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PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	6 July 2016
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	ANNEX to the Proposal for a Council Decision on the signing on behalf of the European Union of the Comprehensive Economic and Trade Agreement between Canada of the one part, and the European Union and its Member States, of the other part ,

Delegations will find attached document COM(2016) 444 final - ANNEX 7.

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EUROPEAN
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ANNEX 7

ANNEX

to the

Proposal for a Council Decision

on the signing on behalf of the European Union of the Comprehensive Economic and Trade Agreement between Canada of the one part, and the European Union and its Member States, of the other part

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Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products

Article 1

Definitions

1. For the purposes of this Protocol:

certificate of GMP compliance means a certificate issued by a regulatory authority attesting to the compliance of a manufacturing facility with Good Manufacturing Practices (GMP);

equivalent authority means a regulatory authority of a Party that is recognised as an equivalent authority by the other Party;

manufacturing includes fabrication, packaging, re-packaging, labelling, testing and storage;

medicinal product or drug means any product qualifying as a drug under the *Food and Drugs Act*, R.S.C., 1985, c. F-27 or qualifying as a medicinal product, whether it is a finished, intermediate or an investigational product or an active substance under the applicable legislation of the European Union;

on-site evaluation means a product-specific evaluation conducted in the context of a marketing application for a medicinal product or drug at the site of manufacture to assess the conformity of the premises where the medicinal product or drug is manufactured, the *conformity* of the process, conditions and control of manufacture with the information submitted, and to address any outstanding issues from the evaluation of the marketing application; and

regulatory authority means an entity in a Party that has the legal right, under the law of the Party, to supervise and control medicinal products or drugs within that Party.

2. Unless specified otherwise, where this Protocol refers to inspections, these references do not include on-site evaluations.

Article 2

Objective

The objective of this Protocol is to strengthen the cooperation between the authorities of the Parties in ensuring that medicinal products and drugs meet appropriate quality standards through the mutual recognition of certificates of GMP compliance.

Article 3

Product scope

This Protocol applies to all medicinal products or drugs to which GMP requirements apply in both Parties, as set out in Annex 1.

Article 4

Recognition of regulatory authorities

1. The procedure for evaluating the equivalency of a new regulatory authority listed in Annex 2 shall be conducted in accordance with Article 12.

2. Each Party shall ensure that a list of regulatory authorities that it recognises as equivalent, including any modifications, is publicly available.

Article 5

Mutual recognition of certificates of GMP compliance

1. A Party shall accept a certificate of GMP compliance issued by an equivalent regulatory authority of the other Party, in conformity with paragraph 3, as demonstrating that the manufacturing facility, that is covered by the certificate and located in the territory of either Party, complies with the good manufacturing practices identified in the certificate.

2. A Party may accept a certificate of GMP compliance issued by an equivalent regulatory authority of the other Party with respect to a manufacturing facility outside the territory of the Parties, in conformity with paragraph 3. A Party may determine the terms and conditions upon which it chooses to accept the certificate.

3. A certificate of GMP compliance must identify:

   (a) the name and address of the manufacturing facility;

   (b) the date on which the equivalent regulatory authority that issued the certificate last inspected the manufacturing facility;

   (c) the manufacturing processes and if relevant, medicinal products or drugs and dosage forms for which the facility is in compliance with good manufacturing practices; and

   (d) the validity period of the certificate of GMP compliance.

4. If an importer, an exporter or a regulatory authority of a Party requests a certificate of GMP compliance for a manufacturing facility that is certified by an equivalent authority of the other Party, the other Party shall ensure that the equivalent regulatory authority issues a certificate of GMP compliance:

   (a) within 30 calendar days of the date on which the certifying authority received the request for the certificate, if a new inspection is not required; and

   (b) within 90 calendar days of the date on which the certifying authority received the request for the certificate, if a new inspection is required, and the manufacturing facility passes the inspection.

Article 6

Other recognition of certificates of GMP compliance

1. A Party may accept a certificate of GMP compliance with respect to a medicinal product or drug that is not included in paragraph 2 of Annex 1.

2. A Party that accepts a certificate under paragraph 1 may determine the terms and conditions under which it will accept the certificate.

Article 7

Acceptance of batch certificates

1. A Party shall accept a batch certificate issued by a manufacturer without re-control of that batch at import provided that:

   (a) the products in the batch were manufactured in a manufacturing facility that has been certified as compliant by an equivalent regulatory authority;

   (b) the batch certificate is consistent with the Content of the Batch Certificate for Medicinal Products of the *Internationally Harmonized Requirements for Batch Certification*; and

   (c) the batch certificate is signed by the person responsible for releasing the batch for sale or supply.

