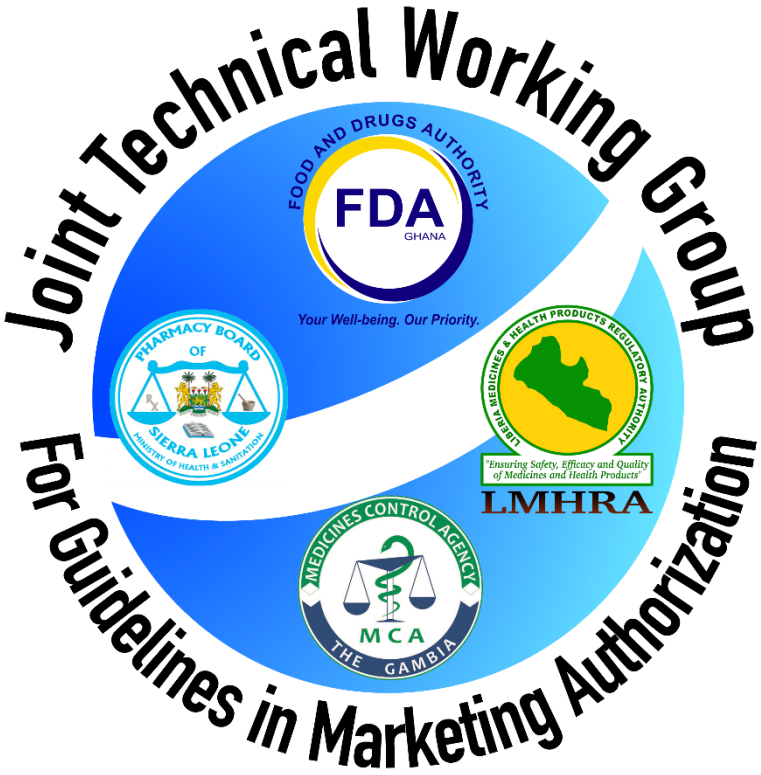

Guideline on Guidelines

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

Updated December 2, 2022

Ownership of the TWG-MAG

NMRAs are welcome to download and use the following guideline if credit is given to the authors - all members of the Joint Technical Working Group for Development of Guidelines in Marketing Authorization (TWG-MAG):

Ms	Allotey-Pappoe, Adah Adede	FDA Ghana
Ms	Bühl, Henrike Gisela	BfArM Germany
Ms	Johnson, Joy Ellaine Bernadette	PBSL Sierra Leone
Mr	Kercula, Juwe Darnuwele	LMHRA Liberia
Ms	Lehnert, Regine Magdalene	BfArM Germany
Mr	Mansaray, Sheku Suma	PBSL Sierra Leone
Mr	Marenah, Essa	MCA The Gambia
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GHP Programme
PharmTrain-Project

<02 December 2022>
Joint Technical Working Group for Guidelines in Marketing Authorization (TWG-MAG):
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)
Global Health Protection Programme (GHPP-PharmTrain Project),
Federal Institute for Drugs and Medical Devices (BfArM, Germany)

Guideline on Guidelines, Version 1, Updated December 2, 2022

Drafted by GHPP PharmTrain-Project Team (BfArM, Germany)	06 October 2020
Draft reviewed and agreed by LMHRA, MCA The Gambia, PBSL, FDA Ghana, GHPP PharmTrain	19 February 2021
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)/Department(s)>	<Month YYYY>
Adopted by <Committee/Board>	<DD Month YYYY>
Date for 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), ghpp.pharmtrain@bfarm.de>.

Keywords	guideline (GL) development; national medicines regulatory authority (NMRA)

[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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An agency of the <……>.

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Guideline on Guidelines Version 1, 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.

Acknowledgements

We duly thank the European Medicines Agency, World Health Organization, Therapeutic Goods Administration Australia for publishing their guidelines that contributed in several aspects relevantly to the development of this guideline.

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 2020 to February 2021.

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.

<This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance.>

1. Introduction (background)

What is a Guideline?

A guideline (GL) is a document with explicit legal basis referred to in the legislative framework. Guidelines provide advice to applicants/marketing authorization holders, sponsors, manufacturers, regulators and/or other interested parties on the best or most appropriate way to fulfil the legal obligation laid down in the pharmaceutical legislation, i.e. <quote title of national medicines Act>. Guidelines will facilitate the assessment, approval and control of medicinal products in <country>. Medicinal products in the context of these guidelines include finished pharmaceutical products, biotherapeutics, and vaccines. Not included are medical devices, *in-vitro* diagnostics, blood products and animal products.

2. Scope

In pursuance of <quote title and section of national medicines Act>, this guideline is hereby made to provide guidance to the NMRA of <country (+abbreviation of NMRA's name)>, on the procedure for drafting guidelines for the registration of medicinal products in <country>.

