EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 November 2014
EMA/591051/2014 *corr.**
Executive Director

Anti-fraud strategy

November 2014

(adopted by the Management Board on the 18th December 2014)

*The date of adoption by the Management Board has been added.

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1. General background

On 24 June 2011, the European Commission adopted its Anti-Fraud Strategy, aiming at improving the prevention and detection of fraud, the conditions for investigation of fraud, and at achieving adequate reparation and deterrence[1]. The European Commission has developed a Common Approach on EU decentralised agencies[2] which requires a set of anti-fraud measures to be put in place, with the declared aim of improving their efficiency, transparency and accountability.

As a decentralised agency of the European Union, the European Medicines Agency (EMA) is "responsible for the management of the operational and administrative resources allocated to [it] to implement EU policies or to contribute to the smooth functioning of the institutions in a cost effective way and reducing administrative burden as far as possible." As for all other agencies, the EMA is "responsible for taking the necessary measures to provide reasonable assurance of achieving prevention and detection of fraud and irregularities."

Taking into consideration the priorities set by the Commission within the framework of the Common Approach on EU decentralised agencies, the need to pursue the Commission's main objectives for its implementation ("more balanced governance, improved efficiency and accountability and greater coherence") and the helpful guidance provided by the European Anti-Fraud Office (OLAF)[3], the European Medicines Agency has now developed its anti-fraud strategy and the related action plan for the years 2015–2016.

The overall objective of this document is to improve prevention, detection and the conditions for investigation of fraud, and to pursue adequate deterrence and reparation, with proportionate and dissuasive sanctions. Moreover, the anti-fraud strategy and action plan are in line with the provisions of Article 69 of Regulation EC No 726/2004 establishing the EMA. This provision calls upon the EMA to combat fraud, corruption and other unlawful activities. This anti-fraud strategy is thus integrated into the broader legal framework setting the tasks of the EMA.

This anti-fraud strategy is part of the Agency's internal controls system and meets the requirements of Article 48 of the Framework Financial Regulations of the European Commission, which refer inter alia to the need for preventing and detecting irregularities[4] and fraud[5]. It is valid for three years and will be updated in the course of its implementation, if necessary, or after its assessment, at the end of the implementation period.

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[1] Communication from the Commission to the European Parliament, the Council, the European and Social Committee, and the Committee of the Regions and the Court of Auditors on the Commission anti-fraud strategy, COM(2011)376 final, 24.6.2011, available here: http://ec.europa.eu/anti_fraud/documents/preventing-fraud-documents/ec_antifraud_strategy_en.pdf

[2] Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralised agencies, available here: http://europa.eu/agencies/documents/joint_statement_and_common_approach_2012_en.pdf

[3] European Anti-Fraud Office, Methodology and guidance for anti-fraud strategies for EU decentralised agencies, Ref. Ares(2013)3560341, 25.11.2013.

[4] Article 1(2) of Regulation No 2988/95 of 18 December 1995 on the protection of the European Communities' financial interests (OJ L 312, 23.12.1995, p.1) defines 'irregularity' as "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] Article 1(1) of the Convention on the protection of the European Communities' financial interests (OJ C 316, 27.11.1995, p.48) defines 'fraud' as "(a) in respect of expenditure, any intentional act or omission relating to: - the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds from the general budget of the European Union or budgets managed by, or on behalf of, the European Union; - non-disclosure of information in violation of a specific obligation, with the same effect; - the misapplication of such funds for purposes other than those for which they were originally granted; (b) in respect of revenue, any intentional act or omission relation to: - the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the illegal diminution of the resources of the general budget of the European Communities or budgets managed by, or on behalf of, the European Communities, - non-disclosure of information in violation of a specific obligation, with the same effect, - misapplication of a legally obtained benefit, with the same effect."

