EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Rules of procedure on the organisation and conduct of public hearings at the Pharmacovigilance Risk Assessment Committee (PRAC)

1. Key principles

The PRAC has the possibility to hold public hearings in the context of safety referral procedures under Article 20 of Regulation (EC) 726/2004, Article 31 or Article 107i of Directive 2001/83/EC. The Committee takes the decision to hold a public hearing on a case-by-case basis, where the urgency of the matter in question permits and after considering that this is appropriate on justified grounds particularly with regard to the extent and seriousness of the safety concern.

1.1. Legal basis

The legal basis for holding public hearings in the defined procedures is Article 107j of Directive 2001/83/EC:

> *"Where the urgency of the matter permits, the Pharmacovigilance Risk Assessment Committee may hold public hearings, where it considers that this is appropriate on justified grounds particularly with regard to the extent and seriousness of the safety concern. The hearings shall be held in accordance with the modalities specified by the Agency and shall be announced by means of the European medicines web-portal. The announcement shall specify the modalities of participation.*
>
> *In the public hearing, due regard shall be given to the therapeutic effect of the medicinal product.*
>
> *The Agency shall, in consultation with the parties concerned, draw up rules of procedure on the organisation and conduct of public hearings, in accordance with Article 78 of Regulation (EC) No 726/2004.*
>
> *Where a marketing authorisation holder or another person intending to submit information has confidential data relevant to the subject matter of the procedure, he may request permission to present that data to the Pharmacovigilance Risk Assessment Committee in a non-public hearing."*

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1.2. Public hearings at the PRAC – a definition

A public hearing is a forum to which the public is invited to express its views, guided by a pre-defined set of questions, on issues related to the safety of a particular medicinal product, a medicinal substance or a therapeutic class, whilst also considering the therapeutic effects of these products.

Public hearings give the PRAC a channel to hear the public's views and concerns and take them into account in its opinion-making, particularly where options for regulatory actions to manage and/or minimise risks will need to be considered in a wider public health context.

Public hearings can add various elements to the considerations of the PRAC. However, the PRAC continues to have the sole responsibility for giving its scientific recommendation on the safety of the medicine(s) concerned.

1.3. Purpose of a public hearing

The primary purpose of a public hearing is to hear the public's view on the acceptability of the risks associated with the medicinal product/medicinal substance/class of medicinal products concerned, particularly in relation to its therapeutic effects and therapeutic alternatives available, as well as to seek suggestions and recommendations on the feasibility and acceptability of risk management and minimisation activities.

The value of a public hearing is considered to be greater in that phase of the process where the PRAC has assessed the scientific evidence coming from different sources and where different regulatory options to manage and/or minimise risks are to be considered in a wider public health context, before reaching its conclusion.

1.4. Who can attend a public hearing

Public hearings are open to all members of the public. For organisational reasons, participants must register in advance. Different modalities of participation will help to ensure that as many citizens as possible have access to the public hearing.

The questions asked by the PRAC to be addressed during the hearing determine the target audience.

The marketing authorisation holder(s) has/have the opportunity to present its/their view(s) to the participants of the public hearing.

Media organisations who wish to cover the public hearing may attend as observers. Specific arrangements will be put in place to allow wide media coverage of the public hearing. However, if they do wish to be present in the room, they must register in advance.

1.5. Language regime

All public hearings will be conducted in English. Participants are encouraged to use English during the public hearing. If they are unable to present in English, the European Medicines Agency (hereafter referred to as "Agency") will provide translation from the official EU languages into English. Participants have to request this when they register to speak at the public hearing.

2. Decision to hold a public hearing

The decision to hold a public hearing is taken by the Committee on a case-by-case basis, depending on the urgency of the matter in question and on other justified grounds, particularly with regard to the extent and seriousness of the safety issue.

2.1. Considering the need for a public hearing

At the start of each referral the PRAC will consider the need to hold a public hearing as described in section 2.2. Early consideration is necessary to allow sufficient time to organise the meeting.

The Committee shall endeavour to reach agreement on holding a public hearing by consensus. If the PRAC cannot reach an agreement by consensus, the decision is taken by vote as provided for in the PRAC rules of procedure.

The outcome of the discussion on the need to hold a public hearing, including a justification of the decision taken will be recorded in the minutes of the PRAC which are published on the Agency's website.

The Committee can reconsider its previous decision not to hold a public hearing during the course of the referral procedure, on the basis of new information.

