



Medicines & Healthcare products
Regulatory Agency

Non- Regulatory Fraud

Anti-Fraud and Bribery Response Plan and Procedure

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Revision History

This table sets out the revision history for the last two versions.

Version No.	Effective date	Author's Title	Change
2.0	May 2017	Head of Corporate Governance & Accountability	Changed to new format, removed 'internal' from title and added bribery section.
3.0	September 2017	Head of Corporate Governance & Accountability	Clarified how to raise concerns anonymously, linkages with Whistleblowing and included a template for raising concerns
4.0	July 2021	Head of Corporate Governance & Accountability	Separated the procedure from the policy and updated to reflect current process.

Consultation

Who	Date
Finance Deputy Director and Governance, Risk and Assurance Manager	January 2021
Regulatory Fraud lead – Head of Operations Unit, IES	March 2021
HR Deputy Director	January 2021
Trades Unions	April 2021

Approval

Approval Path	Date
Deputy Director of Policy Division	April 2021
Audit and Risk Assurance Committee	April 2021
Policy and Procedure Committee	June 2021

Replaces

Internal Anti-Fraud and Bribery Policy and Procedure v 3.0

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1 Introduction

- 1.1 The purpose of this document is to set the procedures to be followed where non-regulatory fraud or bribery is detected or suspected. This document should also be used in cases of suspected corruption or theft.
- 1.2 This document should be read alongside the Agency's Anti-Fraud and Bribery Policy, which sets out what fraud and bribery are, explains the difference between regulatory and non-regulatory fraud and roles and responsibilities in preventing and tackling fraud and bribery. The Policy document also details required competencies, how compliance to the policy and procedure is monitored, how fraud cases are reported and has links to internal and external references and a glossary.
- 1.3 Throughout this document, where 'fraud' is referred to, it should be taken as also referring to bribery, corruption or theft.

2 Scope

- 2.1 This procedure covers all instances of potential non-regulatory fraud (i.e.: internal fraud and external fraud), and bribery whether attempted or committed by those working within or outside the Agency. This document should also be used to deal with potential corruption or theft cases.
- 2.2 Any regulatory fraud is not in scope and should be reported to the Criminal Enforcement Unit (CEU) via the email address: The Bureau <TheBureau@mhra.gov.uk> "

3 Procedure

- 3.1 The process for handling suspected fraud and potential criminal cases is set out below and summarised in the flow diagram in Annex C.
- 3.2 The following should also be notified to the Fraud Officers:
 - Thefts – please see section 3.10, below, for further detail.
 - Impersonation of Agency staff – please see section 3.11, below for further detail.
- 3.3 Notifying the Fraud Officers**
 - 3.3.1 If any member of staff suspects, identifies or otherwise becomes aware of any potential fraudulent or criminal activity he/she should report this immediately:

- to their line manager unless they feel unable to do so or their line manager could be implicated in the potential wrongdoing.
- and to the Agency's Fraud Officers in Governance Office. Contact details are on INsite under Working for Us/Raising a Concern. Note that the Fraud Officers advise and lead on a range of concerns cases; they are also Nominated Officers under the Civil Service Code (i.e.: leading on whistleblowing cases) and the lead Fraud Officer is also the Administrative Complaints Officer.

3.3.2 The template form at Annex B may be used to report concerns. Ideally, reports would be made in person (by email, telephone or verbally) but may be made anonymously in writing to the Fraud Officers, Governance Office 10th Floor, 10 South Colonnade Canary Wharf, E14 4PU.

3.3.3 See the table at Annex A for some 'Dos and Don'ts' on reporting a suspicion of fraud.

3.4 Clarifying the situation

3.4.1 The Fraud Officers will discuss the case with the person or people who reported it to them and may request further information and evidence.

3.4.2 The following factors may be considered to inform the follow up action to be taken:

- nature of the alleged wrongdoing
- history and background of the wrongdoing
- position held by the employee and other parties involved
- duration of the irregularity
- loss or potential loss involved
- voluntary disclosure and or how the alleged wrongdoing came to light
- exposure to ongoing financial and operational risks
- personal factors.

