

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

**List of Contact Points responsible for matters arising under CETA Good Manufacturing  
Practices Protocol**

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

This Administrative Arrangement provides the List of contact points responsible for matters arising from the Administrative Arrangements set out in Article 15.3 of the Protocol to the Canada – European Union Comprehensive Economic and Trade Agreement between the European Union and Canada on the Mutual Recognition of the Compliance and Enforcement Programme Regarding Good Manufacturing Practices for Pharmaceutical Products (CETA GMP Protocol).

### Article 15

3. *The Joint Sectoral Group shall conclude a GMP Administrative Arrangement to facilitate the effective implementation of this Protocol. The GMP Administrative Arrangement shall include:*

- a. the terms of references of the Joint Sectoral Group;*
- b. the two-way alert programme;*
- c. the list of contact points responsible for matters arising under this Protocol;*
- d. the components of the information sharing process;*
- e. the components of a good manufacturing practices compliance programme;*
- f. the procedure for evaluating new regulatory authorities; and*
- g. the equivalence maintenance programme.*

## 2. Purpose

This Administrative Arrangement provides the contact points of both Participants and facilitates the application of the Administrative Arrangements referred to in Article 15.3 of the CETA GMP Protocol.

## 3. Scope

This list of contact points responsible for matters arising under this Protocol applies to:

- 1) Regulatory Authorities listed in Annex 2 to the CETA GMP Protocol which were found equivalent after the initial confirmation pursuant to provisions of *Article 12 Equivalence of new regulatory authorities* of the CETA GMP Protocol.
- 2) Regulatory Authorities that are legal successors of the authorities referred to in paragraph (1).
- 3) Regulatory Authorities which were recognized as equivalent under the EU-Canada Mutual Recognition Agreement (MRA) of 14 May 1998 and which remained equivalent at the time of entry into force of the CETA.
- 4) New regulatory authorities seeking recognition of their equivalency under *Article 12* of the CETA GMP Protocol.

## 4. Contact Points

<b>Administrative Arrangement</b>	<b>FOR CANADA</b>	<b>FOR EUROPEAN UNION</b>
Terms of reference of the Joint Sectoral Group – Article 15.3 (a)	<u>Co-chair</u> Director General, Health Product Compliance Directorate (HPCD) Regulatory Operations and Enforcement Branch (ROEB) Health Canada Phone: (001) 613 957 6836	<u>Co-chair</u> Head of Unit, Unit B 4. Medical products: Quality, Safety, Innovation Directorate General for Health and Food safety European Commission

Administrative Arrangement	FOR CANADA	FOR EUROPEAN UNION
	<p>Email:  <a href="mailto:hc.drug.international.affairs-affaires.internationales.drogue.sc@canada.ca">hc.drug.international.affairs-affaires.internationales.drogue.sc@canada.ca</a></p> <p>Director, Health Product Inspection and Licensing (HPIL)  Regulatory Operations and Enforcement Branch (ROEB)  Health Canada  Phone: (001) 613 954 2996  Email:  <a href="mailto:hc.drug.international.affairs-affaires.internationales.drogue.sc@canada.ca">hc.drug.international.affairs-affaires.internationales.drogue.sc@canada.ca</a></p>	<p>Phone: +32 229 60541  Email:  <a href="mailto:SANTE-PHARMACEUTICALS-B4@ec.europa.eu">SANTE-PHARMACEUTICALS-B4@ec.europa.eu</a></p>
	<p><u>Contact Points</u>  Manager, Mutual Recognition Agreement &amp; International Affairs Unit (HPIL)  Regulatory Operations and Enforcement Branch (ROEB)  Health Canada  Phone: (001) 450 928 4209  Email:  <a href="mailto:hc.drug.international.affairs-affaires.internationales.drogue.sc@canada.ca">hc.drug.international.affairs-affaires.internationales.drogue.sc@canada.ca</a></p>	<p><u>Contact Points</u>  Policy Officer, Unit B 4.  Medical products: Quality, Safety, Innovation  Directorate General for Health and Food safety  European Commission  Phone: +32 229 57667  Email:  <a href="mailto:SANTE-PHARMACEUTICALS-B4@ec.europa.eu">SANTE-PHARMACEUTICALS-B4@ec.europa.eu</a></p> <p><u>DG Trade contact:</u>  Assistant Policy Officer, Unit G3 - Market Access, Industry, Energy and Raw Materials,  Directorate General for Trade,  European Commission  Phone: +32 229 66925  Email: <a href="mailto:TRADE-G3-SEC@ec.europa.eu">TRADE-G3-SEC@ec.europa.eu</a></p>

