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

July 15, 2022 | 9:45 – 11:45am ET

Zoom Virtual Meeting

Disclaimer: *This 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 related to emerging issues in patient engagement. The meeting also included discussions around lessons learned during the COVID-19 pandemic.

Discussion Themes

- *Communicating with the public and media during the COVID-19 pandemic*
- *Combating public misinformation about COVID-19 vaccines and treatments*
- *Emerging issues in patient engagement including raising awareness, educating patients, and increasing participation*

Presentations: PEC and PCWP Patient Engagement

PEC Patient Engagement:

- The FDA and CTTI established the PEC in 2018 based on the EMA's PCWP.
- PEC members have personal experience with diseases as patients, caregivers, or members of patient organizations. Members represent diverse perspectives from different disease groups, demographics, and communities.

EMA Patient Engagement:

- Patients and consumers are nominated to EMA's Management Board, and several of EMA's scientific committees by the European Commission for a renewable term of three years. These individuals represent all patients/consumers in Europe.
- The PCWP includes representatives from patient organizations who participate in EMA discussions, workshops and consultations and do so representing their organisations.
- Patients are also involved as individuals in medicine-specific EMA activities such as scientific advice consultations, committee discussions and review of documents prior to their publication.

Presentations: Communications Lessons Learned from the COVID-19 Pandemic

- At the FDA, the Joint Information Center (JIC) published thousands of communications materials related to the COVID-19 pandemic.
- During the pandemic, the JIC focused on being clear and consistent in communicating with the public and media about COVID-19.
- The EMA shared information about vaccines through social media, public meetings, media interviews, and the European Vaccination Information Portal.
- During the pandemic, the EMA focused on and ensured high levels of transparency and also focused on identifying and proactively combating public misinformation.
- Both agencies acknowledged the importance of communicating quickly with their audiences to provide important updates about COVID-19 and vaccinations.

Discussion:

- Meeting attendees suggested a need to help local health providers communicate with their patients about COVID-19 cases and vaccinations.
- Meeting attendees also suggested a need to use printed materials in addition to digital communications to reach more people with information about COVID-19.

Group Discussion: Emerging Issues in Patient Engagement

Meeting attendees discussed emerging challenges and best practices for patient engagement. Key points discussed include:

- **Raising awareness** about how patients can participate in clinical trials and drug/medicines development processes
- **Educating patients** about how their involvement in clinical trials and drug/ medicines development can benefit them and their communities
- **Increasing patient participation** with virtual options while being mindful of the inclusivity and accessibility of online and in-person meetings

Conclusion and Next Steps

The FDA, CTTI, and EMA will collect feedback on this meeting and use it to plan future PEC-PCWP joint meetings. They will also look for additional opportunities for PEC and PCWP members to work together to improve patient engagement.

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 2021, 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.