Medicines & Healthcare products Regulatory Agency

CORPORATE CONFLICTS OF INTEREST ANNUAL COMPLIANCE REPORT 2024/25

The Medicines and Healthcare products Regulatory Agency (MHRA) must command public trust in order to be effective as a safety regulator and must simultaneously support opportunities for innovation with potential to secure real advances in healthcare product effectiveness in order to benefit patients. To support these aims, MHRA manages risk in a proportionate way. Inevitably, from time-to-time, potential corporate conflicts of interest may arise between different activities delivering these aims. MHRA has in place strong, effective governance which ensures that when such potential conflicts of interest arise the public can be confident that our independence and impartiality is safeguarded while at the same time supporting medical advances with most potential to benefit patients. When there are lessons to learn, we identify these and feed them into our existing policies and decision-making.

PURPOSE OF THIS REPORT

1. As part of the MHRA's commitment to transparency and openness, we publish an annual compliance report in line with our Corporate Conflicts of Interest (COI) Policy and Procedure. This report is agreed and signed off by the Corporate COI Group (COI Group) and submitted to MHRA's Risk Assurance Group (RAG) for assurance and the Board's subcommittee, the Audit, Risk and Assurance Committee (ARAC) for endorsement.

2. This report sets out the corporate COI cases (COI cases) and details the agreed mitigations as well as other matters that were considered by the COI Group from 1 April 2024 to 31 March 2025.

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. Following the restructure of the MHRA in 2022, a refreshed COI Group was established in November 2022 with representation from across the MHRA and an independent Non-Executive Director (who is also the chair of the Audit and

Risk Assurance Committee) in the membership. A revised policy and procedure was published to take account of changes to the MHRA's structure and to include a new 'decision-tree' to aid decision-making about when to escalate a COI matter.

5. No complaints or concerns have ever been received about the operation of the Corporate COI Policy and Procedure.

CORPORATE COI GROUP

6. The COI Group considers cases escalated to it and comes to a decision on whether the proposed activity can be progressed and, if so, agrees to appropriate mitigations.

7. Where an activity is already allowed for in operational guidance and/or in the Corporate COI Policy and Procedure, cases may be brought to the COI Group's attention for information.

MANAGEMENT OF CORPORATE COIs

8. In addition to the specific COI cases that the COI Group considered as detailed in the next section, the COI Group also discussed and progressed other issues as follows:
    - Further developed tools to assist in identifying and managing corporate COIs locally, with clarity on when to escalate these to the COI Group for a decision.
    - Reviewed the operation of newly developed frameworks for management of COIs in Science and Research (S&R) and Clinical Practice Research Datalink (CPRD) which gave them assurance that they were being managed and escalated to the COI Group where necessary.
    - Supported the refreshed approach to staff engagement at external events and the need for them to align with our strategic aims.
    - Reflected on our approach to managing COIs and how best to ensure consistency in this approach across MHRA
    - Reflected on external views on MHRA's independence and management of COIs and how best to instil public confidence in the way we are managing COIs.

CONSIDERATION OF POTENTIAL COI CASES

9. During the reporting period, the COI Group reviewed seven cases, all of which were for decision. The COI Group met three times and considered two cases in correspondence.

Cases that came to the COI Group for decision:

- **Case 1**

The Office of Life Science (OLS) approached the CEO, asking MHRA to join the Regulatory and Implementation Forum for a dementia project

alongside NICE and NHS England. The COI Group agreed that the response should set out the boundaries of MHRA's involvement to protect our regulatory independence; namely through separation of duties (those contributing to the project would not be involved in any resultant regulatory assessments or decisions) and that if the Forum moved towards decision-making on funding for, or procurement of, medical products then the MHRA participant would remove themselves from those discussions.

- **Case 2**

The case concerned a manufacturer that had an interest in understanding potency assay readouts with respect to a rabies vaccine and wished to convene a working group to discuss. They had requested an S&R expert to participate. The work, although co-ordinated by a manufacturer, was intended to provide an output for public dissemination and benefit and, as such, would not be providing advantage to a single manufacturer. The working group would be led by an academic expert in the field of rabies and they would be acting as an independent scientific expert in the field and not in a regulatory capacity. No monies would be accepted by the individual or MHRA for participation in the meetings. The Business Team would ensure that contract protected the scientist and that it was made clear that they would be providing independent advice on the subject area, not MHRA regulatory advice. The COI Group confirmed that they were happy for participation in the project to go ahead on the basis outlined.

