MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDANCE FOR ADOPTION OF INTERNATIONALLY RECOGNISED GUIDANCE DOCUMENTS

JANUARY, 2022

CITATION

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HPT/ISE/GMP/MAN/011	**GUIDANCE FOR ADOPTION OF INTERNATIONALLY RECOGNISED GUIDANCE DOCUMENTS**	Revision No. 0	**Effective Date:** 1/02/2022 **Review Date:** 31/01/2027

Prepared by Deputy Director Inspectorate, Surveillance and Enforcement

Sign.....

Date.....7/02/2022.....

Reviewed by Director HPT

Sign.....

Date.....7/02/2022.....

Checked by HQM

Sign.....

Date.....7/2/2022.....

Authorized by, CEO

Sign.....

Date..07-02-2022.....

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Abbreviations and Acronyms

HPT	Health Products and Technologies
GMP	Good Manufacturing Practices
GUD	Guideline
HQM	Head Quality Management
IEC	The International Electrotechnical Commission
ISO	The International Organization for Standards
CEO	Chief Executive Officer
NRA	National Regulatory Authority
PPB	Pharmacy and Poisons Board
PQS	Pharmaceutical Quality System
TC	Technical Committee
EAC	East African Community
TGA	Therapeutic Goods Administration.

Glossary of terms

NOTE: Guidelines should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum NRA benefits.

International Guideline:
International guideline where the international standards /regional standard has been adopted by an NRA made available for use by the NRA.

Regional Guideline: A guideline developed and used in regional organization.

National /Local guideline: A guideline developed and used by an NRA.

National normative document: A document established and published for use as a guideline.
Adoption of a guideline: Publication of an international guideline into National/ regional guideline to be used as National/Region guideline.
Taking over a guideline: Sometimes used as adoption of a guideline.
Editorial change ⟨of an International guideline in a regional or national guideline⟩ any permitted change that does not alter the technical content of the guideline.
Technical deviation: ⟨from an International guideline in a regional or national guideline⟩ any difference between the technical content of the International guideline and that of the regional or national guideline change in wording ⟨when adopting an International guideline in one of its official languages⟩ replacement of single words or phrases in the regional or national guideline by synonyms to reflect common language use in the region or country adopting the International guideline.

Guiding principle: Anything that is acceptable under the terms of the International guideline is acceptable under the regional or NRA guideline and vice versa, and thus compliance with the International guideline also means compliance with the regional or NRA guideline.

Correspondence: General for comparison of regional or national guideline with relevant International guideline, an indication of their correspondence. An International guideline is considered to have been adopted when the regional or national guideline is identical.

The regional or national guideline is identical to the International guideline under the following conditions:

a) the regional or national guideline is identical in technical content, structure and wording (or is an identical translation); or

b) the regional or national guideline is identical in technical content and structure, although it may contain the following minimal editorial changes:

i) substitution of a decimal comma by a decimal point;

ii) correction of any misprints (e.g. spelling errors) or pagination changes;

iii) deletion of text in one or several languages from a multilingual International guideline

iv) inclusion of any technical corrigenda or amendments issued to the International guideline

v) changes to the title to be consistent with an existing regional or national series;

vi) substitution of “this International guideline” by “this regional/national guideline”

vii) inclusion of any regional or national informative material (e.g. informative annexes that do not alter, add to or delete from the provisions of the International guideline); examples of informative material are advice to users, training guidance or suggested forms or reports;

viii) deletion of informative preliminary material from the International guideline; changes in wording

ix) addition, for informative purposes, of recalculated values of quantity units where a different measurement system is used in an adopting country. The "vice versa principle" is fulfilled.

NOTE Any changes in document layout (e.g. in relation to pagination, font type and font size, etc.), especially in an electronic environment, have no impact on the degree of correspondence.

Modified: The regional or national is modified in relation to the International guideline under the following conditions. Technical deviations are permitted provided they are clearly identified and explained. The regional or national reflects reflects the structure of the International guideline. Changes to the structure are only permitted if an easy comparison of the content and structure of the two guidelines continues to be possible.