<b>Administrative Arrangement</b>	<b>FOR CANADA</b>	<b>FOR EUROPEAN UNION</b>
<p>Two-Way Alert Programme – Article 15.3 (b)</p> <ul style="list-style-type: none"> <li>• Rapid Alert Notification</li> <li>• Notification of confirmed defective product reports</li> <li>• Notification of suspension, restriction or revocation of a manufacturing authorisation / establishment license, restriction/withdrawal of a GMP certificate and notification of non-compliance with GMP</li> <li>• Fraud and Counterfeit Products / Falsification</li> </ul>	<p>Manager, Health Product Compliance &amp; Enforcement Unit Regulatory Operations and Enforcement Branch (ROEB), Health Canada Phone: (001) 613 954 0513 Fax: (001) 613 946 5636 ? Email: <a href="mailto:hc.rapid.alert-alerte.rapide.sc@canada.ca">hc.rapid.alert-alerte.rapide.sc@canada.ca</a></p>	<p>The EU list of contact points for Rapid Alerts is maintained by European Medicines Agency (EMA) and provided to Health Canada at every update</p>
<p>Contact Points responsible for matters arising under CETA GMP Protocol – Article 15.3 (c)</p>	<p>Manager, Mutual Recognition Agreement &amp; International Affairs Unit (HPIL) Regulatory Operations and Enforcement Branch (ROEB) Health Canada Telephone: (001) 450 928 4209 Email: <a href="mailto:hc.drug.international.affaires-affaires.internationales.drogue.sc@canada.ca">hc.drug.international.affaires-affaires.internationales.drogue.sc@canada.ca</a></p>	<p>Policy Officer, Unit B 4. Medical products: Quality, Safety, Innovation Directorate General for Health and Food safety European Commission Phone: +32 229 57667 Email: <a href="mailto:SANTE-PHARMACEUTICALS-B4@ec.europa.eu">SANTE-PHARMACEUTICALS-B4@ec.europa.eu</a>  EMA: <a href="mailto:mra@ema.europa.eu">mra@ema.europa.eu</a>  <u>DG Trade contact:</u> Assistant Policy Officer, Unit G3 - Market Access, Industry, Energy and Raw Materials, Directorate General for Trade, European Commission Phone: +32 229 66925 Email: <a href="mailto:TRADE-G3-SEC@ec.europa.eu">TRADE-G3-SEC@ec.europa.eu</a></p>
<p>Components of the Information Sharing Process – Article 15.3 (d)</p>	<p>Director, Health Product Inspection and Licensing (HPIL) Regulatory Operations and Enforcement Branch (ROEB) Health Canada Phone: (001) 613 954 2996 Email:</p>	<p>Head of Unit, Unit B 4. Medical products: Quality, Safety, Innovation Directorate General for Health and Food safety European Commission Phone: +32 229 60541 Email:</p>