2.2. Evaluating the need for a public hearing

When discussing the merits of holding a public hearing, the PRAC should consider the following elements:

- Feasibility to hold a public hearing in light of the urgency of the matter.
- Nature and extent of the safety concern.
- Therapeutic effect of the medicine/class of medicines and availability of therapeutic alternatives.
- Potential impact of possible regulatory actions on therapeutic practice and availability of treatments.
- Level of public interest.

3. Organisation of a public hearing – before the hearing

3.1. Announcement of the public hearing

The announcement of a public hearing is made in advance of the hearing.

The announcement is published on the Agency's website[1], together with:

- A summary of the safety concern.
- A list of specific questions on which information from the public is sought during the public hearing.
- Information on date and time of the public hearing.

[1] The Agency's website will serve as the European medicines webportal until further notice.

- Information on the location of the public hearing.
- Registration information, including the deadline by which participants can register to attend the hearing as speakers or observers.
- Information on how to ask for the provision of translation from an official EU language into English in case of attendance as a speaker.
- General ground rules guiding the public hearing.
- Agency's contact email address and phone number.
- Information about live-broadcast/web stream.

3.2. Modalities of participation

Public hearings are open to all members of the public. For organisational reasons, participants will be asked to register in advance. Different modalities of participation help to ensure that as many citizens as possible have access to the public hearing process.

Members of the public can participate actively, as speakers, or they can opt to participate as observers. Modalities of participation in a public hearing therefore include the following:

- Speakers can make an intervention in person or via teleconferencing facilities (Adobe Connect) where possible and feasible (See section 3.3 for more information on how to submit a request to participate as a speaker). Supporting documentation presented by the speakers during the intervention will be published on the Agency's website following the public hearing.
- Where space permits, requests to observe the public hearing in person without making an intervention will be accommodated. Requesters will receive a confirmation of their request in advance of the hearing.
- The proceedings of the public hearing can also be observed via video broadcast on the Agency's website.

3.3. Submitting a request to speak at the public hearing

All members of the public who wish to attend the public hearing as a speaker should submit their request in advance of the meeting, by the deadline specified in the Agency's announcement of the public hearing.

Participation requests should be sent in writing to the Agency using a dedicated form and should include the following information:

- Name of the individual.
- Capacity (i.e. whether the person is speaking as a patient or carer, a healthcare professional, an academic or a representative of the pharmaceutical industry, irrespective of whether the person speaks as an individual or a representative of an organisation/pharmaceutical company).
- Affiliation (i.e. name of the organisation/pharmaceutical company the individual represents), if applicable.
- Contact information (postal address, e-mail address, telephone number).
- A brief outline of the planned intervention, specifically how it addresses the questions on which the PRAC is seeking public opinion and the estimated amount of time requested for the presentation.

The time the Agency allocates to each speaker is dependent upon the number of requests received. The Agency aims to allocate 10 minutes per person. However, if a large number of requests have been received to attend the public hearing as a speaker, the Agency may reduce the time allocated for each speaker and/or extend the duration of the public hearing.

- Where relevant, request for the provision of translation in case of attendance as a speaker, including information on which official EU language should be translated into English.

The requester should also clearly indicate whether he or she intends to participate in person or whether the intervention will be made via teleconference.

The information submitted to the Agency will be made public for all participants who make an intervention at the public hearing, with the exception of any personal contact details.[2]

Any requests by a marketing authorisation holder or another person to present in a non-public hearing data, considered confidential, relevant to the subject matter of the procedure should also be made at the time of submitting the request to participate. Arrangements to be put in place for such non-public hearings fall outside the scope of these rules of procedure.

3.4. Submitting a request to attend as observer

Requests for participation as an observer at the public hearing should also be sent to the Agency. These requests will only be accommodated if space permits.

The proceedings of the public hearing can also be followed via video broadcast on the Agency's website. In such case no prior registration is required. Detailed information on how to follow the broadcast will be made available via the Agency's website.

3.5. Review of requests to speak at the public hearing

The requests to speak at the public hearing will be reviewed by the Agency.

The Agency will endeavour to accommodate all speaking requests. However, it may decline a request to speak at the public hearing if the outline of the planned intervention addresses a matter that is not *prima facie* related to the subject matter of the public hearing.

The Agency will group speakers by capacity (see section 3.3.) and will allocate time to each group, giving priority to civil society representatives, such as patients, consumers, healthcare professionals and academic research groups or organisations, particularly those relevant to the therapeutic area.

