30 June 2025
EMA/216030/2025

# European Medicines Agency's Data Protection Notice
## For Microsoft (MS) Copilot 365 - EMA pilot phase

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 Copilot.

Microsoft (MS) Copilot 365 (hereinafter "Copilot" or "Copilot 365") is a generative-AI assistant integrated into MS 365 that allows the user to summarise, generate, translate, analyse content within Outlook, Teams, Word, Excel, PowerPoint and other Microsoft services.

EMA staff members (hereinafter "users") who have a Copilot 365 license can utilise Copilot's AI features in different context to support their day-to-day activities based on a risk-based methodology.[1] The main Copilot MS 365 interface supports general prompts and requests, with "WORK" and "WEB" representing different environments:

1. **WORK**: This pertains to using Copilot within the Agency's Microsoft 365 platform. Users can retrieve information from their Office 365 domain (such as emails, Teams messages, and OneDrive files) and generate content or create summaries. However, Copilot is restricted from accessing data that users do not have permission to view in the first place, adhering to EMA's access policies and security measures.

2. **WEB**: This involves using Copilot to directly access the web for tasks like searching for information, summarizing web content, and generating text based on web inputs. The "Web" version cannot access any data within EMA's MS Office 365 domain (unless explicitly uploaded in Copilot Chat by the user for processing). This mode, also called Copilot Chat, is already available for all staff.

It is important to note that the web search feature is disabled for all EMA users with a Copilot 365 license (Web&Work) for security reasons and to limit the processing of personal data to MS' EU Data Boundary[2] EMA staff members without the Copilot 365 license can still utilise the web search feature in

[1] Use case decision tree for Copilot
[2] A MS commitment to ensure that data from European Union customers is stored and processed within the EU: What is the EU Data Boundary? - Microsoft Privacy | Microsoft Learn

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the Copilot Chat in full compliance with the Guidance for EMA staff on use of AI tools[3]. This Copilot Chat feature is not covered by this Data Protection Notice.

Copilot 365 complies with EMA's established access policies/rules taking into account the respective sensitivity labels assigned to all content. Prompt results are not filtered based on these labels, e.g., documents classified as 'Restricted' are not excluded from the results in accordance with the applicable access rules for the respective EMA user. However, the labels are clearly indicated in the prompt output for the user's awareness **and** to ensure the user's compliance with confidentiality principles and EUDPR data protection rules.

In accordance with Agency's agreed risk-based methodology as referenced above, all EMA users are explicitly instructed not to use Copilot for prompts that could result in processing of special categories of personal data as set out in Article 10 of Regulation (EU) 2018/1725[4] or (commercially) confidential information and to refrain from employing Copilot for activities classified as 'High Risk' under the AI Act[5].

Prior to obtaining a Copilot 365 licence, EMA users are mandated to undergo training on AI literacy and dedicated training on Copilot.

# 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 Information Division 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: Datacontroller.infomanagement@ema.europa.eu

## *1.2. Who is the data processor?*

The Agency may engage third parties to process data on behalf of the Agency. For Copilot, Microsoft acts as the processor on behalf of EMA:

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

Microsoft Ireland Operations Limited

[3] Artificial intelligence (AI) at EMA - EMA intranet
[4] Regulation - EU - 2018/1725 - EN - EUR-Lex
[5] AI use cases that can pose serious risks to health, safety or fundamental rights are classified as high-risk. These high-risk use-cases include:

- AI solutions used in education institutions, that may determine the access to education and course of someone's professional life (e.g. scoring of exams)
- AI-based safety components of products (e.g. AI application in robot-assisted surgery)
- AI tools for employment, management of workers and access to self-employment (e.g. CV-sorting software for recruitment)
- Certain AI use-cases utilised to give access to essential private and public services (e.g. credit scoring denying citizens opportunity to obtain a loan)
- AI systems used for remote biometric identification, emotion recognition and biometric categorisation (e.g AI system to retroactively identify a shoplifter)
- AI use-cases in law enforcement that may interfere with people's fundamental rights (e.g. evaluation of the reliability of evidence)

