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Executive Director

Anti-Fraud Strategy

Revised December 2017

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1. General background

1.1. The EMA context

The European Medicines Agency (EMA) 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[1], 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 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.

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 European 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).

Finally, EMA has gained additional responsibilities under the new legislation on medical devices (Regulation (EU) No 2017/745 on medical devices[2], applicable from 26 May 2020, and Regulation (EU) 2017/746 on in vitro diagnostic medical devices[3], applicable from 26 May 2022). In particular, EMA will have some consultation tasks (i.e. on medical devices incorporating ancillary substances; on a subset of the devices that are composed of substances or combinations of substances intended to be introduced into the human body or applied on skin; on borderline products; on companion diagnostics). This new legislation also introduces changes to the application for marketing authorisation concerning medical devices components that are an integral part of a medicinal product.

The Agency is financed primarily by industry fees, which accounted for nearly 85% in 2016 and more than 90% in 2017. 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.

[1] 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, OJ L 136, 30.04.2004, p.1.
[2] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 05.05.2017, p.1.
[3] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, 05.05.2017, p.176.

1.2. The adoption of EMA's Anti-Fraud Strategy

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[4]. The European Commission has developed a Common Approach on EU decentralised agencies[5] 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 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, 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 European Commission within the framework of the Common Approach on EU decentralised agencies, the need to pursue the European 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)[6], in December 2014 the European Medicines Agency approved its Anti-Fraud Strategy and the related action plan for the years 2015–2016[7]. In December 2016 the Management Board approved four additional actions for 2017.

The overall objective of EMA's Anti-Fraud Strategy adopted in 2014 was 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 were in line with the provisions of Article 69 of Regulation (EC) No 726/2004 establishing the Agency. This provision calls upon EMA to combat fraud, corruption and other unlawful activities. The Anti-Fraud Strategy is thus integrated into the broader legal framework setting the tasks of EMA. The Anti-Fraud Strategy is part of the Agency's internal controls system[8] and meets the requirements of Article 32 of the Framework Financial Regulations of the European Commission[9], which refer *inter alia* to the need for preventing and detecting irregularities[10] and fraud[11].

[4] 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 at: http://ec.europa.eu/anti_fraud/documents/preventing-fraud-documents/ec_antifraud_strategy_en.pdf

[5] Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralised agencies, available at: https://europa.eu/european-union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf

[6] European Anti-Fraud Office, Methodology and guidance for anti-fraud strategies for EU decentralised agencies, Ref. Ares(2013)3560341, 25.11.2013, as well as the last update of the same Methodology dated 23.02.2016, ref. Ares(2016)931345.

[7] Doc. ref. EMA/591051/2014, adopted on 18.12.2014, published on the EMA's public website at: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/12/WC500179569.pdf

[8] See the document "Internal Control Standards and Underlying Frameworks. Strengthening Control Effectiveness", adopted by the Management Board on 20.04.2016, doc. ref. EMA/MB/602884/2015.

[9] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002, OJ L 298, 26.10.2012, p. 1.

[10] 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."

[11] 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

The updated OLAF's Methodology and guidance for anti-fraud strategies for EU decentralised agencies points out that "the anti-fraud strategy is part of risk management, but given the importance and complexity of the issue, fraud should be addressed in a dedicated, comprehensive process, which runs on top of the annual risk management exercise, though closely interlinked with it"[12]. Therefore, despite it being part of the internal control system, the EMA Anti-Fraud Strategy must be deemed as a separate, additional tool to further strengthen the internal control systems.

