SADC GUIDELINES ON IMPORT AND EXPORT PROCEDURES FOR PHARMACEUTICAL PRODUCTS

June 2006
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 DRAs in the SADC region have a responsibility of assuring the quality, safety and efficacy of medicinal products moving nationally and internationally.

This guidance document is intended to summarize and to explain the basic requirements for exporting and importing medicinal products in the region. 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 and exporters of medicinal products may be subjected to additional statutory or regulatory requirements beyond those prescribed in this guidance document.

INTERPRETATION OF TERMS USED IN THESE GUIDELINES

pharmaceutical product (medicine)

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

counterfeit product

means a pharmaceutical product that is fraudulently mislabelled 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

drug regulatory authority (DRA), competent authorities

are used interchangeably to mean the national agency responsible for the registration of, and other regulatory activities concerning, pharmaceutical and
veterinary products.

**importation**
means the act of bringing or causing any goods to be brought into a national territory.

**Parallel importation**

**exportation**
means the act of sending out or causing any goods to be taken out of a national territory.

**should, shall**
are used interchangeably

**narcotic drug**
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

**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

**authorised importer**
means an individual or company or similar legal entity importing or seeking to import a pharmaceutical or veterinary product. A "licensed" or "registered" importer is one who has been granted a licence or registration status for the purpose.

**authorised exporter**
means an individual or company or similar legal entity exporting or seeking to export a pharmaceutical or veterinary product. A "licensed" or "registered" exporter is one who has been granted a licence or registration status for the purpose.

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

**product licence (registration certificate)**
an official document issued by the competent drug regulatory authority for the purpose of the marketing or free distribution of a product
product information
the approved product information for health professionals and the public as approved in the exporting country

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

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

controlled substances
mean narcotic drugs and psychotropic substances under international control

WHO
stands for World Health Organisation

SADC
stands for Southern African Development Community

Batch Certificate
means Certificate of Analysis

LEGAL CONSIDERATIONS

All transactions concerning the importation of consignments of pharmaceutical products should be conducted through Ministry of Health, mission hospitals, any other person authorised by the DRA or through independent authorised pharmaceutical importers licensed by the relevant drug regulatory authority for this purpose.

Unless otherwise specified, only licensed/approved medicinal products will be permitted to be imported (or exported) within the region.

The importation of all consignments of pharmaceutical products should be channelled exclusively through the designated ports of entry and will be cleared by customs in consultation with the inspectorate of the respective DRA. Medicines and their documentation shall not be manipulated while being transported through member states in bonded warehouses.

An application for the issue of an import or export permit shall be made by an authorised importer to the respective Drug Regulatory Authority in a prescribed form.

The period of validity of the import and export permits shall be determined by the respective Drug Regulatory Authority. This period shall not exceed six(6) months.

An applicant for an import permit must be in possession of an import licence issued by the relevant drug regulatory authorities. The validity of the licence shall be determined by the respective Drug Regulatory Authority. The Pharmaceutical Import Licence shall
be subject to renewal upon expiry.

No importation or exportation of pharmaceutical products shall be done by post.

IMPLEMENTATION OF CONTROLS

The drug regulatory authorities shall provide comprehensive and frequently updated lists of licensed or notified medicinal products and authorised dealers/importers which should be easily accessible to designated ports of entry and authorised dealers. Notifications on any product licences that have been withdrawn on grounds of safety or quality and confirmed cases of imported counterfeit products and other illicit activities should immediately be communicated to all the DRAs.

Customs officials in collaboration with a pharmaceutical inspector will carry out physical examination of all imported consignment of medicinal products and their documentation. Where necessary, the pharmaceutical inspector will carry out random sampling of pharmaceutical products in accordance with laid down guidelines on sampling of medicinal products imported into the country for drug analysis.

Consignments of any counterfeit products should be forfeited and destroyed as per provisions in the legislation. Other Drug Regulatory Authorities and the WHO through the Division of Drug Management and Policies should immediately be notified of these confirmed cases of counterfeit products.

