



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public hearings

Guidance for participants



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Introduction

This guidance gives practical information about how the public can participate at EMA's public hearings.

Public hearings at EMA are set up by EMA's Pharmacovigilance Risk Assessment Committee (PRAC). The hearings:

- ▶ contribute to EMA's knowledge of how the public and patients perceive the use of certain medicines;
- ▶ help EMA understand the possible results of its recommendations on the safe use of medicines;
- ▶ present the public with another means to provide input into EMA's decision-making;
- ▶ help the public understand EMA's evaluation of a medicine's safety.

The basis for holding public hearings is outlined within the [Rules of procedure on the organisation and conduct of public hearings at the PRAC](#).

About EMA public hearings



1. What is an EMA public hearing?

A public hearing is a way for EMA's safety committee, PRAC, to gain input and insights from the public. It supplements other well-established methods that EMA already uses for engaging with stakeholders.

The hearings usually cover a specific concern or risk with a medicine or a group of medicines. By working directly with people affected by the medicine, EMA can increase its understanding of how a medicine is used and make sure that EMA's actions to manage risks are appropriate and practical.

Those attending the hearings will be PRAC members, EMA staff and members of the public, including patients, healthcare professionals, pharmaceutical companies and the press.

By following public hearings, participants will learn how EMA works and particularly how EMA aims to improve a medicine's benefits by minimising risks.

Contribution from the public at hearings will inform PRAC's decision making. PRAC assessment reports will show how information from the hearings contributed to the overall evaluation of the medicine under consideration.

2. Who decides to hold a public hearing?

It is EMA's safety committee, PRAC, that decides on holding a public hearing.

The hearing can be held at the beginning of a review on a safety concern of a medicine or later when the evidence is being evaluated.

Details of the discussion on holding a public hearing will be included in the PRAC's [minutes](#), which

are published on the Agency's website after each full meeting.

3. How does EMA decide the subject of a public hearing?

EMA's safety committee considers whether a public hearing can help with the review of a particular medicine. Using the [Rules of procedure](#), the committee considers:

- ▶ the nature of the safety concern;
- ▶ if the public hearing will fit within the timetable set for the review;
- ▶ what the medicine is used for and alternatives for treatment;
- ▶ the impact that the review's outcome may have on those using the medicines;
- ▶ the level of public interest in the subject.

4. Who can attend a public hearing?

Anyone can apply to attend a public hearing. However, it may not be possible to accommodate everybody if more people apply than the number of places and the time available.

Those aged under 18 years may attend, if they bring personal experience or knowledge about the subject of the hearing, but they must be accompanied by their guardian. Children aged under 12 are not allowed to attend the public hearing.

Pharmaceutical companies with an interest in the subject can also apply to attend, and journalists covering the hearing may attend as observers.



Participating at the hearing

5. How will I know there is a hearing?

We will announce an upcoming public hearing on EMA website at least six weeks before the hearing date. We will also send the information through our established network to EU organisations likely to be interested in the subject of the hearing.

The announcement will outline the subject of the hearing, together with questions the committee would like the public to address. The announcement will give the date, time and place of the hearing and the deadline for applying.

6. How can I join a hearing?

You can attend our hearing as a speaker or as an observer. You can also follow it on a live video broadcast on the Agency's website.

You must fill in an application form if you wish to attend in person. The form will ask if you wish to attend as an observer or as a speaker. Those chosen to speak will be given time to give a short oral presentation at the hearing.

You don't need to apply to us if you intend to watch the video broadcast. The link will be available on our website on the day.

7. How do I apply to attend?

If you wish to attend our public hearing, you need to send us a completed application form.

The form is published with the announcement of the hearing on our website.

Be sure to send in your application before the deadline in the hearing announcement. The application form will ask you:

- ▶ your full name (which should match your photographic identification, see Question 26);
- ▶ your contact information;
- ▶ the country you live in;
- ▶ your connection with the subject of the hearing (i.e. if you are a patient, a carer, a healthcare professional, an academic, a company representative, or a journalist);
- ▶ whether you wish to attend as an observer or as a speaker;
- ▶ to give details of how you would address the safety committee's questions if you wish to speak;
- ▶ whether you need an interpreter if you wish to attend as a speaker and you do not speak English;
- ▶ the name of the organisation or the company, if you are representing one;
- ▶ why you are interested in the subject of the hearing.

Use the application form to tell us of any special needs you have and if an official registered carer would need to accompany you.

The application process is simple: fill in the application form on your computer and then send it to us by email.