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;
- a declaration of interests (DoIs) policy for committees' members, experts, Management Board's members and staff members;
- a transparency policy, whereby CVs and DoIs are published to enable public scrutiny;
- breach-of-trust policies for Management Board members and experts;
- a comprehensive auditing system, whereby the Agency is subject to annual audits by four independent audit teams: European Court of Auditors, external auditors auditing the Agency's annual accounts, internal audit service of the European Commission, and the internal audit capability of the Agency;
- ex ante and ex post controls, other controls and supervision mechanisms;
- a whistleblowing policy for staff and procedures for reporting improprieties;
- a policy on handling of information from external sources disclosing alleged improprieties concerning EMA's activities;
- annual risk assessments, including a fraud risk assessment;
- annual reviews of sensitive functions;

2. Guiding principles of EMA's Anti-Fraud Strategy

Ethics, integrity and transparency are key drivers of EMA's actions. EMA's staff, members of EMA's committees and working groups, scientific experts, members of the Management Board and all external contractors must pursue the highest standards of honesty and integrity in the exercise of their duties.

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 these cases[13].

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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."

[12] European Anti-Fraud Office, Methodology and guidance for anti-fraud strategies for EU decentralised agencies, Ref. Ares(2016)931345, dated 23.02.2016, p. 5.

[13] 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 at 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.

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

3. The implementation of EMA's Anti-Fraud Strategy (2014-2017) and its revision

According to the action plan annexed to the Anti-Fraud Strategy approved in 2014, twelve actions were to be performed during the years 2014-2016 and in December 2016 four additional actions were approved by the Management Board for the year 2017. An additional action about assessing the adequacy and effectiveness of the controls in place and designing and implementing additional controls has been performed on an annual basis.

All the actions have been fully implemented within the assigned deadlines. The Agency intends to maintain a fraud-proof environment for the fulfilment of EMA's strategic objectives as laid down in its Multiannual Work Programme to 2020[14] and in the EU Medicines Agencies Network Strategy to 2020[15]. The Anti-Fraud Office established within the Legal Department in February 2015 as one of the actions of the action plan for 2015-2017 ensured that the Agency's approach to managing the risk of fraud kept the pace with anti-fraud related developments, best practices, and legislative requirements.

The actions scheduled for 2015 were mainly focused on fraud prevention and on setting the fraud-proof environment within the Agency. This was pursued mainly through raising anti-fraud awareness among staff, for example through direct messages to staff from EMA's top management and the implementation of a bespoke compulsory anti-fraud e-learning training course. EMA also devoted significant efforts to the development of instruments for fraud detection, for example through the elaboration of internal reporting procedures and whistleblowing policies.

A key feature of the Agency's approach to anti-fraud matters is the close and proactive cooperation with the European Anti-Fraud Office (OLAF), which is mandated by law[16] to carry out internal investigations into the EU Agencies. The cooperation and information exchange with the Office is enshrined both in Regulation (EU, Euratom) No 883/2013 and in the Decision of the European Medicines Agency of 1 June 1999 concerning the terms and conditions for internal investigations in relation to the prevention of fraud, corruption and any illegal activity detrimental to the Community's interests[17]. Over the last three years the Agency has spontaneously reported to OLAF ten suspected fraud behaviours, out of which two were investigated by OLAF and eventually closed with no findings of fraud. In eight instances OLAF decided to dismiss the case during the preliminary selection phase. Two more investigations were opened by OLAF *ex officio*, out of which one was finally dismissed and the other was concluded without any charge for EMA staff members. No EMA employees were found to have breached the rules. Furthermore, close interaction with OLAF is also foreseen by the EMA Policy 0072 on the handling of information from external sources disclosing alleged improprieties concerning the Agency's activities related to the authorisation, supervision and maintenance of human and veterinary medicinal products[18]. EMA's Anti-Fraud Strategy is expressly mentioned as complementing

[14] Multiannual work programme to 2020, adopted on 23.06.2016, doc. ref. EMA/319713/2016.
[15] EU Medicines Agencies Network Strategy to 2020, adopted by the Management Board on 17.12.2015, doc. ref. EMA/MB/151414/2015.
[16] 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), OJ L 248, 18.09.2013, p. 1.
[17] Adopted by the Management Board on 01.06.1999, doc. ref. EMEA/D/15007/99/EN.
[18] Adopted on 17.03.2017, doc. ref. EMA/283205/2013.

such Policy, without prejudice to OLAF's competence to carry out investigations where necessary or requested by EMA.