For transparency and traceability, it is strongly recommended that a national guideline adopt only one single International guideline. Under certain circumstances, it may be appropriate to adopt several International guidelines within one national guideline. However, this is only practicable for the user if an easy comparison of the content is provided in a list identifying and explaining the changes.

Modified guidelines may also include the changes permitted under identical correspondence. The "vice versa principle" is not fulfilled. Modified standards may include such cases as the following:

a) "The regional or national guideline contains less" The regional or national guideline only applies a subset of the available choices in the International guideline, has less stringent requirements, etc.

b) "The regional or national guideline contains more" The regional or national guideline adds aspects or types, has more stringent requirements, includes additional tests, etc.

c) "The regional or national guideline alters a part of the International guideline" Part of the content is identical, but both the regional or national guideline and the International guideline contain some differing requirements.

d) "The regional or national guideline provides an alternative choice" The

regional or national guideline provides a provision of equal status, which may be used as an alternative to that given in the International guideline. A regional or national guideline may include an International Standard in its totality together with additional technical provisions that are not part of the International guideline. In this case, the degree of correspondence to the International guideline is either “modified” or “not equivalent”, depending on whether or not the differences are clearly indicated and technical deviations are listed and explained, although the part comprising the included International guideline may not have been subject to any modifications.

Not equivalent: The regional or national guideline is not equivalent to the International guideline in technical content and structure and the changes have not been clearly identified. This also can include the case where only a minority in number or significance of the international provisions remain in the regional or national guideline. This degree of correspondence does not constitute an adoption.

Acknowledgements

The Pharmacy and Poisons Board wishes to express its appreciation to all whose efforts and valuable contributions in developing this guideline on adoption of internationally recognized guideline/s.

INTRODUCTION

General considerations

GMP applies to the life-cycle stages from the manufacture of investigational medicinal products, technology transfer, and commercial manufacturing, through to product discontinuation. PQS can extend to the pharmaceutical development life-cycle stage and should facilitate innovation and continual improvement and strengthen the link between pharmaceutical development and manufacturing activities. All parts of the PQS should be adequately resourced and maintained, including being provided with sufficient competent personnel, suitable premises, equipment and facilities. GMP inspection is carried out to assess the PQS put in place by the manufacturer. A PQS ensure that the Pharmaceutical products are fit for their intended use, comply with the requirements of the marketing authorization and do not place patients at risk due to inadequate safety, quality or efficacy. The attainment of this quality objective is the responsibility of senior management and requires the participation and commitment of staff in many different departments and at all levels within the company, the company's suppliers and the distributors. To achieve this quality objective reliably there must be a comprehensively designed and correctly implemented pharmaceutical quality system (PQS) incorporating GMP and QRM. GMP inspection is carried out by qualified, experienced and appointed by the regulator. Under certain circumstances, the regulator may face challenges in carrying out the regulatory function in which case adoption of international best practices is applied. The decision on whether to adopt an international guideline rest with appropriate technical committee (TC). PPB should establish TCs charged with the responsibility of adopting international guidelines. The PPB closely aligns its regulatory approaches to those of comparable international regulatory counterparts wherever possible. Prior to adopting any Guideline, the PPB undertakes an extensive process of internal and external consultations to ensure the

Guideline is consistent with prevailing requirements in Kenya. PPB should publish a searchable list of International Guidelines adopted in Kenya.

Reasons for adoption

a) Adoption of international best practices to avoid duplication. International guidelines generally reflect the best practices of regulators worldwide and advances in a variety of countries.
b) Resource constraint especially inadequate and experienced human resource.
c) Participation in international certification schemes is facilitated.
d) Leads to regulatory efficiency thereby assuring quality, safety and efficacy of HPT.
e) Lack of requisite expertise in the NRA (e.g. GMP inspection and MA of vaccines) among others.

