EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The role of members representing patients' and healthcare professionals' organisations on EMA Scientific Committees

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The purpose of this paper is to clarify the role of representatives of patient and healthcare professional organisations within the different EMA scientific committees, focusing in particular on their role as members of such committees. The aim is to provide guidance to current members as well as those who are considering applying for membership of a committee at the EMA. For this purpose, this document addresses the role, workload, challenges and the added value of the patients and healthcare professional representatives in the committees. It also covers the work involved outside of the committee and other related aspects.

This paper has been prepared in collaboration with patients and healthcare professional representatives members of the Human EMA scientific committees, based on their experience to date.

Analysis of the experience acquired demonstrated that participation of patients and healthcare professional representatives in the scientific committees improves the quality of the opinion given by the scientific committees. It is also acknowledged that their contribution increases transparency and trust in regulatory processes and develops mutual respect between regulators and the community.

In accordance with Community legislation, patients and healthcare professional representatives are included as members in four of the six human EMA scientific committees: the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee (PDCO), the Committee for Advanced Therapies (CAT) and the Pharmacovigilance and Risk Assessment Committee (PRAC) (Annex I).

Contents

1. Role and added value of patients and healthcare professionals members

Patient and healthcare professional members of EMA scientific committees have the same rights and responsibilities as all other committee members (i.e. they take part in committee decisions and have equal voting capacity).

As members of scientific committees, these representatives should be prepared to contribute to committee discussions and activities.

The role of the members representing patients' organisation is to bring a unique and critical input based on the real-life perspective of living with a condition and its current therapeutic environment. This element complements the scientific information and fills a gap that other committee members (i.e. scientific experts) cannot fill, and which has proven to be critical for achieving the best possible results within the regulatory process. The role of patient members is not expected to be of a scientific nature and experience has demonstrated that patients can frequently contribute scientifically to the discussion. Although this is welcomed, their added value is to bring their unique real-life perspective as end-users of medicines and to ensure that this is delivered throughout the committee's activities and outcome.

The role of members representing healthcare professionals' organisations is to bring their expertise and the views of the wider community of practicing specialists, general practitioners, nurses and pharmacists. European healthcare professionals support and reinforce existing knowledge within the European Regulatory Network with additional input from day-to-day clinical practice; including at the level of prescribing, dispensing and/or administering medicines and provide valuable insight on the potential impact of regulatory decisions. The healthcare professional members are not expected to bring regulatory expertise to the committees, although they are welcome to contribute in this way. The added value of these members is to ensure the real-life implications of regulatory decisions are taken into account.

Committee members usually have an alternate member (except COMP) who are welcome to attend every meeting and contribute to the work and discussions within the committee.

Although the candidature of members representing patients and healthcare professionals may be supported by a particular organisation or institution, once appointed the role of these members is to represent the entire community of European patients or healthcare professionals.

Representing patients

Patient representatives' contributions should focus on ensuring that the perspectives of the patient community is delivered throughout the committee's activities and outcomes. These can include:

- Patient advocacy to ensure that patients' (parents and carers) perspectives and real-life experience are taken into account in the deliberations of the committee resulting in a balanced outcome;
- Identifying patients with experience of the disease(s) and their treatments who can be consulted as necessary on relevant issues;
- Identifying potential topics that may require or would benefit from additional patient consultation.
- Reflecting on the risk that patients are prepared to take (or identify the appropriate patients to ensure this aspect is adequately considered by the committee).
- Encouraging reflection on real-life implications of regulatory decisions;
- Contributing to improvements in the regulatory processes and committee functioning, where possible.
- Ensuring credibility of the system by helping the scientific committee to act for the benefit of society.
- Providing updates on EU activities relevant to patients with implications for regulatory processes;
- Helping and assisting in decision making so that the best decision is taken.
- Guaranteeing that scientific opinions address patient needs and that there is a rational and adequate use of regulatory incentives for the benefit of patients.

