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Anti-Fraud Strategy

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Abbreviations

AF-LD	EMA's Legal Department
AFS	Anti-Fraud Strategy
AO	Authorising Officer
CAAR	Consolidated Annual Activity Report
CAFS	(European) Commission's Anti-Fraud Strategy
CoI	Conflict of Interests
EMA	European Medicines Agency (also, the "Agency")
EPPO	European Public Prosecutor's Office
FRA	Fraud Risk Assessment
GAF	General Affairs and Anti-Fraud Office within the Legal Department (AF-LD)
IALN	Inter-Agency Legal Network
IAS	Internal Audit Service
NCA	National Competent Authority
OLAF	European Anti-Fraud Office (in French, Office Européen de Lutte Antifraude)
PIF Directive	Directive (EU) 2017/1371 on the fight against fraud to the Union's financial interests by means of criminal law
SO	Strategic Objective
SPD	Single Programming Document
TFEU	Treaty on the Functioning of the European Union

1. Introduction

The Union and the Member States shall counter fraud and any other illegal activities affecting the financial interests of the Union through measures to be taken in accordance with this Article, which shall act as a deterrent and be such as to afford effective protection in the Member States, and in all the Union's institutions, bodies, offices and agencies.[1]

The Treaty on the Functioning of the European Union (TFEU) sets the frame to fight fraud and other illegal activities in the EU administration. As an agency of the EU, the European Medicines Agency is bound by this mandate and, among other things, has adopted several Anti-Fraud Strategies since 2014 and implemented a panoply of measures as part, inter alia, of its internal control framework.

Fraud that affects the EU budget reduces the impact of EU action and undermines the public trust in EU policies. It is thus in the public interest to adopt effective measures countering the risks of fraud by means of prevention, detection and correction activities.

This revised version of the Anti-Fraud Strategy 2021 builds upon the achievements since the adoption of the first Anti-Fraud Strategy. It has been drafted following the new Methodology and guidance for the drafting of Anti-Fraud Strategies in EU decentralised agencies and joint undertakings published by OLAF in May 2024.

2. The need to revise the Anti-Fraud Strategy

The European Medicines Agency (hereinafter, the EMA or the Agency) adopted the latest revision of its Anti-Fraud Strategy (the AFS) in December 2021. The implementation of its Action Plan is largely complete; moreover, several important developments have taken place since, notably legislative initiatives that have led to new tasks and responsibilities for the Agency (see section 3.1).

In 2023 the European Commission revised its Anti-Fraud Strategy (CAFS) Action Plan.[2] The revision was dictated by the need to better protect the EU's budget from the new challenges and realities facing the EU. Among the new priorities, the Commission envisages an increased use of IT tools to prevent, detect and investigate fraud, and the strengthening of the EU Anti-Fraud architecture and its Anti-Fraud and ethics culture. OLAF oversaw the process leading to the revised Action Plan, and it identified the most common and significant fraud risks affecting the EU's financial interests, notably:

- falsification of declarations and documents in procurement, grants and administrative expenditure;
- double funding;
- conflicts of interests (CoI), corruption, favouritism or collusion;
- misuse of insider information;
- plagiarism;
- undue influence;
- unreliable counterparts;
- undue access to IT devices, systems, bank accounts and hacking.

[1] Article 325 of the Treaty on the Functioning of the European Union.
[2] See here: https://anti-fraud.ec.europa.eu/document/download/7cff3f2b-192a-44a0-be7d-ee58c08ba8fc_en?filename=cafs-action-plan-2023-rev_en_0.pdf

2.1. The Agency's legal framework for the fight against fraud

The Agency implements its budget in accordance with the principle of sound financial management[3] and in accordance with Article 325 TFEU. The Agency is committed to ensuring that its policies, rules and procedures enable the effective prevention and detection of fraud.

The budget of the Agency is established and implemented as per the financial rules adopted by the Management Board (the EMA's Financial Rules)[4] which require that, as part of the Single Programming Document (SPD), the Agency adopts an AFS as well as an indication of measures to prevent recurrence of cases of CoI, irregularities and fraud.[5]

The implementation of the Agency's budget is done in compliance with effective and efficient internal controls,[6] which are applied at all levels of management and are designed to provide reasonable assurance of achieving, inter alia, the prevention, detection, correction and follow-up of fraud and irregularities.[7] Without prejudice to the responsibilities of the authorising officer (AO) as regards prevention and detection of fraud and irregularities, the Agency is equally required to participate in fraud prevention activities of the European Anti-Fraud Office (OLAF).[8]

The Agency must have effective internal controls supporting, among other things, the avoidance of CoI.[9] Situations involving a CoI, including those that 'may objectively be perceived' as such, must be prevented and addressed.[10] Accordingly, a CoI exists where the impartial and objective exercise of the functions of a financial actor or other person is compromised for reasons involving family, emotional life, political or national affinity, economic interest or any other direct or indirect personal interest. When Agency staff is concerned, the application of this provision is without prejudice to the application of the rules on CoI as laid down in the Staff Regulations.[11]

In case of procurement and grants, the relevant provisions on professional conflicting interests must be duly applied.[12]

The AO is required to put in place the organisational structure and the internal control systems suited to the performance of her duties[13], and may establish within her departments an expertise and advice function to support the control of risks involved in his or her activities.[14]