Participating at the hearing



8. How will EMA choose who attends?

The number of people that can attend the hearing is limited by room capacity and the time available for the hearing. Therefore, we may need to select participants based on their connection to the subject of the hearing, their experience and where they live.

For speakers, we will look at how they propose to address the safety committee's questions (see also Question 11).

We may also need to limit attendance of observers per organisation or group so that the hearing includes the widest range of participants.

The sooner observers apply the more chance they have of being selected to attend.

9. How will I know if I can attend?

We will write to you soon after the application deadline to let you know whether or not you can attend.

We will also tell you if you will be attending as an observer or as a speaker.

10. What other information should I give if I wish to attend as a speaker?

If you wish to speak at the public hearing, you should select this option in the application form. Your application should outline what you wish to say and why this is relevant to EMA safety committee's questions (included in the hearing announcement). We normally allow about 5 to 10 minutes for each speaker.

If you cannot attend in person, you can take part by teleconference but you must tell us this in your application.

11. How will EMA choose speakers?

We will choose as many speakers as we can for the hearing.

We will group all speakers by affiliation (e.g. patients, health professionals) and will ensure that each group is given an opportunity to speak. If there isn't enough time for all those who have applied, here is how we will manage the number of speakers:

- ▶ limit the number of speakers from each group or organisation;
- ▶ use information in the application to give priority to those who are most strongly connected with the subject or those who are likely to bring unique views;
- ▶ encourage speakers from different groups such as patients, healthcare professionals and academics to team up with others in the group and so combine several views in one presentation;
- ▶ consider where the applicant lives to ensure widest EU representation.

Pharmaceutical companies with an interest in the subject of the hearing may also speak within the time allocated to their group.



Participating at the hearing

12. What if I have not been chosen to speak?

If you applied to speak, but were not selected, you can send us your written views on the questions in the announcement. Send this statement to EMA's safety committee before the public hearing (by writing to publichearings@ema.europa.eu). Written statements will feed into the review in the same way as the oral presentations at the hearing.

13. What language will be used at the hearing?

Our public hearings are in English, the working language of EMA. We strongly encourage participants to use English during the hearing.

As a speaker, if you cannot make your presentation in English you may speak in another official EU language and request interpretation into English as you speak. In this case, you must request an interpreter when you first apply.

However, we cannot arrange interpretations from English to other languages.



Preparing for the hearing

14. Where can I find the hearing agenda and list of speakers?

We will publish the agenda for the hearing and a list of confirmed speakers on EMA website, together with the time given to each speaker, in advance of the hearing.

15. If I have been chosen as a speaker, how long will I have to speak?

We will tell you how long you have to speak. This will normally be between 5 and 10 minutes, but may vary depending on the number of speakers.

When you speak, please keep to the subject of the hearing and to the questions in the hearing announcement. By keeping to the time you are given, the speakers who speak after you will also be able present their views properly. In this way the committee will hear the widest possible range of views.

Do bear in mind that for your oral presentation you will not be able to use any multimedia materials such as presentation software (e.g. PowerPoint) or video clips.

16. Where can I look up technical terms and abbreviations?

We will do our best not to use unnecessary technical language and abbreviations during the hearing. However, if you come across anything you don't understand, then have a look at the following page on our website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/landing/glossary.jsp&mid

17. What should I take to the hearing?

When you arrive, you must show us your passport or official photographic identification to attend the hearing. The name you have registered with us must match the photographic identification.

You can only take a small handbag with you to the meeting room with only essential items (see also Question 32).

18. Are facilities available for people with disabilities?

The Agency building is adapted for people with disabilities and is entirely wheelchair accessible.

Please tell us before you arrive at the hearing if you have any disability that could make it difficult for you to leave the building in an emergency. Do also tell us if a carer will be coming with you and ensure that the carer has completed a separate application form.

Travelling to the hearing

19. Where is the hearing held?

We will say where the public hearing will be held at the time of the announcement. We usually hold the hearings at EMA's offices. Information on how to reach the offices is given under 'How can I get to the hearing at the EMA offices?' (Question 22 below).

20. How long does a hearing take?

We generally hold public hearings in the afternoon and they last about 3 hours. The public hearing announcement on EMA website will give the timings.

21. What are the travel arrangements?

Please don't make any travel arrangements until we have confirmed that there is a place for you.

If we have invited you as an observer, you should arrange and pay for all your travel to the hearing and for any accommodation you need.

