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MCA Technical Working Group

Guideline for Reliance on decisions, reports, or information from other national regulatory authorities (NRAs) or regional and international bodies

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This guideline replaces version 1 dated 24 December 2021 of the '*MCA Guideline for Reliance on decisions, reports, or information from other national medicines regulatory authorities (NMRAs) or regional and international bodies'*

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2	25 June 2025	Guideline restricted to medicines; acknowledgement included;

Comments should be provided by using the template (MCA-F-021/03) for Submission of Comments and sent to info@mca.gm

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Acknowledgements

We duly thank the World Health Organization (WHO), Health Canada, and Food and Drugs Authority (FDA, Ghana) 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 regulatory authorities (NRA) 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 March 2021 to November 2021. Version 1 of the Guideline on Reliance for the National Regulatory Authorities of Ghana, Liberia, Sierra Leone, and The Gambia was finalised on 02 December 2022 for preparation of the NMRA's own guidelines.

This document should be read in conjunction with the relevant sections of other applicable guidance.

1 Introduction (background)

1.1. The legal provision Medicines and Related Products Act, 2014 mandates the MCA to regulate the importation, distribution, and manufacture of all medicines (medicinal products) in The Gambia.

1.2. The term "medicines (medicinal products)" in the context of this guideline includes finished pharmaceutical products (FPPs), biologicals (biotherapeutics) and vaccines.

1.3. NRAs face an increasingly complex regulatory environment, with limited resources and a need to avoid duplication by communicating, collaborating, cooperating and forming coalitions to ensure product quality, safety and efficacy, as well as supply-chain security.

1.4. To this end, MCA is permitted to take into account and give significant weight to assessments performed and decisions made by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision. Using reliance on the expertise and regulatory outcomes of recognised reference institutions (RI) facilitates and accelerates national registration processes.

1.5. Available assessment and inspection reports of reference institutions in addition to the registration dossiers, assure NRAs of the positive benefit-risk of a product and its identical quality with the product already approved elsewhere, while allowing them to reflect their own judgement on the benefit-risk balance as it relates to their specific country situation and the legislation in place. This contributes substantially to savings in regulatory resources, improvements in the quality of regulatory decisions and faster availability of needed therapies for patients.

1.6. Of note, MCA remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions, assessments and information of other reference institutions.

Objectives

1.7. This guideline describes the prerequisites and information requirements of an application (for marketing authorisation or variation) for a medicine that has previously been approved by reference institutions.

1.8. The objectives of this guideline are to provide guidance and clarification to applicants, including sponsors and industry, on how MCA relies on foreign decisions, reports and information, in the assessment of medicines. It describes

the practical steps for MCA regulators and applicants to effectively and efficiently implement and conduct the assessment activities using reliance on decisions, reports, or information from other NRAs or regional and international bodies.

1.9. The MCA reserves the right to request information or material, or define conditions not specifically described in this guidance, in order to adequately assess the safety, efficacy or quality of a medicine. MCA is committed to ensure that such requests are justifiable and that decisions are clearly documented.

1.10. All final decisions on the approval of marketing authorisation or variation of medicines will be made by MCA.

2 Legal basis

2.1. This guideline is coherent with national/regional frameworks and policies. The usage of reliance by MCA is supported/embedded in Part XIII, section 82 (2) of the Medicines and Related Products Regulations, 2020.

3 Scope

3.1. This guideline provides guidance to applicants and MCA's regulators on the requirements and process for the marketing authorisation (registration) of medicines (medicinal products) in The Gambia that have been approved by a recognised reference institution. For details on the reference institutions see section 5 and **Annex 1**.

3.2. By using the approach of reliance, MCA maximises the efficiency in using their own resources. Moreover, MCA is able to focus on value-adding activities. In addition, the burden of duplication of work done by reference institutions and duplication of work for applicants/manufacturers is reduced.

