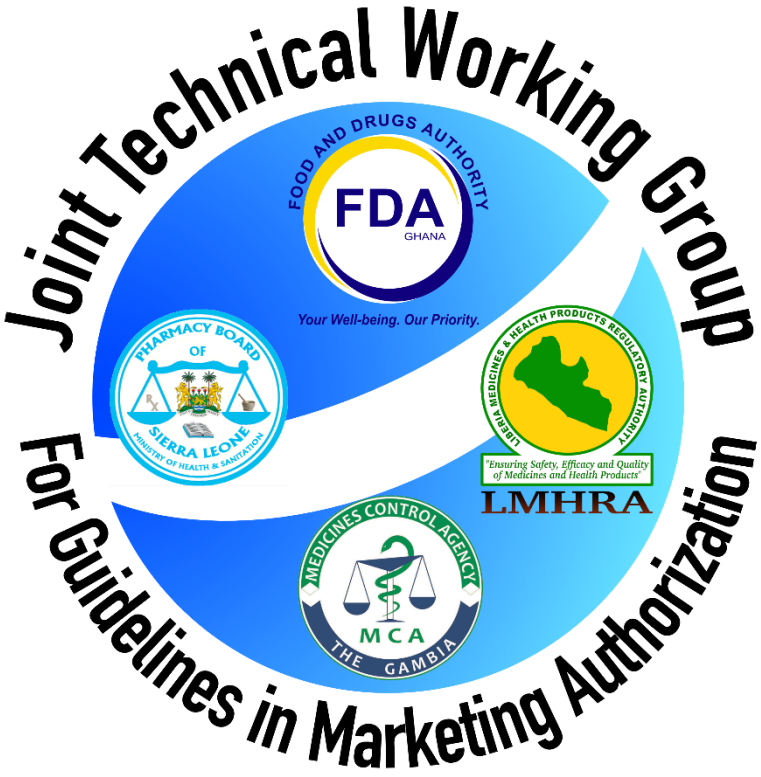

Guideline on Donation

For the National Medicines Regulatory Authorities of Ghana, Liberia, Sierra Leone, and The Gambia

Updated December 2, 2022

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The Guideline on Donation, Version 1.0, Updated December 2, 2022

This Guideline (GL) is an adaptation of the Guidelines for Medicine Donations (Revised 2010, 3rd edition) of the World Health Organization with all annexes, whereby region, country, and national medicines regulatory authorities (NMRA) specific requirements as well as improvements of certain aspects that differ from the adopted GL are specified by <NMRA> annotations in the following document.

Draft written by GHPP PharmTrain-Project Team (BfArM, Germany)	October 2021
Draft annotations reviewed and agreed by TWG-MAG: LMHRA, MCA The Gambia, PBSL, FDA Ghana, GHPP PharmTrain	1st April 2022
Updated by LMHRA, MCA The Gambia, PBSL, FDA Ghana, GHPP PharmTrain	02 December 2022
Adopted by <Committee/Board> for release for consultation	<DD Month YYYY>[1]
Start of public consultation	<DD Month YYYY>[2]
End of consultation (deadline for comments)	<DD Month YYYY>[3]
Agreed by <Working group(s)/Departments>	<Month YYYY>
Adopted by <Committee/Board>	<DD Month YYYY>
Date of coming into effect	<DD Month YYYY>[4]

Comments should be provided using the template for submission of comments. The completed comments form should be sent to <as appropriate (NMRA's Email)>.

Keywords	***donation, receiver, donor***

[1]Last day of relevant Committee meeting.
[2]Date of publication on the NMRA public website/1st day of the month following adoption of the guideline.
[3]Last day of the month concerned.
[4]First day of coming into effect. Latest 3 months after adoption.

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Send a question via our website www.<NMRA>...
An agency of the <.....>.
Country logo

Guideline on Donation, Version 1.0, Updated December 2, 2022

Table of contents

Style notes for this draft version:

[ ] Comments to be removed with finalization

< > Placeholder to be filled with specific information or to be decided if kept or deleted.

Executive summary

The development of this guideline is based on the outcomes and consensus of the meetings convened in January / February 2020 by GHPP-PharmTrain Project team of the Federal Institute for Drugs and Medical Devices (BfArM, Germany) with participants from the national medicines regulatory authorities (NMRA) of Liberia (LMHRA, Liberia Medicines and Health Products Regulatory Authority), Sierra Leone (PBSL, Pharmacy Board of Sierra Leone), and The Gambia (MCA, Medicines Control Agency).

