Kingdom of Swaziland

Ministry of Health

Guidelines on Import and Export Procedures for Medicines

2016

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P. O. Box 5
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FOREWORD

International trade in pharmaceuticals is growing fast due to globalization and liberalization of trade. Real demand for pharmaceuticals has actually remained high and account for about 15% of the health budget in the Kingdom of Swaziland. There is no local or subsidiary manufacturing in the country and all pharmaceuticals are imported from other countries. To ensure that medicines imported and used in Swaziland are of required quality and safe for the health of the public, the Ministry of Health is putting in place systems for controlling imports and exports in accordance with recommendations from WHO.

As one of the means of achieving this goal, all pharmaceuticals and pharmaceutical ingredients intended to be imported for use in Swaziland, have to be subjected to control at the port of entry to ascertain their compliance with set standards of quality and safety. Permits will be issued to companies and individuals strictly based on the scales of the set standards. The Ministry of Health has an obligation of ensuring quality and safety of exported products among other reasons, to safeguard the interests of the nation. For this task to be accomplished, different tools are required to be in place. One of which is having an explicit import procedure guidelines for medicines.

It is therefore anticipated that these guidelines will assist importers of medicines to prepare the application documents according to the requirements set in these guidelines. Compliance to the set requirements will minimize delays in processing applications for import permits.

On the other hand use of the guidelines by inspectors will minimize risks of trading sub standards medicines among nations and therefore prevent dumping of substandard or unfit products to our country.

Dr. Simon Zwane
Director: Health Services

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Finally, the Ministry will also like to acknowledge the contribution of WHO, from who this document was heavily adapted from.

Ms. Fortunate Fakudze
Senior Pharmacist: MOH

LIST OF ABBREVIATIONS

CMS	Central Medical Stores
EML	Essential Medicines List
EPI	Expanded Program on Immunization
GMP	Good Manufacturing Practices
INN	International Non-Proprietary Name
MOH	Ministry of Health
MMAC	Ministerial Medicines Advisory Committee
MRA	Medicines Regulatory Authority
NERCHA	National Emergency Response Council on HIV and AIDS
NGO	Non-Governmental Organization
NF	National Formulary
NPP	National Pharmaceutical Policy
PLWHA	People Living with HIV and AIDS
SACU	Southern Africa Customs Union
SADC	Southern Africa Development Community
SNPP	Swaziland National Pharmaceutical Policy
WHO	World Health Organization

1. INTRODUCTION

Public health concerns demand that the manufacture of pharmaceutical products and their subsequent handling within the distribution chain, both nationally and internationally, must conform to prescribed standards and be rigorously controlled in order to ensure their quality, safety and efficacy.

The Ministry of Health in Swaziland has a responsibility of assuring the quality, safety and efficacy of medicinal products used nationally.

This guidance document is intended to explain the basic requirements for importing medicinal products into the country. However, the need for the effective use of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce - a Scheme which constitutes a formal agreement between countries to provide information on any product under consideration for export, notably on its registration status in the country of origin and whether or not the manufacturer complies with WHO's guidelines on Good Manufacturing Practices (GMP) for pharmaceutical products cannot be overemphasized.

It is important to note that importers of medicinal products may be subjected to additional statutory or regulatory requirements beyond those prescribed in this guidance document in the near future.

2. INTERPRETATION OF TERMS USED IN THIS GUIDELINE

Authorised importer: means an individual or company or similar legal entity granted permission to import a medicine in to the Kingdom of Swaziland by the Ministry of Health.

Authorised exporter: means an individual or company or similar legal entity granted permission to export a medicine out of the Kingdom of Swaziland by the Ministry of Health.

Batch Certificate: means Certificate of Analysis

Controlled substances: mean narcotic drugs and psychotropic substances under international control

Counterfeit product: means a pharmaceutical product that is fraudulently mislabeled with respect to identity and/or source. Both branded and generic products can be counterfeited, and counterfeit products may include products with correct ingredients, with the wrong ingredients, without active ingredients, with insufficient quantity of active ingredients or with fake packaging

Export: means sending out a medicine, medical device or scheduled substance from the Kingdom of Swaziland or cause a medicine, medical device or scheduled substance to be sent out of the Kingdom for other than for personal use.

