals

3.1.5. SAHPRA Port personnel will help enable release of the products if they meet the above-mentioned requirements.

3.2. Medicines for Personal use by Persons entering the RSA

Any person entering the Republic may be in possession, for personal medicinal use, of-

3.2.1. a quantity of a Schedule 3, 4 or 5 substances, which shall not exceed for use for a period of six months; oral quantity of a Schedule 6 substance, which shall not exceed use for a period of 30 days;

3.2.2. a person shall have the original prescription for such a Scheduled substance;

3.2.3. a certified copy of such prescription; or

3.2.4. a certificate or letter issued by the person who prescribed or dispensed such Scheduled substance certifying that the scheduled substance and the quantity concerned was prescribed for the person entering the Republic; and including

3.2.5. the name, physical and email address of the person who prescribed or dispensed the prescription concerned.

3.3. Application for Authorisation for once off Purchases of online/Imported health products

3.3.1. Imported products for personal use will be subject to evaluation at a fee. The outcome of evaluation can be authorization or rejection. Rejected product will be subject to regulations at Ports of Entry.

3.3.2. The turnaround time for providing a final decision to the Applicant for an application for a request for release of health products is four (4) working days calculated from the date of receipt of a complete application including fee.

3.3.3. Application requirements and process regarding imported health products for personal use: the applicant must provide the SAHPRA port officials with the following documentation:

3.3.3.1. Copy of the ID / passport;

3.3.3.2. Background and reason for acquiring the medicines / medical device / other products;

3.3.3.3. Prescription should be clear and readable as well as the doctor's contact details;

3.3.3.4. Copy of invoice;

3.3.3.5. Quantities to be released of each medicine;

3.3.3.6. The screen shots of the 3D picture of the medicines showing full labelling;

3.3.3.7. Address of home and current stay;

3.3.3.8. Shipping number. (AWB, tracking info and the port of entry);

3.3.3.9. Proof of payment.

3.4. Samples for Registration/Analytical Purpose

For applications for release of products imported by legal entities for commercial use, registration or analytical purposes, the applicant must send the following documentation to the SAHPRA port officials

3.4.1. Application letter signed by the responsible pharmacist /delegated pharmacist with details relating to importation;

3.4.2. Copy of the license issued by SAHPRA 22C(1)(b);

3.4.3. Shipment information (AWB, tracking info and the port of entry);

3.4.4. Certificates of analysis the products;

3.4.5. Invoice of commercial operation;

3.4.6. Company details;

3.4.7. Proof of payment;

3.4.8. Fees applicable on first time registration.

3.5. Transmission of Medicines through the Republic

3.5.1. While in the Republic, be stored in a bonded warehouse which is licensed in terms of section 22C by the Authority to import or export medicines or scheduled substances;

3.5.2. Not be manipulated while in the bonded warehouse unless such authority has been issued by the Authority; and

3.5.3. A bonded warehouse referred to in sub regulation (1) shall comply with good distribution practice and licence conditions as determined by the Authority.

4. References

4.1. Related Guidelines