MEDICINES CONTROL AGENCY

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

GUIDELINE FOR LICENSING OF FACILITIES STORING MEDICINES AND RELATED PRODUCTS

Document number and version:	MCA-GL-402, Version 1
Date of implementation:	10 July 2020

1 INTRODUCTION

1.1 LEGAL BASIS

1.1.1. The regulation of medicines and related products 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 IV, Section 16 of the Act states that the Agency may issue a licence for storage facilities.

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

1.1.4. The Agency charges non-refundable application 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 license of a storage facility.

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 AND SCOPE

1.3.1. This guideline describes the application and procedures for new licensing of facilities where medicines or related products are stored, and for the renewal of the licence in accordance with MCA requirements.

Note: Government health facilities are not required to apply for a licence, but their storage facilities would be subject to inspection for compliance with applicable storage requirements.

1.3.2. The licensing of storage facilities by the Agency shall ensure that the facility is suitable for the storage of medicines or related products to maintain their safety, quality and efficacy.

1.3.3. The guideline applies to storage facilities and warehouses including private pharmaceutical businesses, private and NGO clinics and hospitals, distributors of herbal medicinal products, nutritional supplements, cosmetics, medical devices, diagnostics and household chemical substances.

1.3.4. It applies to medicines and related products as defined in the Act and the Regulations.

1.3.5. The guideline applies to corporate bodies, entities or persons engaged in the import, storage, distribution or sale of medicines and related products.

1.3.6. There is a separate guideline for licensing of manufacturing premises.

2 APPLICATION FOR A LICENCE AND RENEWAL

2.1. Any corporate body, entity or person engaged in the import, storage, distribution or sale of medicines and related products are required to apply for a licence for storage facility, unless exempted by the Agency.

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 and renewal of a licence the application form must be completed by the applicant (MCA-F-412/01). The application form shall be signed and dated by the owner or officer in charge of the facility. The application form is available from the MCA website: www.mca.gm.

2.4. The application for a licence for a storage facility shall include:

- a copy of an identification document (e.g. Gambian identification document, valid driver's license, passport);
- a copy of the registration of the business and a copy of the certificate of registration as a pharmacist, where applicable;
- a copy of the wholesale licence from the Pharmacy Council where applicable;
- the items to be stored; and
- any other information as may be requested by the Agency.

2.5. A licence for a storage facility will only be issued by the MCA when the application conforms to the applicable requirements, standards and good practices, confirmed by an inspection by the Agency (for details on inspections, refer to the MCA *Guideline for Inspections*).

2.6. For an inspection, the MCA inspectorate will contact the applicant for a suitable date to conduct the inspection visit which should take place at the premise.

2.7. Approval of an application for a new licence for a storage facility may take up to two (2) weeks by the Agency after the inspection visit.

2.8. A new licence will be valid until the end of ONE (1) CALENDAR YEAR (31st December of each year).

2.9. Owners or officers in charge of storage facilities for medicines and related products are required to renew their licences with the Agency annually. They are requested to apply for renewal of the licence one (1) month before the end of the calendar year.

3 FINAL PROVISIONS

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

3.2. 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-412/01	Application for Licensing of Storage Facilities for 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 Inspections by the Medicines Control Agency (MCA-GL-201)
- MCA Guideline for Storage and Distribution of Medicines and Related Products (MCA-GL-301)

6 DOCUMENT HISTORY

Version:	Implementation Date:	Reasons for Change:
1	10 July 2020	New document