In addition to the cooperation with OLAF, the Agency has also exchanged best practices with the other EU Agencies on anti-fraud matters, for example through the Anti-Fraud Working Group within the Inter Agency Legal Network, whose aim is to enhance harmonised and standardised approaches to anti-fraud strategies among the EU decentralised Agencies. The establishment of this working group has been praised by the Committee on Budgetary Control of the European Parliament in March 2017[19]. This is a public recognition of the right direction of travel taken by the Agency.

The European Commission is also in the process of updating its Anti-Fraud Strategy, the adoption of which was qualified as "major initiative" within the meaning of the Better Regulation Guidelines[20] and is foreseen for Q1 2018. EMA will monitor with interest the progress by the European Commission in this area.

According to paragraph 8 of the EMA Anti-Fraud Strategy ("*Review and monitoring*"), the latter and related action plan was valid for three years, after which they shall be reviewed and updated. This revision takes into account the lessons learnt in the course of the implementation of the Anti-Fraud Strategy over the past three years, the latest fraud trends, the developments in the legislative framework and guidance received from the European Anti-Fraud Office[21] as well as the Agency's new needs with regard to fraud-related matters which have emerged from the annual fraud risk assessments.

With the current revision of the Anti-Fraud Strategy, the Agency wishes to continue raising awareness with regard to fraud matters among staff members and contractors, facilitating detection of possible fraudulent behaviours and acting rapidly in close cooperation with OLAF. The Executive Director has now set the new objectives for the further 3-year period, together with an updated action plan.

As in the previous action plan, the actions planned to reach the revised objectives for the years 2018-2020 are linked to key performance indicators and will be implemented by a set due date.

4. Definition of fraud for the purposes of EMA's Anti-Fraud Strategy

In December 2014 it was decided that for the purposes of the Anti-Fraud Strategy, the concept of fraud encompasses both internal and external misbehaviour (i.e. misbehaviour committed by staff members or persons anyhow linked to the Agency or by external parties) and relies on the assumption that the reputational impact of a misbehaviour might be equally important to, or even 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')[22]. 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

[19] Committee on Budgetary Control, European Parliament, "Report on discharge in respect of the implementation of the budget of the European Union agencies for the financial year 2015: performance, financial management and control", dated 31.03.2017, doc. ref. 2016/2206(DEC), page 11, point 46, available at the address http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A8-2017-0149+0+DOC+PDF+V0//EN

[20] Commission Staff Working Document, "Better Regulation Guidelines", 07.07.2017, doc. ref. SWD (2017) 350.

[21] European Anti-Fraud Office, Methodology and guidance for anti-fraud strategies for EU decentralised agencies, Ref. Ares(2016)931345, dated 23.02.2016.

[22] 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.

material facts, breaches of IT systems, cyber fraud, transmission of confidential information and conflicts of interests that have not been declared intentionally. Favouritism and collusion are also included in the definition of fraud for the purposes of this Anti-Fraud Strategy.

The Agency deems appropriate to maintain this wide definition of fraud for the purpose of the application of this document. This wide definition is shared with the other EU Agencies and serves the purpose of preventing and detecting the highest possible number of illegal behaviours and keeping high the attention of staff members also on instances likely to create a reputational damage. In addition, EMA staff members will have to face a further sharp increase in workload and are likely to be subject to professional and personal challenges due to the Agency's relocation to Amsterdam in 2019, decided by the General Affairs Council of Ministers on the 20th of November 2017. In this challenging framework, the implementation of this revised Anti-Fraud Strategy and related action plan may be of help to further sustain the image of EMA as an example of fraud-free environment.

5. Fraud risk-assessment

In order to further focus on the risk of fraud and in line with the OLAF's Guidance and Methodology, every year the Agency carried out a specific fraud risk-assessment with the participation of middle and senior management.

