GUIDELINE FOR REGISTRATION OF MEDICINES
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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, by which the Medicines Control Agency (MCA) was established as the regulatory body for medicines and related products. The Act replaces the

1.1.2. Part VI of the Act, Registration of Medicines and Related Products, Sections 25, 26 and 30 requires that all medicines manufactured, prepared, imported, exported, distributed, sold, supplied or exhibited for sale has been registered by the Agency.

1.1.3. The Agency charges non-refundable application fees for registrations, variations and renewals as specified in the Fee Schedule. The fee for the processing of an application is due at the time of submission of an application.

1.1.4. Applicants are required to familiarise themselves with this document and the above stated law before applying for a registration, variation or renewal.

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 the law this document provides guidance to applicants on the procedures for registrations of new medicines in The Gambia, for variations of registered medicines and for renewals of registrations.

Note: The registration, variation and renewal of registration of medicines shall be approved by the Agency before importation of these products is permitted into the country, except of those used as samples for the purpose of this application.

1.3.2. 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 as defined in the Act with the exception of herbal medicinal products, for which a separate guideline is available.

1.4.2. It applies to generic medicines manufactured locally or to be imported into The Gambia, and to proprietary medicines authorised for marketing by a regulatory authority or prequalified by the World Health Organisation (WHO).

1.4.3. Medicines marketed in the Gambia before the Act of December 2014 and listed with the Agency will be registered as indicated in Section 10.2 of this guideline.
2 REGISTRATION OF NEW MEDICINES

2.1 GENERAL REQUIREMENTS

2.1.1. A separate application is required for each product.

2.1.2. Products that differ in active pharmaceutical ingredient(s), strength, dosage forms, proprietary names though containing the same ingredients, are considered to be different products and hence require separate applications.

2.1.3. For a fixed dose combination medicine, the applicant must provide proven evidence that the product has been shown to be safe and effective and that all of the active pharmaceutical ingredients contribute to the overall therapeutic effect. In addition, it should be proven that there can be real clinical benefits in the form of increased efficacy and/or a reduced incidence of adverse effects and/or improved patient adherence.

2.1.4. An abbreviated application for registration is possible for a generic medicine (imported or locally manufactured).

2.1.5. The Agency may consider an abbreviated registration for proprietary medicines on a case-by-case basis.

2.1.6. Registration in The Gambia of innovative medicines shall normally not be permitted within the first two years of the initial authorisation and being placed on the market in the country of origin.

2.2 PROCESS OF APPLICATION

2.2.1. For any registration the application form (Attachment 01) must be completed by the applicant for each dosage form and/or strength of the medicine. The application form shall be dated, signed and stamped by the applicant and indicate the Local Representative, if applicable. The application form is available from the MCA website: www.mca.gm.

2.2.2. All applications shall be submitted in the Common Technical Document (CTD) format as provided by the Agency (Attachment 02) including all supporting documents, unless stated otherwise in this guideline.

2.2.3. All documentation submitted shall be in English, and must be legibly printed and not handwritten.

2.2.4. The documents shall be submitted both as hard and soft copies.

2.2.5. Copies of the labels and package inserts, conforming to existing labelling regulations in The Gambia (see Section 7) shall be included in the documentation.

2.2.6. The accompanying cover letter shall be duly signed and addressed to Executive Director, Medicines Control Agency, 54 Kairaba Avenue, K.S.M.D, The Gambia.

2.2.7. If the applicant is not resident in The Gambia, he/she shall appoint a Local Representative who must be a person residing or a company incorporated in The Gambia, and licensed by MCA. The applicant shall provide a notarised power of attorney that complies with The Gambian
law to designate the Local Representative or a duly signed agreement between the Local Representative and applicant, stating the names of the medicines intended to register. The Local Representative shall be responsible for facilitating communication with the applicant.

2.2.8. The marketing authorisation holder shall be responsible for marketing the medicinal product. The designation of a representative shall not relieve the marketing authorisation holder of his legal responsibility.

2.2.9. The proposed marketing authorisation holder and manufacture(s) shall be clearly indicated.

2.2.10. Although clinical trial data including bioequivalence data for generic medicines derived from studies in other countries will be considered in taking a decision with any application, the Agency reserves the right to request for local clinical evaluation, based on existing MCA guidelines for clinical trials, or bioequivalence data for generic medicines based on existing WHO guidelines for bioequivalence studies, where necessary. The cost of this trial shall be borne by the applicant.