The EMA's Financial Rules and the Staff Regulations lay down the obligation of staff to inform to their immediate superior, the Executive Director, the Management Board, OLAF or the European Public Prosecutor's Office (EPPO) directly of any illegal activity, fraud or corruption which may harm the interests of the Union.[15]

The Agency is required to accede to the Interinstitutional Agreement of 25 May 1999 concerning internal investigations by OLAF and to issue the appropriate provisions applicable to all the employees

[3] Article 317 of the TFEU.
[4] The Financial Rules applicable to the budget of the European Medicines Agency from 23 September 2024 (EMA/34384/2025) (the EMA's Financial Rules).
[5] Article 32.1(h) of the EMA's Financial Rules.
[6] Article 30.1 of the EMA's Financial Rules.
[7] Article 30.2 of the EMA's Financial Rules.
[8] Article 39.2 of the EMA's Financial Rules.
[9] Articles 30.3(c) and 42 of the EMA's Financial Rules.
[10] Article 42 of the EMA's Financial Rules.
[11] Regulation No 31 (EEC), 11 (EAEC), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community. OJ P 045 14.6.1962, p. 1385.
[12] See Titles VII and VIII of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (recast). OJ L, 2024/2509.
[13] Article 45.2 of the EMA's Financial Rules.
[14] Ibid.
[15] Article 45.12 of the EMA's Financial Rules.

of the Agency.[16] In terms of investigations, Regulation (EC) No 1073/1999 applies without restriction to the Agency, which has a duty to transmit to OLAF without delay any information relating to possible cases of fraud, corruption or any other illegal activity affecting the financial interests of the Union.[17] The Agency has also the obligation to inform the Commission without delay on cases of presumed fraud and other financial irregularities, as well as of completed or ongoing investigations by OLAF or the EPPO, and of any audits or controls by the Court of Auditors or the Internal Audit Service (IAS), without endangering the confidentiality of the investigations.[18] Equally, the Agency must report to the EPPO any criminal conduct in respect of which the EPPO could exercise its competence.[19]

Regulation No 883/2013 and Council Regulation No 2185/96[20] give the power to OLAF to carry out investigations including on-the-spot checks and inspections with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union.[21]

The Agency, further to its Decision on general implementing provisions on the conduct of administrative inquiries and disciplinary proceedings, may carry out administrative inquiries in cases of possible breaches of statutory obligations, after having consulted OLAF.[22]

2.2. Definitions and scope

The EU's legal framework defining fraud and related criminal offences is complex and has evolved considerably in recent years.

Fraud generally refers to any intentional act or omission designed to deceive others, resulting in the victim suffering a loss and the perpetrator achieving a gain. Article 3 of Directive (EU) 2017/1371 on the fight against fraud to the Union's financial interests by means of criminal law (the PIF Directive) lists the activities that are considered fraud for the purposes of the Directive. [23]

Intention is the key element that distinguishes fraud from other irregularities as regards EU funds and financial interests. For the purposes of this AFS, the term fraud is understood in a broad sense, encompassing various types of criminal and non-criminal wrongdoing, notably:

- Fraud, corruption and misappropriation affecting the EU's financial interests, as defined in Articles 3 and 4 of the PIF Directive;
- Other criminal offences affecting the Union's financial interests, e.g., offences linked to an abuse of procurement procedures where they affect the EU budget;
- Irregularities as defined in Article 1(2) of Regulation (EC, Euratom) No 2988/95 (insofar as they are intentional but not already captured by the criminal offences referred to above)[24];

[16] Article 69 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency. OJ L 136, 30.4.2004, p. 1.
[17] Article 8(1) of 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. 1–22.
[18] Article 86 of the EMA's Financial Rules.
[19] Article 24.1 of Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office ('the EPPO'). OJ L 283, 31.10.2017, p. 1–71.
[20] Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities. OJ L 292, 15.11.1996, p. 2–5.
[21] See also Article 108 of the EMA's Financial Rules.
[22] European Medicines Agency decision laying down general implementing provisions on the conduct of administrative inquiries and disciplinary proceedings (EMA/MB/169781/2022) of 17 June 2022.
[23] Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law. OJ L 198, 28/07/2017, p. 29–41
[24] 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. 1–4

- Any other illegal activity affecting the financial interests of the EU; and
- Serious breaches of professional obligations by staff of the Agency or members of the Management Board of the Agency, as referred to in Article 1(4) of Regulation No 883/2013 and in the second subparagraph of Article 2(1) of Commission Decision (EC, ECSC, Euratom) No 352/1999[25].

3. The EMA's specific context

The Agency is responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products for human and veterinary use. It provides the Member States and EU institutions with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use in accordance with the provisions of applicable EU legislation.

The Agency and its scientific committees evaluate applications for marketing authorisations; facilitate the development of new medicinal products through provision of scientific advice as well as access to medicines; monitor the safety of medicines across their life cycle and provide reliable information on human and veterinary medicines to patients and healthcare professionals. The Agency provides scientific support to the timely development of high-quality, safe and effective medicines during public health emergencies. Furthermore, it develops best practices for medicines evaluation and supervision in the EU and contributes, alongside the Member States and the European Commission, to the harmonisation of regulatory standards at the international level.

With a view to facilitating dialogue on issues of common interest, the Agency engages with a large number of representatives of patients, healthcare professionals, industry and other stakeholders.

