Medicines & Healthcare products Regulatory Agency

# Board Meeting

## The Sustainability of the UK Stem Cell Bank (UKSCB).

22 October 2018

**Issue/ Purpose: To brief the MHRA Board on NIBSC's activities regarding the future sustainability of the UK Stem Cell Bank (UKSCB).**

**Summary:**

The UK Stem Cell Bank (UKSCB) was established in 2003 on the recommendation of the House of Lords Select Committee on Stem Cell Research. It has been housed at NIBSC since its inception with funding via the Medical Research Council (MRC). The UKSCB collects, banks, and supplies all human embryonic stem cell (hES cell) lines generated in the UK (and some from overseas).

The UKSCB is seen as a considerable strategic asset for the UK in the field of regenerative medicine, being able to provide both research-grade and, currently underway, clinical grade hESC lines. The latter can be obtained from the UKSCB as "starting material" for generation of cell-based medicinal products for clinical trials.

Current financial support from the MRC for the UKSCB ceases in 2020. Beyond that, no funding source has been identified. There are structural constraints that limit the capacity of NIBSC to make the Bank financially self-sustaining. Thus, there is a risk that the MHRA will become financially liable for the support of the bank. CET was alerted in March 2018 to the need for a sustainability plan for the UKSCB, with an update presented in August 2018.

This paper is meant to provide visibility to the MHRA Board.

**EU Referendum implications**:
None

**Action required by Board**:
The Board is kindly asked to note the issue and progress being made.

**Links:**

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**CET Sponsor:**
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## Situation

• The UK Stem Cell Bank (UKSCB) was established in 2003 on the recommendation of the House of Lords Select Committee on Stem Cell Research. It has been housed at NIBSC since its inception.

• The UKSCB collects, banks, and supplies all human embryonic stem cell (hES cell) lines generated in the UK (and some from overseas). By law, all UK-derived hES lines must be deposited in the Bank. It is, therefore, a considerable strategic asset for the UK in the field of regenerative medicine. Over the past years, the UKSCB has built up an international reputation.

• The Bank's activities are overseen by a Steering Committee, the secretariat for which lies with the Medical Research council (MRC). It is licenced and authorised by the Human Tissue Authority (HTA).

• The UKSCB has been supported financially by the MRC since it was established. The latest round of funding (Phase 5) was confirmed end of 2017, and runs for 3 years from January 2018. This tranche of funding supports the Bank in two distinct activities:

1. Its statutory role of accepting and banking hES cell lines, and

2. The provision of clinical-grade cell lines, primarily intended as starting material for the production of cell therapy products.

• A problem arises because of the following: in its Phase 5 award letter, the MRC made clear that: *'Beyond this [Ph5] investment…the UKSCB would need* ***to sustain itself without direct MRC funding support****'.* The MRC have confirmed that this directive includes both the statutory and clinical cell activities. Thus, beyond the end of 2020, the Bank will no longer receive research council funding, and will be without any core funding support.

**The question arises therefore of how the UKSCB might become financially sustainable in the future. Specifically, how will NIBSC seek to fund both the statutory and clinical cell activities?**

• Regarding the statutory role, it is difficult to see an alternative to core funding. There is little prospect that a granting authority would support this role. Indeed, the only such granting agency would be the MRC. Unless the MRC decision can be reversed, therefore, this support role would fall to the MHRA. This currently involves roughly £180K p.a. of the MRC Ph5 grant, and might be expected to carry similar financial liability into the future.

• The funding of the clinical-grade cells is more complex. It is clear that the Bank should sustain itself. However, the Bank has no assets to commercialise. It does not own the lines it holds: ownership of the cell lines is retained by the individual depositors.

• The MRC has agreed a financial interest in any future commercial development of banked ES lines, so has some prospect of recovering the public money it has already sunk into the development of the bank. A similar arrangement is not available to NIBSC.

• Currently MRC support for this clinical-grade activity runs to roughly £500K p.a. Future costs would depend on the degree of commitment undertaken.

## Possible ways forward

• As suggested above, the statutory activities of the Bank can only be supported by core funding. We have therefore re-opened discussion with the MRC to see if a core funding stream can be identified (see below). The MRC considers that the Bank should be a Department of Health and Social Care (DHSC) asset. **Thus, it may fall to the MHRA to agree to fund this activity beyond 2020.**

• For the clinical-cell activities, there appear to be three possible routes forward:

1. The UKSCB could discontinue the clinical-grade cell activities at the end of current three-year Ph5 funding, continuing to pursue only the statutory role. NIBSC would still provide cells on request, but seek no further improvement or expansion of the cells beyond the conclusion of the current funding round. We would not, in other words, seek to commercialise our clinical-grade cells, but would make them available, while stocks last beyond the end of Ph5.

2. NIBSC could continue to pursue its goals with regard to the production of clinical grade cells beyond the three years, and seek to make them broadly available as now. We would, however, remain unable to seek any financial compensation from their commercialisation. Effectively, this would mean NIBSC/MHRA becoming the funder of all the bank's activities.

3. NIBSC could seek an arrangement with the depositors that guarantees some sort of financial recompense for the Bank from any third party deals that they might reach.

• Please note that a possible fourth option—relinquishing the bank entirely—is not a realistic proposition. We hold the cells in the bank under the terms of a licence issued by the HTA. In the event of termination of our activities, the terms of that agreement require us, as licence holder, to:

> *'have agreements and procedures in place to ensure that…..stored tissues and cells are transferred to other establishment(s) licensed for storage for human application'*

There then follows eight minimum requirements that such an agreement must include. It seems to us extremely unlikely that such an agreement could be reached, given that the constraints we are experiencing would be inherited by any subsequent custodian of the Bank.

## Direction given by CET in their March 2018 meeting

The CET recognized the UKSCB as important strategic asset that should not be lost. CET agreed option 1 is undesirable. Option 2 may be the most plausible option; an action was taken to open discussions with the user community and research funders, and to discuss ways forward with the MRC. Regarding option 3, CET encouraged continuing discussions.

## Current actions

We are taking various steps currently to provide for financial sustainability of the UKSCB into the future. These include discussions on alternative funding sources, agreements with depositors.

## Conclusion

While these steps are still ongoing, the sustainability of the Bank remains unresolved. We anticipate the situation being clearer by the autumn / winter and would propose to update CET and the Board again early 2019.