MEDICINES CONTROL AGENCY

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GUIDANCE TO MANUFACTURERS, MARKETING AUTHORIZATION HOLDERS AND IMPORTERS FOR LISTING OF MEDICINES AND RELATED PRODUCTS

INTRODUCTION

This document serves as a guidance to assist person or entity submitting application for listing of Medicines and Related Products to Medicines Control Agency (MCA), the Gambia. Applicants are required to familiarize themselves with this document and the below stated law before applying for a listing.

On 10th of October 2023, the President of the Republic of the Gambia, assented and signed the Medicines and Related Products (Amendment) Act, 2023 into law, which included the amendment of Section 26 of the Medicines and Related Products Act 2014 and it states the "Agency may adopt a mechanism other than registration permitting a person to import, distribute, sell, supply, or exhibit for sale any medicine or related product manufactured or produced in a country the Agency considers to have a competent and trusted regulatory authority or institution." In this amendment, the competent and trusted regulatory authority or institution is referred to as "a Stringent Regulatory Authority." Among other provisions, the Agency, by notice published in a Gazette:

(a) shall list the countries it considers to have a Stringent Regulatory Authority; and

(b) may amend the list of countries it considers to have a Stringent Regulatory Authority.

The list of countries considered to have Stringent Regulatory Authority was published in the Gazette and the list was also distributed to all stakeholders including importers.

Sequel to the aforementioned, Medicines and Related Products (Amendment) Act, 2023 and adoption of listing, requires that for each medicine and related product intended to be listed, the responsible person or entity shall submit application to MCA for medicine and related product listing.

The forms for listing of:

(a) Medicines and Related Products (excluding Medical Devices); and

(b) Medical Devices

are available on the MCA website www.mca.gm. It is imperative to note that the listing of Medicines and Related Products as a mechanism other than registration is annual and is reviewed yearly for possible adoption. For example, for the current year, the listing is effective 1st January 2024 and ends 31st December 2024. Thus, listing of Medicines and Related

Products expires end of every year and products listed in previous year are to be listed again in the following year.

This guidance document explains, among other things:

- The statutory requirement to submit medicines and related products for listing (as an adopted mechanism other than registration);
- Who is responsible for making the submissions?;
- What information to include in the submissions?;
- How to make the submissions?;
- When to make the submissions?; and
- Is fee attached to listing application?

Who submits Medicines and Related Products listing application to MCA?

Medicines and Related Products (Amendment) Act, 2023 requires that for each medicine and related product intended to be listed, the responsible person or entity must submit an application for Medicine and Related Products listing to the Agency.

How do you submit Medicines and Related Products listing information required to MCA?

During submission, a complete application is sent to MCA for processing. The timeline for the processing of listing application is within two weeks. It is important to note that, the same product is permitted to be listed by multiple importers since the product is not registered and therefore no one is granted marketing authorization right.

The application consists of the following:

- A copy of cover letter, the accompanying cover letter shall be duly signed and addressed to Executive Director.
- A soft and hard copy of the completed application form. The application form shall be dated, signed and stamped by the applicant. The application form is available on the MCA website: www.mca.gm.
- Evidence of payment of listing fee.

What information is submitted as part of Medicines and Related Products listing to MCA?

The following information are required to be submitted on Medicines and Related products by completing the listing form.

1. Medicines and Related Products (excluding medical devices);

a. Name and description of the product
b. Generic name
c. Dosage form
d. Route of administration
e. Composition of product (name and quantity of active pharmaceutical ingredients)
f. indication/ claim
g. Package size & presentation
h. Dispensing category (OTC/PM/POM/POM-CD)
i. Name & address of manufacturer
j. Name & address of source

2. medical devices

a) Name and description of the product
b) Indication/use
c) Storage conditions
d) Package size & presentation
e) Name & address of manufacturer
f) Name & address of source

When to list your Medicines and Related Products with MCA?

The responsible person or entity can apply for listing of Medicines and Related Products that are intended to be marketed in the Gambia during any time of the year but is important to note that the listing expires on 31st December of each year. Any product that is intended to be imported through the listing mechanism shall be listed prior to importation. MCA would not be responsible and/ or liable for any losses incurred due to failure to follow the procedures of getting your products approved for listing before importation.

Does MCA charge fee for Medicines and Related Products listing application?

The Agency charges non-refundable application fee for listing. The application fee shall be paid at the time of submission of an application prior to importation of Medicines and Related Products.

Products that differ in active pharmaceutical ingredient(s), strength, dosage forms, proprietary names though containing the same ingredients or from different manufacturers, package size and presentation are considered to be different products and hence require separate application for listing.

Queries or Clarification

MCA can be contacted for any questions or clarifications required. For further details, please email info@mca.gm.

APPENDIX 1

LIST OF COUNTRIES CONSIDERED TO HAVE STRINGENT REGULATORY AUTHORITIES

N0.	Country
1	Australia
2	Austria
3	Belgium
4	Bulgaria
5	Canada
6	Croatia
7	Cyprus
8	Czech Republic
9	Denmark
10	Estonia
11	Finland
12	France
13	Germany
14	Greece
15	Hungary
16	Iceland
17	Ireland
18	Italy
19	Japan
20	Latvia

21	Liechtenstein
22	Lithuania
23	Luxembourg
24	Malta
25	Netherlands
26	Norway
27	Poland
28	Portugal
29	Romania
30	Slovakia
31	Slovenia
32	Spain
33	Sweden
34	Switzerland
35	Turkey
36	United Kingdom
37	United States of America