One Microsoft Place, South County Business Park,

Leopardstown, Dublin 18 D18 P521, Ireland

Telephone: +353 (1) 706-3117

Microsoft Data Protection Officer: https://www.microsoft.com/en-gb/privacy/privacy-support-requests

# 2. Purpose of this data processing

The purpose of the data processing activities using Copilot aim to enhance the Agency's digital capabilities and improve its processes taking into account technological advancements in accordance with the Agency's Network Strategy 2028[6]. More specifically, the aim is to leveraging data, digitalisation and artificial intelligence (AI) improving decision-making, optimising processes and increasing efficiency. This is with a view to strengthen EMA's capacities in managing its tasks and obligations and supporting its mission[7] set out in the pharmaceutical legislation[8] and other applicable Union legislation.

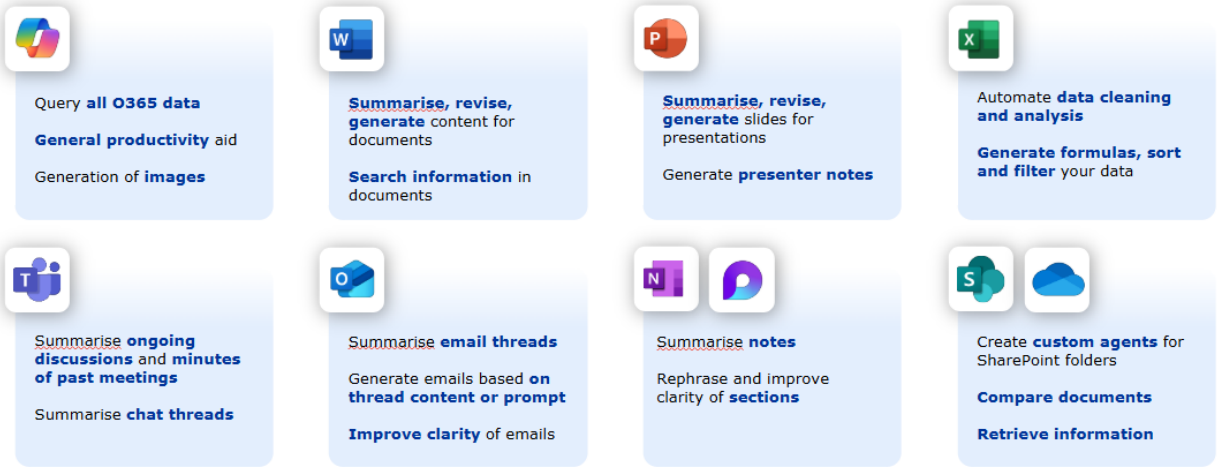
EMA interacts with many stakeholders and works closely with its scientific committees, working parties and experts. This involves the management of large volumes of data which may include personal data and special categories of personal data. The processing of such data and information is essential for EMA to fulfil its mission of fostering scientific excellence in the evaluation and supervision of medicines for the benefit of public and animal health in the European Union (EU) and to fulfil EMA's missions and tasks as set out in Union legislation. The Agency also supports research and innovation in the pharmaceutical sector and promotes the development of new medicines by European micro-, small-, and medium-sized enterprises. Additionally, the EMA has responsibilities for monitoring and mitigating potential, or actual shortages of critical medicines caused by major events and in crisis situations.

### *Use of Copilot in support of EMA's business processes*

The Copilot 365 tool, developed by Microsoft, is intended to provide personalised assistance and recommendations in applications like Word, Outlook, Teams, Excel, OneNote, and PowerPoint. It utilises Large Language Models (LLMs) and business data through Microsoft Graph to offer capabilities such as content design, creation, generation, summarisation, semantic search, natural language to code translation, accelerated automation, language translation, predictive analytics, forecasting, creative writing.

