



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Executive Director

Policy on the handling of information from external persons on breaches related to the authorisation, supervision and maintenance of human and veterinary medicinal products or other EMA activities

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Table of contents

1. Introduction and purpose	2
2. Scope	3
3. Definitions	3
4. Policy statement	4
4.1. Reporting Channels	4
4.1.1. Confidentiality	4
4.1.2. Acknowledgement of Receipt	5
4.1.3. Preliminary Analysis	5
4.1.4. Follow-up	5
4.1.5. Feedback to the Reporting Person	6
4.1.6. Interaction with other EMA Rules	6
4.2. Protection of personal data and record keeping of reports	6
4.3. Publication of information on reports	7
5. Related documents	7
6. Changes since last revision	8

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1. Introduction and purpose

The European Medicines Agency (hereinafter, EMA) is an Agency of the European Union (EU) responsible for the protection and promotion of public and animal health through the evaluation and supervision of medicinal products for human and veterinary use. It coordinates the scientific resources put at its disposal by Member States and provides them and EU institutions with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products. EMA's tasks are laid down in EU legislation, which its staff carry out with the highest standards of professional and personal integrity.

This policy on the handling of information from external persons on breaches was first adopted in 2017 to provide a framework for assessing reports from reporting persons (or external whistleblowers) and coordinating the investigation into the alleged facts, while at the same time protecting the confidentiality of reporting persons. The policy represents a tool to facilitate the detection of breaches of the legal acts on which EMA exercises its competence, contributing to the safeguard of the public interest and the promotion of a culture of public accountability and integrity by creating an environment of trust for reporting persons. This policy also complements EMA's rules on internal whistleblowing, i.e., reports submitted by staff working for the Agency, and EMA's efforts in fighting fraud and irregularities, as mandated under Article 325 of the Treaty on the Functioning of the European Union, and further developed in the Anti-Fraud Strategy adopted by EMA's Management Board.¹

The policy was revised in 2022 to take account of Directive 2019/1937 on the protection of persons who report breaches of Union law (the Directive). The Directive requires that *persons reporting to relevant institutions, bodies, offices or agencies of the Union breaches falling within the scope of this Directive shall qualify for protection as laid down in this Directive under the same conditions as persons who report externally*.² The Directive establishes minimum standards for the protection of individuals who report breaches of EU law in work-related contexts; it also requires the creation of safe channels for reporting both within an organisation and to public authorities, as well as the protection of whistleblowers against retaliation.

Experience since the adoption and first revision of the policy has shown, among other things, that information from external reporters often concern breaches of acts on which EMA does not exercise any competence. In such cases, and considering its lack of competence, EMA will respect the duty of confidentiality of the person in the same manner as in cases that fall under its competence but will aim to offer them the possibility to forward the report to the relevant competent body, if it can be correctly identified. EMA has also received and handled multiple reports from persons who could not be considered as reporting persons in accordance with the definition of the Directive; however, such approach is not effective from a policy perspective, and the current revision clarifies that in such cases, the policy will not be applicable although EMA will aim to handle such information via other mechanisms that may be more suitable. In general, the current revision aims to continue aligning the policy with the Directive, e.g., by clarifying the reporting channels available to reporting persons as well as by promoting further the relevant protections laid down in the Directive.

¹ See EMA's website (<https://www.ema.europa.eu/en/about-us/how-we-work/anti-fraud-strategy>)

² Article 6.4. Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law. OJ L 305, 26.11.2019, pp. 17–56.

2. Scope

This policy governs the handling of information on breaches of legal acts on the authorisation, supervision and maintenance of human and veterinary medicinal products or on other activities for which EMA exercises its competence from a reporting person as defined herein. It includes the reporting channels offered by EMA and the protections granted to a reporting person, notably, the protection of their identity by means of handling their reports in a confidential manner.

The handling of information on breaches of legal acts outside EMA's competence falls outside the scope of this policy.

This policy applies only to individuals who meet the definition of a "reporting person", as set out in this policy. Reports submitted by other individuals which fall outside the scope of this policy, may nonetheless be examined and addressed by EMA through other suitable mechanisms.

This policy does not apply to EMA staff who report breaches that occur in their employment relationship with EMA, as such cases are exclusively covered by the relevant provisions of the Staff Regulations and EMA guidelines on whistleblowing.³ However, it applies where the reported breaches occur in a work-related context outside their employment relationship with EMA, while generally not being intended to replace applicable reporting lines.

