



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 July 2019  
EMA/349369/2019

## Privacy Statement concerning Public Hearings at the European Medicines Agency

Please be aware that all personal data provided in the Public Hearing Application Form (hereinafter “application form”) will be processed 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](#).

This privacy statement provides details on how the European Medicines Agency (hereinafter “EMA” or “Agency”) will process your personal data that you have submitted for the purpose of attending a public hearing at EMA’s safety committee, the Pharmacovigilance Risk Assessment Committee (PRAC).

### 1. Collection of data

EMA will collect all the personal data you provide in the application form, such as your name, your affiliation, your contact details, as well as any personal information included in the outline of your intervention.

If you do not wish to provide your personal data, please note that such refusal might lead to your request for participation being declined.

### 2. Lawfulness and legal basis of the processing

When you provide your data in the application form, you consent to the processing of that data by the Agency as explained in this privacy statement. You have the right to withdraw your consent later at any time. Please note that such withdrawal does not affect the lawfulness of processing carried out by the Agency before the withdrawal of your consent.

In addition, the processing of your data in relation to the organisation and conduct of public hearings is necessary for the Agency’s task carried out in the public interest as explained below.

This processing is based on the legal provisions for holding a public hearing under [Regulation \(EC\) No 726/2004](#) and [Directive 2001/83/EC](#). EMA’s safety committee, the PRAC has the

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



possibility to hold public hearings in the context of safety referral procedures. Such referral procedures are governed 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 in accordance with Article 107j(2) of Directive 2001/83/EC.

Detailed rules on the organisation and conduct of public hearings are set out in the [Rules of procedure on the organisation and conduct of public hearings at the Pharmacovigilance Risk Assessment Committee \(PRAC\)](#).

### **3. Who is the data controller?**

The Agency is ultimately responsible to comply with your data protection rights and freedoms. On behalf of EMA, the Head of Communication and Stakeholders Division is appointed as a 'Data Controller' to ensure the proper implementation of the processing operation.

You may contact the Data Controller through the Public Engagement Department at [publichearings@ema.europa.eu](mailto:publichearings@ema.europa.eu) or [S-DataController@ema.europa.eu](mailto:S-DataController@ema.europa.eu).

### **4. Start of data processing**

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

### **5. Purpose of data processing**

The information collected in the application form will only be used by EMA staff members to assess the applications received and to draw up the list of participants for the public hearing.

For speakers, the appropriateness of their proposed intervention 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.

### **6. Location of data storage and recipients of the data**

All data is stored within a secure data centre within the EMA premises which is password protected and only available to EMA staff members. All data will be processed internally by EMA staff authorised by senior management to carry out the organisation of public hearings.

### **7. Publication of data**

The names of all speakers, including their affiliation and proposed intervention (as submitted within the application form) will be published on the EMA website. The contact details of the speakers will not be published on the EMA website. A written summary of the conclusions and a recording of the hearing will also be published after the public hearing.

### **8. Retention period**

Your personal data will be kept for a period of 2 years following the public hearing, after which time they will be deleted. This is also applicable to information relating to declined

requests. Any information related to mobility issues, shared for practical aspects of attending the hearing, will however be deleted immediately after the hearing.

## 9. Your rights

As data subject, you have a number of rights:

- **Right to be informed** – This privacy statement is aimed at informing you on how EMA collects and uses your personal data.
- **Right to access** – You have the right to access your personal data. You have the right to request and obtain a copy of the personal data held by EMA. Requests for other information, such as information on recipients may also be directed to the Data Controller.
- **Right to rectification** – Data subjects have the right to obtain without undue delay the rectification of inaccurate personal data concerning him or her.
- **Right to withdraw consent** – You have the right to withdraw your consent to the processing of your personal data at any time. However, this will not affect the lawfulness of any processing carried out before consent is withdrawn.
- **Right to erasure** – You have the right to require EMA to delete or stop processing your data, for example where the data is no longer necessary for the purposes of processing.
- **Right to object** – When EMA processes your data based on the fact that it is necessary for the performance of the Agency's tasks in the public interest, you may object to such processing on grounds relating to your particular situation.
- **Right to portability** - Where personal data was directly given to EMA by the data subject and the processing is carried out with his/her consent and by automated means; the data subject has the right to receive their personal data in a machine-readable format. In these cases, data subjects may also request that such data is directly transferred to another controller.

The rights of the data subject can be exercised in accordance with the provisions of Regulation (EU) 2018/1725. You can exercise your rights by contacting the Data Controller through the Public Engagement Department at [S-DataController@ema.europa.eu](mailto:S-DataController@ema.europa.eu).

## 10. Recourse

In case you have any questions regarding the processing of your personal data, or you think that the processing is unlawful or it is not in compliance with this Privacy Statement, please contact the Data Controller.

If you have any complaints about the processing of your personal data, you can contact the EMA Data Protection Officer: [dataprotection@ema.europa.eu](mailto:dataprotection@ema.europa.eu)

You also have the right to lodge a complaint with the European Data Protection Supervisor:

- Email: [edps@edps.europa.eu](mailto:edps@edps.europa.eu)
- Website: [www.edps.europa.eu](http://www.edps.europa.eu)
- Further contact information: [www.edps.europa.eu/about-edps/contact\\_en](http://www.edps.europa.eu/about-edps/contact_en)

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