FDA News Release

FDA takes unprecedented step toward more efficient global pharmaceutical manufacturing inspections

Agency completes eight capability assessments as part of the Mutual Recognition Agreement between the U.S. and European Union

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Release

The U.S. Food and Drug Administration has determined the agency will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in: Austria, Croatia, France, Italy, Malta, Spain, Sweden and the United Kingdom.

This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 U.S.-European Union (EU) Mutual Recognition Agreement (MRA) that enables U.S. and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities.

"At a time in which medical product manufacturing is truly a global enterprise, there is much to be gained by partnering with regulatory counterparts to reduce duplicative efforts and maximize global resources while realizing the greatest bang for our collective inspectional buck," said FDA Commissioner Scott Gottlieb, M.D. "By partnering with these countries we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries."

Some drugs approved in the U.S. are either fully manufactured overseas or made in the U.S. but contain some foreign ingredients. All drugs approved in the U.S., regardless of where they are made, must comply with applicable U.S. regulations. One way the FDA oversees drug manufacturing is by routinely inspecting domestic and foreign drug manufacturing plants for compliance with manufacturing standards that assure quality and product label requirements.

"Beginning November 1 we will take the unprecedented and significant step forward in realizing the key benefits of the Mutual Recognition Agreement with our European counterparts in that we will now rely on the inspectional data obtained by these eight regulatory agencies," said Dara Corrigan, the FDA's acting deputy commissioner for global regulatory operations and policy. "The progress made so far puts us on track to meet our goal of completing all 28 capability assessments in the EU by July 2019."

In June 2017, the European Commission determined that the FDA “has the capability, capacity and procedures in place to carry out GMP inspections at a level equivalent to the EU.” The completion of these capability assessments enables the FDA and the EU to avoid duplication of drug inspections and allows regulators to devote more resources to other manufacturing facilities in countries where there may be greater risk. Ultimately, this prioritization of inspections will help identify potential drug quality problems more quickly and prevent poor quality drugs from entering the U.S. market.

The FDA, an agency within the U.S. Department of Health and Human Services, promotes and protects the public health by, among other things, assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that emit electronic radiation, and for regulating tobacco products.

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Inquiries

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Related Information

- Mutual Recognition Agreement (https://ustr.gov/sites/default/files/IssueAreas/Manufacturing/20170119 Pharma MRA US EU %28FINAL%29.pdf)
- Mutual Recognition promises new framework for pharmaceutical inspections for United States and European Union (/NewsEvents/Newsroom/PressAnnouncements/ucm544357.htm)
- Frequently Asked Questions - Mutual Recognition Agreement (PDF - 247KB) (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/UCM544394.pdf)
- The Mutual Reliance Initiative: A New Path for Pharmaceutical Inspections in Europe and Beyond (http://blogs.fda.gov/fdavoice/index.php/2016/12/the-mutual-reliance-initiative-a-new-path-for-pharmaceutical-inspections-in-europe-and-beyond/)

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