Representing healthcare professionals

Healthcare professional representatives should focus on ensuring that the perspectives of their community is delivered throughout the committee's activities and outcomes. These can include:

- Ensuring that current standards of care, clinical guidelines and practice developments in the context of different national healthcare systems are taken into account in the deliberations of the committee
- Providing clinical experience, relative to issues under discussion as appropriate.
- Identifying experts with experience of the disease(s) and their treatments who can be consulted as necessary on relevant issues.
- Identifying potential topics that may require or benefit from additional healthcare professional consultation (e.g. input on causes of potential and documented medication errors).
- Contributing to improvements in the regulatory processes and committee functioning, where possible.
- Encouraging reflections on the implications of regulatory decisions in clinical practice.
- Helping and assisting in decision making so that the best decision is taken.
- Ensuring credibility of the system by helping the scientific committee to act for the benefit of society.
- Contributing and asking for changes in the system to improve reliability.

Communication and transparency

Patient and healthcare professional representatives are also expected to:

- Contribute actively to information and communication related to medicines including the decision on when to communicate.
- Ensure that individuals and organisations can access useful and understandable information.
- Promote the dissemination of committees' outcomes when they become public, passing on information to other individuals and organisations within the limits of confidentiality.
- Contribute, in a general capacity, to public health (where appropriate by raising awareness of the impact of regulatory and policy decisions, raise awareness of EMA initiatives of relevance to stakeholders) in the context of their organisation.
- Raise awareness of the committee's work and the EU Regulatory network and building confidence and trust in the system
- Contribute to making information for patients, healthcare professionals and the general public clear and understandable by the target audience and ensuring that it fulfils their needs in terms of information content (e.g. Summary of Product Characteristics (SmPC), DHPC, safety communications, package leaflet, educational materials etc.).
- Foster transparency and build confidence and trust in the regulatory process.

2. Other ways that patients and healthcare professionals are represented in scientific committees

In addition to being a member, patients and healthcare professionals can participate in three other ways within the scientific committees:

Experts:

- Advise the committee on specific issues and are selected for their *individual* relevant expertise, experience or knowledge; they bring a real-life experience of the disease and its current therapeutic environment. The suggestion to involve an individual expert comes from the committee and a specific expert could be proposed by a Committee member or by the Agency. They act on their own behalf (Annex II).
- Experts usually only attend part of a meeting to answer specific questions raised by the committee and do not take part in committee conclusions or decisions. They must maintain confidentiality, declare any interest in the pharmaceutical industry and abide by the EMA code of conduct.
- In accordance with article 62(2) of Regulation (EC) No 726/2004, when involved as an expert, the patient or healthcare professional is entered into the EMA European experts' database.

Representatives of a specific organisation:

- Act *on behalf of an organisation* and usually attend part of a committee meeting to express the views of their organisation on a specific issue. They are responsible for liaising with their organisation to present the views of the organisation on the questions to be addressed.
- Representatives are still expected to declare any conflict of interest and the organisations involved should be fully transparent with regard to their activities and funding sources.

Observers:

- May attend the whole meeting but do not take part in committee conclusions or opinions.
- Observers participate in accordance with each committee's rules of procedure and must maintain confidentiality, declare any conflict of interests and abide by the EMA code of conduct.

Independently of how patients or healthcare professionals participate in scientific committees (i.e. members, alternates, experts, observers or representatives) they can bring four different features (which are not mutually exclusive):

Expertise	Convey a combination of specific education, training or professional/personal experience
Experience	Convey practical disease knowledge obtained from direct experience with the disease (affected person or close contact with affected person, e.g. family, carer) or its treatment (e.g. healthcare professional)
Advocacy	Act on behalf of the affected patients in defence of their rights; provide patient-oriented public health / healthcare policy perspective
Empowerment	Participate in decision-making process within the committee; having access to information and process on behalf of patients and healthcare professionals

3. Conditions, workload and challenges

3.1. Conditions of participation

- Members (and alternates) participate in accordance with the committee's rules of procedure and defined tasks. They must maintain confidentiality, declare any interest in the pharmaceutical industry and abide by the EMA code of conduct (Annex III).
- Committee meetings are conducted in English. It is not possible to provide any translation service; therefore the member should be fluent enough to be able to follow and participate in the meeting discussions.
- Patient and healthcare professional members of scientific committees are expected to attend the full meetings, in person. Meetings are held on weekdays and are not usually held during August.
- Travel and accommodation costs are covered by the EMA for each member, who will also receive a daily expenses allowance.
- Although alternates are welcome to attend every meeting and contribute to the work and discussions within the committee, they will only be reimbursed when the member is unable to attend or in other specific cases (e.g. the alternate is acting as coordinator for a dossier).
- Alternates may represent and vote on behalf of the nominated member when he/she is not in attendance at the meeting. Similarly, at the request of the member, the alternate may respond on behalf of the member in case of written procedures or any request for advice outside of meetings.

