COMPREHENSIVE ECONOMIC AND TRADE AGREEMENT (CETA)

THE JOINT SECTORAL GROUP (JSG)

OF THE

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

21 NOVEMBER 2019 BY VIDEOCONFERENCE

REPORT

On Thursday 21 November 2019 by video and tele conference, Directorate General of Health and Food Safety (DG SANTE), European Medicines Agency (EMA) and Health Canada (HC) held the second meeting of the JSG on Pharmaceuticals under CETA. Discussion topics included:

1. Implementation of the CETA GMP Protocol for Pharmaceuticals related Administrative Arrangements.

The administrative arrangements adopted on 23 May 2019 between DG SANTE and Health Canada were published on EC and HC web pages. So far, neither HC nor the EC have received any questions or comments on the administrative arrangements.

2. Extension of the operational scope of the CETA protocol for pharmaceuticals to include active pharmaceutical ingredients (API)

The assessment is ongoing on whether the regulatory framework applicable to APIs and related enforcement activities are equivalent. The EC's audit of Health Canada will be confirmed in the upcoming weeks. Although the EU's assessment will be done in the framework of article 111b of Directive 2001/83/EC, outside of the CETA, the conclusion of the equivalence of HC reached within this framework will be taken over in the CETA.

HC is also in the process of assessing the equivalence of API programs of the different EU Member States.

3. CETA Regulatory Cooperation Forum (RCF): recognition of third countries Drug Facility Inspections conducted by each party.

A comparison of inspection processes conducted by HC, EMA and EC highlighted that both Parties seem to follow a similar approach for inspections in third countries, concluding that the differences observed were the same for both parties. The conclusion of the comparison was approved and endorsed by the co-chairs to continue through internal legal scrutiny and approvals, as per the processes of the respective Parties.

The first step of the proposed approach will be the recognition of inspections conducted in countries outside of the respective Parties' jurisdictions (i.e. extra-jurisdictional inspections) on products included in the operational scope of the Annex 1 of the CETA Protocol on Pharmaceuticals. The completion date is estimated to be end of 2020. An evaluation of this first step is foreseen at the subsequent JSG meeting in 2021.

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.