This guideline enables the <abbreviation of agency's name> to develop guidelines in a consistent manner and compliant with international standards.

3. Steps to develop a guideline

Flow chart of process is included in Annex I.

3.1. Selection of topic

The <responsible person(s)/body/board at the NMRA> identifies the requirement of a guidance document with a certain topic. New guidelines (including replacement/renewal of existing guidelines) are needed if

- no guideline exists for a certain topic/subject
- there has been progress in the development of new technologies, new practices or new therapeutic areas
- frequently encountered problems and/or questions appear with established products, indicating the need for a clearer guidance document
- input arises from cooperation with other (international) regulatory authorities

3.2. Selection of the approach

3.2.1 Adoption of an existing international guideline

Before initiating the development of a new national guideline, clarification should be sought as to already existing guidelines for the same topic, their applicability and acceptability to the national regulatory context.

The benefits of this approach include:

a) Facilitation of global harmonization of drug regulation

b) Optimal use of resources (financial/personal)

An assessment should be made using the decision flow chart with additional information about reliable regulatory authorities/organizations
(included in Annex II).

Optional: **Preparation of <NMRA> specific annotations to complement the adopted guideline.**

Proceed with Section 3.2.2.5

Upon adoption of an international guideline by <country>, stakeholders will be notified accordingly (see sections 3.2.2.8 and 3.2.2.9)**.**

3.2.2 Development of regional/national guideline

3.2.2.1 Appointment of rapporteur/writer

Once the topic has been selected, one person in charge of this guideline, subsequently called rapporteur is appointed from <the NMRA (alternatively in the regional economic communities (REC))>. In the case of a guideline prepared by a scientific committee, the relevant rules of procedure will apply to the appointment of rapporteur.

The rapporteur is responsible for drafting {*optional*: the concept paper and} subsequent versions of the guideline with the support of the relevant working party, group or committee. It is strongly recommended to avoid the 'committee' approach to writing a guideline. One person should be responsible for writing, while the rest of the group reviews and endorses the document. This ensures coherence, clarity and accuracy.

3.2.2.2 Optional: Development of concept paper

A concept paper is a public document that is primarily intended to convey the need for discussing specific issues, innovations or controversial key-points at any stage of the development of medicinal products. It should point out the issues to be covered in the guideline, but should not elaborate already on solutions.

The concept paper should be written in English and should not exceed 2 pages. The document should carry a reference number (version…) and contain line numbering to facilitate subsequent discussions.

The concept paper should contain an

- Introduction
- Problem statement
- Discussion (on the statement) and
- Recommendation(s) (points to be addressed, including proposed objective and scope and options for solutions where possible).
- Timetable for release the draft and final guidelines
- Resource requirements for preparation
- Impact assessment (anticipated benefit to industry, regulatory authorities and other interested parties. Interest parties potentially affected by a particular topic (applicants, patients …)
- References to literature and guidelines.

If more than one working party/group and/or scientific committee are in charge of drafting a guideline (multidisciplinary or joint guidelines), the concept paper, draft guideline, and final guideline should be discussed and agreed by all concerned working parties/committees before adoption and publication.

3.2.2.3 Optional: Adoption and release for consultation of concept paper

Following adoption of the <committee/board>, the concept paper is released for consultation to relevant interested parties through emails, meetings and publication on the <NMRA's> website <web address> for a period of 2 to 3 months (PDF format). The elaboration of a guideline can be accelerated if there is an urgent reason (e.g. in the case of editorial changes, or proposed changes to existing guideline are minor).

Comments collected on the concept paper will be considered in the development of the future guideline, see below. Possible solutions for developing the guideline should be

provided by interested parties, as part of the overall response to the concept paper. Preparation of the initial draft guideline may proceed in parallel to the consultation period. Concept papers will normally not be revised as they are superseded by the draft and final guidelines, respectively.

If a concept paper does not develop into a final guideline or once a final guideline has been published, the concept paper is considered a historical document and will be archived.

3.2.2.4 Preparation of initial draft guideline

The rapporteur prepares the draft text in consideration of existing <national>/<regional> or WHO directives and guidelines (as well as of documents of other regions). The <NMRA> Template for Guidelines serves as template. Comments received during the consultation period on the concept paper should be taken into account in the guideline draft. The rapporteur may consult appropriate experts to provide input.

Presentation style: Language is English, letter size 12, letter type Arial, add line numbering in draft (remove in final version) (see <NMRA> Guideline template – New development approach (included in Annex III) / Guideline template – Adoption approach (included in Annex IV)).

