17 March 2017
EMA/283205/2013
Executive Director

EMA's handling of information from external sources disclosing alleged improprieties concerning EMA activities related to the authorisation, supervision and maintenance of human and veterinary medicinal products

Policy/0072
Status: PUBLIC
Effective date: 17 March 2017
Review date: 17 March 2020
Supersedes: N/A

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 medicines 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 all of 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 external sources of information disclosing allegations of improprieties relevant to EMA's competence.

This policy aims to complement the existing policy on whistleblowing applying to EMA staff. It therefore relates to information sent by persons who are not EMA members of staff, but who are external sources.

Considering that:

- Having a procedure to raise concerns about improprieties is relevant for all responsible organisations, and serves as a necessary tool to detect them.
- Receiving and considering information provided by external sources concerning EMA activities on 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

- The most effective way to encourage external individuals to report information to EMA is to ensure confidentiality.

This policy is intended to inform external sources of information and to promote their reporting of improprieties that may have an impact on the authorisation, supervision and maintenance of medicinal products in the area of EMA activities.

Reports from external sources 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. Secondly, they may contain allegations of improprieties 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 that the integrity of the data in the studies used to support market authorisation cannot be relied upon. This data integrity is fundamental to trust and confidence in the authorised medicinal products. Such problems could arise due to poor training, inadequate implementation of procedures and controls or even falsification of data.

The arrangements established by this policy aim to create an environment of trust for external individuals to report actively to EMA improprieties concerning its activities. In particular, the policy aims to endeavour that the identity of those who report improprieties is maintained, in principle, strictly confidential. Therefore, EMA does not disclose this personal data unless the external source authorizes such disclosure, or where required by judicial authorities. Allegations of improprieties, submitted by the external source, 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 (4.6).

Individual persons accused of improprieties 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 (EC) No 45/2001.

2. Scope

This policy covers the handling information received from external sources on improprieties regarding EMA activities on the authorisation, supervision and maintenance of human and veterinary medicinal products.

EMA has a separate whistle-blowing policy specific to its staff irrespective of their position within the Agency.[1]

3. Definitions

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

- "external source" is any external individual, i.e. other than an EMA staff member, who reports facts which point to the existence of improprieties.
- "External individual" shall mean any natural person who is not an EMA staff member.
- "Staff" and "Staff members" shall mean EMA temporary agents and contract agents.

[1] While the "EMA guidelines on whistleblowing" for its staff (EMA/182359/2014) do not strictly speaking apply to seconded national experts, trainees, interim staff, these categories of staff are also encouraged to make use of the arrangements set out in the "EMA guidelines on whistleblowing" for its staff.

- "Additional workers" shall mean national experts on secondment, interims and trainees working at EMA.
- "Information from external source" shall mean any disclosure of relevant information to EMA by an external source as defined above.
- "Relevant information" shall mean information concerning any suspected, presumed or alleged impropriety concerning EMA activities on the authorisation, supervision and maintenance of human and veterinary medicinal products.
- "Improprieties" shall mean irregularities concerning EMA activities on the authorisation, supervision and maintenance of human and veterinary medicinal products, 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.
- ''Fraud'' shall mean an intentional breach of any legal provision concerning the supervision, evaluation and maintenance of medicinal products for human and/or veterinary use with the aim of obtaining a gain. It may include misbehaviour that may not have a direct impact on the financial interests of the EU but only a reputational impact.

4. Policy principles

Any external source who becomes aware of any facts pointing at an impropriety with a potential impact in the area of EMA activities on the authorisation, supervision and maintenance of human and veterinary medicinal products may, in the public interest, report them to EMA. The following mailbox: **reporting@ema.europa.eu** is available for this purpose. However, other channels can also be used to provide the information (direct emails to staff, letters, etc.).

EMA prefers its external sources to identify themselves, in order to facilitate any subsequent examination of the material sent.