Import: means to bring a medicine, medical device or scheduled substance into the Kingdom of Swaziland or cause a medicine, medical device or scheduled substance to be brought into the Kingdom for other than for personal use.

Manufacture: includes all operations of purchase of materials and products, production, quality control, release, storage, shipment of finished products, and related controls

Medicine: any substance or mixture of substances which is used, or is manufactured, sold or represented as suitable for use, in:

a. the diagnosis, treatment, mitigation, modification, prevention of diseases or any abnormal physical or mental state or symptoms thereof in humans or animals; or

b. restoring, correcting or modifying a physical, mental or organic function in humans or animals and includes
c. a veterinary medicine; or
d. a complementary medicine; or

a substance or mixture of substances declared by the Minister of Health, in consultation with the relevant Authority, by notice in the Gazette to be a medicine or a veterinary medicine or a complementary medicine.

Medicine Regulatory Authority (MRA), competent authorities: are used interchangeably to mean the national agency responsible for the registration of, and other regulatory activities concerning, pharmaceutical and veterinary products.

Narcotic Medicine: also referred to as a controlled substance is any substance listed in Schedules I and II of the 1961 Single Convention on Narcotic drugs as amended by the 1972 Protocol, whether natural or synthetic

Pharmaceutical product: means any medicine intended for human or veterinary use, presented in its finished dosage form, that is subject to control by medicines legislation.

Prescribed Drug or Medicine: a medicine that is ordinarily prescribed by an authorised prescriber, authorised by the relevant regulatory authority in Swaziland. The Minister responsible for Health may classify medicines according to various dispensing levels.

Product Information: the approved product information for health professionals and the public as approved in the exporting country

Product licence (Registration Certificate): an official document issued by the competent Medicine Regulatory Authority for the purpose of marketing or free distribution of a product

Psychotropic substance: also referred to as a controlled substance is any substance whether natural or synthetic listed in Schedules I, II, III or IV of the 1971 Convention on psychotropic substances

Registration: any statutory system of approval required at national level as a precondition for introducing a pharmaceutical product on the market

Registered, licensed, authorised: these words are used in these guidelines as if they are interchangeable

SADC: stands for Southern African Development Community

Should, shall: are used interchangeably

WHO: stands for World Health Organisation

3. LEGAL CONSIDERATIONS

All transactions concerning the importation of consignments of medicinal products should be conducted through the Ministry of Health or through independent authorised pharmaceutical importers authorized by the Ministry of Health.

Unless otherwise specified, only authorized medicinal products will be permitted to be imported (or exported) into (or out of) the country.

The importation of all consignments of medicinal products should be channeled through the designated ports of entry and will be cleared by customs in consultation with the Ministry of Health. Medicines and their documentation shall not be manipulated while being transported to the country in bonded warehouses.

An application for the issue of an import or export permit shall be made by an authorised importer to the Ministry of Health in a prescribed form.

The period of validity of the import and export permits shall be determined by the Ministry of Health. This period shall not exceed six (6) months.

An applicant for an import permit must be in registered with the Ministry of Health as an importer of medicines. The Authority to import medicines shall be determined by the Ministry of Health. The medicines importation authority shall be subject to renewal upon expiry.

No importation or exportation of medicines shall be done by post.

4. IMPLEMENTATION OF CONTROLS

The Ministry of Health shall provide comprehensive and frequently updated lists of authorised importers which shall be easily accessible to designated ports of entry and authorised dealers.

Customs officials will carry out physical examination of all imported consignment of medicines and their documentation.

Where necessary, the Ministry of Health Pharmaceutical Services Department will carry out random inspections of imported medicines.

