

EMA/75470/2019 Stakeholders and Communication Division

European Medicines Agency privacy statement

For the organisation of meetings and events

The European Medicines Agency (hereinafter "EMA" or "the Agency") is committed to respecting the right to the protection of the personal data of its staff members and the public. The Agency collects and uses personal data in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 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 (hereinafter "the Regulation"). This privacy statement explains how the Agency collects and uses personal data for purposes related to meetings and events that it organises in accordance with the Agency's data protection obligations under the Regulation. These meetings and events include:

- regulatory and scientific meetings including participants representing national competent
 authorities (i.e. national medicines regulatory authorities for human and veterinary medicines from
 Member States in the European Union [EU] and European Economic Area [EEA], or NCAs) and
 experts, as well as representatives of EU institutions and bodies, and international regulators;
- external stakeholder events including representatives of patients and consumers, healthcare professionals, academia, industry and other stakeholder organisations.

It is important that you read and retain this statement, together with any other privacy statement the Agency may provide on specific occasions when it is collecting or using personal data about you, so that you are aware of how and why the Agency is using such data and what your rights are under the Regulation.

1. Who is responsible for your data?

1.1. Who is the data controller?

EMA is ultimately responsible for complying with Regulation (EU) 2018/1725. On behalf of EMA, the Head of the Division organising a meeting or event is appointed as a 'data controller' to ensure the lawful conduct of this processing operation.

Should you wish to send a question or request to the data controller, please contact: S-DataController@ema.europa.eu



1.2. Who is the data processor?

The name and contact details of data processors are stated in the invitation letter or meeting announcement.

The Agency may engage third parties to provide meeting support services in relation to a particular event (e.g. a travel agent or an external meeting organiser).

2. Purpose of this data processing

The purpose of this data processing activity is the organisation and management of meetings and events in the context of the performance of the Agency's tasks, including:

- management of the lists of invitations and participants;
- maintenance of the lists of contact details and mailing lists;
- management of access control in accordance with EMA's security policy;
- management required for the organisation of hotel and travel arrangements;
- reimbursement of hotel and travel expenses;
- distribution of information, reports, publications and other meeting documents among invitees and participants;
- arrangement of follow-up meetings and actions;
- sharing meeting content (e.g. audiovisual recording or live streaming) via communication channels (e.g. social media and websites).

3. What personal data do we process and how?

3.1. Personal data concerned

In this processing operation, EMA processes data directly collected from you. Such data may include the following:

- Participants' first name and surname, gender (for the purpose of using the right title), profession, organisation represented, postal and e-mail addresses and telephone number.
- Identification or passport number, date of birth, nationality (for the purpose of access control in accordance with EMA's security policy and travel booking).
- Information on participants' transport costs, bank account details (for the purpose of reimbursement of the expenses related to the participation to the meeting or event whenever this possibility applies to the particular participant).
- Information about mobility issues and dietary requirements.
- Audio-visual recording or live streaming of speakers and participants.

In every case, EMA requests the personal data concerned directly from you prior to the meeting or event through a written invitation or meeting registration form. The invitation or meeting announcement will specify if an audio-visual recording of the meeting will take place.

EMA will process personal data provided by you for registration, organisation (e.g. seating, name cards, collection of post-meeting feedback) and, where applicable, travel reimbursement purposes. In

relation to travel reimbursement, your data may be collected by third-party data processors, as stated in the invitation letter or meeting announcement.

3.2. Legal basis

When you provide the data requested to register your participation in the meeting or to arrange your travel reimbursement, you consent to the processing of that data in accordance with this privacy statement. You may opt out from the processing by replying to the contact person mentioned in the meeting or event announcement prior to the meeting. In your response, please state which personal data you want to exclude and which actual processing activities you do not want EMA to carry out on your data. You also 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 EMA before the withdrawal of your consent.

In addition, the organisation of meetings is necessary for the performance of the Agency's tasks carried out in the public interest as required by Regulation (EC) No 726/2004, Directives 2001/83/EC and 2001/82/EC and other applicable Union legislation. In particular, the processing of data is necessary for the performance of tasks carried out in the public interest, as provided for under:

- Regulation (EC) No 726/2004 as regards the organisation of meetings of the scientific committees
 of the Agency, the standing and temporary working parties and of the scientific advisory groups;
- Article 78 of Regulation (EC) No 726/2004 as regards meetings involving representatives of industry, consumers and patients and the health professions, for example the meetings of the Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP);
- Directive 2001/83/EC as regards the organisation of the meetings of the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) (established in Article 27 of the Directive) and its related working groups;
- Directive 2001/82/EC as regards the organisation of the meetings of the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv) (established in Article 31 of the Directive) and its related working groups.

The details of the meetings of the Management Board meeting, scientific committees, working parties and scientific advisory groups are governed by their applicable rules of procedures adopted in accordance with Article 61(8) of Regulation (EC) No 726/2004 and published on EMA's corporate website (www.ema.europa.eu) pursuant to Article 80.

