Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Guidance on using evaluation reports from Comparable Overseas Bodies

Evaluations of registered complementary medicines, assessed listed medicines and substances for use in listed medicines

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Contents

Scope of guidance document

Where possible, the TGA uses evaluation reports from comparable overseas bodies (COBs) in the evaluation of applications for registered complementary medicines, assessed listed medicines and substances for use as ingredients in listed medicines.

This guidance provides:

- an overview of the COB report-based process and application categories
  - the list of current COBs
  - criteria for the TGA's identification of COBs and acceptance of COB evaluations
- submission requirements for the use of COB evaluation reports.

SECTION A – Overview of the COB report-based process

Purpose of the COB report-based process

The COB report-based process is available for:

- applications for registered complementary medicines
- applications for assessed listed medicines
- applications for the evaluation of a substance for use as an ingredient in listed medicines.

The COB report-based process allows technical evaluation reports from identified bodies to be used by the TGA to assess applications against the Australian requirements through an abridged process. The TGA has criteria to identify suitable COBs using best practice evaluation processes that best aligns with the TGA's regulatory framework to an acceptable level. The list of COBs has been made using Stage 1 criteria (see Appendix) to establish sufficient similarity between the regulatory body and the TGA.

The aim of the process is to:

- encourage harmonisation and sharing of knowledge
- reduce TGA duplication of evaluations undertaken by COBs, while still maintaining existing quality, safety and efficacy standards for medicines supplied in Australia
- allow applications following the Application framework to have shorter evaluation timeframes.

The following guidance for each application type sets out the information and corresponding forms and checklists required to be submitted in an application:

- Application requirements for new substances in listed medicines – Australian regulatory guidelines
- Assessed listed medicines evidence guidelines

- Applications for registered complementary medicines.

Challenges in identifying suitable COB reports

Given the nature of complementary medicines and other low-risk medicinal products, few international bodies evaluate the quality, safety and efficacy of substances or medicines in a single report. Challenges that we face in identifying and using COB reports include, but are not limited to:

- differences in evaluation processes: complementary and other low-risk medicinal substances or products may be regulated internationally as foods, medicines, cosmetics or dietary supplements
- differences in inter-agency decisions: assessing these products or substances against different evaluation processes may lead to differences in inter-agency decisions about quality, safety and efficacy
- difficulties accessing un-redacted or unpublished evaluation reports
- use of a product or substance in the Australian context may differ from how it is used internationally
- language barriers.

Due to these challenges, the TGA makes the final regulatory decision on applications to ensure that safety, quality and/or efficacy are established in line with the Australian regulatory framework.

Application framework

Applications accepted for evaluation through the COB report-based process are expected to have shortened evaluation and decision timeframes when compared to the standard evaluation/assessment processes.

The following application categories allow us to undertake evaluations based on a combination of reports from COBs and/or data independently evaluated by the TGA:

- IN1-IN3 for substances for use as ingredients in listed medicines
- L(A)2 for assessed listed medicines
- RCM2-RCM4 for registered complementary medicines.

Under the application categorisation framework, applications in each category may be evaluated in one of three ways:

1. **Evaluation based on the use of COB evaluation reports**

   Applicants provide evaluation report(s) for the same substance or medicine from a COB that meets all minimum data requirements for safety, quality and/or efficacy (IN1, L(A)2 and RCM2). Safety or quality reports from one COB may also be submitted through the IN1 application category in conjunction with a suitable quality/safety report from another COB, or a monograph in a default standard to support the quality of the substance. The category of COB evaluation report will determine what other documents must be

submitted with an application. See Submission requirements for the COB report-based process for further details.

2. **Mixed evaluation**

   Applicants provide COB evaluation report(s) that meet all minimum data requirements for safety, quality and/or efficacy in combination with minimum data requirements for an independent evaluation of the missing parameters by the TGA (IN2, IN3, RCM3 and RCM4).

3. **Full independent evaluation**

   All quality, safety, and/or efficacy parameters independently evaluated by the TGA (IN4, L(A)3 and RCM5). COB reports may still be provided as supporting information for these application categories; however, the fee and legislated timeframe are not reduced.