The scope of the second pilot focuses on Copilot's capabilities focusing on the following areas:

[6] European medicines agencies network strategy | European Medicines Agency (EMA)
[7] Regulation - 726/2004 - EN - EUR-Lex
[8] EudraLex - Volume 1 - European Commission




| Capability | Purpose |
|---|---|
| O365 | General queries to obtain information in user's O365 domain |
| O365 | Prompt coach to improve quality of the users prompts |
| O365 | General productivity aid – brainstorming, new ideas, preparation for interviews, communicate more effectively (...) |
| O365 | Generation of images and videos |
| Word | Summarisation of content from documents, retrieval of specific information |
| Word | Revise and improve wording of paragraphs and sections |
| Word | Generation of drafts based on general prompts or other documents |
| PowerPoint | Summarisation of content from documents, retrieval of specific information |
| PowerPoint | Revise and improve clarity of slides |
| PowerPoint | Generation of slides based on general prompts or other documents |
| Excel | Support with data cleaning and analysis |
| Outlook | Summarisation of email threads |
| Outlook | Generation of emails based on thread content or on prompt |
| Teams | Summarisation of meeting minutes during and after the meeting (internal, non-confidential meetings) |
| Teams | Summarisation of Teams chat threads |
| Teams | Generation of responses for Teams messages |
| OneNote | Summarisation of notes |
| Loop | Rephrasing of sections |

| Capability | Purpose |
|---|---|
| SharePoint | Creation of Agents for SharePoint folders (no folders containing restricted, personal, sensitive or confidential information; folders like CTIS, EV, individual patient data are blocked at admin level) |
| OneDrive | Retrieval of information from selected documents |
| OneDrive | Comparison of content between documents |

For each Copilot capability, EMA enforces a risk-based approach to determine whether the use case is allowed or prohibited[9]. A Copilot user must score the risk of their use case regarding the data in scope for processing, the target audience of the AI-generated output and the business process for which Copilot is being used. Depending on the outcome of the risk score, a user may use Copilot, if the overall risk is within the acceptable boundary; otherwise, they must refrain from doing so. All Copilot users receive explicit training.

### *Automated decision making*

Copilot provides suggestions but does **not** make binding decisions affecting individuals without human review. No automated decisions with legal or similar significant effect are taken.
Detailed guidance, covering permitted and prohibited Copilot scenarios and safeguards to ensure that no decision with legal or similarly significant effects is taken automatically, is available to all Copilot users.

***All outputs generated by Copilot must undergo thorough review for accuracy and correctness by EMA users. Human oversight is essential to ensure that the information provided is reliable, relevant, and free from errors. This process helps maintain the integrity and trustworthiness of AI-generated content, safeguarding against potential inaccuracies and ensuring compliance with ethical standards.***

## 2.1. Personal data concerned

The categories of data subjects are directly linked to the main processing activities supported by Copilot in the context of the performance of the tasks and responsibilities of EMA (further details on the personal data in scope of EMA's processing activities are available at Data protection and privacy at EMA | European Medicines Agency (EMA) and Processing of EMA colleagues' personal data - EMA intranet). This relates to data subject categories such as:

- EMA staff members, staff members previously working at EMA and prospective staff members including their family members and dependents.
- Scientific committee and working party members and appointed experts or representatives of national Competent Authorities in the EU/EEA and EU enlargement countries, the European

[9] Use case decision tree for Copilot

Commission, non-EU/EEA regulatory authorities/bodies and international organisations (like the WHO and the Council of Europe).

- Stakeholders, partners or individuals who actively collaborate, communicate, or otherwise interact with employees of the EMA.
- Professionals with professional privilege (doctors, lawyers, notaries, private citizens, stakeholders) who actively or passively interact with EMA mentioned in documents or correspondence from or to the EMA.
- Patients and consumers, professionals working in healthcare, representatives of academia, pharmaceutical industry, Health Technology Assessment bodies participating in EMA's framework of interactions.
- Representatives of sponsors of clinical trials, investigators and representatives of Ethics Committees.
- Study participants in clinical trials and non-interventional studies, patients, consumers and healthcare professionals whose data is submitted to the EMA in accordance with the pharmaceutical legislation.
- External end-users (e.g., from other EU institutions, EU bodies, national Competent Authorities, sponsors, MAHs, Patients organisations) who use communication tools provided by the EMA.
- EMA's contractors.

