

## STATEMENT OF APPROACH – SUBMISSIONS AT THE END OF THE ORAL EVIDENCE

- 1. This statement aims to ensure that all core participants and recognised legal representatives understand the process which the Inquiry will adopt to enable closing statements (referred to below as submissions) to be made in accordance with rule 11 of the Inquiry Rules 2006. Under section 24 of the Inquiries Act 2005 it is the duty of the Chair to deliver a report to the Minister setting out (a) his factual determinations (i.e. his findings) on matters relevant to the Terms of Reference and (b) any recommendations he considers it appropriate to make. The written and oral submissions made by or on behalf of core participants should be aimed at assisting the Chair in this task.
- 2. In order to honour the principle that the Inquiry will be completed as quickly as reasonable thoroughness permits and to gain full benefit from the participation of core participants:
  - (a) Time will be allowed for all core participants to make submissions after the conclusion of the oral evidence hearings in 2022; those who are represented will do so through their recognised legal representatives as provided in rule 11 of the Inquiry Rules.
  - (b) The time allowed for those submissions to be made orally will necessarily be limited, and in due course a timetable will be drawn up to which those making oral submissions will be expected to adhere.
  - (c) The Inquiry expects that all those wishing to make oral submissions will provide in advance written submissions. The Inquiry does not intend to impose a limit on the length of written submissions. The Inquiry is, however, likely to be most assisted by submissions that

- are well focused and do not simply repeat the evidence which has been heard.
- (d) The Inquiry recommends that time should be found by recognised legal representatives to begin work on written submissions from now on (awards will be made to enable those in receipt of public funding to do this) – any extension of time sought following the conclusion of the oral evidence hearings on the basis that there is not enough time to complete the submissions is likely to be refused unless the circumstances are both unusual and unexpected as well as highly compelling.
- (e) However, no submissions should be provided to the Inquiry until invited, as below.

## **Written Submissions**

- 3. Written submissions should be delivered electronically, when requested, with paragraphs numbered (for ease of reference) and there should be no restriction on copying. They should be sent to: submissions@infectedbloodinquiry.org.uk
- 4. The deadlines for the provision to the Inquiry of the written submissions are as follows:
  - (a) By 20 June 2022 core participants should provide initial written submissions outlining any recommendations (not related to compensation) that they may want to invite the Chair to consider. The purpose of asking for such submissions by this date is to enable the Chair to decide whether there is any additional evidence that needs to be gathered relevant to the making of recommendations and, if so, to make the necessary arrangements to obtain that evidence. (It is not necessary for these initial submissions to address the question of

- compensation, because the Inquiry is already well aware that this is a recommendation which it will be asked to consider.)
- (b) By 16 December 2022 core participants should provide more detailed written submissions. These should:
  - set out the core participants' position (if they have one) as to the factual findings which the Chair should (or should not) make;
  - ii. set out the recommendations which the core participants invite the Chair to make, including recommendations as to compensation; and
  - iii. set out the core participants' position (if they have one) as to why particular recommendations should, or should not, be made.
- 5. Written submissions will be disclosed by the Inquiry to other core participants and their recognised legal representatives. All are reminded that such disclosure is subject to an obligation of confidentiality not to disclose the document or any extract from it to any person (whether individual, institutional or corporate) who is not a core participant.
- 6. Notwithstanding the duty of confidentiality, core participants and recognised legal representatives are reminded that the full submissions as received by the Inquiry will be published in due course. This is by definition publication to those who have not undertaken to keep disclosed material confidential, as have the core participants and some others, as a condition of having disclosure made to them. Therefore, in the (albeit unlikely) event that core participants wish to alert the Inquiry to material not previously considered by the Inquiry and already disclosed, this must be clearly notified to the Inquiry (as early as possible in the process) so that the rights of individuals to privacy and confidentiality can be adequately protected in accordance with law.

## **Oral Submissions**

- 7. No closing oral statement may be made unless a written submission has first been delivered by the recognised legal representatives concerned (or in the case of unrepresented core participants, the participants themselves), within the time specified.
- 8. Since both the time allowed for any one participant or group of participants to make an oral statement may be insufficient to permit a full exposition of every point that participant might wish to make, and to help limit the extent of unnecessary repetition, participants and their recognised legal representatives should consider the following:
  - (a) those legal representatives whose clients ("A") identify that they share some issues in common with some other core participants ("B" and/or "C" etc) are invited to discuss among themselves whether each can focus on a different aspect of those submissions they wish should be made orally, so that (for example) A deals more fully with one particular submission held (broadly) in common with B and/or C, whilst B and C in turn deal more fully with a second or third submission which A, B and/or C hold in common. If it suits them, they may also identify briefly in writing any part or parts of another's written submission of which they become aware and wish to adopt. It will be understood by the Inquiry that by doing so briefly (e.g. by reference to paragraph number, sub-heading, or content) they are not in any sense detracting from the emphasis they would otherwise have given to that submission, but are aiming to assist the Inquiry and core participants generally.
  - (b) Further, the Inquiry does not by urging co-operation between likeminded core participants on some issues seek to have them reach an artificial consensus: if, therefore, A broadly agrees with B on an issue on which B "majors" but has some reservations, this does not

- preclude those reservations being noted (either by B, or by A, in writing or even orally).
- (c) It is of limited help to urge that the Inquiry take a particular view (whether positive or negative) of the general quality of the evidence of an individual witness on a purely subjective basis. Time doing so is likely to be wasted. By contrast, where there is some objective reason for thinking some evidence wrong, or materially inconsistent with other evidence from the same source (or to be particularly supported by other material), the reasons for that view are likely to be useful.
- (d) Participants are reminded that it is open to the Inquiry to accept all, or to reject all, that a witness has said, or to accept it in part whilst rejecting it in other parts.
- (e) It may be that the Chair raises questions during an oral presentation, if he thinks it is needed to aid his understanding. This should be borne in mind in assessing the time to be taken.
- (f) The closing oral statement may cover factual findings, or recommendations, or both.
- 9. No timetable has yet been finalised for the making of the oral closing statements, or for the order in which they are to be made, but the Inquiry is presently planning on the basis that these closing statements will be made in the weeks of 16 January, 23 January and 30 January 2023. However, it may help representatives and participants both to plan ahead and to focus on the essential points to be made, to know that as far as practicable participants likely to share a common interest in the outcome of the Inquiry will not be heard one after the other in a block, but their contributions will be spread throughout the time allotted. Thus participants with divergent interests are likely to be heard throughout.

