EU-U.S. trade talks: milestone reached in mutual recognition on pharmaceuticals

Brussels, 11 July 2019

Today, the European Union and the United States delivered on a significant element of the Joint Statement agreed by Presidents Juncker and Trump in July 2018. The positive transatlantic trade agenda established in the Joint Statement includes a commitment from both sides to reduce barriers and increase trade in a range of sectors, including pharmaceuticals.

The recognition today by the U.S. Food and Drug Administration (FDA) of Slovakia, the last outstanding EU Member State, marks the full implementation of the EU-U.S. Mutual Recognition Agreement (MRA) for inspections of manufacturing sites for human medicines in their respective territories. This can make it faster and less costly for both sides to bring medicines to the market.

Commissioner Vytenis **Andriukaitis**, in charge of Health and Food Safety said: *"The completion of the Mutual Recognition Agreement is not only a step forward in the trade relations between the EU and the U.S., but it will also ensure high quality medicines for the benefit of patients. It means that, on both sides of the Atlantic, the authorities in charge of medicines can now rely on inspections results to replace their own inspections. Today, the U.S. Food and Drug Administration has completed the capability assessments of the 28 EU competent authorities, the result of five years of close transatlantic cooperation".*

This Mutual Recognition Agreement is underpinned by robust evidence that the EU and the U.S. have comparable procedures to carry out good manufacturing practice inspections for human medicines.

Together, Europe and the United States account for more than 80% of global sales of new medicines. As a result of the full implementation of this agreement, both the industry and public authorities on both sides will be able to free resources that could be used to inspect facilities in other large producing countries.

The pharmaceutical industry is a strategic sector in which EU-U.S. regulatory cooperation is much more advanced than in most other sectors. Since May 2014, teams from the European Commission, EU national competent authorities, the European Medicines Agency (EMA) and the U.S. Food and Drug Administration have been auditing and assessing the respective supervisory systems. The U.S. Food and Drug Administration has now assessed positively all national competent authorities of the EU.

From now on, the batch testing waiver will also start to apply. This means that the qualified persons in the EU pharmaceutical company will be relieved of their task for carrying out the quality controls when carried out already in the United States.

The Mutual Recognition Agreement implementation work will continue with view to expanding the operational scope to veterinary medicines, human vaccines and plasma derived medicinal products.

Background

In 1998, the EU and the U.S. signed a broad Mutual Recognition Agreement, which included a Pharmaceutical Annex providing for anticipated and limited reliance on each other's Good Manufacturing Practices (GMP) inspections.

2017 marked the entry into operation of the agreement between the EU and the U.S. to recognise inspections of manufacturing sites for human medicines conducted in their respective territories. This agreement strengthens reliance upon each other's inspection expertise and resources. Initially it applied between the U.S. Food and Drug Administration and those EU Member States that the U.S. Food and Drug Administration had assessed. This has been gradually extended to all EU countries and now the regulatory authorities in all 28 EU Member States were recognised by the U.S. Food and Drug Administration. Meanwhile, the EU made the same determination about U.S. Food and Drug Administration in June 2017.

IP/19/4090

Press contacts:
   Anca PADURARU (+ 32 2 299 12 69)

Aikaterini APOSTOLA (+32 2 298 76 24)

General public inquiries: Europe Direct by phone 00 800 67 89 10 11 or by email