MEDICINES CONTROL AGENCY

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GUIDELINE FOR IMPORT AND EXPORT OF MEDICINES AND RELATED PRODUCTS

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1 INTRODUCTION

1.1 LEGAL BASIS

1.1.1. The regulation of medicines in The Gambia is governed by the provisions and requirements of the Medicines and Related Products Act, 2014 ("Act"), by which the Medicines Control Agency (MCA) was established as the regulatory body for medicines and related products.

1.1.2. Part VI of the Act, *Registration of Medicines and Related Products*, Sections 36 and 37 requires that the Agency shall grant import permit for importation and/or authorise exportation of medicines or related products.

1.1.3. The Medicines and Related Products Regulations, 2019 ("Regulations") details the legal requirements.

1.1.4. The Agency charges non-refundable import and export permit processing fee as indicated in the MCA Fee Schedule.

1.1.5. A person who wishes to import ("Importer") any medicine and related product is required to become familiar with this document and the above stated law before applying for an import permit.

1.1.6. Any statute governing importation procedures and tax liabilities shall apply to an imported product.

1.2 INTERPRETATION AND ABBREVIATIONS

Interpretations and abbreviations contained in the MCA Glossary can be found on the MCA Website: **www.mca.gm**

1.3 PURPOSE

1.3.1. In pursuance of the law this document provides guidance to persons who wish to import or export medicines and related products in accordance with MCA requirements.

1.3.2. The control of importation of medicines and related products by the Agency ensures that only products of acceptable standards with respect to quality, safety and efficacy are brought into the country.

1.4 SCOPE

1.4.1. This guideline applies to medicines and related products as defined in the Act and the Regulations.

1.4.2. The guideline does not apply to importation of products to be used as samples for registration and medical promotion and products to be used in clinical trials and for personal use in accordance with the Regulations.

1.4.3. It applies to licensed importers and other persons requiring a permit to import or export medicines and related products. For requirements for licensing as an importer refer to MCA *Guideline for Licensing as Importer of Medicines and Related Products*.

2 GENERAL REQUIREMENTS

Import

2.1. Only importers who are licensed by the Agency are permitted to import medicines and related products. For requirements as an importer refer to MCA *Guideline for Licensing as Importer of Medicines and Related Products*.

2.2. Government hospitals, government health facilities and similar health-related institutions that provide healthcare services are authorised to import medicines and related products for use in patients undergoing treatment in its facilities.

2.3. Non-Governmental Organisations, Private Clinics or hospitals including veterinary clinics or hospitals that provide healthcare services may be permitted by the Agency to import reasonable quantities for use only in patients under their care in their facilities and only if the products are not locally available.

2.4. Registered Medical Doctors, Dentists and Veterinary surgeons may be permitted to import reasonable quantities on special request to the Agency for use only by patients under their care in their facilities and only if the products are not locally available.

2.5. Patients with specific prescriptions for specialist medicines may import such medicines for their personal use only.

2.6. A person who enters The Gambia whilst in possession of medicines or related products for personal medicinal use shall not require a permit from the Agency if:

- the quantity of medicines or related products does not exceed the quantity required for use for a period of up to six months or a period determined by the Agency; or
- the quantity of controlled medicines or related product does not exceed the quantity required for use for a period of 30 days or a period determined by the Agency. The person shall provide the Agency with the name, address and contact details of the licensed medical practitioner or dentist; and an original or a certified copy of the prescription for the medicine or related product.

2.7. Permits for importation of **controlled drugs** (e.g. psychotropics and narcotics) including precursors will be processed **only** after approval by MCA and submission of returns on consumption.

2.8. Medicines and related products are required to be registered with the Agency before being permitted to be imported. For registration requirements of medicines in The Gambia refer to MCA *Guideline for Registration of Medicines* and for registration of herbal medicinal products to MCA *Guideline for Registration of Herbal Medicinal Products*. **Note:** Prescribed medicines that are imported for a named patient do not need a registration with the Agency.

2.9. All products imported are required to have at least 60% of its shelf-life remaining on arrival at the port.

2.10. Products containing active pharmaceutical ingredients such as steroids, hydroquinones, etc are considered as medicines and shall not be permitted to be imported as cosmetics.

2.11. Except otherwise provided by this guideline, import clearance permits shall be granted before the importation of a product.

2.12. Products imported shall be inspected by officials of the MCA at the port of entry and/or point of off-loading at the warehouse before they can be released for use.

Export

2.13. Only licensed importers, wholesalers or local manufacturers are permitted to export medicines and related products, unless otherwise approved by the Agency.

2.14. The exportation of medicines and related products should be carried out in accordance with the MCA requirements.

2.15. Products exported shall be inspected by officials of the MCA at the point of loading at the warehouse and/or port of exit.

3 APPLICATION FOR IMPORT CLEARANCE PERMIT

3.1. For the permit to import medicines or related products the application form Import Clearance Permit (MCA-F-113/01) must be completed by the applicant. The form is available from the MCA website: www.mca.gm.

