CORPORATE CONFLICTS OF INTEREST – ANNUAL COMPLIANCE REPORT 2020

PURPOSE OF THIS REPORT

1. Under the Medicines and Healthcare products Regulatory Agency's ('the Agency') Corporate Conflicts of Interest (COI) Policy and Procedure there is a requirement for an annual compliance report to be prepared and for the report to be signed off by a Sub-Group of the Agency's Corporate Executive Team (CET)[1]. Under the policy, the report should subsequently be considered by the Agency's Risk and Audit Committee (ARAC).

2. This report covers the calendar year 2020 and was agreed by the Corporate COI Sub-Group in January 2021 and by ARAC in February 2021.

BACKGROUND

3. A policy was developed to set out the approach to handling potential COIs arising out of the merger of NIBSC with the Agency in April 2013 and the launch of CPRD as a function of the Agency in April 2012.

4. The policy was approved by the CET in April 2013, reviewed in 2016 and then republished. A further review took place in late 2019 to provide assurance that the policy remained fit for purpose. A revised policy that better took account of current activities carried out by the whole Agency was approved by the Sub-Group in December 2019. The updated Policy was approved by the CET in January 2020 and is published on both the Agency's intranet and external website.

PROCESSES THAT APPLY UNDER THE POLICY

5. The Agency will operate in accordance with the following principles when managing potential conflicts of interest;

    - transparency
    - impartiality
    - robustness
    - efficiency
    - maximising the Agency's contribution to public health.

6. The Agency's mission is to protect and improve public health while supporting innovation. Staff are therefore encouraged to progress new work, identifying any potential COIs and ways of mitigating them in a transparent way. This

[1] In late 2020, the Agency's corporate structure was changed and the Corporate Executive Team was replaced by an Executive Committee.

involves consideration of the specific case by a Sub-Group of the Agency's CET which also includes an Agency non-Executive Director.

7. NIBSC and CPRD operate within clearly defined parameters, set out in operational guidance to ensure that COIs are identified and then either managed or avoided.

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

9. Where the proposed mitigation for a potential or perceived 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 Agency, this should be approved by the COI Sub-Group ('Sub-Group') in advance and all instances of this mitigation will be recorded on the COI Tracker by the Sub-Group Secretariat.

10. The escalation arrangements in the policy are as follows:

    - Where possible, the majority of potential COIs will be managed within NIBSC, CPRD or the Regulator at an operational level in accordance with the principles set out above.

    - In those cases where
        - NIBSC and/or CPRD consider that there may be merit in undertaking activities that fall outside the restrictions of operational guidance - including activities that may create a perceived or possible financial COI, or
        - Part of the Regulator identifies something that may create a perceived or possible COI with another part of the Regulator or the rest of the Agency

      they will escalate to the Sub-Group for decision.

    - The Sub-Group has the option to call upon a person external to the Agency for independent input if required.

    - In exceptional cases, where it is felt particular work should proceed (such as for public health or scientific reasons) but where despite agreed mitigations there remains a risk of reputational damage to the Agency, the Sub-Group may decide to seek a Ministerial steer.

CONSIDERATION OF POTENTIAL COI CASES AND OTHER MATTERS

11. The Sub-Group met once in the reporting period (October 2020). At this meeting, all cases identified during the year were reviewed. The Sub-Group considered seven cases during the year including two at the October meeting and five in correspondence as detailed below in paragraphs 13 to 32.

12. Five NIBSC cases and two CPRD case have been added to the tracker document (see Annex A) since the last compliance report.

Case 1

13. In correspondence in May, the Sub-Group considered a case concerning a proposed collaborative grant application between UK Stem Cell Bank (UKSCB) to conduct cell therapy research on the reproducibility of stromal cell differentiation, expansion, transfection, cryostorage and recovery protocols.

14. The potential conflict of interest was that that pre-clinical data generated might be used at a later stage to support a future clinical trial application.

15. The Sub-Group agreed that there was public health justification for carrying out this work and agreed the proposed mitigations (see Annex A).

