South African Health Products
Regulatory Authority
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GUIDELINE FOR THE IMPORTATION AND EXPORTATION OF MEDICINES : REGULATORY COMPLIANCE UNIT June 2022

This document has been prepared to serve as a recommendation to those who wish to import and export medicines in South Africa. The South African Health Products Regulatory Authority (SAHPRA) is committed to ensure that all medicines entering or leaving the country will retain the required quality, safety and efficacy. It is important for the holder of certificate of registration or applicant to adhere to the administrative requirements to avoid delays in the processing of applications.

Document History

Version	Date	Reason for amendment
Version 1	February 2015	Publication in MCC format
V2	October 2021	• Version in SAHPRA format from MCC for implementation • Legislation updates Addition of the relevant email Document number change from 2.1 to SAHPGL-INSP-RC-02

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Contents

Table list

List of abbreviations and definitions

Table 1: List of Abbreviations

GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
SAHPRA	South African Health Products Regulatory Authority
CEO	Chief Executive Officer of SAHPRA

Table 2: List of Definitions

Authority	SAHPRA
Section	Section of the medicines and Related Substances Act 101 of 1965 (as amended)

1. Introduction

The importation and exportation of Medicines and Scheduled substances are subject to control in terms of the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended (Herein referred to as the Act). South Africa is also a signatory to three International Drug Conventions, namely:

- The Single Convention on Narcotic Drugs, 1961; [SAHPRA is responsible for implementing the measures required by the said convention]
- The Convention on Psychotropic Substances, 1971; and [SAHPRA is responsible for implementing the measures required by the said convention]
- The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988. [The Department of Trade and Industry is responsible for implementing the measures required by the said convention (where applicable SAHPRA will collaborate)]

As South Africa is signatory to these conventions, the control measures contained in Act 101 were based directly on the controls required by these conventions. The obligation of South Africa and therefore the policy of the Department of Health is thus to keep national legislation in line with these conventions.

2. Purpose

This document has been prepared to serve as a recommendation to those who wish to import and export medicines in South Africa. The South African Health Products Regulatory Authority (SAHPRA) is committed to ensure that all medicines entering or leaving the country will retain the required quality, safety and efficacy. It is important for the holder of certificate of registration or applicant to adhere to the administrative requirements to avoid delays in the processing of applications

3. Background

Exports and imports are important for the development and growth of national economies because not all countries have the resources and skills required to produce certain goods and services. Nevertheless, countries impose trade barriers, such as tariffs and import quotas, in order to protect their domestic industries.

4. Legal Requirements for the Importation or Exportation of Medicines or Scheduled Substances

4.1. Ordering Medicines from Abroad

No person shall order any medicine from abroad for personal use unless the Authority has granted the said person an authorization in terms of section 21 of the Act to import during a specified period a specified quantity of the particular medicine, which is not registered with SAHPRA.

Purchasing a medication from an illegal website or supplier puts you at risk. You may receive a contaminated, substandard or falsified product. Taking an unsafe or inappropriate medication puts you at risk for dangerous medicines interactions and other serious health consequences.

4.2 Persons Entering or Departing From the Republic

Regulation 8(1) of the Act stipulates that:

1. any person entering or departing from the Republic of South Africa may be in possession, for personal medicinal use, of a quantity of a Schedule 3, Schedule 4, Schedule 5 or 6 substance which shall not exceed a quantity required for use for a period of one month; and

a) the said person must have- a valid prescription for such Scheduled substance or medicine;

b) a certificate to the effect that the Scheduled substance or medicine concerned including its quantity was prescribed for the person including the name and address of such authorised prescriber; and

c) his or her particulars of residence in the Republic, in the case of the person entering the Republic, recorded at the port of entry.

4.3 Authorization in terms of Section 21

In terms of section 14(1) of the Act, no person shall import and supply any medicine, which is subject to registration by virtue of a resolution published in terms of section 14(2) unless it registered with The Authority.

However, in terms of section 21 of the Act, The Authority may in writing authorize any person to import and sell during a specified period to any specified person or institution a specified quantity of any particular medicine, which is not registered. This permission is however subjected to confirmation from a medical professional that the product is needed and that no similar product is available in the country. The Authority will evaluate the requests and may grant the authorization which will be issued by the CEO in the prescribed manner and subject to such conditions as The Authority deems fit.

4.4 Authorization to import a sample for registration purposes

The Authority may in writing authorise any person to import a sample for registration purposes as contemplated in section 15(1) of the Act. An application shall contain at least the following information:

a) name and address (both physical and postal) of the applicant;

b) telephone and email address of the applicant;

c) licence number of the applicant as contemplated in section 22(1)(b) of the Act;

d) purpose for which the application is made;

e) proprietary name, dosage form, batch number, expiry date and quantity of the sample to be imported; and port of entry.