2.2.11. The Agency may ask the applicant to supply other information as may be required to enable reaching a decision on the application.

2.3 REGULATORY STATUS OF PRODUCTS TO BE IMPORTED

2.3.1. The applicant shall provide information on the regulatory situation of the medicine in the country of origin and other countries. A list shall be submitted stating the countries in which the product:

- has a marketing authorisation including copies of the registration certificate(s) from the RA;
- has been withdrawn from any market;
- was intended for registration but the application for marketing has been rejected, suspended, deferred or withdrawn.

2.3.2. A copy of the fully completed current Certificate of Pharmaceutical Product (CPP) issued in accordance with the WHO Certification Scheme for Pharmaceutical Products Moving in International Commerce and issued by the RA of the exporting country shall be submitted.

- The CPP should officially be stamped and dated together with all copies of product information submitted in support of the application for registration.
- The applicant is responsible for providing a notarised translation of the contents of the CPP in English in case when the certifying agency issued the certificate in any other language.
- The CPP should be original and/or a notarised or certified copy and valid.

2.3.3. If the product is not identical to that in the issuing country, the applicant must list any differences in the application form and justify the differences. The Agency will decide whether the differences are minor and have been adequately justified, and consequently whether the CPP is relevant for the intended purposes.
2.4 MANUFACTURING INFORMATION

2.4.1. Locally manufactured medicines can only be registered after the premises were inspected and licensed by the Agency.

2.4.2. For medicines to be imported the manufacturing license and GMP certificate, where applicable should be submitted.

2.4.3. Where the product is manufactured in different countries and the applicant wishes to obtain approval to use all sites of manufacture, the corresponding manufacturing licenses and GMP certificates, where applicable should be submitted from all the countries.

2.4.4. A drug master file (DMF) shall be submitted for all applications, where necessary. The manufacturer of the API should provide a signed declaration stating that the synthesis and subsequent purification is conducted in accordance with what is presented in the DMF.

2.4.5. All oral liquid preparations (e.g. solutions, suspensions, syrups) shall have an appropriate graduated measure included in the final package.

2.4.6. For all solid oral dosage forms, reports of dissolution studies are required. If the monograph used by the applicant does not require dissolution, the dissolution requirement in the USP or equivalent shall apply.

2.4.7. When excipients of animal or human origin are used, (e.g. Stearic acid, Magnesium stearate and other stearates, Gelatine, Phosphates from animal origin) a TSE/BSE free certificate shall be provided; for Talc an Asbestos free certificate is required.

2.4.8. All applications shall be accompanied by three (3) samples from each batch of the product in the commercial pack(s) with batch Certificates of Analysis (CoA), reagents necessary to perform analyses of finished product as described in the dossier and reference or working standard for Active Pharmaceutical Ingredient and related impurities, where necessary.

2.4.9. The CoA for the medicine shall be issued by the authorised or qualified person.

2.5 APPLICATION FOR REGISTRATION

2.5.1. All modules of the CTD are needed for an application for proprietary medicines, unless the Agency accepts an abbreviated application.

2.5.2. For innovator products verifiable information regarding the date of expiry of the patent should be provided.

2.6 ABBREVIATED APPLICATION FOR REGISTRATION

A) Generic medicines

2.6.1. Generic medicines applications are considered "abbreviated" because they are generally not required to include preclinical and clinical data to establish safety and effectiveness. Abbreviated applications for generic medicines should be submitted in the MCA CTD format including all
supporting documents as applicable for generic medicines.

2.6.2. The bioequivalence of the generic medicine must be demonstrated in comparison to the reference medicine. The reference medicine must be authorised by a stringent RA as indicated by WHO, accompanied by a confirmation that the reference medicine is or has been authorised together with the full composition of the reference medicine and if necessary other relevant documentation.

2.6.3. For purposes of verification of compliance to GMP, all applications shall be accompanied by a Site Master File.

**B) Proprietary medicines**

2.6.4. For an application to register a medicine that has a marketing authorisation issued by a regulatory authority that applies standards for quality, safety and efficacy evaluation recommended by WHO (reference RA) or is prequalified by WHO the following documents shall be submitted:

a. The cover letter including a statement confirming that the product including but not limited to composition/formulation, strength, manufacturing, specifications, packaging, product information will, at the time of submission and after registration in all respects be the same as the product registered with the reference RA, and a statement indicating that the product is actually on the market of the reference RA’s country or region.