Structure of the draft guideline: The guideline should, where appropriate, contain, in addition to its scientific and technical content (see <NMRA> Guideline template – New development approach (included in Annex III) / Guideline template – Adoption approach (included in Annex IV)):

- Cover page (including <NMRA> symbol, guideline title, reference number of the document (edition/version), date of approval, responsible authority
- In foot section: <NMRA>address, email, phone and page number e.g. page 1 of 50)
- Timetable of guideline development process (starting from first date of guideline release to final revision)
- Keywords of the document
- Table of contents
- Acknowledgements (if applicable)
- Executive summary
- Introduction (background including objectives)
- Scope
- Legal basis (e.g. Act)
- Main guideline text
- (Proposed timetable (including timetable for discussion with other concerned working parties/committees/boards))
- Definitions

- References (scientific and/or legal and including a reference to the concept paper)
- Annex

The scope should indicate whether the guideline concerns a selected area of medicinal product development, where limited experience is available and knowledge is fast evolving, requiring the need for easy updates and flexibility.

This draft is considered by the relevant working party/scientific advisory or inspectors group. The document is regarded as internal document, which is revised by the rapporteur following each discussion in the working party/committee/board and/or the written comments of the other members of the working party/group.

3.2.2.5 Release for consultation of draft guideline

When the text has been developed to a point where the views of the members of the working party/group are clearly presented, the draft guideline are released for consultation on the <NMRA> website and by other means (email and meetings) (PDF format). The cover page of the draft guideline states that it is open for consultation and gives the date by which comments should be received. A common consultation period lasts for 1-2 months.

Specific procedures or provisions for appropriate consultation of patients, health care professionals, and others may enable to provide comments of these interest parties. To facilitate collection and review of comments, a template for submission of comments is included in Annex V.

3.2.2.6 Collection of comments

Comments are expected from different interest groups; e.g. national and international (regulatory) authorities and organisations (e.g. <NMRA>, Ministry of Health, WHO)), industry associations, scientific/academic societies, health care professionals, patients/consumer groups. Specific interest parties should be encouraged to give comments or other input on the draft.

All comments received are carefully considered and discussed by the rapporteur responsible for the guideline. If necessary, the <NMRA> may convene a meeting with relevant interested parties to discuss aspects of a draft guideline in detail.

An overview of the main comments with an explanation for their acceptance or non-acceptance shall be given by the rapporteur. This overview shall be approved by the committee or group within 1-2 months (in consideration of the meeting schedule) and subsequently published by the <NMRA>on the website https://www. <NMRA> (PDF format).

3.2.2.7 Preparation of final version of guideline

After the period of consultation, all comments received are considered by the rapporteur/working party. Comments considered relevant are accounted during revision of the guideline. The final text is submitted to the relevant scientific committee or other relevant group for adoption, together with a proposed date for implementation.

Structure of the final guideline: The guideline should, where appropriate, contain, in addition to its scientific and technical content (see <NMRA> Guideline template – New development approach (included in Annex III) / Guideline template – Adoption approach (included in Annex IV)):

- Cover page (including <NMRA> symbol, guideline title, reference number of the document (edition/version), date of approval, responsible authority
- In foot section: <NMRA> address, email, phone and page number (e.g. page 1 of 50)
- Timetable of guideline development process (starting from first date of guideline release to final revision)
- Keywords of the document
- Table of contents
- Acknowledgements (if applicable)
- Executive summary
- Introduction (background including objectives)
- Scope
- Legal basis (e.g. Act)
- Main guideline text
- Definitions
- References (scientific and/or legal and including a reference to the concept paper)
- Annex

3.2.2.8 Adoption of final guideline for publication

The committee of the <NMRA> adopts the final guidelines either at a plenary meeting or by written procedure.

The guideline (PDF format) is published on the website of the <NMRA> (https://www.<NMRA>), while previous draft(s) <and the concept paper> are archived. The document reference number of the concept paper, draft and final guideline and any revisions will facilitate document tracking.

3.2.2.9 Implementation

Unless otherwise indicated, guidelines come into operation **within three months *** after their adoption. While applicants may, with the agreement of the competent authority concerned, choose to apply a guideline in advance of this period, competent authorities should wait until this period has expired before requiring the guideline to be taken into account.

***** exact timelines for implementation to be publicly communicated at the stage of release of draft guideline for consultation.

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)”.

Marketing Authorization Holder (MAH)

A person or entity whose product has been authorized by a national medicines regulatory authority to be on the market.

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 include finished pharmaceutical products and biotherapeutics and vaccines. Not included are medical devices, *in-vitro* diagnostics, blood products and animal products.

Reference Institution (RI)/ Reference Regulatory Authority

An authority or institution which assessment and its outcome serve as basis for regulatory reliance. As per WHO guidance (https://www.who.int/news/item/29-04-2021-who-publishes-new-guidance-to-promote-strong-efficient-and-sustainable-regulatory-systems) this encompasses different levels of reliance.