The Agency is equally responsible for organising and maintaining a number of databases, which are made available to the European Commission and Member States, e.g., on the reporting of side effects of drugs (EudraVigilance), manufacturing and import licences (EudraGMDP), and the performance of clinical trials in the European Union (EudraCT).

In the performance of its tasks and mission, the Agency is guided by its commitment to public and animal health, making independent recommendations based on scientific evidence, using state-of-the-art knowledge and expertise in its field. It supports research and innovation to stimulate development of better medicines and seek to support European competitiveness.

The Agency charges fees to pharmaceutical companies for scientific evaluation procedures and services. These fees account for around 90% of the Agency's budget. As of 2025, the new Fee Regulation has changed the level of fees and charges as well as NCA remuneration.

The Agency's fee-funded workload grows every year due to the increasing number of authorised Centrally Authorised Products (hence, more fee-funded post-authorisation monitoring and maintenance activities) and new or expanding activities. On average, each newly authorised product generates 27 subsequent post-authorisation applications, and numerous associated activities in other areas.

In accordance with the Final Programming Document for the period 2025-2027, the total revenue from fees in 2025 is forecasted at €549.3 million, an increase of €114.6 million (26.4%) over the estimated result for 2024. In 2026, the total revenue from fees is expected to reach €557.7 million.[26] Furthermore,

[25] 1999/352/EC, ECSC, Euratom: Commission Decision of 28 April 1999 establishing the European Anti-fraud Office (OLAF) (notified under document number SEC(1999) 802). OJ L 136, 31.5.1999, p. 20–22
[26] See here: https://www.ema.europa.eu/en/about-us/annual-reports-work-programmes

for 2025 the EU/EEA contribution is set at €48.9 million, and in 2026, the Agency may receive an additional contribution linked to the reform of the EU pharmaceutical legislation. This is the provisional revenue expected for the period 2025-2027:

Budget forecast	**2025**	**2026**	**2027**
EU contribution	€ 48,914,000	€ 50,373,000	€ 51,395,000
Other revenue	€ 551,316,000	€ 559,401,000	€ 570,589,000
Total revenue	€ 600,230,000	€ 609,774,000	€ 621,984,000

For expenditure, the Final Programming Document foresees the following for the same period:

	2025	**2026**	**2027**
Title 1 - Staff expenditure	€ 183,127,000	€ 188,367,000	€ 192,134,000
Title 2 - Infrastructure and operating expenditure	€ 92,067,000	€ 91,255,000	€ 93,088,000
Title 3 - Operational expenditure	€ 325,036,000	€ 330,152,000	€ 336,051,000
Total expenditure	€ 600,230,000	€ 609,774,000	€ 621,265,000

In Title 1, the payment of staff salaries represents, in the draft budget 2025, 84,71% of the total expenditure, whereas external services represents another 11,34%. In Title 2, expenses related to corporate information and communication technology represents 52,78% of the total expenditure, and investment in immovable property, renting of buildings and associated costs, another 35,43%. The evaluation of medicinal products amounts to 76% of the total expenditure under Title 3, with expenditure on business related IT projects another 12% and scientific studies and services a total of 8,74%.

As regards human resources, it is envisaged that the Agency will grow from 952 staff members in 2025, including TAs, CAs and Seconded National Experts, to 984 in 2026 and 992 in 2027.

3.1. Changes to the Agency's mandate since 2021

Since the revision of the AFS 2021, the landscape in which the Agency operates has changed slightly, with new legislative initiatives having an impact on its tasks and responsibilities. This revised AFS will thus operate under such an expanded reality. Below is an overview of those changes:

- Regulation (EU) 2022/123 reinforcing EMA's role in crisis preparedness and management of medicinal products and medical devices became applicable in March 2022.[27] The Regulation has created new structures and processes while entrusting several new tasks to the Agency, e.g., the monitoring of medicine shortages that might lead to a crisis situation, the reporting of shortages of critical medicines during a crisis, and coordinating responses to shortages of critical medical devices and in-vitro diagnostics in crisis situations.
- The new Veterinary Medicinal Products Regulation has updated the rules on the authorisation and use of veterinary medicines in the EU.[28] It simplifies the regulatory environment and

[27] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. OJ L 20, 31.1.2022, p. 1–37.
[28] Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human

reduces the administrative burden for pharmaceutical companies developing veterinary medicines.

- In January 2025, a new Regulation on health technology assessment became applicable.[29] The Agency will be required to support the timely conduct of joint clinical assessments by the HTA Coordination Group, and both will collaborate in the context of joint scientific consultations, and the identification of emerging health technologies.
- The new Fee Regulation, applicable since January 2025,[30] aligns fees and national competent authorities' (NCA) remuneration with actual underlying costs to carry out the activities while respecting fee incentives set in existing policies; it also aligns with the provisions of the new Veterinary Medicinal Products Regulation while also reflecting the latest revision of the Agency's founding Regulation, notably the introduction of charges as a possible source of revenue. Further, it provides a single framework for a streamlined fee system of the Agency by harmonising practices of the previous framework. The Regulation simplifies the fee system and introduces a mechanism for adjusting fee levels as well as maintaining the option for new fees and remuneration for future regulatory or administrative initiatives.

On 26 April 2023, the Commission presented a draft legal proposal for the revision of the Pharmaceutical Legislation. The proposal includes several significant changes to the authorisation framework, as well as a set of potential new tasks for the Agency.