This document has been discussed and adapted in exchange between LMHRA, PBSL, The Gambia MCA, Ghana (FDA, Food and Drugs Authority) and the GHPP-PharmTrain project team from October 2021 to April 2022.

From January 2022 the Joint Technical Working Group for Guidelines in Marketing Authorization (TWG-MAG), with the above-mentioned members, was established to continue the successful development of regulatory guidelines.

Information on the adopted Guideline for Medicine Donations

Title: Guidelines for Medicine Donations

Title(s) of Annexes/Appendixes: Examples of problems with medicine donations

Author(s): World Health Organization

Document No:

Version No: Revised 2010, 3rd edition

Date of issue: 2011

Source (e.g. website link 2022): https://www.who.int/publications/i/item/978924150198-9

1. <NMRA> annotations on the adopted Guidelines for Medicine Donations

1.1. Concerning Section 3 Guideline for medicine donations

1.1.1. Concerning Section 3.1 Selection of medicines

1.1.1.1. Aspect 1.

Annotation: The following part needs to be deleted: "*Possible Expectations: In acute emergencies, the need for prior consent by the recipient may be waived, provided that the medicines are among those on the WHO model lists of essential medicines or are included in the United Nations list of emergency relief items recommended for use in acute emergencies.*"

Rationale: The stated possible exceptions are not applicable to <NMRA> because the prior consent by the recipient country is a must even in emergency situations.

1.1.1.2. Aspect 2.

Annotation: The sentence

"*All donated medicines or their generic equivalents should be approved for use in the recipient country and should appear on the national list of essential medicines or equivalent or in the national standard treatment guidelines, if the NEML is not updated. Or, if a national list is not available, it should appear on the WHO model lists of essential medicines, unless specifically requested otherwise and provided with a justification by the recipient."*

is amended by the deletion of a sentences with advices if no NEML exists, by the inclusion of reference to the NEML in the Annex and by an additional ending sentence as follows:

*"All donated medicines or their generic equivalents should be approved for use in the recipient country and should appear on the national list of essential medicines (find NEML in <**Annex X**>) or equivalent or in the national standard treatment guidelines, if the NEML is not updated. In case of a Public Health Emergency any other sources of*

reference, such as WHO model lists of essential medicines, included in the United Nations list of emergency relief items recommended for use in acute emergencies, or the WHO Emergency Use Listing may be used."

Rationale: For better guidance of the reader the NEML is attached as Annex. Since a NEML exists in <country>, the sentence with advices if no NEML exists is not needed.

Action Point for implementation: Each NMRA provides an Annex with the NEML.

1.1.1.3. Aspect 3.

Annotation: "as far as" and "similar" in the sentence

"The presentation, strength, and formulation of donated medicines should, as far as possible, be similar to those of medicines commonly used in the recipient country."

are replaced by the more specific term as follows:

"The presentation, strength, and formulation of donated medicines should be in accordance with national regulations and treatment guidelines used in the recipient country, here <country>."

Rationale: The section was amended, since "*as far as*" and "*similar*" are too vague and can lead to wide interpretation, which is inappropriate in this context.

1.1.1.4. Aspect 4.

Annotation: The sentences

"All donated medicines should be obtained from a quality-ensured source and should comply with quality standards in both donor and recipient countries. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be used."

is amended as follows:

*"All donated medicines should be obtained from a quality-ensured source and should comply with quality standards in both donor and recipient countries <(details can be found in the NMRA specific **Annex X** such as the WHO Certification scheme, if applicable)>."*

Rationale: The use of the WHO certification Scheme is not applicable to all NMRAs, therefore it is optional and details need to be specified in an Annex.

Action Point for implementation: Each NMRA provides an Annex.

1.1.1.5. Aspect 6.

Annotation: Possible exceptions are included in case of an acute public health emergency situation as follows:

"*Possible exceptions: In case of an acute public health emergency situation exceptions regarding the shelf-life requirements are in the discretion of the <NMRA>.*"

Rationale: An exception for acute health emergency situations enables the NMRA to make the final decision, promoting access to urgently needed medicinal products.

1.1.2. Concerning Section 3.2 Presentation, packaging and labelling

1.1.2.1. Aspect 7.

Annotation: All labels should be written in English.