3.3. This guideline covers initial authorisations (registrations) and variations (post approval changes).

4 Assessment activities

4.1. NRAs have several options for organising their assessment activities.

4.2. In addition to a **full review**, there exist two reliance-based approaches to organise the assessment activities; verification or abridged/abbreviated review/regulatory pathway.

4.3. **Verification** is an administrative process to reach a regulatory decision, based on registration or authorisation by a reference institution. The NRA formalises its decision by approving the product or submission and ensures the product for local registration and marketing. The NRA does not undertake any further assessment activity on its own. This may apply to full submissions or parts thereof (see 'Definitions' for details on full and partial reliance). Verification is applied where conformity with requirements of the reference institution is sufficient to meet the requirements of MCA.

4.4. **Abridged/abbreviated review** is the assessment of suitability of use under local conditions and regulatory requirements, while relying partly or fully on prior assessment and inspection outcomes as well as Quality Control (QC)

laboratory reports from the reference institution to inform the local decision (see 'Definitions' for details on abridged/abbreviated procedure).

5 Reference institutions

5.1. Regulatory authorities and regional and international bodies that are considered reference institutions by MCA for the purpose of reliance/use of relevant decisions, reports or information are stated in **Annex 1** (see also "Definitions" for clarification).

6 Dossier requirements

MCA has published guidance documents and policies to assist applicants in the preparation and filing of medicine dossiers, for example, the common technical document CTD guidance (see reference list). Applicants should refer to the MCA website for applicable guidance documents.

This section provides guidance on the documentation specifically required for applying partial or full reliance mechanisms, as detailed in section 4.

6.1 Documentation Requirements

The format of the documentation should correspond to the CTD in accordance with MCA or International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) format/content.

Currency of the documentation, i.e. the sameness of the contents of the application with the documentation available and underlying any regulatory decision of the reference institution is mandatory (see section 6.2).

6.1.1 For marketing authorisation applications

A full dossier (CTD format) should be submitted including:

a. Module 1, regional administrative information, adapted, following the contents/format/structure laid out in **Annex 2** ("Proposed documentation for the abridged procedure for reference institution-approved medicine").

b. Module 2, summaries, complete as submitted to the reference institution.

   Note: In the case of generic medicines for which a Clinical summary is not available, the Clinical overview (Module 2.5) should be included.

c. Module 3, quality documentation, as submitted to the reference institution, unless indicated otherwise according to the requirements of MCA. If climatic zone III–IV stability data are not available, the commitment and protocol should be provided for stability studies under the appropriate climatic conditions for The Gambia. Any preliminary data under the required climatic conditions for MCA should be provided. The stability data will be assessed by the reference institution, where applicable or possible.

d. Module 4, non-clinical documentation, to be provided except for generic/multisource medicines in addition to summary in module 2.

e. Module 5, clinical documentation, (in addition to summary in module 2).

   For innovative medicines to be provided.

For generic (multisource) products, complete documentation on bioequivalence studies should be provided in the submission in line with the MCA *Guideline on the Investigation of Bioequivalence* to establish interchangeability and applicable national regulatory requirements for participating NRAs.

6.1.2 For applications for variations

a. Module 1, adapted, following the contents/format/structure laid out in **Annex 2** ("Proposed documentation for the abridged procedure for reference institution-approved medical products").

b. Module 2, complete as submitted to the reference institution.

Note: In the case of generic medicines for which a Clinical summary is not available, the Clinical overview (Module 2.5) should be included.

c. Modules 3, 4 and/or 5 as submitted to the reference institution for the substantiation of the applied variation.

6.1.3 Additional information for marketing authorisation applications as well as for applications for variations

a. All review(s), assessment reports as well as inspection reports by the reference institution, substantiating the current authorisation status of the medicine, should be provided by the applicant when the submission is filed with MCA.

b. Written confirmation of permission for sharing reference institution-owned non-public information with MCA (see **Annex 3**).