In this document this term relates to a list of authorities/institutions determined by the NMRA including the transitional WHO listed authorities referred to as group B+C (https://www.who.int/publications/m/item/list-of-transitional-wlas) and WHO Prequalification Programme.

References

WHO, World Health Organization, Handbook for Guideline Development – 2nd Edition 2014 https://apps.who.int/iris/handle/10665/145714

(Access of website: October 2020)

EMA, European Medicines Agency, Procedure For European Union Guidelines And Related Documents Within The Pharmaceutical Legislative Framework - 2009

https://www.ema.europa.eu/en/documents/scientific-guideline/procedure-european-union-guidelines-related-documents-within-pharmaceutical-legislative-framework_en.pdf

(Access of website: October 2020)

TGA Australia, International scientific guidelines adopted in Australia

https://www.tga.gov.au/resources/international-scientific-guidelines-adopted-australia

<National legal provisions>

Annex list

I. Flow chart GL on GLs process

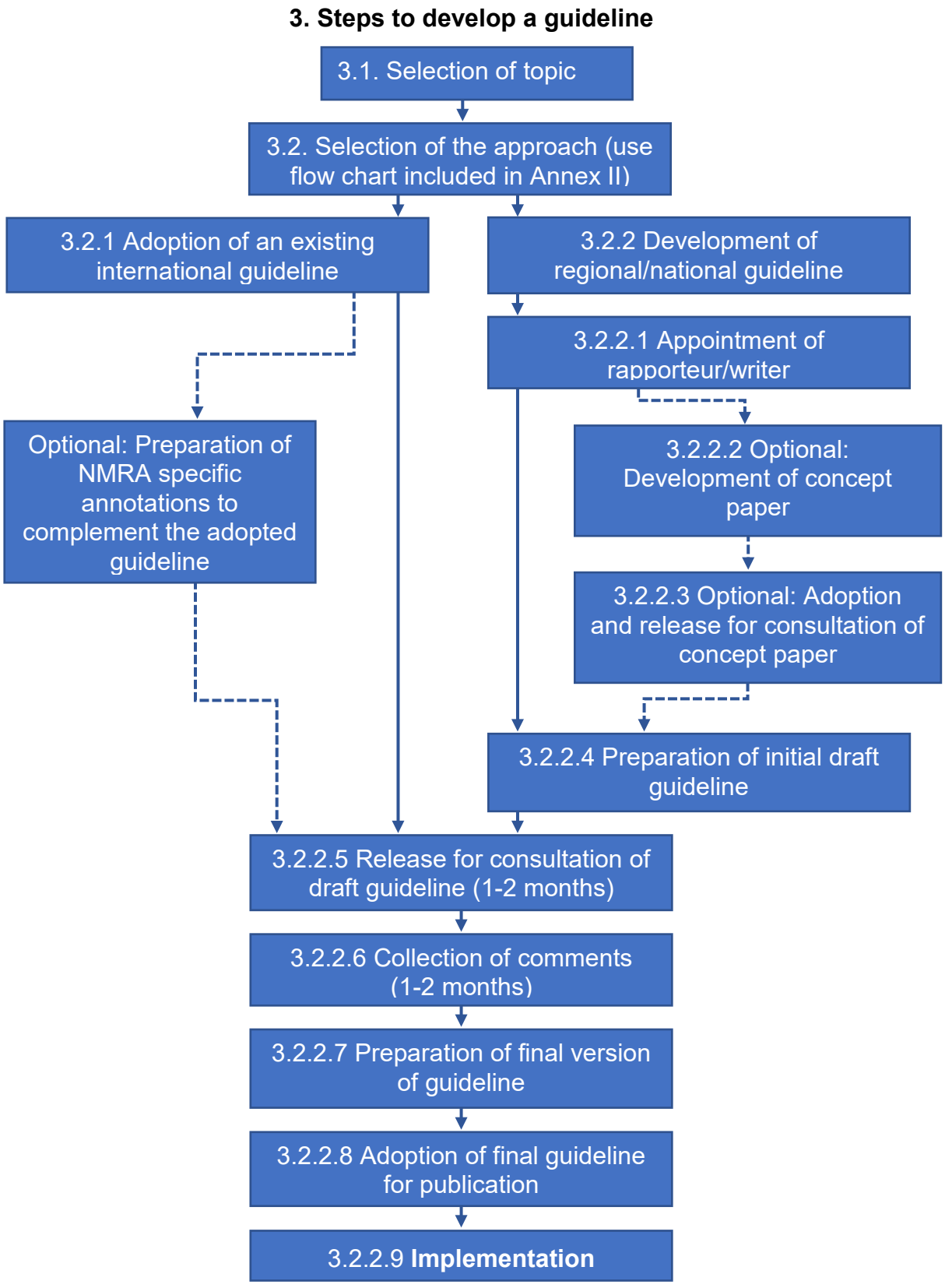
II. Decision flow chart for GL adoption or new development

