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Public Engagement Department

## The role of members representing patients' and healthcare professionals' organisations on EMA scientific committees

The purpose of this paper is to clarify the role of representatives of patient and healthcare professional organisations within the different scientific committees of the European Medicines Agency (EMA), focusing in particular on their role as members of such committees. The aim is to provide guidance to current and new members as well as those who are considering applying for membership of a committee at 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 members of the human medicines EMA scientific committees representing patients and healthcare professionals, 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.

In accordance with European Union (EU) legislation, patients and healthcare professional representatives are included as members in four of the six human medicines 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).

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## 1. Role and added value of patient and healthcare professional 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' organisations 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. While the role of patient members is not expected to be of a scientific nature, experience has demonstrated that patient members 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 outcomes.

The role of members representing healthcare professionals is to bring the expertise and the views of the wider community of practicing specialists, general practitioners, nurses, pharmacists or other healthcare professionals. 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 is welcome to attend every meeting and contribute to the work of 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 are 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.
- 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 taken into account 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 medicines' approval process by supporting the scientific committee's commitment 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.
- Ensuring 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 are 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 considered in the committees' deliberations.
- Providing clinical experience relevant 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).
- Advising on the feasibility of proposed risk minimisation measures or on their effectiveness once they are implemented.
- 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 medicines' approval process by supporting the scientific committee's commitment to act for the benefit of society.
- Contributing and asking for changes in the regulatory process to improve reliability.

## **Communication and transparency**

Patient and healthcare professional representatives are also expected to:

- Contribute actively to the preparation of information and communication related to medicines including the decision on when to communicate.
- Foster transparency by ensuring that individuals and organisations know how to access useful and understandable information.
- Promote the dissemination of committee 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 to stakeholders, 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 build confidence and trust in the medicines' approval process.
- Contribute to making information for patients, healthcare professionals and the general public clear and understandable for the target audience and ensuring that it fulfils their needs in terms of information content (e.g. Summary of Product Characteristics (SmPC), Direct Healthcare professional Communications (DHPC), safety communications, package leaflet, educational materials etc.).

## **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 two 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 on a specific product or topic and do not take part in committee conclusions or decisions. They must maintain confidentiality, declare any interest in the pharmaceutical and medical device 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 Experts Management Tool.

### **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.

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

<i>Expertise</i>	Convey a combination of specific education, training or professional/personal experience
<i>Experience</i>	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)
<i>Advocacy</i>	Act on behalf of the affected patients in defence of their rights; provide a patient-oriented public health / healthcare policy perspective
<i>Empowerment</i>	Participate as member in the decision-making process within the committee

### **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 and medical device industry and abide by the EMA code of conduct (Annex III).
- Committees holds their meetings either physically at the EMA premises or in a fully remote setting, where all participants connect to the meeting remotely. In-person attendance for physical meetings is expected for all members in order to contribute to quorum and voting on committee opinions and other decisions. Meetings are held monthly on weekdays, except August.
- Committee meetings are conducted in English. It is not possible to provide any translation service; therefore, the member (and alternate) should be fluent enough to be able to follow and participate in the meeting discussions.
- Travel and accommodation costs are covered by the EMA for each member participating in a physical meeting, who will also receive a daily subsistence 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 procedure on the meeting's agenda).
- 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.
- In case both the member and alternate are unable to attend a meeting, the member may give a proxy to another member of the committee.

#### ***3.2. Workload***

The workload related to the meetings includes:

- Participation in the plenary meetings (at the EMA):
  - COMP: 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 3-4 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 should be considered by any patient or healthcare professional considering to apply for membership of an EMA scientific committee as well as by any patient or healthcare professional organisation when proposing a candidate for membership.
  - Time should be allocated to share, discuss and disseminate 'non-confidential' information within their organisation and to stakeholders, where appropriate. This may imply additional work for their colleagues within the 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. See [Rules for reimbursement of expense for delegates attending meetings](#).

### **3.3. Challenges**

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

- Abbreviations can make committee discussions very confusing for newcomers. EMA has created documents that can help with abbreviations and medical terms<sup>1</sup>.
- The respective roles and responsibilities of the different EMA committees and how they interact may take time to understand.
- Committee discussions are mostly scientific (as well as regulatory) hence adequate preparation is important. Experience with medicines development and regulatory affairs helps but is not required. EMA, however, enables the necessary support to facilitate participation (see Section 4.).
- 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).

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<sup>1</sup> [Abbreviations in CXMP CMD documents and in relation to EMA regulatory activities \(europa.eu\)](#)  
[Glossaries | European Medicines Agency \(EMA\) \(europa.eu\)](#)

## 4. Support to committee members

### **At appointment:**

At the time of appointment to an EMA scientific committee, all members (and alternates) receive a welcome pack 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, in particular registration in EMA's Experts Management Tool (Annex III)

### **During the mandate:**

Each committee is supported by a committee secretariat and a scientific secretariat.