Note for variation applications: If the confirmation has been obtained for the initial marketing authorisation application with unlimited validity, the confirmation does not have to be renewed with the reference institution. Nonetheless, the written confirmation should be part of each submission.

The legal information accompanying the dossier should be duly certified and authenticated under the procedure, in effect, in the country of origin, and issued by the appropriate entity.

c. Samples of the medicine from commercial batches, submitted to support the application as per sample schedule.

6.2 Requirements for Verification

6.2.1. The applicant should verify the "sameness" of the reference institution-approved medicine with the one applied for the purpose of reliance.

6.2.2. For this,

a. the "Quality information summary" (QIS) has to be provided (in CTD-module 1.2). Details on the information requested for finished pharmaceutical products (FPP) and for biologicals (biotherapeutics) are provided in **Annex 4a** (QIS-RI-FPP) and **Annex 4b** (QIS-RI-BTP), respectively.

b. the applicant should confirm in writing that the review(s) provided is/are complete and unaltered. The applicant should confirm that the documentation filed in the submission is identical to that, on which the review(s) and authorisation decision was based. If it is not identical, all differences should be clearly indicated.

c. The product should have been registered, prequalified and/or granted marketing authorisation and is, in the latter case, actually on the market of the reference authority.

6.3 Requirements for abridged/abbreviated review

6.3.1. The abridged/abbreviated review may pertain to the full submission or parts thereof, depending on the suitability of use under local conditions and regulatory requirements.

6.3.2. An abridged/abbreviated review for **parts of the submission** may be applied for the active pharmaceutical ingredients (API). MCA recognises the Certificates of Suitability to the monographs of the European Pharmacopoeia (CEP) for API as well as the Confirmation of API Prequalification (CPQ) issued by the WHO Prequalification Team Medicines Programme (WHO-PQ) for APIs as a validation of the quality of a certain API.

6.3.3. For an abridged/abbreviated review of the **full submission**, in addition to the documentation/information requirements laid out in sections 6.1 and 6.2 of this guideline, a so-called bridging report should be submitted by the applicant.

The bridging report:

6.3.4. The reference institution's assessments may not always account for specific circumstances that can significantly affect the benefit-risk of a medicine in other countries/regions. Hence, the reference institution's assessment reports may have to be considered incomplete, when a reference institution-approved product is submitted for the regulatory approval in The Gambia and the conditions of use or the benefit–risk profile of the medicine may differ. In these cases, the applicant should support the application by providing evidence of a positive benefit–risk profile for the proposed conditions of use in The Gambia.

6.3.5. Differences in target population, epidemiology and other features of the disease, concomitantly used medicines and hence the interaction potential, local treatment and diagnostic modalities, and other factors can substantially affect the benefit-risk profile of a medicine. There can also be issues related to certain quality parameters, especially in relation to the stability under different climatic conditions.

6.3.6. A bridging report should, in particular, justify the:

- comparability of the studied population to the target population (e.g. ethnicity, gender representation, age groups) as regards demonstration of efficacy and safety;
- relevance of reference institution-approved conditions of use as regards epidemiology and disease pattern in The Gambia as well as other implications for efficacy and safety, e.g. feasibility of monitoring and precautionary measures (e.g. resistance testing or therapeutic drug monitoring);
- interactions with food and with other medications relevant in The Gambia that are not discussed in the reference institution's assessment report;
- therapeutic role of a product and its recommended use according to relevant national and international treatment guidelines;
- quality issues, including but not limited to, storage conditions and conditions of administration and use;

- risk management plan for a new medicine (see 'Definitions' for details)

6.3.7. Provision of a bridging report is not mandatory, but may substantially facilitate conduct of the regulatory assessment, reduce the number of potential regulatory questions and shorten the duration of the regulatory approval process. This report has to be dated and signed by the author and the author's CV be attached.