b. A copy of the marketing authorisation, or the equivalent thereof, issued by the RA to demonstrate that the medicine is registered or licensed in accordance with the RA requirements. If applicable, a copy of the latest renewal of the marketing authorisation should also be provided.

c. The latest RA-approved product information consisting of the summary of product characteristics (SmPC), or an equivalent thereof, the patient information leaflet (PIL), or equivalent thereof, and the container labelling.

d. A list of the RA-approved manufacturer(s) of the medicine, including manufacturers of intermediates, primary packaging sites and release-testing sites, with the physical address of the manufacturing site(s) (and unit if applicable).

e. A list of the RA-approved manufacturer(s) of the active pharmaceutical ingredient(s) used in the manufacture of the medicine, with the physical address of the manufacturing site(s) (and unit if applicable).

f. If available, a public assessment report, such as the Scientific Discussion of the European Public Assessment Report (EPAR), issued by the RA. Assessment report(s) issued by the RA that are not publicly available may be requested.

g. A tabular listing of the batches manufactured for the market of the RA’s region or country since approval or during the past five years, whichever is shorter. The table should include at least the batch
number, batch size (number of units), date of manufacture and pack type/size. A copy of the most recent product quality review, prepared according to the requirements of the RA, should also be provided.

h. A copy of the currently approved medicines specifications (release and shelf-life), dated and signed or certified by authorised personnel, with the analytical test procedures.

2.6.5. For innovator products verifiable information regarding the date of expiry of the patent should be provided.

3 REGISTRATION OF VARIATIONS

3.1. If the applicant makes changes to the details of the medicine registered, such changes, whether administrative or substantive, are referred to as variations and may be subject to acceptance by the Agency prior to implementation.

3.2. Changes that may have minor effects on the overall safety, efficacy and/or quality of the medicine are considered as minor variation and can be implemented, if no objection letter has been issued within one month by the Agency.

3.3. Major variations are changes that could have major effects on the overall safety, efficacy and/or quality of the medicine. Prior acceptance by MCA is required before the changes can be implemented. A letter of acceptance will be issued for all major variations if and when the variation is considered acceptable.

3.4. An application for variation registration of a medicine should be submitted to the Agency by a duly signed cover letter addressed to Executive Director, Medicines Control Agency, 54 Kairaba Avenue, K.S.M.D, The Gambia.

3.5. The application form for product variation (Attachment 03) registration must be completed by the applicant for each dosage form and/or strength of the medicine. The application form is available from the MCA website: www.mca.gm.

3.6. All documentation in support of the variation shall be provided with reference to the respective CTD sections, where applicable.

3.7. If applicable, three (3) samples from each batch of the product in the commercial pack(s) reflecting the variation shall be provided in the commercial pack(s) from one batch with batch CoA, reagents necessary to perform analyses of finished product as described in that dossier and reference or working standard for Active Pharmaceutical Ingredient and related impurities, where necessary.

4 RENEWAL OF REGISTRATION

4.1. An application for renewal of a medicine registration shall be made three (3) months before expiration of the existing registration.

4.2. The application form (Attachment 01) must be completed by the applicant for each dosage form and/or strength of the medicine. The
application form is available from the MCA website: www.mca.gm.

4.3. The application for renewal of a registration of a medicine should be submitted to the Agency by a duly signed cover letter addressed to Executive Director, Medicines Control Agency, 54 Kairaba Avenue, K.S.M.D, The Gambia.

4.4. All documentation in support of the renewal shall be provided with reference to the respective CTD sections, where applicable.

4.5. The applicant shall submit

- A copy of the most recent annual product quality review, prepared according to the requirements of the RA of the manufacturing country, should also be provided.
- Batch Manufacturing (Production) Record of a real batch manufactured within at most six months before the submission of the application.
- Periodic Benefit Safety Update Reports (PBSUR) or Periodic Safety Update Reports (PSUR).
- A site master file in case the product is manufactured at a plant(s) not approved by the Agency.
- Any other requirements that the Agency may determine.

4.6. Three (3) samples from each batch of the product in the commercial pack(s) shall be provided in the commercial pack(s) from one batch with batch CoAs, reagents necessary to perform analyses of finished product as described in that dossier and reference or working standard for Active Pharmaceutical Ingredient and related impurities, where necessary.

5 TIMELINES

5.1. The Agency shall acknowledge receipt of all applications and payment of fees at submission.

5.2. It shall process an application within six (6) months and applications for major variations and renewals within three (3) months.

5.3. During evaluation, additional data and/or samples may be requested through a query letter. Once a query has been raised and issued to the applicant, the process stops until when MCA receives a written response to the query.