A summary of the main processing areas and personal data in scope of the Agency's second pilot phase is provided as follows as follows:

| Processing area | Personal data in scope |
|---|---|
| Processing of information related to data subject categories for stakeholder management | Name, (email) address, (professional) contact details, job role, function, organisation/entity |
| Information Security | Personal data related to user registration, authentication, permissions and access rights, logs, connecting information |
| Systems operation | System generated and telemetry data such as IP addresses, cookies, tenant & user IDs, diagnostics logs, time stamps and features used, (see also EMA DPN for the use of Microsoft applications) |
| Medicines regulatory procedures (Human and Veterinary) including pre- and post-authorisation studies in accordance with EMA's mission and roles and responsibilities set out in Union legislation and internal rules | Personal data processed as part of EMA's medicines regulatory procedures |

| Processing area | Personal data in scope |
|---|---|
| Human Resource management in accordance with Union legislation and internal rules | Personnel number, personal data relating to the employment of the data subject, including employment and career history, recruitment and termination details, attendance records, health and safety records, performance appraisals, training records, and security records |
| Processing of information related to family life, lifestyle and social circumstances | Information relating to the family or lifestyle of data subjects such as marriage and partnership status, marital history, details of family and other household members, housing, travel details and leisure activities and interests |
| Finances and budget management in accordance with Union legislation and internal rules | Information related to financial affairs of data subjects including income, salary, assets and investments, payments, loans, benefits, grants, insurance details, pension information, invoices, fees |
| Contracts and services | Personal data related to goods or services supplied or to be supplied, licences issued, and contracts |
| Stakeholder engagement and interactions | Personal data in the context of methods of communication and interaction with EMA's stakeholders |
| Multimedia | Personal data in the context of sound/video recordings, phone calls and recording transcripts |
| Education and training | Personal data which relates to the education and any professional training of the data subject, including academic records, qualifications, professional and language skills, training records, professional expertise, and student records |
| Validation of identification issued by a public authority (where applicable) | Passport details, national insurance numbers, identity card numbers, driving license details, diplomatic identification cards (excluding special categories of personal data) |

The processing of (pseudonymised[10]) special categories of personal data **in accordance with Article 10 EUDPR i.e.** personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data[11], biometric

[10] Article 3(6) EUDPR: 'pseudonymisation' means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.
[11] Article 3 (17) EUDPR: 'genetic data' means personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question.

data[12] for the purpose of uniquely identifying a natural person, data concerning health[13] or data concerning a natural person's sex life or sexual orientation **is out of scope of the second pilot phase in accordance with the agreed risk-based methodology.** Copilot users are required to adhere to this methodology. These categories of personal data are processed by Copilot when stored within the MS365 domain but are not subject to further processing by EMA Copilot users e.g. as part of a prompt or query.

MS process personal data based on the following data classification[14]:

| Data Category | Data Classification | Description | Examples |
|---|---|---|---|
| a) Customer Data | Customer Content | Content directly provided/created by admins and users<br><br>Customer content also includes customer-owned/provided secrets (passwords, certificates, encryption keys, storage keys) | MS 365 applications in scope of the pilot |
| b) Customer Data | End User Identifiable Information (EUII) | Data that identifies or could be used to identify a user of a MS service. EUII does not contain customer data | User name or display name (DOMAIN/UserName)<br><br>User principal name (name@domain)<br><br>User-specific IP addresses |
| c) Personal Data (data not included in Customer Data) | End User Pseudonymous Identifiers (EUPI) | An identifier created by Microsoft tied to a user of a Microsoft service. When combining with other information, such as a mapping table the EUPI identifies the end user<br><br>EUPI does not contain information uploaded or created by the end user | User GUIDs (Global Unique Identifiers), PUIDs (Personal Unique Identifiers), or Security Identifiers (SIDs)<br><br>Session IDs |