3.4.3 If, after the Fraud Officers have reviewed the evidence and clarified the situation it is clear that no fraud has occurred, the case will be closed. The Fraud Officers may make recommendations to line management and may discuss the case with Finance, HR or other colleagues in cases where any changes could be made to policies etc to help prevent a similar situation occurring in future.

3.5 Investigating the potential fraud

- 3.5.1 Where, after clarifying the situation, a suspicion of fraud remains, The Fraud Officers may carry out an initial investigation of the case to help determine which next steps to recommend.
- 3.5.2 The Fraud Officers will then inform the Director of Governance about the high-level anonymous facts of the case by email including proposed next steps. Next steps would normally include either referring the case to the Department of Health and Social Care's Anti-Fraud Unit (DHSC AFU) for them to investigate using their specialist fraud investigators or for the Agency to investigate under the disciplinary procedure.
- 3.5.3 When a case is referred to the DHSC AFU, HR may be advised to consider beginning the internal disciplinary procedure which may result in an internal investigation (internal disciplinary and fraud investigations may run parallel and are indeed handled separately). Depending on the circumstances of the case, it may be necessary to suspend a member of staff early in the course of the investigation, in accordance with the Agency Disciplinary Policy. Suspension is a neutral act, and not considered lightly, but might be considered essential to ensure a fair investigation.

3.6 Maintaining Records

- 3.6.1 The Fraud Officers will create a new folder on the restricted area of Governance's Office's SharePoint site in which they will save all relevant documents that could be used for evidence in any disciplinary investigation and/or criminal or civil case. They will also create a new case log and will update this as the case progresses.
- 3.6.2 The Fraud Officers will control who can be made aware of the case and at what point, maintaining a list of all those who can be briefed.
- 3.6.3 Files for any suspicions of or actual fraud will be kept for eight years in line with the Agency's Retention and Disposal policy.

3.7 Staff matters

- 3.7.1 Staff raising any concerns may do so under the 'Raising Concerns Policy and Procedure' and may then be subject to the protections under the Public Interest Disclosure Act.
- 3.7.2 Staff support is available from the Agency's confidential Employee Assistance Programme (see INsite), trade unions and staff networks.
- 3.7.3 Staff who are suspected of committing fraudulent activity must cooperate fully

with any investigation and may be interviewed under caution. Interviews under caution should be conducted by specially trained Counter Fraud Specialists in strict accordance with the Police and Criminal Evidence Act (PACE) 1984.

- 3.7.4 If a member of staff resigns before the conclusion of investigative proceedings the proceedings will continue during the contractual notice period of the employee and even after they have resigned.
- 3.7.5 If concerns are raised in good faith, but not confirmed by an investigation, no action will be taken against the individual responsible for raising them. However, action will be taken against any individual found making malicious or vexatious allegations.
- 3.7.6 Staff are entitled to be accompanied to any formal investigation meeting by a recognised Trade Union representative or work colleague, in accordance with the Disciplinary Policy.

3.8 Action after the investigation

- 3.8.1 After a thorough investigation, the Agency will take disciplinary and/or legal action in all cases if this is warranted. Disciplinary procedures should be followed in all cases of alleged fraud and should run concurrently with any criminal or civil proceedings provided that doing so would not compromise these proceedings. If this is the case it may be that disciplinary proceedings may be delayed to allow the criminal or civil proceedings to go ahead first. If managers are in any doubt, they should seek advice from the Fraud Officers.
- 3.8.2 Where it appears that there have been supervisory failures, disciplinary action will be taken following an investigation in accordance with the appropriate HR policies.
- 3.8.3 The Fraud Officers will notify HR, who in turn will notify the Cabinet Office, of civil servants who have been dismissed or would have been dismissed had they not resigned prior to formal action, for internal fraud for their details to be entered on the Internal Fraud Database. Further information about this database is on the Raising Concerns page on INsite.
- 3.8.4 The investigating team will identify whether any fraud case demonstrates a weakness in the Agency's control systems and will make recommendations for action to reduce the future risk. Managers will then be tasked with implementing these actions as soon as possible.

