



GUIDELINE FOR THE IMPORTATION AND EXPORTATION OF MEDICINES

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.

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CEO OF SAHPRA

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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. 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]

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 LEGAL REQUIREMENTS FOR THE IMPORTATION OR EXPORTATION OF MEDICINES OR SCHEDULED SUBSTANCES

2.1 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 Council.

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

2.2 PERSONS ENTERING OR DEPARTING FROM THE REPUBLIC

Regulation 16(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
- (2) the said person must have-
 - (a) 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.

2.3 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 Council.

However, in terms of section 21 of the Act, Council 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. Council will evaluate the requests and may grant the authorization which will be issued by the Registrar in the prescribed manner and subject to such conditions as Council deems fit.

2.4 AUTHORIZATION TO IMPORT A SAMPLE FOR REGISTRATION PURPOSES

Council 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 fax number 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
- (f) port of entry.

2.5 LICENCE TO IMPORT OR EXPORT MEDICINES OR SCHEDULED SUBSTANCES

In terms of section 22C(1)(b) of the Act, Council 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 Council 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 19(1)(a)(i) stipulates that a person referred to in section 22(1)(b) of the Act must apply to the Council for a licence to import or export medicines or Scheduled substances. The person must submit to the Registrar an application for a licence, on a form approved and provided by the Council.

Regulation 20(1) of the Act stipulates that a licence issued in terms of regulation 19 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.

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 Practises entertained at the manufacturer, importer or exporter.
- The review will address Good Manufacturing Practices.

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

Issuing of Certificates by SAHPRA:

- GMP certificates and Certificates of Pharmaceutical Products (WHO-type) needs to be applied for in the prescribed manner at the office of the Registrar of Medicines;
- 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.

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 of Health;
- 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 of South Africa 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.;

2.6 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 15(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.

2.7 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 15(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 15(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 -

- (i) 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;
- (ii) use of such substance or medicine has not been authorised in terms of the Act;
- (iii) the Director-General is of the opinion that the annual importation quota for such substance has been exceeded or will be exceeded;
- (iv) the Director-General is of the opinion that such substance or medicine, of an acceptable quality, is already available in the Republic; or
- (v) the applicant did not comply with the conditions under which a previous permit was issued to him or her.

Regulation 15(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.

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

- (i) to the applicant's furnishing the Registrar annually with the prescribed information (see Annual Returns);
- (ii) 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

2.7 Permit to import or export specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substances - continued

- (iii) 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.

2.8 PERMIT FOR PARALLEL IMPORTATION OF MEDICINES

Regulation 7(1)(c) stipulates that any person desiring to import a medicine referred to in section 15C(b) of the Act, shall be in possession of a permit issued by the Minister.

The applicant shall submit to the Minister an application form in the prescribed manner and subject to such conditions as determined by the Minister. The permit shall be valid for a period of two years.

2.9 PORTS OF ENTRY

Regulation 12(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 7, 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)

2.10 FEES

Fees payable to the Registrar 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.

3 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

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

The importer shall be responsible to submit the MBR 20 document and its attachments immediately to the office of the Registrar of Medicines

4 WHERE TO SEND APPLICATIONS

Applications should be delivered to CSIR, Reception Building 38a, Meiring Naudé Road, Brummeria

Pretoria or send to:

South African Health Products
Private Bag X 828
PRETORIA
0001



GW 12/10

APPLICATION FOR A PERMIT TO IMPORT DRUGS AND/OR PSYCOTROPIC SUBSTANCES IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965), THE SINGLE CONVENTION ON NARCOTIC DRUGS, 1961, AND THE CONVENTION ON PSYCOTROPIC SUBSTANCES, 1971; REGULATION 20(4) AND 20(7)(S)

The Registrar of Medicines
Private Bag X828
Pretoria 0001

From
Postal Address
.....
Telephone

I,
(Name of applicant and, where the application is made on behalf of a body corporate, the name of such body corporate)

Being a registered

Practising /conducting

.....
(Street address)

hereby apply for a permit authorising me to import a substance/ preparation in respect of which the following details are given:

- (a) In the case of the importation of a substance (raw material)
 - (i) the name and quantity of such substance
 - (ii) The quantity of such substance calculated as a base
- (b) In the case of the importation of a preparation (finished product)-
 - (i) the registered name and dosage form of the preparation (in RSA)
 -
 - (ii) the name and quantity of the controlled substances in the preparation (per unit)
 - (iii) the total quantity of such preparation
 - (iv) the total quantity of the controlled substance calculated as a base
 -

I declare that these quantities are reasonable required by me for purposed authorised by law, I estimate that these quantities will meet my requirements for a period months form the present date. I shall comply with all requirements that the permit is subject to, and will return the triplosts copy of the permit to the Director- General WITHIN 10 DAYS after importing the substance.