2. The EMA context

The European Medicines Agency is responsible for coordination of the scientific evaluation and supervision of medicinal products for the benefit of public and animal health, in accordance with the provisions of Regulation (EC) No 726/2004, which replaced its founding regulation, Council Regulation (EEC) 2309/93. The EMA coordinates the scientific resources made available by Member States for the evaluation, supervision and pharmacovigilance of medicinal products.

The EMA's Committee for Medicinal Products for Human Use (CHMP) and Committee for Medicinal Products for Veterinary Use (CVMP) carry out a scientific assessment of the applications for marketing authorisations received and give a recommendation to the European Commission on whether or not to grant a marketing authorisation. Once granted by the European Commission, the centralised marketing authorisation is valid in all EU Member States.

The EMA, in close cooperation with national experts, also gives scientific advice on the development of new medicinal products or new therapeutic indications of existing products. In addition, it has important responsibilities for organising and maintaining a number of databases, which are then made available to the EU Commission and Member States, including those concerning the reporting of side effects of drugs (EudraVigilance), manufacturing and import licences (EudraGMDP), and the performance of clinical trials in the European Union (EudraCT).

The Agency is financed by industry fees, which account for over 85% of its yearly budget. Thirty per cent of its budget is disbursed through procurement, while 70% is disbursed for general and administrative expenditures.

The Agency implements its budget in accordance with the principles of sound financial management (Article 317 TFEU) and with the provision of Article 325 TFEU, which stipulates that the EU and the Member States shall counter fraud and any other illegal activities affecting the financial interests of the Union. These articles provide an explicit legal basis for operations by the EU and its bodies and agencies to combat fraud and other unlawful activities. In this light, the Agency is committed to ensuring that the framework, the policies, the rules and the procedures in place enable the effective prevention and detection of fraud.

The main stakeholders of the Agency are the European Commission, the national competent authorities (NCAs), the Member States, the European Parliament, pharmaceutical industry, patients' organisations and academia.

3. Principles

Ethics and transparency are key concerns for the EMA. The Agency is fully committed to ensuring that these principles are properly applied. Our staff, members of committees and all external contractors must pursue the highest standards of honesty, propriety and integrity in the exercise of their duties. This also needs to be visible to our stakeholders.

The Agency will not tolerate fraud, impropriety or dishonesty and will report, without delay, any instance of suspected fraud to OLAF, which is exclusively competent to investigate those cases[6].

[6] See Commission Decision of 28 April 1999 establishing the European Anti-Fraud office (OLAF), OJ No L 136 of 31.5.1999, p.20, available here: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31999D0352&from=EN
The investigations are conducted in accordance with 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, OJ L 248, 18.9.2013, p.1.

The EMA will take all actions and adopt all measures as appropriate, including termination of their employment agreements, against anyone defrauding or attempting to defraud the EMA and/or stakeholders' assets and resources. In all such cases, the EMA will cooperate fully with OLAF and all other EU authorities and institutions.

4. Definition of fraud

For the purposes of this document, the concept of fraud encompasses both internal and external misbehaviour, and relies on the assumption that the reputational impact of a misbehaviour might be equally important to or more important than the financial damage itself.

It covers in particular, but not only, any infringement of the financial interests of the EU as defined by the Convention on the protection of the European Communities' financial interests ('PIF Convention')[7]. It also covers misbehaviour that may not have a direct effect on the EU's financial interests, but has anyhow a reputational impact, such as some cases of forgery (in CVs for example), concealment of material facts, breaches of IT systems, cyber fraud and conflicts of interests that have not been declared intentionally. Favouritism and collusion are also included in the definition of fraud.

5. Fraud risk-assessment

In order to further focus on the risk of fraud, the Agency carried out, with the support of an internationally reputed external consultant, a specific fraud risk-assessment, in the first half of 2014, with the participation of middle and senior management.

The objective of such fraud risk-assessment was to document the key fraud risks, and as a result, a list of prioritised risks was produced. Out of the risks identified, the Executive Director decided to focus on the following four areas of risk:

- Data security/theft.
- Impartiality of assessment.
- Procurement.
- Recruitment.