Procedure for adoption of International guideline

General outline of the process

The following principles may assist technical committees in achieving adoption:

1. Before any guideline is approved, a review of the international guideline must be undertaken by the NRA as part of adoption process to identify international equivalent guideline.
2. A Committee on adoption of international guideline should take a leading role in identifying International guideline corresponding to their own national interests. It is frequently possible to significantly influence the content of an International guideline so as to make it more suitable for use in the NRA.
3. Any International guideline used as the basis for NRA guideline should be one that is used in practice in other countries. To assess this,

committee may need to gain some information on support for the International guideline in practice.

4. In certain technologies the relevant International guidelines have never been widely implemented and this can result in such guideline not being sufficiently scrutinised in their development and, therefore, either being impractical or lacking in detail. While the lack of quality of the International guideline can delay their adoption by the NRA, it should not be seen as an immovable obstacle; the remedy is to promote wider participation in the development of the International guideline so that they are sufficiently flexible to provide for the varying circumstances of use prevailing in all countries concerned.
5. NRA should recommend regional guideline adoption wherever possible; If an International guideline is identified that fully satisfies local requirements, an assessment needs to be undertaken to determine the value of having a regional adoption rather than allowing the International guideline to be used directly in the marketplace.
6. The decision to adopt an International guideline should be based upon the principles described in this Guide and the timing of any changes to existing national guidelines in order to align with International guideline that should be acceptable to all stakeholders.
7. When variations to an International guideline have been included in the equivalent NRA, it is essential that all technical variations are clearly identified and explained in the NRA guideline.

Methods of guideline adoption

General

1. When International guidelines are adopted, they shall only be adopted as regional or national guideline, that is by a regional or national deliverable of the same type.

2. Any regional or national guideline which adopts an International guideline by any method shall ensure that the identification of the International guideline is clearly stated. For adoption by republication,

the identification of the International guideline shall include, in a prominent position such as on the cover page, the reference number, the title (in at least one of the official languages in which the International guideline was published), date or year of publication and the degree of correspondence.

3. When adopting an International guideline all existing amendments and technical corrigenda to the International guideline shall be included in the regional or national guideline. Amendments and technical corrigenda published after the adoption of an International guideline should be adopted as soon as possible.

4. With particular reference to the development of electronic versions of the guideline, organizations may find new methods of adoption that are not covered in this part, or may combine the existing ones. In this case the method used will not be listed here. However, the recommendations regarding choice and indication of correspondence will still remain applicable. (NOTE: See different types of adoption notices at the end of the document)

Endorsement method

1. If the International guideline is declared by the regional or national body to have the status of a regional or national guideline, an "endorsement notice" may be issued. The endorsement notice may contain information or instructions pertinent to this declaration. Each endorsement notice should only refer to one International guideline (including any amendments and/or technical corrigenda).

2. The endorsement notice may allocate a unique regional or national reference number to each endorsed International guideline. Alternatively, the reference number of the International guideline should be used.

3. The endorsement notice may appear in an official bulletin and/or as an independent document. The text of the International guideline should not usually be attached to the endorsement notice.

4. The endorsement method is one of the simplest methods of adoption. It does not require a reprint of the text of the International guideline. However, the endorsement notice cannot be used without the International guideline and, therefore, the latter shall be made available in some way. Furthermore, if the endorsement notice does not have its own identification number, the International guideline may not be easily traceable as having been adopted within the regional or national guideline system. NOTE Sales and copyright protection of endorsed International guidelines are handled in accordance with the relevant rules and policies of the organization, as appropriate, for the sale of original guideline and other publications.

Republication

General

There are three methods of republication:

reprinting

translation

redrafting.

Independent of which method of republication is chosen, a regional or national identifier of the organization adopting the International guideline shall appear on the cover page and all other pages of the National or Regional guideline.