Consignments of any counterfeit products shall be forfeited and destroyed. Other Medicine Regulatory Authorities in the SADC Region and the WHO through the Pharmaceutical Services Department in the Ministry shall be immediately notified of these confirmed cases of counterfeit products.

Consignments of medicines shall be accorded high priority for clearance through ports of entry.

Since pharmaceutical products tend to degrade on storage and some need to be kept in cold storage, ports of entry need to be provided with secure storage facilities including refrigerated compartments where possible.

The authorised importer should alert customs officials in advance of the anticipated arrival of cold chain consignments so that they can be transferred to the designated storage facilities without breaking the cold chain.

5. EXEMPTIONS FROM REQUIREMENTS OF A PHARMACEUTICAL IMPORT/EXPORT AUTHORISATION CERTIFICATE

a) Importation of Medicines for Personal Use

Importation of medicines for personal use or for use by a member of family will be limited to 90 days' supply, after which prior approval from the Ministry shall be required.

DOCUMENTATION

The authorized importer shall be required to furnish the Ministry of Health with:

1. Full particulars of the authorized importer
2. Full particulars of the manufacturer of the products to be imported
3. The full description of the products to be imported using both generic and trade name
4. The quantities of the products to be imported
5. The Product Registration Certificates for all the medicines s/he intends to import issued by the relevant authorities in the country of normal origin
6. Batch Analysis Certificates of the products s/he intends to import

The authorized importer shall be required to furnish customs officials with:

1. Authorization Certificate issued by the Ministry of Health attesting that the importer is :
    a. An authorised importer of medicines
    b. Importing a medicine that is duly authorised to the imported
2. Relevant invoice(s) and bill of lading
3. Classification of the medicine into either prescribed or none prescribed medicine

b) Importation and Exportation of Controlled Substances

Most of the requirements specified in these guidelines on import and export procedures for medicines also apply to the border control of controlled substances in addition to the requirements of relevant legislation and in accordance with international conventions.

Each member country is required to comply with the Treaty Obligations as enshrined in the United Nations International Narcotics Control Board's (INCB) 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances.

The authorised importer shall present to the customs authorities a certified copy of the respective import permit issued by the Ministry of Health and other relevant documentation issued by the competent authorities of the exporting country, a copy of which must accompany each consignment.

The authorised importer shall furnish the Ministry of Health with the original copy of the export permit issued by the competent authorities of the exporting country, a copy of which must accompany each consignment.

Additional import permit is required for psychotropic substances in Schedules I, II, III and IV of the 1971 Convention and narcotic medicines in Schedules I and II of the 1961 Single Convention on Narcotic drugs as amended by the 1972 Protocol, whether natural or synthetic; so as to prevent attempts to divert psychotropic and narcotic substances such as stimulants, sedative-hypnotics and tranquillizers into illicit trade. These additional import permit shall only be issued to authorised importers with valid pharmaceutical import authorization and appropriate premises.

The additional import permit shall contain at least the following information:

a. Number and date of the import permit
b. Name and address of importer
c. Name of controlled substance(s) (if available, the International Non-proprietary Name)
d. Strength and dosage form of the controlled substance(s) to be imported
e. Quantity to be imported
f. Name and address of the exporter
g. Route of entry through which importation shall be effected
h. The name of the Ministry of Health, date stamp and signature

An application for a permit to import controlled substances will be made to the Ministry of Health in the prescribed form.

6. CRITERIA FOR ISSUE OF AUTHORISATION TO IMPORT

The criteria for issue of a pharmaceutical import permit shall entail that:

a. There are suitable premises, facilities and equipment for proper pharmaceutical warehousing/storage.
b. There are suitably qualified pharmaceutical personnel to oversee the quality assurance (i.e. pharmacist and pharmacy technician) where non OTC medicines are dispensed.

There are suitable arrangements, programmes and systems for procurement, storage, documentation, stock surveillance and distribution.

7. APPLICATION FOR ISSUE OF AN IMPORT PERMIT

An application for issue of an import permit shall be made on the prescribed form.