3.9 Recovery of loss

- 3.9.1 Any overpayment will be recovered by HR and/or Finance in line with the Overpayment Policy. The principles of this policy will be followed to recover

any other type of loss where required.

3.9.2 Losses resulting from third parties will be recovered, where appropriate, using the Agency's debt recovery company if the third party does not repay the amount within the timescale given by the Agency.

3.10 Theft of Agency assets

3.10.1 Anyone discovering a theft from one of the Agency's sites or becoming aware that Agency's assets have been taken or sold, must alert South Mimms Security or 10SC Facilities and Estates team without delay, and the relevant HR Business Partner. In turn, the Fraud Officers must be notified in case what seems to be theft turns into a fraud case and also so that the Fraud Officers can report on all loss to Cabinet Office.

3.10.2 Security/Estates and Facilities should report any thefts to the Police and ensure that any evidence is impounded and/or kept securely and searched as appropriate. Should an investigation be required, it will be the investigating manager's responsibility to pull together all statements and evidence from lead colleagues, including any evidence from a laptop for example to inform their investigation.

3.10.3 If relevant to the theft, please see the Personal Property Procedure and/or Security Data Breach Policy on the Policies and Procedures page of INsite.

3.11 Impersonation of Agency Staff

3.11.1 Fraudsters may contact members of the public saying that they work for the Agency perhaps to obtain sensitive information or to promote the sale of their products.

3.11.2 Anyone in the Agency receiving such a report should obtain as much information as possible from the person reporting it, including asking for - and noting down - their contact details if they are content to give them.

3.11.3 Such cases should then be reported to the Fraud Officers who will:

- Contact the person who reported it to find out more and check whether they are content for the Agency to report it to Action Fraud on their behalf.
- Write a full account of the case and store this on file.
- Report it to Action Fraud (if the reporter is content).
- If it is a potentially serious case, alert senior staff in the Agency, as required, including the CEO and Director of Governance.

- Consult Comms to discuss whether there should be any internal or external communications to warn staff and the public.

3.11.4 In these situations, the advice to members of the public is always that if a caller is not confident that the person they are speaking to is genuine, they should ask for their name and number and ring the Customer Experience Centre to check.

Annex A: Dos and Don'ts for Reporting Fraud and Bribery

DO	DON'T
<ul style="list-style-type: none">• Ascertain promptly and carefully what has occurred or is suspected• Document the details as clearly and as factually as possible (see below)• Report your concerns verbally or in writing (anonymously if you wish) to the Fraud contacts	<ul style="list-style-type: none">• Ignore it• Approach or accuse any individuals directly• Try and investigate the matter yourself• Talk to others about your suspicions (except for your line manager, if you are sure they are not implicated, and the Fraud Officers)• Remove documentation• Delay reporting the matter

Annex B: Template for reporting concerns

This template may be used by staff for reporting concerns to the Fraud Officers and/or to help guide a meeting to discuss the concerns with the Fraud Officers.

<p>Name: (optional, but recommended)</p>	
<p>Details of the concern:</p> <ul style="list-style-type: none"> • how the matter came to light • who is involved or suspected to be involved • what your suspicions are and what the grounds are for them • what evidence you have of the suspected wrongdoing. <i>(This should be readily available to you. Please do not go searching for additional evidence)</i> 	
<p>Action taken to date:</p> <ul style="list-style-type: none"> • By you • By others 	
<p>Do you believe the individual/s concerned are aware of the potential wrongdoing?</p>	
<p>Who else is aware or has been made aware of the situation?</p>	
<p>Any other details?</p>	

Annex C: Flow Diagram Process for handling suspected cases



