



MEDICINES CONTROL AGENCY

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GUIDELINES FOR REGISTRATION OF MEDICINES IN THE GAMBIA

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1. INTRODUCTION

The regulation of medicines and related health products in The Gambia is governed by the provisions and requirements of the Medicines and Related Products Act 2014 and the functions of the Act being implemented by the Medicines Control Agency (MCA).

The law requires that all medicines manufactured, imported or exported, distributed and used in The Gambia should be of acceptable quality, safety and efficacy. The process of medicine registration forms an important basis for evaluating and assuring the safety, efficacy and quality medicines and health products.

Applications should be submitted for registration in the WAHO Common Technical Document (CTD) format.

1.1 LEGAL BASIS

In pursuance of Part VI Section 25-27, 30 of the Act on Registration of Medicines & Related Products, these guidelines are hereby made to provide guidance to applicants on the procedure for registering medicines and related products in The Gambia. Applicants are required to familiarize themselves with this document and the above law before completing the registration application form (Appendix 1).

1.2 INTERPRETATION

In these guidelines, unless the context otherwise states: -

- a) **“AGENCY”** means The Medicines Control Agency (MCA)
- b) **Applicant:** Means a person, manufacturer or company who submits application for registration of medicine and health product to the Agency; and responsible for compilation of information for registration
- c) **“allopathic drug”** means - any product or substance other than a medical device, which is to be administered to one or more human beings on its own, or as an ingredient in the preparation of a substance, for a medicinal purpose.
- d) **“medicinal purpose”** means - use for treating or preventing a disease, diagnosing or ascertaining the presence and extent of a physiological function, contraception, inducing anaesthesia, altering normal physiologic function permanently or temporarily in any way in humans.
- e) **“variation”** means - a change in the indication(s), dosage recommendation(s), drug classification and/or patient group(s) for a previously registered drug being marketed under the same name in The Gambia. A variation also includes, but is not limited to, a change in the product name, site of manufacture and/or source of ingredients.
- f) **“new chemical entity”** means - a chemical or biologically Active Pharmaceutical Ingredient (API) that has not previously been issued with a marketing authorization as an ingredient of any pharmaceutical product in The Gambia

- g) **“lead market brand”** means- a proprietary or branded generic product which has been determined by criteria including but not limited to the following:
- sales volume
 - safety profile
 - number of prescriptions
 - expert opinion
- and so declared by the Medicines Control Agency
- h) **“International Non-proprietary Name (INN)”** means the approved chemical name of the product.
- i) **“Innovator drug”** means - a drug for which a New Drug Application (NDA) has been submitted to a regulatory Agency and marketing authorization granted.
- j) **“Generic drug”** means a finished product based on an active substance which is marketed under a different name from that of the original branded medicinal product or under its common name..
- k) **Active Ingredient:** Means a substance with a therapeutic, diagnostic or prophylactic activity used in a pharmaceutical product. "Drug Substance" and "Active Substance" are synonymous to "Active Ingredient."
- l) **Closure:** Means a part of the container.
- m) **Container:** Is that which holds the article and is or may be in direct contact with the drug.
- n) **Dosage Form:** Formulation of an active ingredient(s) so that it can be administered to a patient in specified quantity/strength e.g. tablets, capsules, injection solution, syrups, ointments, suppositories, etc. "Pharmaceutical Form" and "Finished Product" are synonymous to "Dosage Form."
- o) **Counterfeit Medicine:** Means a medicine that is deliberately and fraudulently mislabelled with respect to identity for source. Counterfeit products may be branded or generic medicines, and may include products with the correct ingredients, with the wrong ingredient, without ingredients, with insufficient active ingredient, or with fake packaging material.
- p) **Immediate or Primary Container:** Is that part of container which is in direct contact with the medicine at all times
- q) **Labeling: Includes any legend,** word or mark attached to, included in, belonging to or accompanying any medicine including: 1) The immediate container label 2) Cartons, wrappers and similar items, 3) Information materials such as instructional brochures and package inserts.
- r) **Manufacture (Manufacturing):** All operations of purchase of materials and products, production, quality control, release, storage, shipment of finished products and the related controls.

- s) **Manufacturer:** A company that carries out at least one step of manufacture.

- t) **Medical Device:** Means an instrument that is not a medicine, as defined herein, that is intended for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or symptoms thereof, in human or animal, or restoring, correcting, or beneficial modification of organic or mental functions in human or animal.

- u) **Medical Supply:** Means article that is intended for diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or symptoms thereof, in human or animal or restoring, correcting or beneficial modification of organic or mental functions in human or animal. This includes suturing materials, syringes, needles, bandages, gauze, cotton, artificial teeth, chemicals, and x-ray film and other similar articles.