3.2. The fee is due at the time of submission of the application.

3.3. All applications for import clearance permits shall bear the following information:

- Full name, telephone number, email, postal address and premises physical address of the exporter and importer;
- Name of port of shipment and port of entry into The Gambia and the dates;
- Total CIF value;
- Name (brand and generic names, compositions, strengths and dosage forms, where applicable), and description of products;
- Total quantity of products and units of issue;
- MCA Product Registration number,
  (**Note:** if a medicine or related product is not yet registered with the Agency, see MCA-F-112/01 for registration application);
- Name of manufacturer and country of origin; and
- Batch numbers and Expiry Dates.

3.4. For pharmaceutical companies and health institutions, the permit shall bear the full name, registration number and signature of the Supervising Pharmacist or duly authorised senior health official.

3.5. For other companies/businesses, the permit shall be signed by the business owner or a duly authorised person of the business owner.

3.6. In applying for a permit, the following documents shall be submitted:

- Three (3) copies of the supplier's invoice(s);
- Three (3) copies of the packing list;
- Three (3) copies of the completed import clearance permit form;
- Three (3) copies of airway bill/bill of lading, where applicable;
- One (1) copy of the stamped customs entry form; and
- For medicines, one (1) copy of the Certificates of Analysis (CoA) for each batch to be imported.

3.7. At the point of clearance, the importer should provide the approved/endorsed documents listed above to the Customs and MCA inspector for verification as applicable.

3.8. At the point of off-loading the importer should present the approved/endorsed Import Clearance Permit form, supplier's invoice(s) and packing list to the MCA inspector for verification.

4 APPLICATION FOR EXPORT PERMIT

4.1. For the permit to export import medicines or related products the application form Export Permit for Medicines and Related Products (MCA-F-113/02) must be completed by the applicant. The form is available from the MCA website: www.mca.gm.

4.2. The fee is due at the time of submission of the application.

4.3. All applications for export permits shall bear the following:

- the name, address and contact details of the exporter and licence number;
- the valid licence number issued by the Agency;
- the contact details of the recipient;
- the name and registration number with the Pharmacy Council of The Gambia of the supervising pharmacist;
- Name of business owner or duly authorised person;
- the source of Source of Supply/Consignment; and
- the purpose of the export.

4.4. The applicant shall list the medicines or related products with:

- a description of the products including the proprietary (brand) name and/or generic name, strength and dosage form;
- the MCA Registration number;
- the name and address of manufacturer
- the country of origin; and
- the batch number, expiry date, unit of issue and total quantity of the medicines or related products.

4.5. The applicant shall submit the following documents:

- Two (2) copies of the Supplier's Invoice;
- Two (2) copies of the packing list (sea and air transport); and
- Two (2) copies of the completed export permit form.

4.6. At the point of loading the exporter should present the approved/endorsed Export Permit form, supplier's invoice(s) and packing list to the MCA inspector for verification.

5 DECISION ON APPLICATION

5.1. Vetting and approval of an application by the Agency for import or export permit may take up to five (5) working days.

5.2. Permits issued for import or export of products shall be valid for **only one** transaction.

5.3. Clearance permits issued for import of products shall be presented to Customs ONLY ONCE, and shall not be re-presented for a second time in case goods are short-landed.

5.4. Applications which do not conform to any of the requirements of the Agency shall not be approved.

5.5. An application for import of a product or a certain quantity of a product may be rejected for several reasons. This may include, but not limited to:

- Applicants not authorised by the Agency to import the proposed products;
- A product with a potential for abuse;
- A controlled drug, when the national quota for that particular drug is exhausted e.g. narcotic drugs and psychotropic substances; or
- A product found to be substandard and/or falsified.

6 UNAUTHORISED IMPORTATION AND NON-COMPLIANT PRODUCTS

6.1. Where a person or entity imports products without a valid import clearance permit as required or a non-compliant product, the imported products would be seized and may be ordered to be re-exported or destroyed.

6.2. The cost of re-export or destruction shall be borne by the importer, who may also be prosecuted accordingly.

6.3. The Agency may quarantine a non-compliant product if the non-compliance is not major and could be rectified by e.g. any sorting, processing, labelling/re-labelling or analysis, which shall be supervised by the Agency at the expense of the importer.

7 FINAL PROVISIONS

7.1. This guideline is the third version published by the MCA and will become effective on 10 July 2020.

7.2. This guideline will be reviewed within 5 years of becoming effective.

8 DOCUMENTS NEEDED FOR THIS GUIDELINE

Document No	**Title** (as referenced on the document)
MCA-F-113/01	Import Clearance Permit
MCA-F-113/02	Export Permit for Medicines and Related Products

9 REFERENCES

- Medicines and Related Products Act, 2014
- Medicines and Related Products Regulations, 2019
- MCA Fee Schedule
- MCA Guideline for Licensing as Importer of Medicines and Related Products (MCA-GL-401)

10 DOCUMENT HISTORY

Version #	**Implementation Date**	**Reasons for Change:**
1	25 July 2017	New document
2	15 February 2018	Editorial changes, harmonisation of format for MCA guidelines, 'fast-track' registration of medicines included and guideline for importer license separated.
3	10 July 2020	Editorial changes, change of Document Title Export included.