EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Executive Director

EMA's handling of information from external reporting persons about alleged breaches related to the authorisation, supervision and maintenance of human and veterinary medicinal products or other EMA activities

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1. Introduction and purpose

The European Medicines Agency's (hereinafter referred to as EMA) main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicinal products for human and veterinary use. EMA provides the Member States and the institutions of the European Union (EU) with the best-possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human and/or veterinary use referred to it in accordance with the provisions of EU legislation.

EMA is strongly committed to carry out its responsibilities and to adhere to the highest standards of professional and personal integrity, hence the need for a policy outlining EMA's approach to individuals reporting information disclosing allegations of breaches relevant to EMA's competence.

This policy aims to complement the existing policy on whistleblowing applying to EMA staff. This policy, therefore, relates to reports or information from a reporting person (who is not an EMA member of staff) and who is therefore considered as an external reporting person.

Considering that:

- Having a procedure to raise concerns about alleged breaches is relevant for all responsible organisations and serves as a necessary tool to detect them.
- Receiving and considering information provided by a reporting person concerning the authorisation, supervision and maintenance of human and veterinary medicinal products is essential in safeguarding public interest and promoting a culture of public accountability and integrity.
- The most effective way to encourage external reporting persons to report information to EMA is to ensure confidentiality.

This policy takes account of 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[1].

This policy is intended to provide a reporting person with information and to promote their reporting of alleged breaches that may have an impact on the authorisation, supervision and maintenance of medicinal products in the area of EMA competences.

Reports from a reporting person may contain two different types of information. Firstly, they may contain personal data which EMA must protect against any unauthorised disclosure or access, accidental or unlawful destruction or accidental loss, or alteration, and must be appropriately secured according to Regulation (EU) No 2018/1725 on the protection of natural persons with regard to the processing of personal data by Union institutions, bodies, offices and agencies. Secondly, the report may contain allegations of breaches in the area of EMA activities on the authorisation, supervision and maintenance of human and veterinary medicinal products that require further examination. Examples of allegations that may be made include the unreliability of the clinical trial data used to support marketing authorisation applications, manufacturing activities not in line with Good Manufacturing Practices or late reporting/low quality of Individual Case Safety Reports/ in pharmacovigilance report.

The arrangements established by this policy aim to create an environment of trust for a reporting person to report actively to EMA any alleged breaches concerning its activities in relation to the authorisation, supervision and maintenance of human and veterinary medicinal products or other EMA activities. In particular, the policy aims not only to pursue an adequate examination of the reported information and possible consequences arising from it, but also to endeavour that the identity of those

[1] 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, p. 17 ff.

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who report alleged breaches is maintained, in principle, strictly confidential. Therefore, EMA does not disclose this personal data unless the reporting person authorises such disclosure, or where required by judicial authorities. Allegations of breaches, submitted by the reporting person, shall be kept confidential, consistent with EMA's need to conduct an adequate examination and to protect its decision-making process. The information may be transferred to other authorities within the limits set out below (Section 4.6).

Individual persons accused of alleged breaches also have a right to the fair and legitimate processing of their personal data. All personal data shall be managed and processed in accordance with Regulation (EU) No 2018/1725.

2. Scope

This policy covers the handling information received from an external reporting person on alleged breaches on the authorisation, supervision and maintenance of human and veterinary medicinal products or other EMA activities.

EMA has a separate whistle-blowing policy specific to its staff and additional workers. The terms staff and additional worker are defined in section 3 – definitions.[2]

3. Definitions

For the purpose of this Policy, the following definitions apply:

- "Breaches" shall mean acts or omissions that are unlawful or defeat the object of the purpose of the authorisation, supervision and maintenance of human and veterinary medicinal products and which are within the competence of EMA, i.e. any conduct or omission amounting to a violation of any legal provision governing the supervision, evaluation and maintenance of medicinal products for human and/or veterinary use, or any other EMA activities.
- 'Staff" and "Staff members" shall mean EMA temporary agents and contract agents.
- "Additional worker" shall mean national experts on secondment, interims and trainees working at EMA.
- "External reporting" means the oral or written communication of information on breaches to EMA
- "Information on breaches" shall mean information including reasonable suspicions, about actual or potential breaches concerning the authorisation, supervision and maintenance of human and veterinary medicinal products within the competence of EMA, or any other EMA activity.
- "Reporting person" is a natural person who reports to EMA or publicly discloses information on breaches as an external person i.e. not an EMA staff member, and not an additional worker.

4. Policy principles

Any reporting person who becomes aware of any facts pointing to an alleged breach with a potential impact on the authorisation, supervision and maintenance of human and veterinary medicinal products within the competence of EMA or any other EMA activity may, in the public interest, report them to

[2] While the "Decision of the EMA laying down guidelines on whistleblowing" for its staff (EMA/MB/232598/2018) do not strictly speaking apply to seconded national experts, trainees and interim staff, these categories of staff are also encouraged to make use of the arrangements set out. In any event, they can also make use of the internal reporting channels referred to under the EMA Anti-Fraud Strategy's internal reporting form, available on the EMA corporate website.

