THE HAEMOPHILIA SOCIETY

# Terms of Reference

## Standards and procedures

- What were the standards and procedures applied by the Department of Health at the time to protect and mitigate the risk of exposure to pathogens viral infection. Were they adequate and how widely were they applied?
- What were the Clinical Standards to prevent infection at the time and how closely were these followed on a national and local basis?
- What were the International standards and procedures at the time and timeline of incorporating updated information and applying,
- Who had ultimate responsibility at the Department of Health to make decisions based on available evidence to ensure the safety of patients requiring blood products.

## Pathogen Identification and Testing

- When were various pathogens identified, including Hep B, Hep C, Hep D, HIV, CJD.
- What were the rates and numbers of people infected, what was the variation by location – regionally and by centres?
- What tests were available, including surrogate testing and when were these adopted, internationally and regionally what influenced these decisions? How widely available were they, what was the accuracy and reliability of the tests?
- Look at recommendations on procedures to protect against the potential for future blood transmissible infections.

## Communication

- To who, how and when were the Department of Health and Clinical Standards and procedures communicated. What was the level of variance in communication received depending upon location. What measures were taken to ensure these were followed?
- Who were the leading voices of authority, how were their views communicated and who was in receipt of this information, how was this disseminated?
- How was the risk of infection to individuals communicated, when was this done and was information provided to facilitate informed choice on treatment given?
- How were infected individuals and their families told about their diagnosis and what level of support was offered?
- What was the level of communication to non-specialist treatment centres about risks of contamination.

**For all people affected by bleeding disorders**

## Self Sufficiency

- How was the issue of self-sufficiency in blood products approached by the Department of Health? What were the levels of funding and commitment to the project and who was responsible for delivery? What was the impact of the delay to achieving self-sufficiency?
- What impact did the collection of blood the infrastructure have on the ability to achieve self- sufficiency?
- What was the level of cross border cooperation and knowledge sharing, and how did this impact the ability to achieve self-sufficiency in the UK?
- How did the internal management of projects to increase production at BPL affect the ability to become self-sufficient?

## Product

- What was the impact of "donor" selection criteria on the rates of infection, how was this monitored, what steps were made to reduce contamination rates and who was responsible for this?
- What procedures were in place to monitor manufacturing standards, licence, regulate and procure blood products both produced in the UK and imported? How did this compare to global and regional standards? What consideration was given to the relative safety risks of UK produced vs. imported products?
- Were the commercial interests of pharmaceutical and blood product companies used to influence decision making on the availability of products and if so how was this affected?
- What steps were taken to reduce contamination via product screening, how was this monitored and what were the timings to recall products? How effectively was this communicated and implemented?
- What level of informed consent was gained from individuals and guardians about testing individuals with new products and being involved in clinical trials?



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## Impact on People

- What was the initial short term and long-term impact on individuals infected their families and carers?
- What has been the emotional and psychological effect of contracting a virus gained through contaminated blood products?
- What level of support, financially, practically and emotionally has been provided to affected individuals and their families and how has access to support been achieved and managed? Did this truly reflect the real loss incurred by individuals and their families after contracting a viral condition?
- What have been the impacts of subsequent treatments to manage the conditions contracted and has access to treatment been equitable and fair?
- How did the way the support was administrated impact people and their families?
- How did the length of time and continued fight to get a Statutory Public Inquiry affect the community and families?

## Response to the issues

- What was the response of government to the disaster, what did they put in place to support infected individuals and their families.
- How transparent have government been in making sure all documentation has been made available and nothing has been hidden or destroyed to cover the truth?
- Has the government been receptive to the voices of the infected community and been open to hear their testimony?
- What has the government done to trace all people affected by the contaminate blood and are in receipt of support packages they are entitled to?
- Have steps been taken since the scandal to ensure all patients have access to safe and effective treatments?



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