EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication

Draft rules of procedures on the organisation and conduct of public hearings at the Pharmacovigilance Risk Assessment Committee (PRAC)

Draft for consultation

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Comments should be provided using this template. The completed comments form should be sent to public-hearings@ema.europa.eu.

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These rules of procedures set out the process by which public hearings will be organised and conducted in the context of safety referral procedures under Article 20 of Regulation (EC) 726/2004, Articles 31 or 107i of Directive 2001/83/EC.

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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."*

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 their opinion-making, particularly where options for regulatory actions and risk management activities will need to be considered in a wider public-health context.

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

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 and are expected to be directed to the general public at large.

The PRAC may proactively invite representatives of patients, consumers, healthcare professionals or researchers with specific expertise in relation to the medicine(s) concerned by the public hearing.

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

The media may follow the public hearing as observers. Specific arrangements will be put in place to allow wide media coverage of the public hearing.

1.5. Language regime

All public hearings will be conducted in English only. Written contributions can be submitted to the EMA in any official EU language.

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. Proposal for a public hearing

Any member of the PRAC may submit a proposal for a public hearing, for consideration by the Committee. This should be done as early in the process as feasible to allow sufficient time to organise the meeting.

The proposal should include:

- objectives to be achieved with the public hearing;
- specific questions on which public opinion should be sought;
- any additional information as appropriate.

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 procedures.

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 the light of the urgency of the matter.
- Nature and extent of the safety concern.
- Risk attitudes of the users of the medicine(s) concerned vis-à-vis therapeutic areas.
- Proportionality and feasibility of envisaged risk minimisation measures.
- Therapeutic effect of the medicine/class of medicines and availability of therapeutic alternatives.
- Impact of possible regulatory actions on therapeutic practice and availability of treatments.
- Expected impact of the feedback obtained through the public hearing on scientific decision-making.
- Level of public interest.
- Expected impact on trust in the regulatory decision-making.
- Scientific complexity of the issue discussed.

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;
- 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 submit written contributions to the public hearings;
- general ground rules guiding the public hearing;
- contact email address and phone number;
- information about live-broadcast/web stream when feasible.

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.
- Participants can submit their contribution in writing for consideration by the PRAC. Contributions received in writing 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, when technically feasible.

[1] The Agency's website will serve as the EU WEBPORTAL until further notice.

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
- Affiliation (e.g. patient, carer, physician, etc.).
- Name of the organisation/group represented, if appropriate.
- 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 shall allocate 10 to 15 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.

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.

Any requests by a marketing authorisation holder or another person for permission to present data considered confidential should also be made at the time of submitting the request to participate.

Should a participant, intending to submit information, have confidential data relevant to the subject matter of the procedure, he or she may request permission to present that data to the PRAC in a non-public hearing (See section 4.5 for more information on how to present information in a non-public hearing).

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, when technically feasible. 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 related to the subject matter of the public hearing.

Where the number of requests cannot be accommodated during the time allocated for the public hearing, the Agency, when drawing up the agenda and list of speakers for the public hearing, will give priority to speakers representing civil society organisations, such as patients, consumers, healthcare professionals and academic research groups or organisations, particularly those relevant to the therapeutic area.

If the number of speakers who are given priority according to the previous paragraph is greater than can be reasonably accommodated during the scheduled public hearing, the Agency may conduct a lottery to determine the speakers for the scheduled hearing, without prejudice to the right of those who have requested to speak and that have not been granted time to speak during the public hearing to submit written statements for consideration.

The Agency may limit attendance to one participant per organisation or group where necessary to allow attendance of the widest possible spectrum of groups, organisations or individuals.

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.

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 speaker. 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.

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.

4.1. Chair

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

The chair is responsible for the preparation of the public hearing and shall take appropriate measures to ensure that the public hearing is run effectively and efficiently.

4.2. Registration

All attendants of the public hearing are required to register upon arrival.

4.3. Opening statements

The 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 an overview of the procedure, including the main issues and present the questions on which public input is sought.

4.4. Interventions

The chair gives the floor to the speakers who will make their interventions one-by-one.

Each speaker will be asked to briefly introduce himself or herself and to declare any interests of an economic or financial nature related to the medicinal products/medicinal substances, including their competitors, discussed at the meeting. The interests declared will be recorded in the minutes of the meeting. The marketing authorisation holder(s) may be given the opportunity to present his(their) view(s) to the participants of the public hearing.

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 limited time to make their intervention.

The order and time available for each intervention is determined in the agenda. At the beginning of their intervention all speakers should clearly state their name and affiliation and declare any financial or other interest they may have pertaining to the medicine(s) concerned by the public hearing.

Speakers are requested to keep to the allocated time in the interest of fairness. The speaker will be alerted when their allocated time has nearly expired. If the allocated time ends before the speaker has concluded his or her intervention, the 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 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 members of the PRAC may ask questions for clarification from the speakers.

4.5. Presenting data in a non-public hearing

Where a marketing authorisation holder or another person intending to submit information that has confidential data relevant to the subject matter of the procedure, he or she may request permission to present that data to the PRAC in a non-public hearing.

Requests for permission to present data in a non-public hearing shall be submitted in advance of the hearing, in accordance with the process set out under 3.3 of these rules of procedures.

Any request should be considered by the PRAC. Where permission is given, the requester shall be informed of the modalities by which he can present the confidential data.

The name and affiliation of anybody presenting confidential information in a non-public hearing shall be made public as part of the official record of the meeting.

4.6. Concluding the hearing

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

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

The PRAC shall not take any decision at the public hearing.

4.7. Meeting records

A record of the meeting, the list of speakers and other participants, their declarations of 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.

4.8. Impact on PRAC opinion

The information gathered in the public hearing informs the debate 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 will be addressed in the decision-making at the level of the PRAC.