

INITIAL WRITTEN SUBMISSIONS FOR THE SCOTTISH GOVERNMENT

1. The Scottish Government ('the SG') is grateful for the opportunity to provide initial written submissions to the Inquiry.
2. The relevant Inquiry Statement of Approach (revised 18 April 2022) § 4(a) invites submissions outlining any recommendations (not related to compensation) which core participants may wish to invite the Chair to consider.
3. The SG does not at this stage wish to propose any substantive recommendations for adoption by the Inquiry.
4. The SG notes that § 5 of the Statement of Approach states that written submissions will be disclosed by the Inquiry to other core participants.
5. The SG is conscious that in their initial submissions other core participants may propose recommendations which could affect its position. The SG submits that it would be appropriate, and would be likely to be of assistance to the Inquiry, if core participants were permitted, having seen any recommendations proposed by other core participants, to respond briefly to those submissions if they may affect the question whether additional evidence should be before the Inquiry.
6. The SG submits that any recommendations that may be proposed by other core participants need to be viewed against the whole background of the arrangements currently in place in Scotland. It may be helpful to add some further brief comment on three areas in which there have been recent developments.

Arrangements to support those infected or affected

7. First, in 2017 the SG established the Scottish Infected Blood Support Scheme ('SIBSS'), in response to the recommendations of the Financial Review Group which was established by the SG in 2015. The scheme has since been amended in order (a) to give effect to recommendations made in 2018 by the Clinical Review of the Impacts of Hepatitis C Group, as well as feedback from scheme beneficiaries via SIBSS surveys;¹ (b) to increase certain payments in order to achieve greater parity with the other infected blood support schemes in operation in the United Kingdom, in June 2021; and (c) to

¹ <https://www.gov.scot/policies/illnesses-and-long-term-conditions/infected-blood/>, where further references are available.

make cost of living increases in the level of payments under the scheme, most recently in April 2022.

8. Second, in order to provide support to all those who are infected and their families, the SG set up the Scottish Infected Blood Psychology Service in May 2021, managed by NHS Lothian, but available across Scotland for infected patients and their family members. The SG also funds the Inherited Bleeding Disorders Psychological Support Service with NHS National Services Scotland's National Services Division. This service has been in place since 2015-16 and is also managed by NHS Lothian, but available to patients across Scotland and their family members.

The current regulatory position

9. In certain respects the regulatory position has recently changed.
10. First, since late 1999 UK plasma has not been used in the manufacture of medicinal products owing to the risk of transmission of variant CJD (vCJD). In 2020, a review by the Commission on Human Medicines ('CHM') and the Medicines and Healthcare Products Regulatory Agency ('MHRA') concluded that the use of plasma from UK donors for these purposes would expose the patient population to no or minimal additional risk of vCJD in the future.² Based on that advice SG and the other UK governments announced **in February 2021** that UK plasma could in future be used for production of immunoglobulins. (MHRA is to carry out a further review on the question whether UK plasma can also be used for production of albumin.)
11. Second, in order to give effect to vCJD risk reduction measures, it had been the practice that individuals born in or after 1996 did not receive UK plasma; instead they received imported plasma or apheresis platelets. (The significance of 1996 is that from that year onwards individuals would not have been exposed to BSE through ingestion of food.) In September 2019 SaBTO (the Advisory Committee on the Safety of Blood, Tissues and Organs) reassessed the risk-reduction measures appropriate for such individuals (as well as those with TTP (thrombotic thrombocytopenic purpura)) and in light of a revised risk

² <https://www.gov.uk/government/publications/critical-risk-assessment-report-use-of-uk-plasma-for-the-manufacture-of-immunoglobulins-and-vcjd-risk#:~:text=The%20Commission%20on%20Human%20Medicines,medicinal%20products%20would%20be%20negligible.>

assessment recommended that certain measures could be withdrawn. That was done from September 2020. Other risk reduction measures remain in place.³

The current testing regime

12. The testing regime has recently been extended. Following recommendations from SaBTO in 2021, SNBTS has recently introduced testing for anti-Hepatitis B core antibodies as an additional measure. This will allow the identification of donors who have previously had Hepatitis B. It is anticipated that only a small number of donors will be in that position, but those who are will no longer be able to donate blood.⁴ Other UK blood services have also recently started such testing.

Conclusion

13. The SG's purpose in setting out these points (about any of which it would be happy to provide further detail) is simply to emphasise its concern to assist the Inquiry in ensuring that it has all relevant information about the arrangements currently in place, both for safety and for support to the infected and affected, since these are clearly relevant to any recommendations which other core participants may invite the Inquiry to make.

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³ <https://www.gov.uk/government/publications/risk-reduction-measures-for-variant-creutzfeldt-jakob-disease-pcwg-report>

⁴ <https://www.scotblood.co.uk/news/hepatitis-b-virus-hbv-core-testing/>