An application for issue of an import permit shall state, for each medicine to be imported at least the following:

i. Generic name or International Non-proprietary Name (INN)

ii. Trade name or proprietary name; if any

iii. Strength and dosage form

iv. Name and strength of the Active Pharmaceutical Ingredient (API)

v. Total quantity to be imported

vi. Name and address of the supplier/importer

vii. Name and address of the manufacturer

viii. Country of origin

ix. Route of entry

x. Expected date of arrival

A separate import permit for controlled substances will apply as prescribed by the Ministry of Health and applicable treaty obligations. The application shall be accompanied by copies of the proforma invoices.

8. APPLICATION FOR ISSUE OF AN EXPORT PERMIT

An application accompanied by a prescribed fee for issue of an export permit shall be made on the prescribed form.

An application for issue of an export permit shall state, for each medicine to be exported at least the following:

(a) generic name or International Non-proprietary Name (INN)
(b) strength and dosage form
(c) name and strength of each ingredient; in case of a product containing more than one ingredient
(d) trade name or proprietary name; if any
(e) pharmacopoeia specification of the medicine, where applicable
(f) total quantity to be exported
(g) name and address of the exporter
(h) name and address of the manufacturer
(i) name and address of consignee
(j) country of consignee
(k) route of dispatch
(l) licence/registration number
(m) cost, insurance, freight (CIF) value
(n) expected date of dispatch

The application shall be accompanied by copies of the purchase orders.

Authorization Certificate No……

MEDICINE IMPORT AUTHORIZATION CERTIFICATE

Name of Importer:

……..

Physical and Postal Address of Importer:

……..……..……..……..

……

……

Email: ……

Telephone Number: …… **Fax Number:** ……

Carrying on business as:

……

Is hereby authorized to Import Medicines into Swaziland.

Name of Supervising Pharmacist: …..……..

Registration Certificate No of Supervising Pharmacist: ……

Conditions imposed by the Ministry of Health (refer to notes overleaf).

……

……

……

This authority is valid from…… **To** ……

……

Ministry of Health

Date Issued …… **Stamp:**

Overleaf notes

Conditions of issue / renewal for import certificate

Consideration of an application for issue / renewal may take advantage to impose any new conditions or insist on any aspects that had been overlooked previously or are brought about due to new or amended legislation or policy.

Conditions for Premises

- Compliance with minimum requirements
- Registered importer of medicines with the Ministry of Health
- No adverse report since the previous issue regarding e.g. wrongful dealing in medicines, lack of proper management and control of the pharmaceutical business, etc
- Appropriately registered pharmacist with practicing license from Medical Council of Swaziland and with no recorded acts of professional misconduct over the previous year (those that may or may not warrant revocation of practicing license).
- Appropriate renewal forms and fees submitted well before previous authority lapsed
- No changes to the previous conditions under which certificate was issued.

Conditions for Amendments

All amendments to conditions under which an import license was issued must be formally applied for and approved. A processing fee must be paid.

An applicant must not effect any changes without prior approval except for situations where e.g. the registered supervising pharmacist leaves without notice and a locum tenens is in attendance for a period less than four weeks or changes of directorship in a company without changes in the effective supervision of the business.

Changes of ownership, effective directorship of a company, structural changes to the premises, changes in effective supervision of business, relocation to other premises require prior and written approval.

Validity

Certificates are valid for six month from time of issue or until formally cancelled by the issuing authority. An annual renewal must be applied for each time an applicant wishes its certificate to be renewed.

Once a certificate has lapsed due to failure to renew by the applicant, there shall not be a requirement for a formal notification of intent by the Ministry of Health to consider the certificate invalid.

Suspension or cancellation of certificate

A certificate may be cancelled under the following situations;

- Failure to comply with specific conditions of authorization
- Wrongful dealing in medicines and allied substances
- Unauthorized change of premises
- Failure to comply with other legislation e.g. local authority licensing, health requirements that were part of the conditions of initial approval

A formal and legislated appeal process must be conducted prior to cancellation of a certificate.

