



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

Privacy Statement on the processing of personal data in the context of administrative inquiries and disciplinary proceedings

The European Medicines Agency (hereinafter “EMA” or “Agency”) is committed to respecting the right to data protection of its Staff Members. The Agency collects and uses personal data in accordance with Regulation (EU) 2018/1725¹ (hereinafter “Regulation”).

This Privacy Statement explains the essential details about how personal data of persons involved in administrative inquiries and disciplinary proceedings (hereinafter “AI&DP”) is processed by the Agency in the context of these procedures. In relation to this data processing activity this document also provides information about the rights of the individuals concerned (i.e. the data subjects) in relation to their personal data which is processed.

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

1. Who is the data controller?

The European Medicines Agency is ultimately responsible for complying with the Regulation. On behalf of EMA the Administration and Corporate Management Division is appointed as the data controller to ensure the lawful conduct of this processing operation.

The appointed data controller may be contacted in the following email address:
datacontroller.administration@ema.europa.eu

2. What is the purpose of this data processing?

The purpose of processing the below personal data is to collect information relevant to the conduct of an AI&DP, should you be directly concerned by the inquiry or a third person such as a witness.

¹ 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, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, available: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R1725>



Please note that hindering an administrative inquiry or a disciplinary proceeding may have possible disciplinary consequences, for example, if a witness maliciously makes a false witness statement or wilfully withhold or destroy evidence it could serve as a ground for a separate inquiry and proceeding.

EMA processes the data for the preliminary assessment stage (pre-inquiry), when the Executive Director or a Head of Division is informed of a situation with a possible disciplinary dimension. An administrative inquiry is opened at the request of the Executive Director or a Head of Division. After a consultation with the European Anti-Fraud Office (OLAF), that no investigation takes place for its own purposes, the Executive Director appoints normally an internal investigator to carry out an inquiry. A disciplinary file is created collecting information about the facts and witnesses of the events. On the basis of the report produced by the investigator the Executive Director might decide to initiate a disciplinary proceeding before the Disciplinary Board.

3. What personal data do we process and how?

3.1. How do we collect your personal data?

In this processing operation we process personal data collected directly from the individual it relates to. In addition, in case you are the subject of the particular AI&DP we process certain categories of data collected from third parties participating in the inquiry (e.g. witnesses, informants) as explained in the next section.

3.2. What personal data is collected and processed?

The following categories of personal data may be processed:

Personal data relating to all data subjects (i.e. person concerned by the AI&DP and other participating in the inquiry):

- staff member's basic personal information (name, surname, rank and personal staff number);
- staff member's contact details and other personal data concerning the recruitment or the evaluation of the staff member (name of line manager, hiring date, contractual category and grade, organisational entity to which one belongs);
- Events, facts and witness testimonies referring to the staff member involved in the AI&DP about the situation with a possible disciplinary dimension;
- Names of the administrative investigator and of the members of the Disciplinary Board.

Personal data relating to data subjects who are the subject of the particular AI&DP (which may be revealed during the inquiry directly from the concerned staff member(s) or indirectly from informants or witnesses or from documents containing personal data used as evidence):

- personal data related to absences, leave, missions, learning and development and generally to the working performance, economic and social behaviour where relevant to the performance of the staff member's tasks;
- personal data related to the private sphere and life of the staff member (social activities, behaviour), additional data related to the staff member's identity and personal status (gender, age), comments on the abilities and efficiency of the concerned staff member(s);
- only when necessary and related to the AI&DI: special categories of personal data (sensitive data) concerning the staff member: health data, religion (or opinions on religion), political opinions (or opinions on political status/opinions), philosophical beliefs (or opinions on philosophical beliefs), or

trade union membership ((or opinions on trade union membership) sex life or sexual orientation (or opinion on sex life or sexual orientation), race or ethnic origin (or opinion on race or ethics origin);

- personal data relating to criminal convictions and offences.

The Agency adheres to the principles of data minimisation, necessity and proportionality regarding the personal data to be collected, the means and steps of the investigation. The collection of personal data will be limited to what is directly and strictly relevant and necessary to the purpose of the inquiry and of the disciplinary proceeding.

3.3. How do we store your personal data?

All documents relevant to the administrative inquiry are stored in an electronic file and in paper form. The paper file is stored in a locked cupboard within the Staff Relations and Support Department. Any subsequent amendments or corrections of these documents are inserted in this file and to the electronic version. Electronic access, as well as, access to the hard copies is strictly limited to authorised Staff Members and other individuals where required by law.