10. Though Counsel to the Inquiry has no brief to present any particular view to the Inquiry, and will not do so, it is important that the Inquiry report is factually accurate and faithful to the evidence it has heard. Accordingly, she has a standing invitation from the Chair to correct any inaccuracies in a closing statement, and will do so in public at a convenient moment after that oral statement has finished.

Issued by the Chair on 1 April 2021.

Reviewed and re-issued as amended on 18 March 2022.

In response to submissions from recognised legal representatives, the Chair revised the deadline for final written submissions on 29 July 2022.

## **Further Note**

- The Inquiry has been asked by some recognised legal representatives to provide some guidance as to the areas on which it would be most useful for core participants and recognised legal representatives to focus in their final written submissions.
- 2. For the avoidance of doubt, this guidance applies to <u>all</u> core participants intending to make final submissions and thus includes those who were infected and affected <u>and</u> those bodies or individuals whose actions and decisions are under scrutiny in the Inquiry.
- First and foremost, of course, core participants should provide submissions on those matters within the Terms of Reference that are of the most importance to them. This will, of course, vary.
- 4. Recognising, however, the breadth of the Terms of Reference, and the huge volume of evidence which has been considered to date, and which continues to be considered, it is hoped that the following guidance may be of some assistance at least.

- 5. Where the Inquiry has produced a detailed presentation or chronology, core participants should not feel it necessary to repeat the factual matters set out within those presentations or chronologies. Rather, the Chair would be assisted by core participants setting out the conclusions they invite the Chair to draw, having regard to those factual matters.
- 6. Core participants may wish to note that Counsel to the Inquiry intends to produce over the summer written presentations/chronologies relating to: the decision-making leading up to the introduction of HIV screening in October 1985; the consideration given to surrogate testing for NANB Hepatitis; and the decision-making leading up to the introduction of HCV screening in September 1991. Core participants should not, therefore, feel that they have to produce their own detailed accounts of these events in their written submissions, but can instead focus on identifying the conclusions that they invite the Chair to draw.
- 7. Inclusion or lack of inclusion of an issue in this note should not be taken as any indication of relative importance. The Inquiry will answer the Terms of Reference in full. Where the expression "particularly welcomes" (etc) is used, it indicates no more than that this is where submissions might best be focused.
- 8. In relation to paragraph 1 of the Inquiry's Terms of Reference (namely what happened and why), core participants will no doubt wish to focus on issues of particular significance for them but the Chair would welcome submissions focused on:
  - (a) The topic of self-sufficiency and in particular when and how it might have been achieved.
  - (b) Viral inactivation and in particular whether and how more could or should have been attempted earlier.

- (c) The decision-making of the Committee on the Safety of Medicines and its Biologicals Sub-Committee.
- (d) The decisions and actions of pharmaceutical companies manufacturing/supplying factor concentrates, in particular what could or should have been done differently by them.
- (e) Transfusion practice and what could or should have been done differently or earlier.
- (f) Whether the organisation of domestic blood collection, plasma supply, product manufacture, and product supply contributed to the extent to which infections were suffered.
- 9. In relation to paragraph 4 of the Inquiry's Terms of Reference ("Impact"), each and every statement submitted by people infected and affected is considered by the Chair, and there is no need, therefore, for core participants to summarise that evidence in their final submissions. However, core participants should of course feel free to set out the overall conclusions which they invite the Chair to draw in relation to the impact of infection.
- 10. The Chair would be particularly assisted by submissions covering paragraph 5 of the Inquiry's Terms of Reference, namely the response of Government and others.
- 11. The Chair would also be particularly assisted by submissions covering paragraph 6b of the Inquiry's Terms of Reference, namely the testing or treatment of previously untreated patients ("PUPS").
- 12. In relation more generally to questions of consent (paragraph 6a of the Terms of Reference) and communication and information-sharing (paragraph 7 of the Terms of Reference), the Chair has well in mind the evidence he has received from those infected and affected, clinicians and

the medical ethics expert group. Again, there is no need for core participants to feel the need to summarise that evidence in their final submissions, but the Chair would welcome submissions regarding the conclusions which core participants may wish to invite him to make.

- 13. The Chair would be particularly assisted by submissions covering paragraph 8 of the Terms of Reference (Treatment, care and support); however, this is an area in which the Inquiry has considered a significant amount of written and oral evidence and core participants should not feel that they have to attempt to summarise that evidence, and thus it would be helpful if the focus of submissions were to be on the conclusions which the Chair is invited to draw from the evidence.
- 14. The Chair would also be particularly assisted by submissions covering paragraph 9 of the Inquiry's Terms of Reference, namely issues of candour, openness and cover-up.
- 15. Where a core participant invites the Chair to consider making a recommendation, the submissions should set out the nature of the suggested recommendation and a summary of the reasons why it is suggested that the recommendation should be made. This includes any submissions about compensation.
- 16. This guidance should be read in conjunction with the Statement of Approach at the end of oral evidence (current version dated 18 March 2022).

Issued by the Chair on 30 May 2022.