Department of Health & Social Care

From the Lord Bethell
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The Rt Hon the Lord Owen CH
By email to: davidowen@lorddavidowen.co.uk

Dear David

Thank you for your correspondence of 7 April to Matt Hancock on behalf of Mr David Donald about blood plasma. I apologise for the long delay in replying, which has been caused by an unprecedented volume of correspondence in recent months.

I understand you have also written to, and had replies from, Professor Jonathan Van Tam and NHS Blood and Transplant (NHSBT).

The COVID-19 global pandemic is the biggest public health emergency this generation has faced and we are doing absolutely everything we can to beat it.

Thousands of people are participating in national trials for potential treatments. On 25 April, the Secretary of State announced that approval had been given for the REMAP-CAP clinical trial to determine if plasma donated by patients who have recovered from COVID-19 can help those battling the illness. NHSBT is supplying convalescent plasma to both the REMAP-CAP and RECOVERY trials, as are the other UK blood services.

With regard to hyperimmune globulin, the Secretary of State has been contacted by some of the companies in the CoVIg-19 Plasma Alliance, a partnership of ten plasma companies, of which BPL is one. Officials at the Medicines and Healthcare products Regulatory Agency (MHRA) and NHSBT have been in contact with BPL and I understand that NHSBT has supplied some plasma to BPL for testing purposes.

I am aware that plasma companies, such as those in the Alliance, are manufacturing the product for use in clinical trials in the US. Once the product is ready, we would be very keen for the Alliance to apply to trial this within the UK.

As you know, to make the medicinal product, the plasma has to go through the process of fractionation. On the advice of the then Committee on Safety of Medicines, no UK plasma has been supplied to companies for fractionation since 1998 as one of the extra safety measures introduced to protect patients from exposure to blood products that may increase the risk of developing variant Creutzfeldt-Jakob disease (vCJD). This remains the

position today, and UK plasma cannot therefore currently be supplied to make hyperimmune globulin.

However, the safety of UK plasma is reviewed periodically, and in September 2019 we announced the implementation of the Advisory Committee on the Safety of Blood, Tissues and Organs' (SaBTO's) recommendation to lift specific vCJD risk-reduction measures in the UK, enabling those born after the bovine spongiform encephalopathy outbreak to routinely receive UK plasma for transfusion.

SaBTO's report makes clear that the conclusions from the analysis on plasma cannot be extrapolated to the manufacture of plasma-derived medicinal products from fractionation of plasma sourced in the UK. Further work would be required to determine the risks and benefits of using UK plasma for fractionation, which is a matter for the MHRA.

The MHRA is conducting a review of the safety of medicinal products produced from fractionated UK plasma and has received initial advice from the Commission on Human Medicines on the use of UK plasma for the manufacture of hyperimmune immunoglobulin G (IgG) for the treatment of COVID-19. The Commission has advised that MHRA defer the decision on lifting the ban on the use of UK-sourced convalescent plasma for the manufacture of hyperimmune IgG for the treatment of COVID-19 until a review of the evidence of the clinical safety and efficacy from ongoing clinical trials on the use of convalescent plasma for the treatment of COVID-19 is completed.

A comprehensive review of the safety of UK plasma is also underway and the MHRA has requested the opinion of vCJD experts. A mathematical modelling of the risk is being undertaken, as was done by SaBTO for UK plasma for transfusion. To maintain public confidence in the safety of blood products, it will be essential that this review is performed to a high scientific standard and we expect to have the outcome of the second stage of the review later in the autumn.

I hope this reply is helpful.

LORD BETHELL