

**Administrative Arrangement under Article 15.3(f) of the Protocol
on the Mutual Recognition of the Compliance and Enforcement Programme
regarding Good Manufacturing Practices for Pharmaceutical Products**

Procedure for Evaluating New Regulatory Authorities

This administrative arrangement is not intended to create rights or obligations under international or domestic law and, in line with Article 15(7) of the Protocol, is not subject of the provision of Chapter 29 of the CETA Agreement.

Between DG SANTE and Health Canada

Friday, November 16, 2018

DG Santé is a Directorate General of the European Commission.

Health Canada is a Federal department of the Government of Canada.

This administrative arrangement has been approved by the European medicines Agency (EMA) and the competent authorities of the Member States.

1. Introduction

The Equivalence of new regulatory authorities is one of the main elements of the CETA Protocol to the Mutual Recognition of the Compliance and Enforcement Programme regarding Good Manufacturing Practices for Pharmaceutical Products (CETA GMP Protocol) which the Participants, through the Joint Sectoral Group (JSG), are required to establish under Article 12 of the CETA GMP Protocol through an Administrative Arrangement pursuant to Article 15.3(f) (Procedure for Evaluating New Regulatory Authorities).

This Administrative Arrangement sets out the operational arrangements to fulfil the requirements of Article 12.

Article 12

Equivalence of new regulatory authorities

1. A Party ("requesting Party") may request that a regulatory authority in its territory that is not recognised as equivalent to regulatory authorities in the other Party ("evaluating Party"), be evaluated to determine whether it should be recognised as equivalent. Upon receiving the request, the evaluating Party shall conduct an evaluation pursuant to the procedure for evaluating new regulatory authorities under the GMP Administrative Arrangement referred to in Article 15.3.

2. The evaluating Party shall evaluate the new regulatory authority by applying the components of a GMP compliance programme under the Administrative Arrangement referred to in Article 15.3. The components of a GMP compliance programme must include such elements as legislative and regulatory requirements, inspection standards, surveillance systems and a quality management system.

3. If, upon completion of its evaluation, the evaluating Party determines that the new regulatory authority is equivalent, it shall notify the requesting Party in writing that it recognises the new regulatory authority as equivalent.

4. If, upon completion of its evaluation, the evaluating Party determines that the new regulatory authority is not equivalent, the evaluating Party shall provide to the requesting Party a written justification demonstrating that it has well-founded reasons for not recognising that the new regulatory authority is equivalent. At the request of the requesting Party, the Joint Sectoral Group on Pharmaceuticals ("Joint Sectoral Group") referred to in Article 15 shall consider the evaluating Party's refusal to recognise the new regulatory authority as equivalent, and may provide recommendations to assist both Parties to resolve the matter.

5. If, upon completion of its evaluation, the evaluating Party determines that the new regulatory authority is only equivalent for a more limited scope than that proposed by the requesting Party, the evaluating Party shall provide to the requesting Party a written justification demonstrating that it has well-founded reasons to determine that the new regulatory authority is only equivalent for the more limited scope. At the request of the requesting Party, the Joint Sectoral Group shall consider the evaluating Party's refusal to recognise the new regulatory authority as equivalent, and may provide recommendations to assist both Parties to resolve the matter.

6. A regulatory authority recognised as equivalent under the Agreement on Mutual Recognition Between the European Community and Canada, done at London on 14 May 1998, is recognised as equivalent under this Agreement from its entry into force.

2. Purpose

The purpose of this Administrative Arrangement is to outline the procedures for evaluating new regulatory authorities (RA) referred to in Article 12 of the *CETA GMP Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products*. Specifically, Article 12 sets out the procedure to determine whether a regulatory authority that is not recognized as equivalent could be determined to be equivalent with respect to its GMP Compliance Programme.

3. Scope and Application

This Administrative Arrangement is applicable to the Requesting Participant (RP) whose RA is not yet recognized as equivalent to the Evaluating Participant (EP) and to the RA of the Participant that is requested to perform the equivalency evaluation. The Participants to this Administrative arrangement are the Regulatory Authorities of the EU on the one side, and Canada on the other side.

4. Evaluation Procedure

The evaluation procedure consists of three general steps before a Participant determines whether a RA of the other Participant is equivalent: documentation review, on-site assessment, and reporting process. A decision on equivalency is made as per Article 12 (3), (4) and (5) of the CETA GMP Protocol. The decision on equivalency will be followed by an operational phase initiated between the Participants.