Other initiatives will equally have an impact on the Agency, e.g., the Cybersecurity Regulation that includes measures for a high common level of cybersecurity in the EU administration[31]; the European Health Data Space (EHDS) Regulation, which will establish a common framework for the use and exchange of electronic health data across the EU; the Artificial Intelligence (AI) Act that will be fully applicable on 2 August 2026[32]; and Regulation (EU) 2024/1938 on standards of quality and safety for substances of human origin intended for human application (SoHO)[33].

4. The revised Anti-Fraud Strategy 2021

The Agency adopted its first AFS in 2014 and updated it in 2018 and 2021. The strategic objectives (SO) included in previous AFS have evolved as the Agency increased its Anti-Fraud capabilities by means of stronger internal controls, targeted instruments and an increased level of staff awareness.

The development, maintenance and enhancement of an Anti-Fraud culture has featured as a SO in all AFS since 2014. This reflects the importance that the Agency attaches to training and awareness-

and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use. OJ L 4, 7.1.2019, p. 24–42.

[29] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU. OJ L 458, 22.12.2021, p. 1–32.

[30] Regulation (EU) 2024/568 of the European Parliament and of the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95. OJ L, 2024/568, 14.2.2024.

[31] Regulation (EU, Euratom) 2023/2841 of the European Parliament and of the Council of 13 December 2023 laying down measures for a high common level of cybersecurity at the institutions, bodies, offices and agencies of the Union. OJ L, 2023/2841, 18.12.2023.

[32] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act). OJ L, 2024/1689, 12.7.2024.

[33] Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC. OJ L, 2024/1938, 17.7.2024

raising activities as one of the most effective measures to prevent and detect fraud. The strengthening of measures to detect suspicious behaviours has equally been among the Agency's top priorities, considering the evolving landscape of fraud, the growing scope of activities of the organisation, and the ongoing technological advancements.

4.1. Results of the revised Anti-Fraud Strategy 2021

The revised AFS 2021 contained three SO, namely:

- SO1: 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).
- SO2: Strengthen measures for detection of suspicious behaviours, including through maintaining an efficient system for internal reporting and handling of suspected irregularities.
- SO3: Implement all actions necessary for fraud risk mitigation, also identified through internal and external audits.

Under SO1, regular communication, training and awareness-raising activities have been organised. Notably, the intranet has been revamped to offer more information on the AFS and links to relevant policies and resources available to staff. The compulsory Anti-Fraud e-learning training course was updated in 2021. In 2024 an online version of that course and on ethics was designed, discontinuing the in-class format. In addition, refresher trainings on ethical principles and rules, and other training on specific topics e.g., prevention of harassment were organised. It is worth noting that the European Parliament praised the robustness of the system in place based on a very high staff awareness of the risks involved and the maturity of the internal controls to manage potential conflicts of interest.[34]

Under SO2, several sessions on internal reporting and whistleblowing procedures were organised in 2021 and 2023. A specific section on wrongdoing prevention and measures was published and updated in the intranet. A joint action between the Information Security Office (ISO) and the Information Management (IM) Division took place in 2021 to raise awareness among staff and equip them with practical tools to identify and prevent cybersecurity fraud or circumvention of the EMA's Security Policy. Furthermore, a revised Information Security Strategy 2022-2027 (ISS) and an implementation plan were adopted in 2022; although not formally part of the AFS, it contributes largely to its goals, as one of its four strategic objectives is to enhance security culture and behaviour within the Agency. The ISS was welcomed by the European Parliament in its discharge of the Agency's 2022 budget.[35]

Finally, under SO3, a stand-alone fraud risk assessment was conducted in 2022, revealing five fraud risks as carrying a high residual risk; the results are presented below. Fraud-related risks are assessed annually during each audit engagement performed by the Agency. No significant fraud-related risks were identified in the latest internal audits. In July 2024, the Agency's Internal Audit Function completed a targeted independent review of Anti-Fraud activities which led to a few observations that have been considered in the present revised AFS.

[34] European Parliament decision of 11 April 2024 on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2022 (2023/2156(DEC))
https://www.europarl.europa.eu/doceo/document/A-9-2024-0133_EN.html#_section3
See also the *European Parliament decision of 10 May 2023 on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2021 (2022/2109(DEC))* on recognising the Agency's existing measures and ongoing efforts to secure transparency, to prevent and manage conflicts of interest, and to provide whistleblower protection *https://www.europarl.europa.eu/doceo/document/TA-9-2023-0155_EN.html#title3*

[35] European Parliament decision of 11 April 2024 on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2022 (2023/2156(DEC))

4.2. Fraud Risk Assessment

The Agency conducted a standalone fraud risk assessment (FRA) in 2022 including a total of 45 new and existing fraud risks. Both inherent and residual risk were evaluated.

Each fraud risk was scored in terms of likelihood and impact in a scale of 1-6, with the highest score being 36 points. Above 18 points, a risk was deemed high. The scale of impact took into account not only financial impact but also the impact on the organisation's strategy or operational activities, the level of stakeholder concern, reputational damage, impact on staff and impact on human or animal health.

A total of four fraud risks were assessed as carrying a high residual risk, notably:

- data security, both
    - intentional leak of confidential information to external parties by internal employees; and
    - intentional access of sensitive and/or confidential data or their intentional removal from EMA network for personal gain through a cyber-attack.

