INFECTED BLOOD INQUIRY

APPENDIX 1

SCOPE AND METHODOLOGY FOR PHE PORTON DOWN

1. Purpose of this document

PHE Porton Down is required to investigate whether there is information and documentation held on site that are potentially relevant to the issues set out in the Inquiry's Terms of Reference. Porton Down's response will be set out in a Witness Statement from PHE Porton Down's Site Director.

To inform the above statement, all areas on the site must make an assessment and, where indicated (i.e. where there is any indication that the area may hold relevant documents), a physical search, to identify any documents that may be relevant to the Inquiry. A low threshold is to be adopted for relevance: if there is any doubt as to whether the information or document is relevant to the Terms of Reference, the Inquiry's attention will be drawn to it.

The purpose of this document is twofold:

A. To be included in the witness statement to provide assurance and transparency on the robustness of the assessment and search for pertinent documentation and information;
B. To provide internal clarity on the approach, requirements and scope of assessment and search by PHE site management.

2. Scope

PHE Porton Down is being asked to consider all documents that it holds from 1970 to date, through the two requests made under Rule 9 of the Inquiry Rules 2006. The requests require PHE Porton Down to provide any correspondence, instructions, notes, advice, reports, briefings, policies, guidance, reviews, minutes of meetings, and any other documentation (paper, electronic, microfiche, video, or otherwise held), particularly (but not limited to) the period 1970-2000, regarding the treatment of persons who were given infected blood, or blood products, through transfusion or any other means, or relating to the knowledge of infection associated with blood donations or blood products.

The following extracts from the two Rule 9 requests provide more detail:

Request for the production of specified documents and information under Rule 9(2) of the Inquiry Rules 2006.

Please provide any additional correspondence, instructions, notes, advice, reports, briefings, policies, guidance, reviews, minutes of meetings and any other documentation, however held (paper, electronic, microfiche, audio, video amongst other means), particularly from 1970-2000, but not limited to this period, regarding:

a. The treatment of person(s) who were given infected blood or blood products though transfusion or other means;

b. The treatment of person(s) with haemophilia or other bleeding disorders who were given infected blood products;

c. The knowledge and risks of infection associated with blood donations and blood products, including but not limited to the risk of infection with:

i. The hepatitis B virus;

ii. The hepatitis C virus;

iii. HIV;

iv. vCJD and/or

v. Other blood-borne diseases.[1]

d. The systems adopted for the screening of donors and the collection, testing, licensing and supply of blood products;

e. The extent to which the supply of infected blood or infected blood products could have been avoided or stopped earlier;

f. The role and response of any of those entities listed in 3.a) to the use of infected blood or blood products;

Request for a written statement under Rule 9 of the Inquiry Rules 2006

In particular:

Please confirm whether documents and data relating to the following entities are contained in the PHE Porton archives, and if so, for which periods:

(i) Microbiological Research Establishment;

(ii) Microbiological Research Authority;

(iii) Centre for Applied Microbiology and Research (CAMR);

(iv) Public Health Laboratory Service, in particular from Oxford, Manchester and Bristol;

(v) Epidemiological Research Establishment;

(vi) Epidemiological Research Laboratory;

(vii) Communicable Disease Surveillance Centre;

(viii) Documents from the Directors of Public Health and Consultants in Communicable Disease Control;

(ix) Blood Transfusion Service;

(x) Blood Products Laboratory;

(xi) any other working groups, committees, or subcommittees you

[1] Other blood-borne diseases – the Porton site has carried out, and does carry out, research on other blood borne pathogens such as Ebola but these are clearly outside the scope of relevance and therefore were considered out of scope, although they are referenced in the departmental assessment overview in Appendix 2 Schedule of Documents in the interests of a clear and full response to the Inquiry.

consider relevant to the Inquiry's Terms of Reference.

Please describe CAMR's function in relation to research into:
The hepatitis B virus;
The hepatitis C virus;
HIV;
vCJD; and/or
Other blood-borne diseases

3. Methodology

On or about 17 December 2018, Alex Sienkiewicz (Director of PHE Porton Down & Director of Corporate Affairs) received an email from Dr Nick Phin of PHE[2] indicating that, as the Centre for Applied Microbiology and Research (CAMR), departments at Porton undertook research into HIV and AIDS – possibly also Hepatitis B and C - and therefore requesting either a schedule of any relevant documents held at Porton Down, or a nil return. Porton Down provided a nil-return. Porton Down has now been asked by the Inquiry for a more detailed response. The following is the methodology proposed to meet this requirement.

The investigation needs to be proportionate i.e. it would not be proportionate in the first instance manually to review every single document (both hard copy and electronic) held on site to determine its potential relevance to the Inquiry. These would be in the tens if not hundreds of thousands. The requests cover both those held centrally on site at PHE Porton Down and locally held material within the various departments (there are 12 departments, all represented on the extended Porton Site Management Team; they are a mix of scientific and support departments located both in the main and auxiliary buildings around the PHE Porton site). In both cases Porton Down will take a hierarchical approach, commencing at a high level of assessing the types of documentation and information held and then only looking at sets and individual documents when there is any indication of the potential for documentation/information to be of relevance. A key action is that reviewers must justify/explain why they believe that there are no potential items of relevance to the Inquiry in a department, laboratory etc.

The search and assessments must take account of both electronic and hard documents, current and historical.

The response to the Rule 9 requests will consist of the following three elements:

A. Site overview and chronology around site ownership

An outline of the activities and purpose of the site over time will be provided, together with the chronology around the changes in ownership for the site.

B. Central Storage

[2] Deputy Director, Tuberculosis, Acute Respiratory, Gastrointestinal, Emerging/Zoonotic Infections and Travel Migrant Health Division (T.A.R.G.E.T.) and Interim Deputy Director, Blood Safety, Hepatitis, Sexually Transmitted Infections and HIV Service, National Infection Service, PHE

i) The context of the storage will be described (**this is not an official corporate archive**) and the documents held will be described and related to the site ownership.
ii) A log of all the sets of documents held will be made.
iii) An initial assessment of each set of documents will be made to determine whether there is the potential for relevant documents. If there is no potential, a written explanation will be provided.
iv) If there is the potential for documents of interest then individual documents will be listed and selected as either of definite or possible relevance, recorded in a log and reviewed with the Deputy Site Director's (Dr Peter Hammond's) oversight.
v) The consolidated logs will be provided as part of the evidence pack for the Site Director who will be providing a Witness Statement to respond to the Rule 9 requests.

C. Locally held documents

i) Each Department as represented at the Porton Site Management Team will make a departmental/sub-departmental level assessment of the potential for that department to hold any relevant documents.
ii) If the assessment concludes that there are no relevant documents, this needs to be recorded and the explanation (including any evidence) for that conclusion provided. This will need to be reviewed and signed off by the Department Head and Review Lead (Dr Tim Harry).
iii) If the assessment indicates that there could be potentially relevant documents, then these need to be identified and the next level of assessment made at a sub-departmental/individual level.
iv) The sub-departmental level assessment needs to record and log items of definite or possible potential relevance.
v) Where no such items are identified or found then this needs to be recorded with an explanation.
vi) Items of definite or possible potential relevance need to be reviewed by the Departmental Head.
vii) The Departmental Head will consolidate all the assessments for their area of responsibility and in turn review these with the Review Lead and Deputy Site Director prior to submission to the Site Director as part of the evidence pack.