

Notification to the Joint Sectoral Committee by the European Union under Article 7 of the Sectoral Annex on Pharmaceutical Good Manufacturing Practices (GMPs) of the Agreement on Mutual Recognition between the European Community and the United States of America

THE EUROPEAN UNION,

Having regard to the Agreement on Mutual Recognition between the European Community and the United States of America (the 'Agreement') done in 1998, and in particular Article 7 of the Sectoral Annex on Pharmaceutical Good Manufacturing Practices (GMPs Annex) as amended on 1 March 2017.

NOTIFIES THE JOINT SECTORAL COMMITTEE THAT:

The European Union has determined that for the product scope indicated in Article 4 and Appendix 3 to the GMPs Annex the Food and Drug Administration of the United States of America has the capability, capacity and procedures in place to carry out GMP inspections at a level equivalent to the EU and enforce compliance with GMP and therefore, shall be added to the list of recognised authorities under the GMPs Annex;

This determination is without prejudice to any future decisions of the Joint Sectoral Committee with respect to the inclusion of vaccines for human use, plasma derived pharmaceuticals, investigational and veterinary products in the operational scope of the GMPs Annex.

This notification shall be effective from the date of its publication in the *Official Journal of the European Union*.

Signed in Brussels, on 11 August 2017.

For the European Union
Vytenis ANDRIUKAITIS
