Medicines & Healthcare products Regulatory Agency

Veterinary Medicines Directorate

LETTER FROM THE UNITED KINGDOM'S MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY AND VETERINARY MEDICINES DIRECTORATE TO CANADA'S REGULATORY OPERATIONS AND ENFORCEMENT BRANCH OF HEALTH CANADA
REGARDING THE MUTUAL RECOGNITION OF GOOD MANUFACTURING PRACTICES FOR PHARMACEUTICAL PRODUCTS

23rd December 2020

Dear Stefania Trombetti,

I have the honour to refer to discussions that have taken place between our two Governments regarding the European Union-Canada Comprehensive Economic and Trade Agreement ("CETA"), signed on 30 October 2016, which is currently being provisionally applied by Canada and the United Kingdom of Great Britain and Northern Ireland (the "United Kingdom").

Mindful of the need to ensure transparency, predictability and legal stability regarding the obligations contained in CETA and its Protocol on the Mutual Recognition of the Compliance and Enforcement Programme regarding Good Manufacturing Practices for Pharmaceutical Products ("the Protocol"), I have the honour to propose that:

1. The Government of the United Kingdom and the Government of Canada (the "Participants") will continue to take the measures listed below, in accordance with their respective existing laws and regulations, from the time and date on which the CETA ceases to apply to the United Kingdom, provided that the Participants continue to apply the same measures. The Government of the United Kingdom is represented by the Medicines and Healthcare products Regulatory Agency and the Veterinary Medicines Directorate.

Good Manufacturing Practices (GMP) for Pharmaceutical Products measures:

2. The Participants will adhere to the scope of this understanding, which is the regulation, inspection, compliance, and enforcement activities of manufacturing facilities located in its respective territory, and to the following medicinal products or drugs for which the GMP requirements and compliance programmes (set out in Article 15(3)(e) of the Protocol) of the Participants are equivalent:

   (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 (NHPs)) manufactured by manufacturers holding a manufacturing authorisation or establishment/site licence, in the case of Canada.

3. Each Participant will continue to accept a certificate of GMP compliance issued by the other Participant in conformity with the requirements of Article 5(3) of the Protocol, as demonstrating that the manufacturing facility that is covered by the certificate and located in the territory of the issuing Participant complies with the good manufacturing practices identified in the certificate, in conformity with Article 5(1) of the Protocol.

4. Each Participant may accept a certificate of GMP compliance issued by the other Participant with respect to a manufacturing facility outside the territory of the issuing Participant, in conformity with the requirements of Article 5(3) of the Protocol. The Participants may determine the terms and conditions upon which each Participant chooses to accept the certificate in conformity with Article 5(2) of the Protocol.

5. The Participants will continue to accept a batch certificate issued by a manufacturer without re-control of that batch at import in conformity with the requirements of Article 7 of the Protocol.

6. The Participants will continue to exchange information under the maintenance programme, the two-way alert programme and information-sharing processes in conformity with the requirements of Article 11 and Article 13 of the Protocol.

7. A Participant will 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 Participant in conformity with the requirements of Article 14.1 of the Protocol.

8. A Participant may disclose the information referred to in paragraph 7 if it deems such disclosure necessary to protect public health and safety in conformity with the requirements of Article 14.2 of the Protocol. The other Participant will be consulted prior to disclosure.

Resolution of Differences

9. (a) The Participants understand that the primary points of contact are the Director General of the Health Product Compliance Directorate (HPCD) of Health Canada, for Canada, and the Chief Executive Officer of the United Kingdom's Veterinary Medicines Directorate (VMD) and the Chief Executive Officer of the Medicines and Healthcare products Regulatory Agency (MHRA).

   (b) The contact points to serve as liaisons for communication on each respective sector are provided in Appendix A.

10. If questions arise as to the interpretation of this understanding, the Participants will resolve such questions through consultations between their appointed contact points.

11. When a Participant discovers particular circumstances, which may cause imminent and serious danger to the public, it will immediately communicate its findings to the other Participant.

Entry into Effect and Termination

12. This understanding will enter into effect when the CETA ceases to apply to the United Kingdom, provided that the conditions in paragraph 1 are satisfied.

13. This understanding may be amended at any time by mutual consent of the Participants.

14. This understanding will be reviewed within six months of the date of its coming into effect.

15. If a Participant wishes to terminate this understanding, it will communicate immediately the intent to terminate to the other Participant. This understanding will terminate:
    (a) when a new agreement on GMP Compliance for Pharmaceuticals between the Participants enters into force; or
    (b) a period of three months has expired following the date on which a Participant gives written notice of its intention to terminate to the other Participant.

If the foregoing proposal is acceptable to the Government of Canada, I have the honour to propose that the present letter and your letter in reply, equally valid in the English and French languages, will constitute an understanding between our two Governments, which will come into effect in accordance with paragraph 12.

