

Health and Food Safety Directorate General

e-News

23 August 2017

Medicine safety:

New commitment allows EU and US to share full medicine inspection reports

This month, the European Commission, the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) signed a new confidentiality commitment related to medicine safety. The commitment allows the EU and US regulators to share non-public and commercially confidential information, including full reports on medicine inspections, potentially improving patient safety on both sides of the Atlantic.

Whereas the EU and the US have had confidentiality arrangements in place since 2003, the step concluded now allows the sharing of more types of non-public information, so that regulators can make better use of their inspection resources to focus on manufacturing sites of higher risk. This enhanced cooperation with US regulatory authorities will improve the EU's ability to identify and address problems at factories before they become a public health risk.

Background

This confidentiality commitment is a milestone in the ongoing implementation of [the Mutual Recognition Agreement](#) concluded between the EU and US on 2 March 2017.

- [For more information](#)