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EMA. The following mailbox: **reporting@ema.europa.eu** is available for this purpose. However, other channels can be used to provide the information (direct emails to staff, letters, etc.).

EMA encourages that a reporting person shall identify themselves, in order to facilitate subsequent contact with them and more informed examination, as necessary, of the information/material sent.

All reports which also concern the protection of the financial interests of the EU can be addressed directly 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) (see OLAF website on Report fraud | European Anti-Fraud Office (europa.eu), as well as EPPO's website).

EMA expects that the disclosure of the information by a reporting person is made in the public interest, in good faith and on reasonable grounds.

This policy takes account of 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.

4.1. Confidentiality

EMA ensures the confidentiality of information from reporting persons and the protection of personal data, whether this data leads to further examination by EMA/investigation by OLAF/EPPO or not.

EMA shall, at every stage of the procedure, make every effort to ensure that the identity of the reporting person is not disclosed to third parties, and that the information is treated in a confidential manner. EMA is bound to ensure the protection of the identity of the reporting person, except when the latter authorises such disclosure, or where required by judicial authorities. Without prejudice to the public's right of access to the EMA documents as laid down in Regulation (EC) No 1049/2001[3] and the provisions of Regulation (EU) No 2018/1725, the information submitted by a reporting person is kept confidential, consistent with the need to conduct an adequate examination and to protect the decision-making process at EMA[4], as well with the need to protect personal data according to the Regulation (EU) No 2018/1725 on the protection of natural persons with regard to the processing of personal data by Union institutions, bodies, offices and agencies and on the free movement of such data.

4.2. Acknowledgement of receipt

Upon receipt of the information, EMA sends an acknowledgement of receipt (by letter or email) within 7 days in line with Directive (EU) 2019/1937, Article 9.1(b).

4.3. Treatment of the information

EMA ensures that the information received is secured in compliance with Article 33 of Regulation (EU) No. 2018/1725. In particular, the storage of the files pertaining to reported cases of alleged breaches will be protected by access restriction measures.

All persons implicated (i.e. against whom allegations are made) are informed of the allegations made against them. Where there is a substantial risk that such notification would jeopardise the ability to effectively examine the allegations or gather the necessary evidence, notification may be deferred, as long as such a risk exists.

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[3] OJ L 145, 31.5.2001, p. 43
[4] http://www.europarl.europa.eu/register/pdf/r1049_en.pdf

All individuals affected (i.e. witnesses, persons against whom allegations are made and third parties) are provided with a privacy statement, as soon as practicable and in accordance with Articles 14, 15 and 16 of Regulation (EU) No 2018/1725.

4.4. Interaction with the EMA Anti-Fraud Strategy

The EMA Anti-Fraud Strategy complements existing policies and procedures, e.g. the EMA code of conduct, EMA's policy on handling competing interests, and this policy.

EMA will report any instance of suspected fraud to OLAF, which is exclusively competent to investigate such cases, or to EPPO. Where a staff member or additional worker becomes aware of facts regarding other staff members or additional workers' activities related to the authorisation, supervision and maintenance of human and veterinary medicinal products, the EMA guidelines on whistleblowing (EMA/MB/232598/2018) apply in his/her regard.

This policy applies without prejudice to OLAF's competence to carry out investigations, on the basis of Regulation (EU, EURATOM) No 883/2013 and to the Agency's Anti-Fraud Strategy (EMA/128273/2021).

4.5. Analysis of competence

EMA will endeavour that all allegations of breaches regarding medicinal products for public and veterinary health are examined by the competent authority. EMA will seek to work closely with institutional partners such as OLAF or EPPO and other national and international partners, as appropriate. EMA's first step is to establish whether it is competent to examine the alleged breaches. If the EMA is not the competent body section 4.6 below will apply. The process regarding any relevant information received under this policy is set out in the standard procedure "Handling of reporting person information on breaches".

4.6. Transfer of information to other authorities

When EMA establishes it does not have the competence to examine facts and allegations disclosed by a reporting person, it will inform the reporting person, without delay, that the information will be transferred to the relevant authority.

Areas where EMA is not competent to act include allegations concerning (i) a nationally authorised product, (ii) a clinical trial or (iii) for a product manufactured and authorised in countries outside the EU or (iv) a stand-alone medical device (not in combination with a medicinal product).

Accordingly, EMA could establish the need to transfer the relevant information to the competent public authorities. EMA transfers personal data in accordance with Regulation (EU) No 2018/1725.