6. Objectives and actions

The strategic objectives are driven by the Agency's priorities and values. The reputation of the Agency and the public trust in the highest standards of professionalism, ethics and integrity that we follow when issuing our recommendations on the quality, safety and efficacy of medicines is a key driver of our actions. For this reason, the Agency needs to set certain objectives to counter fraud at all levels of the organisation and thus reinforce the public trust in our activities.

These objectives aim at encompassing all stages of the anti-fraud cycle: prevention, detection, investigation, recovery and sanction.

Since its inception, the Agency has already successfully developed a number of procedures and policies designed to mitigate identified risks, including major fraud risks, namely:

- a code of conduct;

[7] Council Act of 26 July 1995 drawing up the Convention for the protection of the European Communities' financial interests, OJ No C 316 of 27.11.95, p.48.

- a declaration of interests (DoIs) policy for experts, Management Board and staff;
- a transparency policy, whereby CVs and DoIs are published to enable public scrutiny;
- breach-of-trust policies for Management Board members and experts;
- recruitment procedures, audits, ex ante and ex post controls;
- a whistleblowing policy for staff and procedures for reporting improprieties;
- annual risk assessments;
- annual reviews of sensitive functions;
- other control and supervision mechanisms.

In addition to the mitigating controls already in place, detailed actions will be needed in 2015/2016 to fulfil the objectives described in this strategy.

In order to address the four major risks identified in the preceding section, the following strategic objectives were agreed and endorsed by the Executive Director:

1. Develop an anti-fraud culture underpinned by high levels of awareness, integrity, impartiality and transparency within the organisation.
2. Develop fraud prevention, detection, reporting, monitoring and handling capacity.
3. Improve prevention and detection of favouritism in recruitment and procurement procedures.
4. Focus effort on fraud risk-mitigation in identified areas of the organisation.

Objective 1

Develop an anti-fraud culture underpinned by high levels of awareness, integrity, impartiality and transparency within the organisation

In the Agency's view, fraud deterrence is facilitated by a widespread common understanding and sharing of the ethical values and relevant rules underlining any activity of the Agency.

This objective is inspired by the need to constantly communicate the rules and ethical values of the EU public service from the highest level to each member of staff.

Increasing the employees' education in this regard is of paramount importance to the successful implementation of this anti-fraud strategy. Employees need to gain awareness not only of the detailed specific rules, but also of the general high-level principles and objectives for guidance and motivation. It is crucial that each member of staff knows how to exercise judgement and recognises which principles should be applied in concrete situations.

The aim of promoting these values is to reach a level of awareness whereby the EMA's staff should be guided by a sense of propriety and conduct at all times in a manner that can bear the closest public scrutiny.

Actions to reach objective 1[8]

- Organise initial survey on anti-fraud knowledge.
- Plan regular communication to staff.

[8] For detailed actions, please refer to the Annex: Action plan.

- Design compulsory in-house training.
- Set up a regular anti-fraud survey.

Objective 2

Develop fraud prevention, detection, reporting and handling capacity

This objective aims at providing effective systems and guidance in tackling improprieties and reinforcing fraud prevention across the organisation, and their consistent application. The purpose of having those systems and controls in-house is to tighten potential gaps in managing financial and operational processes, and to empower staff members to handle improprieties. The Agency will also cooperate with, and learn from the experience of, other organisations, such as OLAF, the European Commission and other agencies in countering internal and/or external fraud, with a view to enhancing its established controls.

Actions to reach objective 2[9]

- Develop internal anti-fraud processes.
- Carry out annual, fraud-specific risk-assessments.
- Plan audits based on the current risk-assessment.
- Adopt a whistleblowing policy for external stakeholders.
- Establish an Anti-Fraud Office.
- Review access rights to DREAM.

Objective 3

Improve prevention and detection of favouritism in recruitment and procurement procedures

This objective aims at ensuring that only the best candidates (in staff recruitment procedures) and contractors (in procurement procedures) will be selected to work for the Agency. Recommendations and decisions in procedures involving comparative evaluations should be based only on merit, in the name of the objectivity and impartiality that the Agency applies in performing its mission.

This objective is of paramount importance in the light of the other objectives mentioned. It is argued that only staff selected based solely on merit could ensure the level of commitment to the Agency that is essential to meet objectives 1 and 2. Staff members play a key role in implementing and fostering a 'zero tolerance' culture towards fraud and corruption.

Actions to reach objective 3[10]

- insert anti-fraud clauses in standard contracts agreements;
- review the selection and procurement procedures;

[9] For detailed actions, please refer to the Annex: Action plan.
[10] For detailed actions, please refer to the Annex: Action plan.

Objective 4

Focus effort on reducing residual risk level in certain areas of the organisation

This objective aims at substantiating the remaining level of risks after the current mitigating measures have been applied. The Agency would like to focus its effort on these areas to ensure the levels of risks were correctly assessed and then strengthen prevention measures where the risks scores turned out higher.

Action to reach objective 4[11]

- assess the associated systems of internal controls;

7. Roles and responsibility

The risk of fraud cannot be dealt with in isolation. Addressing and mitigating the risk of fraud properly is a key aspect of sound management. Whilst it is essential that all EMA staff members should have a clear understanding of the Agency's anti-fraud strategy, some individuals and groups have specific leadership roles or responsibilities and these are identified below.

7.1. The Management Board

The Management Board is responsible for the adoption of this anti-fraud strategy.

7.2. Executive Director

The Executive Director, with his 'tone from the top', promotes anti-fraud culture across the Agency, sets anti-fraud objectives and puts in place effective arrangements for combating fraud.

7.3. Heads of Division

Heads of Division are responsible for promoting the anti-fraud culture within their Divisions, checking staff awareness and ensuring that all suspected or reported cases of potential fraud are immediately reported to the Anti-Fraud Office, cooperating with all other functions involved in the implementation of the anti-fraud strategy.

7.4. All managers

The primary responsibility – 'first line controls' - for the prevention and detection of fraud rests with managers throughout the organisation. They have the responsibility to manage the risk of fraud and will be supported and trained so that this task is fulfilled effectively.

7.5. Anti-Fraud Office

The Anti-Fraud Office, within the Legal Department, is responsible for identifying and preventing the risks of breach of legal provisions and ethical behaviour rules which may entail liabilities or reputational loss for the Agency. The Anti-Fraud Office coordinates the implementation of the anti-fraud strategy, follows up actions, reports to the ED and acts as a contact point for OLAF for the Strategy-related issues;

[11] For detailed actions, please refer to the Annex: Action plan.

It provides guidance on managing fraud risk and design of additional controls, it develops training materials for all staff, in close collaboration with competent experts within and outside the Agency.

7.6. Corporate Governance

The Corporate Governance will coordinate the annual anti-fraud risk assessment and regularly follow up the implementation of agreed actions to further mitigate significant risks on regular basis.

7.7. Head of Administration

The Head of Administration is responsible for ensuring that financial systems incorporate strong measures to reduce the risk of fraud and detect potential fraud cases at an early stage.

7.8. Head of Audit

The Head of Audit is responsible to perform regular risk-based audits or ad-hoc checks and consider the effectiveness of the anti-fraud arrangements.

7.9. Head of Human Resources

The Head of Human Resources contributes to promoting staff awareness about the anti-fraud principles and Strategy; it applies sanctions commensurate to the breach by the relevant staff member, as decided by the Executive Director in accordance with the reports and recommendations drawn up following the OLAF investigation[12].

