



EUROPEAN MEDICINES AGENCY
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Press release

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

Transatlantic agreement will help to make better use of inspection capacity and reduce duplication

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.

Each year, national competent authorities from the EU and the US Food and Drug Administration (FDA) inspect many production sites of medicinal products in the EU, the US and elsewhere in the world, to ensure that these sites operate in compliance with Good Manufacturing Practice (GMP). Under the new agreement, EU and US regulators will rely on each other's inspections in their own territories. In future, the need for an EU authority to inspect a site located in the US, or vice versa, will be limited to exceptional circumstances.

The agreement will enable both the EU authorities and the FDA to make better use of their inspection resources to help them to focus on other parts of the world where active pharmaceutical ingredients (APIs) and medicines for the EU or US markets are manufactured. This will ensure that patients can rely on the quality, safety and efficacy of all medicines, no matter where they have been produced. Around 40% of finished medicines marketed in the EU come from overseas and 80% of the manufacturers of APIs for medicines available in the EU are located outside the Union.

In the EU, inspections of manufacturing sites are carried out by national competent authorities from EU Member States. The European Medicines Agency plays an important role in coordinating these activities in collaboration with Member States.

The agreement is underpinned by robust evidence on both sides of the Atlantic that the EU and the US have comparable regulatory and procedural frameworks for inspections of manufacturers of human medicines. Teams from the European Commission, EU national competent authorities, EMA and the US FDA have been auditing and assessing the respective supervisory systems since May 2014, and have worked closely together to reach this agreement.

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.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The EU already has experience with mutual recognition of GMP inspections, having existing MRAs of GMP inspections already for several other countries including Australia, New Zealand, Canada, Japan and Switzerland. More information is available on the EMA website [here](#).
3. More information on Good Manufacturing Practice (GMP) is available [here](#).
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Tel. +44 (0)20 3660 8427

E-mail: press@ema.europa.eu

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