- **Case 3**

The COI Group considered the extent of MHRA's involvement in a consortium which was being set up to consider how to establish a scalable and sustainable new pathway for individualised medicines for the treatment of rare and/or ultra rare conditions. It was felt that MHRA involvement was important to be able to understand the products under development, where the MHRA should be setting the strategy and engaging with all stakeholders.

It was agreed that MHRA involvement in this project should be in an observer and advisor role rather that part of the consortium to avoid real or perceived conflict of interest and to protect MHRA's independence.

- **Case 4**

In the previous reporting year, the COI Group had considered proposals to mitigate COIs arising from the transfer of the Coronavirus Test Devices Approval (CTDA) Programme to the MHRA from the UK Health Security Agency (UKHSA). The COI Group had agreed to the implementation of two COI mitigations, firstly that the Science and Research (S&R) scientist assigned to the application should have had no involvement in the design, development or manufacturing of NIBSC reagents used for assessing the analytical performance of the tests and secondly that the activity should be tracked. In a further paper, the COI Group was asked to agree that it was sufficient mitigation for the CTDA Standard Operation protocol to require each application using NIBSC reagents to be tracked to provide full traceability of the activity. The COI Group agreed that maintaining a

tracking system was sufficient and noted that the use of NIBSC reagents in an application cannot influence the main CTDA approval/rejection criteria.

- **Case 5**

Under an agreement with the Coalition for Epidemic Preparedness Innovations (CEPI), MHRA carries out testing of samples of candidate vaccines. This agreement was extended in 2023 to include high consequence viruses. The COI mitigations that are in place required review and the COI Group heard that these included separation of duties between the assessors reviewing the data and the scientists performing the testing and that testing methods were quantitative, validated and had internal controls. The COI Group noted that there were few candidate vaccines for a specific pathogen, and it would be likely only one in a specific clinical trial phase would require testing. It was felt that the COI mitigations were likely sufficient for what would be a perceived COI, but the Group requested some further information to come to the next 2025 meeting before giving final agreement.

- **Case 6**

The COI Group considered this case which involved the launch of a pilot Real-World Evidence Scientific Dialogue Programme (RWE SDP) as part of MHRA's Data Strategy. The RWE SDP pilot had been designed to help innovators refine their evidence generation strategies while providing clear guidance on regulatory expectations.

It was explained to the COI Group that the perception of a COI could arise where MHRA is providing scientific advice for a product that is later involved in an active regulatory procedure reviewed by the MHRA. The staff leading the RWE SDP were separate to the staff involved in active regulatory procedures. In addition, the written scientific advice would include the standard MHRA disclaimer which explains that the advice cannot be taken as indicative of any future agreed position.

There would be a precompetitive workshop for inclusion in the RWE SDP pilot, of which the output would be published externally, jointly with NICE. The COI Group noted the COI mitigations, indicating that transparency was key and that as much as possible should be published.

- **Case 7**

It had previously been agreed that it did not cause a COI for Medical Research Council cell strain 5 (MRC-5) to be used as a substrate for the development of vaccines and in testing and development of new therapeutics. This case was brought to the COI Group again to clarify whether this approval also covered both (i) intended use of and (ii) subsequent 'decision critical data' arising in customer applications that intend for its use as a substrate only. It was explained that no COI was caused (either perceived or actual) so no mitigation was required. The COI

Group agreed that use of MRC-5s in this way could be added to the COI exemption list so further cases would not need to be brought for approval.

The COI Group considered a case for an extension to the COI exemption for MRC-5 stem cell lines. It was agreed that the wording for this COI exemption would be changed to “MRC-5 cell lines for use as a precursor to generate substrate in the development, testing or manufacture of a vaccine or therapeutic” includes both i) intended use of MRC-5s and ii) any subsequent ‘decision critical data’ arising, and that this be a generic approval if MRC-5s are being used as a substrate only i.e. does not directly constitute the vaccine or therapeutic.

CONCLUSION

10. All COI cases are recorded on our internal tracker, which is an Excel spreadsheet detailing each case, the mitigations agreed and when evidence of those mitigations being put in place has been provided.

11. We are confident that the COI Group has given robust oversight of COI issues brought to it during the year, providing assurance that corporate COIs are being managed effectively and safeguarding public trust.

Agreed by the Corporate COI Group, April 2025
Approved by Risk and Assurance Group, a management committee of Executive Committee, June 2025
Endorsed by Audit, Risk and Assurance Committee, May 2025