Case 2

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16. In correspondence in May, the Sub-Group considered a case concerning contract testing and degradation studies for testing a Measles - COVID 19 spike protein, an early vaccine candidate which was being produced as part of a collaboration.

17. The potential conflict of interest was that NIBSC could be providing assay data which could potentially be used in a regulatory submission at a later date, although this was not stated as an intended use of the data. Working with a single manufacturer, albeit as part of a consortium could be perceived as bias.

18. The Sub-Group agreed that there was public health justification for carrying out this work and agreed the proposed mitigations (see Annex A).

Case 3

19. In correspondence in May the Sub-Group considered a case concerning Contract Testing to undertake laboratory testing of a candidate inactivated COVID-19 vaccine.

20. The potential conflict of interest was that NIBSC would be providing assay data that could be used in a regulatory submission at a later date, although the manufacturer had stated that their intention was to seek independent corroboration, by a renowned laboratory, of their own data.

21. The Sub-Group agreed that there was public health justification for carrying out this work and agreed the proposed mitigations (see Annex A).

Case 4

22. In correspondence in May, August and September, the Sub-Group considered a case concerning the provision of a centralised laboratory at NIBSC for clinical trials testing of candidate vaccines for emerging viruses.

23. The potential conflict of interest was that NIBSC would be testing vaccine manufacturers samples.

24. The Sub-Group noted that NIBSC would be testing samples from 9 different manufacturers and the samples would be blinded. The Sub-Group agreed that there was public health justification for carrying out this work and agreed the proposed mitigations (see Annex A).

Cases 5 and 6

25. At its meeting in October, the Sub-Group considered two cases concerning academic sponsored Phase IV clinical trials. **Case 5** was a Phase IV clinical trial that involved investigating symptom-driven therapy versus maintenance therapy for management of asthma in children and **Case 6** a Phase IV clinical trial investigating the use of direct anticoagulant (DOACs) in younger patients with Atrial Fibrillation.

26. The Sub-Group noted that these were academic sponsored public health trials where the investigators and sponsors derived no financial benefit from the outcome of the trials. The result of these studies may lead to changes in guidelines on use of medicines/therapy offered to a particular age group.

27. CPRD's role was to support the management of each of the two trials and CPRD's services were charged on a cost recovery not-for-profit basis in both of these.

28. The potential conflict of interest for both studies was that CPRD would be supporting Phase IV clinical effectiveness trials which are subject to clinical trial regulation, meaning that CPRD could at some point require regulatory inspection. There was also potential for the outcomes of the trials to lead to changes in the clinical guidelines for the use of one or both of the medicinal products concerned in the UK and worldwide.

29. The Sub-Group agreed that these were low risk studies, there was clear public health benefit in carrying out this work and the proposed mitigations were agreed for both studies (see Annex A). It was also agreed that the CPRD annex in the Corporate Conflicts of Interest Policy and Procedure

should be reviewed to reflect the agreed different mitigation approaches for academic and commercial sponsored studies.

Case 7

30. In November, a further case was considered in correspondence. NIBSC had been asked to apply an appropriate model to test a SARS-COV-2 product developed as a collaboration between The company had already generated safety data through previous studies with other collaborators and they believed this to be sufficient to allow an application to market the product, if it should prove effective. Any adverse effects noted in the NIBSC study would be included into the product safety record.

31. At this stage this was research on a product in development, but with potential for this to go to market, meaning that any data generated could then be used as part of a regulatory submission.

32. The Sub-Group agreed that there was public health justification for carrying out this work and agreed the proposed mitigations (see Annex A).

Other matters

33. The Sub-Group noted a paper from NIBSC on pricing of COVID reference materials.

34. The Sub-Group also considered COI recommendations in the Report of the Medicines and Medical Devices Safety Review (IMMDSR).

ONGOING REVIEW OF THE COI POLICY

35. The next review of the Policy and Procedure is due in January 2023; however, the Agency will review it sooner if there is need to do so.

36. Since the last annual compliance report, no complaints or suggestions had been received.