  In both cases, the materialisation of the fraud risks could lead to exposure, for example, of critical data and thus reputational damage for the Agency as well as risk of litigation.
- CoI of experts from competent authorities participating in scientific assessment work at national level (not included in the EMA Experts database). Should this fraud risk occur, the integrity of scientific procedures and the quality of expert opinions could suffer as a result. Furthermore, the realisation of this fraud risk could lead to an increased risk of litigation, with the additional consequence that regulatory procedures could be declared invalid on procedural grounds. This fraud risk could also lead to reputational damage for the Agency.
- regulatory fraud (i.e., incorrect scientific opinions caused by data fraud by applicants or a third-party supplying data). In the event that this fraud risk materialises, one of the consequences could be, for example, the invalidity of the scientific assessment performed by the Agency and thus of the decision on the authorisation of the medicinal product. Equally, the reputation of the Agency could suffer as a result.

Following the FRA, data security and CoI were included in the corporate risk list endorsed by the Executive Director in 2023 as potentially impacting the Agency's activities and achievement of its objectives.

In addition to the 2022 FRA, a risk exercise was carried out in June-July 2024 to update the Agency's risk register by interviewing the Agency's heads of entities. A total of 13 risks were included in the final list, among them, CoI management and unintended disclosure of sensitive information.

5. The revised Anti-Fraud Strategy 2025

Considering the results of the 2021 AFS, the FRA conducted in 2022, and the new tasks and responsibilities of the Agency, this new revision of the AFS will set new SO to continue addressing all stages of the Anti-Fraud cycle: prevention, detection, investigation and correction.

5.1. Guiding principles of the EMA Anti-Fraud Strategy

Ethics, integrity and transparency are key drivers of the Agency's actions in performing its mission. Staff, members and experts of scientific committees and working groups, Management Board members and external contractors must adhere to the highest standards of ethics and integrity in the exercise of their duties.

Fraud has the potential to jeopardize the Agency's value statements, which must be preserved in the performance of its public health mission.[36] The Agency does not tolerate fraud, impropriety or dishonesty and will report, without delay, any instance of suspected fraud to OLAF, with whom the Agency will cooperate as well as with other EU authorities and institutions. Further to OLAF's recommendations, the Agency will take all actions and adopt all measures as appropriate, against anyone defrauding or attempting to defraud it and/or other EU assets and resources, or otherwise damaging its reputation.

The CAFS sets out the following guiding principles for the fight against fraud. These principles are applicable, mutatis mutandis, to agencies:[37]

- Zero tolerance for fraud;
- Fight against fraud as an integral part of internal controls;
- Cost-effectiveness of controls;
- Professional integrity and competence of EU staff;
- Transparency on how EU funds are used;
- Fraud prevention, notably fraud-proofing of spending programmes;
- Effective detection capacity and timely exchange of information with investigative bodies such as OLAF or prosecutorial bodies such as the EPPO;
- Swift correction (including recovery of defrauded funds and judicial or administrative sanctions);
- Good cooperation between internal and external players, in particular between the EU and national authorities responsible, and among the departments of all EU institutions and bodies concerned;
- Effective internal and external communication on the fight against fraud.

5.2. Roles and Responsibilities

The risks of fraud cannot be dealt with in isolation. Addressing and mitigating them is a key aspect of sound Anti-Fraud management. Thus, whilst it is essential that all staff have a clear understanding of the AFS and Action Plan, some individuals and Agency's entities have specific leadership roles or responsibilities, and these are identified below.

In addition to the internal roles and responsibilities, both OLAF and the EPPO play equally a major role.

- **The Management Board**

The Management Board adopts the Anti-Fraud Strategy and its Action Plan.

[36] The current five value statements were introduced in October 2022
[37] See section 2.1 of OLAF's Methodology and guidance for the drafting of Anti-Fraud Strategies in EU Decentralised Agencies and Joint Undertakings, May 2024.

➢ Executive Director

The Executive Director promotes an Anti-Fraud culture across the Agency by setting a tone-from-the-top approach to integrity and Anti-Fraud. The Executive Director is responsible for the organisational structure and the internal control systems suited to the performance of her duties, establishing an expertise and advice function to support the control of risks involved in the Agency's activities.

➢ Heads of Division and Heads of Task Force

The Heads of Division and Task Force support the promotion of an Anti-Fraud culture within their Divisions and Task Forces, ensuring staff awareness and that all suspected or reported cases of potential fraud are immediately reported via the established channels. They cooperate with all other functions involved in the implementation of the AFS, including the use of ex-ante and ex-post controls where required.

➢ All managers

As 'first line controls', managers have the primary responsibility for the prevention and detection of fraud throughout the organisation. They manage the risks of fraud and should be supported and trained to fulfil effectively this task. They coordinate Fraud Risk Assessments at their management level by identifying and assessing fraud risks and implementing and monitoring measures to mitigate relevant fraud risks.

➢ General Affairs and Anti-Fraud Office

The General Affairs and Anti-Fraud Office (GAF) within the Legal Department (AF-LD) 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. It coordinates the implementation of the AFS and follow-up actions, reports regularly to the Executive Director and acts as a contact point for OLAF and EPPO for both strategy and fraud-related issues. GAF provides guidance on managing fraud risk and design of additional controls and, in collaboration with experts and entities within and outside the Agency, it develops training materials for all staff.

