



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical products: quality, safety, innovation

New step in the Comprehensive Economic and Trade Agreement (CETA) between EU and Canada

19 November 2018

On Friday 16 November 2018 (by videoconference), the DG SANTE, EMA and Health Canada held the first Joint Sectoral Group (JSG) on Pharmaceuticals, a specialised committee established under the Committee on Trade in Goods of the CETA.

As the CETA GMP Protocol is a continuation of the 1998 EC-Canada MRA Treaty, 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.

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. Possible extensions of the scope to include GMP inspections of active substance manufacturers and inspections conducted in third countries were also discussed.

Under the CETA GMP Protocol, regulatory authorities in EU and Canada can make better use of their inspections resources by reducing duplication of inspections in each other's territory and eventually in third countries. This Protocol also enables reduced administrative burden and costs for the pharmaceutical sector while maintaining a high level of health and safety.