Medicines & Healthcare products Regulatory Agency

CORPORATE CONFLICTS OF INTEREST – ANNUAL COMPLIANCE REPORT 2022

PURPOSE OF THIS REPORT

1. Under the Medicines and Healthcare products Regulatory Agency's Corporate Conflicts of Interest (COI) Policy and Procedure there is a requirement for an annual compliance report to be prepared. The report should be signed off by the Corporate COI Group (COI Group) and subsequently submitted to the MHRA's Risk and Audit Committee (ARAC).

2. This compliance report sets out the corporate COI cases that were considered by the COI Group in the calendar year 2022 and details the mitigations that were agreed.

POLICY AND PROCEDURE

3. The COI Group operates under the MHRA's Corporate COI Policy and Procedure which is available on MHRA's website. This policy and procedure was first developed in 2013 following the merger of the National Institute for Biological Standards and Control (NIBSC) with the MHRA and the launch of the Clinical Practice Research Datalink (CPRD) as a function of the MHRA.

4. The policy and procedure is currently being reviewed to reflect the MHRA's new structure.

5. No complaints or concerns have been received about the operation of the Corporate COI Policy and Procedure since the last compliance report.

CORPORATE COI GROUP

6. Following the restructure of the MHRA in 2022, a refreshed COI Group was established.

7. At its first meeting in November 2022, the COI Group considered and agreed new terms of reference. Members noted that their role was to reach a corporate decision on COI cases for the MHRA as the COI Group, rather than representing their team. Consideration was given on how best to ensure that all COI issues were identified, managed where possible and escalated to the COI Group at for decision where required. It was agreed that the Policy and

Procedure should include a decision tree and that levels of authority should be clearly defined. The COI Group agreed that it was very important to raise awareness of the revised policy when complete.

CONSIDERATION OF POTENTIAL COI CASES

8. During the reporting period, the COI Group considered three COI cases. The Group considered some cases in correspondence and met once. In addition, discussions were had in correspondence in support of decisions at the meeting.

Case 1

This case was escalated and considered by Governance Office in August 2022 in the absence of a formal COI Group and a paper submitted to the COI Group for information in November 2022.

An MHRA Assessor was asked by DHSC's Plasma Board to participate in Dialogue Meetings with fractionators of plasma. As a result of these meetings, a preferred fractionator would be appointed who may become involved with the MHRA in any of the following ways: - licensing application/s, clinical trials application/s, inspections and/or future regulatory action. There could be the perception of a conflict of interest if the MHRA was involved in the appointment of a fractionator and the MHRA then approved a licensing application from that fractionator for example.

It was agreed that MHRA's engagement should be limited to answering requests for specific and factual regulatory advice instead of being present at the Dialogue Meetings.

Case 2

The COI Group considered a case of a potential for a COI between MHRA's role as an *In Vitro* Diagnostic Device (IVD) manufacturer and as the Regulator which designates UK Approved Bodies for medical devices.

The MHRA manufactures 86 IVD devices which were placed on European Union (EU) and Great Britain (GB) market. These IVDs are quality control reagents used by diagnostic laboratories to demonstrate the validity of their test results, assays etc. They are not used as diagnostic test kits which determines test results directly for a patient, but instead are used to test the tests are working appropriately and have the relevant level of sensitivity.

MHRA is the only manufacturer for many of these products and has a statutory duty to provide such reference materials. IVDs are CE marked, but the MHRA will be required to UK CA mark these in the future to sell them in the GB market.

The potential for a perceived COI is that MHRA could be seen to be treating the manufacturer (also MHRA) preferentially, specifically in relation to any required enforcement action.

Following the receipt of clarification and assurance regarding the process should there be an issue with one of the IVDs that the MHRA manufactures, the COI Group agreed the following mitigations:

- Put in the tender documents for the Approved Body that should any issue arise with the IVDs requiring regulator involvement, that the MHRA would ask another regulator to scrutinise and provide a recommendation to ensure impartiality, and
- For transparency, include and explain this COI and mitigation in the revised Corporate COI Policy and Procedure.

Case 3

The COI Group considered a request to perform some testing for a former collaborator, generating new data to support an Investigational New Drug (IND) application to FDA (for a novel therapeutic monoclonal antibody).

MHRA, as NIBSC, had collaborated on a project in 2017 to develop and characterise monoclonal antibodies against diphtheria toxin. The objective was to develop a candidate material that could eventually replace the equine serum-derived therapeutics that are currently used for treatment of diphtheria. The results of this project were published in 2020. Following the conclusion of this project, the published data had been used to prepare an IND submission to the US Food and Drug Administration (FDA) to gain regulatory approval for Phase I human trial. After some preliminary discussions with FDA, a request had been made to generate new data to show direct comparability between an existing equine therapeutic product and the novel therapeutic candidate. This would take the form of a cell-based assay that was established at the MHRA's laboratories.

The potential COI was that there was a possibility that a regulatory submission could be made in the future to MHRA as the regulator which may include this new (unpublished) data generated at the MHRA's laboratories.

The original contract stated that the data could not be used in a regulatory submission to MHRA, and it was proposed that this could be included again in the contract for this work. It was agreed that this case could go ahead as

proposed and that it should come back to the COI Group if there was any change in the intended use of the data.

CONCLUSION

9. All corporate COI cases are recorded on our internal tracker and lessons learned are continually fed into our existing policies and decision-making.

Approved by the COI Group June 2023
Endorsed by ARAC July 2023