



## **MEDICINES CONTROL AGENCY**

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# **GUIDELINE FOR DONATION OF MEDICINES AND RELATED PRODUCTS**

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# 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. The Medicines and Related Products Regulations, 2020 ("Regulations") details the legal requirements.
- 1.1.3. Appropriate donated medicines and related products of acceptable quality are an essential element in alleviating part of the country's health care delivery system's problem.

## 1.2 INTERPRETATION AND ABBREVIATIONS

Interpretations and abbreviations contained in the MCA Glossary can be found on the MCA Website: [www.mca.gm](http://www.mca.gm).

- **International donors** refer to governments of other countries, corporate bodies acting directly or through voluntary organisations, Non-Governmental Organisations and individuals wishing to make donations from outside The Gambia.
- **National (Local) donors** refer to corporate bodies, organisations and individuals operating and or residing within the country and wishing to make donations at any level of the health care delivery system in The Gambia.
- **Medical equipment** means medical devices requiring calibration, maintenance, repair, user training, and decommissioning. Medical equipment excludes implantable, disposable or single-use medical devices, which are included under related products.

## 1.3 PURPOSE

- 1.3.1. In pursuance of the law this document provides guidance on donations of medicines and related products in The Gambia to ensure that:
  - The donation benefits the recipient based on an expressed need;
  - The donation is based on effective coordination and collaboration between the donor and the recipient, with all donations made according to a plan formulated by both parties;
  - A donation is given with due respect to the wishes and authority of the recipient, and in conformity with the government policies, administrative arrangements and regulatory requirements of The Gambia; and
  - The donated medicines and related products are of acceptable quality standard and appropriate as determined by the Agency.

## 1.4 SCOPE

- 1.4.1. This guideline applies to all medicines and related products, as defined in

the Act and the Regulations, donated from within and outside the country except products donated for research.

**Note:** In the event that products which were donated for research are intended to be used for non-research purposes, the authorisation by MCA is required.

- 1.4.2. It applies to Donors as defined in this guideline and to Recipients of donations including Government of The Gambia and the Ministry of Health.
- 1.4.3. Although not regulated by the Agency, this guideline may be applicable to health care products other than medicines and related products (e.g. mechanical hospital beds, examination chairs, IV poles, etc).

## **1.5 PURPOSE**

- 1.5.1. The main barriers to effective donation of medicines and related products are considered as the following:
  - Lack of genuine partnership between donor and recipient.
  - Insufficient appreciation for the challenges of the recipient's context.
  - Limited standardised inventory of medical equipment in resource constrained settings to identify needs.
  - Insufficient support for the long term integration of new equipment.
  - Insufficient connectivity between activities undertaken by various organisations working on donations.
  - Lack of accountability - no tracking and monitoring of donations and no existing quantification framework for impact of donations.
  - Insufficient capacity and capacity building programs for recipients.
  - Compatibility and relevance of donations to recipient.

## **2 REQUIREMENTS FOR DONATION**

### **2.1 EXPRESSED NEED FOR DONATION**

- 2.1.1. Government, private health facilities, NGOs, international agencies and other organisations may express the need for donations of medicines and/or related products.
- 2.1.2. The needs should be expressed in terms of the types of products by name, a description and quantities.
- 2.1.3. The requested types of products and quantities should relate to the prevailing diseases, indications, target population and the type of health facility.

### **2.2 DONORS**

- 2.2.1. All donated medicines and related products should be obtained from reliable sources and comply with quality standards in both donor country and The Gambia.
- 2.2.2. Donors should respect the following principles:

- The need of the recipient to guide the donation.
  - Laws, regulations and administrative procedures of recipient are respected.
  - The MCA Guideline on donation is followed and to ensure that MCA approval is received before shipping of products.
  - Agreed plan with the recipient country is followed.
  - Management of disposal of expired or unused products should be agreed in advance.
- 2.2.3. Donors should inform the recipients before any of the medicines and/or related products are sent for donation.
- 2.2.4. For medical equipment:
- The equipment should be free of all patient materials and properly decontaminated prior to packaging and shipment.
  - The donor should ensure that detailed installation instructions, safety instructions and site preparation, where applicable are communicated to the recipient. Such information should include architectural drawings and floor plans, as applicable.
  - The donor should inform the recipient of all necessary materials required for the operation of the equipment such as cables, reagents, filters, electrodes, recording papers, etc.
  - Test equipment for calibration as well as calibration standards must be available through the useful life a related product, where applicable.
  - Detailed maintenance requirements such as technician training, special tools, preventive maintenance materials and schedule should be communicated to the recipient.
  - Plan for training of operators must be agreed upon by both the donor and recipient.
- 2.2.5. Products should be packed in accordance with international shipping requirements to minimise damage in transit, must be accompanied by a detailed packing list and other relevant documents, and indicate that the shipment is a donation.
- 2.2.6. Radioactive sources should be removed and properly packaged in special containers with clear identifications.
- 2.2.7. Medicines should not be mixed with other products in the same carton.
- 2.2.8. All transport costs should be borne by the donor including any Customs warehousing and storage, clearing and other ancillary charges unless clearly agreed otherwise in advance between the donor and the recipient.
- 2.2.9. Any donated medicine or related product rejected by the Agency due to non-compliance with this guideline or applicable regulatory requirements will be returned to the donor at the expense of the donor.
- 2.2.10. The declared value of donated products should be based on the wholesale price of its generic equivalent in The Gambia or the wholesale world market price of generic or therapeutic equivalent of patented medicines.

