Council of the European Union
General Secretariat

Brussels, 05 December 2018

WK 15073/2018 INIT

LIMITE

WTO
MI

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

MEETING DOCUMENT

From:	European Commission
To:	Trade Policy Committee (Deputies)
Subject:	CETA – Joint Sectoral Group Pharmaceuticals

EUROPEAN COMMISSION
Directorate-General for Trade

Directorate E - Neighbouring countries, USA and Canada
USA and Canada

Brussels, 4 December 2018

NOTE FOR THE ATTENTION OF THE TRADE POLICY COMMITTEE

SUBJECT: ***CETA – Joint Sectoral Group Pharmaceuticals***

ORIGIN: **Commission DG Trade Unit E1 and DG SANTE Unit B4**

Ms AMPELAS Anna Eva
Head of Unit B4, DG SANTE
+32 229 60541
Anna-eva.ampelas@ec.europa.eu

BHASKAR Renita
Deputy Head of Unit E1, DG TRADE
+32 229 63071
Renita.Bhaskar@ec.europa.eu

OBJECTIVE: For information

REMARKS:

The attached note informs the Committee on the report of the Joint Sectoral Group Pharmaceuticals of the Protocol to the CETA between the European Union (EU) and Canada on the Mutual Recognition of the Compliance and Enforcement Programs regarding Good Manufacturing Practices (GMP) for Pharmaceutical Products which took place by videoconference on 16 November 2018.

* * *

COMPREHENSIVE ECONOMIC AND TRADE AGREEMENT (CETA)

MEETING OF THE JOINT SECTORAL GROUP (JSG)

OF THE

PROTOCOL TO THE CETA BETWEEN THE EUROPEAN UNION (EU) AND CANADA ON THE MUTUAL RECOGNITION OF THE COMPLIANCE AND ENFORCEMENT PROGRAMS REGARDING GOOD MANUFACTURING PRACTICES (GMP) FOR PHARMACEUTICAL PRODUCTS

REPORT

On Friday 16 November 2018 by videoconference, the Directorate-General for Health and Food Safety (DG SANTE), European Medicines Agency (EMA) and Health Canada (HC) held the first meeting of the JSG on Pharmaceuticals under CETA. Discussion topics included:

CETA GMP Protocol and related Administrative Arrangements. The JSG confirmed the continued mutual recognition of GMP inspections and batch certification between EU and Canada for medicinal products for human use and veterinary medicines.

The JSG adopted the Rules of Procedure (ROP) with the understanding that they could revisit as necessary their decision in the future, if there is a need to adapt them to better align with JSG activities. In addition, six administrative arrangements to facilitate the effective implementation and monitoring of the CETA GMP Protocol were approved in principle and are expected to be adopted early in 2019. These administrative arrangements are:

i. Components of the Information Sharing Process

ii. Two-way Alert Program

iii. Procedure for Evaluating New Regulatory Authorities

iv. Equivalence Maintenance Program

v. Components of a GMP Compliance Program

vi. Contact Points

Recognition of the Active Pharmaceutical Ingredients Program under the CETA GMP Protocol on Pharmaceuticals. Possible extension of the scope to include GMP inspections of active pharmaceutical ingredient manufacturers was discussed. Officials will meet to develop an approach and timeframe.

Canada's Proposal on Mutual Recognition Agreement (MRA) for Drug Facility Inspections in third countries (re: CETA Regulatory Cooperation Forum (RCF)). Possible extensions of the scope to include GMP inspections conducted in third countries was discussed. Regulatory authorities in EU and Canada can continue to reduce duplication of inspections in each other's territory while maintaining high standards of drug product safety and quality and are examining the possibility to extend this recognition to inspections outside their respective territories. Officials will further advance and propose a plan.

The DG SANTE, EMA and HC agreed to a number of action items related to the advancement of the topics discussed above.

The results of the meeting will be reported to the CETA Joint Committee via the CETA Committee on Trade in Goods.

Participants:

Unit B4 – Medical products: quality, safety, innovation, Directorate General for health and Food Safety, European Commission

European Medicines Agency

Regulatory Operations and Region Branch / Direction générale des opérations réglementaires et des régions
Health Canada / Santé Canada