Overview of the COB-based application process

Applicants should follow the below process:

1. Establish whether you have an evaluation report from a COB included on the List of bodies or jurisdictions determined to be Comparable Overseas Bodies.
2. Use the Stage 2 Criteria for acceptance of COB evaluation reports to determine if a particular COB evaluation report is suitable for a particular application.
3. Review the Submission requirements for the COB report-based process.

Please note: if the TGA has approved a substance/product based on a report that met the TGA's technical requirements at the time, the TGA will not retrospectively remove this substance/product unless there is a concern.

It is the responsibility of the applicant to obtain any relevant un-redacted COB evaluation reports, in English.

During application screening, the TGA will confirm whether the application is eligible for the COB report-based process and that the correct application category has been selected.

Depending on the quality and scope of the COB evaluation report(s) provided to the TGA, the TGA will not re-evaluate the data provided in the dossier that has been previously evaluated and approved by a COB. Where an applicant provides COB report(s) that meet all minimum data requirements, the TGA will only need to evaluate data generated specifically for the Australian context (for example: Australian labels or storage conditions). If any issues arise during the TGA's review of the COB evaluation report, the TGA may need to consider additional information.

Where the submission requirements for COB evaluation reports are not met, the application must be resubmitted for independent evaluation through the appropriate application category.

Pre-submission meetings

Due to differences in regulatory frameworks and evaluation process requirements, some applications may not be suited to the COB report-

based process. Applicants may wish to request a pre-submission meeting with TGA to discuss their application before lodging.

List of COBs for registered complementary medicines, assessed listed medicines and substances for use in listed medicines

The TGA will consider evaluation reports from the bodies specified in Table 1 (below) for use in the COB report-based process. This list has been determined by the Secretary for the purposes of regulation 16GJ of the *Therapeutic Goods Regulations 1990.*

Other regulatory frameworks and approaches taken by COBs may not remain static. Applicants will need to consider that not all reports may meet the requirements for the COB report-based process (see Gap analysis requirements). The list has been made using Stage 1 criteria to establish sufficient similarity between the regulatory body and the TGA (see Appendix). The TGA will refine this list as necessary.

Some products regulated as complementary or listed medicines in Australia may be evaluated as prescription medicines overseas. These products are assessed against more stringent safety/quality/efficacy requirements than the equivalent products in Australia. Therefore, the TGA will accept COB reports for such products that have been evaluated as prescription medicines by the COBs listed in Table 1 where the regulatory pathway has required a full data package/complete data dossier for assessment.

Table 1: List of bodies or jurisdictions determined to be Comparable Overseas Bodies (COBs) for registered complementary medicines, assessed listed medicines and substances for use in listed medicines

This table must be read in conjunction with the requirements specified for the relevant application category (see Application Framework and Submission requirements for the COB report-based process). There are some instances where multiple COB reports might need to be provided to satisfy specific application category requirements. For an IN1 application for example, the applicant may provide a report that covers both safety and quality from a single COB. Alternatively, a report that covers the safety of the ingredient from one COB, and a report that covers the quality of the ingredient from a different COB.

Body	Country or jurisdiction	How evaluation reports can be used			
		Safety	Quality	Efficacy	Notes
Australian Industrial Chemicals Introduction Scheme (formerly NICNAS)	Australia	ü	û	û	Reports may be used to support safety of **substances** proposed for use as ingredients in listed medicines (IN1 or IN2) when the substance is intended to be used as an excipient ingredient in sunscreens or other topical products.
Cosmetic Ingredient Review (CIR)	United States	ü	û	û	Reports may be used to support safety of **substances** proposed for use as ingredients in listed medicines (IN1 or IN2) when the substance is intended to be used as an excipient ingredient in sunscreens or other topical products.
European Food Safety Authority (EFSA)	European Union	ü	ü	û	Reports may be used to support safety and quality of **substances** proposed for use as ingredients in listed medicines (IN1, IN2 or IN3) when the substance is intended for oral use.
European Medicines Agency (EMA)	European Union	ü	û	û	Assessment reports for EU herbal monographs may be used to support safety of **substances** proposed for use as ingredients in listed medicines (IN1 or IN2) when the substance is a herbal material.