Reprinting

The International guideline is printed as a regional or national guideline by direct reproduction of the published document (e.g. by photography,

scanning or from an electronic file). In addition, the regional or national guideline may include the following:

a) a regional or national introduction, preface or foreword

(b) a translation of the text

c) a different title

(d) amendments and/or technical corrigenda to the International guideline

e) regional or national informative material in a regional or national foreword, notes or annexes

f) editorial changes or technical deviations

A regional or national introduction, preface or foreword may contain information or instructions pertinent to the regional or national adoption of the guideline. Such information would normally include the following:

a) the original parent publication title and reference number (with the year of publication)

b) the regional or national body responsible for the guideline (e.g. technical committee number and title)

c) if appropriate, details of editorial changes

d) if appropriate, reference to technical deviations and changes in structure, together with their explanations, or to the annex giving this information (NOTE Examples of regional or national introductory material)

It is also possible to add technical deviations and any information, instructions, notes, etc. directly to those clauses to which they refer. However, this additional text shall be clearly identified as being distinct from the original standard.

To align with an established series of regional or national guideline the title of the regional or national guideline may vary from that of the adopted International guideline. However, the title of the International

guideline should be clearly shown on the cover page. It is recommended that the explanation for the change of title be provided in the introduction, preface or foreword of the regional or national guideline. Technical corrigenda and amendments to an International guideline are often issued before it is adopted as a regional or national guideline. When adopting an International guideline all existing amendments and technical corrigenda shall be included. NOTE For an appropriate method of identifying the included amendments and technical corrigenda see the relevant section. It is also possible to add technical deviations and any information, instructions, notes, etc. directly to those clauses to which they refer. However, this additional text shall be clearly identified as being distinct from the original guideline.

Translation (with or without reprint of the original)

a) If the regional or national guideline is solely the translation of an International one, it may be published in a bilingual or monolingual form. In either case, a regional or national introduction, preface or foreword is usually included
b) Where there has been a translation, and the monolingual regional or national guideline has been declared “identical”, then compliance with the original International guideline is deemed to be compliance with the translation; that is, the vice versa principle applies.
c) Bilingual editions that contain the text of the guideline in another language and in an official language of the international organization by which it was issued, may contain a statement concerning the validity of the original or of the translation. Where no statement is made, both versions are equally valid.
d) Both monolingual and bilingual editions may contain notes stating editorial changes and/or technical deviations made with reference to the International guideline. They usually appear after the clause to which

they refer and/or are mentioned in the regional or national introduction, preface or foreword. The degree of correspondence depends upon the editorial changes and/or technical deviations added.

e) Monolingual editions should indicate which language served as a basis for the translation.

Redrafting

1. If an International guideline is published as a regional or national guideline and the regional/national guideline is not a reprint or identical translation of the International guideline, this is considered to be a redraft.
2. If an International guideline is redrafted as a regional or national guideline it should state that it has been redrafted, whether or not the regional or national guideline deviates from the International Standard. If there are deviations, then the reasons for these should be given and the deviations should also be identified in the text using one of the methods given in this guideline. Although redrafting is a valid method of adopting an International guideline, the possibility of overlooking important technical deviations which may be disguised by the changes in the structure or wording makes the comparison between the International guideline and the regional or national guideline difficult and the degree of correspondence cannot be easily determined. Redrafting also makes it difficult to verify the degree of correspondence between such regional or national guideline from different countries.

Choice among adoption methods

a) If no editorial changes or technical deviations are made, any method of adoption is suitable, although reprinting of the full text is the method recommended for those countries whose language is one of the official

languages. Where a translation is involved, the country should consider binding the original text with the translation.

b) If editorial changes or technical deviations are inevitable, it is recommended that the reprint method or the translation method with the incorporation of deviations within the text or in an annex be used. For the indication of technical deviations and editorial changes, see section on deviations and editorial changes. The redrafting of guideline is not recommended.

Methods of indicating technical deviations and editorial changes

General

1. The regional or national guideline should include:
   a) an explanation in a regional or national introduction, preface or foreword and, where appropriate,
   b) an annex describing any editorial changes and/or technical deviations which have been made, why they have been made, and how they are identified in the text.

2. Where technical deviations (and reasons for them) or editorial changes are few, they may be placed in the regional or national introduction, preface or foreword.

3. Specific deviations or advice (with suitable cross references) may also be included in the regional or national introduction, preface or foreword. Alternatively, they may be included in the text or in a special regional or national annex. For paper-based production, the mechanical difficulties of inserting blocks of text makes it preferable to use a simple, but unambiguous, method of including changes.