## 2.3 RECIPIENTS

- 2.3.1. Recipients should respect the following principles:
  - The MCA guideline on donation is followed.
  - Needs are specified in accordance with Section 2.1 of this guideline.
  - Mechanisms for adequate handling of donations are in place.
- 2.3.2. The applicant or recipient shall upon release of the donated products deliver all medicines and related products to the intended institution. No person shall remove any portion of the donation for personal use or for financial gains.
- 2.3.3. The recipient must provide evidence to have the facility and capacity to store and distribute the products in accordance with the applicable requirements for storage and distribution as determined by the Agency.
- 2.3.4. The recipient must ensure to have qualified personnel at disposal to handle the donated products appropriately.
- 2.3.5. Receipt of a suspected product or any observed irregularity should be communicated immediately to the donor.
- 2.3.6. Upon receipt, the recipient should send a letter of confirmation and acknowledgement to the donor.
- 2.3.7. For medical equipment:
  - If the equipment is technically complex, the recipient should ensure that unpacking is done by technically competent persons.
  - Installation should be performed by a technically competent person according to the instructions received from donor.
  - Equipment should be test run and operational before commissioning.
  - When equipment is operational, recipient should assess the level of operational success of the medical equipment and provide feedback to the donor. This assessment will enable both parties to learn from previous mistakes and encourage continued support of the donor.
  - Commissioning should be carried out by adequately trained personnel and in line with good technical services practice.
  - Proper and safe operation must be verified before the equipment is put to clinical use.

## 2.4 PRODUCTS FOR DONATION

### Requirements for Medicines

- 2.4.1. Donated medicines should appear in the current edition of the Essential Medicines List (EML) of The Gambia or equivalent or in the national Standard Treatment Guidelines or be approved for use in The Gambia as determined by the Agency if:
  - They are supplied for use by an individual patient or specialised department of a health institution; or
  - They are provided in situations of disease outbreaks or newly emerging

diseases; and

- They have not at any time been rejected for registration in The Gambia.
- 2.4.2. The presentation, dosage form and strength should, as far as possible, be similar to those of medicines commonly used in The Gambia.
- 2.4.3. Patients' partly used medicines and samples of medicines must not be donated.
- 2.4.4. Only medicines that have a marketing authorisation or registration by a MCA recognised regulatory authority should be donated for use in The Gambia.
- 2.4.5. All donated medicines should have a remaining shelf life of at least one year after arrival in the country unless approved otherwise by MCA. The only exceptions to this are:
- Vaccines or other biologicals, which should have at least three quarters of their stated shelf life remaining on arrival;
  - Products which have been specifically requested to meet a particular need and where the Agency is confident that the products can be effectively distributed and used well within the expiry date.
- 2.4.6. Donated medicines should be presented in pack sizes that are suitable for the recipient and appropriate to the setting in which they will be distributed or dispensed.
- 2.4.7. All medicines should be appropriately labelled and in English (refer to the *MCA Guideline for Repackaging and Labelling of Medicines*). If the original label is not English, donations of such medicines must be accompanied by patient's/manufacturer's information in English and the label should bear the following minimum information:
- Name and address of the manufacturer;
  - Proprietary or generic name and the active ingredients, dosage form and strength;
  - Batch or lot number and expiry date; and
  - Storage conditions.

#### **Requirements for Related Products**

- 2.4.8. All products must have appropriate English instruction, operational and/or service manuals or equivalent along with full service records, where applicable.
- 2.4.9. The products must be fully operational and all essential accessories and supplies should be included in the shipment.
- 2.4.10. The products must meet all safety and performance specifications as provided by the manufacturer.
- 2.4.11. Obsolete products or products for which required replacement parts are not available must not be donated.
- 2.4.12. The level of technology to operate the product, where applicable, should be in line with local capacity or the donor is prepared to build capacity.
- 2.4.13. The product should be environmentally friendly.