- v) **Medicine:** Means any substance or mixture of substances intended for use in:
 - (i) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or the symptoms thereof, in man or animal; or,

 - (ii) restoring, correcting or beneficial modification of organic or mental functions in man or animal; or,

 - (iii) medicine shall include traditional medicine, narcotic drugs, psychotropic substances, blood and blood products, vaccines, sera, and radiopharmaceuticals, but not health products as defined herein.

- w) **Pharmaceutical Importer:** Means a registered entity and licensed by MCA to procure and import medicines and health products from foreign countries and/or distribution in the commerce of The Gambia

- x) **Related product:** means an article other than medicine which includes cosmetics, homeopathic medicines, medical device, instrument or apparatus including, components, parts and accessories of it, manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptom of it in man or animal;

2.0. REGISTRATION OF MEDICINES

2.1 NEW APPLICATION

An application for registration of a medicine, either locally manufactured or imported, shall be made in writing, accompanied by an Application Form and addressed as stated below.

The Application Form shall be completed as required and shall be dated, signed and stamped by the applicant/license holder.

Every applicant who is not resident in The Gambia shall appoint a local agent who must be a person residing or a company incorporated in The Gambia, and authorized by MCA to deal in Medicines and Related Health Products. Power of attorney that complies with The Gambia laws and accompanied with duly signed agreement between the local representative and manufacturers of the finished product(s) and the list of products should be attached and submitted to the Agency.

The local agent shall be responsible for facilitating communication with the applicant. He/she shall assume all legal responsibilities regarding the registered product in the Gambian market.

Applications shall be accompanied by:

- a) a duly signed cover letter addressed to **Executive Director, Medicines Control Agency, 54 Kairaba Avenue, K.S.M.D, The Gambia**
- b) two (2) completed application forms
- c) samples of the product in the final package as specified in Samples Schedule
- d) reference or working standard for Active Pharmaceutical Ingredient and related impurities where necessary.
- e) Dossier in WAHO CTD format including all supporting documents specified in the application form
- f) clinical trial and/or bioequivalence trial certificate where applicable
- g) non-refundable application fee as specified in Fee Schedule

The Agency shall approve the application before importation of the product(s), other than those used as samples for the purpose of this application, shall be allowed into the country.

2.2. REGISTRATION VARIATION

An application for variation registration of a product should be submitted to the Agency.

The application shall be accompanied by:

- a) a duly signed cover letter addressed to **Executive Director, Medicines Control Agency**
- b) documentation in support of the variation
- c) samples reflecting the variation as specified in the Samples Schedule.
- d) a non-refundable variation fee as specified in the Fee Schedule

This variation shall be approved by the Agency before importation of the product, other than those used as samples for the purpose of this application, shall be permitted into the country.

2.3. RE-REGISTRATION

2.3.1 An application for re-registration of a medicine shall be made three (3) months before expiration of the last registration.

The application shall be accompanied by:

- a) a cover letter addressed to the **Executive Director, Medicines Control Agency, The Gambia**
- b) supporting documents for any variations since the product was last registered
- c) samples of the product in the final package as specified in the Samples Schedule.
- d) a non-refundable application fee as specified in Fee Schedule

The re-registration of medicines and related products shall be approved by the Agency before importation of the product, other those used as samples for the purpose of this application, shall be permitted into the country.

3.0. GENERAL REQUIREMENTS

3.1 SAMPLES

3.1.1 The presentation of the product shall not have any resemblance in spelling and pronunciation of name or packaging to another product that has been previously registered by the Agency.

3.1.2 All samples of oral liquid preparations (solutions, suspensions, syrups) shall have an appropriate graduated measure included in the final package.

3.1.3 All samples submitted shall conform to labeling requirements of MCA of The Gambia.

3.1.4 The use of an International Non-proprietary Name (INN) as a brand shall not be permitted.

3.1.5 The brand name of the product shall not have any resemblance in spelling and pronunciation to the INN.

3.2 General labeling requirement;

- Each product should be accompanied with appropriate labeling including package insert and the primary labeling of the container.
- All label statements should be in English.
- 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.
- Statement required to appear on the label should be clear, prominent, indelible and readily legible to the consumer under normal conditions of purchase and use.

3.2.1 Minimum required information for labeling:

- Name of product
- Dosage form
- Indication and recommended dosage of the product
- Mode of administration
- Duration of use
- Major adverse effects, if any
- Symptoms and management of overdose
- Contraindication, warning, precautions and major drug interactions
- Use during pregnancy and lactation
- Expiry date
- Batch number /Lot number
- Shelf life and storage condition
- Name of manufacturer and/or applicant with full location address

3.3 NEW CHEMICAL ENTITIES OR INNOVATOR PRODUCTS

3.3.1 Registration in The Gambia shall normally not be permitted within the first two years of the first registration of the drug on the international market.

3.3.2 Verifiable information shall be provided regarding the date of expiry of the patent.

3.3.3 Although clinical trial data 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 guidelines for clinical trials, where necessary. The cost of this trial shall be borne by the applicant.