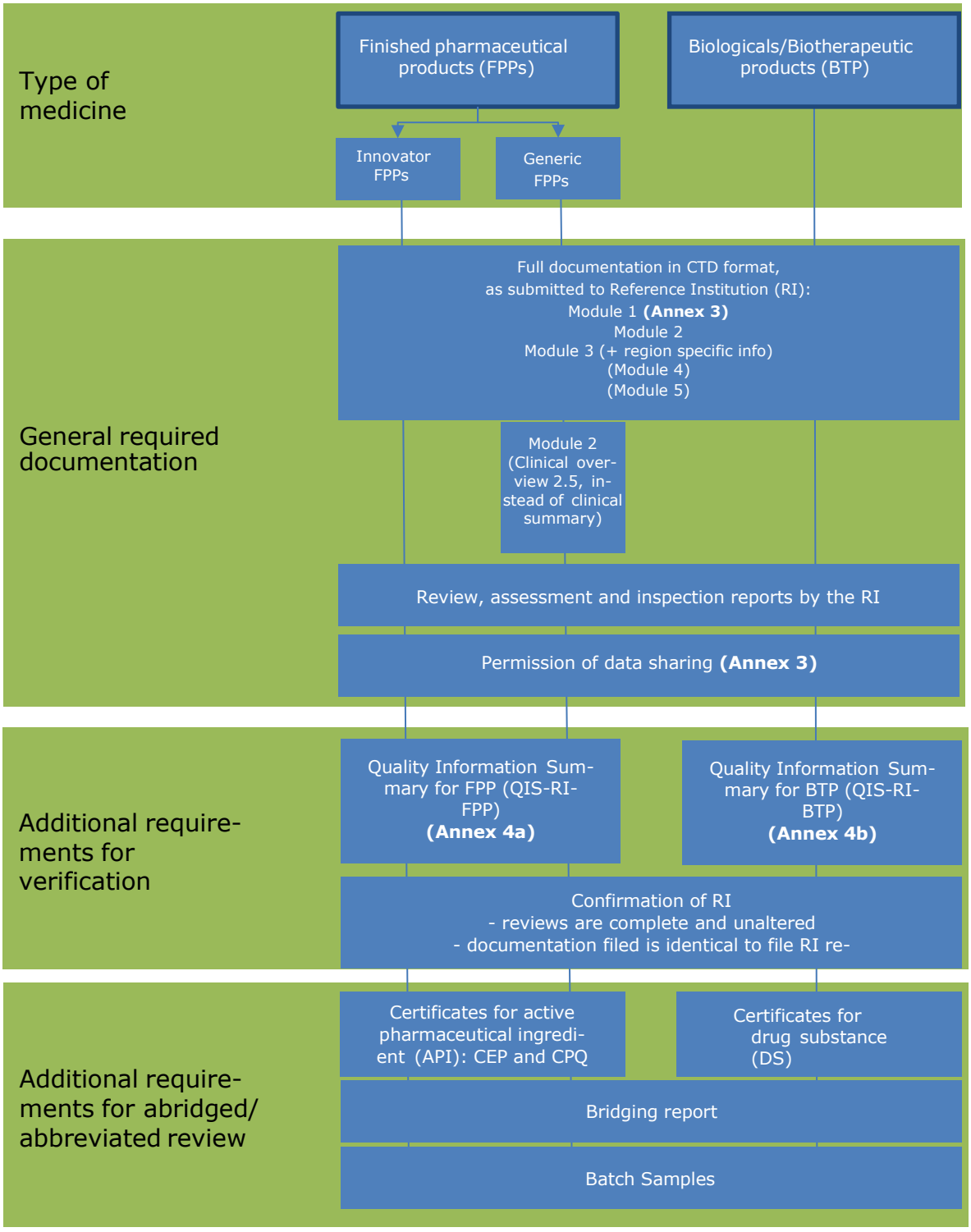

Figure 1: Documentation requirements in reliance-based approach for the application of marketing authorisation/registration or variations of medicines provided by the applicant