3.4. Legal basis of this personal data processing

The Regulation allows the processing of personal data if the processing is necessary for the performance of a task carried out in the public interest on the basis of the Treaties or on an EU legal instrument based on the Treaties. The processing of your data is necessary for the management and functioning of the Agency in accordance with Article 86 and Annex IX of the Staff Regulations as well as Articles 49, 50 and 119 of the Conditions of Employment of Other Servants ([Regulation No 31 \(EEC\), 11 \(EAEC\)](#)). The specific legal basis for the processing of personal data in relation to AI&DP is the EMA's Implementing Rules the *EMA's Implementing Rules on the conduct of administrative inquiries and disciplinary procedures adopted on 8 June 2012* as well as the *Decision of the Management Board of the European Medicines Agency on internal rules concerning restrictions of certain rights of data subjects in relation to processing of personal data in the framework of the functioning of the Agency* adopted on 12 June 2019.²

Prior to processing special categories of personal data, the Agency will establish the applicable lawful ground under Article 10 of the Regulation, and more specifically where: 1) the processing is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller or of the data subject in the field of employment and social security and social protection law insofar as it is authorised by Union law providing for appropriate safeguards for the fundamental rights and the interests of the data subject; 2) the processing is necessary for the establishment, exercise or defence of legal claims; or 3) the processing is necessary for reasons of substantial public interest, on the basis of Union law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

Where processing of personal data relating to criminal convictions and offences is carried, this will be in line with Article 11 of the Regulation and the above mentioned Implementing Rules.

² Available here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.209.01.0019.01.ENG&toc=OJ:L:2019:209:TOC

4. How long do we keep your data?

In line with Article 4(1)(e) of the Regulation, personal data shall be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed. In determining the maximum retention periods, the Agency has taken into account the nature of the sanction, possible legal recourses, legal, auditing, archiving and reporting obligations.

Documents of administrative inquiry proceedings without a disciplinary follow-up or where there is no charge against the staff member are held for 5 years from the date of the last document on the file.

Documents of the disciplinary board are retained for 10 years from the date of the last document inserted to the file.

Where a disciplinary penalty other than dismissal has been made, the decision is notified to you in writing and the original decision is inserted in your personal file. After 3 years in the case of a written warning or reprimand or after six years in the case of any other penalty, you may request deletion from your personal file of all reference to the measure. This request should be addressed to the Executive Director. If such request is granted, the data will also be removed from the disciplinary file. Where there is no disciplinary penalty, there will be no trace of the acquittal decision in your personal file unless you request it.

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

The Staff Relations and Support Department store your personal data within a disciplinary file, which gathers only the information related to an inquiry, including the decision of the Executive Director to open the inquiry, the report of the investigator(s) and the decision taken by the Executive Director and/or the Disciplinary Board. The Head of Administration, the Executive Director, the investigator(s) and the Disciplinary Board will have access to the data in the case file. Any person other than the members of the investigating team or the disciplinary board who might be involved in the processing of personal data in the context of the inquiry or disciplinary proceeding (such as IT staff potentially involved in case evidence in the form of electronic information is necessary and relevant for the inquiry or proceeding on question) will be authorised to process such information on a strictly need-to-know basis. The investigator(s) request should be specific so that only specific and relevant information would be extracted and further processed.

Information about the case may be shared with the European Anti-Fraud Office (OLAF) for consultation to ensure that no parallel inquiry is pending at OLAF. The disciplinary file may be transferred to the European Court of Justice in the case of an appeal and alternatively to the European Ombudsman in the case of maladministration. Any transfer of personal data to recipients within or to other EU institutions must comply with specific requirements. Transfers of personal information within the EU institutions may only take place as long as they are necessary for the performance of the recipient's tasks and competences and should also occur on a strict need-to-know basis.

6. What are your rights in relation this processing?

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

- **Right to be informed** – You have the right to be informed about the collection and use of your personal data 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 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 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 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 by the data controller 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

The rights of the data subject can be exercised in accordance with the provisions of Regulation (EU) 2018/1725. The rights and obligations under Regulation (EU) 2018/1725 can be restricted if they would jeopardise the purpose of administrative inquiries, pre-disciplinary, disciplinary and suspension proceedings or would affect the rights and freedoms of other data subjects. For anything that is not specifically provided for in this privacy notice, please refer to the contents of the general EMA Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement.

Please note that certain rights of data subjects involved in administrative enquiry or disciplinary proceedings may be restricted in accordance with the *Decision of the Management Board of the European Medicines Agency on internal rules concerning restrictions of certain rights of data subjects in relation to processing of personal data in the framework of the functioning of the Agency adopted on 12 June 2019*.³ Such decisions will be taken strictly on a case by case basis. The Agency will document the reasons for taking such decision to demonstrate that the restriction is proportionate and necessary in line with the provisions of Regulation 2018/1725.

The applicable legislation and the Implementing Rules (see Section [3.4 above](#)) govern and address other procedural rights of subjects and participants of AI&DP which are not related to personal data protection.

7. 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 you may contact the data controller directly on the following email address: datacontroller.administration@ema.europa.eu.

³ Available here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.209.01.0019.01.ENG&toc=OJ:L:2019:209:TOC

In addition, you may submit a question or complaint to the **EMA Data Protection Officer** (dataprotection@ema.europa.eu) or you may lodge a complaint with the **European Data Protection Supervisor** via the following contact details:

Email: edps@edps.europa.eu

Website: www.edps.europa.eu

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