Rationale: The official language in <country> is English, therefore the language that is easily understood by health professionals in the recipient country is English.

1.1.2.2. Aspect 8.

Annotation: In this section the WHO Model List of Essential Medicines for Children is replaced by the <quote title of National Essential Medicines List of country>.

Rationale: In <country> the WHO Model List of Essential Medicines for Children is not applied. The corresponding national list of <country> covers all; adults and children.

1.1.2.3. Aspect 8.

Annotation: Possible exceptions are included in case of an acute public health emergency situation as follows:

"*Possible exceptions: In case of an acute public health emergency situation exceptions regarding the pack size are in the discretion of the <NMRA>.*"

Rationale: An exception for acute health emergency situations enables the NMRA to make the final decision, promoting access to urgently needed medicinal products.

1.1.2.4. Aspect 9.

Annotation: Possible exceptions are included in case of an acute public health emergency situation as follows:

"*Possible exceptions: In case of an acute public health emergency situation exceptions regarding the weight per carton are in the discretion of the <NMRA>.*"

Rationale: An exception for acute health emergency situations enables the NMRA to make the final decision, promoting access to urgently needed medicinal products.

1.1.3. Concerning Section 4 Guidance to donors and recipients

1.1.3.1. Concerning Section 4.1 Collaboration, roles and responsibilities

Annotation: The end of the sentence is amended by replacing the

"*NGO networks and with WHO health clusters. (See Box 1)"* with the following:

"*institutions. A network depicting all collaborations of the <NMRA> with relevant national and international collaboration partners / institutions in the event of an emergency is attached to this document in* ***Annex X."***

Moreover the entire Box WHO global health cluster is deleted.

Rationale: Since <NMRA> is not part of the WHO global health clusters, a <country/NMRA> specific Network is attached as annex.

Action Point for implementation: Each NMRA provides an Annex with collaboration network.

1.1.4. Concerning Section 4.2 Guidance to donors,

1.1.4.1. "Administrative arrangements should not be ignored"

Annotation: In the sentence:

"*Donors should consult the relevant Ministry of the recipient country for special documentation requirements in order to ensure smooth reception and clearance*."

the "relevant Ministry" is replaced by the more specific term "*<President> / <Ministry of Health> / <NMRA>*" as follows:

"*Donors should consult the <President> / <Ministry of Health> / <NMRA> of the recipient country for special documentation requirements in order to ensure smooth reception and clearance."*

Rationale: The Ministry of Health (MoH) is the relevant Ministry for consultation in <country>. Because the relevant agency and president may provide additional important information, the MoH is not exclusively the contact person for the donor.

1.1.4.2. "Management of expired products must be agreed in advance"

Annotation: The sentence

"*Where national laws or guidance are insufficient, WHO's Guidelines for safe disposal of unwanted pharmaceuticals in and after emergencies should be followed for destruction of expired medicines*"

is replaced by the sentence: *"<Country's> law/guideline <Quote title> (for safe disposal of unwanted pharmaceuticals in and after emergencies) should be followed*."

Rationale: In <country> the WHO's Guidelines for safe disposal are not applied since a national guideline is available.

1.1.4.3. "Other ways donors can help"

Annotation: The entire section dealing with donation of Health Kits and Cash was deleted.

"*Other ways donors can help*

The interagency emergency health kit

In the acute phase of an emergency, such as internal displacement or where refugee populations cross the border, it is often best to supply standardized kits of medicines

and medical supplies that are specifically designed for this purpose. The interagency emergency health kit,7 which has been widely used during the past two decades and the contents of which have been twice updated, contains medicines, disposable supplies and basic equipment needed for the general medical care of a population of 10 000 for three months. The kit is permanently stocked by several major international suppliers (e.g. the International Dispensary Association, Médecins Sans Frontières, UNICEF) and can be made available within 48 hours. It is especially relevant when recipients cannot quickly prepare well defined requests.

Donations in cash

Donations in cash for regular supplies of essential medicines are sometimes more welcome than (further) medicine donations in kind. Cash contributions can support the activities of the local government or coordinating committee and local and regional industries. They may also be more cost-effective. With cash donations, governments may be able to procure health products that prescribers and patients are familiar with, as opposed to those that international agencies are able to supply. In emergencies, donors need to look out for appeals indicating priority areas of need for funding."

