



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 November 2022
EMA/905403/2022

European Medicines Agency's Data Protection Notice

For the procedure for handling and reporting internally potential fraud and irregularities

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 procedure for handling internally and reporting potential fraud and irregularities as described in the document "Implementation of the EMA Anti-Fraud Strategy: the Fraud Reporting Process" dated 22 March 2017 and available on the EMA's public website¹.

This includes the processing of personal data concerning the reporting person (if not anonymous), data concerning the activities described in the report and personal data of the persons involved.

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 Anti-Fraud Officer 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: afo@ema.europa.eu

2. Purpose of this data processing

The purpose of this data processing activity is the processing by the EMA's General Affairs and Anti-Fraud Office (GAF) of reported information regarding irregularities and potential fraud cases that are brought to its attention by way of internal or external reporting (in various forms, e.g., ad hoc reporting template, or other forms, e.g., email to the functional mailbox), in the context of performing of the Agency's tasks, including those in line with Article 69 of Regulation (EC) No 726/2004.

This reporting process, which might concern irregularities/fraud allegedly committed within the Agency and/or by an external party vis-à-vis the Agency, allows gathering information in relation to the reported conducts, also in order to assess and identify which cases require to be transmitted to the European Anti-Fraud Office (OLAF) according to Article 8 of Regulation (EU, Euratom) No 883/2013.

¹ Available at this address: https://www.ema.europa.eu/en/documents/template-form/fraud-reporting-process-reporting-template_en.pdf



2.1. Personal data concerned

In this processing operation we process data directly collected from you when you submit information to the General Affairs and Anti-Fraud Office. Such data may include the following: name and surname of the reporting person, name and surname of the person concerned in the alleged irregularity, or any other person mentioned, email address of the reporting person, professional position of the persons involved, phone numbers if provided, data on the nature of the facts potentially constituting fraud, any other personal data reported by the reporting person. The data processed might also contain data of third parties (e.g., if the facts came to the attention of the reporting person through a letter sent by a third party, the General Affairs and Anti-Fraud Office might need to process the data contained in such a letter).

Other data processed might not be collected directly from the reporting person, but obtained through other internal sources, for example HR databases (e.g., SAP), in case this information is needed to confirm elements derived from the reporting.

2.2. Legal basis of the processing

The processing of data in the context of the procedure for handling internally and reporting potential fraud and irregularities is necessary for the performance of the Agency's tasks carried out in the public interest. In particular, the processing of data is necessary to perform the activities as provided for under Regulation (EU, Euratom) No 883/2013, in particular Article 8 thereof, the Financial Regulation applicable to the budget of the EMA, in particular Article 45(12) thereof, and the EMA's Anti-Fraud Strategy and related action plan, adopted by the Management Board in its December 2014 meeting and further revised in December 2017 and March 2021 (doc. ref. EMA/128273/2021) in particular its Objective No 2 ("Strengthen measures for detection of suspicious behaviours, including through maintaining an efficient system for internal reporting and handling of suspected irregularities").

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

3. How long do we keep your data?

With regard to cases which will not be notified to OLAF and for which no further action is needed, the retention period by EMA will be 12 months from the termination of the relevant assessment leading to the decision that no notification or further action is needed.

With regard to cases which will be notified to OLAF, the EMA aligns its conservation period with those of OLAF's policy on the retention of personal data. Therefore, the data will be kept for a period of 15, 8, or 5 years depending on the case type. Data in cases with follow-up will be kept for 15 years, data in cases without follow-up for 8 years and data in cases that have been dismissed will be kept for 5 years.

Improper or manifestly pointless messages will be deleted immediately.

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

The data collected will be processed internally by staff within the General Affairs and Anti-Fraud Office, which is responsible for receiving the reported information and for centralising the reports. According to the other reporting procedures available to staff members (e.g., Article 22a of the Staff

Regulations), the immediate superior of the Executive Director might be the first recipients of this report, who, according to the procedure, will inform the General Affairs Anti-Fraud Office without delay.

In accordance with the obligation set out by Regulation (EU, Euratom) No 883/2013 to transmit to OLAF without delay any information related to possible cases of fraud/irregularities affecting the financial interests of the Union, the information received by the General Affairs Anti-Fraud Office might be transmitted to OLAF's staff members.

Moreover, in the initial phase of internal assessment of the reported information, the data can be communicated to HR or Audit, the relevant Head of Division/Task Force, Head of the Legal Department, investigators appointed to undertake administrative inquiries or Disciplinary Board members, on a strictly need-to-know basis, and to the Executive Director, if there is a need to involve OLAF.

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 data 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's 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.

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 the general EMA's 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's

Privacy Statement, please contact the **Internal Controller** at afo@ema.europa.eu or the **EMA's 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: <https://edps.europa.eu/en>
- Further contact information: www.edps.europa.eu/about-edps/contact_en