3. Definitions

The following definitions apply:

- "Breaches" means acts or omissions that are unlawful or defeat the object of the purpose of the rules in the Union acts on which EMA exercises its competence in accordance with Union legislation.
- "Information on breaches" means information, including reasonable suspicions, about actual or potential breaches, which occurred or are very likely to occur in the organisation in which the reporting person works or has worked or in another organisation with which the reporting person is or was in contact through his or her work, including participation in a clinical study, and about attempts to conceal such breaches.
- "Report" or "to report" means the oral or written communication of information on breaches.
- "External reporting" means the oral or written communication of information on breaches to EMA.
- "Reporting person" means a natural person working in the private or public sector who acquired information on breaches in a work-related context, including participation in a clinical study, and who reports to EMA or publicly discloses this information as an external person.
- "EMA staff" means EMA staff members (i.e., Temporary Agents and Contract Agents), Seconded National Experts, Interims and Trainees.
- "Follow-up" means any action taken by EMA to assess the accuracy of the allegations made in the report and, where relevant, to address the breach reported, including the closure of the procedure.
- "Person concerned" means a natural or legal person who is referred to in the report or public disclosure as a person to whom the breach is attributed or with whom that person is associated.

³ Article 22a and Article 22b of Regulation No 31 (EEC), 11 (EAEC), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community, OJ 45, 14.6.1962, pp. 1385–1386.

4. Policy statement

Reports should be made on reasonable grounds, i.e., in the belief that the information on breaches reported was true at the time of reporting and that such information fell within EMA's scope of competence.

EMA strives to process reports in a timely manner. In the event of high inflow of reports, it may prioritise them according to their seriousness.

4.1. Reporting Channels

A reporting person may use EMA's dedicated mailbox indicated on EMA's website for the purposes of submitting information on breaches of the legal acts on the authorisation, supervision and maintenance of human and veterinary medicinal products or on other activities for which EMA exercises its competence.⁴

A reporting person may also report orally in person, via telephone or in writing via mail.

When a report is made orally, EMA, subject to the consent of the reporting person, will document the oral reporting by making a recording of the conversation, or through a transcript of the conversation, or through minutes of the conversation. The reporting person will be offered the possibility to check, rectify and agree the transcript or the minutes of the conversation.

Access to the dedicated mailbox and any information received through it will be restricted to as little staff members as possible, including those who are involved in managing/processing the whistleblower report, or those who require awareness of the report. Where a member of the EMA staff receives a report, they will forward it without any modifications or undue delay to the dedicated mailbox and destroy any copies that they could have kept in the process. They will keep strictly confidential any information that could identify the reporting person or the person concerned.

EMA publishes information in its website on the available reporting channels, as well as other relevant information to facilitate the task of submitting reports to EMA by reporting persons⁴.

4.1.1. Confidentiality

EMA ensures that the identity of the reporting person, or any other information from which the identity could be directly or indirectly deduced, is not disclosed to anyone not authorised to receive or follow up on the report, unless the reporting person provides their explicit consent. It will only be disclosed where it is a necessary and proportionate obligation imposed by Union law in the context of investigations or judicial proceedings, including with a view to safeguarding the rights of defence of the person concerned. In such cases, the reporting person will be informed beforehand with an explanation of the reasons for the disclosure, unless such information would jeopardise the related investigations or judicial proceedings.

While EMA accepts anonymous reports and will handle and review them in accordance with the present policy, reporting persons are encouraged to provide their identity in order to allow EMA to provide them with feedback as well as to request clarifications, if needed.

EMA will not disclose or use any information on breaches received that includes trade secrets for purposes going beyond what is necessary for proper follow-up.

⁴ See EMA's website (<https://www.ema.europa.eu/en/about-us/how-we-work/external-whistleblowing-policy>)

EMA aims to apply the same level of confidentiality to persons who come forward with information on breaches that falls outside the scope of application of the policy, considering that such information may point to breaches of legal acts for which a different competent authority is responsible and thus that person could potentially benefit from the protections offered by the Directive and/or other policies adopted by the competent authority in question.

4.1.2. Acknowledgement of Receipt

EMA aims to acknowledge receipt of a report submitted to the dedicated mailbox within seven days of its receipt.

When a report is made orally or during a meeting, the transcript or the minutes, if shared with the reporting person for checking, rectification and/or agreement, will serve the purpose of acknowledging receipt.

The reporting person may indicate in the report that they do not wish to receive an acknowledgement of receipt. EMA may also decide not to send such an acknowledgement where it reasonably believes that it could lead to the disclosure of the reporting person's identity.

4.1.3. Preliminary Analysis

Following receipt of a report, EMA will assess it and decide, without undue delay, whether it falls under its competence.

If EMA is competent to deal with the report, it will inform the reporting person thereof as well as of the timeframe to provide feedback.

If EMA is not competent to deal with the report, EMA will inform the reporting person thereof, and may offer, if applicable and upon their express consent, to transmit the report including name and contact details of the reporting person in a secured manner to the relevant competent authority able to deal with it. If the reporting person has not expressed their consent but EMA considers that the information received is of sufficient importance, it may transmit the report to the relevant competent authority while maintaining the confidentiality of the reporting person, who will be informed of such transmission.