4. If included within the text, any regional or national explanatory notes, editorial changes and/or technical deviations made with reference to the International guideline should be clearly highlighted in the text, for example by inclusion in a box immediately following the clause to which they relate, or by a single vertical bar in the margin, or dotted underlining of the applicable text. They should be introduced by the following titles:

   a) "regional or national explanatory note" or "regional or national explanation" if their content is limited to editorial changes; and/or

   b) "regional or national deviation" if their content is not limited to editorial changes.

   An alternative method of indicating explanatory notes, editorial changes or technical deviations, and one which does not require cutting and assembling the text of the International guideline, is to use a single vertical bar (|) in the margin, or dotted underlining, to indicate the applicable text of the International guideline which is to be changed. The regional or national notes, changes and/or deviations are then collected together in an annex at the end of the document. Each variation is cross-referenced to the clause, etc. of the International guideline, usually with normative deviations in one annex, together with reasons for the deviations, and informative notes and guidance in another.

6. Often, when adopting an International guideline, there are amendments and/or technical corrigenda. These may be incorporated into the text, or the amendments and/or technical corrigenda may be bound together at the end of the document. The changed text should be indicated in the main body of the guideline by double marginal bars (||). This also has the advantage of distinguishing regional or national requirements (single bars or dotted underlining) from the international changes.

Reference to other International guidelines

1. If an adopted International guideline makes normative reference to other International guideline, the references should be left unchanged within the text, regardless of the validity of those guidelines in the regional or national adoption, or their status as regional or national guideline. If other documents have to be substituted for those originally referenced, they should be identified in a regional or national note. This is most conveniently done in the regional or national introduction, preface or foreword.

   NOTE:

   These recommendations do not need to be applied to references given for information only, although it may be useful to do so.

2. If the referenced International guidelines have been adopted as regional or national guideline, this should be stated in the regional or national introduction, preface or foreword, and their regional or national reference numbers should be given. Similarly, where there are no valid regional or national documents, this should also be indicated. A convenient method of indicating these relationships is a list in the introduction, preface or foreword showing the reference numbers of the corresponding guideline and their degree of correspondence. The referenced documents should be quoted exactly as they appear in the International guideline. The technical committee responsible for the regional or national guideline should review all the cited regional or national guidelines to ensure they are equivalent and have validity for the purposes of the guideline being adopted. If an error in an International guideline has been detected, a regional or national footnote should provide correct reference information, and the relevant international organization should be informed.

3. If some of the referenced International guideline have not been adopted as regional or national guideline in the region or country, then the regional or national introduction, preface or foreword should identify the documents that are to be considered valid in their stead, if reference to the International guideline is not considered appropriate. Information should also be given regarding any technical deviations in the regional or national documents from the International guideline replaced by them. When a document other than an identical regional or national guideline is substituted for a referenced International guideline, the referencing guideline is considered to contain a technical deviation and, therefore, to have “modified” correspondence.

Presentation of adopted guideline

The method of presenting International guideline as NRA one is to electronically reproduce the International guideline as a PDF file, and add a Preface which sets out the international origin of the document and whether there are local variations and the reasons for these variations. The variations shall be presented in a ‘ZZ Appendix’ following the source text. Additional normative or informative material may also be added as NRA appendices. This method is known as normative "adoption". Variations shall not be applied to the text of the source document, such as the use of strikeout, highlighted, inserted variations or marginal bars.

The levels of correspondence, identical (IDT) and modified (MOD), described in an Appendix are possible when adopting International guideline. The most important point to note is that the level of correspondence to the International guideline must be immediately apparent to the reader; and for identical or modified adoptions, any local variations clearly indicated.

Maintenance of adopted guideline

Once an NRA guideline has been aligned with its international counterpart, it is important to ensure that amendments to, and revisions of, the International guideline are mirrored in the local guideline so that international equivalence is maintained. Similarly, the effect on international equivalence needs to be considered before any local amendment to an adopted guideline is made.

