REGULATORY NEWS
JULY 2017

EU NEWS

European and US regulators agree on mutual recognition of inspections of medicines manufacturers:

Regulators in the European Union (EU) and the United States (US) have agreed to recognise inspections of manufacturing sites for human medicines conducted in their respective territories on both sides of the Atlantic. The agreement is an annex to the EU-US Mutual Recognition Agreement (MRA) which was signed in 1998 but is not yet implemented. Many provisions of the agreement have already entered into force and others will enter into force on November 1, 2017. By that date, the EU will have completed its assessment of the FDA and the FDA is expected to have completed its assessment of at least eight EU Member States, and will be gradually expanded to all Member States. The text of this agreement is now published on the website of the European Commission's Directorate General for Trade.

New EU Regulations for medical devices and *in vitro* diagnostics:

New EU Regulations for medical devices and *in vitro* diagnostics were published in the *Official Journal of the European Union* on May 5, 2017 and will come into effect at the end of May*.

The Regulations are:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices

*Both Regulations are subject to transitional periods with full application of the Medical Devices Regulation after three years and full application of the *In Vitro* Diagnostic Regulation after five years.

Public consultation launched on EU blood, tissues and cells legislation:

The European Commission has launched a stakeholder consultation on the EU legislation on blood, tissues and cells.

The general public and all stakeholders are welcome to contribute to this consultation, which runs from May 29, 2017 to August 31, 2017. The purpose of this consultation is to support a comprehensive evaluation of the blood and tissues and cells legislation, examining their functioning across the EU. In particular, the consultation aims to gather views on whether the legislation has achieved its original objectives and if the directives remain fit for purpose.