Body	Country or jurisdiction	How evaluation reports can be used			
		Safety	Quality	Efficacy	Notes
		ü	ü	ü	Reports for medicines submitted under Article 8(3) of Directive 2001/83/EC (full or full-mixed application, complete dossier) and assessed via the centralised procedure[1] may be used to support safety, quality and efficacy of **registered complementary medicines** (RCM2, RCM3 or RCM4) and efficacy of **assessed listed medicines** (L(A)2).
Food and Drug Administration (FDA) **Center for Drug Evaluation and Research (CDER)**	United States	ü	ü	ü	Reports that form part of a New Drug Application may be used to support the safety, quality and efficacy of **registered complementary medicines** (RCM2, RCM3 or RCM4); safety and quality of **substances** for use as ingredients in listed medicines (IN1, IN2 or IN3)**;** and efficacy of **assessed listed medicines** (L(A)2).
		ü	û	û	Assessment reports for monographs for OTC ingredients determined to be 'Generally Recognized as Safe and Effective (GRASE)' may be used to support the safety of **substances** proposed for use as ingredients in listed medicines (IN1 or IN2)

[1] See https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines#centralised-authorisation-procedure-section for information about the types of medicines that can be evaluated under the centralised procedure.

Body	Country or jurisdiction	How evaluation reports can be used			
		Safety	Quality	Efficacy	Notes
Food Standards Australia New Zealand (FSANZ)	Australia	ü	û	û	Reports may be used to support the safety of **substances** proposed for use as ingredients in listed medicines (IN1 or IN2) when the substance is intended for oral use.
Health Canada (HC)	Canada	ü	û	û	Reports for Natural Health Products may be used to support safety of **substances** proposed for use as ingredients in listed medicines (IN1 or IN2).
		û	û	ü	Reports for Natural Health Products may be used to support efficacy[2] of **assessed listed medicines** (L(A)2).
		ü	û	ü	Reports for Natural Health Products may be used to support safety and efficacy[3] of **registered complementary medicines** (RCM3 or RCM4).
		ü	ü	û	Assessment reports for Monographs from the Compendium of monographs may be used to support the safety and quality of **substances** proposed for use as ingredients in listed medicines (IN1, IN2 or IN3).

[2] Health Canada reports to support efficacy must rely primarily on clinical trial reports, systematic reviews and meta-analyses to support the indications.
[3] Health Canada reports to support efficacy must rely primarily on clinical trial reports, systematic reviews and meta-analyses to support the indications.

Body	Country or jurisdiction	How evaluation reports can be used			
		Safety	Quality	Efficacy	Notes
Health Sciences Authority (HSA)	Singapore	ü	û	û	Reports for existing ingredients used in Chinese Proprietary medicines with a proposed new scope for use (e.g.: dose, therapeutic use, route of administration) or with emerging safety concerns may be used to support safety of **substances** proposed for use as ingredients in listed medicines (IN1 or IN2).
Joint FAO/WHO Expert Committee on Food Additives (JECFA)	Global	ü	û	û	The WHO Technical Report Series and WHO Food Additives series (FAS) may be used to support safety of **substances** proposed for use as ingredients in listed medicines (IN1 or IN2) when the substance is intended for oral use.
		û	ü	û	Assessment reports for the FAO JECFA Monographs may be used to support quality of **substances** proposed for use as ingredients in listed medicines (IN1 or IN3) when the substance is intended for oral use.
Pharmaceutical and Medical Devices Agency (PMDA)	Japan	ü	ü	ü	Reports for Category 1[4] OTC products (herbal medicines) may be used to support the safety, quality and efficacy of **registered complementary medicines** (RCM2, RCM3 or RCM4)**.**
		û	û	ü	Reports for Category 1 OTC products may be used to support efficacy of **assessed listed medicines** (L(A)2).

[4] Category 1 products are those with new active ingredients only.

Body	Country or jurisdiction	How evaluation reports can be used			
		Safety	Quality	Efficacy	Notes
		ü	ü	û	Reports for Category 1 Quasi drugs (herbal medicines) may be used to support the safety and quality of **registered complementary medicines** (RCM3 or RCM4).
Scientific Committee on Consumer Safety (SCCS)	European Union	ü	ü	û	Reports may be used to support safety and quality of **substances** proposed for use as ingredients in listed medicines (IN1, IN2 or IN3) when the substance is intended to be used as an ingredient in sunscreens or other topical products.

