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Betsy Bassis  
**NHS Blood and Transplant**  
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Date: 24 June 2021

Dear Betsy

**Plasma for Medicines Programme 2021-22**

I am writing following my letter of 17 March in which the Department instructed NHSBT to collect plasma for fractionation from April to June 2021.

Following approval by DHSC's Investment Committee, Ministers and HMT for the plasma business case, this letter instructs NHSBT to continue collecting plasma for fractionation (to manufacture immunoglobulins), through until the end of March 2022.

HMT has approved funding of £53m for 2021-22 on the basis of:

- NHSBT collecting plasma from whole blood donations and plasma by apheresis, with the aim of establishing a UK domestic supply of plasma for medicines, achieving 30% by the third year (subject to forward year funding approvals);
- NHSBT retaining a proportion of the infrastructure and staff recruited during the 20-21 convalescent plasma programme; and
- NHSBT adhering to HMT's approval conditions which are set out in **Annex A**.
- This money is ring fenced for the activities outlined in the business case, with any under-spends flagged at the earliest opportunity and returned to the Department unless agreed otherwise.

The £53m is inclusive of the £6.5m received from April to June 2021.

Additional approval to spend this funding may be needed in line with the Cabinet Office's efficiency controls and NHSBT's delegations.

We ask NHSBT not to enter into contractual commitments beyond March 2022 or above the maximum committed funding for the period.

As your Sponsor, DHSC will work with NHSBT to determine how future funding flows are to work for this programme beyond 21-22. This will include submitting a bid through the Spending Review 2021 (we are awaiting confirmation of both the timelines and the underlying process). We will continue to oversee this work through the Plasma to Manufacture Medicines Programme Board and DHSC / NHSBT accountability meetings.

I note NHSBT staff were informed on 9 June of the need to decommission three clinics, from 14 clinics to 11 clinics, and that NHSBT will seek to re-deploy the staff where it can. I also appreciate your confirmation at the 4 June Programme Board that retaining 11 clinics, rather than the nine set out in the business case, will not have an impact on expenditure and is considered a more efficient way of deploying the 72 beds for plasma collection.

As a fractionator has not yet been selected, we recognise there is a risk that the plasma collected may not be suitable to manufacture immunoglobulins. As you know, the Memorandum of Understanding between DHSC, NHSEI and NHSBT was also recently approved and signed. NHSEI and NHSBT now need to plan for a suppliers' engagement as soon as possible to help inform the plasma specification being collected.

I appreciate the challenges ahead for 21-22 and would like to thank NHSBT staff for their hard work getting us to this position.

Yours sincerely

**GRO-C**

**Mark Davies**

Director – Population Health

DHSC

On behalf of the Secretary of State for Health and Social Care

## ANNEX A

### HM Treasury's Approval Conditions

- i) This approval is strictly for approval to spend only of £53m RDEL in 21/22, funding for future years will be subject to the Spending Review;
- ii) The Programme will provide confirmation of the actual savings to DHSC Finance and HMT once procurement of fractionation has been completed;
- iii) Any future SR bid should make clear which budget future year funding will impact, and should seek funding for net costs only;
- iv) The SRO is responsible for delivering the scope of work and benefits set out in this business case and should notify DHSC Investment Appraisal ([IA](#) **GRO-C**) immediately if these change;
- v) Should MHRA approve additional medicines that could be manufactured from UK plasma, the associated funding will be subject to a separate business case review;
- vi) The Programme will ensure that DHSC, NHSEI and NHSBT continue to engage with other countries who have pursued similar policies, drawing from best practice and lessons learnt;
- vii) The Programme will ensure that the plasma programme does not undermine the supply of blood components to NHS hospitals by competing for the same donor pool;
- viii) The Programme will ensure that NHSEI continue to manage the guidance, policy and procurement activities for the supply of immunoglobins via suppliers of fractionation services;
- ix) Should NHSEI market engagement indicate a lack of appetite or limited competition for the proposed commercial models, the Programme will work alongside DHSC Commercial to ensure that the Procurement strategy is reviewed and delivers a VfM solution;
- x) A Joint MOU between NHSEI, NHSBT and DHSC is approved;
- xi) The Programme will ensure that NHSBT provide appropriate and or acceptable levels of assurance to the fractionators to allow use of the domestically collected plasma;
- xii) The Programme will ensure that NHSBT provide assurance of sufficient supply volumes of domestically collected plasma thereby making production sustainable/cost effective;
- xiii) The Programme will ensure that NHSEI build in sufficient flexibility to accommodate the additional volumes to incorporate any future demand from Devolved Health Services;
- xiv) As part of the pre-procurement strategy, the Programme will ensure that NHSEI review any existing contracts to ensure either that no TUPE provisions need to be made or any TUPE provisions that do exist are included;

- xv) The Programme will undertake further work to clarify how funding that sits with NHSEI, will be used to reimburse NHSBT for the cost of supplying plasma to the fractionator(s). And how any future savings will be distributed and utilised within the system. The Programme will provide an update to the FBP and we expect a written proposal to be ratified by the FBP ([Jayesh.Patel](#); **GRO-C**) within one month of the receipt of this letter;
- xvi) The Programme will ensure that NHSEI take appropriate legal advice on ensuring a legally compliant procurement is undertaken to select a fractionator and take account of the guidelines provided by DHSC on the criteria to be used in the tender process;
- xvii) The Programme will ensure that NHSEI and NHSBT take legal advice to ensure that all regulatory obligations are complied with in the performance of their respective obligations under the Domestic Plasma Programme;
- xviii) An agreed representative from DHSC Finance will attend the Plasma Programme Board meetings;
- xix) The Programme will provide a monthly update on YTD spend against budget and collection levels of plasma to the FBP ([Jayesh.Patel](#); **GRO-C**) and an update on how conversations are progressing with the NHS regarding the purchase of plasma next year.