

Public Hearing Application Form Valproate - 26 September 2017

Contact Information

Title

First and middle name*

Family name*

Nationality

Address

Postal Code

City

Country

Phone number

E-mail address

To complete your application form, please read the [guidance for participants](#). You must answer all the questions on this form, otherwise we may not be able to process your application.

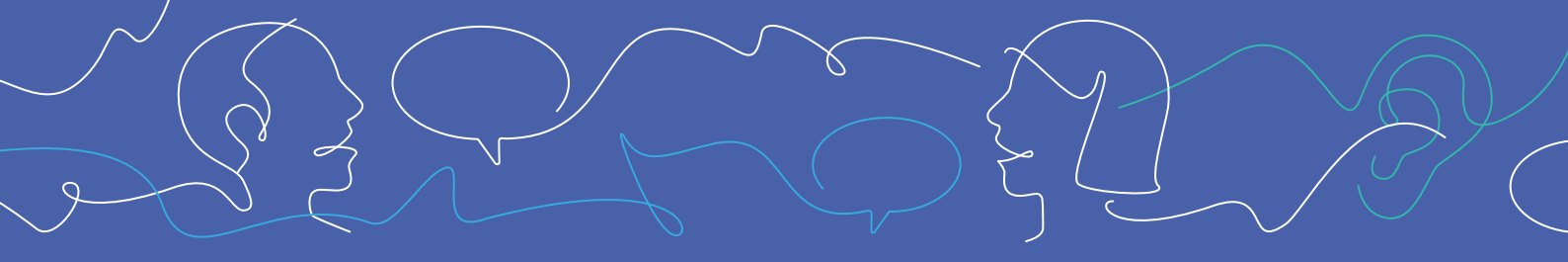
Please choose the role in which you would like to participate at the hearing:

Speaker (in person)

Observer

Speaker (by teleconference; exceptionally, if travel is not feasible)

* Please write your full name as stated on your Passport/ ID Card



Profile

In what capacity would you like to attend?

Patient/ carer

Consumer/ general public

Healthcare professional

Academia

Pharmaceutical industry

Media

Other, namely

Will you attend the Public Hearing:

As an individual

On behalf of an organisation, namely

If you have any disability or mobility impairment, please explain below what assistance you would require:

Will a carer accompany you?

No

Yes, name of carer:

Note that your carer needs to fill in a separate application form.

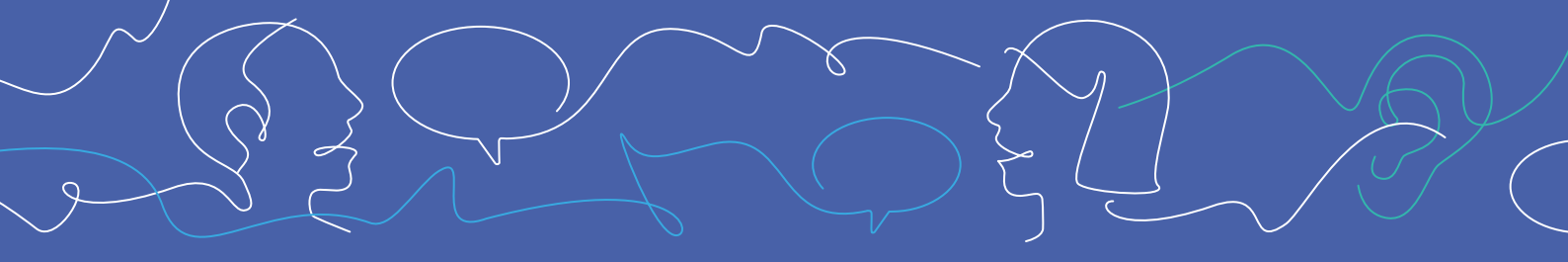
If you are a carer, please provide the name of the patient you are accompanying:

The information you provide under the sections above will be used only for the purposes of the management of the meeting and for providing the necessary assistance.

Speaker Applications

The questions below apply only to those requesting to speak during the Public Hearing.

Public Hearings will be conducted in English. However, interpretation of your oral presentation from an [official European language](#) to English can be provided. If you require interpretation, please indicate below which language:



If you are not selected to speak, would you like to be considered to attend as an observer? Please note that the Public Hearing will be broadcast live on the EMA website.

