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

19 November 2018

On Friday 16 November 2018, 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.

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 to monitoring the CETA GMP Protocol were approved in principle and should be adopted before the end of the year. Possible extensions of the scope to include GMP inspections of active substance manufacturers and inspection conducted in third countries were also discussed.

Thanks to this agreement, 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 later perhaps even outside. This agreement also allows reducing administrative burden and costs for the pharmaceutical sector.