**MEDICINES CONTROL AGENCY**

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# GUIDELINE FOR IMPORTATION OF MEDICINES AND RELATED PRODUCTS INTO THE GAMBIA

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| Document number: MCA-GL-103 | Date of issue: 12 February 2018 |
| Version: 2.0 | Date of implementation: 15 February 2018 |

# 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, 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*, requires that the Agency shall grant import permit for importation of medicines or related products and that a medicine or a related product shall be registered with the Agency.

1.1.3. The Agency charges non-refundable import permit processing fee as indicated in the Fee Schedule. The fee for the processing of an import permit is due at the time of submission for Customs clearance.

1.1.4. Importers are required to familiarise themselves with this document and the above stated law before applying for an import permit.

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

## 1.2 INTERPRETATION AND ABBREVIATIONS

For interpretation and abbreviation refer to the MCA Glossary on the MCA Website: www.mca.gm.

## 1.3 PURPOSE

1.3.1. In pursuance of Part II Section 4, sub-sections (b) and (f) of the Act this document provides guidance to importers for permit to import medicines and related products into The Gambia.

1.3.2. This guideline also addresses the requirements for registration of medicines and related products that are listed by the Agency.

1.3.3. The registration of medicines by the Agency ensures that they

- meet international standards of quality, safety and efficacy; and
- are manufactured and controlled to consistently meet acceptable standards.

## 1.4 SCOPE

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

1.4.2. Medicines and related products currently listed with the Agency should be registered concurrently with the application for importation from five years following the first import after the Act came into force in December 2014. For those medicines and related products a 'fast track' registration will be possible (see Attachment 02).

1.4.3. The guideline does not apply to importation of samples for registration, medical promotion and/or clinical trials.

# 2 GENERAL REQUIREMENTS

## 2.1 REQUIREMENTS FOR IMPORTERS

2.1.1. 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 Registration as Importer of Medicines and Related Products*.

2.1.2. Governmental (hospitals, health facilities or similar health related institutions) and Non-Governmental Organisations (NGO's) that provide healthcare services may be permitted to import reasonable quantities for use **only** in their facilities and only if the products are not locally available.

2.1.3. Registered Medical doctors, Dentists, Veterinary surgeons and private clinics may be permitted to import reasonable quantities on special request for use **only** in their facilities and only if the products are not locally available.

2.1.4. Patients with specific prescriptions for specialist medicines may on request import such medicines for their personal use **only**.

## 2.2 REQUIREMENTS ON PRODUCTS

2.2.1. Medicines and related products will only be permitted to be imported when they are registered with the Agency. For registration requirements of new medicines in The Gambia refer to MCA *Guideline for Registration of Medicines in The Gambia* and for registration requirements of medicines and related products listed by the Agency refer to Attachment 02.
**Note:** Prescribed medicines that are imported for a named patient do not need a registration with the Agency.

2.2.2. All products imported shall have at least 60% of its shelf-life remaining on arrival at the port.

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

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

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

2.2.6. 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.

# 3 APPLICATION FOR IMPORT PERMIT

3.1. For the permit to import medicines or related products the Import Permit form must be completed and by the applicant (Attachment 01). The

application form is available from the MCA website: www.mca.gm.

3.2. All import permits shall bear the following:

(a) Full name, telephone number, fax, email, postal address and premises physical address of the exporter and importer;

(b) Name of port of shipment and port of entry into The Gambia and the dates

(c) Total CIF value

(d) Name (brand and generic names, compositions, strengths and dosage forms, where applicable), and description of products;

(e) Total quantity of products and units of issue;

(f) MCA Product Registration number,
(**Note:** if a medicine or related product is not yet registered with the Agency, see Attachment 02 for registration application);

(g) Name of manufacturer and country of origin

(h) Batch numbers and Expiry Dates

(i) 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.

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

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

(i) Three (3) copies of the supplier's invoice(s)

(j) Three (3) copies of the packing list;

(ii) Three (3) copies of the completed import permit form;

(iii) Three (3) copies of airway bill/bill of lading, where applicable

(iv) One (1) copy of the stamped customs entry form

(v) For medicines, one (1) copy of the Certificates of Analysis (CoA) for each batch to be imported or a certificate of pharmaceutical product (CPP) issued by the regulatory authority of the exporting country.

3.3. At the point of clearance, the client should provide the approved/endorsed documents listed above (i – iv) to the customs.

3.4. At the point of clearance or off-loading show the approved/endorsed client's copies of the import permit form, supplier's invoice(s) and packing list to the MCA port inspector for verification.

# 4 TIMELINES AND VALIDITY

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

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

5.3. 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. For short-landed goods, a new import permit shall be obtained from the Agency.

# 5 DECISION ON APPLICATION

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

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

(a) Applicants not authorised by the Agency to import proposed products;

(b) A product not registered with the Agency.

(c) A product with a potential for abuse.

(d) A controlled drug, when the national quota for that particular drug is exhausted e.g. narcotic drugs and psychotropic substances.

(e) A product found to be substandard and/or falsified.

# 6 SANCTIONS AND PENALTIES

## 6.1 NON-COMPLIANT PRODUCTS

6.1.1. The Agency may apply the following regulatory actions in case of the importation of a non-compliant product after detention and issuance of appropriate detention notice:

(i) Order the re-export of the product at the cost of the importer.

(ii) Confiscate a non-compliant product, which may be destroyed and the cost of destruction borne by the importer, who may be prosecuted accordingly.

## 6.2 BRINGING INTO COMPLIANCE / RECTIFYING NON-COMPLIANT PRODUCTS

6.2.1. The Agency may permit an importer to bring an imported non-compliant product into compliance with the law. The product will be quarantined and any sorting, processing, labelling/re-labelling or analysis shall be supervised by an officer of the Agency at the expense of the importer.

6.2.2. Where the product is not registered, the importer shall be made to submit the product for registration and pay the appropriate fees in addition to a possible penalty to be determined by the Agency.

## 6.3 UNAUTHORISED IMPORTATION

6.3.1. Where a person or entity imports products without valid authorisation by the Agency the imported products will be confiscated and may be re-exported or destroyed.

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

# 7 FINAL PROVISIONS

10.1. This guideline is the second version published by the MCA and will become effective on 15 February 2018.

10.2. This guideline will be reviewed before December 2019.

# 8 ATTACHMENTS

| **Attachment No** | **Title** (as referenced on the attachment) |
|---|---|
| 01 | Import Permit for Medicines and Related Products - Form |
| 02 | Guidance for Registration of Medicines Listed by MCA |

# 9 REFERENCES

- Medicines and Related Products Act, 2014
- Fee Schedule 2017
- MCA Guideline for Registration as Importer of Medicines and Related Products (MCA-GL-104)

# 10 DOCUMENT HISTORY

| **Version:** | **Issue Date:** | **Reasons for Change:** |
|---|---|---|
| 1.0 | 25 July 2017 | New document |
| 2.0 | 12 February 2018 | Editorial changes, harmonisation of format for MCA guidelines, 'fast-track' registration of medicines included, guideline for importer license separated. |