The consignment to be imported from
.....
(name and street address of firm in exporting country from whom the substance is to be obtained).

The consignment to be imported through
(post of entry or post office)

Date
Signature of applicant



GW 12/44

APPLICATION FOR A PERMIT TO EXPORT NARCOTIC AND/OR PSYCHOTROPIC SUBSTANCES IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965), THE SINGLE CONVENTION ON NARCOTIC DRUGS, 1961, AND THE CONVENTION ON PSYCHOTROPIC SUBSTANCES, 1971: REGULATION 20(4) AND 20(7)(a)

The CEO of SAHPRA
Private Bag X828
Pretoria 0001

From
Postal Address
.....
Telephone

I,
(Name of applicant and, where the application is made on behalf of a body corporate, the name of such body corporate)

Being a registered

Practising /conducting

(Street address)

hereby apply for a permit authorising me to **export to**

(name & street address of the firm or person in the importing country to which or to whom the substances are to be supplied)

substances/preparation in respect of which the following details are given:

- (a) In the case of the exportation of a substance (raw material)-
 - (i) the name and quantity of such substance.....
 - (ii) the quantity of such substance calculated as a base

- (b) In the case of the exportation of a preparation (finished product) containing such substance-
 - (i) the registered name and dosage form of the preparation (in RSA).....
 - (ii) the name and quantity of the controlled substance in the preparation (per unit).....
 - (iii) the total quantity of such preparation
 - (iv) the total quantity of the controlled substance calculated as a base.....

I declare that the quantities applied for are appropriate. I shall comply with all requirements that the permit is subject to, and will return the triplicate copy of the permit to the Director-General within 10 days after exporting the substance.

THE NECESSARY GOVERNMENT AUTHORISATION ISSUED IN TERMS OF THE SAID CONVENTIONS IN RESPECT OF THE IMPORTATION BY THE ABOVE-MENTIONED IMPORTER IS ATTACHED FOR YOUR RECORDS.

The consignment will be exported by through
(airfreight / road transport) (Port / border gate or post office)

Date
Signature of applicant



**MBR 20
GW 12/11**

IMPORTATION OF ANY MEDICINES AND / OR SPECIFIED SCHEDULE 5, SCHEDULE 6, SCHEDULE 7 OR SCHEDULE 8 SUBSTANCES INTO THE REPUBLIC OF SOUTH AFRICA IN TERMS OF THE PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

- 1. The importer shall complete the MBR 20 document in duplicate and attach the following documentation:
 - (a) Copy of invoice for the medicines and / or Scheduled substances; and
 - (b) Copy of licence to import medicines as contemplated in section 22C(1)(b) of the Act; and
 - (c) Copy of permit to import specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substances as contemplated in section 22(11)(a) of the Act; or
 - (d) Copy of authorization to import samples for registration purposes as contemplated in section 15(2)(a) of the Act; or
 - (e) Copy of authorization to import unregistered medicines as contemplated in section 21 of the Act.
- 3. The importer shall retain a copy of the MBR 20 document and the attachments at his or her business address.
- 4. The importer shall submit a copy of the MBR 20 document and the attachments to the Port Health Officer at the authorized port of entry
- 5. The importer shall fax a copy of the MBR 20 document and the attachments to:

The Law Enforcement Unit
 Directorate: Inspectorate and Law Enforcement
 Department of Health
 Private Bag X 828
 PRETORIA
 0001

Fax: (012) 395 9201

Name of Importer:..... Licence / Authorisation number:.....

Business (physical) address: Postal address:

Telephone number: Fax number:.....

Names, quantities and registration numbers of medicines (finished products):

- 1.....
- 2.....
- 3.....
- 4.....

Names and quantities of raw materials:

- 1.....
- 2.....
- 3.....
- 4.....

Importation and Exportation

I,, hereby certify that I have imported the abovementioned medicines / Scheduled substances through the authorised port of entry indicated below with an “X”

- Port Elizabeth Airport Port Elizabeth Harbour Oliver Tambo International Airport
- Cape Town Airport Cape Town Harbour Durban Airport Durban Harbour

Signature: Licensed Importer:

Date: