



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 December 2014
EMA/495411/2014
Administration



Médiateur européen

12 JAN. 2015

Date d'arrivée

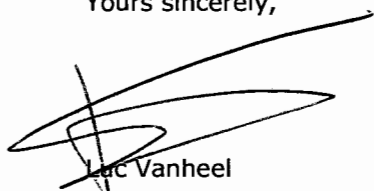
Ms. E. O'Reilly
European Ombudsman
1 avenue du Président Robert Schuman
CS 30403
F-67001 Strasbourg Cedex
France

Subject: Ombudsman's own-initiative inquiry concerning whistleblowing (OI/1/2014/PMC)

Dear Ms O' Reilly

I refer to your letter of 24 July 2014 on this matter that has been copied to this Agency. I can inform you that the EMA has adopted the Commission Guidelines on Whistleblowing SEC(2012) 679 final to apply, by analogy to the staff of this Agency.

Yours sincerely,



Luc Vanheel
Head of Administration





EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

COPY

11 December 2014
EMA/182359/2014
Chief Policy Adviser

EMA guidelines on whistleblowing¹

1. Introduction

1.1. General

Having procedures for raising concerns about fraud, corruption or other serious wrongdoing is relevant for all responsible organisations and for the people who work there. While good internal control systems can reduce the probability of something going seriously wrong, this risk can never be reduced to zero. Where this risk materialises, the first people to realise or suspect the problem will often be those who work in or with the organisation. Yet unless the culture is one where employees believe that it is safe and accepted that such concerns are raised, the risk is that people will stay silent. This silence denies the organisation an important opportunity to detect and investigate the concern, to take any appropriate action and to protect its assets, integrity, and reputation.

The most effective way to encourage staff to report concerns is to provide assurance of protection of their position. Clearly defined channels for internal reporting as well as safe and accepted routes through which staff may raise concerns outside the organisation as an option of last resort should be in place.

Viewed in this way, having whistleblowing procedures and whistleblower protection in place is simply a question of good management and a means of putting into practice the principle of accountability. They contribute to improving the diligence, integrity, and responsibility of an organisation.

It is against this background that rules on whistleblowing were adopted and included in the Staff Regulations (articles 22a and 22b) in 2004. They complement the general principle of loyalty to the European Union, the obligation to assist and tender advice to superiors (Article 21) as well as the rules on how to deal with orders which are considered to be irregular or likely to give rise to serious difficulties (Article 21a).

While these rules have already triggered a number of significant investigations by the European Anti-Fraud Office (OLAF), some staff may be reticent to make full use of the whistleblowing procedure, because of a fear of negative repercussions on their reputation or career. As part of EMA's duty to have regard for the interests of staff ("devoir de sollicitude"), it is necessary to ensure that staff members who report serious wrongdoings or concerns in good faith are afforded the utmost confidentiality and greatest degree of protection against any retaliation as a result of their whistleblowing.

As whistleblowing arrangements are widely recognised as an important tool to detect fraud, corruption and serious irregularities, it is important that staff fully understand the types of situations where the obligation to "blow the whistle" applies, and to whom they should address their concerns. Providing

¹ This EMA guideline reproduces the text of the Communication to the Commission on Guidelines on Whistleblowing SEC(2012) 679 of 6.12.2012 save for technical changes to reflect EMA's organisation.



guidance on this issue is part of EMA's overall ethics policy, which aims *inter alia* at clarifying the rules regarding professional ethics in EMA.

Accordingly, EMA has issued the following guidelines, in agreement with OLAF.

1.2. Basic principles

- EMA staff have a duty to report serious irregularities.
- For this purpose, staff must have a choice between a number of reporting channels for whistleblowing. The principal channel is the normal chain of hierarchical command. If staff consider it to be safer to bypass the normal chain of hierarchical command, they must be able to do so. Under certain conditions, staff may address their concerns to another EU institution as an option of last resort.
- Staff who report serious irregularities in good faith must not under any circumstances be subject to retaliation for whistleblowing. They must be protected and their identity must remain confidential if they so desire.
- The reported facts must be verified in the appropriate manner and, if they are confirmed, EMA will take all necessary steps to ensure the appropriate follow-up.
- The rights of defence of any person implicated by the reported incidents must be respected.
- Malicious or frivolous denunciations will not be tolerated.

1.3. Scope of the policy

EMA's whistleblowing rules and guidelines apply to all staff of EMA, irrespective of their administrative position².

1.4. Definitions

For the purpose of these guidelines, a whistleblower is a staff member, acting in good faith, who reports facts discovered in the course of or in connection with his or her duties which point to the existence of serious irregularities. The reporting should be done in writing and without delay.³

Under the whistleblowing rules, staff are obliged to report serious irregularities. In the present context, serious irregularities are illegal activities, including fraud and corruption, and serious professional wrongdoings. As the whistleblowing arrangements are essentially a detection mechanism to bring cases to the attention of OLAF, the duty to report concerns only serious professional wrongdoings, and particularly those that may be detrimental to the financial interests of the European Union.

Accordingly, not every disclosure of any type of information qualifies as whistleblowing in the sense of these rules. For example, the rules are not intended to apply to the reporting of the following types of information:

- Information already in the public domain (for example: newspaper articles, publicly available audits);
- Unsubstantiated rumours and hearsay;
- Matters of a trivial nature;
- Disagreements over legitimate policy;
- Information not linked to the performance of one's duties.⁴

² While the whistleblowing rules 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 this document. EMA undertakes to protect these categories of staff against retaliation if they do so in good faith.

³ Prior to reporting, a staff member may seek guidance and support as described in section 5 which does not have to be done in writing.

Neither do the rules apply to information for which specific procedures are available to staff:

- Personnel issues where staff have a personal interest in the outcome. In these cases, staff may wish to exercise their statutory rights, for example by lodging a request or complaint with under Article 90 of the Staff Regulations;
- Harassment claims and personal disagreements or conflicts with colleagues or hierarchy. In appropriate cases, staff may wish to address themselves to HR Department or to lodge a request for assistance under Article 24 of the Staff Regulations.

Nor do the rules apply to disclosures that cannot be considered as reasonable or honest, such as:

- Abusive disclosures (repeated disclosures of alleged facts aimed merely at paralysing a service);
- Malicious, frivolous or potentially defamatory disclosures (i.e. false or unverifiable accusations with the aim of harming another person's integrity or reputation).

"Good faith" can be taken to mean the belief in the veracity of the reported facts, i.e. the fact that the member of staff reasonably and honestly believes the transmitted information to be true. Good faith is presumed unless and until proven otherwise.

"Retaliation" is defined as any direct or indirect action or threat of action which is unjustly detrimental to the whistleblower and resulting from the whistleblowing, including, but not limited to, harassment, discrimination, negative appraisals, and acts of vindictiveness.

"Confidentiality of identity" means that the identity of the whistleblower is known to the recipient of the information, but is kept confidential vis-à-vis the person(s) potentially implicated in the serious irregularity reported and used on a strict need-to-know basis.

"Anonymity" refers to the situation whereby the identity of the source of the information is not known to the recipient.

Staff who make a report in bad faith, particularly if it is based knowingly on false or misleading information, shall not be protected and shall normally be subject to disciplinary measures. The burden of proof in this context is on EMA.

2. Reporting procedures

Internal whistleblowing – first option

Staff who, in the course of or in connection with their duties, discover that serious irregularities may have occurred or may be occurring, are obliged to report this discovery forthwith and in writing to either their manager (Head of /Department/Division) or to the Deputy Executive Director or the Executive Director.

Internal whistleblowing – second option

If there is a concern that this disclosure may lead to retaliation or that the intended recipient of the report is personally implicated in the serious irregularities, then the staff member may also bypass this direct means of internal reporting and address his or her report to the Chair of the Management Board or directly to OLAF. OLAF may also be notified through the Fraud Notification System⁵.

In any case, the recipient of the information is in turn obliged to transmit the information thus received without delay to OLAF. Therefore, while the staff member concerned has a choice of reporting channels, the information should ultimately reach OLAF in a short period of time.

External whistleblowing – option of last resort

Upon receipt of the information reported internally, OLAF or EMA must give the whistleblower within 60 days of receipt of the information an indication of the period of time that it considers reasonable and necessary to take appropriate action.

⁴ It is not to say that EMA does not react to this information, but that the rules on whistleblowing do not apply in this case.

⁵ http://ec.europa.eu/anti_fraud/contact_us/index_en.html

If no action is taken within that period of time, or if the whistleblower can demonstrate that the period of time set is unreasonable in light of all the circumstances of the case, he or she may make use of the possibility of external whistleblowing as provided for in Article 22b of the Staff Regulations.

Under this Article, if neither EMA nor OLAF has taken appropriate action within a reasonable period, the staff member who reported the wrongdoing has the right to bring his or her concerns to the attention of the President of either the Commission, the Council, the Parliament or the Court of Auditors, or to the Ombudsman. In this case, the whistleblower protection continues to apply.

However, the duties of discretion and of loyalty imply that this is an option of last resort, justifiable only if the staff member concerned honestly and reasonably believes that the information disclosed, and any allegation contained in it, are substantially true and if he or she has allowed EMA or OLAF a reasonable period of time to take the appropriate action.

While the obligation to report serious wrongdoings applies to staff members of EMA, the Staff Regulations also impose a duty on staff to act with discretion and circumspection.

External disclosure to other EU institutions, which are clearly able to hold EMA to account because of their institutional role, but are also themselves subjected to the duty of discretion, therefore strikes an effective balance between the public interests of confidentiality and loyalty and those of transparency and accountability.

It is up to the staff member to choose the most appropriate channel for reporting the serious irregularities that they must disclose. However, if a matter is reported to a Agency's Department/Division that is not competent to deal with it, it is up to that Department/Division to transmit, in the strictest confidence, the relevant information and documents to the competent unit and to inform the member of staff accordingly.

3. Protection for whistleblowers

Any staff member who reports a serious irregularity, provided that this is done in good faith and in compliance with the provisions of these guidelines, shall be protected against any acts of retaliation. Regarding burden of proof, it shall be up to the person taking any adverse measure against a whistleblower to establish that the measure was motivated by reasons other than the reporting.

It should be noted that staff will not be expected to prove that the wrongdoing is occurring, nor will they lose protection simply because their honest concern turned out to be unfounded.

The protection continues to apply in cases of external disclosures, provided that the staff member honestly and reasonably believes that the information and any allegation in it are substantially true. In this context, account will be taken of any information the staff member has had from EMA and from OLAF following the initial internal reporting.

The following specific protective measures apply:

Confidentiality of identity

The protection of a person reporting a serious irregularity in good faith shall be guaranteed first of all by the fact that their identity will be treated in confidence. This means that their name will not be revealed to the person(s) potentially implicated in the alleged wrongdoings or to any other person without a strict need to know, unless the whistleblower personally authorises the disclosure of his or her identity or it is a requirement in any subsequent criminal law proceedings. In all other cases, EMA is committed to keeping the identity of the whistleblower confidential.

In this respect the Court has ruled that disciplinary procedures that are opened on the basis of information of which the source is not revealed are regular, as long as it does not affect the possibility of the person who is subject to a subsequent disciplinary procedure to comment on the facts or documents transmitted, or on the conclusions that EMA draws from them.⁶ The disciplinary rules of EMA allow it to keep the identity of the whistleblower confidential, while ensuring that the rights of defence of the person concerned are fully respected.

⁶ Judgment of 15 May 1997, N / Commission (T-273/94, RecFP_p_II-289) (cf. point 81) (ECLI:EU:T:1997:71).

Mobility

If the staff member concerned wishes to be moved to another department or division in order to safeguard him- or herself against potential hostile reactions from his or her immediate work environment, then EMA will take reasonable steps to facilitate such a move, compatibly with the resources available at the Agency. In practice, those staff who consider it necessary to move to a different department or division may address themselves to the Head of Administration or to the Executive Director, who will provide them with advice in order to identify the type of post which fits their profile and professional aspirations.

Appraisal and promotion or reclassification

Particular care will be taken during staff appraisal and reclassification procedures to ensure that the whistleblower suffers no adverse consequences in this context. Accordingly, a staff member who has provided information under Article 22a (1) and (2) of the Staff Regulations may, at the time of his or her reasoned refusal to accept the report as provided in the Decision on general provisions implementing Article 43 of the Staff Regulations, request that the Commission member of the Management Board act as appeal assessor.

Anonymity

In order for EMA to be able to apply protective measures, the staff member concerned should identify him- or herself as a whistleblower to the institution, and to observe the procedures as outlined above.

The protection which is offered reduces the need and justification for anonymity. Anonymity deprives the investigative services of the possibility of asking the source for clarification or more information and enhances the risk of frivolous, malicious, or unreliable information.

For these reasons, anonymous reporting is not encouraged.⁷

Penalties for those taking retaliatory action

No staff or managers at EMA may use their position to prevent other staff members from complying with their obligation to report serious irregularities.

Any form of retaliation undertaken by a staff member against any person for reporting a serious irregularity in good faith is prohibited. In such cases, disciplinary measures will normally be taken.

Where staff members consider that they have been the victim of retaliation as a result of the disclosure of a serious irregularity, they shall be entitled to ask for assistance from EMA under Article 24 of the Staff Regulations and to request that protective measures be adopted. Such requests should be addressed to the Executive Director or, in duly justified cases, to the Chair of the Management Board.

Limits

As explained above, the whistleblowing provisions are concerned with disclosure of information pointing to fraud, corruption and other comparable serious wrongdoings. They are not intended to be used as substitutes for grievance procedures where staff have some personal interest in - or seek to dictate - the outcome. They are also inappropriate for dealing with disagreements over legitimate policies. Their purpose is to allow staff to raise concerns about wrongdoings so that those in charge may look into it.

It should be noted that the protection may be lost if the staff member makes unwarranted or damaging allegations that he or she cannot show to be honest or reasonable. The effect of this is that wherever a staff member is contemplating a disclosure in the sense of these guidelines, it is advisable to let the facts speak for themselves.

Similarly, if the staff member makes the disclosure for purposes of private gain - for instance by selling the information to external parties - he or she will forfeit this protection, as that would not be a legitimate disclosure in the sense of the whistleblowing rules.

⁷ As potential whistleblowers may hesitate to come forward with their identity for fear of retaliatory action, the OLAF Fraud Notification System offers the facility to enter into an initially anonymous dialogue with specialised staff before a person decides to come forward and make use of the whistleblowing procedures.

Finally, if the staff member is him- or herself implicated in the serious irregularities and decides to come forward and report these irregularities, this fact may constitute a significant attenuating circumstance in any ensuing disciplinary proceedings, but it is not a qualifying disclosure in the sense of this policy and does not provide him or her with full protection against disciplinary consequences on the basis of the whistleblowing rules.

4. Feedback to the whistleblower

According to Article 22b of the Staff Regulations, OLAF or EMA must give the whistleblower an indication of the time needed to take appropriate action. If no action is taken within that period of time, or if the whistleblower can demonstrate that the period of time set is unreasonable in light of all the circumstances of the case, he or she may address his or her concerns to one of the other institutions referred to above.

It should be noted that the whistleblower is entitled to be informed within 60 days of the time needed to take appropriate action, but that it is up to OLAF and/or EMA to determine the appropriate course of action.

5. Guidance and support

While reporting serious irregularities is an obligation under the Staff Regulations, some staff may be reticent to come forward and report their concerns. In order to help staff who is unsure of whether or not certain facts should be reported, EMA offers confidential and impartial guidance and support to (potential) whistleblowers.

Guidance to potential whistleblowers in an early stage also helps to avoid ill-advised reporting, which may cause frustration to the staff member concerned and may be detrimental to the interests and the reputation of EMA. This guidance therefore lessens the risks of disclosure-related conflicts.

The guidance and support function was until recently offered by the judicial and legal advice unit in OLAF. However, experience suggests that this is best carried out by a point of contact not connected with the investigation function of OLAF, taking account of the fact that, in particular, support to whistleblowers is essentially the responsibility of EMA as employer.

HR and/or Audit will provide confidential and impartial guidance on, for example, whether the information in question is covered by the whistleblowing rules, which reporting channel may best be used for the information concerned, and which alternative procedures are available if the information concerned does not qualify for whistleblowing ('signposting'). They will also be able to tender advice and guidance to staff on protective measures that the staff member may wish to seek following the reporting.

Naturally, this guidance function is without prejudice to the possibility of staff members to consult their line manager, or a specialised service⁸.

In addition, the web-based Fraud Notification System of OLAF gives potential whistleblowers who hesitate to come forward the opportunity to enter into a dialogue with OLAF investigators, which allow these staff members to verify whether the information in their possession fall within the remit of OLAF.

In case of doubt, staff are encouraged to seek the guidance offered to them when contemplating a disclosure under the whistleblowing rules.

⁸ An example is OLAF

6. Role of management

The duty on managers to notify OLAF of information received on the basis of the whistleblowing rules does not of itself discharge them from their own responsibilities to tackle the wrongdoing.

Managers will therefore have to reflect on whether the evidence provided reveals shortcomings that could be redressed or requires other measures, in addition, to the transmission of the information to OLAF. In particular, if following such information, it occurs that a procedural or organisational change could prevent the risk of serious professional wrongdoings in the future; such measures should be considered and, where appropriate, taken as soon as possible. Care should be taken that any such measure does not harm any future OLAF investigation into the reported facts. In case of doubt, managers are therefore advised to consult OLAF before taking any such measures.

7. Communication and awareness-raising

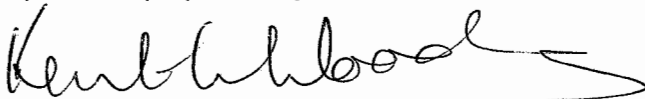
In order to increase the awareness of the whistleblowing arrangements amongst staff, these guidelines will be given adequate publicity through the internal communication channels in EMA and will be included in the course material of EMA's training on ethics and integrity.

8. Revision

The practical application and effectiveness of these whistleblowing guidelines will be evaluated at the end of a period of three years following their adoption. In light of the results of this evaluation, these guidelines may be revised as appropriate.

9. Final provision

These guidelines take effect on 24 November 2014. The decision of 4 January 2006 'Reporting suspected improprieties' (EMA/12699/2006) is hereby repealed.



Sir Kent Woods
Chair EMA Management Board

ANNEX 1: Staff Regulations – Articles on whistleblowing

Article 22a

1. Any staff member who, in the course of or in connection with the performance of his duties, becomes aware of facts which gives rise to a presumption of the existence of possible illegal activity, including fraud or corruption, detrimental to the interests of the Communities, or of conduct relating to the discharge of professional duties which may constitute a serious failure to comply with the obligations of staff members of the Communities shall without delay inform either his immediate superior or his Director-General or, if he considers it useful, the Secretary-General, or the persons in equivalent positions, or the European Anti-Fraud Office (OLAF) direct.

Information mentioned in the first subparagraph shall be given in writing.

This paragraph shall also apply in the event of serious failure to comply with a similar obligation on the part of a Member of an institution or any other person in the service of or carrying out work for an institution.

2. Any staff member receiving the information referred to in paragraph 1 shall without delay transmit to OLAF any evidence of which he is aware from which the existence of the irregularities referred to in paragraph 1 may be presumed.

3. A staff member shall not suffer any prejudicial effects on the part of the institution as a result of having communicated the information referred to in paragraphs 1 and 2, provided that he acted reasonably and honestly.

4. Paragraphs 1 to 3 shall not apply to documents, deeds, reports, notes, or information in any form whatsoever held for the purposes of, or created or disclosed to the staff member in the course of, proceedings in legal cases, whether pending or closed.

Article 22b

1. A staff member who further discloses information as defined in Article 22a to the President of the Commission or of the Court of Auditors or of the Council or of the European Parliament, or to the European Ombudsman, shall not suffer any prejudicial effects on the part of the institution to which he belongs provided that both of the following conditions are met:

(a) the staff member honestly and reasonably believes that the information disclosed, and any allegation contained in it, are substantially true; and

(b) the staff member has previously disclosed the same information to OLAF or to his own institution and has allowed the OLAF or that institution the period of time set by the Office or the institution, given the complexity of the case, to take appropriate action. The staff member shall be duly informed of that period of time within 60 days.

2. The period referred to in paragraph 1 shall not apply where the staff member can demonstrate that it is unreasonable having regard to all the circumstances of the case.

3. Paragraphs 1 and 2 shall not apply to documents, deeds, reports, notes, or information in any form whatsoever held for the purposes of, or created or disclosed to the staff member in the course of, proceedings in legal cases, whether pending or closed.

Article 22c

In accordance with Articles 24 and 90, each institution shall put in place a procedure for the handling of complaints made by officials concerning the way in which they were treated after or in consequence of the fulfilment by them of their obligations under Article 22a or 22b. The institution concerned shall

ensure that such complaints are handled confidentially and, where warranted by the circumstances, before the expiry of the deadlines set out in Article 90.

The appointing authority of each institution shall lay down internal rules on inter alia:

- the provision to officials referred to in Article 22a (1) or Article 22b of information on the handling of the matters reported by them,
- the protection of the legitimate interests of those officials and of their privacy, and
- the procedure for the handling of complaints referred to in the first paragraph of this Article.

ANNEX 2: WHISTLEBLOWING REPORTING CHANNELS IN AGENCY