7 Guidance for Implementation

7.1 Guiding Principles

7.1.1. MCA adheres to the following guiding principles when using reference institutions' reviews:

a. MCA uses, where appropriate, reference institutions' reviews to perform part of the evaluation or to inform MCA's decision-making. However, MCA does grant (or refuse to grant) a marketing authorization or approve a variation based solely on the existence of a reference institution's review and its corresponding regulatory decision.

b. The use of reference institutions' reviews may be applicable, to variable degrees, to the regulatory review of medicines covered under the scope of this guideline and when available, are considered when determining the review strategy. However, an applicant will not be required to file a submission at a reference institution, nor will MCA unilaterally decide to delay the Gambia's review until a reference institution's review is available.

c. The extent to which a reference institution's review may be used to inform MCA's regulatory decision on a medicine will be guided by MCA's estimation of the benefits and risks/limitations of using that review (or components thereof) to inform the Gambian regulatory decision-making process.

d. The MCA reserves the right to subject all submissions for approval to an 'abridged' evaluation of a certain part of the application (e.g. relevant to use under local condition), such as product quality data in relation to climatic conditions and distribution infrastructure and a benefit-risk assessment in relation to use in the local ethnic population, medical practice/culture and patterns of disease and nutrition.

e. While the use of reference institutions' reviews may enhance timely access to high quality medicines, it is essential that benefit-risk assessments of health products be made within the context of the Gambia's health care system. Final regulatory decisions on the granting or refusal or approval of a marketing authorisation or variation of medicines for the citizens are made by MCA.

f. In all cases, the Gambia's product labelling (e.g. summary of product characteristics or professional product information, package insert or patient information leaflet) will be reviewed by MCA to ensure it meets Gambia's requirements, in accordance with the Medicines and Related Products Regulations, applying MCA standard operating procedures and current practices.

g. Confidentiality of submitted data and non-disclosure to a third party is assured by the organisational policies applied by MCA.

7.2 Timelines

7.2.1. Formal deficiencies in the submitted application and the dossier will be communicated to the applicant, in line with the MCA procedures. Timelines for

decisions from MCA as well as applicant response timelines are detailed in the respective authorisation guidelines.

7.3 Reliance Principles for variations

7.3.1. NRAs are encouraged to establish alternative accelerated timelines for variations on medicines that have previously been approved by the other NRAs. Accordingly, those NRAs should create a list of the NRA approvals they will recognise. As an expedite regulatory pathway the following approaches of accelerated timelines could be established:

- The NRA recognises the decision of other regulatory authorities and does not perform a review of supporting data but is informed of the change. Using this approach, NRA could allow changes to be implemented immediately after receipt of the change notification.
- The NRA performs an assessment of the decision of the NRA of the licensing country to determine if recognition of the latter NRA's decision is appropriate. Using this reliance-based approach, NRAs established abbreviated review timelines (for details see the respective authorisation (registration) guidelines).
- The NRA performs a partial review and evaluation of a complete supporting data package, as originally submitted to the licensing country. Using this approach, timelines would be expected to be shorter than the timelines of a common approval of variation.

7.3.2. If a variation application is rejected by MCA, this will be communicated to the applicant with an explanation for the rejection. As appropriate, there should be an opportunity for dialogue between the MCA and the applicant, as necessary, with the aim of resolving the NRA's concerns with the application.

7.3.3. Withhold/Suspension/Withdrawal of the product as authorised by the reference authority (or from the list of prequalified products) must be reported by the Marketing Authorisation Holder (MAH) to the MCA within 30 days including official document stating the reason for this action. When applicable, this should be a letter/document issued by the reference authority.

Definitions

Interpretations and abbreviations contained in the MCA Glossary can be found on the MCA Website: **www.mca.gm.**

The definitions provided below apply to the terms used in this guideline. They may have different meanings in other contexts and documents.

