CORPORATE CONFLICTS OF INTEREST – ANNUAL COMPLIANCE REPORT 2019

PURPOSE OF THIS REPORT

1. Under the Medicine and Healthcare products Regulatory Agency's ('the Agency') Corporate Conflicts of Interest (COI) Policy 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). 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 2019.

3. This report was agreed by the CET COI Sub-Group in February and by ARAC in March 2020.

BACKGROUND

4. 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.

5. 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 assess if it 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 will be published on both the Agency's intranet and external website.

PROCESSES THAT APPLY UNDER THE POLICY

6. 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.

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

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

9. 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.

10. 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 CET COI Sub-Group ('Sub-Group') in advance and all instances recorded on the COI Tracker by the Sub-Group Secretariat.

11. 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 CPRD consider 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.

    - 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.

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

CONSIDERATION OF POTENTIAL COI CASES AND OTHER MATTERS

12. The CET Sub-Group met twice in the reporting period (May and November 2019). At these meetings, all cases identified during the year were reviewed. The Sub-Group considered four cases during the year including one at the May meeting and three in correspondence as detailed below in paragraphs 13 to 20.

13. Three NIBSC cases and one MHRA Regulator (Devices) case have been added to the tracker document (see Annex A) since the last compliance report. There were no CPRD cases.

Case 1

14. In correspondence (January 2019), the Sub-Group considered a case on Polio immunisation. The case concerned the testing of sera from a clinical trial performed by Public Health England (PHE) to generate important information on whether there is a susceptibility gap to polio in UK children between completion of their primary immunisation and receipt of the first booster at 3-4 years of age.

15. As PHE were not in a position to test sera, NIBSC were asked to provide end point titres for each sera to the 3 polio serotypes using the validated method. NIBSC would only provide the result (Polio antibody titre) back to PHE. PHE would assess all the data together. There would be no interpretation of individual results by NIBSC.

16. The potential conflict of interest was that this study could lead to MHRA Inspectorate colleagues inspecting NIBSC as part of a GCP inspection. The Sub-Group agreed that there was significant public health justification for this project and agreed the proposed mitigations (see Annex A).

Case 2

17. In correspondence in January and at the May meeting, the Sub-Group was asked to consider again the issue of the distribution of UK Stem Cell Bank (UKSCB's) cell lines by NIBSC (this case had been brought to the Sub-Group in 2018). Although the work was very similar to the distribution of biological reference standards, a key difference - which raised a potential conflict of interest - was that the cells could become part of a medicinal product and could therefore be subject to review by the Regulator. The data would be provided non-exclusively and it was an important public health role of NIBSC's.

18. The Sub-Group accepted that the cell lines had to be offered with the accompanying information to be of real use. The charge for the access was at the beginning and there was no further cost to the user from thereon in. The market for this material was currently very small. The Sub-Group agreed that this work could proceed, managing the potential COIs that arose as proposed.

Case 3

19. In correspondence (March 2019), the Sub-Group considered an MHRA Regulator (Devices) case setting out two activities engaging with the National Institute for Health Research (NIHR). Activity 1 was for Devices Division to join a panel that selects projects/products that will receive NIHR funding and Activity 2 was to join a steering group for a project that is developing outcomes for the evaluation of new surgeries and surgical devices. The Sub-Group agreed that Activity 2 did not represent a COI and therefore should proceed and had requested that MHRA (Devices) come back to the Sub-Group with a proposed way forward to mitigate the COIs in Activity 1 if they

did want to pursue this. MHRA (Devices) subsequently confirmed that they were not planning to proceed with Activity 1 but were looking at exploring a non-voting role with NIHR.

Case 4

20. In correspondence (October 2019) the Sub-Group considered a case concerning preclinical testing of candidate vaccines for emerging diseases. NIBSC would be undertaking studies, with financial support coming from Coalition for Epidemic Preparedness Innovation (CEPI), to undertake specific pieces of regulatory science information with the purpose of facilitating licensing of the vaccine. 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

21. At its May meeting the Sub-Group considered the agreements it had with two other regulators (Paul-Ehrlich Institute, Germany, and the Health Protection Regulatory Authority, Ireland) to provide an independent opinion, where required, that the MHRA Regulator would take into account when reaching its regulatory decision on matters which could give rise to a potential COI. In the light of the discussion the Corporate Conflict of Interest Policy and Procedure was amended to better set out the inspection element. The Sub-Group would give further consideration to these agreements when the outcome of Brexit was clear.

22. During the year, the Sub-Group discussed the need for awareness raising within NIBSC about the policy and process for managing potential Conflicts of Interest. In particular, the objective was to identify and manage potential COIs in a transparent way; it was not to prevent new work from being explored or taken on.

23. In November, NIBSC and the Sub-Group secretariat held a workshop for relevant staff covering the role of the Opportunities Assessment Group and the CET COI Sub-Group and how potential COIs can be managed. These staff were then invited to attend a COI CET Sub-Group meeting and to take part in a discussion about the revised policy and procedure and to ask any questions.

24. The Sub-Group agreed that NIBSC should hold further awareness raising opportunities in the New Year.

ONGOING REVIEW OF THE COI POLICY

25. 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.

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