



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# EMA Training Strategy

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For patients and consumers



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An agency of the European Union





# Background

- Patients/consumers are involved in a wide range of activities at the EMA, as individuals and/or as representatives of their organisations.
- To aid and optimize involvement appropriate support and training is necessary, prior to, and during their participation in any EMA activity.
- They should be fully aware of the Agency's work and their expected role.
- This has already been highlighted and will be part of the revised "*framework of interaction with patients and consumers' organisations*".
- A training strategy has been developed describing the specific training activities and material that is provided to patients/consumers when taking part in EMA activities.
- The strategy takes into account feedback obtained during discussions held in the margin of PCWP meetings.



# Objectives

- Identify patient/consumer training requirements for involvement in EMA activities;
- Define a training methodology which delivers training packages in line with requirements;
- Construct an approach that can be used by all while providing targeted material depending on specific activities;
- Define a continuous training implementation plan, including frequency, priorities & monitoring



# Context

## **Activities in which patients and consumers are involved:**

- Members of EMA scientific committees, and Management Board;
- Members of the PCWP
- Participation in CHMP scientific advisory group/ad-hoc expert group meetings;
- Consultations from scientific committees and working parties, including benefit/risk evaluations;
- Reviewing information on medicines (package leaflet, EPAR summary, Q&A);
- Participating in EMA project-groups, e.g. user group for Eudravigilance;
- Participating in Agency conferences and workshops;
- Public hearings.



# Context

## **Training required:**

- Information on general EMA role/responsibilities (e.g. centralised procedure, pharmacovigilance);
- Information on patient/consumer involvement in EMA activities, including practical aspects (e.g. completing DOI, etc);
- Information on specific EMA procedures (e.g. CHMP consultation, SAG meeting);
- Information on expected role and contribution of patient organisation or expert, by activity;
- Information regarding experience in collaborating with the Agency, given by patients' representatives with experience.



# Proposed training methods/material

## Written information, including:

- Training manual - Review of EMA documents by patients and consumers, including modules on EMA, reviewing a package leaflet, an EPAR summary & a Q&A document
- Agency leaflet, with general information on PCO involvement in Agency activities
- Product-specific background information (for SAG participation or committee/working party consultation)
- Document: "The role of patients as members of the EMA human scientific committees"
- Document: "Rules of involvement of members of patients' and/or consumers' and healthcare professionals' organisations in committee related activities".
- Topic-specific background information (for project-groups)



# Proposed training methods/material

## Agency website, including:

- Webpage with general information on EMA
  - Video tutorials specifically on EMA, Pharmacovigilance, COMP
- Webpage dedicated to patients/consumers involvement, including:
  - Video tutorial on participation in SAG meetings (further videos to be developed)
- Online glossary giving definitions of EMA-related acronyms
- Webpage dedicated to PCWP



# Proposed training methods/material

## **In-house training, held at the EMA including sessions on:**

- EMA activities; e.g. centralised procedure, pharmacovigilance, scientific advice
- Review of EMA information
- Other ad-hoc topics
- Mentorship program, whereby experienced patients help newer representatives.





# Proposed training methods/material

**Personalised assistance (usually by telephone), including individual provision of information/training on:**

- Participation in SAG/ad-hoc expert meetings
- Consultations from Committees / working parties
- Whenever necessary or requested

**Information sessions - conferences / workshops**



# **DETAILED TRAINING PLAN BY ACTIVITY**

See training strategy document....