III. GL template: New development approach

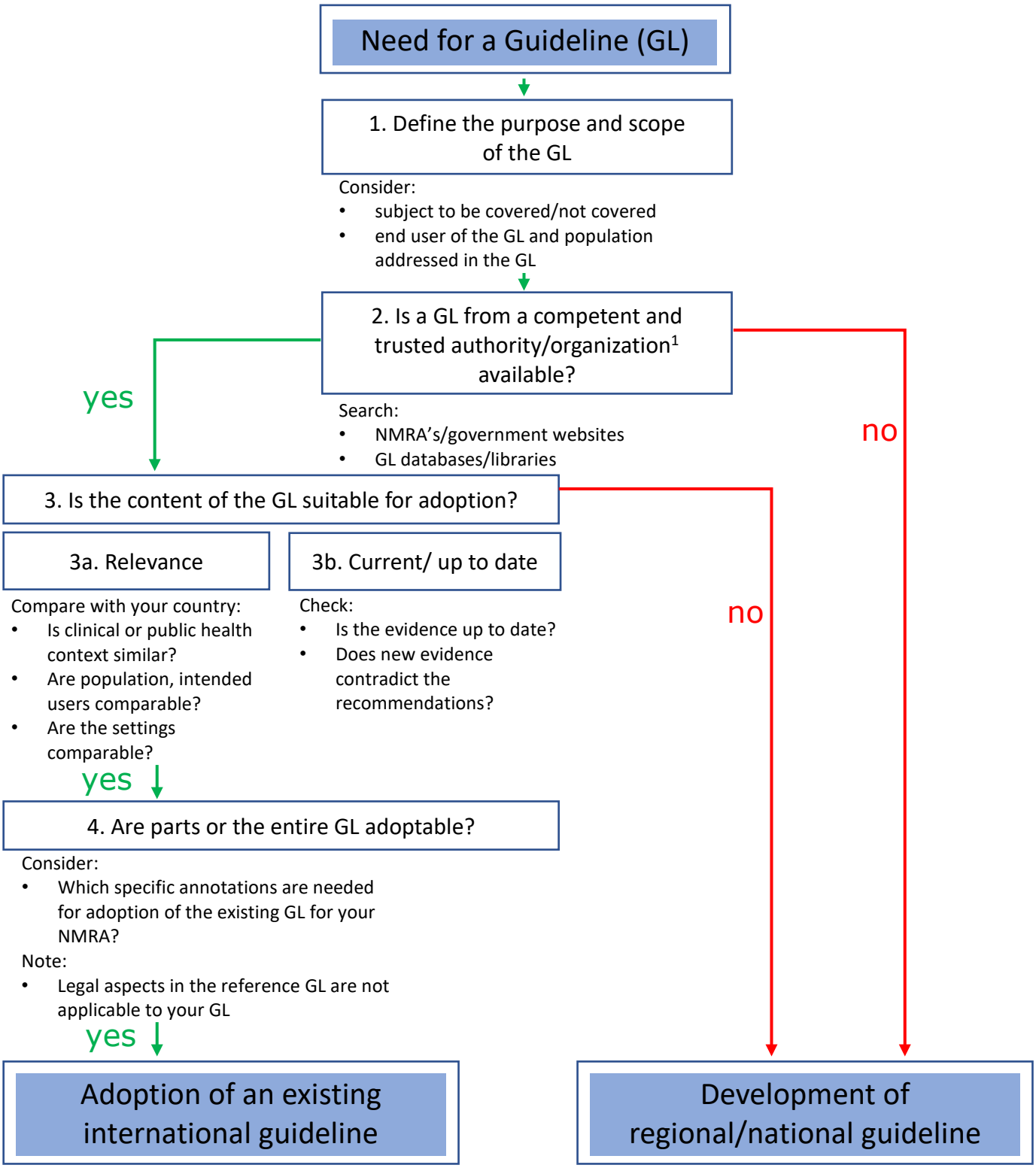
IV. GL template: Adoption approach

V. Template for submission of comments

Annex I: Guideline on Guidelines Process Flow chart



Annex II: Flow chart to decide to adopt an existing guideline or to develop a new guideline



[1] concept note about reliable authority/organization on the next 2 following pages

Designation of Reliable Authorities/Organizations for the purpose of reliance for regulatory and scientific guidelines

Approach of WHO, as per summary of relevant sections from the following website:

https://www.who.int/initiatives/who-listed-authority-reg-authorities

A Framework for evaluating and publicly designating regulatory authorities as WHO Listed Authorities (WLA)

This initiative at WHO aims at establishing and implementing a framework for designating and publicly listing a regulatory authority as a WHO Listed Authority (WLA). This provides a transparent and evidence-based pathway for regulatory authorities operating at an advanced level of performance to be globally recognized, thereby replacing the procurement-oriented concept of stringent regulatory authorities.