➢ Quality and Risk Management Office

The Quality and Risk Management service (A-SG-QRM) contributes to the coordination of Fraud Risk Assessment (FRA) exercises alongside GAF and managers and supports the follow-up of the implementation of agreed actions to mitigate fraud risks.

➢ Head of Finance Department

The Head of Finance Department (A-FI) ensures that financial systems incorporate effective measures to reduce the risks of fraud and detect potential fraud cases at an early stage.

➢ Head of Audit

The Head of Audit (AF-AUD) performs regular risk-based *ad hoc* audits and consider the effectiveness of Anti-Fraud arrangements within the Agency.

➢ Head of Staff Relations and Support Department

The Head of Staff Relations and Support Department (A-ST) contributes to promoting staff awareness on Anti-Fraud and integrity matters. The Head of A-ST ensures the effective implementation of sanctions

and other measures to staff members commensurate to the breach caused, as decided by the Executive Director in accordance with OLAF reports and recommendations following an investigation.[38]

- **Staff members**

All staff members must comply with the Agency's Anti-Fraud principles and strategy. They must report any reasonable concerns about fraud or other irregularities in accordance with established procedures.

- **Members/experts, partners, suppliers, contractors and consultants**

All members and experts of scientific committees and other bodies, partners, suppliers, contractors and consultants comply with the Agency's Anti-Fraud principles and strategy and, with their actions, support the Agency in mitigating fraud risk.

5.3. Strategic Objectives

This revised AFS has considered the results of the Anti-Fraud activities carried out so far in the Agency. As well as continuing with regular activities and controls that already contribute to the fight against fraud, it includes three new strategic objectives (SO), proportionate to the risks faced by the Agency, that aim at stepping up the overall Anti-Fraud efforts.

Strategic Objective 1: Reinforce internal and external awareness on Anti-Fraud matters by continuing promoting an Anti-Fraud culture

Since the adoption of the first AFS, training and awareness-raising have featured as core components of every revised AFS.

Staff and other external parties and stakeholders with adequate knowledge and information about what constitutes fraud, and the consequences of fraudulent acts on the organisation and the public trust, should not only be conducive to increasing the level of prevention, but also the actual detection capabilities of such fraudulent and illegal activities. OLAF found, in the process of revising the CAFS Action Plan, that one of the most useful measures of the previous Action Plan was training and awareness raising on fraud-related matters.

Suspicions of fraud are situations that most of staff will rarely face during their careers. That is why it is necessary to continue offering training and awareness-raising opportunities on the risks of fraud and the need to stay vigilant. Further, as organisations and technological means become more complex, the shape that fraud takes can also change, thus requiring that knowledge and information on fraud keeps pace with it.

The Agency will continue organising these activities while also making available information and communication materials to staff as well as to members and experts involved in its activities, and other stakeholders, in particular, although not only, from an integrity and transparency angle.

To measure the effectiveness of the activities implemented, a survey for staff will be conducted both at the start and end of the AFS seeking their views about their knowledge on Anti-Fraud matters and the impact of the activities conducted.

[38] See article 11 of Regulation No 883/2013, in particular paragraph 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*".

With this SO and the activities envisaged in the Action Plan, a large number of fraud risks as identified in the FRA 2022 should be tackled by generally reducing the level of residual risk.

Strategic Objective 2: Increase the Agency's fraud detection capabilities and mitigation of fraud risks

Under SO2, the Agency aims to increase its detection capabilities by means of developing further its fraud risk assessment (FRA) toolkit. A new, robust methodology will be adopted for the performance of FRA going forward. The new methodology should improve the way that FRA are conducted and, as a result, lead to obtaining better information on fraud risks within the organisation and thus, a greater ability to identify and treat them.

A general FRA will be performed during this AFS. It will consider the Agency's new tasks and the changes brought about by the new pieces of legislation extending the powers and tasks of the Agency; to the extent possible, it will also consider the new pharma legislation if it has been adopted and becomes applicable. The FRA will be complemented, where necessary, with ad-hoc and targeted FRAs in specific areas to obtain more information on the effectiveness of mitigating controls and the evolution of fraud risks in those areas. Lastly, the results of a final FRA focusing on the most relevant fraud risks will inform the revision of the AFS.

The policy on whistleblowing by external sources is due for review in 2025. The Agency will update it considering Directive (EU) 2019/1937 on the protection of persons who report breaches of Union law.

The setting up of a *red flags register* across different activities of the Agency has not been developed to its full extent. The Agency will start creating its own register based on existing registers which are relevant to its activities, while considering their nature and scope. The FRA will also serve to identify red flags in relevant processes. Where own red flags exist, these will be evaluated, updated if needed and consolidated in the register. Wide communication of red flags to staff, under SO1, will generally support the prevention and detection objectives of the Anti-Fraud cycle.

Strategic Objective 3: Develop further the mechanisms of exchange of information with OLAF and cooperation with the IALN

Investigation is one of the objectives of the Anti-Fraud cycle. OLAF has the exclusive competence to investigate cases of fraud or irregularities, and the Inter-Agency Legal Network (IALN) is in the process of concluding a template for administrative arrangements between decentralised agencies and OLAF, of a technical nature, to facilitate the sharing of information between EU agencies and OLAF for the conduct of investigations.