Consignments of pharmaceutical products should 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.

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

EXEMPTIONS FROM REQUIREMENTS OF A PHARMACEUTICAL IMPORT/EXPORT LICENCES

(a) IMPORTATION OF DONATED PHARMACEUTICAL PRODUCTS

Importation of donated pharmaceutical products shall be dealt with in accordance with SADC guidelines on donated drugs.

(b) IMPORTATION OF PHARMACEUTICAL PRODUCTS IN EMERGENCY SITUATIONS
The respective DRAs will reserve discretionary powers to waive product licensing requirements in respect of consignments of pharmaceutical products imported in response to emergency situations and, exceptionally, in response to requests from clinicians for limited supplies of unlicensed medicines needed for treatment of specific named patients.

(c) IMPORTATION OF PHARMACEUTICAL PRODUCTS FOR PERSONAL USE

Importation of pharmaceutical products for personal use or for use by a member of a family will be limited for 28 days after which prior approval from the DRA shall be required. It must be emphasized that the intent of the ‘personal use importation’ guidance is to generally permit the DRA exercise its enforcement discretion for medicines that may not otherwise be available in the country.

(d) IMPORTATION OF MEDICINES TO BE USED FOR CLINICAL TRIALS

Authorisation to be sought from the DRA for the purposes.

(e) IMPORTATION OF BIOTECHNOLOGICAL/BIOLOGICAL/BLOOD PRODUCTS, SERA AND VACCINES

Authorisation to be sought from the DRA for the purposes.

DOCUMENTATION

The authorised importer shall be required to furnish customs and DRA officials with:

1. certified copies of documents issued by the relevant DRA attesting that the importer is:
   
   (a) an authorised importer (produce a valid Pharmaceutical Import Licence)
   
   (b) importing a medicine that is duly authorised/licensed (produce a valid product licence)

2. batch certificate issued by the manufacturer in conformity with the requirements of WHO Certification Scheme

3. relevant invoice or bill together with an import permit or export permit

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 shall be 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 copy of the respective import licence issued by the DRA and other relevant documents issued by the competent authorities of the exporting country, a copy of which must accompany each consignment.

Import authorisations are required for psychotropic substances in Schedules I, II, III and IV of the 1971 Convention so as to prevent attempts to divert psychotropic substances such as stimulants, sedative-hypnotics and tranquillizers into illicit trade. These Import authorisations shall only be issued to authorised importers with valid pharmaceutical import and wholesale dealer's licences and appropriate premises.

The import and export authorisations shall contain at least the following information:

(a) name of controlled substance(s) (if available, the International Non-proprietary Name)
(b) quantity to be imported/exported expressed in terms of anhydrous base content
(c) name & address of the importer and exporter
(d) period of validity of the authorisation
(e) route of entry/exit through which importation/exportation shall be effected
(f) number and date of the corresponding import/export authorisation and the name of the competent authorities of the importing/exporting countries by whom it was issued
(g) strength and dosage form

An application for a licence to import/export controlled substances will be made to the respective Drug Regulatory Authorities in the prescribed form backed by legislation.

CRITERIA FOR ISSUE OF AUTHORISATION TO IMPORT

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

(a) there are suitable premises, facilities and equipment for proper pharmaceutical warehousing
(b) there are suitably qualified pharmaceutical personnel that shall oversee the quality assurance i.e. pharmacist and pharmacy technologist/technician
(c) there are suitable arrangements, programmes and systems for procurement, storage, documentation, stock surveillance and distribution
APPLICATION FOR ISSUE OF AN IMPORT PERMIT

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

An application for issue of an import permit shall state, for each medicine to be imported 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 imported
(g) name and address of the supplier
(h) name and address of the manufacturer
(i) country of origin
(j) route of entry
(k) licence/registration number
(l) cost, insurance, freight (CIF) value
(m) expected date of arrival

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

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 backed by legislation.