5.4. The applicant shall submit written responses to queries within 6 months from the date of their issuance. If the queries have been reissued for a second time and the applicant provides unsatisfactory responses, the product will be disqualified and the application will be rejected. The applicant will be required to apply afresh.

5.5. If no response is received within six months of the request, it will be deemed that the applicant has withdrawn the application and the application will be discontinued.

5.6. The registration of a medicine, unless otherwise stated, shall be valid for a period of five (5) years and may be renewed for a period of not more than three (3) years.
6 STABILITY DATA

6.1. Stability study reports conducted for three (3) trial batches of the product, and suited to the conditions (WHO Zone IV A climatic) specified below, shall be submitted:

<table>
<thead>
<tr>
<th>Study</th>
<th>Temperature</th>
<th>Relative Humidity</th>
<th>Minimum Time*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accelerated</td>
<td>40 ± 2°C</td>
<td>75 ± 5 %</td>
<td>6 months</td>
</tr>
<tr>
<td>Long-term</td>
<td>30 ± 2°C</td>
<td>65 ± 5 %</td>
<td>12 months</td>
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</table>

* Period covered by data at submission

6.2. The stability study shall be conducted in the container-closure system in which the medicine will be marketed in The Gambia. Where the product is to be marketed in more than one container-closure system, stability data shall be provided for each presentation.

6.3. Real-time stability data are required for all biological medicines.

6.4. The results of the stability tests shall be presented in both tabular and graphical forms and the proposed shelf-life and storage conditions shall be determined on the basis of these results.

7 LABELLING REQUIREMENTS

7.1 LABELLING

7.1.1. All medicines shall conform to labelling requirements of MCA (see below).

7.1.2. Each medicine should be accompanied with appropriate labelling of the primary and secondary container including a patient information leaflet (package insert) and with a summary of product characteristics (SmPC) or equivalent. The format of the document should be consistent with the WHO or ICH SmPC template.

7.1.3. All label statements must be in English.

7.1.4. Statements required to appear on the label should be clear, prominent, indelible and readily legible to the consumer under normal conditions of purchase and use.

7.1.5. The label should not be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its use in any respect either pictorially or in words.

7.1.6. The presentation of the product shall not have any resemblance in spelling, pronunciation and layout of brand name or packaging to another product from a different manufacturer or MAH.

7.2 NAME OF THE PRODUCT

7.2.1. A generic medicine shall not be marketed in The Gambia in a name
similar in pronunciation or form to the reference medicine or brand generic product.

7.2.2. The use of an International Non-proprietary Name (INN) as a brand name shall not be permitted, and the brand name of the product shall not have any resemblance in spelling and pronunciation to the INN.

7.3 **MINIMUM REQUIRED INFORMATION**

7.3.1. Patient information leaflet (package insert):
   a. Name of medicine (generic name or brand name, as applicable)
   b. Strength and dosage form (if not included in the name)
   c. Active ingredients as INN or other recognised name and contents by weight, volume or dosage unit, and the excipients
   d. The pharmacotherapeutic group/ATC Code
   e. Indication(s)
   f. Method and route of administration
   g. Recommended dosage
   h. Duration of use
   i. Adverse reactions and side effects
   j. Symptoms and management of overdose
   k. Contraindication, special warnings, precautions and drug interactions
   l. Use during pregnancy and lactation
   m. Reference to the expiry date
   n. Presentation (packing and pack sizes)
   o. Storage conditions
   p. Name and address of marketing authorisation holder and manufacturer
   q. Date of publication of the insert

7.3.2. Primary and, where applicable Secondary container:
   a. Name of medicine (generic name or brand name, as applicable)
   b. Strength and dosage form (if not included in the name)
   c. Active ingredients as INN or other recognised name and contents by weight, volume or dosage unit, and excipients known to have a pharmacological effect
   d. Method and route of administration
   e. Instruction for use in case of non-prescription medicines
   f. Nutritional information in case of nutritional supplements
   g. Special warnings and warning that medicines must be stored out of the sight and reach of children
   h. Batch/Lot number, manufacture date and expiry date
   i. Storage conditions
   j. Pack size
   k. Name and address of marketing authorisation holder/manufacturer.
7.3.3. If primary container is blister:
   a. Name of medicine (generic name or brand name, as applicable)
   b. Strength and dosage form (if not included in the name)
   c. Batch/Lot number and expiry date
   d. Name of marketing authorisation holder/manufacturer.