Rationale: This subject is not applicable here, since the scope of the guideline does not cover these types of donations.

1.1.5. Concerning Section 4.3 Guidance to recipients,

1.1.5.1. "Define national guidelines for medicine donations"

Annotation: The introductory sentence

"To be prepared for a situation in which donations of medicine are useful or needed, countries should formulate their own national donation policy and guidelines for medicine donations."

is complemented by the following sentence:

"*The <quote title of national medicines Act/policy if applicable> of <country> provides national guidance for medicine donations."*

Rationale: In this section the need for a national donation policy and guideline for medicine donations is stated and they are available in <country>.

1.1.5.2. "Define national guidelines for medicine donations"

Annotation: National Minimum Requirements and Restrictions for donations should be specified in the guideline. Therefore **Annex I** was drafted (see Annex I at the end of the Document).

Rationale: Specifying the Minimum Requirements and Restrictions for donations facilitates better guidance of the donor and recipient.

1.1.5.3. "Define national guidelines for medicine donations"

Annotation: How Emergency Responses are Coordinated should be specified in the guideline. Therefore **Annex II** was drafted (see Annex II at the end of the Document).

Rationale: Specifying how emergency responses are coordinated for donations provides better guidance of the donor and recipient.

1.1.5.4. "Needs for donated medicines should be well specified"

Annotation: The appropriate language of use on products and special medications for children in <country> is English. The sentence is therefore amended as follows:

"In addition, it is recommended to use English as appropriate language of use on products and special medications for children."

Rationale: The official language in <country> is English, therefore the language that is easily understood by health professionals in the recipient country is English.

1.1.5.5. "Rapid customs clearance of donated medicines is important"

Annotation: In the sentence

"*Customs and health ministry officials managing medicine donations have the responsibility to allow entry of useful donations and to reject unsuitable donations."*

the "Customs and health ministry officials" are replaced by the respective <NMRA>. The sentence is amended as follows:

"<NMRA> officials managing medicine donations have the responsibility to allow entry of useful donations and to reject unsuitable donations."

Rationale: This activity should be limited to the NMRA since they are responsible for issuance and rejection of permits as well as disposal of substandard medicines.

Definitions

Applicant (for MA)

A person or entity who has applied for regulatory approval of a product or a change thereof. All applicants are to own the product. Representatives of product owners may not hold themselves as applicants unless they own the product.

In some jurisdictions this term is used in a wider sense (see “marketing authorization holder)”.

Distribution

The procuring, purchasing, holding, storing, selling, supplying, importing, or exporting of medicinal products, with the exception of the dispensing or providing them directly to a patient.

Donor

An individual/organization or country that provides assistance in form of a medicinal product supplies to an individual, organization or country.

Dosage Form

The pharmaceutical form in which the active pharmaceutical ingredient, excipients and physical formulation of a medicinal product is presented e.g. tablet, capsule, solution for injection, cream, inhalation etc..

Essential medicines

Essential medicines satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.

Excipient

Any constituent of a pharmaceutical form that is not an active pharmaceutical ingredient.

Expiry Date

The date stated on the label of a medicinal product up to which the product is expected to remain within specifications, if stored correctly; it is established for each batch by adding the shelf life to the date of manufacture and is determined by using stability studies.

Generic Name

See International Non-proprietary Name

Good Distribution Practice (GDP)

A standard that a wholesale distributor must meet to ensure that the quality and integrity of medicinal products is maintained throughout the supply chain or distribution network, so that authorized medicinal products are distributed to retail pharmacists and others selling medicinal products to the general public without any alteration of their properties.

International Non-proprietary Name (INN)

An official, unique name given to a pharmaceutical ingredient recommended by World Health Organization and that is globally recognized and public property used to identify the active ingredient in a medicinal product.

Local agent

A person or company authorized by the marketing authorization holder to act as agent for one or more companies in a particular community and usually paid by commission.

Medicinal Product

Any substance or combination of substances prepared, sold or presented for use in the diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it or restoring, correcting or modifying organic functions in human beings

Medicinal products in the context of the TWG-MAG guidelines includes finished pharmaceutical products, biotherapeutics, and vaccines. Not included are medical devices, *in-vitro* diagnostics, blood products, and animal products.

Medicine

See medicinal product

National Essential Medicines List (NEML)

The list of essential medicines that has been defined, adopted, and published at country level.