Yes

No

If you are applying to speak at the Public Hearing, please outline what you wish to say in your oral presentation. It is important to state how you will address the safety committee (PRAC) question(s). An overview of the questions can be found on the [public hearing webpage](#).

Please note there is a maximum of 3000 characters.

Please indicate the time you need for your oral presentation (max. 10 minutes):

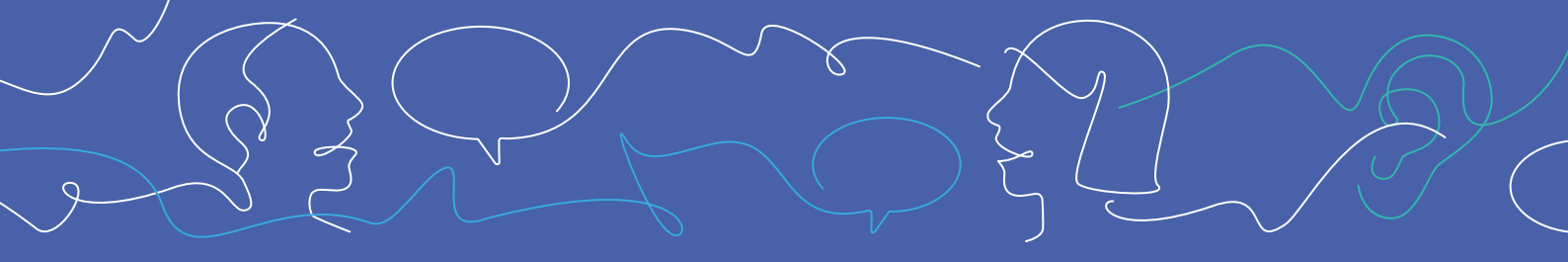
In the case a large number of attendees apply to speak at the Public Hearing, the Agency will use your oral presentation outline above to select the final speakers. For more information on the criteria for selection, please read the [guidance for participants](#).

The names of all speakers, their affiliation, a recording of the hearing and a summary of the conclusions of the meeting will be published on the EMA website.

Please tick the box to confirm that you have read and understood the [guidance for participants](#), and that if you are selected to attend the meeting you will respect these guidelines.

Once you have completed this application form, please save it using the following format: *First name_Last name_Valproate* and send it to publichearings@ema.europa.eu

You should hear from us about your application within 2 weeks after the registration has closed.



Data Protection Statement

All personal data provided within this form will be processed in accordance with Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies on the free movement of such data.

This data protection statement provides details on how the Agency, in its capacity as data controller, will process information that you have submitted for the purpose of attending a Public Hearing at the Pharmacovigilance Risk Assessment Committee (PRAC).

Collection of data

EMA will collect all the personal data you provide in this form, such as your name, the capacity in which you wish to attend, your contact details, as well as any personal information included in the outline of your oral presentation.

Refusal to provide your personal data could lead to your request for participation being declined.

Start of data processing

EMA will commence the processing of your personal data as soon as the application form is received.

Purpose of data processing

The information collected in this form will only be used by EMA staff members to assess the application and to draw up the list of participants for the Public Hearing.

For speakers, the appropriateness of their proposed oral presentation will be reviewed, as well as affiliation and geographical location. For observers, only affiliation and geographical location will be considered. No further processing of your personal data for any other purposes outside the scope of this specific context is envisaged.

Location of data storage

All data is stored within a secure data centre within the EMA premises which is password protected and only available to EMA staff members.

Publication of data

The names of all speakers, including their affiliation and proposed oral presentation (as submitted in this form) will be published on the EMA website. The contact details of the speakers will not be published on the EMA website. A summary of the conclusions and a recording of the hearing will also be published after the Public Hearing.

Retention period

Your personal data will be kept for a period of 2 years after the Public Hearing, after which time they will be deleted. This also applies to information relating to declined requests.

Your rights

You have the right to access your personal data and the right to rectify these data, and you may also request erasure or blocking of your personal data in accordance with Articles 13-19 of Regulation (EC) No 45/2001.

You can exercise your right by contacting the Public Engagement Department or sending an e-mail to publichearings@ema.europa.eu

If you have any complaints or concerns about the processing of your personal data, you can contact the EMA Data Protection Officer: dataprotection@ema.europa.eu

You have the right to have recourse to the European Data Protection Supervisor: edps@edps.europa.eu

To find out more about how EMA processes personal data in general, please view the [Privacy Statement](#) on EMA's website.