



Global Speak Up Policy

Document Approved by the Board of Directors of
Alfasigma S.p.A. on 30 October 2024

(replacing SOP G002-V2.0)

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1. PURPOSE

We, at Alfasigma, foster an inclusive workplace that encourages individuals to express their opinions, ideas, and concerns without fear of retaliation.

The objective of this policy is to describe the principles that apply to reporting Compliance Concerns¹ regarding our activities, with the aim of maintaining and improving our industry and internal standards throughout the organization.

This policy describes the roles and responsibilities for assessing, investigating, and reporting Compliance Concerns, regardless of how a report is received within Alfasigma and all Alfasigma Group companies ("Alfasigma"). As such, this policy is applicable to relevant members of the functions described in the RACI table (see *Appendix II: Assigned functional responsibilities for investigating Compliance Concerns*).

2. SCOPE & APPLICABILITY

All employees, staff, contract workers ("Employees"), and other representatives acting on behalf of Alfasigma ("Representatives") are in the scope of this policy.

All Compliance Concerns regarding potential non-conformance(s) / violation(s) of:

- the requirements of the Global C&E Program, Policies, and / or Procedures
- the requirements of Industry Codes and associated laws and regulations ("the Code").

The following are not in scope of this policy and alternative mechanisms are in place to manage and escalate such matters:

- pharmacovigilance related claims and reports
- GxP incidents of non-compliance²
- product-related materials and content
- results from routine audit and monitoring procedures (except where such outcomes indicate an incidence of non-compliance or misconduct that would otherwise be reportable).

3. GUIDING PRINCIPLES

Routine working practices can address some Compliance Concerns without the need for a formal investigation.

Compliance Concerns that fall in scope of this policy will be investigated, when deemed necessary, in accordance with the following principles:

Confidentiality

All reports of Compliance Concerns will be kept confidential, the details will only be shared on a need-to-know basis whilst maintaining confidentiality regarding the identity of all parties involved, including the reporter³, individuals associated, the facilitator, and the reported person⁴ (if not the reporter). We

¹ All capitalized terms within this document are defined at the end if they are specific to this document. Otherwise, they align with the definitions provided in the Global Policy and Principles on Interactions with the Healthcare Community.

² Due to the nature of our business, transport safety, radiation protection and nuclear safety are considered GxP.

³ Also known as whistleblower

⁴ Derogation is allowed when necessary and proportionate under union or national law for investigations or judicial proceedings, including safeguarding the defense rights of the person concerned.

will process all personal data and information in accordance with the principles of the EU Regulation no. 2016/679 ("GDPR") and associated laws and regulations.

Minimization of data

We will only collect data required to conduct the investigation. We will not collect, process, or store any data that is irrelevant to the objective(s) of the investigation.

Objectivity, impartiality, and proportionality

The investigation will be carried out with impartiality and those involved must refrain from making assumptions regarding culpability or innocence.

Investigations will be proportionate to achieving their purpose. Action(s) will only be taken against the reported person(s) on objective findings after conducting the investigation and verifying the reported facts.

Timeliness

Investigations require time. However, we will be prompt and prevent unnecessary delays. The reporter will receive an acknowledgement within 7 calendar days for the receipt of the report.

The target resolution period is 60 business days or as soon as possible thereafter; any significant delays will be communicated to the reporter.

Consistency

We will maintain a consistent approach to investigations, to ensure fairness for all parties, in line with the Speak Up Standard Operating Procedure.

Integrity

We will treat all parties involved with respect, and act in a diligent and fair manner, while acknowledging the necessity of a robust approach to the investigation which may not always be easy for those involved.

Documented

We will maintain records of all investigative steps and associated documentation.

Transparency

To grow and improve, we will, wherever possible and in compliance with GDPR and associated laws and regulations, share the lessons learned from any investigation.

Anonymity and confidentiality

Where permitted by local data privacy laws, Employees and third parties may submit Compliance Concerns anonymously through the Alfasigma Speak Up hotline (EthicsALine).

While it is not always possible to maintain anonymity when employing alternative reporting channels, confidentiality is a fundamental principle in managing Compliance Concerns. Individuals who are informed of, or presumed to be aware of, the identity of a reporter or the specifics of the reported facts are obligated to maintain appropriate / required confidentiality to ensure a fair and thorough investigation can be performed.

Anonymous reports will be considered in the same manner as named reports, provided that they are clear, substantiable, and relevant to work at Alfasigma. This applies regardless of the difficulty of contacting an anonymous reporter when additional information is required.

Non-retaliation

Retaliation against an individual who has raised a Compliance Concern is strictly prohibited.