2. Paragraph 1 does not affect a Party’s right to conduct official batch release.

3. The person responsible for releasing the batch:

   (a) of the finished medicinal product for sale or supply for manufacturing facilities in the European Union, must be a "qualified person" as defined in Article 48 of Directive 2001/83/EC and Article 52 of Directive 2001/82/EC; or

   (b) for sale or supply of a drug for manufacturing facilities in Canada, is the person in charge of the quality control department as provided for by the *Food and Drugs Regulations*, C.R.C., c. 870, Part C, Division 2, section C.02.014.

Article 8

On-site evaluation

1. A Party has the right to conduct its own on-site evaluation of a manufacturing facility that has been certified as compliant by an equivalent regulatory authority of the other Party.

2. A Party, prior to conducting an on-site evaluation under paragraph 1, shall notify the other Party in writing and inform that other Party of the scope of the on-site evaluation. The Party shall endeavour to notify the other Party in writing at least 30 days before a proposed on-site evaluation, but may provide less notice in urgent situations. The other Party has the right to join the on-site evaluation conducted by the Party.

Article 9

Inspections and on-site evaluations at the request of a Party

1. At the request of a Party, the other Party shall inspect a facility involved in the manufacturing process of a medicinal product or drug that is being imported into the territory of the requesting Party in order to verify that the facility is in compliance with good manufacturing practices.

2. At the request of a Party, the other Party may conduct an on-site evaluation based on the assessment of data contained in a product submission dossier. The Parties may exchange relevant product information with respect to a request to conduct an on-site evaluation in accordance with Article 14.

Article 10

Safeguards

1. A Party has the right to conduct its own inspection of a manufacturing facility that has been certified as compliant by an equivalent regulatory authority of the other Party. Recourse to this right should be an exception from the normal practice of the Party.

2. A Party, prior to conducting an inspection under paragraph 1, shall notify the other Party in writing and shall inform the other Party of the reasons for conducting its own inspection. The Party shall endeavour to notify the other Party in writing at least 30 days before a proposed inspection, but may provide less notice in urgent situations. The other Party has the right to join the inspection conducted by the Party.

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.

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, inspections 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.

Article 13

Equivalence maintenance programme

1. The Joint Sectoral Group shall develop an equivalence maintenance programme under the GMP Administrative Arrangement referred to in Article 15.3 to maintain the equivalence of the regulatory authorities. The Parties shall act in accordance with this programme when deciding whether to change the equivalence status of a regulatory authority.

2. If the equivalence status of a regulatory authority changes, a Party may re-evaluate that regulatory authority. Any re-evaluation must be undertaken pursuant to the procedure set out in Article 12. The scope of re-evaluation shall be limited to the elements that caused the change of the equivalence status.

3. The Parties shall exchange all the necessary information to ensure that both Parties remain confident that equivalent regulatory authorities are in fact equivalent.

4. A Party shall inform the other Party before adopting changes to its technical guidance or regulations relating to good manufacturing practices.

5. A Party shall inform the other Party of any new technical guidance, inspection procedures or regulations relating to good manufacturing practices.

Article 14

Confidentiality

1. A Party shall not publicly disclose non-public and confidential technical, commercial or scientific information, including trade secrets and proprietary information that it has received from the other Party.

2. A Party may disclose the information referred to in paragraph 1 if it deems such disclosure necessary to protect public health and safety. The other Party shall be consulted prior to disclosure.

Article 15

Management of the Protocol

1. The Joint Sectoral Group, established under Article 26.2.1(a) (Committees), is composed of representatives from both Parties.

2. The Joint Sectoral Group shall establish its composition and determine its rules and procedures.

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.

4. The Joint Sectoral Group may modify the GMP Administrative Arrangement if it considers it necessary.

5. At the request of the Parties, the Joint Sectoral Group shall review the Annexes to this Protocol, and shall develop recommendations for amendments to these Annexes for consideration by the CETA Joint Committee.

6. Pursuant to paragraph 5, the Joint Sectoral Group shall review the operational scope of medicinal products or drugs under paragraph 2 of Annex 1, with a view to including those medicinal products or drugs listed in paragraph 1 of Annex 1.

7. The Parties shall establish the GMP Administrative Arrangement upon entry into force of the Agreement. This Arrangement is not subject to the provisions of Chapter Twenty-Nine (Dispute Settlement).

Article 16

Fees

1. For the purposes of this Article, a fee includes a cost-recovery measure such as a user fee, a regulatory charge or an amount set under a contract.