The objective of such fraud risk-assessment was to document the key fraud risks. As a result, a list of prioritised risks was presented to EMA Executive Director to enable him define the objectives for the next three years.

The Executive Director decided to focus on the following areas of risk:

- Data security/theft
- Conflicts of interest
- Whistleblowing and overall strengthening of fraud detection measures

6. Objectives and actions

The strategic objectives of the Anti-Fraud Strategy 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 EMA follows when issuing 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 its activities.

These objectives aim at encompassing all stages of the anti-fraud cycle: prevention, detection, investigation, recovery and sanction. Whilst prevention should remain one of the most important objectives of the revised Anti-Fraud Strategy, it is deemed appropriate to focus the efforts also on detection, in particular by encouraging internal reporting of any possible case of fraud as well as proactive random verifications in some areas.

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

1. Maintain and enhance an anti-fraud culture underpinned by high levels of awareness, integrity, impartiality and transparency within the organisation (also among non-staff members).

2. Maintain an efficient system for internal reporting of suspected fraud or irregularities.
3. Strengthen measures for detection of suspicious behaviours and deterrence.
4. Focus efforts on fraud risk-mitigation in identified areas of the organisation.

Objective 1

Maintain and enhance an anti-fraud culture underpinned by high levels of awareness, integrity, impartiality and transparency within the organisation (also among non-staff members)

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.

The development of a compulsory anti-fraud e-learning training course for all staff members served the purpose of promoting the values of ethics and integrity amongst staff members. Also through the tailor-made presentations delivered by the Anti-Fraud Office to the different Agency's Divisions, staff members were guided to understand how to exercise judgement and to recognise which principles should be applied in concrete situations. The anti-fraud training course will be updated in 2018, also in light of the most recent OLAF trends and indications.

Actions to reach objective 1[23]

- Maintain the regular communication to staff on anti-fraud related matters.
- Update the compulsory anti-fraud e-learning training course.
- Develop a specific training instrument for the contractors working at/with the Agency.

Objective 2

Maintain an efficient system for internal reporting of suspected fraud or irregularities

This objective aims at providing effective guidance in tackling improprieties and reinforcing fraud prevention across the organisation. The purpose of having these controls in-house is to tighten potential gaps in managing financial and operational processes, and to help staff members report improprieties without any fear of a retaliation. To the extent feasible due to the need to protect OLAF's investigations and the personal data of the individuals concerned, communication on past and on-going handling of reported suspicions of fraud will be enhanced.

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.

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

Actions to reach objective 2[24]

- Improve the staff's awareness of internal reporting and whistleblowing procedures.
- Create a register for internal whistleblowing and, to the extent feasible, share anonymised cases with the generality of staff members.
- Make the anti-fraud tools (e.g. reporting template, regularly updated table with past fraud cases, etc.) more visible on the intranet.

Objective 3

Strengthen measures for detection of suspicious behaviours and deterrence

This objective aims at ensuring that suspicious behaviours are promptly detected and reported via the available reporting channels. This allows the Agency to liaise with OLAF if need be. Some cases dismissed by OLAF can nevertheless be the object of administrative enquiries or give rise to organisational measures aimed at improving the quality of output and preventing similar concerns from arising in the future.

Actions to reach objective 3[25]

- Administrative enquiries where required or appropriate.
- Perform proactive random verifications in co-operation with the relevant Head of Division.
- Perform an impact assessment of possible revisions of EMA's Policies on Conflict of interests, also in order to deter and detect improper behaviours.

Objective 4

Focus effort on fraud-risk mitigation in identified 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[26].

The regular fraud risk assessments would also allow identifying additional actions which might be required or desirable.

[24] For the detailed actions, please refer to the Annex: Action plan.
[25] For the detailed actions, please refer to the Annex: Action plan.
[26] For example, audits are planned in 2018 on a) the risks of possible disclosure of commercially confidential information to unintended recipients; b) compliance with data protection in contracts with external service providers.