3.2. Workload

The workload related to the meetings includes:

- Participation in the plenary meetings (at the EMA):
  - COMP: 2 - 3 day meeting per month (11 meetings per year)
  - PDCO: 4 day meeting per month (11 meetings per year)
  - CAT: 2 day meeting per month (11 meetings per year)
  - PRAC: 4 day meeting per month (11 meetings per year)
- Preparation for the plenary meetings and follow-up:
  - Up to 7 days per month preparation and follow-up work outside of the plenary meeting is felt necessary to guarantee an adequate contribution to the scientific committee; this fact should be clearly considered by any patient or healthcare professional organisation when proposing a member for an EMA scientific committee.
  - Time should be allocated to share, discuss and disseminate 'non-confidential' information within their organisation and to other stakeholders, where appropriate. This may imply additional work for other members or colleagues within an organisation.
  - The meeting attendance and work can be shared between the member and the alternate (where one exists), with good communication to avoid discontinuity.
  - Members may be asked to contribute to working groups inside the Committee or cross-Committee task forces related to other activities of the Agency
  - Members are not obliged to be rapporteur or peer reviewers however in some committees, this may bring added value to the discussions

Please note: attendance to meetings requires also time away from work/home due to travel and hotel stay, adding approximately half day to a whole day.

3.3. Challenges

Based on their experience to date, patients' and healthcare professionals' representatives who are members in EMA scientific committees have identified the following challenges they encounter and have also provided an indication of the implications of membership in terms of workload.

- Acronyms can make committee discusions very confusing for newcomers.
- The respective roles and responsibilities of the different EMA committees and how they interact may take time to understand.
- Committees discussions are mostly scientific (as well as regulatory) hence adequate preparation is important. Experience with medicines development and regulatory affairs, would help, but is not required. As stated in Section 4. , EMA will enable the necessary support to facilitate participation.
- The pre-mail documentation sent in advance of the meeting can be difficult to manage in the beginning.
- Patient and healthcare professional representatives do not have the same resources as other delegates, both in terms of available time, financial resources, technical and institution support and access to information, including the possibility to discuss procedures with colleagues in the field because of confidentiality issues (unlike members from national competent authorities).

4. Support to committee members

At nomination:

At the time of appointment to an EMA scientific committee, all members receive a welcome pack (Annex IV) and induction describing:

- the general role and responsibilities of EMA;
- the pathways of medicines development and authorisation;
- information on patient and healthcare professional involvement at EMA;
- administrative aspects such handling of competing interests.

During mandate:

Each committee is supported by a committee secretariat that provides administrative support. It is most beneficial for each committee to optimise their involvement and facilitate the members' specific input by flagging procedures that might be of interest in view of their expertise.

The preferred way would be that during the pre-meeting briefing call with the (vice-) Chairs scheduled the week before the committee plenary, EMA colleagues and/or the (vice-) Chairs discuss the procedures that would benefit specifically from the members' input. In order to facilitate the members' input and ease the preparation for the upcoming plenary, EMA colleagues are requested to share with the member(s) relevant assessment report(s) and any additional information with copy to the Rapporteur, committee secretariat and (vice-) Chair to highlight the procedure(s) and seek the relevant input.

Members are also encouraged to identify, as long as relevant tools are available, certain procedures, which are of specific interest and/or falling under their expertise. They could then send a request to the Rapporteur, EMA colleagues for additional information, as appropriate, with the (Vice) Chair and committee secretariat in copy.

In addition, regular interactions with a dedicated department within EMA dealing with stakeholders are organised along with an annual meeting of all patient and healthcare professional representatives on committees.

Committee members are also able to register to access training with the EU Network Training Centre (EU-NTC). The aim of the EU NTC is to ensure that provision of high quality and relevant scientific and regulatory training is shared through a European central platform.

Involvement of external experts to support patients and healthcare professionals in committees

Experience has shown that it is beneficial to invite, the most appropriate experts in the field, wherever necessary, in addition to the patient or healthcare professional member (Annex II).