Good faith

Reporters are safeguarded by this policy even if their report is unfounded, provided that they made the report in good faith i.e., the reporter had reasonable grounds to believe that the information relating to the potential violation(s) was true at the time of the report, and that the information fell within the scope of the policy. Reporter(s) must not use these safeguards to avoid disciplinary action against them, should they be subject to an investigation themselves i.e., this policy does not circumvent normal disciplinary proceedings.

Conflict of interest

Decisions made on behalf of Alfasigma should always be made in the best interests of Alfasigma and its Stakeholders, including Employees and Patients.

All situations or activities that have the potential to lead to a Conflict of Interest or hinder an Employee / representative(s) ability to make impartial decisions, and in full compliance with the principles and content of the Global Code of Conduct, must be appropriately managed to ensure they do not negatively affect Alfasigma.

Additionally, there are internal reporting channels to mitigate Conflicts of Interest, allowing only responsible persons to access and manage such reports.

4. POLICY

Regardless of who is the first to receive the report of a Compliance Concern via one of the Speak Up channels (see section **Submitting a Report** in the corresponding SOP) or sources, they must report the concern directly to the Global Head of Compliance and Ethics or via Speakup@Alfasigma.com for triage and onward reporting within one working day.

Managing Concerns

The Speak Up Committee ("Committee") is responsible for assessing the Compliance Concern and determining, based on its potential seriousness and materiality, whether a formal investigation is needed and how it will proceed. If no investigation is necessary, the accountable function⁵ bears the responsibility of documenting this decision, providing a clear rationale, and communicating it to the relevant parties.

Where an investigation is necessary, the Committee will appoint an Investigation Manager in the accountable function. The Investigation Manager will be responsible for ensuring the investigation is appropriately conducted in line with the principles and requirements set out here.

⁵ See Appendix II: Assigned functional responsibilities for investigating Compliance Concerns

The Investigation Manager must keep the Committee, and the functions designated as "Consulted" (see *Appendix II: Assigned functional responsibilities for investigating Compliance Concerns*) informed about the progress of any investigation, including when deciding whether corrective or preventative actions may be necessary.

Legal consultation may determine that the investigation should continue to fall under the purview of the legal function, ensuring the preservation of legal privilege. In such cases, the Investigation Manager and General Counsel will establish the respective roles and responsibilities for the investigation upfront.

The accountable function at the HQ level will handle the matter if

- the local Alfasigma affiliate lacks the necessary resources and/or expertise to investigate, **or**
- if the Compliance Concern is significant enough to potentially affect our license to operate or cause significant harm to Alfasigma.

The assigned functional responsibilities for investigating Compliance Concerns table (Appendix II)

- indicates that local Alfasigma affiliates can oversee assessment and investigation, but all matters must first be aligned with the respective HQ functional head
- provides guidance on whether the accountable function at the local Alfasigma affiliate or HQ should manage investigations.

Who can submit reports?

All Employees (including trainees, managers, and directors), corporate bodies (such as the shareholders' meeting, board of directors, and board of statutory auditors, etc.), and third parties who have interacted with Alfasigma may submit reports.

Alfasigma may receive information about reportable matters from both internal and external sources.

Internal sources may be, but are not limited to:

- Employees or contractors working directly for Alfasigma
- reports via Line Managers or escalated via other individuals but originating from Employees or contractors
- significant results of routine audit and monitoring activities.

External reports may be received via the Alfasigma reporting platform (EthicsALine).

Protection of the Reporter

If a retaliatory or discriminatory act should result from a Speak Up report, the reporter must inform a member of the Speak Up Committee and / or HR. In such circumstances the Committee will assess:

- the necessity or appropriateness of correcting the situation and / or remedying the adverse effects of discrimination
- if there are grounds to propose disciplinary actions against those responsible for retaliation and / or discrimination.

Protection for the Reported Person

This policy mandates a thorough investigation before action can be taken on a report of a Compliance Concern / potential violation.

NOTE: Reports that are not submitted in good faith and / or that are found to be intentionally for the purpose or intent of maleficence may result in an investigation into the actions of the reporter and could lead to sanctions, and proportionate consequence including disciplinary actions. In such circumstance the reporter will not benefit from the safeguarding of this policy.

Documenting Investigation Outcomes

The Investigation Manager will follow up on all reports that are in scope of this policy, through to resolution in accordance with the corresponding SOP.

The accountable Function Head / Line Manager (of the reported person) of the risk identified must, where possible, issue a correction, and determine the corrective and / or preventative action for all Substantiated cases.

Escalation and Reporting

Following governance practices and contractual obligations, we will escalate and report Compliance Concerns as required.

The Investigation Manager should report the outcome of all investigations conducted to their respective functional heads in Alfasigma HQ (Headquarters). The HQ functional head will ensure that all substantiated Compliance Concerns are reported to:

- relevant Alfasigma management, and,
- in accordance with the Committee Charter, the Committee will determine whether further reporting to the Alfasigma Risk & Control Committee / Supervisory Board is also necessary.