The member's involvement could be optimised and facilitated by flagging procedures that might be of interest in view of their expertise:

- at start of procedure by the scientific secretariat
- during assessment by rapporteurs or committee members to proactively consider where patient and healthcare professional contribution could be valuable to the assessment
- during the preparation of a committee plenary by the scientific and/or committee secretariat.

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 EMA's department dedicated to stakeholder engagement 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).

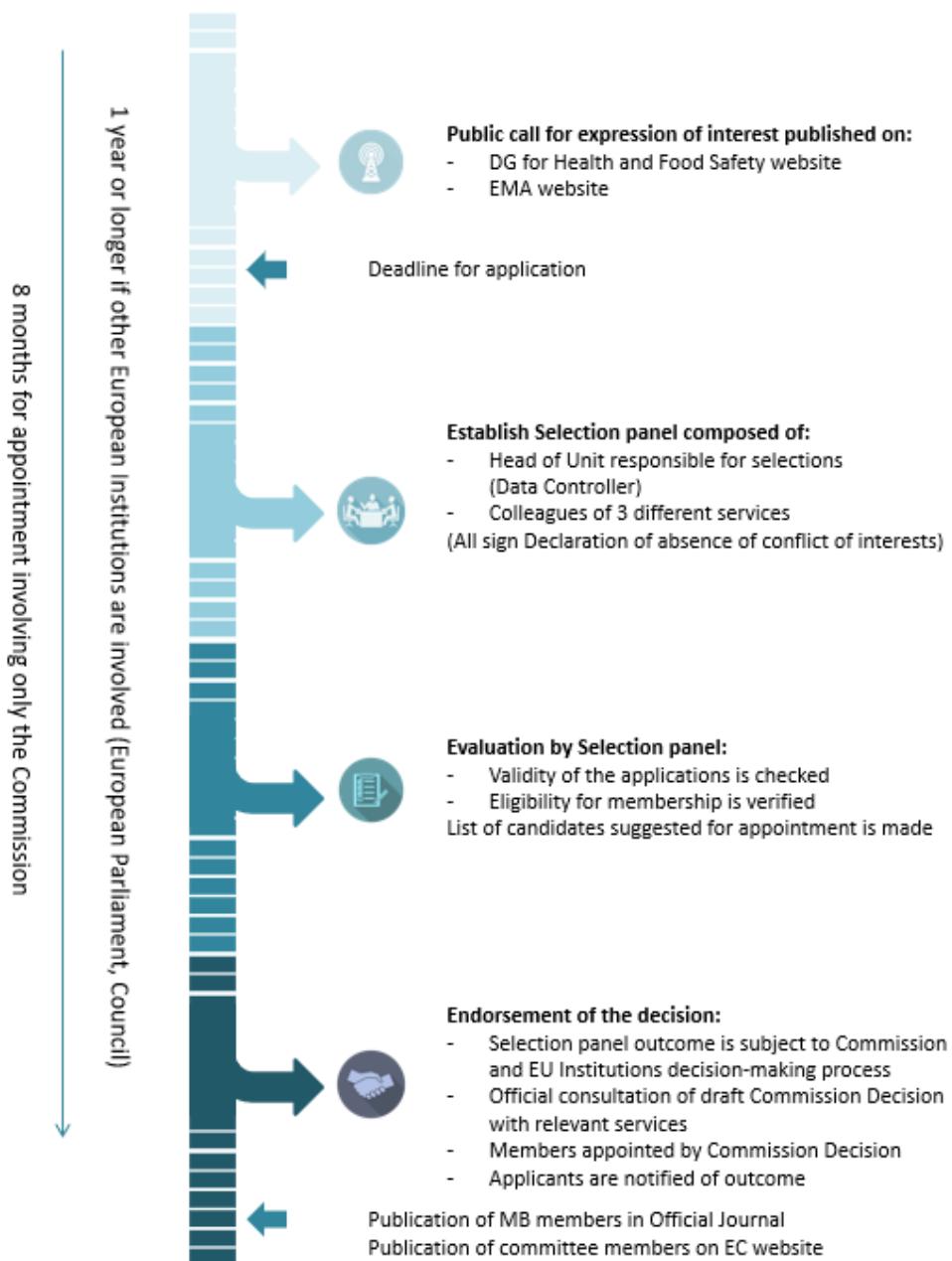
Several methodologies exist to support their involvement and ensure that the expertise of additional patients or healthcare professionals can be captured. These include inviting experts to committee plenaries in person, participation of a larger group in written consultations or surveys/questionnaires.

## 5. Appointment process by European Commission

All selections for members representing patients and healthcare professionals to EMA scientific committees are under the responsibility of DG SANTE. They 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 European Commission [website](#) and are also 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**

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

The mission of the EMA is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the EU.

- [What we do](#),
- [Who we are](#),
- [How we work](#)

### ***Committee for Orphan Medicinal Products (COMP)***

Article 4 (3) of [Regulation \(EC\) № 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.c and d) of [Regulation \(EC\) № 1901/2006](#)

(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;

(d) 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 patient associations.

