South African Health Products
Regulatory Authority
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REQUIREMENTS FOR RELEASE OF IMPORT HEALTH PRODUCTS AT PORT OF ENTRIES

GUIDELINE FOR RELEASE OF IMPORT HEALTH PRODUCTS AT PORT OF ENTRIES: REGULATOY COMPLIANCE UNIT

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

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CEO of SAHPRA

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 health products at Port of entries meet importation requirements in terms of the Medicines Act and the general regulations whether for personal or commercial purposes.

2. PURPOSE

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

3. SCOPE

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

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

4. DEFINITIONS

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

4.2 Health products: Medicines, Medical Devices and Complimentary Health products

4.3 AWB: Air Way Bill

4.4 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

4.5 Transmission of medicines via SA : these are destined for other countries, transmitted through the Republic of South Africa and must be declared accordingly and stored in a bonded warehouse until they are transported to their destination

4.6 Pharmacist: means a person registered as such under the Pharmacy Act, 1974;

4.7 Port of Entries: There are seven health products port of entries O.R. Tambo International Airport (ORTIA), King Shaka International Airport, Durban Harbour, Cape Town International Airport, Cape Town Harbour, Port Elizabeth Airport and Port Elizabeth Harbour.

5. FOR RELEASE OF IMPORTS THE FOLLOWING MUST BE IN PLACE

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

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

5.1.2 For complimentary products, framework will be implemented on July 2021

5.2 Imported product 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;

5.2.1 applicable to certain Medical Devices such as COVID-19 related products

5.2.2 not yet applicable to Complimentary medicines

5.2.3 a certified copy of registration in terms of the Pharmacy Act for scheduled medicines

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

5.3 In addition to 5.1 and 5.2 narcotics and psychotropic substances, i.e. schedule 5, 6 and 8 products can only be imported with a permit issued in terms of Section 22A(11)

5.4 Port Health will enable release of the products if they meet the above-mentioned requirements.

6. Personal medicinal use by persons entering republic

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

6.1 a quantity of a Schedule 3, 4 or 5 substance, which shall not exceed for use for a period of six months; or

6.2 a quantity of a Schedule 6 substance, which shall not exceed use for a period of 30 days

6.3 A person shall have the original prescription for such a Scheduled substance;

6.1.1 a certified copy of such prescription; or

6.1.2 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

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

7. Application for authorisation for Once off purchases of online/imported health products

7.1 Imported products for personal use will be subject to evaluation at a fee. The outcome of evaluation can be authorisation or rejection. Rejected product will be subject to regulations at port of entries.

7.2 The turnaround time for an application for a request for release of health products is four (4) working days from the date of receipt of a complete application including fees.

7.3 Application requirements and process: Imported health products for personal use the applicant must provide and send to the mail portreleases@saphra.org.za with the following documentation.

7.3.1 Copy of the ID / passport

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

7.3.3 Prescription should be clear and readable as well as the doctor's contact details

7.3.4 Copy of invoice

7.3.5 Quantities to be released of each medicine

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

7.3.7 Address of home and current stay

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

7.3.9 Proof of payment

8. 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 email portreleases@saphra.org.za .

8.1.1 Application letter signed by the responsible pharmacist with details relating to importation.

8.1.2 Copy of the license issued by SAHPRA 22C(1)(b)

8.1.3 Shipment information (AWB, tracking info and the port of entry

8.1.4 Certificates of analysis the products

8.1.5 Invoice of commercial operation

8.1.6 Company details

8.1.7 Proof of payment

The following types of import permits/authorisations will be issued for release at port of entries.

a) For personal use (Annex 1),

b) For commercial purpose (Annex 2)

9. Transmission of medicines through the Republic

9.1 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; and

9.2 not be manipulated while in the bonded warehouse unless such authority has been issued by the Authority

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

FEES PAYABLE PER PERMIT AND TYPE

No	Permit type	Payment reference abbreviation	Fees
1	Port of Entries Releases/ Authorisation	RCAuthNo/yyyy	R350
2	Samples for either registration or analytical purposes	RCSampleNo/yyyy	R350

Banking details

Account name: SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Special name: The Medicines Control Council

Account type: Cheque/Current Account

Account number: 40-5939-2080

Bank: ABSA

Bank Branch Code: 632005

Bank physical address: 240 VERMEULEN STREET, PRETORIA, 0001, SOUTH AFRICA

Swift Code: ABSAZAJJ

6 UPDATE HISTORY

Date	Reason for update	Version & Publication
23 September 221	First publication MCC	Version 1, 23 September 221