2. A Party shall have the right to determine a fee applicable to manufacturing facilities in its territory, including fees related to issuing certificates of GMP compliance and fees related to inspections or on-site evaluations.

3. The fees charged to a manufacturing facility in case of an inspection or on-site evaluation conducted by a Party at the request of the other Party must be consistent with paragraph 2.

ANNEX 1

MEDICINAL PRODUCTS OR DRUGS

Scope of medicinal products or drugs

1. This Protocol applies to the following medicinal products or drugs as defined in the legislation of the Parties referred to in Annex 3, provided that the GMP requirements and compliance programmes of both Parties, with respect to these medicinal products or drugs, are equivalent:

   (a) human pharmaceuticals including prescription and non-prescription medicinal products or drugs and medicinal gases;

   (b) human biologicals including immunologicals, stable medicinal products derived from human blood or human plasma, and biotherapeutics;

   (c) human radiopharmaceuticals;

   (d) veterinary pharmaceuticals, including prescription and non-prescription medicinal products or drugs, and pre-mixes for the preparation of veterinary medicated feeds;

   (e) veterinary biologicals;

   (f) if appropriate, vitamins, minerals, herbal remedies and homeopathic medicinal products;

   (g) active pharmaceutical ingredients;

(h) intermediate products and bulk pharmaceuticals (for example, bulk tablets);

(i) products intended for use in clinical trials or investigational medicinal products; and

(j) advanced therapy medicinal products.

Operational scope of medicinal products or drugs

2. Further to paragraph 1, the GMP requirements and compliance programmes of both Parties are equivalent for the following medicinal products or drugs:

(a) human pharmaceuticals including prescription and non-prescription medicinal products or drugs and medicinal gases;

(b) human biologicals including immunologicals and biotherapeutics;

(c) human radiopharmaceuticals;

(d) veterinary pharmaceuticals, including prescription and non-prescription medicinal products or drugs, and pre-mixes for the preparation of veterinary medicated feeds;

(e) intermediate products and bulk pharmaceuticals;

(f) products intended for use in clinical trials or investigational medicinal products; manufactured by the manufacturers holding a manufacturing authorisation or establishment licence; and

(g) vitamins, minerals and herbal remedies, homeopathic medicinal products (known in Canada as natural health products) manufactured by manufacturers holding a manufacturing authorisation or establishment licence, in the case of Canada.

ANNEX 2

REGULATORY AUTHORITIES

The Parties recognise the following entities, or their successors notified by a Party to the Joint Sectoral Group, as their respective regulatory authorities:

For the European Union:

Country	For medicinal products for human use	For medicinal products for veterinary use
Belgium	Federal agency for medicines and health products / Federaal Agentschap voor geneesmiddelen en gezondheidsproducten/ Agence fédérale des médicaments et produits de santé	See responsible authority for human medicinal products
Czech Republic	State Institute for Drug Control/ Státní ústav pro kontrolu léčiv (SÚKL)	Institute for State Control of Veterinary Biologicals andMedicaments/ Ústav pro státní kontrolu veterinárních biopreparátů a léčiv (ÚSKVBL)
Croatia	Agency for Medicinal Products and Medical Devices / Agencija za lijekove i medicinske proizvode (HALMED)	Ministry of Agriculture, Veterinary and Food Safety Directorate / Ministarstvo Poljoprivrede, Uprava za veterinarstvo i sigurnost hrane

Country	For medicinal products for human use	For medicinal products for veterinary use
Denmark	Danish Health and Medicines Authority / Laegemiddelstyrelsen	See responsible authority for human medicinal products
Germany	Federal Institute for Drugs and Medical Devices / Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) Paul-Ehrlich-Institute (PEI), Federal Institute for Vaccines and Biomedicines / Paul-Ehrlich-Institut (PEI) Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel	Federal Office for Consumer Protection and Food Safety / Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) Federal Ministry of Food and Agriculture, Bundesministerium für Ernährung und Landwirtschaft
Estonia	State Agency of Medicines / Ravimiamet	See responsible authority for human medicinal products
Greece	National Organisation for Medicines / Ethnikos Organismos Farmakon (EOF) - (ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ))	See responsible authority for human medicinal products
Spain	Spanish Agency of Medicines and Medical Devices / Agencia Española de Medicamentos y Productos Sanitários	See responsible authority for human medicinal products