2.4.14. Where applicable, warranty of at least one year for maintenance should be provided for the products.

2.4.15. Caution should be exercised by donors and recipients in handling refurbished equipment. Unless financial savings are considerable (e.g. costly radiographic equipment and CT scanners) and the donor can provide adequate warranty, donations should be restricted to new equipment.

### **3 IMPORT OF DONATED PRODUCTS**

#### **3.1 REQUIREMENTS FOR IMPORTATION**

3.1.1. The clearance of donated products is the responsibility of the donor and recipient.

3.1.2. All medicines and related products to be donated must follow the regulatory requirements as determined by the Agency.

3.1.3. The Agency should respect the following principles:

- The Agency is responsible for allowing entry of useful donations or rejection of unsuitable donations.
- A registry for recording data on donations is established by the Agency.

3.1.4. An application for a permit to import medicines and related products for donation shall be made to the Agency by the donor or recipient prior to shipping.

3.1.5. The application form to import medicines and related products for donation must be completed by the applicant, accompanied by a cover letter of request including information on the donor and recipient. The Clearance Permit for Donations (MCA-F-010/01) form is available on the MCA website: [www.mca.gm](http://www.mca.gm).

3.1.6. All applications for importation of donated medicines or related products shall provide the following information and documents:

- Name, address and contact details of the donor;
- Copy of certificate of registration of the donating organisation;
- Name, address and contact details of the recipient;
- Name, address and contact details of the applicant, if different from donor or recipient;
- Purpose of donation;
- Value/Cost;
- Source of supply;
- A list of products to be donated including name, description, name of manufacturer, country of origin, unit of issue and total quantity;
- In case of medicines their brand and generic name including strength and dosage form, active ingredient(s), batch number and expiry date, and a Certificate of Analysis for each batch, unless approved otherwise by the Agency;
- The port of shipment, expected date of arrival and port of entry;



- Place and manner in which the medicines or related products shall be stored safely;
  - Disposal arrangements of expired or unused products agreed between the donor and recipient;
  - Two (2) copies of the packing list (sea and air transport);
  - Letter of expressed need for the donated products by the recipient; and
  - Letter of consent with the shipment by the recipient.
- 3.1.7. The Agency may issue a clearance permit within five (5) working days if the application and the product complies with the applicable regulatory requirements and if the quantity for donation is in accordance with the anticipated consumption and within the expiry date, where applicable.
- 3.1.8. Permits issued for import of donations shall be valid for **only one** transaction.
- 3.1.9. Personal or commercial items should not be included in the list presented for donation. In case they are being shipped together with donated items, it should be clearly declared and indicated.
- 3.1.10. The checklist (MCA-F-101/02) provided with this guideline may support donors, recipients and the Agency to adhere to requirements and should be submitted along with the application form.

## 3.2 INSPECTION OF DONATIONS

- 3.2.1. Upon receipt, the medicines and related products should be inspected by the Agency before release to the recipient.
- 3.2.2. Any medicine or related product, which arrives at a Customs port of entry without a clearance permit, is liable to rejection and return to its source at the expense of the donor.

## 4 FINAL PROVISIONS

- 4.1. This guideline is the first version published by the MCA and will become effective on 19 May 2021.
- 4.2. It replaces the 'Donations Guidelines for Medicines, Medical Supplies and Health Care Equipment in The Gambia' by the Ministry of Health & Social Welfare in June 2010.
- 4.3. This guideline will be reviewed within 5 years of becoming effective.

## 5 DOCUMENTS NEEDED FOR THIS GUIDELINE

Document No	Title (as referenced on the document)
MCA-F-010/01	Clearance Permit for Donations
MCA-F-010/02	Checklist for Donations

## 6 REFERENCES

- Medicines and Related Products Act, 2014

- Medicines and Related Products Regulations, 2020
- MCA Guideline for Import and Export of Medicines and Related Products (MCA-GL-103)
- MCA Guideline for Repackaging and Labelling of Medicines (MCA-GL-101)
- MCA Guideline for Storage and Distribution of Medicines and Related Products (MCA-GL-301)
- WHO Guidelines for Medicine Donations - Revised 2010
- WHO, Medical device donations: considerations for solicitation and provision, Medical device technical series, 2011

## 7 DOCUMENT HISTORY

<b>Version #</b>	<b>Implementation Date</b>	<b>Reasons for Change:</b>
1	19 May 2021	New document