EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patients and Healthcare Professionals

Training strategy for patients and consumers involved in EMA activities

Background

Patients and consumers are systematically called-upon to be involved in a wide range of activities at the EMA, either as individual patient experts or as representatives of their organisations. In order to aid and optimise their involvement, it is vital that they receive appropriate support and training prior to, and during their participation in any EMA activity. For their contribution to be useful, patients should have adequate knowledge on the Agency's work, as well as their expected role as a patient/consumer representative.

This has been highlighted in the "*reflection paper on the further involvement of patients and consumers in the Agency's activities*", which proposes that the revision of the "*framework of interaction with patients and consumers' organisations*" should provide the following:

- A definition of the role of patients/consumers in the different scientific committees
- Adequate training for patients/consumers to facilitate and optimise their contribution

On this basis, the Agency has prepared a training strategy that describes the specific training activities and the material that is available to patients and consumers taking part in EMA activities and events. This strategy takes into account feedback obtained from patient and consumer organisations during discussions held in the context of PCWP meetings, as well as the support and training that has already been provided to patients in previous years in the different areas.

Objectives

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

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Context

Activities in which patients and consumers are involved:

- Members of EMA scientific committees, and Management Board;
- Members of the Patients' and Consumers' Working Party (PCWP);
- Participation in scientific advisory group (SAG) and ad-hoc expert group meetings;
- Participation in scientific advice procedures via Scientific Advice Working Party (SAWP);
- Consultations with scientific committees and working parties;
- Reviewing public information on medicines prepared by the Agency (package leaflets, European Public Assessment Report (EPAR) summaries and safety communications);
- Participating in EMA project-groups (e.g. user group for Eudravigilance, clinical trials register operational group);
- Participating in Agency conferences and workshops.

Training identified

- Information on general EMA role/responsibilities;
- Pathway of medicines development and authorisation;
- Information on patient/consumer involvement in EMA activities;
- Practical aspects of participating in EMA activities (e.g. completing Declaration of Interests (DOI), confidentiality agreement, etc.);
- Information on specific EMA procedures (e.g. CHMP consultation, SAG meeting, Package Leaflet (PL) template);
- Information on role and expected contribution of patient organisation or expert, by activity;
- A mentorship programme organised by the organisations themselves to provide support and information on collaborating with the Agency. More experienced patients' representatives to mentor newcomers;
- Participation as members of EMA scientific committees; given directly by the relevant committee secretariat; see training plan below "Committees".

Overview of Proposed training methods/supporting material

- **Written information:**
  - Training manual on the review of EMA documents, including modules on reviewing a package leaflet / EPAR summary / safety communication;
  - Agency leaflet; Working with patients and consumers (also online) ;
  - Product-specific information (e.g. for SAG involvement or committee consultation);
  - Document: “Rules of involvement of members of patients' and/or consumers' and healthcare professionals' organisations in committee related activities”;
  - Topic-specific information (for project/working groups);
  - Document: “The role of patients as members of the EMA human scientific committees”.
- **Agency website information:**
  - Webpage(s) “About Us”;
  - EMA videos, e.g. Pharmacovigilance, COMP;
  - Webpage – Patients’ and Consumers’ Working Party (PCWP);
  - Webpage - patients / consumers involvement;
  - Webpage - training and support for patient/consumer representatives, including video for patients invited to participate in scientific meetings;
  - Online glossary giving definitions of EMA-related acronyms.
- **In-house training:**
  - EMA activities (e.g. pharmacovigilance, scientific advice), review of EMA information and ad-hoc topics upon request.
- **Personalised assistance** (usually by telephone), including provision of information/training on:
  - Participation in SAG/ad-hoc expert, scientific advice meetings;
  - Consultations from Committees / working parties;
  - Whenever necessary or requested.
- **Information sessions - conferences / workshops**

DETAILED TRAINING PLAN – BY ACTIVITY

Patients' are involved in a diverse array of Agency activities either as **individual experts** where they provide input on product-specific issues or where they represent a **patient organisation**.