If you are attending as a speaker then we will organise and cover the cost of the main part of your travel (see Question 24). We will send you an official invitation, which includes a link to an online form where you tell us your travel requirements. We do not generally cover accommodation costs, but if an overnight stay is absolutely necessary for health reasons then please let us know in advance and we will arrange your accommodation. We cannot reimburse you for any travel (or accommodation) that you book yourself.

If you have any questions about the travel arrangements for speakers do please contact our

Meeting Support Service:

email: mms-e@ema.europa.eu

telephone: +44 (0)203 660 7523

22. How can I get to the hearing at EMA offices?

You can find our address, together with a map and information about travel to our offices on the following page on our website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000129.jsp&mid=WC0b01ac058097a27b

Canary Wharf station is very close to our offices on 30 Churchill Place. This is the best station to use if you are travelling by public transport. You can travel to the station on the Jubilee (underground) line or on the Docklands Light Railway (DLR). These lines use different parts of the station so how you reach our offices will depend on which line you use.

From the Jubilee line

We suggest you take the East exit, which is closest to our offices. When you leave the station, turn left into Upper Bank Street, turn right at Canada Square and continue straight into Churchill Place.

If you leave the station by the West exit, on leaving the station, turn right into Canada Place, turn left into The South Colonnade towards Canada Square and then continue straight into Churchill Place.

From the Docklands Light Railway (DLR)

Leave the station into South Colonnade, turn left towards Canada Square and continue straight into Churchill Place.

Travelling to the hearing



23. Can I use Canary Wharf station if I have mobility problems?

Canary Wharf station has step-free access.

If you travel on the Jubilee (underground) line, then there is a lift (elevator) at both the East and West exits. The East exit is closer to our offices. To avoid any steps, we suggest you take the East exit to Upper Bank Street, cross to Montgomery Street and then take the lift (elevator) up to the footbridge that brings you to our offices.

If you arrive on the Docklands Light Railway (DLR), you can take a lift (elevator) from all platforms.

24. Will my travel costs be covered?

We cannot pay any costs if you are attending as an observer.

If you have been invited to speak, then we will arrange your travel by air or train between cities or main travel hubs but you have to cover all other costs such as local transportation (i.e. underground, bus, taxi) and meals. If you wish to stay overnight in London this will be at your own cost, unless we have agreed that an overnight stay is essential for health reasons.

Speakers must book air and train tickets through EMA. You will receive information in your invitation on how to do this. See also Question 21.

25. How can I join the hearing if I cannot attend in person?

All public hearings are broadcast and you can view them live on EMA website.

Speakers who cannot travel may take part by teleconference.

After the hearing, you can view a recording of the hearing and read a summary of the conclusions on EMA website.

Arriving at the hearing



26. What happens when I arrive?

You should aim to arrive at the EMA offices at least 45 minutes before the public hearing.

When you arrive, you should go to the reception desk. We will check your photographic identification, check that you are on our list for the hearing, and give you a building pass. Do make sure that the name you have registered with us matches your photographic identification.

You will then go through an airport-style security screening and we will show you to a lounge to wait for the hearing. We can store your luggage in a special area on the ground floor. You can take only a small handbag and a small bottle of water to the hearing. You cannot take any electronic devices to the meeting room except your mobile phone, which should be switched off during the hearing.

We will take you to the meeting room 15 minutes before the hearing starts.

Your building pass must be visible while you are in the building. You can go only to the meeting room for the hearing and the public areas around it (such as the toilets).

27. What do I do if I have been chosen to speak but am delayed?

If you have been chosen to speak but you are delayed or you cannot attend, please contact us as soon as you can (Tel: +44 (0)203 660 8400 or email: publichearings@ema.europa.eu). If you arrive late and would still like to speak, we will try our best to arrange for you to speak at a different time during the hearing.

If you cannot attend, send us a speaker's statement and we may be able to arrange for a representative

to read it, if there is time and this is feasible. Alternatively, your contribution will be shared with the Committee in writing.

28. What happens if there is an emergency when I am in the building?

In the very unlikely event that we need to leave the building because of an emergency, we will tell you what to do. Please follow our staff's instructions.

You should make sure you know where the emergency exits are so you can leave the building quickly in an emergency. All emergency exits are signposted and they will also be pointed out to you at the beginning of the hearing.

If you need help because of disability, tell us in advance and we will put you in touch with a 'buddy' to help you in case there is an emergency.



During the hearing

29. What are the rules for the hearing?

You should:

- ▶ follow the Chairperson's instructions during the meeting;
- ▶ switch off your mobile phone or set it to silent;
- ▶ respect the views and opinions of other speakers;
- ▶ report to us if anyone contacts you to try to influence the hearing discussions.