Recipient

An individual, organization, government, NGO, or health facility that receives assistance in the form of medicinal product supplies from an individual, institution or country (donor).

Shelf-life

The period of time during which a medicinal product, if stored correctly, is expected to comply with the specifications as determined by stability studies on a number of batches of the product; the shelf-life is used to establish the expiry date of each batch.

Storage

The storing of medicinal products and related products from manufacturing up to their point of use.

Strength

The content of the active substances in a medicinal product expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form.

Specifications

A document describing in detail the requirements such as physical, chemical, biological and microbiological test requirements with which the products or materials used or obtained during manufacture have to conform.

References

WHO. Guidelines for Medicine Donations (Revised 2010, 3rd edition). World Health Organization. 2010

FDA Ghana. Guideline for Donation of Drugs. FDA/DRI/DER/GL-DOM/2019/13. Published by the Food and Drugs Authority of Ghana. Date of Issue: 2019/03/15.

WHO. Guidelines For Health Care Equipment Donation (WHO/ARA/97.3). World Health Organization. 2000

This guideline template is based on the structure of the adoption approach of the Guideline on Guidelines V1, February 2021 developed by the joint working group of Food and Drugs Authority (FDA, Ghana), Liberia Medicines & Health Products Regulatory Authority (LMHRA, Liberia), Medicines Control Agency (MCA, The Gambia), Pharmacy Board of Sierra Leone (PBSL, Sierra Leone), and the Global Health Protection Programme (GHPP) PharmTrain-Project of the Federal Institute for Drugs and Medical Devices (BfArM, Germany).

Annex

<Rapporteur to include text if new annex in addition to the annex documents of the adopted Guideline need to be included in the guideline.>

[Delete Annex if not applicable.]

Annex I: Minimum requirements and restrictions

Annex II: How emergency responses are coordinated

Annex I: Minimum requirements and restrictions

1. All donations should be based on an expressed need and be relevant to the disease pattern in <country>. These should be based on existing and approved <National Essential Medicines List (NEML)>. In case of a Public Health Emergency any other sources of reference, such as WHO model lists of essential medicines, included in the United Nations list of emergency relief items recommended for use in acute emergencies, or the WHO Emergency Use Listing may be used.

2. The specifications (dosage form, active ingredients, strength etc.) of donated items should in accordance with national regulations and treatment guidelines used in the recipient country, here <country>

3. All product intended for donation shall have at least <X>% of its shelf life remaining. This notwithstanding, products with a shelf life of less than <X>months shall have at least <X>% of its shelf life remaining at the time of importation. National requirements are specified in the attached <**Annex X**>.

Action Point for implementation: Each NMRA should add national Annex.

4. Products requiring refrigeration or freezing for stability must specifically indicate storage requirements, both on labels and containers as well as on the documents and be shipped in special containers to ensure that the cold chain is maintained.

5. In accordance with section <quote title of national medicines Act if applicable> of <country>, the recipient is to ensure that all monitored and reported adverse drug reactions will be communicated accordingly to the Authority.

<6. Donations for products limited to be manufactured only by local manufacturers cannot be imported for donations.> *[The requirement "6. Donations for products limited to be manufactured only by local manufacturers cannot be imported for donations." Should be deleted during the adoption process by the NMRA, if it does not fit the requirements of the respective NMRA.]*

Annex II: How emergency responses are coordinated

1. A non-resident applicant would be required to appoint a local agent with the requisite mandate to represent the said applicant. For donation of drugs the local agent may be the recipient of the donated drugs. The agent would be required to produce the relevant documentation including, but not limited to, a power of attorney or any other documentation, affirming his/her appointment as an agent.

2. Where the drug to be donated has been registered in <country> by the <NMRA>, the recipient of the donated item would be required to liaise with the company that holds the market authorization in <country>. This would be for the purposes of monitoring the safety of the drug.

3. Where the drug is not registered in the country, the donation would be permitted only after the drug has been duly registered please refer to the <NMRA>'s guidelines for the registration of the drug.

4. The timeline of the completion of the registration process is a minimum period of 1(one) month for previously registered products, three month for abridged review and within six month for normal registration guideline.

5. All applications for processing of drug donations shall be made by submitting a letter addressed to:

<Insert the appropriate address of the NMRA here>

<Head of Agency>

<No, street>

<Postcode> <country>