4.5 Licence to Import or Export Medicines or Scheduled Substances

In terms of section 22C (1) (b) of the Act, The Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a manufacturer, importer or exporter of a medicine a licence to import or export, upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the Authority may determine.

Section 22C (6) of the Act stipulates that no manufacturer, importer or exporter shall import or export any medicine unless he or she is the holder of a licence as contemplated in section 22C (1) (b) of the Act. Regulation 23(1) (a) (i) stipulates that a person referred to in section 22(1) (b) of the Act must apply to the Authority for a licence to import or export medicines or Scheduled substances. The person must submit to the CEO an application for a licence, on a form approved and provided by the Authority.

Regulation 24(1) of the Act stipulates that a licence issued in terms of regulation 23 shall be valid for a period of 5 years from the date of issue. Every application for a licence by a manufacturer, importer or exporter of a medicine, must have a responsible pharmacist with the knowledge and responsibility to ensure that the correct procedures are followed during wholesale and distribution. The owner of the manufacturer, importer or exporter of a medicine, must provide and maintain such staff, premises, equipment and facilities to enable the responsible pharmacist to carry out the said functions.

4.5.1 SAHPRA upon issuing a licence and/or reviewing a licence holder will review the following aspects and conditions:

- The manufacturer, importer or exporter of a medicine applying for a licence must be registered with the Department of Health relating to the ownership of the manufacturer, importer or exporter;
- The manufacturer, importer or exporter of a medicine applying for a licence must be registered with SAHPRA relating to the Good Manufacturing Practices entertained at the manufacturer, importer or exporter.
- The review will address Good Manufacturing Practices.

4.5.2 In order to comply with the above aspects and conditions the following should be covered and implemented:

- A Quality System addressing all aspects of quality assurance must be in place, covering Contracts (Agreements); Purchasing; Final Product handling, storage; facility installation, servicing, cleanliness; documentation controls and records; international regulatory control; internal and external audits; training; complaint handling; emergency plan and recalls; quality assurance and management review; distribution (transport, delivery, temperature control); counterfeit medicines; theft of product; export documentation (proof of export);
- If any of the Quality System aspects are delegated to a competent third party it should be done in a written formal agreement

4.5.3 Issuing of Certificates by SAHPRA:

- GMP certificates and Certificates of Pharmaceutical Products (WHO-type) need to be applied for in the prescribed manner at the office of the CEO;
- GMP certificates will be issued subject to the status of the current SAHPRA endorsed audit report pertaining to the relevant facility;
- Certificates of Pharmaceutical Products (WHO-type) will be issued to medicines registered by SAHPRA in accordance with the current legal registration dossier;
- Inclusion of additional information on the Certificate of Pharmaceutical Product (WHO-type) will be evaluated per application and could be considered in cases as i.e. additional, SAHPRA GMP-approved packaging facility capable of the process involved according to the current SAHPRA audit report of the facility in accordance with the international registered information.

4.5.4 Compliance to International Registration requirements:

- It is the responsibility of the licensed Exporter and Registration Holder of the importing country to comply with the legal registration information approved by the relevant Ministry;
- If it entails deviation from the registered medicine registration information as approved by SAHPRA, any manipulation i.e. manufacture, packaging, labelling, final pack size or container when performed in South Africa needs to take place according to current GMP in SAHPRA approved GMP facility;
- Medicines registered by another Health Authority however not registered by SAHPRA and not intended for sale or distribution in South Africa however manipulated i.e. manufactured, packed, labelled, stored in South Africa prior to export to the importing country will be subject to GMP, GWP and GDP. Meaning any manipulation that takes place need to be performed in a SAHPRA GMP-approved facility according to the standard of current GMP, GWP and GDP guidelines of SAHPRA as stipulated in Regulation 7.

4.6 Permit to Export Scheduled Substances for Analytical Purposes, Manufacture of Foods, Cosmetics, Educational or Scientific Purposes

Section 22A(7)(a) of the Act determines that no person other than a pharmacist, pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist shall export a Schedule 1, Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance for analytical purposes, manufacture of foods, cosmetics, educational or scientific purposes, unless a permit, issued in accordance with the prescribed conditions has, subject to paragraph (b), been obtained from the Director-General of Health for such purpose. The applicant shall use the official form GW 12/44 to apply for an export permit.

The export of specified Schedule 5 and Schedule 6 substances are under international control. Regulation 27(2) of the Act stipulates that the applicant must submit with the application a certified copy of the permit for importation issued by the country to which the substance is to be exported.

