

EU-US FDA mutual recognition of inspections of medicines manufacturers enters operational phase

Today marks the beginning of mutual recognition of inspections of manufacturing sites for human medicines between the US and eight Member States of the European Union (Austria, Croatia, France, Greece, Italy, Spain, Sweden, United Kingdom).

The US Food and Drug Administration (FDA) has completed the capability assessments of drug manufacturing regulatory authorities in these eight EU Member States, recognising them as capable to carry out good manufacturing practice (GMP). The remaining Member States will be assessed by the FDA on a rolling basis, to be completed by 15 July 2019.

For its part, the European Commission confirmed that the US FDA has the capability, capacity and procedures in place to carry out good manufacturing practice (GMP) inspections at a level equivalent to the EU, earlier in the year.

This important agreement, which updates the mutual recognition agreement from 1998, strengthens reliance upon each other's inspection expertise and resources. Mutual benefits for EU authorities and the FDA include:

- The ability to focus inspection resources on other parts of the world where active pharmaceutical ingredients and medicines for the EU or US markets are manufactured;
- Prioritising inspections of medicines manufacturing sites for higher risk cases;
- Reassuring patients that they can rely on the quality, safety and efficacy of all medicines, no matter where they have been manufactured;
- Improving the ability to identify and address problems at manufacturing sites before they become a public health risk; and
- Reducing the administrative burdens and costs facing pharmaceutical manufacturers, including smaller producers.

To make this agreement operational, teams from the EU national competent authorities, European Commission, European Medicines Agency and the US FDA have been working intensively on auditing and assessing the respective supervisory system.

Mutual recognition covers medicinal products for human use with the exception of vaccines, plasma derived medicinal products and investigational medicinal products (clinical trial material).

FDA press release:

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm>

EMA press release:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/10/news_detail_002842.jsp&mid=WC0b01ac058004d5c1

For more information:

Commission adopts updated EU-US agreement on mutual recognition of inspections of medicine manufacturers (news item dated 02/03/2017)

<http://europa.eu/!Hc93WW>

Notification to the Joint Sectoral Committee

<http://europa.eu/!Pd69XQ>

EU policy on medicinal products for human use

http://ec.europa.eu/health/human-use/quality_en

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