9. IMPORT PERMIT FOR CONTROLLED MEDICINES:

SWAZILAND

No. _____

Permit to import or acquire "Habit-Forming Drugs" as defined in Section fifteen of the Swaziland Opium and Habit-Forming Drug Regulation Proclamation 1922, issues under Section three of the said Proclamation.

Messrs: **Profession:**

……

Address (Physical):……

……

Is hereby authorized to import or acquire the under mentioned Habit-Forming Drugs in the quantities specified opposite each:

Drug (INN Name) **Quantity(in-words)**

……

……..

……

Address of Manufacturer (Physical):

……

……..

It is a condition of this Permit the Drugs imported or acquired hereunder shall not be used by the person to whom the Permit is otherwise than for medicinal or scientific purposes or for purpose of being sold or supplies to some other person in accordance with the provisions of the Swaziland Opium and Habit-Forming Drugs Regulations Proclamation, 1922.

Ministry of Health
P.O. Box 5
Mbabane

Director of Medical Services

Date:……

10. IMPORT AUTHORIZATION APPLICATION FORM FOR MEDICINES:

APPLICATION TO IMPORT MEDICINE(S)

Name of Importer:

……

Physical and Postal Address of Importer:

……..……..……

……

……

Email: ……

Telephone Number:..…… **Fax Number:**…….

Carrying on business as: ……..……

Is hereby applying for authority to Import Medicine(s) into Swaziland during the period of:

……..……..……..

From (Name of Exporter):

……..

Postal, Physical address and contact details of exporter:

……

……

……

……

Country of Origin: ……..

Invoice Number(s): ……..

Expected Route of Entry:

……

Expected Date of Arrival of Consignment: ……

Name of Supervising Pharmacist: ……..

Registration Certificate No. of Supervising Pharmacist: ……..

Please attach the following:

Name(s) of Medicine(s) to be imported (using either generic/INN and Trade Name(s)

Strength and Dosage form(s) for medicine(s) to be imported

Total quantity of each medicine to be imported

Copies of registration certificates for each of the medicines from the country of origin

Invoices or Proforma Invoices of the products to be imported

11. IMPORT AUTHORIZATION FOR MEDICINE(S):

AUTHORIZATION TO IMPORT MEDICINE(S)

Name of Importer:

……..

Physical and Postal Address of Importer:

……..……..……..……..

……

……

Telephone Number: …… **Fax Number:** ……..…….....

Carrying on business as: ……..……..……..……

Is hereby authorized to Import Medicine(s) into Swaziland during the period:

……..……..……..……..

From (Name of Exporter):

……..

Postal, Physical address and contact details of exporter:

……

……

……

……

Country of Origin: ……..

Invoice Number(s): ……..

Expected Route of entry: ……

Expected Date of Arrival of Consignment: ……

Name of Supervising Pharmacist: ……..

Registration Certificate No. of Supervising Pharmacist: ……

Attachment(s):

Invoices or Proforma Invoices of the products to be imported

12. EXPORT AUTHORIZATION APPLICATION FORM FOR MEDICINES:

APPLICATION TO EXPORT MEDICINE(S)

Name of Exporter:

……

Physical and Postal Address of Exporter:

……..……..……

……

……

Email: ……

Telephone Number:..…… **Fax Number:**…….

Carrying on business as: ……..……

Is hereby applying for authority to Export Medicine(s) out of Swaziland during the period of:

……..……..……..

To (Name of Importer):

……..

Postal, Physical address and contact details of Importer:

……

……

……

……

Country of Destination:

……

Invoice Number(s): ……..

Expected Route of Departure:

……

Expected Date of Departure of Consignment: ……

Name of Supervising Pharmacist: ……..

Registration Certificate No. of Supervising Pharmacist: ……..

Please attach the following:

Name(s) of Medicine(s) to be exported (using either generic/INN and Trade Name(s)
Strength and Dosage form(s) for medicine(s) to be exported
Total quantity of each medicine to be exported
Invoices for the products to be exported

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