



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

2 April 2026  
EMA/368013/2025

## European Medicines Agency's Data Protection Notice

### For the implementation of the Instrument for Pre-accession Assistance (IPA) programme

This Data Protection Notice explains the most essential details of the processing of personal data by the European Medicines Agency (hereinafter "EMA" or "Agency") in the context of the implementation of the Instrument for Pre-accession Assistance (IPA) programme, i.e. regarding EMA's cooperation with EU candidate countries.

## 1. Who is responsible for processing your data?

### 1.1. Who is the data controller?

The European Medicines Agency ("EMA") is ultimately responsible to comply with your data protection rights and freedoms. On behalf of EMA, the Head of International Affairs department is appointed as 'Internal Controller' to ensure the lawful conduct of this processing operation.

You may contact the Internal Controller via the following email address:  
emainternational@ema.europa.eu.

### 1.2. Who is the data processor?

The Agency may engage third parties to process data on behalf of the Agency and, in particular, to carry out the following activities: hosting of online meetings and exchange of information.

The contact details of the data processor(s) are the following:

Microsoft Ireland Operations Limited One Microsoft Place,  
South County Business Park,  
Leopardstown, Dublin 18 D18 P521,  
Ireland Telephone: +353 (1) 706-3117

## 2. Purpose of this data processing

The purpose of this data processing activity is the implementation of the Instrument for Pre-Accession assistance programme in the context of performing of the Agency tasks, including:

- Facilitating access for EU candidate country observers to EMA's working parties and working groups.

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**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



## **2.1. Personal data concerned**

In this processing operation we process personal data when EU candidate country participants attend EMA's working groups and working parties. Processing activities also include that relevant documents are shared in the course of the work of these working groups and working parties. The personal data processed may include the following:

- First and last name
- E-mail
- Affiliation with a national competent authority
- All elements related to hotel and travel arrangements (name, first name, passport details, date of birth, place of origin, disability details (if any)).
- All elements related to reimbursements of expenses (bank details).
- All elements related to declaration of interest.

## **2.2. Legal basis of the processing**

EMA's cooperation with EU candidate countries in the context of the IPA programme is necessary for the performance of the Agency tasks carried out in the public interest as required by Regulation (EC) No 726/2004, Directive 2001/83/EC, Regulation (EU) 2019/6 and other applicable Union legislation. In particular, the processing of data is necessary for the performance of tasks carried out in the public interest, including those provided for under Article 57(1)(j) of Regulation (EC) No 726/2004.

In this respect, the Instrument for Pre-accession Assistance programme is an instrument funded by the European Commission designed to support the participation of EU candidate countries in the work of EU agencies.

The European Medicines Agency has concluded a contribution agreement No 700001692 with the European Commission: "*EU4 Alignment on medicines regulation in the Western Balkans and Türkiye*" with the purpose to provide a financial contribution to finance activities for EU candidate countries in support of their preparation for their accession to the EU.

Under the agreement, EMA assists Albania, Bosnia and Herzegovina, Kosovo, Montenegro, North Macedonia, Serbia and Türkiye by implementing following actions:

- Organising ad hoc conferences and training sessions to exchange views, explain the EU legal framework and identify areas for action
- Assisting beneficiary countries with participating in EMA meetings and training courses as observers
- Providing beneficiary countries with access to selected e-learning modules in the EU Network Training Centre (EU NTC)

Moldova, Georgia and Ukraine also take part of the program initiatives

In this regard, please note that data subjects have the **right to object** against the processing as explained in Section 5 below.

### **2.3. Transfer of personal data outside of EU**

As explained, EU candidate countries take part in EMA meetings and training courses as observers. During this process, personal data of EU attendees (name, e-mail, NCA affiliation) is shared with EU candidate countries. The exchange of this data is essential to the work carried out.

In these specific situations, in the absence of an applicable adequacy decisions or appropriate safeguards, transfer of personal data to the respective destination countries is based on the condition that such transfer is necessary for important reasons of public interest as explained above.

## **3. How long do we keep your data?**

The general data retention term is 3 years, except data included in financial documents that are legally required to be stored for 5 years with the beginning of the next fiscal year.

## **4. Who has access to your information and to whom is it disclosed?**

The data collected will be processed internally by staff within the EMA Departments responsible for International Affairs, Finance and Human and Veterinary medicines departments.

## **5. Your data protection rights**

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

- **Right to be informed** – This Data Protection Notice provides information on how EMA collects and uses your personal data. Requests for other information regarding the processing may also be directed to the Internal Controller.
- **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 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 the EMA General Privacy Statement, hosted at [www.ema.europa.eu/en/about-us/legal/privacy-statement](http://www.ema.europa.eu/en/about-us/legal/privacy-statement).
- **Right to object** – You have the right to object at any time to this processing on grounds related to your particular situation. If you do so, EMA may only continue processing your personal data if it demonstrates overriding legitimate grounds to do so or if this is necessary for the establishment, exercise or defence of legal claims.

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 Data Protection Notice, please refer

to the contents of the general EMA Privacy Statement: [www.ema.europa.eu/en/about-us/legal/privacy-statement](http://www.ema.europa.eu/en/about-us/legal/privacy-statement)

## 6. 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 Data Protection Notice or the general EMA Privacy Statement, please contact:

**Internal Controller** at [emainternational@ema.europa.eu](mailto:emainternational@ema.europa.eu)

**EMA Data Protection Officer** at [dataprotection@ema.europa.eu](mailto:dataprotection@ema.europa.eu).

Address	Postal Address	EMA Switch Board
European Medicines Agency Domenico Scarlattilaan 6 1083 HS Amsterdam The Netherlands	European Medicines Agency PO Box 71010 1008 BA Amsterdam The Netherlands	+31 (0)88 781 6000

You also have the right to lodge a complaint with the **European Data Protection Supervisor (EDPS)** at any time at the following address:

- 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)