MEDICINES CONTROL AGENCY

54 Kairaba Avenue, Pipeline, The Gambia. Tel.no. +220 4380632, www.mca.gm

GUIDELINE FOR LICENSING AS IMPORTER OF MEDICINES AND RELATED PRODUCTS

Document number and version:	MCA-GL-401, Version 3
Date of implementation:	10 July 2020

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*, requires that a person has to be issued with a licence by the Agency to import 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 importers licence fee as indicated in the MCA Fee Schedule.

1.1.5. Applicants are required to familiarise themselves with this document and the above stated law before applying for licensing as an importer.

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 applicants on the procedures for licensing as an importer to import medicines and related products into The Gambia and for the renewal of a licence in accordance with MCA requirements.

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. It applies to a person or entity eligible to be licensed as importer for a pharmaceutical business.

1.4.3. For other person(s) or entities that need permit to import, there is a separate guideline that addresses importation requirements for medicines and related products.

2 APPLICATION FOR A NEW LICENCE AND RENEWAL

2.1. Only corporate bodies or entities duly registered as pharmaceutical companies/ business by the Registrar of Companies in The Gambia with a supervising pharmacist duly registered by the Pharmacy Council shall be licensed by the MCA as importers for medicines and related products.

2.2. The fee for a new licence or renewal is due at the time of submission of the application.

2.3. For a new licence as an importer and renewal of the licence the application form must be completed by the applicant (MCA-F-411/01). The application form shall be signed and dated by the head/owner of the entity and the supervising pharmacist. The application form is available from the MCA website: www.mca.gm.

2.4. The application for a licence as importer shall include:

- a copy of an identification document (e.g. Gambian identification document, valid driver's license, passport);
- a copy of the certificate of registration of the supervising pharmacist with the Pharmacy Council the Gambia;
- the items to be imported; and
- any other information as may be requested by the Agency.

2.5. Approval of applications for a new licence may take up to two (2) weeks by the Agency.

2.6. An importer licence will be valid until the end of ONE (1) CALENDAR YEAR (31st December of each year).

2.7. Importers are required to renew their licence with the Agency annually. The importer is required to apply for renewal one (1) month before the end of the calendar year.

3 FINAL PROVISIONS

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

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

4 DOCUMENTS NEEDED FOR THIS GUIDELINES

Document No	**Title** (as referenced on the document)
MCA-F-411/01	Application for Licensing as Importer of Medicines and Related Products

5 REFERENCES

- Medicines and Related Products Act, 2014
- Medicines and Related Products Regulations, 2019
- MCA Fee Schedule
- Pharmacy Council Act, 2014
- MCA Guideline for Import and Export of Medicines and Related (MCA-GL-103)

6 DOCUMENT HISTORY

Version #	**Implementation Date**	**Reasons for Change:**
1	25 July 2017	New document
2	12 February 2018	Editorial changes, harmonisation of format for MCA guidelines, separate guideline for importation
3	10 July 2020	Editorial changes, change of Document Identification and Title