The framework also provides for the optimal use of limited resources by facilitating reliance on the work products and decisions of trusted institutions.

The *WHO Global Benchmarking Tool (GBT)* remains the foundation for classifying regulatory systems according to maturity level. Regulatory authorities that have attained an overall maturity level 3 classification are eligible for consideration as a WLA. In addition, following public consultation on the draft WLA Operational Guidance and discussions with Member States, transitional arrangements were developed that afford all regulatory authorities on the public WHO Interim list of National Regulatory Authorities the opportunity to be considered for WLA evaluation and listing - as reflected by their placement on a list of transitional WLAs (tWLAs).

The tWLA list replaces the WHO Interim list, which compiled categories of authorities recognized by WHO to have achieved levels of operation necessary for the regulation of medicines and/or vaccines.
In this guideline this term relates to a list of authorities determined by the NMRA including the transitional WHO listed authorities referred to as group B+C.

Group B are Stringent Regulatory Authorities (SRAs) as defined in the WHO Technical Report Series 1003.

Group C includes NMRAs exhibiting high level of performance of WHO's six recommended regulatory functions and exercising full regulatory oversight of any given vaccine (WHO Technical Report Series 978 Annex 6).

List of transitional WLAs categorized as B or B and C (in alphabetical order)

As of 31 March 2022

For any further information on WLA transitional arrangements, please refer to https://www.who.int/initiatives/who-listed-authority-reg-authorities

National Regulatory Authority		Origin of transition *As per WHO interim list at 31/03/2022*[1] **B** SRA (medicines[2])[3] **C** Highly performing NMRA (vaccines)[4]
1. Australia	TGA	B, C
2. Austria	AGES	B
3. Belgium	FAMPH	B
4. Bulgaria	BDA	B
5. Canada	Health Canada	B, C
6. Croatia	HALMED	B
7. Cyprus	MoH-PHS	B
8. Czech Republic	SUKL	B
9. Denmark	DKMA	B
10. Estonia	SAM	B
11. Finland	FIMEA	B
12. France	ANSM	B
13. Germany	BfARM PEI	B C
14. Greece	EOF	B
15. Hungary	OGYEI	B
16. Iceland	IMA	B
17. Ireland	HPRA	B
18. Italy	AIFA	B
19. Japan	PMDA	B
20. Latvia	ZVA	B
21. Liechtenstein	Office of Health	B
22. Lithuania	VVKT	B
23. Luxembourg	MoH	B
24. Malta	Medicines Authority	B
25. Netherlands	MEB	B
26. Norway	NOMA	B
27. Poland	URPL	B
28. Portugal	INFARMED	B
29. Romania	ANMDMR	B
30. Slovakia	SUKLO	B
31. Slovenia	JAZMP	B
32. Spain	AEMPS	B
33. Sweden	SMPA	B
34. Switzerland	Swissmedic	B, C
35. Slovakia	SUKLO	B

36. Slovenia	JAZMP	B
37. Spain	AEMPS	B
38. Sweden	SMPA	B
39. Switzerland	Swissmedic	B, C
40. United Kingdom of Great Britain and Northern Ireland	MHRA	B, C
41. United States of America	US-FDA	B, C
Regional Regulatory System		
European Medicines Regulatory Network[5]		B, C

[1] The time-limited WHO interim list of National Regulatory Authorities was established in September 2019 as part of the planned transformation from the term Stringent Regulatory Authorities (SRAs) to WHO-Listed Authorities (WLA)

[2] Precise scope of designation for tWLAs (new medicines, multisource, biotherapeutics, biosimilar products) will be further defined in agreement with each Regulatory Authority as part of the roadmap to listing

[3] Stringent Regulatory Authorities (SRAs) as defined in the WHO Technical Report Series 1003

[4] NRAs exhibiting high level of performance of WHO's six recommended regulatory functions and exercising full regulatory oversight of any given vaccine (WHO Technical Report Series 978 Annex 6)

5 This is composed of the European Commission, the European Medicines Agency and the following 30 member states: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain

Summary

Proposal as to determining authorities/organizations for the purpose of reliance for regulatory and scientific guidelines

Apparently there aren't any guidance documents from Swissmedic or Health Canada, which would differ relevantly from those of EMA or US FDA (when an ICH guideline is not available). Iceland, Liechtenstein and Norway are associated with EMA. These countries as well as Australia rely primarily on EMA guidelines. Reliance to documents from PMDA would be hampered by language issues.

Therefore, it is proposed to list **WHO** (not mentioned before, since not a regulatory authority in itself), **ICH, EMA and US FDA** as potential sources. This would reflect the order from international, to supranational, regional and national institutions/organizations issuing guidance documents.