Criteria for acceptance of COB evaluation reports

Once an applicant has determined that a report is from a COB included on the List of bodies or jurisdictions determined to be Comparable Overseas Bodies, applicants must determine if the report is suitable for an abridged application. The Stage 2 criteria below focus on the specifics of a particular application. The criteria will be applied to determine whether a COB evaluation report is suitable for the particular application and therefore can be used to support the application. The COB checklist addresses most of the Stage 2 criteria.

Note that we will consider accepting reports from COBs that may not meet all the criteria where the applicant can provide adequate justification and/or additional data as required. The TGA reserves the right to require the applicant to resubmit their application under a different application category if the COB evaluation report provided by the applicant does not meet the Stage 2 criteria.

Stage 2 criterion 1

The substance or medicine described in the COB report should be equivalent to that proposed in the application.

Any differences in characteristics such as formulation, manufacture, and indications must be clearly justified by the applicant. To meet this criterion:

- The evaluation report should relate to the same medicine or substance as approved by or submitted to the COB, and have the same:
  - formulation (quality specifications)

  - quality aspects
  - dosage form
  - dose
  - directions for use
  - route of administration.

- The manufacturing process should be comparable to that evaluated by the COB. Under certain conditions, additional manufacturing sites can be included in the application to the TGA, where that manufacturing site has been validated and shown to be the same or better than the original manufacturer.
- For products, the proposed indication(s) for the medicine should be based on similar:
  - population demographics
  - disease profiles
  - expectations regarding public health outcomes between Australia and the COB.

There should be no new indications proposed beyond what the report considered.

For generic products, the proposed indication(s) should be the same as the indication(s) approved for the originator. For non-generic products, acceptable differences between the COB-approved and proposed indication(s) are limited to minor changes in the wording or minor differences in expression, as long as the text describes the same:

  - dosing range
  - patient population
  - health outcome expectation
  - intent and meaning.

Inter-agency comparison of efficacy is a complex process due to the different levels of indications/claims allowed and evidence required by each body.

The evidence requirements may be comparable in some situations; however, in other circumstances this will not be the case. In these circumstances, the TGA will make the final regulatory decision ensuring that efficacy is established in line with the Australian regulatory framework.

Stage 2 criterion 2

Evaluation reports should be prepared using guidelines and standards consistent with those used by the TGA.

To meet this criterion:

- Evaluation reports should be consistent with the methodology used by the TGA, for example they should contain information consistent with the Common Technical Document (CTD) requirements for product applications.

- Evaluation reports should contain all information necessary to support the relevant assessment parameters (safety, quality and/or efficacy).

Differences in methodology do not necessarily prevent the use of evaluation reports. Applicants should address any differences between TGA requirements and the COB report (see Gap analysis requirements for more information).

Stage 2 criterion 3

Evaluation reports should be un-redacted and complete.

To meet this criterion, the evaluation reports should, where possible, include correspondence related to the application (for example, questions asked of, and deliberations by advisory bodies). The Australian applicant is responsible for providing the reports to us when lodging the application.

Stage 2 criterion 4

The TGA should be able to use evaluation reports from COBs and any supplementary information to publish general information about the safety, quality and/or efficacy of the medicine.

To meet this criterion, evaluation reports that are provided to us should not be subject to any restrictions on use or disclosure by the TGA beyond what would normally apply with any application.

For more information, see:

- TGA approach to disclosure of commercially confidential information (CCI).

Stage 2 criterion 5

The report should be an independent evaluation made by a COB.

To meet this criterion:

- The submitted evaluation report should be fully written by the COB (a *de novo* report).
- The submitted evaluation report should present an independent evaluation of the data provided to the COB and not be an acceptance of another body's marketing approval.

Reports drafted as part of a self-affirmed/self-assessed report, for example: the Generally Recognized as Safe (GRAS) self-affirmation, are not suitable as an independent *de novo* evaluation.

Stage 2 criterion 6

Where the COB makes decisions relating to market approval, the criteria below are required.

For new medicine applications (RCM or Assessed listed medicines), the medicine should have received full marketing approval following the evaluation of the application by the COB.

To meet this criterion:

- The medicine should not be subject to any further restrictions or conditions that have not been identified in the report.
- The medicine must have current approval in the COB jurisdiction (unless otherwise justified).
- The medicine should not have resulted in a rejected, refused, cancelled, or withdrawn marketing approval at any time, or received a ‘refusal to approve’, or be the subject of an application that is currently delayed or deferred, in any jurisdiction (unless otherwise justified).