International scientific/regional guidelines adopted by PPB

PPB adopts internationally recognized guidelines in recognition of best practice and avoid duplication. The adopted guidelines will periodically be published on PPB's website. The following guidelines have been adopted by PPB and in the event of addition of any guideline the same will be added to the website (Review and add any guideline adopted by PPB):

REFERENCES:

1. Compendium of good manufacturing practices (GMP) Technical documents for harmonization of medicines regulation in the East African Community (EAC). Version September 2014.
2. Australian government department of Health Therapeutic Goods Administration (TGA): International Scientific guidelines adopted in Australia.
3. ISO/IEC 21-1, regional or national adoption of international standards and other International deliverables – Adoption of international standards first edition, 2005.
4. ISO/IEC Guide 99, code of good standardization practice, first edition 1994.
5. ISO/IEC Guide 59, code of good standardization practice, is also acknowledged as a useful reference document.

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ANNEXES

Annex A (informative)

Examples of adoption notices A1

General

For the purposes of this annex, the examples have been drafted as if for a national adoption of an International guideline but may equally be applied for a regional adoption. Depending on the context in the examples, the letters XYZ represent variously the imaginary country, national guidelines body, or the prefix in the reference number of the national guideline

A2. Example of an endorsement notice for use with an identical adoption only: “International guideline ABC Products intended for use in the global market — General requirements, including its Amendment is endorsed as an XYZ national guideline with the reference number A/B/C International guideline and International guideline/Amd.1 can be obtained from the QMS department of XYZ.”

A3. Examples of adoption notices for republications NOTE The following notices may be given separately or may form part of the national foreword or other national introductory material.

A3.1 Reprint EXAMPLE 1 “The (E or F version of) International guideline ABC, Products intended for use in the global market — General requirements, including its Amendment, is adopted as the identical XYZ national guideline with the reference number A/B/C.”

EXAMPLE 2 “The (E or F version of) International guideline ABC, Products intended for use in the global market — General requirements, including its Amendment, is adopted with national modifications as an XYZ national guideline with the reference number X/Y/Z.
See the national foreword for details of modifications and their identification within the text.”

A4. **Translation**

EXAMPLE 1 “International guideline ABC, Products intended for use in the global market — General requirements, including its Amendment ABC/Amended, is adopted by translation as the identical XYZ national guideline with the reference number D/E/F.

EXAMPLE 2 “International guideline ABC, Products intended for use in the global market — General requirements, including its Amendment ABC/Amended is adopted by translation as the identical EFG national guideline with the reference number X/Y/Z. The English language version is reproduced together with the translation.”– All rights reserved.

EXAMPLE 3 “International guideline ABC, Products intended for use in the global market — General requirements, including its Amendment ABC/Amended is adopted by translation, with national modifications, as the XYZ national guideline with the reference number XY/Z /N See the national foreword for details of modifications and their identification within the text.

A5. REDRAFT

“International guideline ABC, Products intended for use in the global market — General requirements, including its Amendment ABC/Amended., is adopted with national modifications as an XYZ

national guideline with the reference number X/Y/Z/modified. The national guideline is a redrafted version of the International guideline. See the national foreword for further information, including details of modifications and their identification within the text."

Annex B (informative)

Examples of regional or NRA introductory material

B.1 General

For the purposes of this annex, the examples have been drafted as if for a national adoption of an International guideline but may equally be applied for a regional adoption. Depending on the context in the examples, the letters XYZ represent variously the imaginary country, national NRA, or the prefix in the reference number of the national guideline.

B.2 National foreword for an identical national guideline "This XYZ guideline is identical with (the E or F version of) International guideline ABC, Products intended for use in the global market — General requirements, including its Amendment ABC/Amended. The national committee responsible for this guideline is Technical Committee A1, Products for the XYZ market. This guideline contains requirements that are relevant under the XYZ Law on Products. This guideline replaces XYZ, Products for the XYZ market — Requirements, which has become technically obsolete due to international developments. For the purposes of this guideline the following editorial changes have been made:

a) in the title, the word "global" has been changed to "worldwide" to be consistent with the title of other XYZ guidelines

b) a national informative annex has been included giving guidance to users. A list of XYZ guidelines identical to the International guideline

which are referenced in International guideline ABC, including its Amendment, is given in Annex X." of National foreword for an adopted national guideline with modifications