When it is necessary to notify a partner of Alfasigma about a Compliance Concern, we will only do so after reporting it to the Alfasigma General Counsel.

Upon resolution of a Compliance Concern, the HQ functional head, in consultation with the relevant functions (see *Appendix II: Assigned functional responsibilities for investigating Compliance Concerns*), should provide full and constructive feedback to the individual who submitted the report.

Non-Retaliation Plan

The Investigation Manager will decide whether a customized non-retaliation plan (to ensure safeguarding of those involved) is required either during or after completing an investigation.

The details of such a plan will depend on the individual case, but the primary goal will always be to protect the reporter and anyone who contributed to an investigation (see *Appendix III: Factors to consider when developing a non-retaliation plan*).

The Investigation Manager must keep a full record of all steps taken as part of any non-retaliation plan.

5. DEFINITIONS AND ABBREVIATIONS

Term	Definition
Compliance Concern	Potential non-conformance(s) / violation(s) of: - the requirements of the Global C&E program, policies, and / or procedures - the requirements of Industry Codes and associated laws and regulations ("the Code").
Investigation Manager	The individual responsible for overseeing and coordinating the entire process of an investigation within an organization.
Substantiated	The report has been substantiated.

6. REFERENCES

- Global Code of Conduct of the Alfasigma Group
- Anti-Corruption Policy of the Alfasigma Group
- European Regulation 2016/679 (GDPR)
- ISO 37001: Anti-Bribery Management Systems
- European Directive 2019/1937 (Whistleblowing Directive).

7. DOCUMENT HISTORY

Description of Change
- Clearer and more accessible language. - Reorganization of the document to enhance coherence. - Inclusion of a RACI table for easier reference to roles and responsibilities.

8. APPENDICES

Appendix I: Sensitivity levels for Compliance Concerns

Level 1: high sensitivity (significant risk with immediate or direct impact)

Allegations of wrongdoing that:

- could significantly, immediately/ directly damage the internal control and risk management system and/or
- pose a significant reputational risk (such as in different countries, a potential significant breach of industry regulations or legal obligations) and financial losses and/or
- pose threats to company's business continuity and/or
- relate to potential serious ethical violations by senior management, discriminatory or harassing behavior and / or misrepresentation or falsification of company information.

Level 2: moderate sensitivity (moderate risk with potential long-term impact but less immediate or direct)

Allegations of wrongdoing that:

- (i) relate to a potential minor breach of industry regulations or legal obligations and/or
- (ii) relate to a potential breach of the Global Code of Conduct and /or
- (iii) relate to inappropriate leadership behaviour (such as unprofessional conduct, verbal abuse that affects workplace culture but does not yet result in significant public or legal consequences) and/or
- (iv) pose a moderate reputational risk (such as in one country).

Level 3: low sensitivity (minor risk with little immediate or long-term consequence)

Allegations of wrongdoing that relate to:

- (i) minor potential procedural breaches and/or
- (ii) isolated unprofessional behavior and/or
- (iii) isolated failure to lead by example.

Appendix II: Assigned functional responsibilities for investigating Compliance Concerns

Key:

- **Responsible (R)**: The function from which the Investigation Manager will be appointed.
- **Accountable (A)**: The function that owns the compliance risk, which is the subject of the Compliance Concern, and under whose process the investigation will be conducted.
- **Consulted (C)**: The functions that need to be involved in the assessment of the Compliance Concern as well as in relation to determining any corrective or preventative actions.
- **Informed (I)**: The functions who should be informed of the receipt of a Compliance Concern and the outcome of any investigation.

Sensitivity Level	HQ accountable function	Local accountable function	Committee
Level 1: high sensitivity (significant risk with immediate or direct impact)	A R	I	C I
Level 2: moderate sensitivity (moderate risk with potential long-term impact but less immediate or direct)	A R	A R	C I
Level 3: low sensitivity (minor risk with little immediate or long-term consequence)	C I	A R	C I

NOTES:

Depending on the sensitivity level of the Compliance Concern, the HQ or local accountable function will investigate the matter.

Level 2 Compliance Concerns can be investigated either by the local accountable function or by the HQ accountable function in alignment with the Global Speak Up Committee.

To notify the Committee, send an email to Speakup@Alfasigma.com or contact the Global Head of C&E.

Appendix III: Factors to consider when developing a non-retaliation plan

- Does the reporter consent to being contacted for the purposes of monitoring non-retaliation?
- If so, should we contact the reporter regularly e.g., every six months or annually?
- When should we close the formal non-retaliation plan? Regardless of the formal plan's closure, the reporter can always raise concerns about potential retaliation.
- Are there any additional steps necessary to monitor for potential retaliation, such as tracking pay rises, bonuses, relocations, etc.?