For new substance applications (IN1-IN3), the substance should have been evaluated by a COB to ascertain the quality or safety of the substance.

To meet this criterion:

- The substance should not be subject to any further restrictions or conditions that have not been identified in the evaluation report.
- The substance must have a current approval in the COB jurisdiction (unless otherwise justified).
- The substance should not have resulted in a rejected, refused, cancelled or withdrawn application or received a ‘refusal to approve’ at any time, or be currently the subject of an application that is delayed or deferred, in another jurisdiction (unless otherwise justified). Applicants should identify whether public information is available on the application status of the substance in other jurisdictions through the systematic literature search and by searching relevant websites, including from the list of COBs.

SECTION B – Submission requirements for the COB report-based process

The information below provides guidance on the submission requirements for the COB report-based process.

COB checklists

You must complete and submit the relevant COB checklist as part of your application. This checklist is mandatory and will enable the TGA to assess whether the application meets the requirements of the selected application category and to confirm the extent of additional data that will require evaluation by the TGA.

If you are providing multiple COB evaluation reports (i.e. separate for Quality, Safety and/or Efficacy), complete the checklist for each COB report.

Gap analysis

COB regulatory frameworks may change over time; therefore, there is a possibility that reports from a particular COB may not always meet Australia's mandatory requirements.

Applicants must provide a gap analysis:

- discussing how the COB evaluation report addresses the Australian mandatory requirements for safety, quality and/or efficacy for the relevant application type (registered complementary medicines, assessed listed medicines, or substances for use as ingredients in listed medicines). This could be provided in a simple table with references to pages within the COB report. If there is missing information, you may provide a justification outlining why the missing information is not required to adequately demonstrate the safety, quality and/or efficacy of the medicine or substance, or submission of additional data to address any gaps (e.g. Australian labels).
- to determine any relevant data that may have been generated since the COB report was approved (e.g. an updated literature search with new toxicity or clinical studies, or new adverse event reports).

When is the dossier of information used to support a COB report required?

The TGA recognises that not all COB evaluation reports are initiated by a sponsor *per se*, meaning that industry partners are not responsible for preparing, and therefore do not possess the safety, quality and/or efficacy dossier upon which the evaluation report(s) are based.

Substances for use in listed medicines

In general, the underlying dossier (e.g. the copies of the clinical trials, toxicology studies etc.) that supports the COB report is not required for applications for new substances for use in listed medicines. This is in recognition that many evaluation reports generated for substances are not initiated by an applicant. However, for applicant-driven reports, if the original dossier submitted to the COB is available this can be provided.

Registered complementary medicines and assessed listed medicines

The underlying dossier is required for all applications for new products (i.e. assessed listed medicines and registered complementary medicines) as described in the requirements specific to different application types section below. This is because product applications are generally initiated by an applicant, and TGA requires detailed product specific information (e.g. the details of the formulation) to support approval of the medicine and consideration of future changes that may be made to the medicine while it is included on the ARTG.

Requirements specific to different application types

Substances for use in listed medicines

For the COB report-based process, applicants must submit the information as described in the Mandatory requirements for an effective application to vary the Permissible Ingredients Determination. These requirements include:

- The complete and un-redacted set of final COB evaluation report(s) in English.
- The completed COB checklist for substance evaluations.
- A gap analysis.

Registered complementary medicines and assessed listed medicines

For the COB report-based process, applicants must submit the complete dossier that was submitted to the COB with an Australian-specific Module 1. Requirements for registered complementary medicines are outlined in the Mandatory requirements for an effective registered complementary medicine application, and those for assessed listed medicines in the Mandatory requirements for an assessed listed medicine application to pass preliminary assessment. The requirements include:

- In Module 1.2, the relevant completed COB checklist:
  - for registered complementary medicines
  - for assessed listed medicines
- For generic medicines, in Module 1.2, evidence that the reference product used in any evaluation of bioequivalence is identical to the Australian reference product (see Guidance 15: Biopharmaceutic studies).
- In Module 1.11.1, full details of whether the application has been approved, approved on appeal, rejected, refused, cancelled, withdrawn or has received a ‘refusal to approve’ at any time, or is currently delayed or deferred, in another jurisdiction.
- In Module 1.11.4, the complete and un-redacted final COB evaluation report(s) in English.
- In Module 1.11.4, a gap analysis.

