

AGENDA

Joint Meeting of CTTI/FDA Patient Engagement Collaborative (PEC) and EMA Patients' and Consumers' Working Party (PCWP)

Thursday, June 12, 2025
9:30 a.m. – 11:00 a.m. (EDT) / 15.30 – 17.00 (CEST)

The meeting will open early at 9:15 / 15.15 for an optional icebreaker and audio check.

9:30/15.30 Welcome and Overview of Agenda

Facilitator: Maria Mavris, European Medicines Agency

- ▶ Welcome and Agenda

9:35/15.35 Presentations

Facilitator: Maria Mavris, European Medicines Agency

- ▶ Speaker 1: Klaus Krutwig, EMA
Medicines and Medical Devices Shortages Specialist

Presentation: How Shortages Are Handled in the EU

- ▶ Question and Answer with EMA

- ▶ Speaker 2: CDR Robert Kosko, FDA
Senior Program Management Officer, Drug Shortage Staff
Center for Drug Evaluation and Research

Presentation: FDA's Drug Shortage Role and Patient Resources

- ▶ Question and Answer with FDA

10:05/16.05 BREAK

10:20/16.20 PEC and PCWP Member Reactions

Facilitator: Lori Wiggins, U.S. Food and Drug Administration

- ▶ Discussion
 - ▶ PCWP Members: TBD
 - ▶ PEC Members: Heather Guidone
Carter Hemion

10:55/16.55 Final Comments and Announcements

Facilitator: Dayle Cristinzio, FDA

11:00/17.00 Adjourn

Background Information

About the EMA:

<https://www.ema.europa.eu/en>

About the PCWP:

<https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/patients-consumers-working-party>

About the FDA:

<https://www.fda.gov/>

About the PEC:

<https://www.fda.gov/patients/learn-about-fda-patient-engagement/patient-engagement-collaborative>

Resources: Medical Product Shortages

FDA

FDA Drug Shortages

<https://dps.fda.gov/drugshortages>

Report a Drug Shortage

<https://cdernextgenportal.fda.gov/publicportal/s/dsm-submission>

Frequently Asked Questions about Drug Shortages

<https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages>

Drug Shortages Infographic

<https://www.fda.gov/drugs/drug-shortages/drug-shortages-infographic>

Medical Device Supply Chain and Shortages

<https://www.fda.gov/medical-devices/medical-device-safety/medical-device-supply-chain-and-shortages>

EMA

Medicine shortages and availability issues

<https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues>

Medicine Shortages Single Point of Contact (SPOC) Working Party

<https://www.ema.europa.eu/en/committees/working-parties-other-groups/medicines-shortages-single-point-contact-spoc-working-party>

Executive Steering Group on Shortages and Safety of Medicinal Products

<https://www.ema.europa.eu/en/about-us/who-we-are/executive-steering-group-shortages-medicinal-products>

Public information on medicine shortages

<https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/public-information-medicine-shortages>