Medicines & Healthcare products Regulatory Agency

CORPORATE CONFLICTS OF INTEREST ANNUAL COMPLIANCE REPORT 2025/26

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 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 2025 to 31 March 2026.

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. The policy and procedure is due to be reviewed in the latter part of 2026.

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 (the 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 Group's attention for information.

MANAGEMENT OF CORPORATE COIs

8. In addition to the specific COI cases that the Group considered as detailed in the next section, the Group also discussed and progressed other issues as follows:
    - COI implications of commercialisation of MHRA's Intellectual Property Assets
    - Further development of tools to assist in identifying and managing corporate COIs locally, with clarity on when to escalate these to the Group for a decision.
    - Increasing transparency of COI management on MHRA website
    - Management of COIs in the Commercial/Procurement process.

CONSIDERATION OF POTENTIAL COI CASES

9. During the reporting period, the Group met three times and considered one case in correspondence. Of the 5 cases the Group reviewed, all required a decision and these are summarised as follows:

Case 1: Agreement with the Coalition for Epidemic Preparedness Innovations for testing of samples

Under an agreement with the Coalition for Epidemic Preparedness Innovations (CEPI), MHRA carries out testing of samples from clinical trials of candidate vaccines. This agreement was extended in 2023 to include high consequence viruses, most of those are not circulating in UK with exception of travel-imported cases. Also, for high consequence pathogens, outside a pandemic, the number of vaccines developed is limited.

The potential COI was that the data derived from the testing by MHRA scientists could potential be used at a future date as part of a regulatory submission.

The Group considered the proposed mitigations for the revised agreement in January 2025 but requested further clarification and information on the separation of duties COI mitigation. The testing work is carried out at the Science

Campus, which is a dedicated scientific site, and by Agency staff who are not involved in the regulatory decision making.

Decision: The Group agreed that additional clarification and information was helpful and members were content for the project to proceed on the basis that the proposed separation of duties COI mitigations outlined were implemented.

Case 2: Mental Health Mission

Mental health was one of the five Healthcare Goals Programme areas, which also includes Dame Barbara's Dementia mission. The Group noted that there was a strategic health imperative to improve development and innovation of mental health products in the UK, and a key barrier to this is perception there may be specific regulatory challenges for these sorts of product. The Mental Health Mission (MHM) was launched in 2023, focussed on developing innovative new treatments and technologies (as part of the Life Sciences Vision). Dedicated resource has been seconded into the MHRA until 2028 to explore the potential regulatory challenges that could limit innovation in mental health products, and to help educate MH-TRC MHM colleagues on the regulatory process.

The Group considered two potential COIs regarding MHRA's involvement in the Mental Health Mission: firstly that this was it was the only one of the Healthcare Goals Programmes to have a dedicated resource in MHRA (secondee) and it could be perceived as MHRA favouring innovation in one disease area over others and, secondly, a potential COI could arise through the perception that these mental health products are being given priority through the regulatory process or that the companies are being given extra support or information to which others cannot access.

Decision: In discussion, the COI group as agreed that it was clear that the Agency would consider providing secondees for the other healthcare goals programmes on invitation so on that basis the first potential COI was unlikely to be a COI due to MHRA having offered the option of, and being open to, having secondees for the other four Healthcare Goals Programmes. For the second potential COI, it was agreed that the perceived COI should be managed through being transparent about the separation of duties, making the nature of the secondment clear, specifying the independence of the regulator and that the secondee has no influence or say in regulatory decisions. The COI group requested more information on separation of duties to ensure this was clear in the proposal and amendment of the job description to ensure the job holder would not have regulatory decision-making authority or influence over regulatory decisions.

Case 3: National Commission into the Regulatory of AI in Healthcare

The 10 Year Health Plan for England and the Life Sciences Sector Plan both commit to the NHS becoming the most AI-enabled healthcare system in the world, supported by the delivery of a new regulatory framework for medical devices including AI.

The proposed National Commission into the Regulatory of AI in Healthcare by MHRA would be responsible for advising the MHRA on the new framework for AI products and making Great Britain the fastest and safest place to regulate AI and software in the world. The Commission would have external experts some of whom would have COIs that must be transparently managed to maintain public trust.

The Group considered proposals for managing these COIs which included declaration on appointment, annually and at each discussion. Any declared COIs would be published in every Commission publication. Where COIs were directly related to the topic under consideration, MHRA would recuse participants from the discussion to ensure impartiality.

Decision: The Group recognised the importance of the initiative and supported the proposed mitigations for managing the potential COI. The Group asked for an update on COI management to be brought back once the AI commission had been operating for a while.

Case 4: Regulatory Innovation Corridor initiative between the MHRA and HSA in Singapore

The Group considered a case on a Regulatory Innovation Corridor initiative between the MHRA and HSA in Singapore. The corridor aims to enable joint regulatory learning and horizon scanning.

A potential COI was that one of MHRA's Non-Executive Directors (NED) was a senior partner of the company which was identified as the first industry partner as a pilot project in this initiative for their expertise and experience. The NED involved had recused themselves from discussions about the project.

The Group highlighted the importance of being able to demonstrate that COI processes have been followed and that the NED had not been present at meetings and to ensure the NED is not involved in any future discussions or communications about the project.

Decision: The Group agreed that they were assured that relevant steps had been taken to avoid the NED being conflicted as per the NED COI policy mechanisms but stressed the importance of transparency and awareness of public perception.

Case 5: IP and Commercialisation

The Group considered the broad concept of IP and Commercialisation in the scientific research space and managing potential or perceived COI, but it was agreed that that further discussion was needed in the context of the wider project exploring opportunities to generate revenue and reduce reliance on public funding, while ensuring alignment with managing public money principles. MHRA had been working with the Government Office for Technology Transfer to help identify potential work strands to realise the value of those IP assets.

The Group discussed the challenges of valuing early-stage research assets. The Group considered a specific project which was at a very early stage and had no commercial value but could become significant if developed further.

Decision: It was agreed that the Macrophage Therapy against Tuberculosis – MHRA IP jointly owned with a third-party project outlined in the paper should proceed with a clause in the agreement with a partner university allowing future review if the project comes closer to being regulated.

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 2026
Approved by Risk and Assurance Group, a management committee of Executive Committee, May 2026
Endorsed by Audit, Risk and Assurance Committee, July 2026