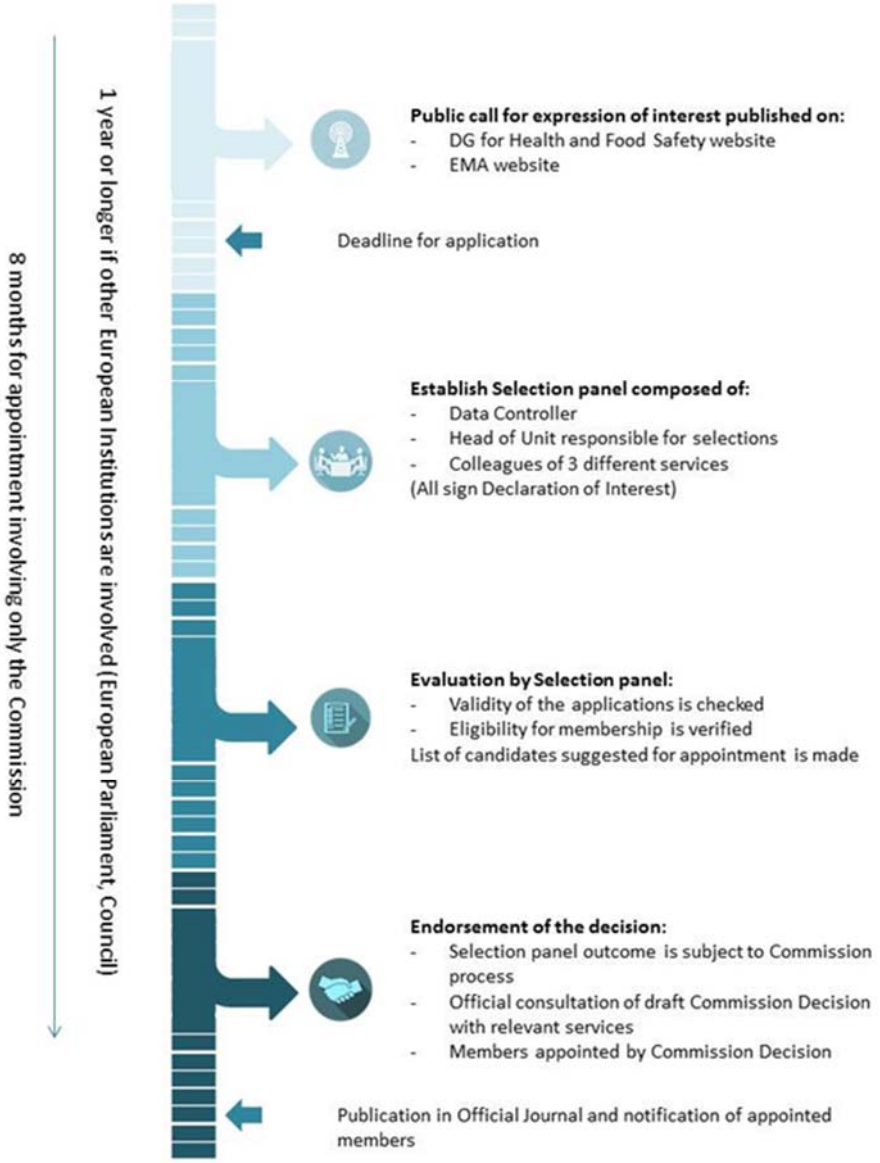
Several methodologies exist to support their involvement and ensure that the expertise of additional patients or healthcare professionals can be captured. These include inviting experts to committee plenaries in person, participation of a larger group in written consultations or surveys/questionnaires.

5. Nomination process by European Commission

All selections for members representing patients and healthcare professionals to EMA scientific committees under DG SANTE responsibility are handled according to the internal institutional procedures of the European Commission and the principles and standards applicable to selection processes (e.g. equal treatment, no discrimination).

The calls for expressions of interest are published on the webpages of the European Commission and the call is disseminated by EMA through various channels. A selection panel composed of representatives from different Commission services is established that evaluates the candidatures received. The selection panel prepares a list of candidates suggested for appointment. This Commission proposal is consulted with the European Parliament, if required by the relevant Regulation, and later endorsed by the College of Commissioners.