APPENDIX

Stage 1 Criteria: Establishing similarity between the COB and the TGA

Below is an overview of how the COBs included in the List of bodies or jurisdictions determined to be COBs for complementary and listed medicines were identified by the TGA. The Stage 1 criteria explain how sufficient similarity between the overseas body and the TGA is established. Evaluation reports from these COBs can then be used to support an application submitted through a COB report-based process, provided the evaluation report(s) also meets the Stage 2 criteria.

Stage 1 criterion 1

The COB is an internationally recognised body with an established track record of evaluating similar food, chemical or medicinal products/substances.

To meet this criterion, the COB:

- Has a similar evaluation process to the TGA in terms of what must and must not be taken into account when making decisions.
- Conducts:
  - independent *de novo* pre-market evaluations of the type of applications that are of interest to us (for example, evaluations of plant or herbal materials, vitamins and minerals)
  - similar pre-market safety, quality and efficacy evaluations of substances and/or medicines
  - similar post-market activities including pharmacovigilance programs.

Stage 1 criterion 2

The COB has a transparent system for decision-making.

Noting the uniqueness of the Australian complementary and listed medicines regulatory framework, this criterion does not limit the contexts or frameworks from which we will accept evaluation reports. Instead, it requires that the TGA be able to develop confidence in the transparency and robustness of the operating principles of the COB.

To meet this criterion, the COB would need to:

- Have a transparent system for its evaluation processes.
- Have a transparent system for legal accountability including:
  - confidentiality
  - intellectual property
  - impartiality
  - transparency
  - conflict of interest processes.

- Have a clear decision-making framework.
- Have clear risk-assessment methodologies that do not conflict with our operating principles.

Stage 1 criterion 3

The COB uses international guidelines and standards consistent with those adopted by the TGA.

Rather than mandating specific guidelines, this criterion captures the principle that we need to have confidence in the scientific processes used. To best make use of overseas evaluations, any differences in how these international standards are adopted needs to be well understood.

To meet this criterion, the COB would need to:

- Have established scientific evaluation processes, such as processes in accordance with:
  - pharmacopoeial standards adopted by Australia:
    - European Pharmacopoeia
    - British Pharmacopoeia
    - United States Pharmacopeia – National Formulary
  - the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) or other international guidelines.

Stage 1 criterion 4

The TGA should have, or be able to establish, a relationship with the COB.

To meet this criterion, the COB would need to:

- Be able to conduct their business and release reports in English.
- Give Australian applicants the evaluation reports in English for inclusion in the Australian application (this can include reports that have been translated into English from another language by the COB). Obtaining a certified translation is not the responsibility of the TGA.
- Be able to interact with the TGA in English, particularly where a sponsor submits certified English translations of evaluations.
- Be able to clarify information and address issues of confidentiality or data protection with the TGA if required.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Complementary and Over the Counter Medicines Branch	November 2019
V1.1	Amendments to the List of COBs including: • Removal of '*European Pharmacopoeia* monographs' • Updated NICNAS to Australian Industrial Chemicals Introduction Scheme (formerly NICNAS) Minor amendments to document including: • Removal of the mention of default standards as these are not within the scope of this document • Typographical errors	Complementary and Over the Counter Medicines Branch	April 2022
V2.0	New document structure to improve readability. Update all links. Update references to IN1 application category to align with new Regulations. Clarification that a COB may have changed processes or regulatory frameworks over time so not all reports from that agency may meet Stage 2 criteria. Table 1 changes: - Revise PMDA entry to include efficacy reports that may be accepted. - Revise SCCS entry to accept reports to support safety and quality of excipient and active substances for dermal use. - Revise Health Canada entry for Monographs from the Compendium of monographs to clarify assessment reports are required.	Complementary and Over the Counter Medicines Branch	February 2023

Version	Description of change	Author	Effective date
	New text to clarify submission requirements for COB report-based process, and when a dossier and gap analysis are required. Change reference to Module 1.2.1 to Module 1.2 in submission requirements. Correct error in Appendix 1 to clarify the COB must provide the report in English. Clarification of COB stage 2 requirements. Formatting and typographical changes.		

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