Country	For medicinal products for human use	For medicinal products for veterinary use
France	French National Agency for Medicines and Health Products Safety Agence nationale de sécurité du médicament et des produits de santé (ANSM)	French agency for food, environmental and occupational health safety- *National Agency for Veterinary Medicinal Products/* Agence Nationale de Sécurité Sanitaire de l'alimentation, de l'environnement et du travail- Agence Nationale du Médicament Vétérinaire (Anses-ANMV)
Ireland	Health Products Regulatory Authority (HPRA)	See responsible authority for human medicinal products
Italy	*Italian Medicines Agency /* Agenzia Italiana del Farmaco	*Direction General for Animal Health and Veterinary Medicinal Products* Ministero della Salute, Direzione Generale della Sanità Animale e dei Farmaci Veterinari
Cyprus	Ministry of Health - Pharmaceutical Services / Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας	Ministry of Agriculture, Rural Development and Environment- Veterinary Services / Κτηνιατρικές Υπηρεσίες- Υπουργείο Γεωργίας, Αγροτικής Ανάπτυξης και Περιβάλλοντος

Country	For medicinal products for human use	For medicinal products for veterinary use
Latvia	State Agency of Medicines / Zāļu valsts aģentūra	Assessment and Registration Department of the Food and Veterinary Service/Pārtikas un veterinārā dienesta Novērtēšanas un reģistrācijas departaments
Lithuania	State Medicines Control Agency / Valstybinė maisto ir veterinarijos tarnyba	State Food and Veterinary Service / Valstybinės maisto ir veterinarijo tarnyba
Luxembourg	Minìstere de la Santé, Division de la Pharmacie et des Médicaments	See responsible authority for human medicinal products
Hungary	National Institute of Pharmacy/ Országos Gyógyszerészeti Intézet (OGYI)	National Food Chain Safety Office, Directorate of Veterinary Medicinal Products / Nemzeti Élelmiszerlánc-biztonsági Hivatal, Állatgyógyászati Termékek Igazgatósága (ÁTI)
Malta	Medicines Regulatory Authority	Veterinary Medicines and Animal Nutrition section VMANS) (Veterinary Regulation Directorate (VRD) within The Veterinary and Phytosanitary Regulation Department (VPRD)

Country	For medicinal products for human use	For medicinal products for veterinary use
Netherlands	Healthcare Inspectorate / Inspectie voor de Gezondheidszorg (IGZ)	Medicines Evaluation Board / Bureau Diergeneesmiddelen, College ter Beoordeling van Geneesmiddelen (CBG)/
Austria	Austrian Agency for Health and Food Safety / Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH	See responsible authority for human medicinal products
Poland	The Main Pharmaceutical Inspectorate / Główny Inspektorat Farmaceutyczny (GIF) /	See responsible authority for human medicinal products
Portugal	National Authority of Medicines and Health Products / INFARMED, I.P Autoridade Nacional do Medicamento e Produtos de Saúde, I.P	General Directorate of Food and Veterinary / DGAV - Direção Geral de Alimentação e Veterinária (PT)
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia / Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP)	See responsible authority for human medicinal products

Country	For medicinal products for human use	For medicinal products for veterinary use
Slovak Republic (Slovakia)	State Institute for Drug Control / Štátny ústav pre kontrolu liečiv (ŠÚKL)	Institute for State Control of Veterinary Biologicals and Medicaments / Ústav štátnej kontroly veterinárnych biopreparátov a liečiv (USKVBL)
Finland	Finnish Medicines Agency / Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA)	See responsible authority for human medicinal products
Sweden	Medical Products Agency / Läkemedelsverket	See responsible authority for human medicinal products
United Kingdom	Medicines and Healthcare products Regulatory Agency	Veterinary Medicines Directorate
Bulgaria	Bulgarian Drug Agency / ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА	Bulgarian Food Safety Agency/ Българска агенция по безопасност на храните
Romania	National Agency for Medicines and Medical Devices / Agenţia Naţională a Medicamentului şi a Dispozitivelor Medicale	National Sanitary Veterinary and Food Safety Authority / Autoritatea Naţională Sanitară Veterinară şi pentru Siguranţa Alimentelor

For Canada:

	Health Canada	Health Canada

ANNEX 3

APPLICABLE LEGISLATION

For the European Union:

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products;

Directive 2001/20/EC of European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;

Regulation (EU) 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC;

Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use;

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products;

Commission delegated Regulation (EU) 1252/2014 of 28 May 2014 of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use;

Current version of the Guide to good manufacturing practices contained in volume IV of Rules governing medicinal products in the European Union and compilation of the community procedures on inspections and exchange of information;

For Canada:

Food and Drugs Act, R.S.C., 1985, c. F-27.