Process of nomination of Commission appointees to EMA committees



Annexes

Annex I: Key documents related to patients and healthcare professionals at EMA

Committee for Orphan Medicinal Products (COMP)

Article 4 (3) of Regulation (EC) Nº 141/2000

3. The Committee shall consist of one member nominated by each Member State, three members nominated by the Commission to represent patients' organisations and three members nominated by the Commission on the basis of a recommendation from the Agency. The members of the Committee shall be appointed for a term of three years, which shall be renewable. They may be accompanied by experts.

Rules of Procedure of COMP

Paediatric Committee (PDCO)

Article 4 (1.b and c) of Regulation (EC) Nº 1901/2006

b) one member and one alternate appointed by each Member State whose national competent authority is not represented through the members appointed by the Committee for Medicinal Products for Human Use;

(c) three members and three alternates appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent health professionals;

The members of the Paediatric Committee shall be appointed for a renewable period of three years. At meetings of the Paediatric Committee, they may be accompanied by experts.

Rules of Procedure of PDCO

Committee for Advanced Therapies (CAT)

Article 21 (1.c and d) of Regulation (EC) Nº 1394/2007

c) two members and two alternates appointed by the Commission, on the basis of a public call for expressions of interest and after consulting the European Parliament, in order to represent clinicians;

(d) two members and two alternates appointed by the Commission, on the basis of a public call for expressions of interest and after consulting the European Parliament, in order to represent patients' associations

The members of the Committee for Advanced Therapies shall be appointed for a renewable period of three years. At meetings of the Committee for Advanced Therapies, they may be accompanied by experts

Rules of Procedure of CAT

Pharmacovigilance and Risk Assessment Committee (PRAC)

Articles 61a (c) and (d) of Regulation (EU) Nº 1235/2010 amending Regulation (EC) Nº 726/2004.

(c) one member and one alternate member appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent healthcare professionals;

(d) one member and one alternate member appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent patient organisations

who shall be appointed for a term of 3 years, which may be prolonged once and thereafter renewed.