4.7 Permit to Import or Export Specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 Substances

In terms of section 22A (11) (a) of the Act, no person shall import or export any specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substance or medicine prescribed for that purpose unless a permit has been issued to him or her by the Director-General of Health in the prescribed manner and subject to such conditions as may be determined by the Director-General.

Regulation 27(1) of the Act stipulates that any person desiring to import or export specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substances shall apply to the Director-General for a permit to import or export such substances.

The applicant shall use the official form GW 12/10 to apply for an import permit and form GW 12/44 to apply for an export permit

Regulation 26(4) of the Act stipulates that the applicant must submit with the application a certified copy of the permit for importation issued by the country to which the substance is to be exported.

In terms of the provisions of section 22A (11)(c) of the Act, the issue of the permit may be refused if -the Director-General is not convinced that the applicant is capable of keeping or storing the substance or medicine in a satisfactory manner in order to prevent the loss thereof;

i. use of such substance or medicine has not been authorised in terms of the Act;

ii. the Director-General is of the opinion that the annual importation quota for such substance has been exceeded or will be exceeded;

iii. the Director-General is of the opinion that such substance or medicine, of an acceptable quality, is already available in the Republic; or

iv. the applicant did not comply with the conditions under which a previous permit was issued to him or her.

v. Regulation 26(4) of the Act stipulates that the applicant must submit with the application a certified copy of the permit for importation issued by the country to which the substance is to be exported.

vi. Any permit issued under section 22A(11)(a) of the Act, shall be subject-

vii. to the applicant's furnishing the CEO annually with the prescribed information (see Annual Returns);

viii. to the requirement that there shall be no deviation from the particulars reflected on the permit: Provided that if the quantity of such substance or medicine to be imported is less than that provided for in the permit, the Director-General shall be informed in writing thereof within 10 days after the importation of such substance or medicine; and

Permit to import or export specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substances - continued to the conditions, as detailed on the permit, having been complied with, the triplicate copy of the permit having been certified by a customs officer or an employee of the S.A. Post Office Limited.

In terms of section 22A (11)(e) of the Act, an import or export permit shall be valid for a period of six months from the date of issue thereof.

4.8 Ports of Entry

Regulation 6(1) of the Act states that no person shall import any medicine or Scheduled substance, including medicines imported in terms of section 15C of the Act, read together with regulation 5, into the Republic except through one of the following ports of entry:

a) Cape Town Airport or harbour;
b) Port Elizabeth Airport or harbour;
c) Durban Airport or harbour;
d) Oliver Tambo International Airport (Johannesburg)

4.9 Fees

Fees payable to the CEO as contemplated in regulation 35 of the Regulations shall be levied in respect of all permits and authorizations issued for the importation or exportation of medicines and / or Scheduled substances.

5. MBR 20 Document

For each consignment of medicines and / or specified Schedule 5, Schedule 6, Schedule 7 or

Schedule 8 substances, the importer shall complete and personally sign the MBR 20 document (GW 12/11).

The importer shall attach the following documentation to the MBR 20 document and submit it to the customs officer at the port of entry:

a) Copy of the invoice for the medicines and / or Scheduled substances which have been imported; and

b) Copy of the licence to import medicines as contemplated in section 22C(1)(b) of the Act; and

c) Copy of the import permit for specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 medicines and / or substances as contemplated in section 22(11)(a) of the Act; or

d) Copy of the import authorization to import samples for registration purposes as contemplated in section 15(2)(a) of the Act; or

e) Copy of the import authorization to import unregistered medicines as contemplated in section 21 of the Act

f) The importer shall retain a copy of this document at his business address for inspection purposes.

g) The importer shall be responsible to submit the MBR 20 document and its attachments immediately to the office of the CEO;

6. Where to Send Applications

Applications should be emailed to sec22a_permits@sahpra.org.za and upon request be delivered to: **Building A ,SAHPRA Offices, Loftus Park ,402 Kirkness Street, Arcadia ,Pretoria or send to: South African Health Products Regulatory Authority ,Private Bag X 828 ,PRETORIA 0001**

7. References

7.1. Related Regulations

- Medicines and Related Substances Act, 1965 (Act 101 of 1965

7.2. Related SOP's

- Missing SOP'S

7.3. Related Templates

- Missing Templates

8. Annexure

8.1. Annexure A: OF-INSP-RC-11A **MBR 20 Document: Port of Entry Guide Importation of Medicines including Narcotics and Psychotropics**

8.2. Annexure B: OF-INSP-RC-12A **Rapid Alert Tracker**