Moreover, it is suggested to include ECOWAS and AVAREF as important sources for reliance and harmonization on the regional/continental level. While not relevant to this harmonization process, since Ghana FDA is taking part, reference to Ghana FDA, one of the two NMRAs in West Africa at WHO GBT maturity level 3, is, in principle, also valid.

In conclusion, the following order of reliable authorities/organizations for guideline development is proposed:

WHO, **AVAREF[5], ECOWAS[6], ICH, EMA, US FDA and Ghana FDA**

[5] Subject to final confirmation by partner NMRAs
[6] Subject to confirmation, as ECOWAS guidelines are not publicly available and have not yet been made available by partner NMRAs. Therefore, neither subjects nor contents could be checked.

Annex III: Guideline template – New development approach

<*current date:* DD Month YYYY>
<NMRA's Abbreviation>/<version of the GL>/<year>
<Name of adopting committee/board (Committee abbreviation)>

Guideline on <…>, <Version>

Draft[1]

[Delete drafting notes, footnotes and other non-applicable parts of this document before publishing.]

Draft written by <Authoring group/Department(s)>[2]	<Month YYYY>
Draft reviewed and agreed by <Working group(s)>	<DD Month YYYY>
Adopted by <Committee/Board> for release for consultation	<DD Month YYYY>[3]
Start of public consultation	<DD Month YYYY>[4]
End of consultation (deadline for comments)	<DD Month YYYY>[5]
Agreed by <Working group(s)/Department(s)>	<Month YYYY>
Adopted by <Committee/Board>	<DD Month YYYY>
Date of coming into effect	<DD Month YYYY>[6]

This guideline replaces '<guideline>' (NMRA/…/…).[7]

Comments should be provided using a comment template. The completed comments form should be sent to <as appropriate (NMRA's Email)>

Keywords	***<Text>***[8]

[1]Leave the wording 'Draft' if the guideline is adopted for release for public consultation. Delete the guideline is adopted as final. Do NOT the delete the subtitle line it sits in. –
[2]Specify other WPs involved in drafting of the guideline.
[3]Last day of relevant Committee meeting.
[4]Date of publication on the <NMRA> public website/1st day of the month following adoption of the guideline.
[5]Last day of the month concerned.
[6]First day of coming into effect. Latest 3 months after adoption.
[7]If this supersedes a previous guideline – otherwise delete.
[8] To be identified here during preparation of the guideline - keywords represent an internet search tool – Rapporteur(s) to propose and Working Party/Committee to adopt.

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Guideline on <…>

Table of contents

[Note: The proposed structure can be adapted according to the needs for a particular guideline. The table of contents must be finally checked against the main guideline text and corrected before submission for publication.]

Style notes for this draft version:

[ ] Drafting notes/Comments to be removed after finalization

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

Acknowledgements

<Rapporteur to include text>

[Note: Add Acknowledgments if applicable.]

Executive summary

<Rapporteur to include text>

[Note: For the current draft - to be updated at subsequent stages.]

1. Introduction (background)

1.1. Objectives:

<Rapporteur to include text>

[Note: This section also includes the objectives.]

2. Scope

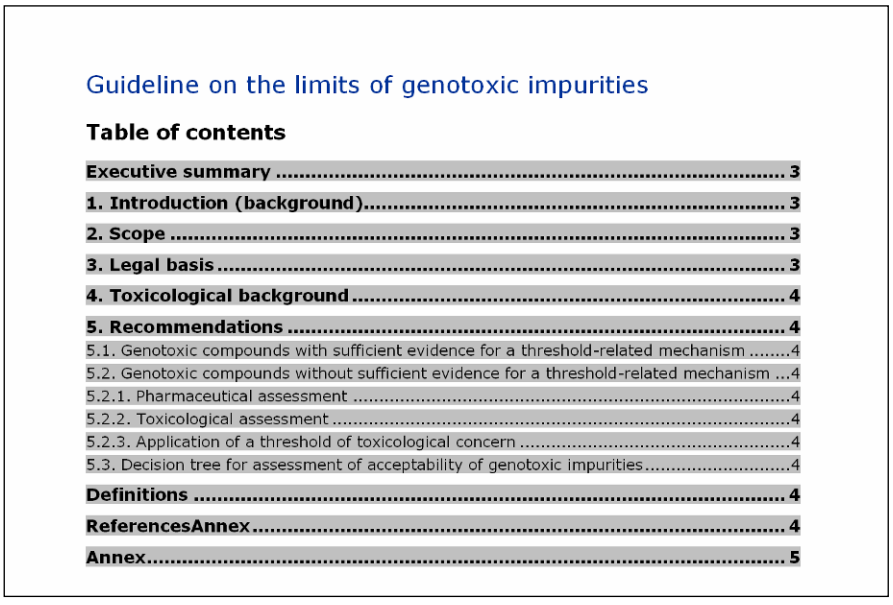
<Rapporteur to include text>

3. Legal basis

[Where applicable, i.e. for scientific guidelines in relation to quality, safety and efficacy.]