B3. National foreword for an adopted national guideline with modifications "This XYZ guideline is a modified adoption of (the E or F version of) International guideline ABC, Products intended for use in the global market — General requirements, including its Amendment ABC/Amended. The Technical committee responsible for this guideline is Technical Committee TC, Products for the XYZ market. This guideline contains requirements that are relevant under the XYZ Law on Products. This guideline replaces XYZ, Products for the XYZ market — Requirements, which has become technically obsolete due to international developments. In this guideline, certain modifications due to national legal requirements and the particular needs of XYZ industry have been made. These technical deviations and additional information have been added directly to the clauses to which they refer, and are marked by a different font type and the heading "National deviation" or "National explanation". A complete list of modifications, together with their justification, is given in Annex EF

For the purposes of this guideline, the following editorial changes have also been made:

a) in the title, the word "global" has been changed to "worldwide" to be consistent with the titles of other XYZ guideline;

b) the words "this International guideline" have been replaced by "this national guideline". A list of XYZ guidelines identical to the International guideline which are referenced in ABC, including its Amendment, is given in Annex." EF

B4. National foreword for an identical translation “This XYZ guideline is an identical translation of International guideline ABC, Products intended for use in the global market — General requirements, including its Amendment XYZ/Amended. The Technical committee responsible for this guideline and its translation is Technical Committee A1, Products for the XYZ market. This guideline contains requirements that are relevant under the XYZ Law on GMP. This guideline replaces XYZ, requirements for the XYZ NRA — Requirements, which has become technically obsolete due to international developments. Within the text of this guideline, the following editorial changes have been made:

a) the decimal comma has been replaced by the decimal point;

b) a national informative annex has been included giving guidance to users. A list of XYZ guidelines identical to the International guideline which are referenced in ABC, including its Amendment, is given in the Annex

B.5 National foreword for a translation with modifications

“This XYZ guideline is a translation of International ABC, Products intended for use in the global market — General requirements, including its Amendment DEF/Amended, with certain technical modifications. The Technical committee responsible for this guideline and its translation is Technical Committee A1, Products for the XYZ market. This guideline contains requirements that are relevant under the XYZ Law on GMP/MA This guideline replaces XYZ, Products for the XYZ market — Requirements, which has become technically obsolete due to international developments. In this guideline, certain modifications due to national legal requirements and the particular needs of XYZ industry have been made. These technical deviations and additional information have been added directly to the clauses to which they refer, and are marked by a different font type and the heading “National deviation” or

“National explanation”. A complete list of modifications, together with their justification, is given in Annex NA. For the purposes of this guideline, the following editorial changes have also been made:
a) the decimal comma has been replaced by the decimal point;
b) a national informative annex has been included giving guidance to users. A list of XYZ guidelines identical to the International guidelines which are referenced in guideline XYZ, including its Amendment, is given in Annex NB.”

B. 6 NRA foreword for a redraft

“This XYZ guideline is a modified adoption of (the E or F version of) International guideline ABC, Products intended for use in the global market — General requirements, including its Amendment ABC/Amd. The TC committee responsible for this guideline is Technical Committee A1, Products for the XYZ market. This guideline contains requirements that are relevant under the XYZ Law on Products. This guideline replaces DEF, Products for the XYZ market — Requirements, which has become technically obsolete due to international developments. This guideline has been redrafted in order to provide a structure consistent with that of other NRA guidelines in this series. For comparison purposes, a list of the clauses in the XYZ guideline and the equivalent clauses in the International guideline is given in the informative Annex NA. Certain modifications due to national legal requirements and the particular needs of XYZ industry have also been made. These technical deviations have been incorporated and are marked by a single bar in the margin. A complete list of modifications, together with their justification, is given in Annex NB. For the purposes of this guideline, the following editorial changes have also been made: a) the decimal comma has been replaced by the decimal point;

b) the words “this International guideline” have been replaced by “this NRA guideline.”

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