Representing Patients' Organisations

Training method	Training material	Frequency / timing
EMA ELIGIBLE ORGANISATION When a new patients' or consumers' organisation becomes eligible to work with the EMA they are provided with the following information and invited to attend the next in-house training session.		
EMA website	• "What we do" - webpage • Patients and consumers – webpage • Training and support for patient/consumer representatives - webpage • Glossary • Agency leaflet: Working with patients and consumers	When a new organisation becomes eligible to work with the EMA
Written information	• "Orientation guide to EMA for PCOs" document • Training manual on the review of documents • Agency leaflet: Working with patients and consumers • Policy on conflicts of interest	
In-House training	• Annual one-day training session • Eligible organisation representatives are invited to attend PCWP meetings as observers • System of mentorship where more experienced organisations provide assistance (information, support) to new organisations	Once per year Each PCWP meeting (budget allowing) Whenever requested
Personalised assistance	• Personal assistance (usually by telephone) provided by EMA secretariat to go through options for involvement and also respond to any specific queries.	When a new organisation becomes eligible and thereafter whenever necessary

PATIENT AND CONSUMER WORKING PARTY (PCWP) When a patients' or consumers' organisation becomes a member of the PCWP they are provided with the following information and invited to attend the next in-house training session		
EMA website	• Patients and consumers working party webpage • Training and support for patient/consumer representatives - webpage	When an eligible organisation becomes a member of the PCWP
Written information	• Mandate, objectives and rules of procedure • Work plan	
In-House training	• Annual one-day training session	Once per year
PARTICIPATING IN EMA PROJECT-GROUPS When a patients'/consumers' organisation representative(s) is selected to be part of a group (e.g. EudraCT register operational group), they are provided with the following information		
Written information	• Background information on the topic will be provided by the EMA sector organising the group, before start of work and throughout the duration of the mandate	Continuous
Telephone	• Possibility of a telephone conversation with EMA staff at any time for any queries	Prior to, and during meetings
PARTICIPATING IN EMA CONFERENCES AND WORKSHOPS[i] When an organisation or patient representative are invited to take part in a conference or workshop, they are provided with the following (website information would only be provided for new participants)		
EMA website	• "What we do" – webpage • Patients and consumers involvement – webpage • Glossary	Prior to workshop/conference (if they are new representatives)
Written information	• Agenda and background documents	

Individual Patient Experts

Training method	Training material	Frequency / Timing
REVIEW OF EMA INFORMATION ON MEDICINES When an eligible organisation wishes to nominate individuals to be involved in the review of EMA documents (package leaflets, EPAR summaries and safety communications), they are sent the following information and invited to attend the next in-house training session		
Written information	• Training manual on the review of documents • Glossary	After expressing interest to participate
In-House training	• Annual one-day training session	Once per year
PARTICIPATION IN SAG (AND AD-HOC EXPERT) MEETINGS When an individual patient representative is invited to participate in a SAG (or ad-hoc expert group) meeting, they are provided with the following information and contacted by telephone		
EMA website	• Video - participation in scientific meeting • Glossary • "What we do" - webpage • Patients and consumers involvement – webpage • Policy on conflicts of interest	Following first contact and interest to be involved
Written information	• Background information on the issues under discussion (prepared on a case-by-case basis by the EMA)	Prior to the meeting (after they have completed DOI)
Telephone	• Telephone conversation with EMA to provide any additional background information and to answer any particular queries	Prior to the meeting (after they have received background information)
PARTICIPATION IN SCIENTIFIC ADVICE (SA) MEETINGS When an individual patient representative is invited to participate in a SA meeting, they are provided with the following information and contacted by telephone		
EMA website	• Video - participation in scientific meeting • "What we do" - webpage • Patients and consumers involvement – webpage • Policy on conflicts of interest • Glossary	Following first contact and interest to be involved
Written information	• Information letter on scientific advice and the role of patient representatives • Background information on the issues under discussion (prepared on a case-by-case basis by the EMA)	Prior to the meeting (after they have completed DOI)