<Rapporteur to include text>

[Note: After the first 3 standard headings, please insert further headings relevant to the specific guideline, with sequential numbering (4, 5, 6, etc.) as needed. Use prepared headings below. Add extra headings or delete headings as needed. See this example and delete afterwards.]



Guideline on the limits of genotoxic impurities

Table of contents

4. <Heading (Main guideline text)>

<Rapporteur to include text>

4.1. <Heading>

<Rapporteur to include text>

4.1.1. <Heading>

<Rapporteur to include text>

4.1.2. <Heading>

<Rapporteur to include text>

4.2. <Heading>

<Rapporteur to include text>

4.3. <Heading>

<Rapporteur to include text>

5. <Heading>

<Rapporteur to include text>

6. <Heading>

<Rapporteur to include text>

7. <Heading>

<Rapporteur to include text>

8. <Heading>

<Rapporteur to include text>

Definitions

<Rapporteur to include text>

References

<Rapporteur to include text>

[Note: Include references if relevant; if not, delete this section.]

This Guideline template is based on the structure of guidelines from the European Medicine Agency (EMA).

Annex

<Rapporteur to include text.>

[Delete Annex if not applicable.]

Annex IV: Guideline template – Adoption approach

<*current date:* DD Month YYYY>
<NMRA's Abbreviation>/<version of the GL>/<year>
<Name of adopting committee/board (Committee abbreviation)>
Working group:<…>

The Guideline on <…>, Version <…>

This Guideline (GL) is an adaptation of the Guidelines on <name, author, version No, date of issue> <with/without <all/number> annexes/appendixes>, 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[1]

[Delete drafting notes, footnotes and other non-applicable parts of this document before publishing.]

Draft of annotation written by <Authoring group/Departments>[2]	<Month YYYY>
Draft annotations reviewed and agreed by <Working group(s)>	<DD Month YYYY>
Adopted by <Committee/Board> for release for consultation	<DD Month YYYY>[3]
Start of public consultation	<DD Month YYYY>[4]
End of consultation (deadline for comments)	<DD Month YYYY>[5]
Agreed by <Working group(s)/Department(s)>	<Month YYYY>
Adopted by <Committee/Board>	<DD Month YYYY>
Date of coming into effect	<DD Month YYYY>[6]

[1]Leave the wording 'Draft' if the guideline is adopted for release for public consultation. Delete the guideline is adopted as final. Do NOT the delete the subtitle line it sits in. –
[2]Specify other WPs involved in drafting of the guideline.
[3]Last day of relevant Committee meeting.
[4]Date of publication on the NMRA public website/1st day of the month following adoption of the guideline.
[5]Last day of the month concerned.
[6]First day of coming into effect. Latest 3 months after adoption.

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This guideline replaces '<guideline>' (NMRA/…/…).[1]

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	***<Text>***[2]

[1] If this supersedes a previous guideline – otherwise delete.
[2] To be identified here during preparation of the guideline - keywords represent an internet search tool – Rapporteur(s) to propose and Working Party/Committee to adopt.

Guideline on <…>

Table of contents

[Note: The proposed structure can be adapted according to the needs for a particular guideline. The table of contents must be finally checked against the main guideline text and corrected before submission for publication.]

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

<Rapporteur to include text>

[Note: For the current draft - to be updated at subsequent stages.]

Information on the adopted Guideline on <>

<Rapporteur to include text>

Title:

Title(s) of Annexes/Appendixes: *[when also adopted]*

Author(s):

Document No:

Version No:

Date of issue:

Source (e.g. website link):

1. <NMRA> annotations on the adopted Guideline on < >

<Rapporteur to include text>

1.1. Concerning Section <xx + heading>

[Proposed] **Annotation:**

Rationale:

1.2. Concerning Section <xx + heading >

[Proposed] **Annotation:**

Rationale*:*

1.3. Concerning Section <xx + heading >

[Proposed] **Annotation:**

Rationale*:*

[Note: Please insert extra headings for further annotations with sequential numbering (1.4, 1.5, 1.6, etc.) as needed.]

Definitions

References

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 V: Template for submission of comments

<Date of submission>

Submission of comments on '<document title>' (GHPP PharmTrain/<NMRA>/…)

Comments from:

Name of organization or individual

When completed, this form should be sent to the GHPP-PharmTrain project (ghpp.pharmtrain@bfarm.de) electronically, in Word format (not PDF).

20

21 # General comments

General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*

22

23

Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
	Comment: Proposed change (if any):	
	Comment: Proposed change (if any):	
	Comment: Proposed change (if any):	

Please add more rows if needed.