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

In conclusion, importation of drugs that lack approval and are not in line with these guidelines whether for personal use or otherwise will be considered as illegal importation and could be refused entry into any of the SADC countries or seized by customs officials.
Pharmaceutical Import Licence

Messrs (Name of Importer)……………………………………………………………………

………………………………………………………………………………………………………………………………………

………………………………………………………………………………………………………………………………………

of (address i.e. Plot No. Street/Road, Town/City, P.O. Box) ……………………………………………………………

………………………………………………………………………………………………………………………………………

………………………………………………………………………………………………………………………………………

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

Are hereby authorised to Import Pharmaceutical Products (Medicines, herbal medicines and allied substances) into the Country
during the calendar year………………………………………………………………………………………………………..

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

Registration Certificate No: …………………………………………………..

Conditions imposed by the Pharmaceutical Regulatory Authority (refer to notes overleaf).

This licence is valid from……….. to…

……………….                                                         ……………..

Registrar of medicines

Date Issued …………..xxxxxxx.

Date stamp

Overleaf notes

Conditions of issue / renewal for import licence
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
• Valid local authority licence
• 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 a Country and with no recorded acts of professional misconduct over the previous year (those that may or may not warrant revocation of practicing licence).
• Appropriate renewal forms and fees submitted well before previous licence lapsed
• No changes to the previous conditions under which licence was issued.

**Conditions for Amendments**

All amendments to conditions under which an import licence 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. a registered pharmacist leaves without notice and a locum tenens is in attendance for a period less than four weeks, 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 another premises require prior and written approval.

**Validity**

Certificates are valid for one calendar year 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 licence to be renewed.

Once a licence has lapsed due to failure to renew by the licensee, there should not be a requirement for a formal notification of intent by the licensing authority to consider the licence invalid.

**Suspension or cancellation of licences**

A licence may be cancelled under the following situations;

• Failure to comply with specific conditions of licensing
• Wrongful dealing in medicines, herbal 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 licence.
Licence No.
Registration No.

Pharmaceutical Export Licence

Messrs (Name of Exporter)………………………………………………………………………………………………………………………………………………
of (address i.e. Plot No. Street/Road, Town/City. P.O. Box)………………………………………………………………………………………………………………………………………………
……………………………………………………………………………………………………………………………………………………………………………………………………………………………………
Carrying on business as …………………………………………………………………………………………………………………………………………………………………………………
Are hereby authorised to export Pharmaceutical Products (Medicines, herbal medicines and allied Substances) during the calendar year…………………………………………………………………………………………………………………………
Name of Supervising Pharmacist ……………………………………………………………………………………………………………………………………………………………………………
Registration Certificate No: ……………………………………………………………………………………………………………………………………………………………………………
Conditions imposed by the Drug Regulatory Authority (refer to notes overleaf).
This licence is valid from………… to…………………
………………………………………………………………………………………………………………………………………………………………………………………………………………
Registrar of medicines
Date Issued …………….. Date stamp

Overleaf notes

Conditions of issue / renewal for export licence
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
• Valid local authority licence
• 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 and with no recorded acts of professional misconduct over the previous year (those that may or may not warrant revocation of practicing licence).
• Appropriate renewal forms and fees submitted well before previous licence lapsed
• No changes to the previous conditions under which licence was issued.

Conditions for Amendments
All amendments to conditions under which an export licence 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. a registered pharmacist leaves without notice and a locum tenens is in attendance for a period less than four weeks, 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 another premises require prior and written approval.

**Validity**
Licences are valid for one calendar year 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 licence to be renewed. Once a licence has lapsed due to failure to renew by the licensee, there should not be a requirement for a formal notification of intent by the licensing authority to consider the licence invalid.

**Suspension or cancellation of licences**
A licence may be cancelled under the following situations;

- Failure to comply with specific conditions of licensing
- Wrongful dealing in medicines, herbal 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 licence.