U.S. FOOD & DRUG ADMINISTRATION

Office of Global Policy and Strategy

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Danish Minister of Health and Danish Medicines Agency Meet with FDA to Discuss Future Collaborations

Today, FDA Deputy Commissioner for Policy, Legislation, and International Affairs Andi Fristedt and other FDA officials met with a delegation of Danish health officials led by Denmark's Minister of the Interior and Health Sophie Løhde to discuss existing and potential future collaborations.

Accompanying Minister Løhde were officials from the Danish Medicines Agency (DKMA), the national pharmaceutical regulatory authority in Denmark. The DKMA authorizes and inspects pharmaceutical companies and licenses medicinal products in the Danish market, monitors adverse reactions from medical products, authorizes clinical trials, decides which medicines are eligible for reimbursement, and oversees the pharmacy industry.

During her meeting with Minister Løhde and DKMA officials, Fristedt emphasized that the FDA values its strong relationship with the medicines agency, which is among the leaders in the European Union on the use of big data, digital health, and real-world data. Officials from the FDA's Office of Global Policy and Strategy were also present in the meeting.

In addition to meeting with Deputy Commissioner Fristedt, the Danish delegation participated in a technical meeting with FDA subject matter experts from the Office of the Commissioner, the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health. The delegation shared information on the Danish ENFORCE study, a national prospective cohort study to investigate the long-term effectiveness, safety, and durability of SARS-CoV-2 vaccines used in Denmark. Other topics discussed included Denmark's Data Analytics Centre, which uses real-world data in the regulatory environment, and regulatory approaches to combination products.

The meeting was facilitated in a hybrid fashion, with some participating in person at the FDA's headquarters in White Oak, Maryland, and others participating virtually.

Accompanying Minister Løhde from the Danish delegation were Lars Bo Nielsen, Director General of the Danish Medicines Agency, Ambassador Stig P. Piras, Deputy Chief of Mission at the Embassy of Denmark in the United States, Svend Særkjær, Permanent Secretary for the Ministry of Interior and Health, and Dorte Bech Vizard, Deputy Permanent Secretary for the Danish Ministry of Interior and Health, with responsibility for Patient Safety, Medicines, and Global Health.

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