U.S. FOOD & DRUG ADMINISTRATION

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FDA Officials Meet with EMA

Officials from the FDA and the European Medicines Agency (EMA) met today at the EMA's office in Amsterdam to discuss their recent collaborative successes and consider new potential areas of collaboration.

The FDA and the EMA have been sharing information since signing a confidentiality arrangement in 2010 to protect nonpublic information. This arrangement opened the door for the creation of a series of working groups or clusters, which have become the bedrock for FDA and EMA engagement. Each of the more than 20 clusters focus on a special topic or therapeutic area that have been identified as requiring an intensified exchange of information and collaboration. Cluster participants identify bottom-up technical challenges, policy gaps, and real-world examples of public health matters best addressed collaboratively. In 2021, a new cluster was formed to further efforts to include pregnant and lactating individuals in clinical research.

The long-standing partnership between the FDA and the EMA has paid off during the COVID-19 pandemic, making it easier for the two agencies to work together to address a broad variety of public health issues involving antiviral drugs, vaccines, drug safety, and drug shortages, FDA officials said.

Moreover, the existence of the ongoing U.S.-EU Mutual Recognition Sectoral Annex for Pharmaceutical Good Manufacturing Practices, which allows the FDA and European regulatory agencies to rely on each other's inspectional data, has proven to be instrumental in ensuring continued oversight of foreign facilities despite COVID-related travel restrictions, FDA said. Over the last two years, the FDA has been able to defer close to 300 inspections in Europe by relying on inspections conducted by EU partners. In the EU, inspections of manufacturing sites are carried out by national competent authorities from EU Member States. The European Commission and the EMA play an important role in coordinating these activities in collaboration with the Member States.

Other topics discussed today included potential new areas of cooperation such as illicit trade in health products, advanced manufacturing and regulatory science, food outbreak response, and nutrition labeling.

FDA Associate Commissioner for Global Policy and Strategy Mark Abdoo led the FDA delegation, while EMA Executive Director Emer Cooke led the EMA delegation.