

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

Components of the Information Sharing Process

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 Information Sharing Process 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 11 of the CETA GMP Protocol through an Administrative Arrangement pursuant to Article 15.3(d) (The Components of the Information Sharing Process).

This Administrative Arrangement sets out the operational arrangements to fulfil the requirements of Article 11.

Article 11

Two-way alert programme and information sharing

1. A Party shall, pursuant to the two-way alert programme under the GMP Administrative Arrangement referred to in Article 15.3:

a. ensure that a restriction, suspension or withdrawal of a manufacturing authorisation that could affect the protection of public health is communicated from the relevant regulatory authority in its territory to the relevant regulatory authority in the territory of the other Party; and

b. if relevant, proactively notify the other Party in writing of a confirmed report of a serious problem relating to a manufacturing facility in its territory, or as identified through an on-site evaluation or inspection in the territory of the other Party, including a problem related to quality defects, batch recalls, counterfeited or falsified medicinal products or drugs, or potential serious shortages.

2. A Party shall, as part of the components of the information sharing process under the GMP Administrative Arrangement referred to in Article 15.3:

a. respond to a special request for information, including a reasonable request for an inspection report or an on-site evaluation report; and

b. ensure that, at the request of the other Party or of an equivalent authority of the other Party, an equivalent authority within its territory provides relevant information.

3. A Party shall provide the other Party, through written notification, contact points for each equivalent authority in its territory.

2. Purpose

- 2.1 This Administrative Arrangement provides the framework for the sharing of information between the Participants.
- 2.2 The Regulatory Authorities (RAs) of the Participant to the CETA GMP Protocol on the Mutual Recognition of the Compliance and Enforcement Programme regarding Good Manufacturing Practices for Pharmaceutical Products (herein referred to as the CETA GMP Protocol), should:
- a. cooperate on the exchange of information;
 - b. structure the nature and scope of information shared between the Participants; and,
 - c. identify respective accountabilities and roles of the RAs when information is shared.

3. Scope and Application

- 3.1 Information that may be shared under this Administrative Arrangement is set out in the CETA GMP Protocol.
- 3.2 The aim of the sharing of information under this Administrative Arrangement is to facilitate the risk management of all medicinal products or drugs as set out in Annex I of the CETA GMP Protocol.
- 3.3 This Administrative Arrangement does not have an effect on the ability of the RA of each Participant to carry out their respective regulatory responsibilities and programs, nor does it create legally binding obligations on a Participant to share information with the other Participant.
- 3.4 This Administrative Arrangement does not affect the roles of the RAs of the Participant under the existing Memoranda of Understanding, nor does it preclude RAs of the Participant from entering into separate bilateral or multilateral instruments with third parties for special programs that can be handled more efficiently and expeditiously by special arrangements.

4. Requesting and Providing Information

- 4.1 RA(s) of each Participant will request information in writing through its respective contact points, as set out in the list pursuant to Article 15.3(c), who are in charge of matters arising under the CETA GMP Protocol.
- 4.2 RA(s) of each Participant will request information relating to types of information referred to in paragraph 6 of this Administrative Arrangement, and that falls within the parameters and scope of the CETA GMP Protocol.
- 4.3 Each Participant will endeavour to provide requested information within the timeframe identified by the requesting Participant in its request. The volume and complexity of

data/information requested by a Participant affect the ability of the responding Participant to provide information in a timely manner.

5. Factors Affecting the Request

5.1 RA(s) of each Participant should consider the following factors in preparing requests for information, or in its response to a request for information:

- a. the nature, scope, significance, urgency of the matter and, impact on public health;
- b. the relevance of the information to its regulatory and legislative mandate;
- c. the degree to which internal discussion has occurred, and whether a position or administrative action is planned or has been taken; and,
- d. The lack of scientific certainty or conclusive data with respect to the information and whether the Requesting Participant needs more advice to supplement its expertise on the matter.

6. Types of Information

6.1 In response to a written request for information, the RA responding to a request should share information including, but not limited to, the following:

- a. laws, regulations, policies, guidance documents, procedures relating to the requested information of the Responding Participant;
- b. information related to the good manufacturing practices for pharmaceutical products that could have an impact on public health; and,
- c. the Responding Participant's regulatory action, including its proposed market withdrawals, product recalls and enforcement activities.

6.2 The information shared by the RA responding to request should be the most recent valid information available on the subject.

6.3 The date when the shared information was generated by the RA responding to a request can be prior to the date of the entry in force of the CETA Protocol.

7. Confidentiality

7.1 Article 14 of the CETA GMP Protocol (confidentiality) applies to the sharing of information under this Administrative Arrangement.

7.2 If a judicial or legislative mandate requires disclosure of non-public information, each Participant will inform the other Participant within two working days of any effort made to obtain non-public information received from the other Participant.

8. Administration

8.1 RA(s) of each Participant should promptly notify the other Participant of any changes to laws, regulations, policies or procedures that would affect its ability to act in accordance with this Administrative Arrangement.

8.2 The Participants may amend and/or terminate this Administrative Arrangement upon their mutual written consent and in consultation with the JSG.

8.3 The RA responding to a request for information should not levy costs or charges in providing responses to such requests for information.

9. Effective Date

This programme comes into operation on the date of its adoption by the Joint Sectoral Group on Pharmaceuticals.