In addition, allegations of irregularities, as defined in Article 1(2) of Regulation 2988/1995[5], or allegations of criminal law offences affecting the protection of the financial interests of the European Union, as defined in Directive (EU) 2017/1371[6], or the reputation of the Agency will be forwarded without delay to OLAF and/or EPPO. Any reporting person is, of course, free to contact OLAF or the

[5] Article 1(2) of Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests, OJ L 312, 23.12.1995, p. 1: "'Irregularity' shall mean any infringement of a provision of Community law resulting from an act or omission by an economic operator, which has, or would have, the effect of prejudicing the general budget of the Communities or budgets managed by them, either by reducing or losing revenue accruing from own resources collected directly on behalf of the Communities, or by an unjustified item of expenditure".
[6] Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law, OJ L 198, 28.07.2017, p. 29.

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national authorities directly. See Report fraud | European Anti-Fraud Office (europa.eu) (OLAF website), as well as EPPO's website.

4.7. Notification to reporting person

For an alleged breach where EMA is the competent body, it informs the reporting person of the outcome of its examination, once a decision has been taken. Where possible this notification is made within a reasonable timeframe not exceeding 3 months or 6 months in duly justified cases from issuance of the acknowledgement. In cases that require a longer period for review e.g. involving an inspection, EMA will send to the reporting person an interim update pending the final outcome of the examination.

Where EMA is not the competent body, it notifies the reporting person of the transfer of the information reported regarding the alleged breach and to which body the case has been transferred for examination. If this notification could jeopardize enquiries or investigations, it is deferred until it is no longer the case.

4.8. Interaction with the EMA rules on competing interests

Where an allegation concerns the declaration of interests of EMA Scientific Committees' members and experts, it may also have an impact on the trust placed in these experts. Accordingly, the ''European Medicines Agency breach of trust procedure on conflicts of interests for scientific committee members and experts" may become applicable at some point[7]. The conclusions reached by EMA after the examination of the information received from a reporting person may potentially form a basis for the application of the breach of trust procedure.

4.9. Information published

Public statistical information of the number and status of reported cases s published each year in the Annual Activity Report.

4.10. Effective Date and revision

This policy shall be effective on 1 April 2022. It shall be reviewed three years following its adoption.

5. Related documents

- REGULATION (EC) No 726/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 Laying Down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency.
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004R0726-20190330

- 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.)
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1725&from=en

[7] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/04/WC500124976.pdf

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- 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
http://www.europarl.europa.eu/register/pdf/r1049_en.pdf

- 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)
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02013R0883-20210117

- Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office (the EPPO)
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R1939-20210110

- 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 (L305/17); see link.

- EMA guidelines on whistleblowing for its staff (EMA/MB/232598/2018)
https://docs.eudra.org/webtop/drl/objectId/090142b283fd9d

- Policy 0044 EMA Policy on handling of competing interests of scientific committees' members and experts (EMA/MB/89351/2020 Rev. 2)
https://www.ema.europa.eu/documents/other/policy-44-european-medicines-agency-policy-handling-competing-interests-scientific-committees_en-0.pdf

- European Medicines Agency breach of trust procedure on conflicts of interests for scientific committee members and experts (EMA/154320/2012, Rev 2)
https://www.ema.europa.eu/documents/other/european-medicines-agency-breach-trust-procedure-competing-interests-disclosure-confidential_en.pdf

- Policy 0058 Handling of competing interests of Management Board member (EMA/MB/89374/2020)
https://www.ema.europa.eu/documents/other/policy-58-european-medicines-agency-policy-handling-competing-interests-management-board-members_en.pdf

- European Medicines Agency breach of trust procedure on declarations of competing interests for Management Board members (EMA/MB/309079/2012, Rev. 2)
https://www.ema.europa.eu/documents/other/european-medicines-agency-breach-trust-procedure-declarations-competing-interests-management-board_en.pdf

- EMA Anti-Fraud strategy (EMA/128273/2021)
https://www.ema.europa.eu/documents/other/european-medicines-agencys-anti-fraud-strategy-revised-march-2021_en.pdf

- SOP on Handling reporting person information

0129 SOP - Handling external reporting person reports, EMA/641948/2012
https://docs.eudra.org/webtop/drl/objectId/090142b2851c96ac

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6. Changes since last revision

References to data protection legislation have been updated for Regulation (EU) No 1725/2018 on the protection of natural persons with regard to the processing of personal data by Union institutions, bodies, offices and agencies, references to the European Public Prosecutor Office (EPPO) have been added, all references and links in section 5 of the policy have been updated as well as elsewhere in the document together with the address of the Agency. A table of contents has been added. Publication of yearly statistics on the cases reported in the Annual Activity Report has been added.

The Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of person who report breaches of Union law, that was adopted after the original version of this policy came into force, has been taken into account. The definitions and minimum time periods set out in the Directive have been reflected.

[Signature on file]

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