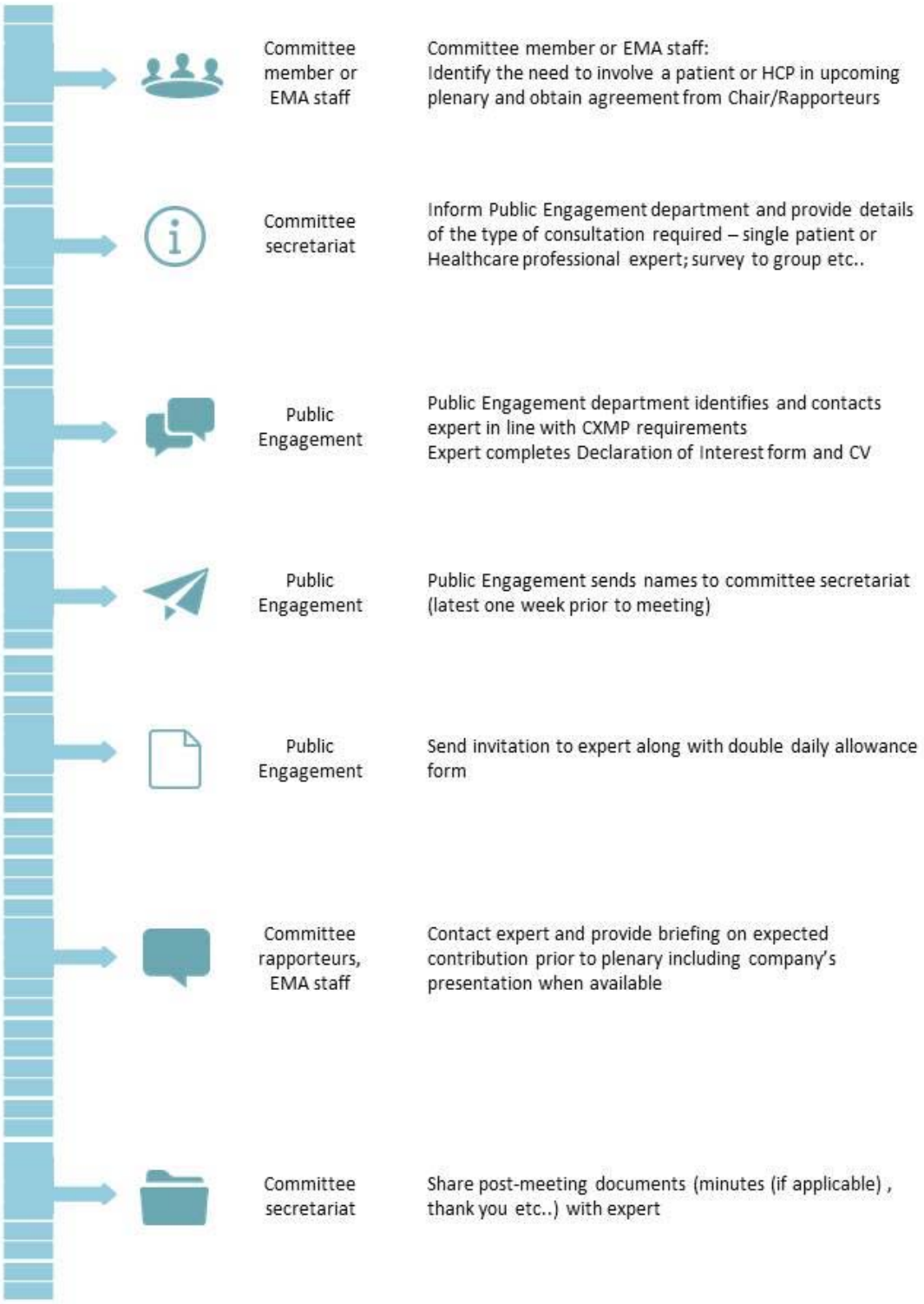
Rules of Procedure of PRAC

Frameworks related to patient and healthcare professional involvement in EMA

Revised Framework on the Interaction between the EMA and **patients, consumers** and their Organisations (EMA/637573/2014) describes further the interaction between patients in these committees

Revised Framework on the Interaction between the EMA and **healthcare professionals** and their organisations (EMA/89918/2016) describes further the interaction between healthcare professionals in these committees

Annex II: Inviting experts (patients and healthcare professionals) to committee meetings



Annex III: Competing interests: when contacted by parties external to EMA

Members are often contacted by external patients, healthcare professionals, consumers or anyone seeking information. When this occurs, members are strongly advised to refer them to the Public Engagement Department, especially if the request relates to an ongoing evaluation.

Members can also be invited to participate in workshops or conferences in the context of their role at EMA (please see policy pp 6-8). They should take the policy on handling of competing interests into consideration. Participation as speaker, panellist or in a similar role at conferences and seminars organised by (or with the involvement of) pharmaceutical companies and open to the public (fee or non-fee paying) with only reimbursement of reasonable expenses incurred in relation to attendance (i.e. accommodation and travel costs), is allowed as it is not considered a consultancy advice to be declared as an interests in the pharmaceutical industry. Involvement in lectures, presentations or training organised by individual pharmaceutical companies, given to participants invited by pharmaceutical companies and not open to the public is considered provision of consultancy advice to a pharmaceutical company and hence incompatible with involvement in EMA activities.

Members should refrain from any current direct interests in the pharmaceutical industry during their membership, i.e. employment, consultancy, strategic advisory role and financial interests in a pharmaceutical company.

If members are requested to contribute to a publication, they should do so in accordance with the EMA Policy on Publication

Annex IV: Training material

Topic	Existing material/ support
Information on general EMA role/responsibilities	Delegates Welcome Pack EMABasic What we do
Pathway of medicines development and authorisation	Delegates Welcome Pack EMABasic Authorisation of Medicines
Information on patient/consumer involvement in EMA activities	Partners and networks EMABasic
Practical aspects of participating in EMA activities (e.g. completing Declaration of Interests (DOI), confidentiality agreement, etc.)	Handling competing interests EMABasic
Information on specific EMA procedures (e.g. CHMP consultation, SAG meeting, Package Leaflet (PL) template);	EMABasic Training manual on review of documents
Information on role and expected contribution of patient organisation or expert, by activity	Personalised support Info sheets – more in progress
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	Provided directly by the relevant committee secretariat

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