A. Documentation Review

1. The RP, through its RA that should be assessed, may initiate the request for equivalency by submitting a letter signed by the person in authority to the relevant EU and Canadian contact points specified in the Administrative Arrangement under Article 15.3(c) confirming that the RA is ready to be evaluated.
2. The EP will request to hold an “Introductory teleconference” with the RA after receiving the request. The teleconference will be to discuss the assessment process, confirm the scope of products included in the Annex 1 to the CETA GMP Protocol, and to familiarize the EP with the RA’s organization.
3. The Participants may also work in accordance with a jointly established schedule setting out the necessary timelines to address the different steps of the evaluation process. The schedule will be approved by the Joint Sectoral Group (JSG) at meetings or through other means.
4. The RA will conduct a self-assessment based on the evaluation guide for the components of a good manufacturing practices compliance programme set out in the Administrative Arrangement pursuant to Article 15.3 (e) of the CETA GMP Protocol. The RP’s self-assessment and the provision of complete supporting documentation will be done in accordance with the schedule. The receipt of these documents by the EP will initiate the documentation review process.
 - 4.1 The documents will be approved as per the RA approval process and provided in an electronic format.

4.2 The documentation review process commences if documents are provided to the EP in English.

4.3 The EP will proceed with the documentation review once the self-assessment and supportive documents are received. The EP will assess the information provided for each component of a good manufacturing practices compliance programme, as set out in the Administrative Arrangement pursuant to Article 15.3 (e) of the CETA GMP Protocol. The EP may request additional supporting documents that substantiate the information provided by the RP. The EP may organize technical teleconferences to obtain clarifications on the information provided by the RP, if needed.

B. On-Site Assessment

5. The EP should inform the RA based on the documentation review whether to proceed with an on-site assessment. If the decision is not to proceed with the on-site assessment, the EP will provide a written rationale for the decision to the RP and JSG.

5.1 The EP should coordinate the on-site assessment with the RA. The on-site assessment consists of an evaluation of the Inspectorate of the RA, the RA Laboratories and manufacturing sites that will be inspected by the RP and observed by the EP. The on-site assessment may be extended to other departments and/or agencies/ministries where activities of the GMP compliance programme are delegated to external distinct organizations.

5.2 The RA will identify a number of manufacturing sites (including one sterile site) in their domestic inspection planning cycle that may be chosen for the on-site assessment within the period of the evaluation process.

C. Reporting Process

6. The RA will provide the final inspection reports for the observed sites to the EP in accordance with the RP's legislative or policy timeframe.

6.1 The EP will provide a draft evaluation report to the RP after the review of the inspection reports from the EP. The RP will have the opportunity to provide comments and corrective measures, if applicable, within a jointly decided upon time period.

6.2 The EP will finalize the report after having received comments, if any, from the RP. The EP will inform the RP of its decision on equivalency and the final report. The EP will inform the JSG of the main conclusions.

6.3 Articles 12.3, 12.4 and 12.5 of the CETA GMP Protocol will apply to the process following the completion of the evaluation of the new RA.

D. Initiation of the Operational Phase

7. Once the RA of the RP has been determined to be equivalent by the EP and upon agreement by the JSG, the operational phase is initiated on a date jointly decided by the Participants.

7.1 The operational phase implements immediately the following elements of the CETA GMP Protocol:

- a. Recognition and exchange of Certificates of GMP Compliance
 - b. Acceptance of batch certificates
 - c. Inclusion of the RA in the Two-Way Alert Programme
 - d. Inclusion of the RA in the Equivalence Maintenance Programme
 - e. Exchange of contact names/contact points of the RAs for operational matters
 - f. Listing the RA in the public domain in accordance with CETA GMP Protocol Article 4.2.
8. The evaluation of the RA will remain valid as long as the CETA GMP Protocol will be in force and significant changes to the GMP compliance programme of a RA have been assessed and determined as having no impact on equivalence.

Summary overview of the assessment process

	STEP	WHO
1.	Request for assessment	RP
2.	Organize an introductory teleconference with RP	EP
3.	Provide self-assessment and the complete supporting documentation requested by EP	RA
4.	Finalize documentation review (or written rationale if no on-site visit)	EP
5.	Inform the RP whether proceeding or not with the on-site assessment	EP
6.	Organize and conduct the on-site assessment, if applicable	EP
7.	Provide final inspection reports from observed inspections to EP	RA
8.	Provide a draft evaluation report to RP after review of the inspection reports	EP
9.	Provide comments on the draft evaluation report and corrective actions to EP	RA
10.	Finalize the evaluation report and inform RP and JSG of the main conclusion and equivalence decision	EP
11.	Initiation of the Operational Phase	EP & RP