Dr June Raine CBE

Chief Executive Officer
Medicine and Healthcare products Agency of the United Kingdom

Professor Peter Borriello CB

Chief Executive Officer
Veterinary Medicines Directorate of the United Kingdom

Health Canada Santé Canada

LETTER FROM CANADA'S REGULATORY OPERATIONS AND ENFORCEMENT BRANCH OF HEALTH CANADA TO THE UNITED KINGDOM'S MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY AND VETERINARY MEDICINES DIRECTORATE REGARDING THE MUTUAL RECOGNITION OF GOOD MANUFACTURING PRACTICES FOR PHARMACEUTICAL PRODUCTS

December 23, 2020

Dear Dr June Raine and Professor Peter Borriello,

I have the honour to acknowledge receipt of your letter dated December 23, 2020, in which you refer to discussions that have taken place between our two Governments regarding the European Union-Canada Comprehensive Economic and Trade Agreement ("CETA"), signed on 30 October 2016, which is currently being provisionally applied by Canada and the United Kingdom of Great Britain and Northern Ireland (the "United Kingdom").

Mindful of the need to ensure transparency, predictability and legal stability regarding the obligations contained in CETA and its Protocol on the Mutual Recognition of the Compliance and Enforcement Programme regarding Good Manufacturing Practices for Pharmaceutical Products ("the Protocol"), I have the honour to concur with your proposal that:

1. The Government of the United Kingdom and the Government of Canada (the "Participants") will continue to take the measures listed below, in accordance with their respective existing laws and regulations, from the time and date on which the CETA ceases to apply to the United Kingdom, provided that the Participants continue to apply the same measures. The Government of the United Kingdom is represented by the Medicines and Healthcare products Regulatory Agency and the Veterinary Medicines Directorate.

Good Manufacturing Practices (GMP) for Pharmaceutical Products measures:

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   (b) human biologicals including immunologicals and biotherapeutics;
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   (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 (NHPs)) manufactured by manufacturers holding a manufacturing authorisation or establishment/site licence, in the case of Canada.

3. Each Participant will continue to accept a certificate of GMP compliance issued by the other Participant in conformity with the requirements of Article 5(3) of the Protocol, as demonstrating that the manufacturing facility that is covered by the certificate and located in the territory of the issuing Participant complies with the good manufacturing practices identified in the certificate, in conformity with Article 5(1) of the Protocol.

4. Each Participant may accept a certificate of GMP compliance issued by the other Participant with respect to a manufacturing facility outside the territory of the issuing Participant, in conformity with the requirements of Article 5(3) of the Protocol. The Participants may determine the terms and conditions upon which each Participant chooses to accept the certificate in conformity with Article 5(2) of the Protocol.

5. The Participants will continue to accept a batch certificate issued by a manufacturer without re-control of that batch at import in conformity with the requirements of Article 7 of the Protocol.

6. The Participants will continue to exchange information under the maintenance programme, the two-way alert programme and information-sharing processes in conformity with the requirements of Article 11 and Article 13 of the Protocol.

7. A Participant will 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 Participant in conformity with the requirements of Article 14.1 of the Protocol.

8. A Participant may disclose the information referred to in paragraph 7 if it deems such disclosure necessary to protect public health and safety in conformity with the requirements of Article 14.2 of the Protocol. The other Participant will be consulted prior to disclosure.

Resolution of Differences

9. (a) The Participants understand that the primary points of contact are the Director General of the Health Product Compliance Directorate (HPCD) of Health Canada, for Canada, and the Chief Executive Officer of the United Kingdom's Veterinary Medicines Directorate (VMD) and the Chief Executive Officer of the Medicines and Healthcare products Regulatory Agency (MHRA).

(b) The contact points to serve as liaisons for communication on each respective sector are provided in Appendix A.

10. If questions arise as to the interpretation of this understanding, the Participants will resolve such questions through consultations between their appointed contact points.

11. When a Participant discovers particular circumstances, which may cause imminent and serious danger to the public, it will immediately communicate its findings to the other Participant.

Entry into Effect and Termination

12. This understanding will enter into effect when the CETA ceases to apply to the United Kingdom, provided that the conditions in paragraph 1 are satisfied.

13. This understanding may be amended at any time by mutual consent of the Participants.

14. This understanding will be reviewed within six months of the date of its coming into effect.

15. If a Participant wishes to terminate this understanding, it will communicate immediately the intent to terminate to the other Participant. This understanding will terminate:
    (a) when a new agreement on GMP Compliance for Pharmaceuticals between the Participants enters into force; or
    (b) a period of three months has expired following the date on which a Participant gives written notice of its intention to terminate to the other Participant.

I have the further honour of confirming that my government shares this understanding and that your letter and this letter in reply, equally valid in the English and French languages, will constitute an understanding between our two Governments, which will come into effect in accordance with paragraph 12.

Stefania Trombetti

Assistant Deputy Minister
Regulatory Operations and Enforcement Branch
Health Canada