# CORPORATE CONFLICTS OF INTEREST – ANNUAL COMPLIANCE REPORT 2018

## PURPOSE OF THIS REPORT

1. Under the Medicine and Healthcare products Regulatory Agency's ('the Agency') Conflicts of Interest (COI) Policy there is a requirement for an annual compliance report to be prepared by both the National Institute of Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD) and for the report to be signed off by a subgroup 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 2018.

3. This report was agreed by the CET COI Subgroup in February 2019 and by ARAC in March 2019.

## 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 and the Board in April 2013 and last reviewed in 2016 to assess if it remained fit for purpose. A revised policy that better took account of financial conflicts of interest, current activities carried out by CPRD, and the role of the Chief Executive in the COI process, was agreed by the CET COI sub-group and then by the CET and Board at their May 2016 meetings. The policy was then published and is available on the Agency's website.

## PROCESSES THAT APPLY UNDER THE POLICY

6. The key arrangements that apply under the policy are as follows:

    - Both NIBSC and CPRD operate within clearly defined parameters in accordance with their operational guidance.
    - NIBSC and CPRD consider all new areas of business from the perspective of potential COI.
    - NIBSC and CPRD ensure that in taking on any new business appropriate strategies are in place to avoid any COI.
    - NIBSC and CPRD identify cases that fall outside the operational parameters but where there may be justification on public health grounds for undertaking those activities.
    - In those exceptional cases where NIBSC and CPRD consider there may be justification in undertaking activities that fall outside the restrictions of operational arrangements, a specific escalation process applies. This involves consideration of the specific case by

a sub-group of the Agency's CET which also includes an Agency non-Executive Director.

- In those exceptional cases, where the CET sub-group considers there is justification for undertaking activities that fall outside the parameters of operational arrangements, an arrangement is in place whereby the Agency can call upon another EU regulatory authority to provide any independent regulatory oversight that may be required.

The escalation arrangements in the policy are as follows:

i. Where possible, potential COIs will be managed within NIBSC and CPRD at an operational level in accordance with the criteria and principles set out in the policy. This is anticipated to address the majority of potential COI cases and this has been the case since the policy came into operation.
ii. NIBSC and CPRD are responsible for ensuring that their activities are carried out in accordance with the requirements laid down in operational guidance.
iii. NIBSC and CPRD are responsible for considering any activities they carry out which may create a perceived or possible financial COI. For example, this includes cases where the Agency provides a service and receives a fee for provision of the service.
iv. NIBSC and CPRD are responsible for considering cases where there might be a public health justification for undertaking activities that fall outside the restrictions of operational guidance.
v. 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, they will escalate to a group comprising representatives from the CET (the Chief Operating Officer; Directors of the regulatory divisions, NIBSC and CPRD; a representative from Legal Services; a non-executive representative from the Board and chaired by the Director of Policy Division) for decision.
vi. In those cases where there is a significant risk of reputational damage to the Agency, or where there is a risk of perceived or possible financial COI, the CET sub-group will provide advice to the Chief Executive, who will take account of that advice in deciding an appropriate course of action. Such cases might include services provided by either NIBSC or CPRD where there is a significant financial fee charged for provision of a service and where there is a possibility that MHRA may be required to undertake a regulatory function in the future.
vii. The Chief Executive, taking into account the advice of the CET sub-group, may decide to escalate the issue to the Chairman or another member of the Board for decision. To preserve separation and clarity of roles, there will not be overlap between NEDs on the sub-group and those on the Agency's Audit, Risk and Assurance committee (ARAC).

viii. The CET sub-group will also have the option to call upon a person independent to the Agency for independent input.

## CONSIDERATION OF POTENTIAL COI CASES AND OTHER MATTERS

7. The CET sub-group met twice in the reporting period (March and September 2018). At these meetings, all cases identified during the year were reviewed. The sub-group considered one case during the year as detailed below in paragraphs 9 and 10.

8. One NIBSC case, and no CPRD cases, have been added to the tracker document (see Annex A) since the last compliance report.

9. At the September meeting, the group was asked to consider the issue of the distribution of UK Stem Cell Bank's (UKSCB's) cell lines by NIBSC. Although the work was very similar to the distribution of biological reference standards, a key difference - which had 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. NIBSC saw the provision of data with the cell-lines as the same type of work as for biological reference standards. The data would be provided non-exclusively and it was an important public health role of NIBSC's. It was 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 there on in. The market for this material was currently very small. One proposed mitigation was for the Human Tissue Authority (HTA) to review UKSCB's work where cells did end up being part of a medicine that the regulator was asked to licence. UKSCB already operated under HTA rules and there was an MOU between the Agency and the HTA.

10. The group asked NIBSC colleagues to consider the mitigations further and come back to the group covering how Licensing Assessors would be made aware of NIBSC's involvement in cell-lines for resultant drugs.

11. During the year the group had also considered CPRD's management of COI. In August, a paper was taken to the CET on the framework of CPRD's activities supporting interventional research and the mitigation of potential COIs. The paper set out that the areas presenting direct conflicts of interest were study sponsorship, protocol authorship and study data analysis. CET noted that with appropriate mitigation in place, it would be possible for CPRD to carry out data analysis as part of the management of a clinical trial, and, as such, data analysis should be included in CPRD's interventional research provision. Following discussion, the group agreed to give further consideration - in a future meeting - to the use of another country's inspectorate to either supervise the Agency's inspections or perform their own if required, review how the mitigations outlined in the paper were working and consider any further developments.

## ONGOING REVIEW OF THE COI POLICY

12. There are plans to review the policy in 2019 to ensure it continues to fulfil its purpose and covers the Agency's role appropriately. Any such review will take account of any complaints or suggestions received about the policy. Since the last review, no complaints or suggestions had been received.