10 July 2024
EMA/325178/2024
Stakeholders and Communication Division

# Draft Agenda – Training session for patients, consumers and healthcare professionals involved in medicines regulatory activities

5 December 14:00–17:00 CET – Competing interests (3 hours)

11 December 09:00–12:00 CET – Scientific advice (3 hours)

13 December 09:30–12:00 CET – Document reviews (2.5 hours)

All sessions are held virtually using Webex.

Please note: Connection 15 minutes before the start of the meeting for technical checks.

## DAY 1: 5 December, 14:00–17:00 CET

**Chair:** Juan Garcia-Burgos (EMA)

| Time | Agenda item | Speaker |
|---|---|---|
| 13:45 | Arrival and technical checks | |
| 14:00 | Welcome and introduction to the training session<br><br>*Learning outcomes:*<br>• *Understand why EMA has a policy on competing interests in place*<br>• *Understand what interests must be declared and how these may impact the different roles patient and HCP experts may have in EMA activities*<br>• *Know how to fill in a public declaration of interests* | Juan Garcia Burgos |
| **1. Introduction to competing interests** | | |
| 14:10 | Ice-breaker quiz<br><br>Presentation: EMA policy on competing interests | EMA Expert Management Team |
| 14:30 | Q&A | |

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| Time | Agenda item | Speaker |
|---|---|---|
| **2. Scenarios for discussion (interactive session)** | | |
| 15:00 | Discussion of practical scenarios covering several situations applicable to patient and/or HCP representatives | EMA Expert Management Team |
| | *Coffee break* | |
| 16:40 | Presentation: how to register as an EMA expert and fill in a public declaration of interests | Maria Mavris |
| | Q&A | |
| 17:20 | Feedback and conclusions | Juan Garcia Burgos |
| 17:30 | End of session | |

## DAY 2: 11 December, 09:00–12:00 CET

**Chair:** Juan Garcia-Burgos (EMA)

| Time | Agenda item | Speaker |
|---|---|---|
| 08:45 | Connection and technical checks | |
| **1. Introduction** | | |
| 09:00 | Welcome and objectives of the training<br>*Learning outcomes:*<br>• *Gain an understanding of EMA scientific advice*<br>• *Understand areas where patients and healthcare professionals can contribute to EMA scientific advice procedures* | Juan Garcia Burgos |
| 09:15 | 1.1. Overview of the regulatory pathway of a medicine | Maria Mavris |
| 09:45 | 1.2. Introduction to the breakout sessions and facilitators | Kaisa Immonen |
| **2. Breakout sessions** | | |
| 10:00 | **Scientific advice**<br>Discussion of a pedagogic scientific advice document (includes coffee break) | Scientific Advice Team |
| 11:50 | Feedback and conclusions | Juan Garcia Burgos |
| 12:00 | End of session | |

## DAY 3: 13 December, 09:30–12:00 CET

**Chair:** Juan Garcia-Burgos (EMA)

| Time | Agenda item | Speaker |
|---|---|---|
| 13:45 | Connection and technical checks | |
| **1. Introduction** | | |
| 14:00 | Welcome and introduction to the session on review of documents intended for patients, healthcare professionals and the general public<br>*Learning outcomes:*<br>• *Appreciate the aim, scope and structure of the documents*<br>• *Understand what is expected from the reviewer*<br>• *Feel confident about reviewing the documents*<br>Introduction to breakout session and facilitators | Juan Garcia Burgos<br>Kaisa Immonen |
| **2. Breakout sessions** | | |
| 14:15 | **Document review**<br>Discussion of a pedagogic document (incudes coffee break) | Medical Writers Team |
| 16:15 | Feedback and conclusions | Juan Garcia Burgos |
| 16:30 | End of the training | |