Training method	Training material	Frequency / Timing
Telephone	• Telephone conversation with EMA to provide any additional background information and to answer any particular queries	Prior to the meeting (after they have received background information)
RESPONDING TO WRITTEN CONSULTATIONS FROM COMMITTEES AND WORKING PARTIES When an eligible organisation or individual patient expert is contacted concerning a consultation from a committee or working party they are provided with the following information		
EMA website	• Background information on the regulatory procedure, if necessary	Prior to consultation
Written information	• Policy on conflicts of interest • Detailed information on the issue(s) for consultation (prepared "case-by-case" with the PTL/WP/committee secretariat)	Prior to consultation (after they have completed DOI)
Telephone	• Telephone conversation with EMA to provide any additional background information and to answer any particular queries, if necessary	Prior to, and during consultation

Committees		
COMP (Committee for Orphan Medicinal Products)		
EMA website	• Committee for Orphan Medicinal Products (COMP) webpage • Patients and consumers involvement – webpage • Glossary	
Written information	• Document: The role of patients as members of the EMA human scientific committees • Introduction to the COMP EMA/506578/2013 • COMP Information Pack 2014_Annex EMA/508433/2013	
Personal/TC/in-house	• Personal/in-house trainings on EMA business software (Eudralink, MMD, Adobe Connect, MMS)	
CAT (Committee for Advanced Therapies)		
EMA website	• Committee for Advanced Therapies (CAT) webpage • Advanced Therapies webpage • Patients and consumers involvement – webpage	

Committees		
	• Glossary	
Written information	• Document: The role of patients as members of the EMA human scientific committees • Welcome pack (currently being updated)	
Personal/TC/in-house	• EudraPortal: CAT Assessors Training 2011 and 2012 • Personal/in-house trainings on EMA business software (Eudralink, MMD, MMS, Adobe Connect, Connectra key, external EMA email) • Training session in September 2013 for the civil societies	
PDCO (Paediatric Committee)		
EMA website	• Paediatric Committee (PDCO) webpage • Patients and consumers involvement – webpage • Glossary	
Written information	• Document: The role of patients as members of the EMA human scientific committees • Introduction to the EMA - Delegates Information Pack EMA/338299/2013 • Introduction to the PDCO - Member Information Pack EMA/506580/2013 • PDCO Information Pack 2014_Annex EMA/508432/2013 IT Practicalities	
Personal/TC/in-house	• Induction training of new PDCO members (Conflict of Interests, Electronic submission of DoIs and CVs, meeting invitations, reimbursement and allowance, PDCO procedures –overview, Working documents and processes of the committee: agenda, minutes and monthly report) • Personal/in-house trainings on EMA business software (Eudralink, MMD, e-MMS, Adobe Connect, EudraNet)	
PRAC (Pharmacovigilance and Risk Assessment Committee)		
EMA website	• Pharmacovigilance and Risk Assessment Committee (PRAC) webpage • Patients and consumers involvement – webpage • Glossary	At nomination
Written information	• Document: The role of patients as members of the	At nomination

Committees		
	EMA human scientific committees • "Orientation guide to EMA for PCOs" document • Working with patients and consumers - leaflet • Policy on conflicts of interest • Pharmacovigilance risk assessment committee (PRAC) on EMA website (members and alternates page, meetings, agenda minutes, highlights) • PRAC new member welcome pack • Introduction to the EMA - Delegates Information Pack EMA/563901/2014 • Introduction to the PRAC- Member Information Pack EMA/494521/2013	
Personal/TC/in-house	• Training for assessors on specific PRAC related procedures • Personal/in-house trainings on EMA business software (Eudralink, MMD, MMS, Adobe Connect)	At nomination and first meetings

Implementation (Organisational)

It is proposed to maintain the current organisational arrangements.

Performance Monitoring

Related questions to be included within the general performance evaluation questionnaires sent every two years; the training strategy will be reviewed following this outcome.

[i] Most frequently this involves Patient Organisations but can also be individual patient experts depending on topic.