All reports which also concern the protection of the financial interests of the EU can be addressed directly to OLAF. See OLAF website on http://ec.europa.eu/anti-fraud/olaf-and-you/report-fraud_en

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

4.1 Confidentiality

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

EMA shall, at every stage of the procedure, make every effort to ensure that the identity of the external source 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 external source, 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[2] and the provisions of Regulation (EC) No 45/2001, the information submitted by an external source is kept confidential, consistent with the need to conduct an adequate examination and to protect the decision-making process at EMA[3], as well with the need to protect personal data according to the Regulation on

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

the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (*Regulation (EC) No 45/2001*).

4.2 Acknowledgement of receipt

Upon receipt of the information, EMA sends an acknowledgement of receipt (by letter or email) within 15 working days.

4.3 Treatment of the information

EMA ensures that the information received is secured in compliance with Article 22 of Regulation (EC) No. 45/2001. In particular, the storage of the files pertaining to reported cases of alleged improprieties will be protected by access restriction measures.
All persons implicated (i.e. against whom allegations are made) are informed in good time 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.

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 11 and 12 of Regulation (EC) No 45/2001.

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.

Where a staff member 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 whistle-blowing (EMA/182359/2014) 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/591051/2014).

4.5 Analysis of competence

EMA will endeavour that all suspicions of problems 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 and other national and international partners, as appropriate. EMA's first step is to establish whether it is competent to examine the allegations. If not, 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 external source information".

4.6 Transfer of information to other authorities

When EMA establishes it does not have the competence to examine facts and allegations disclosed by an external source, it will inform this source, within 15 working days, 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.

Accordingly, EMA could establish the need to transfer the relevant information to the competent public authorities. EMA transfers data in accordance with Regulation (EC) No 45/2001.

In addition, allegations of irregularities, as defined in Article 1(2) of Regulation 2988/1995 or allegations of criminal law offences such as fraud or corruption affecting the Protection of the Financial Interests of the European Union[4] or the reputation of the Agency will be forwarded without delay to OLAF. Any external source is of course free to contact OLAF or the national authorities directly. See http://ec.europa.eu/anti-fraud/olaf-and-you/report-fraud_en (OLAF website).

4.7 Notification to external source

Where EMA is the competent body, it informs the external source of the outcome of its examination, once a decision has been taken.

Where EMA is not the competent body, it notifies the external source of the transfer 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 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 towards 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[5]. The conclusions reached by EMA after the examination of the information received from an external source may potentially form a basis for the application of the breach of trust procedure.

4.9 Effective Date and revision

This policy shall be effective on 17 March 2017. 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.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:en:PDF

- REGULATION (EC) No 45/2001, OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:008:0001:0022:en:PDF

[4] 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".
[5] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/04/WC500124976.pdf

- 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)

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:248:0001:0022:EN:PDF

- EMA guidelines on whistleblowing for its staff (EMA/182359/2014)

https://docs.eudra.org/webtop/drl/objectId/090142b282a6ee63

- Policy 0044 Policy on handling of competing interests of scientific committees' members and experts (EMA/626261/2014)

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/11/WC500216190.pdf

- European Medicines Agency breach of trust procedure on conflicts of interests for scientific committee members and experts
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/04/WC500124976.pdf

- Policy 0058 Handling of competing interests of Management Board member (EMA/MB/715362/2015)

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/11/WC500216192.pdf

- European Medicines Agency breach of trust procedure on declarations of competing interests for Management Board members (EMA/MB/309079/2012)

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/06/WC500129044.pdf

- EMA Anti-Fraud strategy (EMA/591051/2014)

https://docs.eudra.org/webtop/drl/objectId/090142b283102d8b

- SOP on Handling external source information

0129 SOP - Handling external Whistle Blower reports

EMA/641948/2012

https://docs.eudra.org/webtop/drl/objectId/090142b2836193b2

6. Changes since last revision

New Policy

[Signature on file]

Guido Rasi
Executive Director