You should not:

- ▶ disrupt or hinder the running of the hearing;
- ▶ take a laptop or a tablet computer to the meeting room;
- ▶ use audio- or video-recording or transmission devices, cameras and mobile phones during the hearing (which will be broadcast live and, afterwards, a recording of the hearing will be available on our website);
- ▶ distribute any documents or ask for documents to be circulated.

30. How will the hearing run?

Public hearings are held during the monthly safety committee meetings, typically in the afternoon. The committee Chairperson will chair the hearing.

The Chairperson will begin the hearing with opening comments. We will also give you some general information about the hearing. The main assessors

involved in the scientific evaluation will set out the safety concerns and outline the questions that are the focus of the hearing.

The Chairperson will then invite presentations from speakers. The speakers will have been informed of the order in which they will speak and how long they will have. This information is also shown in the agenda.

Once all the speakers have made their presentation, the Chairperson will summarise the presentations and explain the next steps of the review. If time permits, the Chairperson may invite participants (including observers) to make additional points about the presentations during the hearing.

When the public hearing ends we will lead all participants back to the reception area where they can collect their belongings and return their passes before leaving the building.

31. What are the rules for those speaking at the hearing?

Each speaker will speak from the podium into a microphone. The speakers should briefly introduce themselves and say if they are representing any organisation or group. They also need to mention any potential conflicts of interest they may have in connection with the subject of the hearing (we will give information to speakers on what should be declared).

Speakers should keep to the time they have been given. We will time each speaker with a visible timer in the room so you will know how much time you have left.

If the time given to the speaker is about to end and the speaker has not started concluding the presentation, the Chairperson will ask the speaker



During the hearing

to end the presentation with final remarks. If the speaker does not end the presentation after being asked to do so, we may turn off the speaker's microphone. The Chairperson may also interrupt the speaker if the speaker deviates from the subject of the hearing.

At the end of a presentation, committee members may ask questions or ask the speaker to clarify certain points.

32. Can I use my laptop at the hearing?

You cannot take any electronic equipment to the public hearing except your mobile phone, which must be switched off or set to silent during the hearing.

All other electronic equipment should be stored with your personal luggage in the reception area lounge. Personal recording of the public hearing is not permitted because of data protection regulations (see also Question 39).

33. Can observers speak at the hearing?

Observers should not speak during a public hearing. However, if there is time at the end of a hearing, the Chairperson may invite anyone in the room to speak briefly on the subject of the hearing and on the questions in the announcement.

After the hearing



34. What record will be available of the hearing?

A recording of the meeting, the list of all speakers, including their connection with the subject of the hearing, and any declared interests as well as a summary of the conclusions of the meeting will be published on EMA website.

35. Can participants report on a public hearing?

Those attending a public hearing, including the media, may report on the meeting, but they must not quote or identify individuals. They may quote or refer to the Chairperson's conclusions on summing up the discussion.

36. How will the hearing contribute to EMA's work?

EMA's safety committee will consider the contributions from the public hearing in its review of the subject of the hearing. The committee's assessment report, which is available to the public once the review is complete, will include information about the hearing and how the committee used its outcome.

Additional information



37. How can I get more information about the hearing?

If you have any other questions or if you need more information, please ask us by sending an email to: publichearings@ema.europa.eu

38. What is the legal basis for holding a public hearing?

EMA's safety committee (Pharmacovigilance Risk Assessment Committee) calls a public hearing to help it consider certain matters about the safe use of medicines. These matters are brought to the committee through procedures set out in Article 20 of [Regulation \(EC\) 726/2004](#) and Articles 31 and 107i of [Directive 2001/83/EC](#). The procedures are also called 'referrals' (we have called them 'reviews' in these questions and answers).

39. How will the Agency handle my personal information?

We protect your personal data and process it according to Regulation (EC) No. 45/2001 – the Agency's website says how we process personal data under '[Privacy statement](#)'. More details are also included in the application form.

By sending in your application, you declare that you have read and understood the guidelines on personal data, and that you will respect these guidelines if you attend the public hearing.

40. Can the hearing be cancelled or postponed?

We may have to cancel a public hearing in case of unexpected circumstances. We will announce the cancellation as soon as we can but EMA cannot be held liable for any expenses incurred.

If we cannot arrange another date for the public hearing, we will ask for written contributions.

If the hearing is postponed and you have been invited as an observer or a speaker, you should tell us as soon as possible if you cannot attend the re-arranged hearing. We can then give your place to somebody else who wants to attend.

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Send questions on public hearings to: publichearings@ema.europa.eu

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