The Agency will put in place the necessary internal arrangements to facilitate the smooth implementation of said administrative arrangement, when signed, thus ensuring that it has in place adequate tools to support investigations by OLAF.

Furthermore, the Agency will continue participating and having a leading role on Anti-Fraud matters in the context of IALN, a forum where best practices are shared, and new ideas can be generated and incorporated into the Agency's Anti-Fraud toolkit.

5.4. Monitoring, Reporting and Communication

Annually, the Agency will evaluate the performance of the AFS against the indicators included in the Action Plan and, if necessary, it will update it to ensure that the SO are achieved. Information on the

results of the monitoring of the Action Plan will be included in the Consolidated Annual Activity Report (CAAR) submitted annually to the Management Board.[39] Information on the follow up to OLAF's recommendations will also be included.

At a more technical level, GAF will inform the Executive Director and the Executive Board on the progress of the AFS and Action Plan, so that corrective action can be discussed and adopted where necessary. Such regular information will also aim to ensure awareness and engagement on Anti-Fraud matters at top management level and to support their role in promoting an Anti-Fraud culture across the organisation.

The AFS will be published in the Agency's website and shared with OLAF. It will be communicated to staff during the second half of 2025 and following its adoption by the Management Board. Furthermore, the results of the monitoring of the Action Plan will be communicated to staff as part of the activities envisaged under SO1 (training, intranet, blog entries, etc.)

5.5. Evaluation and Update of the Anti-Fraud Strategy

As part of the monitoring activities, and in view of the results of the Action Plan and feedback by the Management Board, the Agency will consider the update of the Action Plan and/or the Strategic Objectives.

Such evaluation of the AFS will also take into consideration new, emerging fraud risks. It will also consider other developments at Agency-level, e.g., changes to the internal control systems, recommendations from EU institutions (European Parliament, European Court of Auditors, etc.) that can have an impact on the AFS, etc.

The overall update of the AFS should take place in principle every three years and will observe the OLAF's methodology of 1 May 2024.

5.6. Action Plan

The Action Plan envisaged under this revised AFS contains different activities to carry out under each SO until June 2028. The Action Plan describes the activities, the fraud risk that they intend to address, the owner/s of the activity, the timeline for their implementation, and performance indicators with specific targets to inform the AFS monitoring.

[39] Article 48.1.(a)(v) of the EMA's Financial Rules.

Strategic Objective 1 – Reinforce internal and external awareness on Anti-Fraud matters by continuing promoting an Anti-Fraud culture				
Action	**Related fraud risk**	**Lead entity**	**Performance Indicators**	**Timeline**
1. Carry out an Agency-wide survey at the start of the AFS, to determine staff awareness on Anti-Fraud matters to better inform the scope and intensity of the activities in the Action Plan.	Not related to a specific fraud risk, but to the need to obtain objective metrics to measure the impact of the AFS actions and use the results for monitoring and review purposes	AF-LD with A-ICR	– Report presented to the ED and EXB at one EXB meeting following evaluation of the survey results.	4Q 2025
2. Communicate the new AFS to staff.	Risk of lack of awareness of legal provisions on Anti-Fraud and procedures which could lead to non-compliance; risk of low engagement by staff on Anti-Fraud matters	AF-LD with A-ICR support	– 2 sessions (e.g., General Assembly, lunch talks). – Several messages on screens, and one email to all staff. – One entry in the Anti-Fraud blog. – Presentation of the AFS and expectations on engagement at one management meeting in 2025.	3Q & 4Q 2025
3. Create and promote a blog with information on fraud, both general and specific to the Agency, and drawing from internal and external sources, the results of other AFS activities, lessons learned from fraud cases, FRA results, etc.	HFR1 HFR4	AF-LD with A-ICR	– Set up of a blog on Anti-Fraud. – At least 8 blog entries per year, starting in 2026. – Promotion via different channels and activities under SO1.	4Q 2025 Continuous
4. Adopt an Anti-Fraud Charter setting out the Agency's obligations and expectations on Anti-Fraud and internal and external promotion.	HFR1 HFR2 HFR4	AF-LD with A-ICR support	– Design an Anti-Fraud Charter. – Promotion via different channels and use in awareness-raising activities under SO1.	1Q 2026 Continuous
5. Update of the Anti-Fraud intranet and website page.		A-ICR and AF-LD	*Current baseline is "update as necessary".* – Quarterly update of information in the intranet – Regular update of website with relevant information for external audiences.	Continuous

Strategic Objective 1 – Reinforce internal and external awareness on Anti-Fraud matters by continuing promoting an Anti-Fraud culture				
6. Mandatory refresher training on Anti-Fraud, Integrity and Internal Whistleblowing for staff.	HFR1 HFR4 MFR1 MFR7	AF-LD and A-ST with A-SG-DEV support	*Current baseline is "as required".* – Organise at least two live sessions per year. – Staff to take either online training or attend live training sessions every 18 months. – Biannual report to line managers on training attendance/completion by their staff.	Continuous
7. Update the mandatory Anti-Fraud online training for new joiners and ensure that all new joiners take it.[40]	HFR1 HFR4 MFR7	AF-LD with A-SG-DEV support	– Review of current content of Anti-Fraud online training for new joiners and update where necessary. – 100% of new joiners to take the online Anti-Fraud training module within first 3 months after joining the Agency. – Quarterly report to line managers on completion of training by their staff.	Continuous
8. Set up an Anti-Fraud Suggestion Box to encourage staff to submit ideas to improve Anti-Fraud prevention and detection, e.g., new red flags, risky practices that could require attention, etc.	Risk of low staff engagement on Anti-Fraud matters	AF-LD and A-ICR	– Suggestion Box available in intranet. – Regular promotion via different channels.	1Q 2026 Continuous
9. Prepare and disseminate informative materials on the Agency's fight against fraud addressed to members and experts of scientific committees, working parties and other bodies, as well as other stakeholders, contractors, etc. with whom the Agency engages.	HFR2 MFR3 HFR3 MFR4 MFR1 MFR5 MFR2 MFR6	AF-LD in coordination with H-QA-SEC and S-PH	– Different materials (e.g., newsletter, power point presentations, etc.) distributed/communicated regularly to selected audiences.	Continuous