7.10. Staff members

All staff members comply with the Agency's Anti-Fraud principles and Strategy; forward any reasonable concerns with regard to fraud to their reporting officer and/or senior management, in accordance with the existing guidelines, for example, on internal whistleblowing.

7.11. Delegates/experts, partners, suppliers, contractors and consultants

All delegates/experts, partners, suppliers, contractors and consultants comply with the Agency's Anti-Fraud principles and Strategy.

8. Review and monitoring

The Anti-Fraud Office will ensure it that the Agency's approach to managing the risk of fraud is kept up to date with developments, in best practice, and legislative requirements. The anti-fraud strategy will be reviewed every 3 years.

The implementation of the Agency's anti-fraud strategy, policy and procedures will be subject to periodic review on the basis of an evaluation of the impact of the Strategy, measured using the key performance indicators developed, among which:

1. Number of files sent to OLAF for investigation.

[12] See article 11 of Regulation No 883/2013, in particular par. 4: "Reports and recommendations drawn up following an internal investigation and any relevant related document shall be sent to the institution, body, office or agency concerned. That institution, body, office, or agency shall take such action, in particular of a disciplinary or legal nature, as the results of the internal investigation warrant, and shall report thereon to the Office, within a time-limit laid down in the recommendations accompanying the report, and, in addition, at the request of the Office".

2. Number of contracts subject to close monitoring due to an assessment of high risk of fraud.
3. Time elapsed between OLAF requests for information and date when information is provided to OLAF.
4. Time elapsed between receipt of an OLAF report and the decision on disciplinary sanctions by the Agency.

9. Annex

Action plan for the years 2015–2016

Action	Responsible	Due date
Plan regular communication to staff by the top management on anti-fraud ethical matters	Legal Department (Anti-Fraud Office) in cooperation with Corporate Governance, HR and AF-Audit	15.2.2015
Perform an initial in-house survey benchmarking the ethical and professional knowledge among staff	Legal Department (Anti-Fraud Office) in cooperation with Corporate Governance and HR	28.2.2015
Organise a compulsory in-house training covering general ethical and professional integrity principles, the scope of 'fraud' and fraud prevention and detection.	Legal Department (Anti-Fraud Office) in cooperation with HR	23.12.2015
Perform regular survey on anti-fraud and ethics knowledge with all staff and organise further trainings according to the results	Legal Department (Anti-Fraud Office) in cooperation with HR	30.3.2016, then ongoing
Develop internal processes on how to report and tackle alleged fraud instances.	Legal Department (Anti-Fraud Office)	30.6.2015
Carry out annual, fraud specific risk assessment and update the list of measures taking into account fraud trends in the EU context; in this framework, a fraud library will be created.	Corporate Governance in cooperation with Anti-Fraud Office	30.9.2015
In the development of the audit strategy, identify fraud-specific risks and plan audits or ad-hoc audit engagement performed at strategic and operational level. On the basis of the current risk assessment develop an audit plan addressing data security fraud.	Audit	31.10.2015
Extend Agency draft whistleblowing policy for external stakeholders, to include areas outside of the specific scope of the pharmaceutical legislation.	CPA to draft EEB to adopt	31.3.2015
Establish an Anti-Fraud Office.	DED	1.1.2015
Review access rights to DREAM and data bases for all users to optimise access to documented software	CPA policy IT Operations	30.6.2016
Insert anti-fraud clauses (suspension of payments, damages, etc.) in standard contracts agreements used for procurements, purchases, etc. and develop a complaint procedure for procurement.	Legal Department (Anti-Fraud Office)	28.2.2015
Assess if selection and procurement procedures demonstrate sufficient fraud resistance and address the gaps identified in the process.	Legal Department (Anti-Fraud Office) in cooperation with HR	31.3.2016
Assess the adequacy and effectiveness of the associated systems of internal controls; where control needs have been identified, design and implement additional controls and tools.	Legal Department (Anti-Fraud Office) & Corporate Governance	Ongoing