Joint Meeting of the U.S. Food and Drug Administration (FDA) Clinical Trials Transformation Initiative's (CTTI)/ Patient Engagement Collaborative (PEC) and the European Medicines Agency's (EMA) Patients' and Consumers' Working Party (PCWP)

June 12, 2025 | 9:30 – 11:00 am EDT

Zoom Virtual Meeting

Disclaimer: *The purpose of this meeting was to facilitate a discussion of ideas, and as such, not all of the content below will be within the scope of the FDA, CTTI, or EMA. The views and opinions expressed in this meeting are those of the individual speakers and participants and do not necessarily reflect the official views of their organizations, the FDA, CTTI, or EMA.*

Meeting Overview

The purpose of this virtual meeting was to facilitate discussion between members of the PEC and PCWP patient communities related to drug shortages. Representatives from the EMA and FDA presented on the mechanisms in place to monitor, mitigate, and prevent drug shortages. This was followed by a panel discussion in which the speakers and patient representatives from the PEC and PCWP reflected on key patient concerns regarding drug shortages.

EMA/FDA Presentations:

How Shortages Are handled in the European Union (EU):

- A representative from EMA presented on national and EU-level coordination, in particular on how the Executive Steering Group on Shortages and Safety of medicinal products (MSSG), supported by the Medicine Shortages Single Point of Contact (SPOC) Working Party, monitors, manages, and prevents critical shortages of medicines in the EU.
- In addition, further information on international collaboration was presented, highlighting the work of the Drug Shortages Global Regulatory (DSGR) Working Group.
- The European Shortage Monitoring Platform (ESMP) is designed to improve the prevention, monitoring, and management of medicines shortages across the EU.

FDA's Drug Shortage Role and Patient Resources:

- A representative from FDA's Center for Drug Evaluation and Research (CDER) presented on definitions and reasons for drug shortages as well as how the FDA's Drug Shortage Staff (DSS) actively collaborates with internal FDA teams, other federal agencies, manufacturers, and international partners to assess, address, and communicate about drug shortages, using a case-by-case risk-benefit analysis approach.

- Patients and healthcare providers can check current shortages on FDA's Drug Shortage Database or report them through the FDA's public portal, helping the agency identify and address national supply issues.

Discussion Questions:

- *Could findings during manufacturing site inspections trigger concerns that could suspend manufacturing and cause a shortage?*
    - Before the inspection, the FDA would evaluate the products being manufactured at that site, so if the inspector does identify any major concerns or the manufacturer indicates they'll be stopping production, the FDA can consider strategies to assist with supply.
- *Does the FDA have a mechanism when there is excessive demand and limited supply in one U.S. state to ship supply where it is needed?*
    - Yes, the FDA could reach out to the manufacturer(s) and request that they send specific product to the affected region. But the FDA cannot require manufacturers to comply with these requests.

Panel Discussion: PEC and PCWP Member Reactions

Panel participants reflected on key patient concerns around the issue of drug shortages. Key points discussed include:

- Medicine shortages can impact **patient health, well-being, stress, and finances.**
- Definitions of **medical necessity** do not always consider the **distress, logistical challenges, and potential harm** that drug shortages can cause.
- Strategies are needed to ensure **equitable distribution** of drugs during a shortage.
- Communication strategies are needed to ensure patients and healthcare providers are **aware of therapeutic alternatives and mechanisms to report drug shortages**.

Conclusion and Next Steps

The FDA, CTTI, and EMA expressed the need to continue to identify opportunities to further expand patient engagement. Feedback from this meeting may be incorporated in future PEC-PCWP joint meetings.

The PEC is a public-private partnership between the FDA and the Clinical Trials Transformation Initiative (CTTI) that is not intended to advise or direct the activities of either organization. The PEC is primarily a forum to facilitate the exchange of information between patient community representatives and the FDA on areas of common interest, including regulatory discussions and strategies to increase patient engagement. Public summaries of all PEC meetings, including the last PEC-PCWP Joint Meeting in 2023, are available on the PEC website.

The Patients' and Consumers' Working Party (PCWP) provides a platform for exchange of information and discussion of issues of common interest between EMA and patients and consumers. The PCWP, established in 2006, has enabled the Agency to build upon its existing interactions with patients and consumers. It provides recommendations to EMA and its human scientific committees on all matters of interest in relation to medicines.