Where the number of requests within a group cannot be accommodated during the time allocated, people interested in speaking at the public hearing are encouraged to team-up among themselves. The Agency will facilitate these efforts. If the number of requests still exceeds the allocated time, the Agency will review the requests and decide on the list of speakers, taking into account elements such as the most relevant speakers with regard to the questions to be addressed at the public hearing and/or the geographical spread of the speakers.

[2] The Agency processes personal data in accordance with *Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data*. Further information is provided in the specific privacy statement for Public Hearings published on EMA website (https://www.ema.europa.eu/en/documents/other/privacy-statement-concerning-public-hearings-european-medicines-agency_en.pdf).

All individuals admitted as speakers will receive confirmation in advance of the hearing. Anybody who has submitted a request to speak at the public hearing to the Agency and who has not been admitted as a speaker will be informed at the same time. He or she shall also receive the reasons why the request has not been accepted. However, each individual who has not been admitted as a speaker has the right to submit, prior to the public hearing, a written statement for consideration by the PRAC.

3.6. Draft agenda and list of speakers

The Agency will prepare a list of speakers and a draft agenda for the public hearing, stating the time allocated to each group of speakers, grouped by capacity, and each speaker within a group. These documents will be published in advance of the public hearing on the Agency's website.

3.7. Cancellation

The Agency reserves the right to cancel a public hearing in case circumstances emerge that impact on the feasibility of holding it. In case of cancellation, the Agency will publically announce as early as possible, and will provide a justification for such cancellation. The Agency cannot be held liable for any expenses occurred in case of cancellation. In situations where it is not feasible for the Agency to reschedule the public hearing, the Agency will announce on its website the modalities for receiving written contributions.

4. Conduct of a public hearing – during the hearing

Public hearings will take place as part of meetings of the PRAC, with attendance of the Committee members.

4.1. Chair

The public hearing will be chaired by the PRAC Chair. He or she will be assisted by Agency staff on any administrative and organisational issues. In the absence of the PRAC Chair, the PRAC Vice-Chair will chair the public hearing.

The PRAC Chair, in collaboration with Agency staff, is responsible for the preparation of the public hearing and the conduct of the public hearing and shall take appropriate measures to ensure that the public hearing is run effectively and efficiently.

4.2. Opening statements

The PRAC Chair opens the public hearing. He or she states the purpose of the public hearing and presents the order of the day and operational aspects for the meeting.

Following the opening of the public hearing, the PRAC Rapporteur and/ or PRAC Co-Rapporteur give(s) an overview of the procedure, including the main issues and present(s) the questions on which public input is sought.

4.3. Interventions

The PRAC Chair gives the floor to the speakers. The order and time available for each intervention is determined in the agenda.

Each speaker will be asked to briefly introduce himself or herself, clearly state their name and the organisation/group the speaker represents, where applicable, and to declare any interests related to the medicinal products/medicinal substances, including their competitors, discussed at the meeting. The interests declared will be minuted in the meeting record.

Interventions given by participants at the public hearing should focus on providing responses to the questions asked by the PRAC. Speakers should be aware that they have a fixed maximum time to make their intervention.

Speakers will be alerted when their allocated time has nearly expired. If the allocated time ends before a speaker has concluded his or her intervention, the PRAC Chair should remind him or her to do so. If the speaker does not conclude his or her intervention after being asked to do so, the microphone may be turned off.

The PRAC Chair can also stop a speaker if his or her intervention does not address the questions asked by the PRAC or if the speaker does not adhere to the general ground rules. The PRAC members may ask questions for clarification from the speaker once the speaker's intervention has finished.

4.4. Concluding the hearing

At the end of the interventions the PRAC Chair summarises the interventions heard. Where time permits, the PRAC Chair can open the floor to all participants in the room, for additional statements on the points made during the hearing.

The PRAC Chair concludes the public hearing and explains the next steps of the procedure.

5. Follow-up to the public hearing

5.1. Meeting records

A record of the meeting, the list of speakers and all other participants, including their affiliation, their declared interests, any supporting documentation presented by speakers and a summary of the conclusions of the meeting will be made available following the public hearing on the Agency's website.

5.2. Impact on PRAC opinion

The information gathered in the public hearing will be taken into account during the considerations within the PRAC. The contributions made by the public during a public hearing will be considered by the PRAC. The assessment report will reference how the outcome of the public hearing has been addressed during the considerations at the level of the PRAC. The assessment report will be made public once the decision-making process has been finalised.