[12] Article 3(18) EUDPR: 'biometric data' means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data.
[13] Article 3 (19) EUDPR: 'data concerning health' means personal data related to the physical or mental health of a natural person, including the provision of healthcare services, which reveal information about his or her health status.
[14] Data retention, deletion, and destruction in Microsoft 365 - Microsoft Service Assurance | Microsoft Learn

## 2.2. Legal basis of the processing

In accordance with the Agency's Network Strategy 2028 and the Agency's mission and obligations as set out in Union legislation, the use of Copilot for the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the Union institution or body (Article 5(1)(a) of Regulation (EU) 2018/1725).

## 2.3. Transfer of personal data outside of EU

If applicable[15], any transfer of personal data to a third country or an international organisation by the Agency's processor shall be done only on the basis of documented instructions from the Agency or in order to fulfil a specific requirement under Union or Member State law to which the processor is subject and shall take place in compliance with Chapter V of Regulation (EU) 2016/679 or the EUDPR. Microsoft commits that it will never use any data involved in processing, as well as the prompts submitted by a user, to train Copilot's underlying models and affirms its compliance with EUDPR, the EU Data Boundary initiative, and the ISO/IEC 27018 cloud-privacy standard[16][17].

# 3. How long do we keep your data?

Microsoft retains Copilot prompts and responses for a period of 6 months, after which the prompts and responses are permanently deleted within a maximum of 30 days following expiration[18]. The same applies to audit logs containing customer data. [19],[20]

Copilot prompts and responses can also be deleted under the following circumstances:

- A user explicitly deletes the associated chat in Microsoft 365 Copilot.
- A user deletes his/her Copilot activity history (in accordance with the guidance provided by Microsoft) [21]...

In such instances, the prompts and responses will be scheduled for deletion within a maximum of 30 days from the moment the deletion takes place or the request is submitted[22].

The outputs generated by Copilot, for example a summary of a document or a PowerPoint presentation, are maintained according to the applicable retention policies[23], [24].

| Copilot inputs and outputs | Retention Period – Automatic Deletion (default) | Retention Period – Manual deletion by the user |
|---|---|---|
| **Copilot - Prompt text** (what you type) | 6 months +Up to 30 days for permanent deletion* | Immediate deletion from the user interface |

[15] Services excluded from the EU Data Boundary - Microsoft Privacy | Microsoft Learn
[16] Enterprise data protection in Microsoft 365 Copilot and Microsoft 365 Copilot Chat
[17] Data, Privacy, and Security for Microsoft 365 Copilot
[18] Data retention, deletion, and destruction in Microsoft 365 - Microsoft Service Assurance | Microsoft Learn
[19] Audit logs for Copilot and AI activities
[20] Data retention, deletion, and destruction in Microsoft 365 - Microsoft Service Assurance | Microsoft Learn
[21] Delete your Microsoft 365 Copilot activity history - Microsoft Support
[22] Copilot prompts and responses can also be deleted under the following circumstances
[23] EMA Records management and archives policy
[24] EMA DPN for the use of Microsoft applications
* At this point, EMA will no longer have access to the data

| Copilot inputs and outputs | Retention Period – Automatic Deletion (default) | Retention Period – Manual deletion by the user |
|---|---|---|
| | | Up to 30 days for permanent deletion* |
| **Copilot - Response text** with citations and references | 6 months + Up to 30 days for permanent deletion* | Immediate deletion from the user interface<br><br>Up to 30 days for permanent deletion* |
| **Copilot – Generated content** in apps, mails and Teams | Following the retention period of the type of content generated[25] | Following the retention period of the type of content generated[25] |
| **Copilot - Grounding data** pulled through Microsoft Graph (documents, emails, chats, calendar, contacts, files, meeting transcripts) | Following the retention period of the type of content sourced[25] | Following the retention period of the type of content sourced[25] |
| **Copilot -** Audit logs and metadata (timestamps, user ID, app surface) | 6 months + Up to 30 days for permanent deletion* | 6 months + Up to 30 days for permanent deletion* |
| **Copilot – System generated logs**[26] | 18 months | 30 days following request for deletion[27]* |
| Teams Meeting recording, transcript and automatic meeting summaries | For call/meeting recordings these are retained by default for 30 days but the owner can amend the expiry date.<br><br>The file will be completely deleted 30 days* after deactivation of the owners account. | Immediate deletion<br><br>Users are responsible for deleting any files that are no longer required in line with the principle of storage limitation |