7.3.4. If primary container is of small volume (nominal value of 10 ml or less):
   a. Name of medicine (generic name or brand name, as applicable)
   b. Strength and dosage form (if not included in the name)
   c. Contents by weight, volume or dosage unit;
   d. Method of administration;
   e. Batch/Lot number and expiry date.

8 DECISION ON REGISTRATION

8.1. The Agency in considering an application for registration:
   • shall state the therapeutic value of the medicine;
   • shall have proven evidence in case of a fixed dose combination medicine, that the product is clinically rational;
   • may consult with other bodies and experts with knowledge of the medicine;
   • reserves the right to conduct a Good Manufacturing Practice (GMP) inspection on the manufacturing facility for the product at a fee prescribed by the Agency; and
   • may request the applicant to satisfy the Agency that he has the resources and facility to execute an effective recall of the product if the need arises.

8.2. Decisions on registration by MCA shall be based on the report of the dossier evaluation, quality control results of the samples and inspection on compliance to GMP, if applicable.

8.3. An appeal for the review of an application may be made in writing to the Executive Director within sixty (60) days of receipt of the rejection notice.

8.4. Where all requirements for the registration of a medicine have been met, the Agency shall issue to the applicant a certificate of registration, subject to such conditions as may be prescribed by the Agency.

8.5. The Agency shall publish annually a notice in the Gazette on the registered products.

8.6. No information given in this application shall be disclosed by the MCA to a third party except:
   • with the written consent of the applicant/marketing authorisation holder; or
   • in accordance with the directive of the Board of Directors of MCA; or
• for the purpose of a legal process under the Medicines and Related Products Act, 2014.

9 **REVOCATION, WITHDRAWAL OR SUSPENSION OF REGISTRATION**

9.1. The Agency shall revoke, withdraw or suspend the registration of a medicine if:
• the basis on which the medicine was registered is later found to be false; or
• the circumstances under which the medicine was registered no longer exist; or
• any of the provisions under which the medicine was registered has been contravened; or
• the standard of quality, safety and/or efficacy, as prescribed in the documentation for registration is not being complied with; or
• the premises, in which the medicine or part thereof is manufactured, packaged or stored by or on behalf of the holder of the Certificate of Registration is unsuitable for the manufacture, packaging or storage of the medicine.

9.2. Where the registration of a medicine is revoked, withdrawn or suspended, the Agency shall withdraw from circulation that medicine and shall accordingly cause the revocation, withdrawal or suspension to be published in the Gazette.

10 **FINAL PROVISIONS**

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

10.2. Medicines currently listed with the Agency will be requested to be registered with the next application for importation from five years following the first import after the Act came into force in December 2014. For those medicines a ‘fast track’ registration will be possible (see MCA Guideline for Importation of Medicines and Related Products into The Gambia).

10.3. This guideline will be reviewed within 2 years of becoming effective.
11 ATTACHMENTS

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<thead>
<tr>
<th>Attachment No</th>
<th>Title (as referenced on the attachment)</th>
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<tr>
<td>01</td>
<td>Medicines Registration Application - Form</td>
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<tr>
<td>02</td>
<td>Guidance for the Application in the Common Technical Document (CTD) Format</td>
</tr>
<tr>
<td>03</td>
<td>Medicines Variation Registration Application – Form</td>
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12 REFERENCES

- Medicines and Related Products Act, 2014
- Fee Schedule 2017
- MCA Guideline for Importation of Medicines and Related Products into The Gambia (MCA-GL-103)
- MCA Guideline for Registration of Herbal Medicinal Products (MCA-GL-106)

13 DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Version</th>
<th>Issue Date</th>
<th>Reasons for Change</th>
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<tbody>
<tr>
<td>1.0</td>
<td>25 July 2017</td>
<td>New document</td>
</tr>
<tr>
<td>2.0</td>
<td>12 February 2018</td>
<td>Editorial changes, harmonisation of format for MCA guidelines, adaptation to the CTD, nutritional supplements integrated.</td>
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</table>
14 FLOW CHART: APPLICATION FOR REGISTRATION

Start

Prepare cover letter

Applicant Gambian resident

Yes

Complete Application Form

Fast Track

Yes

Submit requested documents

No

No

Submit CTD dossier

Pay required fee

Provide samples and materials as needed

End

Yes

Appoint Local Representative

Provide power of attorney or agreement

Abbreviated

No

Submit CTD dossier for generica

or

Submit requested documents for proprietary medicines