Actions to reach objective 4[27]

- Carry out annual, fraud-specific risk assessments.
- Plan audits based on the current risk assessment, also in light of the additional operational concerns stemming from the Agency's relocation in 2019 to a new host Member State.
- Implementing the EMA's Document Classification Policy[28] and adopt other technical measures as appropriate to enhance data security.
- Continuous monitoring of the effectiveness of the measures in place.

7. Roles and responsibilities

The risk of fraud cannot be dealt with in isolation. Addressing and mitigating properly the risk of fraud 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 and of its action plan, some individuals and Agency's entities 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, including through the use of ex ante and ex post controls where required.

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 established 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 and the follow-up actions, reports regularly to the Executive Director on such

[27] For the detailed actions, please refer to the Annex: Action plan.
[28] Policy 0081 'Document Classification Policy', adopted on 14.12.2016, doc. ref. EMA/174602/2016.

implementation and acts as a contact point for OLAF for the strategy-related issues and for all fraud-related issues.

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

7.6. Quality and Risk Management Office

The Quality and Risk Management Office will coordinate the annual anti-fraud risk assessment and will regularly follow up on the implementation of agreed actions to further mitigate significant risks.

7.7. Head of Finance Department

The Head of Finance Department 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 *ad hoc* audits and consider the effectiveness of the anti-fraud arrangements.

7.9. Head of Staff Relations and Support Department

The Head of Staff Relations and Support Department 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 by OLAF following an OLAF investigation[29].

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.

[29] 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".

8. Review and monitoring

The Anti-Fraud Office will ensure that the Agency's approach to managing the risk of fraud is kept up to date with developments in best practices and with legislative requirements. The Anti-Fraud Strategy and its action plan 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 some key performance indicators, among which for example the number of cases notified to OLAF, the number of notified cases dismissed by OLAF, the number of internal reporting about suspicious behaviours received.

9. Annex

Action plan for the years 2018–2020

Action	Responsible	Due date
Create a register for internal whistleblowing and, to the extent feasible, share anonymised cases with the generality of staff members	Anti-Fraud Office and Staff Relations and Support Department	30.06.2018
Make the anti-fraud tools more visible on the intranet	Anti-Fraud Office in cooperation with Internal Corporate Relations Office	30.07.2018
Update the compulsory anti-fraud e-learning training course	Anti-Fraud Office	30.09.2018
Implementing the EMA's Document Classification Policy on the classification of information and adopt other technical measures as appropriate to enhance data security	Information Security in cooperation with Anti-Fraud Office	31.12.2018
Perform an impact assessment of possible revisions of EMA's Policies on Conflict of interest	Deputy Executive Director	30.09.2018
Develop a specific training instrument for the contractors working at/with the Agency	Anti-Fraud Office	31.12.2018
Improve the staff's awareness of internal reporting and whistleblowing procedures	Anti-Fraud Office in cooperation with Staff Relations and Support Department	31.12.2018
Perform proactive random verifications	Head of Divisions in cooperation with Anti-Fraud Office and Information Security	31.12.2019
Carry out annual, fraud-specific risk assessments	Quality & Risk Management Office in cooperation with Anti-Fraud Office	Permanent action, by 31.12 each year
Plan audits based on the current risk assessment, also in light of the additional operational concerns stemming from the Agency's relocation	Audit	By the finalisation of the yearly audit plan
Administrative enquiries where required or appropriate	Enquirers to be nominated on *ad hoc* basis by the Executive Director	As needed
Maintain the regular communication to staff on anti-fraud related matters	Anti-Fraud Office in cooperation with Internal Corporate Relations Office	Permanent action
Additional actions possibly needed based on the continuous monitoring of ethical behaviours	Anti-Fraud Office in concertation with the Executive Director	Permanent action
Assess the adequacy and effectiveness of the associated systems of internal controls; where control needs have been identified, design and implement additional controls	Quality & Risk Management in cooperation with Anti-Fraud Office	Permanent action

Action	Responsible	Due date
and tools.		