



## Office of Global Policy and Strategy

### OGPS STATEMENT

July 8, 2022

#### FDA Meets with European Food and Drug Regulators

An FDA delegation led by Mark Abdoo, Associate Commissioner for Global Policy and Strategy, held a series of meetings with European regulators on July 7-8.

On July 7, the FDA delegation met with Emer Cooke, executive director of the European Medicines Agency, at the EMA's offices in Amsterdam to discuss their recent collaborative successes and consider potential new areas of partnership. Today in Brussels, the FDA delegation held separate meetings with food and medical product officials from the European Commission's Directorate-General for Health and Food Safety, DG SANTE.

The EMA is an agency of the European Union in charge of the evaluation and supervision of medicinal products. DG SANTE is responsible for EU policy on health and food safety and for monitoring the implementation of related laws.

The FDA and the EMA have been sharing information since signing a confidentiality arrangement in 2010. This arrangement opened the door for the creation of a series of working groups or clusters, which have become the bedrock of FDA and EMA engagement. Each of the more than 20 clusters focuses on a special topic or therapeutic area that has 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. For example, 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 EMA ensured they could work together seamlessly during the COVID-19 pandemic. The two agencies addressed a broad variety of public health issues involving COVID-19 therapies, vaccines, safety monitoring, and drug shortages, FDA officials said.

One of the topics that came up today during the meeting with Andrzej Rys, Director of DG SANTE Directorate B - Health Systems, Medical Products and Innovation, was the Mutual Recognition Agreement (MRA) regarding pharmaceutical inspections. The agreement allows FDA and European regulatory agencies to rely on each other's good manufacturing practice inspectional information for human drugs manufacturing facilities. Currently, the MRA is being applied to surveillance inspections — including those conducted within our respective borders — as well as inspections conducted by capable authorities of manufacturing facilities located outside the U.S. and EU. It has been instrumental in helping to ensure continued oversight of foreign facilities when COVID-related travel restrictions have been in place.

Over the last two years, the FDA has been able to defer close to 300 inspections in Europe by relying on GMP information from inspections conducted by EU partners. In the EU, inspections of manufacturing sites are carried out by national competent authorities from EU Member States. The EC 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. Koen Van Dyck, DG SANTE's head of international relations unit, led the DG SANTE delegation for talks on food issues.

Following its meeting with DG SANTE, the FDA delegation met for the first time with Director-General Pierre Delsaux and staff from the European Health Emergency Preparedness and Response Authority or HERA. HERA, a new Directorate General within the European Commission, was launched in September 2021 in response to preparedness and supply chain issues identified during the COVID-19 pandemic.