EMA is required to report any instance of fraud, corruption and any other illegal activity affecting the EU's financial interests to the European Anti-Fraud Office (OLAF) or, if they concern a crime affecting the financial interests of the EU, to the European Public Prosecutor Office (EPPO). Reporting persons are advised to address such reports to OLAF or to EPPO; if EMA receives such a report, it will notify the reporting person that it will forward it to OLAF or to EPPO.

4.1.4. Follow-up

EMA may draw up an internal report with an assessment of the information received and any possible actions to remedy the breach. Any such internal report will be drawn up in a fashion that guarantees the anonymity of the reporting person.

Action to remedy the breach could be e.g., a review of a scientific opinion, interaction with other competent authorities (European Commission, national competent authorities, etc.) to discuss the necessity of a joint follow-up, other regulatory action, etc.

If EMA concludes that the breach is minor and does not merit any follow-up, it may decide to close the procedure and will notify the reporting person accordingly, including a rationale for the closure.

If EMA concludes that the breach represents a repetitive allegation which does not contain any meaningful new information on breaches of a past report in respect of which the relevant procedure was concluded, it may decide to close the procedure and will notify the reporting person, accordingly, including a rationale for the closure.

4.1.5. Feedback to the Reporting Person

EMA will provide feedback to the reporting person on the follow-up of the report within a reasonable timeframe not exceeding three months since the acknowledgement of receipt, or six months in duly justified cases.

4.1.6. Interaction with other EMA Rules

Where a report includes information on breaches of the rules on competing interests applicable to members, alternates and experts of the Agency's scientific committees and other groups (Policy 0044) or applicable to members of the Management board (Policy 0058) or of their obligation of professional secrecy, the report or parts thereof, in case there are allegations of other breaches, will be assessed in accordance with EMA's breach of trust procedures⁵.

4.2. Protection of personal data and record keeping of reports

All personal data collected and processed for the purposes of operating this Policy will be handled in accordance with Regulation (EU) 2018/1725 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.⁶

All reports and related information will be stored in a secure manner for no longer than it is necessary and proportionate to comply with this policy, the Agency's records management and archives policy or other requirements applicable under Union law. Access to the information will be granted on a need-to-know basis to staff involved in the handling or follow-up of reports.

In storing and securing such information, EMA will consider the need to protect the confidentiality of the reporting person's identity and, if relevant, of the person concerned, and of other information contained in the report and related information.

A data protection notice providing further details about the processing of personal data is published in EMA's website.

When EMA receives a request for access to documents under Regulation (EC) No 1049/2001⁷, it will refuse access to any personal data of natural persons and any other information from which their identity could be deduced directly or indirectly, when access would undermine the privacy and the integrity of the natural persons, account taken of Union legislation on the protection of personal data and the protection of the identity intended under this Policy for the effective reporting and handling of reports of breaches and the prevention of potential retaliation against the reporting person.

⁵ See EMA's website (<https://www.ema.europa.eu/en/about-us/how-we-work/handling-competing-interests>)

4.3. Publication of information on reports

EMA publishes annually information on reports only in an aggregated form, including statistical information of the number and status of reported cases. This information will not in any case reveal confidential information of any reported case or any information from which the identity of reporting persons could be deduced directly or indirectly.

5. Related documents

[Regulation No 31 \(EEC\), 11 \(EAEC\), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community](#)

[Regulation \(EC\) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents](#)

[Regulation \(EU, Euratom\) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office \(OLAF\) and repealing Regulation \(EC\) No 1073/1999 of the European Parliament and of the Council and Council Regulation \(Euratom\) No 1074/1999](#)

[Council Regulation \(EU\) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office \('the EPPO'\)](#)

[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 \(Text with EEA relevance.\)](#)

[Directive \(EU\) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law](#)

[Privacy Statement for handling allegations of breaches in the area of the EMA's responsibilities reported by external reporting persons](#) [European Medicines Agency guidelines on whistleblowing](#)

[European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts \(Policy 0044\).](#)

[European Medicines Agency policy on the handling of competing interests of Management Board members \(Policy 0058\).](#)

[European Medicines Agency records management and archives policy \(Policy 0026\)](#)

[European Medicines Agency anti-fraud strategy](#)

6. Changes since last revision

The policy has been adapted to more closely align with Directive (EU) 2019/1937. The scope to reporting persons as defined in the Directive was tightened, competence analysis and onward transmission (including consent and redaction logic) were clarified, the policy principles were consolidated into an operational flow, personal data/record-keeping rules were elevated, and the publication of annual aggregated statistics was codified. Editorial updates included standardised terminology and structure.

Amsterdam,

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