The interpretation of terms provided in the Act and Regulations apply, unless further defined in this guideline.

Abridged/abbreviated regulatory pathway/review
Regulatory procedures facilitated by reliance, whereby a regulatory decision is solely or partially based on application of reliance. This usually involves some work by the national regulatory authority (NRA) that is practising reliance. It is expected that use of reliance in these pathways will save resources and time as compared with standard pathways, while ensuring that the standards of regulatory oversight are maintained.

Applicant
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 authorisation holder)".

Finished Pharmaceutical Product (FPP)
Product that has undergone all stages of production, including packaging in its final container and labelling. An FPP may contain one or more active pharmaceutical ingredients.

Innovator finished pharmaceutical product
A novel medicinal product (medicine), which was the first product authorised for marketing by any country (normally as a patented product) on the basis of documentation of efficacy, safety and quality according to requirements at the time of the authorisation.

Marketing Authorisation Holder (MAH)
A company or other legal entity that has the authorisation by a regulatory authority to market a medicine or related product and who is responsible for its quality, efficacy and safety and for compliance with conditions of authorisation (registration)

Medicines/Medicinal Products
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

The term "medicines/medicinal products" in the context of this guideline includes finished pharmaceutical products (FPPs), biologicals (biotherapeutics), and vaccines. Not included are medical devices, in-vitro diagnostics, blood products and animal products.

Generic (multisource) finished pharmaceutical product
A medicine (medicinal product), which has the same qualitative and quantitative composition in active pharmaceutical ingredients and the same pharmaceutical form as the authorised reference medicine and which bioequivalence with the reference medicine has been demonstrated by appropriate bioavailability studies.

National regulatory authority (NRA)
A National s Regulatory Authority is a country's entity responsible for the registration, marketing authorisation, and other regulatory functions concerning medicines.

New Drug
A generic copy of an innovator product, that has not been previously registered as a pharmaceutical or biological product in The Gambia or which has been marketed in The Gambia for a period of not more than ten (10) years or any other period to be determined by the authority from time to time, for public health reasons.

Package
A box, packet or any other article in which one or more primary containers of medicines is or are to be enclosed in one or more other boxes, packets or articles

Patient Information Leaflet (PIL)
A leaflet in every pack of medicine containing information on the medicine for the user, such as patients.

Recognition
The acceptance of the regulatory decision of another regulator or other trusted institution. Recognition should be based on evidence of conformity that the regulatory requirements of the reference regulatory authority are sufficient to meet the regulatory requirements of the relying authority. Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement

Reliance (full and partial)
The act whereby the National Regulatory Authority (NRA) in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others. Full reliance means that the authority relies on the entire assessments/inspection and quality control reports performed by another regulatory authority. Partial reliance means that the authority relies on certain documents/parts of the assessments performed by another regulatory authority, while for the other part(s) an independent, full assessment of the documentation submitted by the applicant is conducted.

Reference institution
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 NRA (see **Annex 1**).

Summary of Product Characteristics (SmPC)
A document describing the properties and the officially approved conditions of use of a medicine; summaries of product characteristics form the basis of information for healthcare professionals on how to use the medicine safely and effectively

Variation
A variation is a change to the terms of a marketing authorisation. There are different types of variations with different regulatory requirements and procedures. For more detail for regulatory and procedural guidance proceed to MCA *Guideline for Variations* (MCA-GL-114).

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- MCA Guidance for the Application in the Common Technical Document (CTD) Format (MCA-G-112/02)
- MCA Guideline for Variations (MCA-GL-114)
- MCA Guideline for Stability Testing of Active Pharmaceutical Ingredients and Finished Pharmaceutical Products (MCA-GL-102)

List of Annexes

Annex 1: List of reference institutions

Annex 2: Documentation abridged procedure

Annex 3: Confirmation of data sharing

Annex 4a: QIS-RI-FPP

Annex 4b: QIS-RI-BTP