Medicines & Healthcare products Regulatory Agency

Corporate Conflicts of Interest Policy and Procedure

Accountable Director:	Carly McGurry
Date approved:	October 2023
Review Date:	October 2026

Document Status

This is a controlled document. The controlled version is posted on the intranet. You may print this document if you need to but be aware that it is only valid the day it is printed as the controlled version may change. For the same reason, do not save this it in personal or shared areas.

Revision History

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

Version No.	Effective date	Author's Title	Change
4.0	January 2020	Head of Corporate Governance & Accountability, Policy Division	Document put in the standard format and revised to take account of current practice.
5.0	February 2021	Head of Corporate Governance & Accountability, Policy Division	Updated the CPRD annex to include all current types of potential COI. No changes to the main document.
6.0	September 2023	Head of Governance. Compliance and Concerns – Governance Office	Revised to take account of transformed Agency and new COI Group. Moved the previous annex to a standalone 'living' document.

Consultation

Who	Date
Corporate COI Group	October 2023

Approval

Approval Path	Date
Risk and Assurance Group (RAG)	October 2023

Contents

This table of contents contains hyperlinks. You can hover over a section and press ‘Ctrl’ + ‘Click’ to go directly to it.

1 Introduction 4

2 Scope 4

3 Policy 5

4 Roles and responsibilities 6

5 Procedure 7

6 Competence 9

7 Monitoring compliance 10

8 References 10

9 Glossary 11

Annex A: Decision Tree 12

12

1 Introduction

1.1 This document outlines the approach to handling potential corporate conflicts of interest (COI) arising from the operation of the MHRA.

1.2 A corporate conflict of interest may arise where one part of the MHRA undertakes work that may require oversight or review by another part of MHRA now or in the future. The risk of an actual COI, or the perception of one, can arise where the MHRA is in a position where its decisions might be – or be seen to be – influenced by its other interests.

1.3 While much of the work undertaken by the MHRA is for third parties, and not via direct contact, this transparent policy for handling potential corporate COIs has been developed to manage this risk and ensure the Agency's regulatory integrity and impartiality is maintained whilst enabling the Agency to support innovation.

1.4 Aims and objectives

1.4.1 The overall aim of the policy is to ensure corporate conflicts of interests are dealt with in an appropriate and open manner, maintaining the MHRA's regulatory integrity and impartiality.

1.4.2 The objective of this policy is to enable MHRA to continue its activities and develop new areas of work, in the interests of public health, whilst identifying and acknowledging potential actual or perceived COI and taking steps to manage, mitigate or avoid actual COIs in a way that is transparent and maintains stakeholder confidence.

2 Scope

2.1 All staff, which includes anyone working for MHRA, must follow this policy and procedure.

2.2 This policy applies to all activities carried out by any part of the MHRA, whether fee paying or not, that could pose a potential COI with activities carried out in another part of the MHRA.

2.3 This policy does not cover how to deal with individual staff, Board or Expert Committee COIs which are covered in other documents (see section 8, References).

3 Policy

3.1 This policy has been developed in line with the principles laid down in the Statutory Code of Practice for Regulators (see section 8, References). It sits alongside the MHRA's staff COI policy and the Civil Service Code (see section 8, References), which provides general guidance on the duties and obligations of all civil servants.

3.2 The MHRA will operate in accordance with the following principles when managing potential conflicts of interest:

- **Transparent and open** process, decision-making and outcomes.
- **Proactive** in identifying and managing COIs, and monitoring compliance.
- **Balanced and consistent decision-making**, maintaining integrity and impartiality whilst maximising our public health contribution.

3.3 The MHRA's mission is to keep patients safe and enable access to high quality, safe and effective medical products. Staff are therefore encouraged to progress new work, identifying any potential perceived or actual COIs. Where there is a potential perception of a COI, staff are asked to set out transparently how the activity does not cause an actual COI (which could include separation of duties, different line management chains etc) Where an activity could give rise to an actual COI, staff are asked to set out clearly the proposed way or ways of mitigating them sufficiently.

3.4 Particular care must be taken where a new area of business might give rise to a financial benefit. For example, this includes cases where the MHRA provides a service and receives a fee for provision of the service.

3.5 While operating in the interests of public health and innovation, the MHRA will take steps to avoid having a stake in the success of a product, company or organisation which it also regulates.

3.6 Where the proposed mitigation for a COI is to ask another regulatory authority, individual or organisation to review a decision or finding, or to carry out some work on behalf of the MHRA, this should be approved by the Corporate COI Group ('COI Group') in advance and all instances recorded on the COI Tracker by the COI Group Secretariat.