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 \(EC\) № 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 \(EU\) № 1235/2010](#) amending Regulation (EC) № 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.*

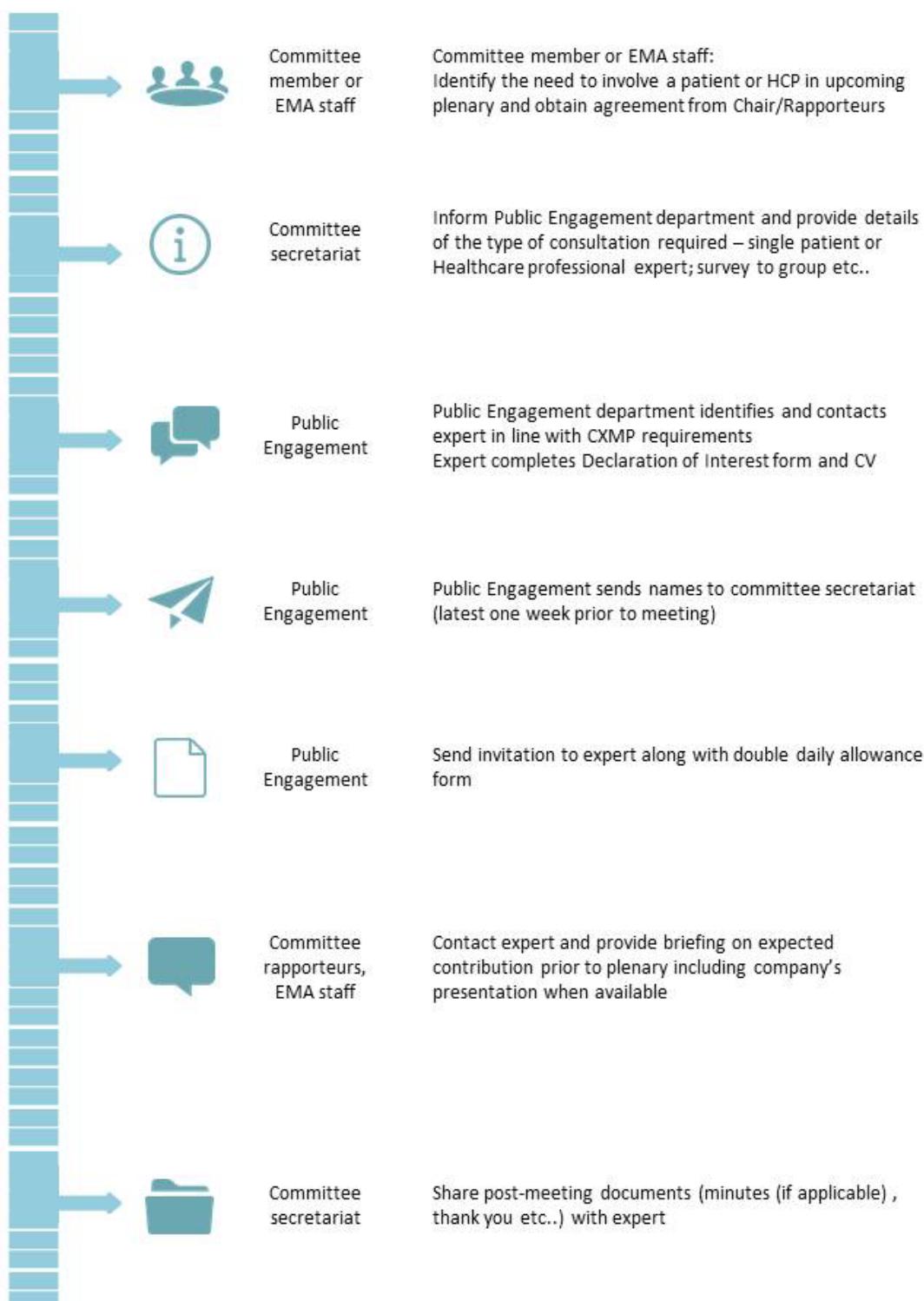
### [Rules of Procedure of PRAC](#)

## **Frameworks related to patient and healthcare professional involvement in EMA**

[Engagement Framework](#): EMA and **patients, consumers** and their organisations (EMA/649909/2021) 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**

Committee members may be 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 of medicinal products.

Members can also be invited by a party external to EMA to participate in workshops or conferences in the context of their role at EMA (please see [policy](#)). Before deciding to accept, they should take the policy on handling of competing interests into consideration ([policy 0044](#)). 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 or medical device industry. A speaker's fee, lecture's honorarium or any other compensation from a pharmaceutical or medical device company for such participation is considered as a financial interests and hence not allowed. 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, and for CAT members and alternates in the biotechnology sector.

If members are requested to contribute to a publication, they should do so in accordance with the [EMA Policy on Publication](#).