3.4 GENERIC DRUGS

3.4.1 Shall not be marketed in a name similar in pronunciation or form to the innovator product.

3.4.2 A bio-equivalence study report shall be submitted in line with existing guidelines WHO Guidelines

3.4.3 Although bio-equivalence data 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 WHO guidelines for bio-equivalence studies, where necessary. The cost of this trial shall be borne by the applicant.

3.4.5 For **all solid oral dosage forms**, reports of dissolution studies will be required. If the official compendia monograph doesn't require dissolution, the dissolution requirement in the USP shall apply.

3.4.6 If the product is manufactured on contract basis, evidence of the contract shall be submitted. This information shall be clearly stated on the product label and package insert.

3.4.7 **For both locally manufactured and imported medicines** the original Certificate of Analysis for the medicine, issued by an authorized analyst, shall be submitted.

3.4.8 **For imported medicines** a Certificate of Pharmaceutical Product (CPP) issued by the competent national drug regulatory Agency, in accordance with the World Health Organization (WHO) Certification Scheme for Pharmaceutical Products Moving in International Commerce, shall be submitted along with the Certificate of Analysis.

- **If the product is not identical to that in the issuing country, the applicants 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 certificate is relevant for the intended purposes.**

- Different phases of manufacture may be conducted in different countries. Where different phases of the manufacturing are conducted in different countries, the CPP must be issued by the competent authorities in the country that directly exports the product to The Gambia.
- Where the product is fully manufactured in different countries and the applicant wishes to obtain approval to use both sites of manufacture, the certificate should be submitted from both countries.
- The certificate should officially be stamped and dated together with all copies of product information submitted in support of an application for registration.
- The applicant is responsible for providing a notarized translation of the contents of the certificate in English in case when the certifying Agency issued the certificate in any other language.
- The certificate should be original and/or a notarized or certified copy and current.
- **A Drug Master File and process validation protocols shall be submitted for all applications, where necessary.**

3.4.9 Stability study reports conducted for three (3) trial batches of the product, and suited to the conditions specified below, shall be submitted :-

a) WHO Zone IV climatic conditions

Condition	Accelerated	Real Time
Storage Temperature	40 ± 2 °C	30 °C
Relative Humidity	75 ± 5 %	70 +/- 5 %
Duration	6 months	Until end of shelf life

b) The stability study shall be conducted in the container closure system in which the product will be marketed in The Gambia.

- **Where the product is to be registered in more than one container closure system, stability data shall be provided for each presentation. Real-time stability data shall be required for all biologicals.**
- **The result of the stability test 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.**

3.4.10 The Agency in considering an application:

- shall satisfy itself that there is need to have the medicine registered in The Gambia.
- shall request the applicant to submit a manufacturer's authorization to register the medicine.
- may consult with other bodies and experts with knowledge of the medicine.
- for purposes of verification of compliance to cGMP, all applications shall be accompanied by a Site Master File.
- reserves the right to conduct a Good Manufacturing Practice (GMP) audit inspection on the manufacturing facility for the product at a fee prescribed by the Agency.
- may ask the applicant to supply such other information as may be required to enable it reach a decision on the application.

- g) shall acknowledge receipt of all applications at submission and payment of fees and shall be processed within **three** months. Where it becomes necessary to ask for additional information from the applicant, this time period may be lengthened.
- h) When the applicant fails to submit written responses to queries within 6 months from the date of their issuance, it will be deemed that the applicant has withdrawn the application or 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.
- i) If no response is received within six months of the request, the application will be discontinued.
- j) Decisions on registration shall be based on the report of the dossier evaluation, quality control and inspection on compliance to cGMP.

3.4.11 An appeal for the review of an application may be made in writing to the Chairman of the MCA Board within thirty (30) days of receipt of the rejection notice.

3.4.12 Where the Agency is satisfied that there is the need to register a medicinal product, and all requirements for its registration have been satisfied, it shall do so and issue to the applicant a certificate of registration, subject to such conditions as may be prescribed by the Agency.

3.4.13 The registration of a drug under these regulations, unless otherwise revoked, shall be valid for a period of five (5) years and may be renewed for a period of not more than three (3) years.

- **The Agency shall from time to time, publish a notice in the Gazette the registered products under these regulations.**

3.4.14 No information given in this application shall be disclosed by the MCA to a third party except:-

- a) with the written consent of the license holder; or
- b) in accordance with the directive of the Board of Directors of MCA or
- c) for the purpose of a legal process under the Medicines & Related Products Act of 2014

3.4.15 The Agency shall cancel, suspend, or withdraw the registration of a medicine if:-

- a) the basis on which the medicine was registered is later found to be false; or
- b) the circumstances under which the medicine was registered no longer exist; or
- c) any of the provisions under which the drug was registered has been contravened; or
- d) the standard of quality, safety and efficacy, as prescribed in the documentation for registration is not being complied with; or
- e) 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.

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