[40] The current Anti-fraud eLearning SCORM file is no longer available for modifications and thus, a new eLearning will need to be designed. The official app used for eLearning is Articulate.

Strategic Objective 1 – Reinforce internal and external awareness on Anti-Fraud matters by continuing promoting an Anti-Fraud culture				
10. Carry out an Agency-wide survey at the end of the AFS to measure its impact on staff awareness on Anti-Fraud matters.	Not related to a specific fraud risk, but to the need to obtain objective metrics to measure the impact of the AFS actions and use the results for monitoring and review purposes	AF-LD with A-ICR	– Report presented to the ED and EXB at one EXB meeting after completion and evaluation of the results of the survey.	1Q 2028

Strategic Objective 2 – Increase the Agency's fraud detection capabilities and mitigation of fraud risks				
Action	**Related fraud risk**	**Lead entity**	**Performance Indicators**	**Timeline**
1. Develop a specific methodology for Fraud Risk Assessments (FRA).	Proactive approach to the management of fraud risks	AF-LD with A-SG-QRM support	– Adoption of a Methodological document by AF-LD. – If necessary, update before launch of a new FRA exercise.	1Q 2026 Continuous
2. Perform one general FRA and integrate its results in the general risk management system.	Proactive approach to the management of fraud risks	AF-LD and managers with A-SG-QRM support	*Current baseline is "annual FRA".* – Final Report with FRA results presented to ED and EXB at one EXB meeting. – Submission of final report to SG-QRM once it is approved by the EXB.	2Q-3Q 2026[41]

[41] The Agency's risk assessment is performed annually during 2Q and the FRA results should feed into it.

Strategic Objective 2 – Increase the Agency's fraud detection capabilities and mitigation of fraud risks				
3. Targeted FRAs depending on the results of the general FRA and the new activities of the Agency.	Proactive approach to the management of fraud risks	AF-LD and managers with A-SG-QRM support	*Current baseline is "as necessary".* – Final Report with FRA results presented to ED and EXB at one EXB meeting. – Submission of final report to SG-QRM once it is approved by the EXB.	2027
4. Perform a final FRA with the highest fraud risks to inform the AFS update.	Proactive approach to the management of fraud risks	AF-LD and managers with A-SG-QRM support	– Final Report with FRA results presented to ED and EXB at one EXB meeting. – Submission of final report to SG-QRM once it is approved by the EXB.	4Q 2027 – 1Q 2028
5. Analyse the impact of the new tasks assigned to the Agency since the adoption of the latest AFS, both in the context of the FRA and a targeted analysis, and the need to reinforce, or adopt new mitigating controls.	Risk of incomplete assessment of all processes and of mitigations in place	AF-LD in coordination with relevant departments	– Report presented to relevant managers upon finalisation of analysis. – Integration of new fraud risks in following FRA.	2Q-4Q 2026
6. Develop red flags registers for specific areas as identified in the FRA.	HFR1 MFR7	As relevant	– Finalisation (i.e., consolidation of red flags, or update of existing ones) of one red flags register in a selected area per year.	Continuous
7. Update the policy on whistleblowing by external reporters.	HFR2 HFR3 MFR1 MFR5	H-QS-ISP with AF-LD support	– Adoption by the ED of an updated version of Policy 0072.	1Q 2026

Strategic Objective 3 – Develop further the mechanisms of exchange of information with OLAF and cooperation with the IALN				
Action	**Related fraud risk**	**Lead entity**	**Performance Indicators**	**Timeline**
1. Put in place the necessary practical arrangements to facilitate the implementation of the template for administrative arrangements between decentralised agencies and OLAF.	Proactive approach to the management of fraud risks	AF-LD	– As soon as the template is finalised and the EMA has signed it, AF-LD will evaluate how to implement the different elements included therein.	4Q 2025 – 1Q 2026
2. Evaluate, and reinforce where necessary, the confidentiality controls of information exchanged with OLAF on alleged fraud and investigations.	HFR1 HFR4	AF-LD	– Report by AF-LD with recommendations for action.	Continuous
3. Maintain the coordination efforts with other EU agencies, OLAF and EPPO in the context of the IALN Workstream on Anti-Fraud.	Proactive approach to the management of fraud risks	AF-LD	– Chairing and participating in the IALN Workstream on Anti-Fraud regularly. – Information on IALN activities on Anti-Fraud to be included in the annual report to MB.	Continuous

6. Annex

EMA'S Fraud Risk Assessment 2022
High risks

EMA'S Fraud Risk Assessment 2022
Medium Risks