4 Roles and responsibilities

4.1 Senior Management Teams (SMTs)

4.1.1 SMTs are responsible for maintaining clear procedures aligned with this policy and procedure, for identifying and handling any potential COIs that arise, including when cases should be escalated to the COI Group for information or for decision. SMTs should ensure all staff in their teams are fully aware of their internal COI procedures and chief officers will be asked to provide assurance to the CEO that such procedures have been properly embedded and followed throughout the year, as part of their assurance statement at year end.

4.1.2 When considering new areas of business, potential COIs and their mitigation should be established by SMTs so that they can be discussed and agreed before work commences.

4.1.3 SMTs must ensure that a clear record is made of all COI discussions and decisions made at their meetings. SMTs may either submit any relevant minutes to the Secretariat or draft a 'for information' paper. The 'for information' paper template is available from the Secretariat or the COI INsite page.

4.2 COI Group

4.2.1 A COI Group will consider any cases escalated to it in accordance with this policy and procedure.

4.2.2 The COI Group will:

- Consider escalated cases, coming to a decision on whether the proposed activity can be progressed and, if so, to agree any mitigations
- Escalate any cases which exceed the COI Group's authority to Risk and Assurance Group (RAG), which reports to ExCo, such as novel or contentious cases which would impact on public health or reputation significantly or where members cannot agree.
- Ensure a tracker is kept monitoring activities giving rise to a COI and implementation of agreed actions to mitigate them.
- Monitor any emerging issues that might require the Corporate COI policy and/or its operation to be reviewed.
- Review relevant activities carried out by the MHRA to ensure compliance with the Corporate COI Policy and Procedure
- Consider any concerns received from stakeholders about corporate COIs.

- Sign off minutes as an accurate record of the Group's discussions.
- Approve an Annual Compliance Report to be published on the MHRA's website.

4.2.3 See the published Terms of Reference document on the Agency's intranet for information on composition, membership, quorum and frequency of meetings (see section 8, References).

4.3 Secretariat

4.3.1 The Secretariat is responsible for:

- Ensuring all cases that are escalated to the COI Group for a decision are given full consideration
- Working with operational groups to ensure that the COI case is documented clearly on the COI template to enable effective discussion at the COI Group
- Preparing the agenda for each meeting in consultation with the Chair
- Circulating papers to members, normally five working days in advance of each meeting
- Producing and circulating draft minutes/decisions of each meeting within a week of the meeting
- Confirming decisions and outcomes of cases, including any actions and evidence required of COI mitigations being implemented, to the case owner by email
- Maintaining a tracker of cases escalated to the COI Group.
- Maintaining organised records of papers and evidence supplied.
- Drafting, seeking COI Group and then RAG approval to the Annual Compliance Report and providing the report to ARAC as assurance, prior to publication on the website.

5 Procedure

5.1 Identification of potential COI

5.1.1 All staff have a role in considering whether new or changed activities might give rise to a potential corporate COI. Staff should escalate any potential COIs to their SMTs for discussion. Members of the public and staff in other organisations can also raise concerns through Customer Services (MHRACustomerServices@mhra.gov.uk) if they believe there may be a COI in activities undertaken by parts of the MHRA. Please refer to the Agency's 'Activities, Products and Services and Potential Corporate COIs' document for examples of previous agreed activities which do or do not cause a COI (see references, Section 8).

5.2 Consideration by SMTs

5.2.1 Group and function SMTs will consider potential corporate COIs, discussing these with other parts of MHRA as required to establish potential mitigations and any public health justification for carrying out the work.

5.2.2 SMTs may approve activities which give rise to corporate COIs where these are set out in approved operational guidelines (which may be in the form of a COI checklist). SMTs should record these decisions and send relevant minutes or a 'for information' paper to the COI Group Secretariat.

5.2.3 Where activities do not come within operational guidelines, or even when they do but it is felt that COI Group should be aware or their advice would be helpful (eg: in a very sensitive case), then SMTs should escalate the case to the COI Group for decision.

5.3 Consideration by the COI Group

5.3.1 Cases that are escalated to the COI Group for decision or sent to the Group for information may be considered by them at a formal meeting or in correspondence: - either as part of a virtual meeting or separately where a quicker response is required.

5.3.2 Where papers are circulated in correspondence, the Secretariat manages the process, sending the paper to all members with a clear deadline and then collating and saving responses electronically. The Secretariat appends a summary of responses to the minutes for the next meeting for information and updates the COI Tracker.

5.3.3 Where cases are considered in a formal meeting, the Secretariat records any decisions in the minutes and updates the COI Tracker.

5.3.4 Paper authors should request a paper template from the Secretariat. In summary, papers should include:

- A short summary of the proposed work
- How this work could give rise to a perceived or potential COI
- How any potential actual COIs could be managed, for example seeking an independent view on a regulatory decision or particular matter.
- Any public health justification for carrying out the proposed work, for example:
    - If MHRA is responding to a world-wide public health need?

- If MHRA is unique in its offering and no other organisation is able to respond?
- MHRA is appropriately positioned within government to offer advice, services or products without bias?

- Who else in the MHRA should be aware of the decision (such as those who will need to contribute or who have already been consulted).

5.4 Escalation by the COI Group

5.4.1 The COI Group will escalate any cases which exceed the COI Group's authority to RAG, which reports to ExCo, such as novel or contentious cases which would impact on income or reputation significantly or where members cannot agree.

5.5 Communicating and implementing the agreed actions

5.5.1 Once the COI Group has made a decision on proposed COI mitigations, these will be recorded in both the minutes and on the COI Tracker. The Secretariat will communicate the agreed mitigations and evidence they expect to see once the mitigations are in place to the leads and to anyone else indicated in the paper as needing to be aware of the decision.

5.5.2 If the agreed mitigation includes asking another body to review an MHRA decision or finding (e.g.: a licensing decision) or undertake other activities on behalf of the MHRA, the relevant leads should inform the Secretariat of these approaches as they will update the COI Tracker.

5.5.3 The Secretariat will recommend cases for closure to the COI Group where evidence that the COI mitigations have been implemented has been provided or the work is no longer being progressed. If the COI Group agrees, closed cases will be moved to the closed tab on the spreadsheet.

5.5.4 The minutes and the tracker are stored on SharePoint and a link is available on the COI INsite page.

6 Competence

6.1 The COI Group requires a blend of perspective and expertise.

6.2 Staff may contact the COI Group Secretariat for advice and guidance on identifying and mitigating corporate COIs.

7 Monitoring compliance

7.1 An annual compliance report will be published reviewing the Agency's adherence to this policy and procedure in the preceding year. This report will include a summary of cases considered by the COI Group and the mitigations agreed. The report will be approved by the COI Group itself before being sent to RAG for endorsement and ARAC for assurance and evidence. The report then will be published on the Agency's website.

7.2 Compliance with this COI policy and procedure may be reviewed as part of the MHRA's internal audit programme.

7.3 Members of the public and staff in other organisations can raise concerns through Customer Services (MHRACustomerServices@mhra.gov.uk) about the application of this policy and procedure and if they believe there may be a COI in activities undertaken by parts of the MHRA.

7.4 Staff should ideally raise any concerns or make any comments about the application of this policy and procedure to their line manager or someone else in their line management chain in the first instance. Alternatively, concerns or comments can be addressed to the Secretariat or a member of the COI Group.

7.5 This policy and procedure will be reviewed at least every three years to take account of any new issues that emerge and any complaints or comments received.

8 References

8.1 The following internal documents are associated with or linked to this document:

Internal Document	Document Location
(Staff) Conflicts of Interest Policy	INsite/Policies and Procedures
Raising Concerns Policy and Procedure	INsite/Policies and Procedures
MHRA Board COI Policy and Procedure	COI Policy for the Board
Administrative Complaints Policy and Procedure	INsite/Policies and Procedures
COI Group Terms of Reference	INsite/Working for Us/Conflicts of Interest
Activities, Products and Services and Potential Corporate COIs	INsite/Working for Us/Conflicts of Interest
Code of Practice for the Commission on	2022.09.07_The_Code.pdf

Internal Document	Document Location
Human Medicines, the British Pharmacopoeia Commission, the Devices Expert Advisory Committee (and its successors), the United Kingdom Stem Cell Bank Steering Committee, and other expert advisory committees	(publishing.service.gov.uk)

8.2 The following external documents are associated with or linked to this document:

External Document	Document Location
Seven Principles of Public Life	http://www.public-standards.gov.uk/about-us/what-we-do/the-seven-principles/
Civil Service Code	https://www.gov.uk/government/publications/civil-service-code/the-civil-service-code
Statutory Code of Practice for Regulators	https://www.gov.uk/government/publications/regulators-code
Information about the MHRA's role and responsibilities	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about
How to make a complaint to the MHRA	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/complaints-procedure

9 Glossary

9.1 The following key terms are used in this document:

Term	Definition of term
Corporate conflict of interest (COI)	These may arise in situations where the work of different parts of the MHRA overlaps and there could be the suggestion that decisions in one part are being influenced by another part. For example, the MHRA could be asked to make a regulatory decision on something on which another part of the MHRA has produced some data, which could be seen as a COI.

Annex A: Decision Tree