MS retains personal data based on the following data classification[28]:

| Data Category | Data Classification | Retention Period |
|---|---|---|
| a) Customer Data | Customer Content | **Active Deletion Scenario** (the process where a user explicitly deletes their Copilot activity history or associated chat): at most 30 days |

[25] European Medicines Agency's Data Protection Notice for the use of Microsoft Applications: OneDrive, Outlook 365, Teams and SharePoint
[26] v2-Response-to-MS-Letter-from-12.16.24.pdf
[27] Office 365 Data Subject Requests Under the GDPR and CCPA - Microsoft GDPR | Microsoft Learn
[28] Data retention, deletion, and destruction in Microsoft 365 - Microsoft Service Assurance | Microsoft Learn

| Data Category | Data Classification | Retention Period |
|---|---|---|
| | | **Passive Deletion Scenario**: at most 180 days |
| b) Customer Data | End User Identifiable Information (EUII) | **Active Deletion Scenario**: at most 180 days (only a tenant administrator action)<br>**Passive Deletion Scenario**: at most 180 days |
| c) Personal Data (data not included in Customer Data) | End User Pseudonymous Identifiers (EUPI) | **Active Deletion Scenario**: at most 30 days<br>**Passive Deletion Scenario**: at most 180 days |

When a Copilot user leaves EMA, their account is disabled and the same retention period as for MS Outlook 365 applies[29].

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

Personal data related to user registration, authentication, permissions and access rights, logs, connecting information is accessible to appointed EMA security personnel (AF-INS).

Authorised EMA network administrators of the Agency's Information Management Division (I-Division) and Information Security Service (DED-INS) can temporarily access all exchanges made with Copilot in all platforms if there is a legitimate reason to do so, e.g., for the purpose of providing technical support and compliance with applicable terms of use and EMA's code of conduct (see https://www.ema.europa.eu/en/documents/other/european-medicines-agency-code-conduct_en.pdf) . This might include information like exchanges in chats or email threads that the administrator is not a member of, if they have been incorporated in the response provided by Copilot.

Microsoft and their sub-processors may access customer and personal data (see points b. and c. of section 3) as necessary for the purposes of providing the service. In accordance with EMA's security measures, Microsoft does not have access to prompts and does not use prompts to train the models.

Personal data is accessible to authorised EMA users in accordance with the Agency's access policies/rules including Copilot prompt outputs. EMA staff abide by statutory confidentiality agreements and compliance with Union data protection rules.

This is without prejudice to a possible transfer to bodies in charge of a monitoring, auditing or inspection function (e.g. Court of Auditors, EU Court of Justice, European Data Protection Supervisor) in accordance with Union legislation.

Data may also be accessed in relation to administrative inquiries and disciplinary proceedings. Please refer to the EMA Data Protection Notice covering this processing.[30]

[29] EMA DPN for the use of Microsoft applications
[30] https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-privacy-statement-processing-personal-data-context-administrative-inquiries-disciplinary-proceedings_en.pdf

Where EMA receives a request for access to data from a data subject, the EMA data protection officer may access data within the Microsoft applications for the purpose of fulfilling the request.

# 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.
- **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.
- **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 directly 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 Data Protection Notice, please refer to the contents of the general EMA Privacy Statement: 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 the **Internal Controller** at Datacontroller.infomanagement@ema.europa.eu or the **EMA Data Protection Officer** at dataprotection@ema.europa.eu.

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