The details of the meetings of the CMDh and CMDv are governed by their applicable rules of procedures and published on the website of the Heads of Medicines Agencies (HMA) (www.hma.eu).

Live web streaming, video recording, and images of the speakers, attendees and participants, as well as photographs of participants and organisers may be taken in the context of an event or meeting. Participants who do not wish to be part of the above recording activities can opt out by sending an email to the controller or organiser prior to the event. Their contact details are available in the meeting or event announcement.

3.3. Transfer of personal data outside of the EU

Meeting documents (such as lists of participants, agendas, presentations, minutes or meeting reports) may be shared with regulatory authorities and international organisations of third countries based on

mutual cooperation agreements or confidentiality arrangements and in accordance with Regulation (EU) 2018/1725.

4. How long does EMA keep your data?

To provide an audit trail on transactions executed by EMA, the Agency will retain personal data required for any financial transactions (e.g. reimbursement of travel and expenses) for a maximum of 10 years after the last transactions. It will hold other personal data in its database for a predefined period from the date the meeting is held: 2 years for public hearings and 5 years for other meetings and events. EMA will delete information regarding mobility issues and dietary requirements after the event has closed and when such data are no longer necessary for organisational purposes.

Nevertheless, EMA will retain recognition of participation in a meeting (e.g. an entry in a list of participants, or audio-visual recordings where applicable) as part of the records on the activities carried out within the Agency's sphere of responsibility.

All data retained by third parties authorised to act on behalf of the Agency (e.g. relevant to the organisation of hotel and travel arrangements) will be automatically destroyed by these third party service providers when the contract between the Agency and the third party expires, or after 5 years, whichever comes first.

5. Who has access to your information and to whom is it disclosed?

The data collected will be processed internally by staff within the EMA division responsible for the meeting's or event's organisation, and by dedicated staff within meeting support, security and reception services. Where applicable, the data will be processed by authorised staff of third parties authorised to act on behalf of the Agency (e.g. travel agents or external meeting organisers).

Lists of meeting participants (names and organisation represented) may be disclosed to NCAs, EU institutions, and organisations of patient and healthcare professionals.

Meeting documents (such as lists of participants, agendas, presentations, minutes or meeting reports) may be published on the EMA's corporate website.

6. Data security

The Agency has put appropriate technical and organisational measures in place (security policies and procedures) to protect personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access.

The Agency takes all necessary measures to ensure the maximum safety and security of personal data held both offline and online, in hardcopy and digital form.

7. Your data protection rights

As a data subject (i.e. an individual whose personal data is processed), you have a number of rights:

- **Right to be informed** This privacy statement provides information 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 processed by EMA.

- **Right to rectification** You have the right to obtain without undue delay the rectification or completion of your personal if it is incorrect or incomplete.
- Right to withdraw consent You have the right to withdraw consent in line with Article 7 of Regulation (EU) 2018/1725 where the Agency relies on consent to process your personal data. However, this will not affect the lawfulness of any processing carried out before consent is withdrawn.
 - Please note that if you withdraw your consent, the Agency may not be able to provide certain services to you (e.g. travel reimbursement). EMA will advise you if this is the case at the time you withdraw your consent.
- **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. In certain cases your data may be kept to the extent it is necessary, for example, to comply with a legal obligation of the Agency or if it is necessary for reasons of public interest in the area of public health.
- **Right to restrict processing** In a few, codified cases, you have the right to obtain the restriction of the processing, meaning that your data will only be stored, but not actively processed for a limited period of time. For more information about this right and its limitations, see EMA's general privacy statement (www.ema.europa.eu/en/about-us/legal/privacy-statement).
- **Right to object** If the Agency processes your data for the performance of a task in the public interest (without your consent or another lawful basis), you have the right to object to this processing on grounds related to your particular situation.
- **Right to portability** Where the processing is carried out based on your consent and in automated means you have the right to receive your personal data (which was provided to the EMA by you) in a machine-readable format. You may also ask the EMA to directly transfer such data to another controller.

The rights of the data subject can be exercised in accordance with the provisions of Regulation (EU) 2018/1725.

For anything that is not specifically provided for in this privacy notice, please refer to the contents of EMA's general privacy statement (www.ema.europa.eu/en/about-us/legal/privacy-statement).

8. Contact information

If you have any questions regarding the processing of your personal data, or you think that the processing is unlawful or not in compliance with this privacy statement or EMA's general privacy statement, please contact the data controller.

The contact details of the data controller are: S-DataController@ema.europa.eu

9. Recourse

Data subjects may lodge a complaint with the **EMA Data Protection Officer**: dataprotection@ema.europa.eu.

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

• Email: edps@edps.europa.eu

Website: www.edps.europa.eu

Further contact information: www.edps.europa.eu/about-edps/contact_en