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	<p><a href="mailto:hc.drug.international.affairs-affaires.internationales.drogue.sc@canada.ca">hc.drug.international.affairs-affaires.internationales.drogue.sc@canada.ca</a></p> <p>Manager, Mutual Recognition Agreement &amp; International Affairs Unit (HPIL) Regulatory Operations and Enforcement Branch (ROEB) Health Canada Telephone: (001) 450 928 4209 Email: <a href="mailto:hc.drug.international.affairs-affaires.internationales.drogue.sc@canada.ca">hc.drug.international.affairs-affaires.internationales.drogue.sc@canada.ca</a></p>	<p><a href="mailto:SANTE-PHARMACEUTICALS-B4@ec.europa.eu">SANTE-PHARMACEUTICALS-B4@ec.europa.eu</a></p> <p>EMA: <a href="mailto:mra@ema.europa.eu">mra@ema.europa.eu</a></p> <p>EU National Competent Authorities: as provided in the annual reports under the Equivalence Maintenance Programme (Appendix A to Adm. Arrangements Article 15.3(g) )</p>
Components of a GMP Compliance Programme – Article 15.3 (e)	<p>Manager, Mutual Recognition Agreement &amp; International Affairs Unit (HPIL) Regulatory Operations and Enforcement Branch (ROEB) Health Canada Telephone: (001) 450 928 4209 Email: <a href="mailto:hc.drug.international.affairs-affaires.internationales.drogue.sc@canada.ca">hc.drug.international.affairs-affaires.internationales.drogue.sc@canada.ca</a></p>	<p>Policy Officer, Unit B 4. Medical products: Quality, Safety, Innovation Directorate General for Health and Food safety European Commission Phone: +32 229 57667 Email: <a href="mailto:SANTE-PHARMACEUTICALS-B4@ec.europa.eu">SANTE-PHARMACEUTICALS-B4@ec.europa.eu</a></p> <p>EMA: <a href="mailto:mra@ema.europa.eu">mra@ema.europa.eu</a></p> <p><u>DG Trade contact:</u> Assistant Policy Officer, Unit G3 - Market Access, Industry, Energy and Raw Materials, Directorate General for Trade, European Commission Phone: +32 229 66925 Email: <a href="mailto:TRADE-G3-SEC@ec.europa.eu">TRADE-G3-SEC@ec.europa.eu</a>.</p>
Procedure for evaluating New Regulatory Authorities – Article 15.3 (f)	<p>Manager, Mutual Recognition Agreement &amp; International Affairs Unit (HPIL) Regulatory Operations and Enforcement Branch (ROEB) Health Canada Telephone: (001) 450 928 4209 Email: <a href="mailto:hc.drug.international.affairs-affaires.internationales.drogue.sc@canada.ca">hc.drug.international.affairs-affaires.internationales.drogue.sc@canada.ca</a></p>	<p>Policy Officer, Unit B 4. Medical products: Quality, Safety, Innovation Directorate General for Health and Food safety European Commission Phone: +32 229 57667 Email: <a href="mailto:SANTE-PHARMACEUTICALS-B4@ec.europa.eu">SANTE-PHARMACEUTICALS-B4@ec.europa.eu</a></p> <p>EMA: <a href="mailto:mra@ema.europa.eu">mra@ema.europa.eu</a></p>

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<p>Equivalence Maintenance Program  – Article 15.3(g)</p>	<p>Manager, Mutual Recognition Agreement &amp; International Affairs Unit (HPIL)  Regulatory Operations and Enforcement Branch (ROEB)  Health Canada  Phone: (001) 450 928 4209  Email: <a href="mailto:hc.drug.international.affairs@affaires.internationales.drogue.sc@canada.ca">hc.drug.international.affairs@affaires.internationales.drogue.sc@canada.ca</a></p>	<p>Policy Officer, Unit B 4.  Medical products: Quality, Safety, Innovation  Directorate General for Health and Food safety  European Commission  Phone: +32 229 57667  Email: <a href="mailto:SANTE-PHARMACEUTICALS-B4@ec.europa.eu">SANTE-PHARMACEUTICALS-B4@ec.europa.eu</a></p> <p>EMA: <a href="mailto:mra@ema.europa.eu">mra@ema.europa.eu</a></p> <p>EU National Competent Authorities: as provided in the annual reports under the Equivalence Maintenance Programme (Appendix A to Adm. Arrangements Article 15.3(g) )</p> <p>DG Trade contact:  Assistant Policy Officer, Unit G3 - Market Access, Industry, Energy and Raw Materials, Directorate General for Trade, European Commission  Phone: +32 229 66925  Email: <a href="mailto:TRADE-G3-SEC@ec.europa.eu">TRADE-G3-SEC@ec.europa.eu</a>.</p>